COMMITTEE NAME **Committee for the Evaluation of Intended Use Hazards during Retail Meat Grinding**

DATE OF FINAL REPORT: *12/5/2022*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☐ ***Council II*** ☒ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Hilary Thesmar, FMI and Ellen Shumaker, NCSU

COMMITTEE CHARGE(S):

Issue # 2020 III-015

1. Evaluate prior developed 'CFP Beef Grinding Log Template Guidance Document' to consider inclusion of information for the prevention of common hazards known to be associated with grinding processes:
   A.) "Intended Use" policy, purpose, and control measures including supply chain communication.
   B.) Examples of common control measures, such as supplier guarantees or certificates of analysis and ongoing verification;
   C.) Reference to FSIS guideline for minimizing STEC in Raw Beef Processing Operations (https://www.fsis.usda.gov/guidelines/2021-0007)
2. Consider developing educational materials (e.g., handout(s) to support grinding log assessment by regulatory authorities, industry personnel, and the public. Examples may include:
   A.) Educational fact sheets detailing hazards represented by the non-intact handling of beef intended for whole intact use;
   B.) Plain language explanations of "Intended Use" policy purpose.
3. Evaluating potential changes to the Food Code to address the hazards associated with establishments grinding of beef that is manufactured as "Intended for Intact Use".
4. Determining appropriate mechanisms for sharing the committee's work, and
5. Reporting progress back to the next Biennial Meeting in 2023 and the committee's findings and recommendations may be presented at the subsequent Biennial Meeting if necessary.

COMMITTEE WORK PLAN AND TIMELINE:

The committee was established in October 2021 and began work on the charges in early November 2021. The committee completed charge 1 and began work on charges 2 and 3.

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls:

1. ***Overview of committee activities:***

   The committee held calls via MS Teams every two weeks. Calls dates were 11/2/2021, 11/16/2021, 11/30/2021, 12/14/2021, 1/11/2022, 1/25/2022, 2/8/2022, 2/22/2022, 3/8/2022, 3/22/2022, 4/5/2022, 4/19/2022, 5/3/2022, 5/17/2022, 5/31/2022, 6/14/2022, 6/28/2022, 7/19/2022, 8/23/2022, 9/6/2022.

2. ***Charges COMPLETED and the rationale for each specific recommendation:***
   a. Charge 1- Guidance document was created and is complete
   b. Charge 2 – The committee considered developing educational material and determined that the committee lacked the qualifications and experience to develop educational materials. The committee had expertise in food safety management and mitigation of risk. The committee focused on the guidance document and encouraged food safety education experts to draft educational material based on the content in the guidance document.
   c. Charge 3 – The committee spent considerable time contemplating potential food code language changes and determined that the FDA Food Code Annex 2 section K is the appropriate location for the guidance document and to provide resources for regulatory officials and the industry. Recommending language in the Food Code was contemplated and many committee members expressed concern about the confusion with multiple agencies having regulatory authority as well as concerns about local and state resources to train regulatory officials appropriately. For all of these

reasons, the committee agreed that the FDA Food Code Annex 2 section K is the appropriate place for the reference to the guidance document.

d. Charge 4 – The committee recommends that the guidance document be posted on the CFP website for access by CFP stakeholders.
e. Charge 5 – Completed report and guidance document for CFP website

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.**

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

Issue #1: Report – Committee Name:
Committee for the Evaluation of Intended Use Hazards - Issue 1- Committee Report

a. **List of content documents submitted with this Issue:**

Report of the Committee for the Evaluation of Intended Use Hazards During Retail Meat Grinding

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:***

Roster

List of supporting attachments: ☐ ***Not applicable***

(1) Committee Report
(2) Roster
(3) Guidance document created "Evaluation of Intended Use Hazards During Retail Meat Grinding"

Committee Issue #2:
Committee for the Evaluation of Intended Use Hazards - Issue #2– Approval of guidance "Evaluation of Intended Use Hazards During Retail Meat Grinding"

List of supporting attachments: ☐ ***Not applicable***

Guidance document created "Evaluation of Intended Use Hazards During Retail Meat Grinding"

Committee Issue #3:

Committee for the Evaluation of Intended Use Hazards -Issue #3 – Amend FDA Food Code Annex 2 to reference approved Guidance Document

List of supporting attachments: ☐ ***Not applicable***

Guidance document created "Evaluation of Intended Use Hazards During Retail Meat Grinding"

CFP Committee Membership Roster and Instructions

Committee for the Evaluation of Intended Use Hazards during Retail Meat Grinding

2022

Committee Name:									
Last Name	**First Name**	**Position (Chair, Member, etc.)**	**Voting Status**	**Constituency**	**Employer**	**City**	**State**	**Phone**	**Email**
Thesmar	Hilary	Chair		Industry	FMI	Arlington	VA		hthesmar@fmi.org
Shumaker	Ellen	Co-Chair		Academia	NCSU	Raleigh	NC		ellen_shumaker@ncsu.edu
Burgess	Victoria	Member	Yes	Industry	Pubix Super Markets, Inc	Boynton Beach	FL		Victoria.Burgess@Publix.com
Danos	Trista	Member	Yes	Industry	Whole Foods Markets	Austin	TX		trista.danos@wholefoods.com
English	Amber	Member	Yes	Regulatory - Local	Washoe County Health D	Reno	NV		aeenglish@washoecounty.us
Hess	Erich	Member	Yes	Industry	Jewel-Osco	Itasca	IL		erich.hess@jewelosco.com
Hofer	Vasanthi	Member	Yes	Regulatory - Local	MARICOPA COUNTY EN	Phoenix	AZ		vasanthi.hofer@maricopa.gov
Kendrick	Susan	Member	Yes	Regulatory - State	Oregon Department of Ag	Salem	OR		susan.kendrick@oda.oregon.gov
Mello	Wayne	Member	Yes	Industry	Ahold Delhaize/Retail Bu	Scarborough	ME		wayne.mello@retailbusinessservices.com
Otzenberger	Michael	Member	Yes	Regulatory- State	Wisconsin	Madison	WI		michael.otzelberger@wisconsin.gov
Pease	Robert	Member	Yes	Industry	HEB	San Antonio	TX		pease.robert@heb.com
Rivas	Rose	Member	Yes	Industry	Rivas	Pfafftown	NC		april@rivasranch.com
Moore	Veronica	FDA Consultant	No	Regulatory - Federal	FDA	College Park	MD		Veronica.Moore@fda.hhs.gov
Collaro	Thomas	USDA Consultant	No	Regulatory - Federal	USDA-FSIS	Washington	DC		Thomas.collaro@usda.gov
Barlow	Kristina	USDA Consultant	No	Regulatory - Federal	USDA-FSIS	Washington	DC		kristina.barlow@usda.gov
Beckett	John	alternate	No	Industry	Publix	Plantation	FL		john.beckett@publix.com
Hollingsworth	Jill	alternate	No	Industry	Ecolab	Winston Salem	NC		jill.hollingsworth@ecolab.com
Prince	Gale	alternate	No	Industry	SAGE Food Safety LLC	Cincinnati	OH		Gale@GalePrince.Com

Conference for Food Protection

Evaluation of Intended Use Hazards During Retail Meat Grinding
December 2022

Table of Contents:

1. Charge of the Committee

Council III of the Conference for Food Protection (CFP) formed the Evaluation of Intended Use Hazards during Retail Meat Grinding committee with the directive to:

1.) Evaluate prior developed 'CFP Beef Grinding Log Template Guidance Document' to consider inclusion of information for the prevention of common hazards known to be associated with grinding processes

A.) "Intended Use" policy, purpose, and control measures including supply chain communication

B.) Examples of common control measures, such as supplier guarantees or certificates of analysis and ongoing verification

C.) Reference to FSIS guideline for minimizing STEC in Raw Beef Processing Operations (https://www.fsis.usda.gov/guidelines/2021-0007)

2.) Consider developing educational materials (e.g., handout(s) to support grinding log assessment by regulatory authorities, industry personnel, and the public. Examples may include:

A.) Educational fact sheets detailing hazards represented by the non-intact handling of beef intended for whole intact use

B.) Plain language explanations of “Intended Use” policy purpose.

3.) Evaluating potential changes to the Food Code to address the hazards associated with establishments grinding of beef that is manufactured as “Intended for Intact Use”.

4.) Determining appropriate mechanisms for sharing the committee's work, and

5.) Reporting progress back to the next Biennial Meeting in 2023 and the committee's findings and recommendations may be presented at the subsequent Biennial Meeting if necessary.

2. Introduction

This committee was charged with enhancing the Conference for Food Protection (CFP) "Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments"[1] to include information on how retail food establishments can prevent common hazards associated with beef grinding processes.

Shiga toxin-producing *Escherichia coli* (STEC) is estimated to cause 265,000 illnesses in the US annually, including 3,600 hospitalizations and thirty deaths. To date, at least four outbreaks have been associated with beef ground at retail that was not intended for grinding (e.g., trim from intact steaks or roasts, and "pull backs"). Inadequate grinding records and insufficient sanitation between source lots at retail have hindered public health investigators' ability to determine the ultimate source of the implicated beef.

After reviewing the 2014 CFP beef-grinding document, the United States Department of Agriculture, Food Safety Inspection Service (USDA, FSIS) guidance documents and beef supplier risk elimination program presentations, the committee proposes the following changes and additions to the guidance document including:

1. Definition of "Intended Use", its purpose and regulations,
2. Beef product examples in both categories (intended and not intended to be ground) and what risk is associated with each,
3. Recommended common control measures that can be done in a retail setting to reduce risk, such as supplier communication.

The Committee agreed that creating educational materials was out of the scope of the committee and should be created by experts in education based on the needs of their communities following the release of this guidance document.

This document is intended to be guidance for retail food establishments that grind beef and to assist with creating protocols and training materials for their establishments. The recommendations are not intended to replace, or otherwise serve as, the rules and regulations applicable to food establishments in any given federal, state, local or tribal jurisdiction. Please refer to the appropriate inspection authority in your jurisdiction for further guidance. Inspectors often have deep expertise and can assist with food safety management programs and compliance with existing regulations.

[1] CFP Beef Grinding Log Committee. "Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments". Conference for Food Protection. 2012-2014. Available from: http://www.foodprotect.org/guides-documents/cfp-beef-grinding-log-template-guidance-document/.

3. Definitions

Note – These definitions generally represent terms used in retail establishments. When multiple definitions are available from regulatory agencies applicable to retail establishments, references are provided.

Active Managerial Control
Active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.[2]

Batch/Set
An identified quantity of beef that is ground based on specific attributes, such as percent lean, which will all be labeled as the same product.

Bench Trim
Product derived from cattle not slaughtered at the establishment.[3] In retail establishments with meat cutting operations, bench trim is generated in store. (Retailers tend to use the terms bench trim and trim interchangeably)

Chub
Rolls of ground beef that have been packaged to keep air out.[4] Chubs come in a variety of packaged sizes.

Customer requested grinding
As a service to customers, retailers may offer grinding of a cut of beef selected by the customer from the service case or packaged product that was not originally intended to be ground. This product is subject to the recordkeeping requirements for ground beef.

Grind Cycle
The amount of ground beef (measured by quantity and/or time) for one **lot** of product as documented by complete sanitation cycles. A grind cycle may include multiple batches/sets within a sanitation cycle.

Ground Beef
Chopped fresh and/or frozen beef or veal with or without seasoning and without the addition of beef fat as such, will not contain more than 30% fat, and shall not contain added water, phosphates, binders, or extenders.[5]

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[2] 2017 FDA Food Code Annex, page 551.
[3] FSIS Directive 10,010.1. Available from: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/10010.1.pdf
[4] "Ground Beef Packaging, What's the difference?" Meat Science Organization. 2017. Available from: https://meatscience.org/TheMeatWeEat/topics/fresh-meat/article/2017/04/26/ground-beef-packaging-what's-the-difference
[5] *9 CFR 319.15a*

Intact Meat
A cut of whole muscle(s) meat that has not undergone comminution, mechanical, tenderization, vacuum tumbling with solutions, or reconstruction, cubing or pounding.[6]

Intended Use
How the federal establishment (producer) intends the product to be safely consumed or if further processing or further controls are needed. *9 CFR 417.2(a)(2)* requires each establishment to identify the intended use or consumers of the finished product. The product's intended use may affect the **STEC** controls in place at both the shipping and receiving establishments. Establishments that purchase beef from slaughter establishments should be aware of the slaughter establishment's intended use for the specific products they receive. [7]

Lot
For the purposes of FSIS requirements in *9 CFR 320.1(b)(4),* a lot is defined as the amount of raw ground beef produced during particular dates and times, following clean-up and until the next clean-up, during which the same source materials are used.[8]

Lot code
Defined volume or timeframe of finished product.

Non-Intact
Non-intact beef products include: ground beef; chopped beef; flaked or, minced product; beef that is vacuum tumbled with solutions; beef that an establishment has mechanically tenderized by needling (including injecting with solutions), cubing, pounding devices (with or without marinade); beef that an establishment has reconstructed into formed entrees; beef with proteolytic enzymes applied; and diced beef less than ¾ inch (dial setting) in any one dimension on average.[9]

Mechanically tenderized (non-intact)
Manipulating meat by piercing with a set of needles, pins, blades or any mechanical device, which breaks up muscle fiber and tough connective tissue, to increase tenderness. This includes INJECTION, scoring, and processes which may be referred to as "blade tenderizing," "jaccarding," "pinning," or "needling."[10,11]

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[6] "Non-intact beef products". askUSDA. Available from: https://ask.usda.gov/s/article/Non-intact-beef-products
[7] "FSIS Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Processing Operations". 2021. Available from: https://www.fsis.usda.gov/guidelines/2021-0007
[8] *9 CFR 320.1(b)(4)(iii).*
[9] "FSIS Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Processing Operations". 2021. Available from: https://www.fsis.usda.gov/guidelines/2021-0007.
[10] U.S. Department of Health and Human Services, U.S. Food and Drug Administration. FDA Food Code. 2017 Available from: www.fda.gov/FoodCode.
[11] Federal Register Vol. 80, No. 95 Monday, May 18, 2015 (p. 28153-28172) Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products.

Primal cut
From FDA Food Code: A basic major cut into which carcasses and sides of meat are separated, such as a beef round, pork loin, lamb flank, or veal breast.[12]

From FSIS: Primal parts are the wholesale cuts of carcasses as customarily distributed to retailers. The round, flank, loin, rib, plate, brisket, chuck, and shank are primal parts of beef carcasses. Veal, mutton, and goat primal parts are the leg; flank, loin, rack, breast, and shoulder.[13] *(For the purpose of this document, only beef and veal are in scope.)*

Production Cycle
Consists of one or more **Grind Cycles.**

Production Log
Documents used to facilitate or supplement the recordkeeping requirement for ground beef. Some retailers find it helpful to maintain a production log that contains additional details on timing and products used to help with internal records. Production logs are not required in the FSIS regulation on recordkeeping, and do not take the place of the official records required by FSIS. See Appendix for a sample production log.

Pull backs
Retail packaged cuts, such as steaks or roasts, removed from the self- service refrigerated display cases and either reworked into smaller cuts, such as stew beef or cube steak, or ground product. “Pull-backs” can be ground separately but are sometimes co-mingled with in-store produced bench trim.

Recordkeeping requirements for beef (grinding log)
FSIS finalized a rule on December 21, 2015, requiring additional records be kept for establishments and retailers grinding beef. The rule is titled “Records to Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products.” [14]

Re-work
Changing the form of a meat or poultry cut by reprocessing it down into smaller pieces or transformed to a different product to maximize shelf life.

FDA Definition: Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.[15]

[12] U.S. Department of Health and Human Services, U.S. Food and Drug Administration. FDA Food Code. 2017.
[13] *9 CFR 316.9(b).*
[14] Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products. *Federal Register*.2015. Available from: https://www.federalregister.gov/documents/2015/12/21/2015-31795/records-to-be-kept-by-official-establishments-and-retail-stores-that-grind-raw-beef-products
[15] *21 CFR 117.3*.

Standard Operating Procedures (SOP)
Written procedures that an establishment develops and implements to prevent direct contamination or adulteration of product, internal protocols. [16]

Sanitation Standard Operating Procedures (SSOP)
Written procedures (specific to sanitation) that an establishment develops and implements to prevent direct contamination or adulteration of product, internal protocols. [17]

Subprimal cuts
The first division of a whole carcass is into primal cuts. The four major **primal cuts** into which beef is separated are chuck, loin, rib and round. All primal cuts may or may not be intended for use in ground products. **Primal cuts** are then divided into subprimal cuts. Examples of subprimal cuts of beef are the top round, whole tenderloin, and rib eye. Any subprimal cut may or may not be intended for use in ground products.[18]

STEC
FSIS uses the term STEC to refer to Shiga toxin-producing *Escherichia coli* (*E. coli*) O157:H7 and six non O157 serogroups O26, O45, O103, O111, O121, and O145 that are adulterants in raw non-intact beef and raw intact beef intended for non-intact use.[19]

Trim
Beef products produced from in-house source materials.[20] (Retailers tend to use the terms bench trim and trim interchangeably)

Vacuum packaged
Source product (**primal cuts**) packaged in vacuum packed bags from supplier are typically considered to be **intended for intact use**.

[16] FSIS Standard Operating Procedure Guide. *USDA*. Available from: https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/Sanitation-SOP-Guide.pdf
[17] FSIS Standard Operating Procedure Guide. *USDA.* Available from: https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/Sanitation-SOP-Guide.pdf
[18] "What are primal cuts?" AskUSDA. Available from: https://ask.usda.gov/s/article/What-are-the-primal-cuts
[19] "Expansion of FSIS Shiga Toxin-Producing Escherichia coli (STEC) Testing to Additional Raw Beef Products". Available from: https://www.fsis.usda.gov/node/2272
[20] FSIS Directive 10,010.1. available from: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/10010.1.pdf

4. Intended Use

Federally inspected beef suppliers (approved suppliers to retail food establishments) should determine the intended use of the products shipped including the determination if the product is meant to be safely consumed (following proper food handling practices) or if further processing or further controls are needed for the product to be safety consumed.

Through regulations specified in *9 CFR 417.2(a)(2),* FSIS requires each establishment (supplier) to identify the intended use or consumers of the finished product. The product's intended use may affect the STEC controls in place at both the shipping and receiving establishments. Intended use of beef products for use at retail should be known, communicated and considered when planning production of retail packaged products. The intended use for the purpose of this document is to facilitate the safe consumption of the beef product or to clarify if additional controls or treatment is needed.

STEC is not an adulterant on raw intact beef products, such as steaks and roasts, which are "intended" for intact consumer use. This is because STEC contamination would be limited to the exterior surfaces of intact beef products and, if these products remain intact, normal consumer cooking will destroy any STEC on the outer surfaces, even if the product is cooked to a rare or medium internal state. STEC is an adulterant in raw non-intact beef products (ground beef) and raw intact beef products intended for raw non-intact use because the same consumer cooking practice will not destroy any STEC that have been internalized by the non-intact processing. STEC is also considered an adulterant in products for which the intended use is not clearly defined or supported.[21]

USDA FSIS documentation in askFSIS states that regulated establishments (beef suppliers) should[22]:

- Identify the intended use of the product as per *9 CFR 417.2(a)(2).*
- Develop decision-making documents based on objective measures which identify the intended use of the product. A hazard analysis must be included with the documents and must be consistent with the establishment's assertion that the product in question is/is not for use in raw non-intact product.
- Have measures in place to restrict products that are for intact use only. Such measures may include letters to the purchasers, website postings, bill of lading communications, and a receipt of acknowledgement that the purchasers understand that this product is intended solely for intact use as described in detail by the posted askFSIS answer "Adequate Support for the Intended Use of Beef Primal and Subprimal Cuts".[23]

[21] "FSIS Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Processing Operations". Available from: https://www.fsis.usda.gov/guidelines/2021-0007
[22] "Adequate Support for the Intended Use of Beef Primal and Subprimal Cuts". AskUSDA. https://ask.usda.gov/s/article/Adequate-Support-for-the-Intended-Use-of-Beef-Primal-and-Subprimal-Cuts
[23] Supporting the supply of raw beef intended for intact use. AskUSDA. Available from: https://ask.usda.gov/s/article/Supporting

Some acceptable ways that the establishment can support that primal and subprimal cuts are intended for raw intact product include:

- The establishment communicates the intended use to the receiving establishment or facility by making the letter of intended use available on the producing establishment's company website and references the letter of intended use on bills of lading.
- The establishment receives letters of guarantee showing that all product is used in raw intact product only and maintains on-going communication with the receiving establishment or facility to verify that product is being processed as raw intact product only.
- The establishment has a contractual agreement with the receiving establishment or facility so the producing establishment has knowledge of the receiving establishment or facility's production process.[24]

Intended use should be considered when retailers are grinding primals, subprimals, purchased trim, boxed beef, or other components (e.g., mechanically separated beef or partially defatted beef fatty tissue) that are not accompanied by records of negative *E. coli* O157:H7 or other STEC test results.

Supplier labeling designating the intended use is not required. Therefore, retailers should work with their suppliers to be sure they understand how the supplier will communicate the intended use of beef products. There are various ways a supplier can communicate the intended use of beef to the retailer. Following are some examples:

- Direct communication with the supplier of raw beef products
- Receiving a letter identifying the intended use with each lot of product
- Contractual agreement with the supplying establishment
- Receiving a Certificate of Analysis (COA), testing results, or similar documentation showing the basis for the supplier’s designated intended use
- Documentation showing that the product has been tested and found to not contain *E. coli* O157:H7 or other STEC
- Other documents such as Bill of Lading or Letter of Guarantee
- Using a code or labeling to identify the intended use of the product

If the retailer is unclear on the intended use of a product, they should contact their supplier for further clarification.

[24] Adequate Support for the Intended Use of Beef Primal and Subprimal Cuts". AskUSDA. Available from: https://ask.usda.gov/s/article/Adequate-Support-for-the-Intended-Use-of-Beef-Primal-and-Subprimal-Cuts

5. Recordkeeping for Beef Ground at Retail

Existing regulations from FSIS require that all facilities grinding beef (including retail establishments) maintain records regarding the source materials and cleaning and sanitation practices. In a rule published in December 2015, FSIS specified the recordkeeping requirements in *9 CFR 320.1(b).*

Official establishments and retail stores are required to maintain records that fully disclose:

1. The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product;
2. All supplier lot numbers and production dates;
3. The names of the supplied materials, including beef components and any materials carried over from one production lot to the next;
4. The date and time each lot of raw ground beef product is produced; and
5. The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.

Records can be in any format but should be legible and accessible at all times. Records must be maintained for one year. When feasible, all retailers are encouraged to adopt electronic recordkeeping to collect and maintain this important data in a secure and usable format. Technology will facilitate accurate and timely tracebacks, although smaller retailers may find it challenging due to limited financial and human resources support to move to digital records. Retailers that adopt electronic recordkeeping should develop SOPs to address how to capture key grinding data for system issues or malfunction.

Template: Sample Recordkeeping Template for Grinding Beef

Retail Establishment Name: Store # **Retail Establishment Production Date**

Date and time of grind (required)	Manufacturer name of source material used for product produced (required)	Establishment number(s) of establishment providing source material (required)	Supplier lot #s, product code and/or pack date of source material used (required)	Date and time grinder and related Food Contact Surfaces cleaned and sanitized (required)	Comments	Information linking to the retail package (recommended)

6. Retail Practices, Risk Reduction, and Supplier Communications

Implementing retail practices and strategies for reducing risks in the retail meat department should be part of an Active Managerial Control program. Active Managerial Control is the purposeful incorporation of specific actions or procedures by management into the retail operations to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.

Beef Handling and Grinding Practices at Retail

A producer or supplier of beef cannot verify that all pathogens have been eliminated from raw beef. However, producers have procedures in place for handling, treating, and testing beef in accordance with a HACCP plan and under FSIS federal inspection oversight to minimize the risk of contamination. The risk control steps taken by a supplier are used to designate the intended use of the meat once that meat is in a retail facility.

The risks associated with beef at a retail establishment will depend on several factors including how the supplier intended the beef to be handled, processed, labeled, and sold at retail. When implementing retail practices, the risk should be considered based on product type and intended use.

All the practices in the following examples are permitted. Some of these practices are based on following the supplier's intended use designation for the product. Other retail practices may present additional risk because they are not in accordance with the supplier's intended use and these are designated as non-intended use practices.

1. Practices/Products Based on Intended Use

Beef products from a supplier that are intended to be consumed intact.

> Examples: Steaks, roasts, smaller cuts of beef such as stew beef or primals in vacuum packaging. It does not include meat that has been ground, comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded.
>
> Rationale: These products are least likely to have contamination. Contamination, if present, is on the cut surface only. These pieces of beef may have surface contamination, but the outside surfaces will receive sufficient heat treatment when cooked by the consumer to render them safe.

Beef products from a supplier that can be cut at the retail facility provided they retain an intact surface that will be heat-treated when cooked by the consumer.

> Examples: Primals, sub-primals, or large roasts that are cut into steaks or smaller pieces. It does not include meat that has been ground, comminuted, mechanically

tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded. Nothing has been done at retail to introduce pathogens into the interior of the meat and any contaminants will remain on an exterior surface.

Rationale: Contamination, if present, is on the cut surface only. These pieces of beef may have surface contamination, but the outside surfaces will receive sufficient heat treatment when cooked by the consumer to render them safe.

Beef that has been ground, comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded by the supplier. This is non-intact meat which the supplier intended to be consumed in this form.

Examples: Beef ground by the supplier (may be pre-packed or bulk), cubed steaks, mechanically tenderized steaks. In all these examples, the meat was converted into non-intact beef by the supplier.

Rationale: Although this meat is not intact, the supplier has taken additional steps for handling, treating, and testing this beef in accordance with a HACCP plan and under FSIS federal inspection oversight to minimize the risk of STEC contamination.

Beef that has been ground or comminuted by the supplier but will be re-ground at the retail establishment. This is non-intact meat which the supplier intended to be consumed in this form.

Examples: Large chubs or containers of ground beef or coarse ground beef that will be re-ground at the retail facility.

Rationale: The supplier has already converted this beef into non-intact product. The supplier has taken additional steps for handling, treating, and testing this beef in accordance with a HACCP plan and under FSIS federal inspection oversight to minimize the risk of STEC contamination.

Beef trimmings from the supplier that are intended to be ground at retail. This meat will be converted into non-intact beef at retail.

Examples: Combo bins of trimmings, fat, and other small pieces of beef intended by the supplier to be ground at retail.

Rationale: The supplier has taken additional steps for handling, treating, and testing this beef in accordance with a HACCP plan and under FSIS federal inspection oversight to minimize the risk of STEC contamination.

2. Practices Not Based on Intended Use

Non-intended use practices may require additional controls to help mitigate risk of cross contamination if STEC is present on the exterior portion of the beef prior to grinding. Although the controls will help mitigate cross contamination, they will not address the risk of STEC in the product. Examples of non-intended use include the following:

Beef that is intact and which the supplier did not intend to be ground at retail. Intact beef that is not intended by the supplier to be comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded at the retail establishment.

> Examples: Converting store-generated trim (bench trim, market trim, case trim, block trim), re-work, pull-backs, and customer orders into ground beef. Cubing steaks or needle tenderizing beef at the retail facility.
>
> Rationale: Although suppliers have procedures in place for handling, treating, and testing beef in accordance with a HACCP plan and under FSIS federal inspection, this product did not receive any additional treatment or testing to further reduce the risk of STEC contamination. The supplier did not intend for this meat to be converted into non-intact beef at retail.

Controls to Reduce Risk at Retail

There are steps that can be taken at retail to help reduce the risks of contamination of beef. These include developing a written beef grinding protocol that specifies, at a minimum, segregation, separation, grinding practices, lotting, recordkeeping, and labeling.

Retail practices may include:

- Grinding product in small batches to reduce co-mingling of different products
- Labeling products with different source materials to ensure proper identification
- Maintaining complete and accurate production logs and grinding logs
- Segregating products based on designation of intended use
- Establishing consistent grinding sequence (Examples: from intact to non-intact; from most lean to higher fat content)
- Separating production cycles based on type of products or species
- Designating shelf life and/or use by date
- Sourcing meat from approved suppliers following all FSIS regulations

Additional good retail practices include:

- Rotate supply first-in first-out and pay attention to dates.
- Avoid mixing species unless intentional and clearly labeled. Clean and sanitize equipment between species.
- All food contact surfaces should be cleaned and sanitized before use.
- All products should be held at proper temperatures.

- Properly label all products with source, date, time and other required information.
- Avoid mixing multiple products from different suppliers because it makes the recordkeeping and traceback difficult.
- Control other hazards including foreign material.
- Develop a written cleaning and sanitizing program.

The control program should address the cleaning and sanitizing of food contact surfaces, equipment, utensils, implements, and the meat processing areas including frequency of cleaning, cleaning/sanitizing chemicals and tools that will be used. The time of each cleaning and sanitizing should be documented in the recordkeeping system for beef ground at retail. Training is recommended for all employees with responsibilities for cleaning and sanitizing.

Refer to the FDA Food Code and your state, local, tribal or territory requirements for cleaning and sanitation best practices. Section 4-602.11 of the FDA Food Code states that all food contact surfaces shall be cleaned at least every four hours. The food code provides for cleaning less frequently than every four hours if the utensils and equipment are held in a refrigerated room and cleaned according to the frequencies provided in the food code. (See *2017 FDA Food Code* Section 4-602.11)

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

Breaks in the grinding cycle

When grinding beef, intentional breaks in the grinding cycle are critical and should not be overlooked. A break in the grinding cycle is a combination of a complete cleaning and sanitizing step in conjunction with no carryover of product. Breaks should be used to separate lots, batches, or cycles of product to reduce the risk of cross-contamination. Breaks in the production of ground beef can be the difference between needing to recall product from only part of a day or all product produced over several days. The day and time of all cleaning and sanitizing breaks in the cycle should be documented and included as part of the grinding log.

Employee Training and Personal Health and Hygiene

Proper training of all employees with access to food production, storage, and packaging areas is essential. Only properly trained employees should be allowed in designated areas.

The Food Code and/or state and local regulations have guidelines for employee health and hygiene including illness procedures and policies for hand washing, proper clothing, coverings, hair restraints, gloves, etc. Local, state, and federal regulations should be followed at all times.

Retailers should develop specific training programs for the employees, certified food protection manager (CFPM), and person in charge (PIC) specific to working in the meat department. This includes grinding practices and protocols along with collecting, recording, and maintaining grind log data during their daily job duties.

Lotting at Retail

The package of beef produced at retail must be linked to the lot code(s) of the product from which it was made, i.e., the source product. The retail-ground lot should have a supportable definition and should link the packaged product to the source material.

Official establishments and retail stores are to define a lot of raw ground beef product as the amount of raw ground beef produced during particular dates and times, following clean-up and until the next clean-up, during which the same source materials are used. This ground beef recordkeeping lot definition is distinct from the STEC lot definition used by official establishments; the establishment lot may not be the same as retailer lot.)

The practices above also apply to product that is comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded at retail.

Communication with Suppliers

It is important that retailers understand how a supplier indicates the intended use of beef products. Suppliers should provide information on the intended use so retailers can assess the risk associated with grinding different types of beef products.

Intended use should be considered when retailers are grinding primals, sub-primals, purchased trim, boxed beef, or other components (e.g., mechanically separated beef or partially defatted beef fatty tissue).

Supplier labeling designating the intended use is not required. Therefore, retailers should work with their suppliers to be sure they understand how the supplier will communicate the intended use of beef products. There are various ways a supplier can communicate the intended use of beef to the retailer. Following are some examples:

- Direct communication with the supplier of raw beef products
- Receiving a letter identifying the intended use with each lot of product
- Contractual agreement with the supplying establishment
- Receiving a Certificate of Analysis (COA), testing results, or similar documentation showing the basis for the supplier's designated intended use
- Documentation showing that the product has been tested and found to not contain *E.coli* O157:H7 or other STEC
- Other documents such as Bill of Lading or Letter of Guarantee
- Using a code or labeling to identify the intended use of the product

7. Regulatory Requirements

Procedures outlined in this document are based on well-established food safety principles and set forth as guidance for planning and conducting safe grinding activities at retail. The use of this guidance is voluntary, and it is not a regulatory document. Retail food establishments that participate in beef grinding should operate in accordance with any applicable federal, state, and local food safety statutes and regulations. For example, retail food establishments conducting grinding activities may also be subject to the FDA Food Safety Modernization Act (FSMA) as well as applicable Current Good Manufacturing Practices (CGMPs) or USDA Food Safety Inspection Service's (FSIS) requirements. It is important that retail food establishments understand all legal and regulatory requirements, as well as industry guidelines, governing the safety of food throughout the grinding process

State, territorial, and local establishments with regulations modeled after the FDA model Food Code should include the following in their operations:

1. Presence of a Certified Food Protection Manager (U. S. Food and Drug Administration, § 2-102.12(A))
2. Compliance with Food Law (Approved Source) (U. S. Food and Drug Administration, §3-201.11(A))
3. Compliance with Food Law (Safe Handling Instructions) (U. S. Food and Drug Administration, §3-201.11(F))
4. Packaged and Unpackaged Food-Separation, Packaging, and Segregation (Food Storage) (U. S. Food and Drug Administration, §3-302.11)
5. Equipment Food-Contact Surfaces and Utensils. (Cleaning Frequency) (U. S. Food and Drug Administration, §4-602.11)
6. Employee Health (U. S. Food and Drug Administration, Subpart 2-201)
7. Hygienic Practices (U. S. Food and Drug Administration, Part 2-4)

It is strongly recommended that establishments focus on the following:

1. Establishing active managerial control, including developing policies, training staff, and maintaining detailed logs/records.
2. Understanding the concerns associated with using beef that is not intended for grinding.
3. Understanding the importance of having a clean break in the production cycle.

8. Other Resources and References

"Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments" CFP 2014
http://www.foodprotect.org/guides-documents/cfp-beef-grinding-log-template-guidance-document/

"Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations" FSIS 2021
https://www.fsis.usda.gov/guidelines/2021-0007

"FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations" FSIS 2021
https://www.fsis.usda.gov/guidelines/2021-0007

"Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products" Federal Register Vol. 80, No. 244 Monday, December 21, 2015 (p. 79231-79250)
https://www.govinfo.gov/content/pkg/FR-2015-12-21/pdf/2015-31795.pdf

"Best Practices for Raw Ground Beef Products" BIFSCo 2020
https://www.bifsco.org/Media/BIFSCO/Docs/bp_for_raw_ground_products_final_2020.pdf

9. Appendices

Appendix 1 - Production logs and additional records

A Beef Grinding Log may be used in conjunction with a company's beef production log (or cutting list) log. Production logs are used by retailers to project and produce specific types and amounts of steaks and roasts needed in a production cycle. A fall-out benefit of a production log is that they collect the source material of any bench trim that may have been produced by the retailer while fabricating steaks and roasts for the refrigerated display case. For those retailers grinding bench trim, this becomes the easiest way to collect the necessary data. Production logs or cutting lists will need to contain the supplier establishment number, manufacturer's name of the primal, and pack date and lot or serial number of the primal. (Note: Beef packers will reuse lot and serial numbers. However, documenting *both* the lot or serial number and pack date or use by date for a source material would make the lot or serial number unique.) Retailers will then need to file together both the production log and grind log for record keeping. The *Sample Primal Production Log for Retail Food Establishments below* shows the pertinent information that must be tracked on a production log if an establishment is grinding in-store produced bench trim and/or pull back material.

Completed grinding records must be maintained for a minimum of one year[25]. All such records should be accessible within 24 hours and are required to be maintained at the location where the raw beef was ground.

Production Log for Trim
Sample Primal Production Log for Retail Food Establishments

Examples for use include customer requested grinds and pull backs

Store Location: Store #55			**Production Date**: 08/04/2022	
Primal Product Name as Listed on the Box	**Vendor/Supplier Name**	**Establishment #**	**Lot Number**	**Pack Date**
BEEF KNUCKLE	Swift	3D	7846515	07/24/2022

*Note: This sample production log is being provided as an example to visually provide the pertinent information that must be tracked (in addition to a beef grinding log) if an establishment is grinding in-store produced bench trim and/or pull back material. This document must not be misconstrued to prohibit an establishment from keeping this information in a different manner or format.

[25] 9 CFR 320.1(b)4

Appendix 2 - Required and recommended information for records

Required Recordkeeping (9 CFR 320.1(b)	Recommended data elements for records
	Retail Establishment Name
	Supplier Name
(A) The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product;	Establishment Number(s) of Beef Supplier
(B) All supplier lot numbers and production dates;	Lot Number of product ground Pack Date of product ground
(C) The names of the supplied materials, including beef components and any materials carried over from one production lot to the next;	Common Name of Primal
	Common name of product made
(D) The date and time each lot of raw ground beef product is produced; and	Date and time of grind
(E) The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.	Date and time for cleaning and sanitation of grinding equipment
	Link to package label created by retailer

Appendix 3 - Examples of language for intended use from beef suppliers

Suppliers typically provided intended use information in letters of guarantee (LOG) or other information posted on their websites. The following are examples of LOG from beef suppliers:

https://www.cargill.com/doc/1432077201913/mfs-subprimal-fsis-mt65-ltr-pdf.pdf

https://pacfoods.com/wp-content/uploads/2021/02/JBS-Beef-Food-Safety-Letter-01.04.21.pdf

Disclaimer: These letters should not be considered an endorsement of any particular supplier or company.

10. Acknowledgements

Multiple CFP members, volunteers and external experts participated in the development of this document.

Sherri Trujillo, JBS and Mandy Carr Johnson, BIFSCo provided valuable information during the development of this document on industry practices and scientific insights related to grinding raw beef and risk management.

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Conference for Food Protection

Evaluation of Intended Use Hazards During Retail Meat Grinding
December 2022

Table of Contents:

1. Charge of the Committee

Council III of the Conference for Food Protection (CFP) formed the Evaluation of Intended Use Hazards during Retail Meat Grinding committee with the directive to:

1.) Evaluate prior developed 'CFP Beef Grinding Log Template Guidance Document' to consider inclusion of information for the prevention of common hazards known to be associated with grinding processes

A.) "Intended Use" policy, purpose, and control measures including supply chain communication

B.) Examples of common control measures, such as supplier guarantees or certificates of analysis and ongoing verification

C.) Reference to FSIS guideline for minimizing STEC in Raw Beef Processing Operations (https://www.fsis.usda.gov/guidelines/2021-0007)

2.) Consider developing educational materials (e.g., handout(s) to support grinding log assessment by regulatory authorities, industry personnel, and the public. Examples may include:

A.) Educational fact sheets detailing hazards represented by the non-intact handling of beef intended for whole intact use

B.) Plain language explanations of “Intended Use” policy purpose.

3.) Evaluating potential changes to the Food Code to address the hazards associated with establishments grinding of beef that is manufactured as “Intended for Intact Use”.

4.) Determining appropriate mechanisms for sharing the committee's work, and

5.) Reporting progress back to the next Biennial Meeting in 2023 and the committee's findings and recommendations may be presented at the subsequent Biennial Meeting if necessary.

2. Introduction

This committee was charged with enhancing the Conference for Food Protection (CFP) "Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments"[1] to include information on how retail food establishments can prevent common hazards associated with beef grinding processes.

Shiga toxin-producing *Escherichia coli* (STEC) is estimated to cause 265,000 illnesses in the US annually, including 3,600 hospitalizations and thirty deaths. To date, at least four outbreaks have been associated with beef ground at retail that was not intended for grinding (e.g., trim from intact steaks or roasts, and "pull backs"). Inadequate grinding records and insufficient sanitation between source lots at retail have hindered public health investigators' ability to determine the ultimate source of the implicated beef.

After reviewing the 2014 CFP beef-grinding document, the United States Department of Agriculture, Food Safety Inspection Service (USDA, FSIS) guidance documents and beef supplier risk elimination program presentations, the committee proposes the following changes and additions to the guidance document including:

1. Definition of "Intended Use", its purpose and regulations,
2. Beef product examples in both categories (intended and not intended to be ground) and what risk is associated with each,
3. Recommended common control measures that can be done in a retail setting to reduce risk, such as supplier communication.

The Committee agreed that creating educational materials was out of the scope of the committee and should be created by experts in education based on the needs of their communities following the release of this guidance document.

This document is intended to be guidance for retail food establishments that grind beef and to assist with creating protocols and training materials for their establishments. The recommendations are not intended to replace, or otherwise serve as, the rules and regulations applicable to food establishments in any given federal, state, local or tribal jurisdiction. Please refer to the appropriate inspection authority in your jurisdiction for further guidance. Inspectors often have deep expertise and can assist with food safety management programs and compliance with existing regulations.

1 CFP Beef Grinding Log Committee. "Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments". Conference for Food Protection. 2012-2014. Available from: http://www.foodprotect.org/guides-documents/cfp-beef-grinding-log-template-guidance-document/.

3. Definitions

Note – These definitions generally represent terms used in retail establishments. When multiple definitions are available from regulatory agencies applicable to retail establishments, references are provided.

Active Managerial Control
Active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.[2]

Batch/Set
An identified quantity of beef that is ground based on specific attributes, such as percent lean, which will all be labeled as the same product.

Bench Trim
Product derived from cattle not slaughtered at the establishment.[3] In retail establishments with meat cutting operations, bench trim is generated in store. (Retailers tend to use the terms bench trim and trim interchangeably)

Chub
Rolls of ground beef that have been packaged to keep air out.[4] Chubs come in a variety of packaged sizes.

Customer requested grinding
As a service to customers, retailers may offer grinding of a cut of beef selected by the customer from the service case or packaged product that was not originally intended to be ground. This product is subject to the recordkeeping requirements for ground beef.

Grind Cycle
The amount of ground beef (measured by quantity and/or time) for one **lot** of product as documented by complete sanitation cycles. A grind cycle may include multiple batches/sets within a sanitation cycle.

Ground Beef

2 2017 FDA Food Code Annex, page 551.
3 FSIS Directive 10,010.1. Available from: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/10010.1.pdf
4 "Ground Beef Packaging, What's the difference?" Meat Science Organization. 2017. Available from: https://meatscience.org/TheMeatWeEat/topics/fresh-meat/article/2017/04/26/ground-beef-packaging-what's-the-difference

Chopped fresh and/or frozen beef or veal with or without seasoning and without the addition of beef fat as such, will not contain more than 30% fat, and shall not contain added water, phosphates, binders, or extenders.[5]

Intact Meat
A cut of whole muscle(s) meat that has not undergone comminution, mechanical, tenderization, vacuum tumbling with solutions, or reconstruction, cubing or pounding.[6]

Intended Use
How the federal establishment (producer) intends the product to be safely consumed or if further processing or further controls are needed. *9 CFR 417.2(a)(2)* requires each establishment to identify the intended use or consumers of the finished product. The product's intended use may affect the **STEC** controls in place at both the shipping and receiving establishments. Establishments that purchase beef from slaughter establishments should be aware of the slaughter establishment's intended use for the specific products they receive. [7]

Lot
For the purposes of FSIS requirements in *9 CFR 320.1(b)(4),* a lot is defined as the amount of raw ground beef produced during particular dates and times, following clean-up and until the next clean-up, during which the same source materials are used.[8]

Lot code
Defined volume or timeframe of finished product.

Non-Intact
Non-intact beef products include: ground beef; chopped beef; flaked or, minced product; beef that is vacuum tumbled with solutions; beef that an establishment has mechanically tenderized by needling (including injecting with solutions), cubing, pounding devices (with or without marinade); beef that an establishment has reconstructed into formed entrees; beef with proteolytic enzymes applied; and diced beef less than ¾ inch (dial setting) in any one dimension on average.[9]

Mechanically tenderized (non-intact)
Manipulating meat by piercing with a set of needles, pins, blades or any mechanical device, which breaks up muscle fiber and tough connective tissue, to increase tenderness.

5 *9 CFR 319.15a*
6 "Non-intact beef products". askUSDA. Available from: https://ask.usda.gov/s/article/Non-intact-beef-products
7 "FSIS Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Processing Operations". 2021. Available from: https://www.fsis.usda.gov/guidelines/2021-0007
8 *9 CFR 320.1(b)(4)(iii).*
9 "FSIS Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Processing Operations". 2021. Available from: https://www.fsis.usda.gov/guidelines/2021-0007.

This includes INJECTION, scoring, and processes which may be referred to as "blade tenderizing," "jaccarding," "pinning," or "needling."[10,11]

Primal cut
From FDA Food Code: A basic major cut into which carcasses and sides of meat are separated, such as a beef round, pork loin, lamb flank, or veal breast.[12]

From FSIS: Primal parts are the wholesale cuts of carcasses as customarily distributed to retailers. The round, flank, loin, rib, plate, brisket, chuck, and shank are primal parts of beef carcasses. Veal, mutton, and goat primal parts are the leg; flank, loin, rack, breast, and shoulder.[13] *(For the purpose of this document, only beef and veal are in scope.)*

Production Cycle
Consists of one or more **Grind Cycles.**

Production Log
Documents used to facilitate or supplement the recordkeeping requirement for ground beef. Some retailers find it helpful to maintain a production log that contains additional details on timing and products used to help with internal records. Production logs are not required in the FSIS regulation on recordkeeping, and do not take the place of the official records required by FSIS. See Appendix for a sample production log.

Pull backs
Retail packaged cuts, such as steaks or roasts, removed from the self- service refrigerated display cases and either reworked into smaller cuts, such as stew beef or cube steak, or ground product. "Pull-backs" can be ground separately but are sometimes co-mingled with in-store produced bench trim.

Recordkeeping requirements for beef (grinding log)
FSIS finalized a rule on December 21, 2015, requiring additional records be kept for establishments and retailers grinding beef. The rule is titled "Records to Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products."[14]

Re-work

10 U.S. Department of Health and Human Services, U.S. Food and Drug Administration. FDA Food Code. 2017 Available from: www.fda.gov/FoodCode.

11 Federal Register Vol. 80, No. 95 Monday, May 18, 2015 (p. 28153-28172) Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products.

12 U.S. Department of Health and Human Services, U.S. Food and Drug Administration. FDA Food Code. 2017.

13 *9 CFR 316.9(b).*

14 Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products. *Federal Register.*2015. Available from: https://www.federalregister.gov/documents/2015/12/21/2015-31795/records-to-be-kept-by-official-establishments-and-retail-stores-that-grind-raw-beef-products

Changing the form of a meat or poultry cut by reprocessing it down into smaller pieces or transformed to a different product to maximize shelf life.

FDA Definition: Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.[15]

Standard Operating Procedures (SOP)
Written procedures that an establishment develops and implements to prevent direct contamination or adulteration of product, internal protocols. [16]

Sanitation Standard Operating Procedures (SSOP)
Written procedures (specific to sanitation) that an establishment develops and implements to prevent direct contamination or adulteration of product, internal protocols. [17]

Subprimal cuts
The first division of a whole carcass is into primal cuts. The four major **primal cuts** into which beef is separated are chuck, loin, rib and round. All primal cuts may or may not be intended for use in ground products. **Primal cuts** are then divided into subprimal cuts. Examples of subprimal cuts of beef are the top round, whole tenderloin, and rib eye. Any subprimal cut may or may not be intended for use in ground products.[18]

STEC
FSIS uses the term STEC to refer to Shiga toxin-producing *Escherichia coli* (*E. coli*) O157:H7 and six non O157 serogroups O26, O45, O103, O111, O121, and O145 that are adulterants in raw non-intact beef and raw intact beef intended for non-intact use.[19]

Trim
Beef products produced from in-house source materials.[20] (Retailers tend to use the terms bench trim and trim interchangeably)

Vacuum packaged

15 *21 CFR 117.3*.
16 FSIS Standard Operating Procedure Guide. *USDA*. Available from: https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/Sanitation-SOP-Guide.pdf
17 FSIS Standard Operating Procedure Guide. *USDA*. Available from: https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/Sanitation-SOP-Guide.pdf
18 "What are primal cuts?" AskUSDA. Available from: https://ask.usda.gov/s/article/What-are-the-primal-cuts
19 "Expansion of FSIS Shiga Toxin-Producing Escherichia coli (STEC) Testing to Additional Raw Beef Products". Available from: https://www.fsis.usda.gov/node/2272
20 FSIS Directive 10,010.1. available from: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/10010.1.pdf

Source product (**primal cuts**) packaged in vacuum packed bags from supplier are typically considered to be **intended for intact use**.

4. Intended Use

Federally inspected beef suppliers (approved suppliers to retail food establishments) should determine the intended use of the products shipped including the determination if the product is meant to be safely consumed (following proper food handling practices) or if further processing or further controls are needed for the product to be safety consumed.

Through regulations specified in *9 CFR 417.2(a)(2),* FSIS requires each establishment (supplier) to identify the intended use or consumers of the finished product. The product's intended use may affect the STEC controls in place at both the shipping and receiving establishments. Intended use of beef products for use at retail should be known, communicated and considered when planning production of retail packaged products. The intended use for the purpose of this document is to facilitate the safe consumption of the beef product or to clarify if additional controls or treatment is needed.

STEC is not an adulterant on raw intact beef products, such as steaks and roasts, which are "intended" for intact consumer use. This is because STEC contamination would be limited to the exterior surfaces of intact beef products and, if these products remain intact, normal consumer cooking will destroy any STEC on the outer surfaces, even if the product is cooked to a rare or medium internal state. STEC is an adulterant in raw non-intact beef products (ground beef) and raw intact beef products intended for raw non-intact use because the same consumer cooking practice will not destroy any STEC that have been internalized by the non-intact processing. STEC is also considered an adulterant in products for which the intended use is not clearly defined or supported.[21]

USDA FSIS documentation in askFSIS states that regulated establishments (beef suppliers) should[22]:

- Identify the intended use of the product as per *9 CFR 417.2(a)(2).*
- Develop decision-making documents based on objective measures which identify the intended use of the product. A hazard analysis must be included with the documents and must be consistent with the establishment's assertion that the product in question is/is not for use in raw non-intact product.
- Have measures in place to restrict products that are for intact use only. Such measures may include letters to the purchasers, website postings, bill of lading communications, and a receipt of acknowledgement that the purchasers understand that this product is intended solely for intact use as described in detail

21 "FSIS Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Beef (including Veal) Processing Operations". Available from: https://www.fsis.usda.gov/guidelines/2021-0007

22 "Adequate Support for the Intended Use of Beef Primal and Subprimal Cuts". AskUSDA. https://ask.usda.gov/s/article/Adequate-Support-for-the-Intended-Use-of-Beef-Primal-and-Subprimal-Cuts

by the posted askFSIS answer "Adequate Support for the Intended Use of Beef Primal and Subprimal Cuts".[23]

Some acceptable ways that the establishment can support that primal and subprimal cuts are intended for raw intact product include:

- The establishment communicates the intended use to the receiving establishment or facility by making the letter of intended use available on the producing establishment's company website and references the letter of intended use on bills of lading.
- The establishment receives letters of guarantee showing that all product is used in raw intact product only and maintains on-going communication with the receiving establishment or facility to verify that product is being processed as raw intact product only.
- The establishment has a contractual agreement with the receiving establishment or facility so the producing establishment has knowledge of the receiving establishment or facility's production process.[24]

Intended use should be considered when retailers are grinding primals, subprimals, purchased trim, boxed beef, or other components (e.g., mechanically separated beef or partially defatted beef fatty tissue) that are not accompanied by records of negative *E. coli* O157:H7 or other STEC test results.

Supplier labeling designating the intended use is not required. Therefore, retailers should work with their suppliers to be sure they understand how the supplier will communicate the intended use of beef products. There are various ways a supplier can communicate the intended use of beef to the retailer. Following are some examples:

- Direct communication with the supplier of raw beef products
- Receiving a letter identifying the intended use with each lot of product
- Contractual agreement with the supplying establishment
- Receiving a Certificate of Analysis (COA), testing results, or similar documentation showing the basis for the supplier's designated intended use
- Documentation showing that the product has been tested and found to not contain *E. coli* O157:H7 or other STEC
- Other documents such as Bill of Lading or Letter of Guarantee
- Using a code or labeling to identify the intended use of the product

If the retailer is unclear on the intended use of a product, they should contact their supplier for further clarification.

23 Supporting the supply of raw beef intended for intact use. AskUSDA. Available from: https://ask.usda.gov/s/article/Supporting

24 Adequate Support for the Intended Use of Beef Primal and Subprimal Cuts". AskUSDA. Available from: https://ask.usda.gov/s/article/Adequate-Support-for-the-Intended-Use-of-Beef-Primal-and-Subprimal-Cuts

5. Recordkeeping for Beef Ground at Retail

Existing regulations from FSIS require that all facilities grinding beef (including retail establishments) maintain records regarding the source materials and cleaning and sanitation practices. In a rule published in December 2015, FSIS specified the recordkeeping requirements in *9 CFR 320.1(b).*

Official establishments and retail stores are required to maintain records that fully disclose:

1. The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product;
2. All supplier lot numbers and production dates;
3. The names of the supplied materials, including beef components and any materials carried over from one production lot to the next;
4. The date and time each lot of raw ground beef product is produced; and
5. The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.

Records can be in any format but should be legible and accessible at all times. Records must be maintained for one year. When feasible, all retailers are encouraged to adopt electronic recordkeeping to collect and maintain this important data in a secure and usable format. Technology will facilitate accurate and timely tracebacks, although smaller retailers may find it challenging due to limited financial and human resources support to move to digital records. Retailers that adopt electronic recordkeeping should develop SOPs to address how to capture key grinding data for system issues or malfunction.

Template: Sample Recordkeeping Template for Grinding Beef

Retail Establishment Name: Store # **Retail Establishment Production Date**

Date and time of grind (required)	Manufacturer name of source material used for product produced (required)	Establishment number(s) of establishment providing source material (required)	Supplier lot #s, product code and/or pack date of source material used (required)	Date and time grinder and related Food Contact Surfaces cleaned and sanitized (required)	Comments	Information linking to the retail package (recommended)

6. Retail Practices, Risk Reduction, and Supplier Communications

Implementing retail practices and strategies for reducing risks in the retail meat department should be part of an Active Managerial Control program. Active Managerial Control is the purposeful incorporation of specific actions or procedures by management into the retail operations to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.

Beef Handling and Grinding Practices at Retail

A producer or supplier of beef cannot verify that all pathogens have been eliminated from raw beef. However, producers have procedures in place for handling, treating, and testing beef in accordance with a HACCP plan and under FSIS federal inspection oversight to minimize the risk of contamination. The risk control steps taken by a supplier are used to designate the intended use of the meat once that meat is in a retail facility.

The risks associated with beef at a retail establishment will depend on several factors including how the supplier intended the beef to be handled, processed, labeled, and sold at retail. When implementing retail practices, the risk should be considered based on product type and intended use.

All the practices in the following examples are permitted. Some of these practices are based on following the supplier's intended use designation for the product. Other retail practices may present additional risk because they are not in accordance with the supplier's intended use and these are designated as non-intended use practices.

1. **Practices/Products Based on Intended Use**

Beef products from a supplier that are intended to be consumed intact.

> Examples: Steaks, roasts, smaller cuts of beef such as stew beef or primals in vacuum packaging. It does not include meat that has been ground, comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded.
>
> Rationale: These products are least likely to have contamination. Contamination, if present, is on the cut surface only. These pieces of beef may have surface contamination, but the outside surfaces will receive sufficient heat treatment when cooked by the consumer to render them safe.

Beef products from a supplier that can be cut at the retail facility provided they retain an intact surface that will be heat-treated when cooked by the consumer.

Examples: Primals, sub-primals, or large roasts that are cut into steaks or smaller pieces. It does not include meat that has been ground, comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded. Nothing has been done at retail to introduce pathogens into the interior of the meat and any contaminants will remain on an exterior surface.

Rationale: Contamination, if present, is on the cut surface only. These pieces of beef may have surface contamination, but the outside surfaces will receive sufficient heat treatment when cooked by the consumer to render them safe.

Beef that has been ground, comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded by the supplier. This is non-intact meat which the supplier intended to be consumed in this form.

Examples: Beef ground by the supplier (may be pre-packed or bulk), cubed steaks, mechanically tenderized steaks. In all these examples, the meat was converted into non-intact beef by the supplier.

Rationale: Although this meat is not intact, the supplier has taken additional steps for handling, treating, and testing this beef in accordance with a HACCP plan and under FSIS federal inspection oversight to minimize the risk of STEC contamination.

Beef that has been ground or comminuted by the supplier but will be re-ground at the retail establishment. This is non-intact meat which the supplier intended to be consumed in this form.

Examples: Large chubs or containers of ground beef or coarse ground beef that will be re-ground at the retail facility.

Rationale: The supplier has already converted this beef into non-intact product. The supplier has taken additional steps for handling, treating, and testing this beef in accordance with a HACCP plan and under FSIS federal inspection oversight to minimize the risk of STEC contamination.

Beef trimmings from the supplier that are intended to be ground at retail. This meat will be converted into non-intact beef at retail.

Examples: Combo bins of trimmings, fat, and other small pieces of beef intended by the supplier to be ground at retail.

Rationale: The supplier has taken additional steps for handling, treating, and testing this beef in accordance with a HACCP plan and under FSIS federal inspection oversight to minimize the risk of STEC contamination.

2. Practices Not Based on Intended Use

Non-intended use practices may require additional controls to help mitigate risk of cross contamination if STEC is present on the exterior portion of the beef prior to grinding. Although the controls will help mitigate cross contamination, they will not address the risk of STEC in the product. Examples of non-intended use include the following:

Beef that is intact and which the supplier did not intend to be ground at retail. Intact beef that is not intended by the supplier to be comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded at the retail establishment.

> Examples: Converting store-generated trim (bench trim, market trim, case trim, block trim), re-work, pull-backs, and customer orders into ground beef. Cubing steaks or needle tenderizing beef at the retail facility.
>
> Rationale: Although suppliers have procedures in place for handling, treating, and testing beef in accordance with a HACCP plan and under FSIS federal inspection, this product did not receive any additional treatment or testing to further reduce the risk of STEC contamination. The supplier did not intend for this meat to be converted into non-intact beef at retail.

Controls to Reduce Risk at Retail

There are steps that can be taken at retail to help reduce the risks of contamination of beef. These include developing a written beef grinding protocol that specifies, at a minimum, segregation, separation, grinding practices, lotting, recordkeeping, and labeling.

Retail practices may include:

- Grinding product in small batches to reduce co-mingling of different products
- Labeling products with different source materials to ensure proper identification
- Maintaining complete and accurate production logs and grinding logs
- Segregating products based on designation of intended use
- Establishing consistent grinding sequence (Examples: from intact to non-intact; from most lean to higher fat content)
- Separating production cycles based on type of products or species
- Designating shelf life and/or use by date
- Sourcing meat from approved suppliers following all FSIS regulations

Additional good retail practices include:

- Rotate supply first-in first-out and pay attention to dates.
- Avoid mixing species unless intentional and clearly labeled. Clean and sanitize equipment between species.
- All food contact surfaces should be cleaned and sanitized before use.
- All products should be held at proper temperatures.
- Properly label all products with source, date, time and other required information.
- Avoid mixing multiple products from different suppliers because it makes the recordkeeping and traceback difficult.
- Control other hazards including foreign material.
- Develop a written cleaning and sanitizing program.

The control program should address the cleaning and sanitizing of food contact surfaces, equipment, utensils, implements, and the meat processing areas including frequency of cleaning, cleaning/sanitizing chemicals and tools that will be used. The time of each cleaning and sanitizing should be documented in the recordkeeping system for beef ground at retail. Training is recommended for all employees with responsibilities for cleaning and sanitizing.

Refer to the FDA Food Code and your state, local, tribal or territory requirements for cleaning and sanitation best practices. Section 4-602.11 of the FDA Food Code states that all food contact surfaces shall be cleaned at least every four hours. The food code provides for cleaning less frequently than every four hours if the utensils and equipment are held in a refrigerated room and cleaned according to the frequencies provided in the food code. (See *2017 FDA Food Code* Section 4-602.11)

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

Breaks in the grinding cycle

When grinding beef, intentional breaks in the grinding cycle are critical and should not be overlooked. A break in the grinding cycle is a combination of a complete cleaning and sanitizing step in conjunction with no carryover of product. Breaks should be used to separate lots, batches, or cycles of product to reduce the risk of cross-contamination. Breaks in the production of ground beef can be the difference between needing to recall product from only part of a day or all product produced over several days. The day and time of all cleaning and sanitizing breaks in the cycle should be documented and included as part of the grinding log.

Employee Training and Personal Health and Hygiene

Proper training of all employees with access to food production, storage, and packaging areas is essential. Only properly trained employees should be allowed in designated areas.

The Food Code and/or state and local regulations have guidelines for employee health and hygiene including illness procedures and policies for hand washing, proper clothing, coverings, hair restraints, gloves, etc. Local, state, and federal regulations should be followed at all times.

Retailers should develop specific training programs for the employees, certified food protection manager (CFPM), and person in charge (PIC) specific to working in the meat department. This includes grinding practices and protocols along with collecting, recording, and maintaining grind log data during their daily job duties.

Lotting at Retail

The package of beef produced at retail must be linked to the lot code(s) of the product from which it was made, i.e., the source product. The retail-ground lot should have a supportable definition and should link the packaged product to the source material.

Official establishments and retail stores are to define a lot of raw ground beef product as the amount of raw ground beef produced during particular dates and times, following clean-up and until the next clean-up, during which the same source materials are used. This ground beef recordkeeping lot definition is distinct from the STEC lot definition used by official establishments; the establishment lot may not be the same as retailer lot.)

The practices above also apply to product that is comminuted, mechanically tenderized (needled), vacuum tumbled, reconstructed, cubed, or pounded at retail.

Communication with Suppliers

It is important that retailers understand how a supplier indicates the intended use of beef products. Suppliers should provide information on the intended use so retailers can assess the risk associated with grinding different types of beef products.

Intended use should be considered when retailers are grinding primals, sub-primals, purchased trim, boxed beef, or other components (e.g., mechanically separated beef or partially defatted beef fatty tissue).

Supplier labeling designating the intended use is not required. Therefore, retailers should work with their suppliers to be sure they understand how the supplier will communicate the intended use of beef products. There are various ways a supplier can communicate the intended use of beef to the retailer. Following are some examples:

- Direct communication with the supplier of raw beef products
- Receiving a letter identifying the intended use with each lot of product
- Contractual agreement with the supplying establishment
- Receiving a Certificate of Analysis (COA), testing results, or similar documentation showing the basis for the supplier's designated intended use
- Documentation showing that the product has been tested and found to not contain *E.coli* O157:H7 or other STEC
- Other documents such as Bill of Lading or Letter of Guarantee
- Using a code or labeling to identify the intended use of the product

7. Regulatory Requirements

Procedures outlined in this document are based on well-established food safety principles and set forth as guidance for planning and conducting safe grinding activities at retail. The use of this guidance is voluntary, and it is not a regulatory document. Retail food establishments that participate in beef grinding should operate in accordance with any applicable federal, state, and local food safety statutes and regulations. For example, retail food establishments conducting grinding activities may also be subject to the FDA Food Safety Modernization Act (FSMA) as well as applicable Current Good Manufacturing Practices (CGMPs) or USDA Food Safety Inspection Service's (FSIS) requirements. It is important that retail food establishments understand all legal and regulatory requirements, as well as industry guidelines, governing the safety of food throughout the grinding process

State, territorial, and local establishments with regulations modeled after the FDA model Food Code should include the following in their operations:

1. Presence of a Certified Food Protection Manager (U. S. Food and Drug Administration, § 2-102.12(A))
2. Compliance with Food Law (Approved Source) (U. S. Food and Drug Administration, §3-201.11(A))
3. Compliance with Food Law (Safe Handling Instructions) (U. S. Food and Drug Administration, §3-201.11(F))
4. Packaged and Unpackaged Food-Separation, Packaging, and Segregation (Food Storage) (U. S. Food and Drug Administration, §3-302.11)
5. Equipment Food-Contact Surfaces and Utensils. (Cleaning Frequency) (U. S. Food and Drug Administration, §4-602.11)
6. Employee Health (U. S. Food and Drug Administration, Subpart 2-201)
7. Hygienic Practices (U. S. Food and Drug Administration, Part 2-4)

It is strongly recommended that establishments focus on the following:

1. Establishing active managerial control, including developing policies, training staff, and maintaining detailed logs/records.
2. Understanding the concerns associated with using beef that is not intended for grinding.
3. Understanding the importance of having a clean break in the production cycle.

8. Other Resources and References

"Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments" CFP 2014
http://www.foodprotect.org/guides-documents/cfp-beef-grinding-log-template-guidance-document/

"Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations" FSIS 2021
https://www.fsis.usda.gov/guidelines/2021-0007

"FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations" FSIS 2021
https://www.fsis.usda.gov/guidelines/2021-0007

"Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products" Federal Register Vol. 80, No. 244 Monday, December 21, 2015 (p. 79231-79250)
https://www.govinfo.gov/content/pkg/FR-2015-12-21/pdf/2015-31795.pdf

"Best Practices for Raw Ground Beef Products" BIFSCo 2020
https://www.bifsco.org/Media/BIFSCO/Docs/bp_for_raw_ground_products_final_2020.pdf

9. Appendices

Appendix 1 - Production logs and additional records

A Beef Grinding Log may be used in conjunction with a company's beef production log (or cutting list) log. Production logs are used by retailers to project and produce specific types and amounts of steaks and roasts needed in a production cycle. A fall-out benefit of a production log is that they collect the source material of any bench trim that may have been produced by the retailer while fabricating steaks and roasts for the refrigerated display case. For those retailers grinding bench trim, this becomes the easiest way to collect the necessary data. Production logs or cutting lists will need to contain the supplier establishment number, manufacturer's name of the primal, and pack date and lot or serial number of the primal. (Note: Beef packers will reuse lot and serial numbers. However, documenting *both* the lot or serial number and pack date or use by date for a source material would make the lot or serial number unique.) Retailers will then need to file together both the production log and grind log for record keeping. The *Sample Primal Production Log for Retail Food Establishments below* shows the pertinent information that must be tracked on a production log if an establishment is grinding in-store produced bench trim and/or pull back material.

Completed grinding records must be maintained for a minimum of one year[25]. All such records should be accessible within 24 hours and are required to be maintained at the location where the raw beef was ground.

Production Log for Trim
Sample Primal Production Log for Retail Food Establishments

Examples for use include customer requested grinds and pull backs

Store Location: Store #55			**Production Date**: 08/04/2022	
Primal Product Name as Listed on the Box	**Vendor/Supplier Name**	**Establishment #**	**Lot Number**	**Pack Date**
BEEF KNUCKLE	Swift	3D	7846515	07/24/2022

*Note: This sample production log is being provided as an example to visually provide the pertinent information that must be tracked (in addition to a beef grinding log) if an establishment is grinding in-store produced bench trim and/or pull back material. This

25 9 CFR 320.1(b)4

document must not be misconstrued to prohibit an establishment from keeping this information in a different manner or format.

Appendix 2 - Required and recommended information for records

Required Recordkeeping (9 CFR 320.1(b)	**Recommended data elements for records**
	Retail Establishment Name
	Supplier Name
(A) The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product;	Establishment Number(s) of Beef Supplier
(B) All supplier lot numbers and production dates;	Lot Number of product ground Pack Date of product ground
(C) The names of the supplied materials, including beef components and any materials carried over from one production lot to the next;	Common Name of Primal
	Common name of product made
(D) The date and time each lot of raw ground beef product is produced; and	Date and time of grind
(E) The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.	Date and time for cleaning and sanitation of grinding equipment
	Link to package label created by retailer

Appendix 3 - Examples of language for intended use from beef suppliers

Suppliers typically provided intended use information in letters of guarantee (LOG) or other information posted on their websites. The following are examples of LOG from beef suppliers:

https://www.cargill.com/doc/1432077201913/mfs-subprimal-fsis-mt65-ltr-pdf.pdf

https://pacfoods.com/wp-content/uploads/2021/02/JBS-Beef-Food-Safety-Letter-01.04.21.pdf

Disclaimer: These letters should not be considered an endorsement of any particular supplier or company.

10. Acknowledgements

Multiple CFP members, volunteers and external experts participated in the development of this document.

Sherri Trujillo, JBS and Mandy Carr Johnson, BIFSCo provided valuable information during the development of this document on industry practices and scientific insights related to grinding raw beef and risk management.

2021-2023 CFP Intended Use Committee

CFP Leadership

Vought, Becky	CFP Chair
Rossow, Todd	CFP Vice Chair
Schaffner, Donald	CFP Council III Chair
Manuel, Chip	CFP Council III Vice Chair

Voting Members

Thesmar, Hilary	FMI	Chair
Shumaker, Ellen	NCSU	Co-Chair
Burgess, Victoria	Pubix Super Markets, Inc	
Danos, Trista	Whole Foods Markets	
English, Amber	Washoe County Health District	
Hess, Erich	Jewel-Osco	
Hofer, Vasanthi	Maricopa County Environmental Services Department	
Kendrick, Susan	Oregon Department of Agriculture	
Mello, Wayne	Ahold Delhaize/Retail Business Services	
Otzenberger, Michael	State of Wisconsin	
Pease, Robert	H-E-B Grocery Company, LP	
Rivas, Rose	Rivas Ranch	

Non-Voting Members and Federal Agency Consultants

Moore,Veronica	FDA
Destromp, Kimberly	FDA
Williams, Juhi	FDA
Collaro,Thomas	USDA FSIS
Barlow,Kristina	USDA FSIS
Beckett, John	Publix Super Markets, In
Hollingsworth, Jill	Ecolab
Prince, Gale	SAGE Food Safety LLC

COMMITTEE NAME Retail Sushi HACCP Standardization Committee Final Report

DATE OF FINAL REPORT: 11/10/2022

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☐ ***Council II*** ☒ ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: Veronica Bryant, Chair and Rupesh Modi, Vice Chair

COMMITTEE CHARGE(S):

Issue # 2020 III-017 stated that a Retail Sushi HACCP Standardization Committee be formed with the following charges:

1. Review current industry practices, collect available guidance documents, and current state codes pertaining to the production of sushi prepared at retail establishments.
2. Update the current CFP guidance document for production of sushi prepared at retail establishments.
3. Referencing the guidance document in the Food Code Annex, or wherever the committee deems appropriate.
4. Identifying whether the Food Code adequately addresses sushi production at retail as a whole and make suggestions for changes (if necessary) at the next CFP Biennial Conference.
5. Identifying the recommended methods to disseminate the committee's findings.
6. Reporting the committee's findings at the next CFP Biennial Conference

COMMITTEE WORK PLAN AND TIMELINE:

Initial Committee Meeting held November 10, 2021. Regular monthly meetings were held on the second Wednesday of each month

1. Work plan was discussed with full committee, decision was made to work on charges sequentially.
2. First charge was completed between November and December meetings.
3. Charge #2 to update guidance will take most of the time for the committee. Guidance document was discussed during December, January, and February meetings.
4. Committee has agreed to split topics to be covered in the guidance document among members and work in small groups to write sections of the documents and create infographics and decision trees.
5. Guidance document will be assembled with a target date of July 1.
6. Editing and review of the document will be completed with target date of August 1. Actual editing and review were not completed until September 14 meeting. Vote on the final version of the document was completed at the end of October via email vote.
7. Recommendations to the FDA from the committee were discussed and submitted via email vote.
8. The chair and co-chair will monitor attendance of voting and non-voting members and voting members of the full committee will vote to excuse members if unexcused absence of the voting member becomes a pattern.
9. Periodic reports will be submitted by March 1, 2022 and July 1, 2022 to the Council Chair.
10. Final guidance document to be submitted to Council Chairs by November 15, 2022.

COMMITTEE ACTIVITIES: Dates of committee meetings or conference calls: 11/10/21, 12/15/21, 1/12/22, 2/9/22, 3/9/22, 5/11/22, 6/8/22, 7/13/22, 8/10/22. 9/14/22, 10/12/22

1. ***Overview of committee activities:***

   Committee completed review of existing sushi guidance. Research was compiled, trends and discrepancies were noted, and a summary of the research will be included in the background of the guidance document.

   Committee has determined content to be discussed in guidance document, and what additional tools may be included.

   Committee has provided feedback on which section of the guidance document they are interested in writing, and groups of committee members were formed to prepare guidance document.

   Committee members wrote draft language for sections of the document, document was then combined.

   Committee members worked to provide edits and prepare a final document with a decision tree and checklist included

   Draft guidance document was submitted to committee at the May 11 meeting. Meetings in June, July, August and September were used to discuss the document and edits to be made.

Additional charges and recommendations to FDA were discussed during the September and October meetings.

Final edits were completed, and vote was taken via email vote. Vote was 20 for, 1 against, 2 abstained. Two abstained votes were committee members who were no longer regularly participating in meetings.

Final votes were taken on additional issues to be submitted by committee. Vote was 19 for, 2 against, 2 abstain for issue on requesting FDA to streamline chain HACCP process and 18 for, 3 against, 2 abstain for issue on adding acidification of rice directly to the Food Code.

Committee work was completed as of 11/7/2022 and committee will request to be disbanded at the 2023 Annual Meeting.

2. ***Charges COMPLETED and the rationale for each specific recommendation:***
   a. Review current industry practices, collect available guidance documents, and current state codes pertaining to the production of sushi prepared at retail establishments.
   Review was completed and document that summarizes findings is attached to this report.
   b. Update the current CFP guidance document for production of sushi prepared at retail establishments.
   Committee determined that guidance needed was not able to be included in the current CFP document. The committee created a separate document that will be submitted. Guidance document is attached to this report.
   c. Referencing the guidance document in the Food Code Annex, or wherever the committee deems appropriate.
   Issue will be submitted by the committee asking for the document to be posted on the website and included in resources provided for acidification of foods, specifically Annex 2 – Supporting Documents or Annex 3 in Section 3-502.11.
   d. Identifying whether the Food Code adequately addresses sushi production at retail as a whole and make suggestions for changes (if necessary) at the next CFP Biennial Conference.
   Two additional issues were voted to be submitted to the 2023 meeting based on discussions of this charge. Committee will ask for letter to be sent to the FDA to review and streamline process for chain HACCP review, and for FDA to include acidification of rice parameters in 3-502.11.
   e. Identifying the recommended methods to disseminate the committee's findings.
   f. Reporting the committee's findings at the next CFP Biennial Conference

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

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.
2.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. ***Issue #1:*** **Report – Retail Sushi HACCP Standardization Committee (RSRHSC) 1**

b. **List of content documents submitted with this Issue:** ***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:***
Guidance Document
Review of National Requirements for HACCP/Variance for Acidification of Rice

c. **List of supporting attachments:** ☐ ***Not applicable***

(1) **Final Roster**

(2) **Roster with attendance**

1. ***Committee Issue #2***: **RSHSC 2– Approval of Guidance Document**
2. **Committee Issue #3**: **RSHSC 3 – Amend Food Code Annex to Reference Approved Document**
3. **Committee Issue #4*:* RSHSC 4 – Review and Streamlining of Retail Sushi HACCP Process**
4. **Committee Issue #5: RSHSC 5 – Including Rice Acidification Parameters in Food Code**

Committee Name: Council III Retail Sushi HACCP Standardization Committee

First Name	Last Name	Postion (Votir	Constituency	Employer	City	State	Phone	Email
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Guidance Document for Retail Sushi HACCP Standardization

Prepared By the CFP Council III Retail Sushi HACCP Standardization Committee

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Introduction

Preface

Council III of the Conference for Food Protection created the Standardization of HACCP Plans for Sushi at Retail Committee in response to Issue 2020-III-017. The committee was charged with:

1. Reviewing current industry practices, collecting available guidance documents, and current state codes pertaining to the production of sushi prepared at retail establishments.
2. Updating the current CFP guidance document for the production of sushi prepared at retail establishments.
3. Referencing the guidance document in the Food Code Annex, or wherever the committee deems appropriate.
4. Identifying whether the Food Code adequately addresses sushi production at retail as a whole

The committee reviewed the current CFP guidance document related to sushi created by the 2016-2018 Special Process Controls Committee titled "Single Hazard Special Process HACCP Template" and it was determined that the information prepared by the committee is not easily integrated into the existing document. This document was created to supplement the templates and guidance provided for acidified rice in that document. This document is intended to provide guidance for food service operators and regulators, is not binding and does not replace regulatory requirements.

Note: This summary was developed around the 2017 FDA Model Food Code. Not all jurisdictions will have adopted this version of the Food Code, however, the references will be similar among versions of the Food Code. Be sure to verify your regulatory authority's requirements.

Sushi Background

The word "sushi" describes the specific preparation of the rice used in formed sushi-making. Sushi rice is a specific variety of rice that has its own unique flavor and ability to stick together to form finished products when combined with vinegar or other acidic products. In its conventional usage, sushi is described as cooked rice that has been acidified with vinegar solutions and formed with raw or cooked fish other seafood, imitation crabmeat, shellfish and fish egg, surimi, fresh chopped vegetables, produce, pickles, tofu, etc.

Sushi products may be formed manually using mats made of bamboo or plastic, specialized tools, or mechanically using sushi forming machines. Popular product forms can include:

- Nigiri, small balls of rice with raw or cooked fish or shellfish, optionally held in place with strips of dried seaweed (nori).
- Maki Rolls, layers of rice and nori sheets rolled with a bamboo or plastic mat to form cylinders that contain various seafood, vegetables, and other ingredients, [i.e., California roll cucumber, avocado and surimi or imitation crab, Philly roll with cream cheese, Tekka maki raw tuna)]; and
- Hand rolls, cone shaped rolls formed by a sheet of nori filled with various ingredients."

Sashimi is a separate food from sushi, even though the two are often used interchangeably. Sashimi, loosely translated, means "pierced body "and it refers to a delicacy of thinly sliced fish or other types of meat. Sashimi is eaten plain, without rice or other foods. Sashimi-grade fish is not a regulatory term but is used as a culinary one. Some of the most popular varieties of sashimi include salmon, fatty tuna, yellowtail, and squid.

An example of a food flow diagram that outlines the entire process of preparing sushi can be found in Appendix A.

Existing Problem

Due to the number and types of local regulatory agencies responsible for food safety across the country, there is inconsistent interpretation and enforcement of existing Food and Drug Administration (FDA) Model Food Code, herein called Food Code, requirements for specialized processes. Establishments that operate in multiple jurisdictions with separate regulatory agencies may be required to provide different documentation for the same food item produced the same way. Examples of these inconsistencies include, but are not limited to:

- When a full HACCP plan and/or variance may be required
- Requirements for variance submittal
- pH value for acidification of rice
- Requirements for submitting sample to lab for pH verification
- Final cooling temperature of rice
- Labeling requirements
- Additional regulatory requirements, such as when seafood HACCP is required

Audience and Benefits of Document

This document provides standardized information for reference and use by both regulatory agencies and retail food establishments that make and sell sushi. Providing standardized guidance for sushi and acidified rice should not only shorten plan review and approval times but would greatly reduce the number of HACCP plans that each retail food establishment or sushi company must create and maintain.

The goal of this guidance is to help jurisdictions achieve a more standardized review of HACCP Plans. Uniform criteria for retail sushi HACCP plans allow for more consistent oversight for regulatory agencies and allows for training of food safety regulators on established critical control points across all facilities. Furthermore, this approach would help ensure that risks associated with the production of sushi at retail and food establishments were properly identified and addressed.

Purpose and Limitations of Guidance Document

This guidance document addresses the specialized process of acidifying rice to make it a non-time/temperature control for safety (TCS) food. This process requires a variance in the current version of the Food Code. This document does not address the requirement of seafood HACCP for fish used as an ingredient in sushi. Seafood HACCP is a requirement for reputable suppliers, and since requirements for approved/reputable suppliers are outlined in the Food Code, adherence to regulation is sufficient for retail HACCP.

Sushi Preparation Food Code References

The application of the Food Code requirements to sushi will vary depending on methods the establishment utilizes to prepare sushi products. Just like all TCS food, the Food Code requirements for parasite destruction, consumer advisory, cold holding, and cooling need to be considered for all sushi operations. Depending on the establishment's operation, time as a public health control or the special process of acidification of rice may also need to be addressed. The establishment's choice of sushi products served, and methods of operation will guide their best approach to meeting the Food Code requirements.

References for all sushi operations:
Parasite Destruction 3-402.11
Cooling 3-501.14
Temperature Control 3-501.16
Consumer Advisory 3-603.11

Additional Considerations for some operations:
Date Marking 3-501.17
Time as a Public Health Control 3-501.19
Special Process (Acidification) 3-502.11
Labeling 3-602.11

References that Apply to all Sushi Operations

Parasite Destruction 3-402.11

Sushi products that include raw or undercooked fish may have naturally occurring parasitic hazards that need to be controlled. The Food Code requires fish that will be served raw or undercooked to be frozen to specific time and temperature parameters found in 3-402.11, unless an exemption is met. Exemptions include molluscan shellfish, shucked scallop adductor muscle, select tuna species [*Thunnus alalunga, Thunnus albacares* (Yellowfin tuna), *Thunnus atlanticus, Thunnus maccoyii* (Bluefin tuna, Southern), *Thunnus obesus* (Bigeye tuna), or *Thunnus thynnus* (Bluefin tuna, Northern)], and fish raised under specified aquaculture practices. Retail establishments commonly rely on suppliers to address parasite controls. Documentation of proper parasite control is required which may include in-house freezing records or letters of guarantee from suppliers.

Cooling 3-501.14

TCS foods held in the Danger Zone have the potential to cause foodborne illnesses. To help control these foodborne illnesses, the Food Code requires rapid cooling of TCS foods, such as cooked rice, cooked fish products, and assembled finished products. TCS food must be rapidly cooled using a two-tiered cooling system that includes cooling TCS from 135°F (57°C) to 70°F (21°C) within 2 hrs., then to 41°F (5°C) within a total of 6 hours.

Sushi usually contains multiple components that include both TCS and non-TCS ingredients. The TCS ingredients and TCS containing finished products must be rapidly cooled to prevent foodborne illness. Sushi rice when acidified below 4.2 is not considered a TCS food. However, the finished, assembled sushi roll containing TCS foods must be rapidly cooled in accordance with 3-501.14.

Temperature Control 3-501.16

Cold holding may occur at several different steps in the production of sushi products. This commonly includes cold holding of fish, some sushi ingredients and sauces, non-acidified cooked rice, and the assembled sushi product if not immediately served. Keeping TCS food at or below 41°F (5°C) reduces opportunity for pathogen growth and/or toxin formation. Keeping TCS foods at 135°F (57°C) or above additionally controls pathogen growth. In sushi operations, hot holding may not be a feasible option due to quality.

Consumer Advisory 3-603.11

The Food Code requires that the consumer be informed about the risks of consuming undercooked or raw animal foods, including raw or undercooked fish often found in sushi. The consumer advisory requires 1) **disclosure** identifying any raw or undercooked animal foods and 2) **reminder** of risks associated with consuming undercooked or raw animal foods such as fish. Consumer advisories are commonly placed on menus, signage at place of order, or on label of packaged product.

References for Some Operations (based on preparation methods)

Date Marking 3-501.17

Date marking in the Food Code applies to ready-to-eat, TCS foods held cold for more than 24 hours within the establishment. Food components that go into finished sushi products, as well as the completed rolls, may require date marking if held over 24 hours. Fish used in sushi products is considered ready-to-eat even if it remains in an undercooked or raw form. Date marking for these ready-to-eat fish components would begin when removed from manufacturers' packaging or removal from in-house freezing for parasite destruction step. When food items are combined, the oldest date needs to be used for the new item. Many sushi products are prepared and sold to consumers the same day, so date marking may not apply.

However, all sushi operations should review use of components that were opened in advance and possible end of day carry-over to determine if the Food Code date marking requirements would apply.

Time as a Public Health Control 3-501.19

Time as a public health control (TPHC) is an option under the Food Code 3-501.19. This can allow use of food products for up to four hours after being cooked without temperature control or control of pH, with any remaining product being discarded. This practice requires written procedures, labeling food when removed from temperature control, and discarding unlabeled products and any remaining at the end of four hours. This option does not allow for saving or restarting once a TPHC procedure is started. This approach works frequently for finished sushi rolls intended for immediate consumption. However, retail establishments packaging sushi for to-go service methods will find TPHC impractical.

Special Process - Acidification of Rice 3-502.11

Acidification of TCS foods with the intent of making them non-TCS is considered a special process in the Food Code. In the case of sushi rice, this process takes a TCS food (cooked rice) and adds acid (typically vinegar) to drop the pH and allow the cooked rice to be held without time or temperature controls. This acid addition needs to adjust the equilibrium pH to less than 4.2 to control the identified hazards.

Addition of vinegar for flavor only, when pH is not monitored, is not considered a special process and rice must be temperature controlled just like any other TCS food. It is also important to remember once the acidified rice is combined with other sushi ingredients the final product would be considered TCS again requiring time and temperature control.

Retail food operations who wish to handle food outside the Food Code parameters can do so by use of a Variance and HACCP Plan. HACCP plan (discussed following sections) specifies the process and how food safety hazards will be controlled. The Food Code 8-103.11 outlines requirements for obtaining a regulatory variance, and 8-201.14 identifies required elements of HACCP plans. The variance issued by the regulatory authority allows the establishment to implement a reviewed HACCP plan which controls food safety hazards in an alternate manner. The Food Code 8-103.10 has additional information about variances.

Labeling 3-602.11

Sushi that is packaged for retail sale, for example clam shell packaged sushi products in a consumer display case, will also require labeling. Package labeling is required to allow the consumer to make informed decisions on food selections and avoid major food allergens. The definition of “packaged” is included in the Food Code and excludes over wraps or carry-out containers facilitating service of food upon consumer request. Basic elements required on label include identity statement, ingredient list, net quantity, major allergens, and name and place of business. In addition to the Food Code, labeling may meet 21 CFR 101.

When a Variance and HACCP Plan is Needed

Based on the food process the establishment has chosen, a variance and HACCP Plan may be required for a retail sushi establishment. As noted above, the Food Code requires a variance and HACCP when acidifying rice to render it non-TCS; however, regulations will vary with jurisdictions. In determining whether a HACCP Plan is needed, the establishment needs to consult with the regulatory authority for specific requirements and procedures for receiving a variance. This document is intended for retail food service establishments and does not cover food processing plants. Example scenarios to help determine whether a food business is a retail food establishment, or a food processing plant can be found in Appendix B. A decision tree is included in Appendix C to assist in determining if a variance and HACCP approval is needed. The sections below provide guidance for creating the HACCP plan for acidified rice only.

Contents of a Sushi Rice HACCP Plan

There are seven principles of HACCP: Hazard Analysis, Determine Critical Control Point, Establish Critical Limit, Establish Monitoring Procedures, Establish Corrective Action, Verification and Record Keeping. A Sushi Rice HACCP Plan should address each of these principles. Additional items are required for a HACCP Plan as stated in 8-201.14, such as general information regarding the operation, recipes, flow diagrams, sample blank log forms, and Standard Operating Procedures.

- **General Information:** General information should be included on the plan to include the owner/operator's name, location of business, Person-In-Charge (PIC), and contact information.
- **Recipe(s)**: Included in your HACCP Plan should be the recipe for your sushi rice. Include each different sushi rice recipe, including alternative grains such as quinoa, brown rice, or similar.
- **Flow Diagram or Chart**: A flow diagram will visually explain the exact process of preparing the sushi rice. Your plan should include a flow diagram or chart. The first step in the flow of food should be receiving ingredients and the last step is consumption or sale of sushi rice. An example food flow can be found in Appendix D.
- **Sample log form**s: A copy of the blank logs should be attached to the HACCP plan. There should be at least one log for each of the critical control points.
- **Standard Operating Procedure**s: Standard operating procedures (SOPs), are written procedures that provide specific instructions on performing food safety tasks related to the HACCP plan.

Hazard Analysis

A hazard analysis identifies the known or reasonably foreseeable hazards associated with a specific food. There are two main biological hazards associated with sushi rice held at room temperature: *Bacillus cereus (B. cereus) and Staphylococcus aureus*. If they are allowed time to grow in the rice, both bacteria can form toxins that cause vomiting and diarrhea. *B. cereus* is a spore forming bacteria often associated with rice. The spores may be present in rice and other grains, and then survive the cooking step. *S. aureus* is associated with food preparation environments and may be introduced to sushi rice due to the amount of handling throughout the sushi preparation process. These bacteria can produce toxins when left for too long in temperature danger zone, of above 41°F- below 135°F (5°F - 57°C). These bacteria are commonly associated with unacidified or improperly acidified sushi rice because it is typically kept in the temperature danger zone. A full hazard analysis for sushi rice process can be found in Appendix D.

Control Measure

Control measures are those processes or procedures put into place to control, reduce, or inactivate pathogens. The main control for the growth of *B. cereus* and *S. aureus*, aside from time/temperature control, is acidification. In the preparation of sushi rice, vinegar is typically mixed thoroughly into cooked sushi rice to reduce the pH of the rice to less than 4.2. This pH threshold meets the definition of a non-TCS food, found in Table B of the FDA Model Food Code (note that water activity of cooked rice is greater than 0.88, and so is not a factor in this determination). This control is effective only when the pH of the rice is correctly monitored by using a pH meter. Colorimetric methods for the determination of pH may be allowed in some instances when the pH is 4.0 or lower.

Critical Control Point (CCP)

The critical control point, or CCP, is the point in the flow of the process at which there is control over the identified hazard, typically the growth of pathogens. If not done correctly, pathogens could grow and/or produce toxins, resulting in consumer illness. The step in which vinegar is added to the rice is the critical control point for sushi rice. This is the step where the two hazards of concern, *Bacillus cereus and Staph aureus*, must be controlled to prevent illness.

Critical Limit(s)

Critical limits are those measurable parameters and values that are based on science that demonstrate a critical control point is effective controlling the identified hazard. In the case of acidified sushi rice the critical limit is a pH of below 4.2to be considered non-TCS. When using FDA Interaction Table B, rice acidified to below 4.2 would not need further evaluation and would be considered non-TCS. Cooked short grain white rice has available water measurement (known as water activity, a_w) of approximately 0.98.

Alternative grains such as brown rice or wild rice, quinoa, couscous, cauliflower rice, are sometimes proposed to be used instead of sushi rice. Any alternate grains are required to meet this same pH critical limit unless alternate science is provided.

Monitoring

A HACCP Plan must include information on how the production of the acidified rice will be monitored. An example monitoring procedure is included in this document. When preparing the sample, 21 CFR 114.90 states that a ratio of 10-20 mL of water to 100 grams of product should be used. Both the acidification of the rice and the final pH of the rice should be monitored. The plan will indicate what is being monitored, how it will be monitored, what is the frequency of monitoring, and who will do the monitoring. With sushi rice, monitoring should be done by a trained individual using a calibrated pH meter.

Corrective Action

Corrective actions are steps taken when a critical limit is not met during the preparation process. It is important that any time a corrective action is needed it must be recorded on a log sheet. If the pH of the measurement is 4.2 or greater; then repeat the measurement with a new sample. If that sample reads 4.2 or greater; add more vinegar to the acidified rice. Mix well and repeat the pH measurement. Repeat this corrective action until the pH is below 4.2. The rice can also be held using time as a public health control, cooled, and held cold, or discarded as a corrective action. Additional long term corrective actions should be applied, including reviewing the process, adjusting recipe, or substituting vinegar type. Note all corrective actions applied in a corrective action log.

Verification vs Validation

Verification and Validation are not the same thing. **Verification** is making sure the HACCP Plan is working as written. **Validation** is making sure the HACCP Plan will work to control the hazards identified based on science. Most sushi rice HACCP plans are written based on already validated science (i.e., pH below 4.2), because of this, scientific validation is not required. If a method is used that is not already recognized in the scientific literature as controlling the identified hazard, a validation (other science or challenge studies) may be required.

Verification

The Person-in-Charge (PIC) is responsible for reviewing and signing the sushi rice acidification log and making sure the HACCP plan is being followed as written. This is considered a verification of the HACCP plan. The HACCP plan should indicate who will do the verification, the frequency of the verification and what verification activities are taking place. The PIC should also observe employees performing the pH measurement and recording required data periodically. All verification activities should be noted in the appropriate log notes along with the signature of the PIC performing the verification activities. An example checklist can be found in Appendix E that can help with verification activities.

Record Keeping

Records (logs or log forms) are an integral part of the HACCP Plan and should be kept for all monitoring of critical control points. Required records include pH meter calibration logs, sushi rice pH measurement logs, corrective action logs, PIC verification logs, and training logs.

Note: Once records are created, they must be kept for at least six months or as otherwise specified by the jurisdiction based on inspection frequency and made available to the Regulatory Authority upon inspection request.

Training

Any employee involved in the acidification of rice is required to receive training to show that they understand the hazards and controls associated with making acidified rice. The training plan must address any food safety issues of concern as stated in 8-201.14(F) (1) and should include training on all facility standard operating procedures. The PIC must review sections relating to the flow diagram, hazards, control measures, CCPs, critical limits, verification and record keeping. Hands-on training is essential. A blank training log form should be attached to the HACCP Plan. The training sessions must be recorded in the log, and must include date, employees present, and instructor.

Standard Operating Procedures

Standard operating procedures, or SOPs, are an important part of a HACCP Plan. These are specific written instructions that give details on how to perform tasks associated with food safety and the sushi rice HACCP Plan. SOPs should already align with the regulation unless a variance is in place. SOPs should include pH meter calibration, cleaning and sanitizing food contact surfaces, personal hygiene and employee health policies, hand washing, eliminating bare hand contact, and proper chemical storage. Many of the SOPs needed for sushi rice acidification are contained within the Food Code, but should include the following (these are examples only, additional SOPs may be needed):

- **Bare hand contact:** Clarify that bare hand contact with ready to eat (RTE) food is not permitted at any time and what is done with RTE food touched with bare hands
- **Employee health policy:** Address the symptoms of foodborne illness, pathogens associated with illness, symptom and illness reporting requirements, exclusion/restriction plan, return to work criteria, etc.
- **Personal hygiene:** Address wounds/sores, jewelry, fingernails, hair restraints, clothing (i.e., uniform, apron), tasting food, eating/drinking, what is done when employees do not follow the personal hygiene information
- **Hand washing:** Clarify when, how, and where to wash hands, and any corrective actions
- **Labeling:** Include details of all applicable dates (packaging, expiration), consumer advisory (if applicable), and what is done with food that is not labeled or is incorrectly labeled
- **Cleaning and sanitizing food contact surfaces:** Specify how to properly clean and sanitize food contact surfaces, and what to do with food contact surfaces that have not been properly cleaned and sanitized
- **Thermometer use and calibration:** Address the method and frequency of thermometer calibration and what is done with thermometers that cannot be calibrated, and provide details of documenting thermometer calibration
- **pH meter use and calibration:** Address the method and frequency of pH meter use; calibration, verification of accuracy of calibration and what is done with pH meters that cannot be calibrated and provide information on calibration and use logs.
- **Cold holding:** Address proper cold holding temperatures and corrective actions if food is found to be out of temperature, including allowances for cooling or discarding food
- **Transporting:** Address proper cold holding temperatures and applicable corrective actions if food is found to be out of temperature, including allowances for cooling or discarding food

Example Standard Operating Procedures

The following are examples of standard operating procedures that can be used for thermometer calibration, pH meter calibration, and pH monitoring. Be sure to follow any manufacturer's instructions related to specific equipment. *****These are only examples; sushi operations may choose another SOP to align with business needs. *****

Standard Operating Procedure for Thermometer Calibration

- Thermometers used for specialized processes should meet the same requirements as outlined in the Food Code Sections 4-201.12, 4-203.11 and 4-302.12.
- All thermometers must be accurate to +/-2 degrees Fahrenheit.
- Thermometers must be calibrated according to the Food Code Section 4.502.11(B). Thermometers should be calibrated at least once per day and whenever they are exposed to extreme temperatures or dropped.
- The ice water calibration method is the most common and reliable, and is outlined below:
- Fill a cup with ice, preferably crushed, with enough ice so the thermometer remains upright.
- Add cold water to the cup and stir, allowing the temperature to equilibrate.
- Place the thermometer probe in the cup. Temperature should read at 32°F, if it does not, adjust the thermometer according to manufacturer's instructions.
- When taking product temperature, the probe should be placed in the thickest portion of the food. For rice and other grains, it is recommended to stir first before taking temperature.

Standard Operating Procedure for pH meter Calibration

- The pH meters used for sushi rice should be designed for food and not designed simply for water or liquids. Appropriate meters will be portable, able to be calibrated and read to at least two decimal points
- pH should be calibrated daily and according to the manufacturer's instructions. Typically, pH meters come with 2-3 buffer solutions which are typically pH 4, pH 7 and pH 10. These solutions may be in aqueous or powder form and will come with any applicable mixing and handling instructions.
- The following outlines a basic calibration procedure, but always follow specific manufacturer's guidance.
    1. Prepare buffer solutions according to the package instructions.
    2. Remove the electrode from the storage solution, rinse thoroughly with distilled water and carefully blot (do not wipe) dry with a lint-free wipe.
    3. Turn the pH meter on and submerge the probe in the pH 7 solution, gently moving the probe around until the pH reading stabilizes. Select the calibrate button and then rinse the probe with distilled water and blot dry.
    4. Repeat step 3 with the pH 4 buffer solution.
- After calibration is complete, check the pH in the 4.0 buffer solution to make sure it reads correctly. The reading should be within 0.1 pH units of its true value (for example, the 4.0 buffer should read between 3.9 and 4.1).
- If results aren't within 0.1 pH unit of the true value for the buffer, the meter must be recalibrated.
- Record the calibration in your pH meter calibration log. You are now ready to test product samples.
- A second pH meter will ensure acidification operation can continue if there is failure of the pH meter. Having an additional pH meter for use as a backup is recommended.

Standard Operating Procedure for pH monitoring

- Each batch of acidified rice must be measured for pH as follows.
- Prepare rice and acidify according to the approved recipe. Allow rice to sit so vinegar can uniformly penetrate the rice. The pH is typically measured within 30 minutes or within timeframe specified in HACCP plan
- Prepare and calibrate the pH meter according to the manufacturer's directions. Record the calibration of the pH meter in the log. Calibration should be done daily or as required to maintain calibration.
- One quarter cup of rice should be collected from various locations in the batch of sushi rice. Press the rice down during sampling in the measuring cup so that it is flat and level. Repeat the procedure so there are two different samples.
- Add ¾ cup of distilled water to the ¼ cup of sushi rice for each sample. Mix the rice and water until a consistent slurry develops. The cooked and acidified grains will need to be crushed, mashed or blended with distilled water to reach a semi-liquid consistency.
- Insert the pH electrode into the first rice slurry and press the button to measure the pH. The electrode should be fully submerged in the sample and should be gently and slowly stirred until the probe reading is complete.
- Record your measurement on in your log, including the signature of the person who performed the acidification/monitoring. Take the pH of the second sample. Record it.
- **If either sample has a pH of 4.2 or above, corrective action is required**.

Prerequisite Programs

PARASITE DESTRUCTION

- Raw, ready-to-eat seafood, except for those exempt under 3-402.11(B), require freezing utilizing one of the following options: frozen and stored at a temperature of -20 ˚C (-4 ˚F) or below for a minimum of 168 hours (7 days) in a freezer, frozen at -35 ˚C (-31 ˚F) or below until solid and stored at -35 ˚C (-31 ˚F) or below for a minimum of 15 hours; or frozen at -35 ˚C (-31 ˚F) or below until solid and stored at -20 ˚C (-4 ˚F) or below for a minimum of 24 hours.
- In addition to exempt tuna species, some aquacultured fish products that have met specific requirements in 3-402.11(B) are exempt from freezing.
- The Food Code requires that "If the fish are frozen by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified under § 3-402.11" be provided. A similar written agreement is required to verify aquacultured fish products have met exemption requirements.
- Either purchase specifications or a letter of guarantee would be an acceptable way to verify the parasite destruction requirement.
- A document containing the following information would meet the requirement for verifying parasite destruction.
- Name of processing facility, or other entity, that has documented and carried out the freezing process.
- Draft date (within one year of purchase)
- Seafood item name
- Clear description of master cartons, or packaging, logo/brand reference to aid in cross referencing the letter to the item.

- One of the following specifications, depending on whether fish has been frozen or is exempt from parasite destruction
    - For fish that has been frozen: specific freezing process (one of the above) used to destroy parasites
    - For exempt/aquacultured fish: specifics on feed type and farm type (open water, net-pens, ponds, tanks, etc.)

- Where freezing is not applied for raw ready-to-eat seafood, and a parasite destruction exemption exists, documentation shall be secured from the supplier/processor to include, at a minimum, the following:
- Additionally, fish served raw in sushi products should be labeled as "ready-to-eat." Retail sushi operations should read packaging and labels as all fish and fish products are not intended for raw consumption. If the label or package does not state information about whether it is intended for raw consumption, the sushi operator should verify the intended use with the supplier.

REFERENCES

- FDA Food Code 2017: 3-402.11 Parasite Destruction
- Fish and Fish Products Hazards and Controls Guidance – Fourth Edition – June 2021
- FDA Appendix 1 - https://www.fda.gov/media/99581/download

ACKNOWLEDGEMENTS

Special thanks to the following people who were vital in the preparation and review of this document:

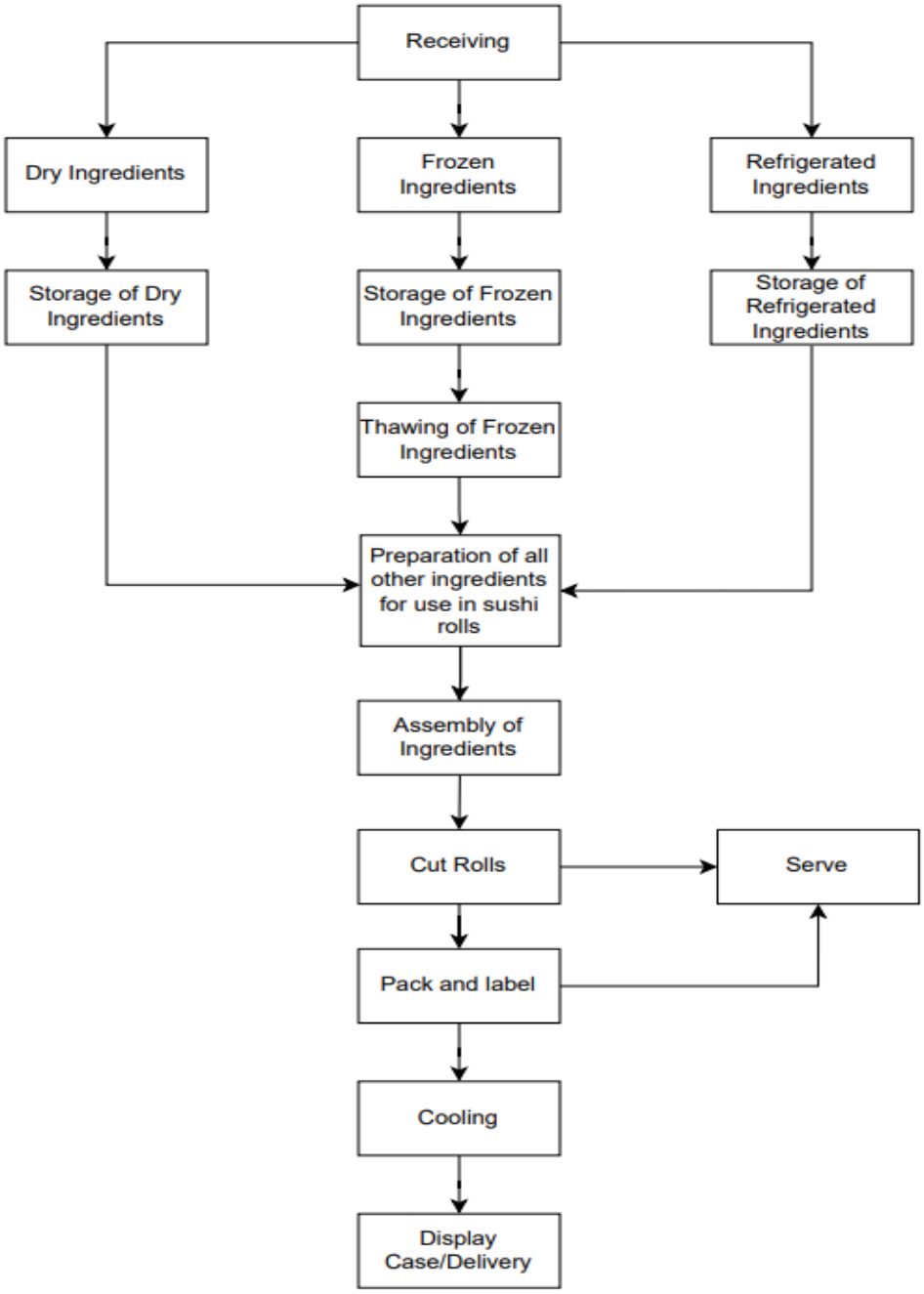
- 2021-2022 CFP Council III Chairs: Christine Applewhite and Dr. Don Schaffner
- FDA Consultants: Veronica Moore and Jonathan Tran
- 2021-2022 CFP Executive Board
- Members of Retail Sushi HACCP Standardization Committee

Appendix

A – Food Flow Diagram for Sushi Process
B – Example Permitting Scenarios
C – Decision Tree
D – Food Flow Diagram and Hazard Analysis for Sushi Rice
E – Sample Validation and Verification Checklist

Appendix A: Food Flow Diagram for Sushi Process

This food flow diagram is designed to illustrate the entire process for preparing sushi products and is not intended to be submitted with the HACCP Plan. **This food flow includes many steps that do not need to appear in the food flow diagram for the sushi rice HACCP plan. The only components of this food flow diagram that are required in a HACCP Plan are receiving, storing, preparation, and service.** An example of the food flow diagram that should be submitted with a HACCP plan can be found in Appendix D.



Appendix B: Examples permitting scenarios and how to interpret

Definitions:

I. ***Retail Food Establishments*** are sushi producers that prepare sushi products for direct distribution to the end consumer. The distribution methods may include but are not limited to dine in restaurant, to-go distribution, delivery, mobile food establishments, and vending machines, and can be fixed or temporary facilities or locations. Additional specifics of the retail food establishment definition can be found in FDA Food Code 1-201.10.

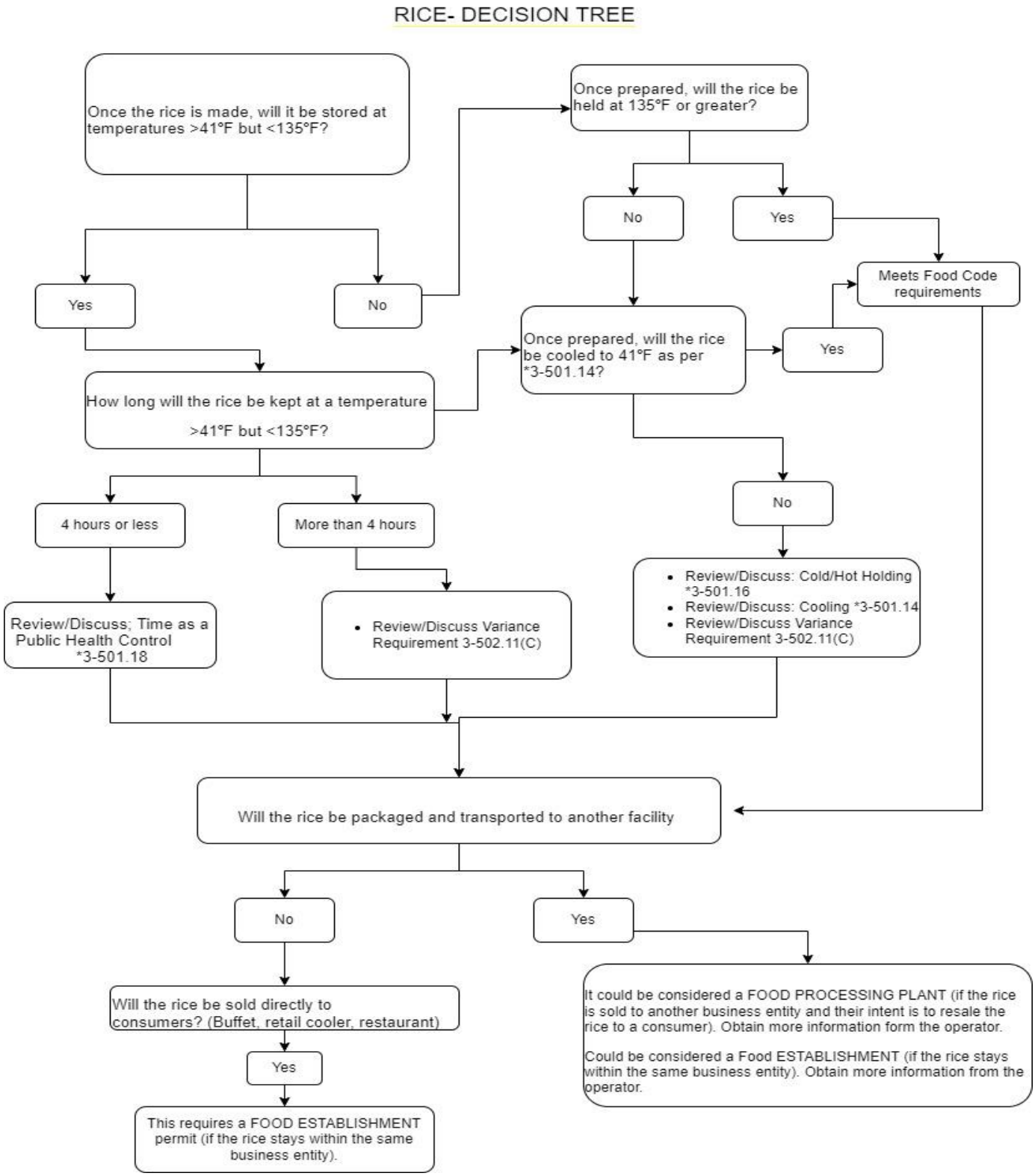
II. ***Food Processing Plants*** are commercial sushi operations that manufacture, package, label, or stores sushi and provides it for sale or distribution to other business entities. These sushi operations are generally offsite from a retail food establishment and sell or distribute to a business (Food Establishment) prior to distribution to the end consumer.

Examples:

1. Sushi is prepared in a restaurant and offered for sale to the consumer either for dine in, take out, or other third-party delivery service. These operations would be **Retail Food Establishments**.
2. Sushi is prepared in retail grocery store by a third-party vendor and the grocery store does not take ownership of the product. The vendor is leasing space, the sushi producer provides finished sushi to the end consumer, and the grocery store takes payment. These operations would be **Retail Food Establishments**.
    - Distribution often includes stocked refrigerators, 3rd party delivery services, and/or vending machines. The sushi establishment does not need to collect money directly for sale of its products.
3. Sushi is prepared at an off-site commissary and delivered to other retail stores or businesses that do not produce onsite. These operations are **Food Processing Plants**.
    - Sushi products made at a food processing plant may be produced at a central commissary location and distributed to other Food Establishments not operated by the company. In this instance, there is a business that receives the products as an intermediary before the final consumer receives the sushi or sushi product.
4. Sushi is produced by a chain operation at a grocery store and distributes it to another kiosk owned by the same operation. These operations would be **Retail Food Establishments**.
    - Sushi products may be prepared or produced at a central commissary location and delivered to other operations owned by the same company. Ownership of the product cannot change, but the product may be made in a different location than where it is offered for sale to the consumer.
5. Sushi is prepared at a preparation site/kitchen/commissary and ends up in university campus/hospital/airport. These operations are **Food Processing Plants**.
    - This would apply to sushi provided to locations such as universities, airports, etc. where the sushi company does not retain ownership of the product. These end locations may have a retail establishment component, but the sushi prepared for service within these locations is considered from a food processing plant, unless the distribution is via vending machine or other direct to consumer Food Establishment criteria.

Appendix C: Decision Tree

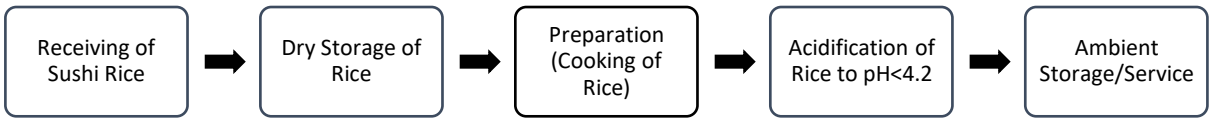
The decision tree is based off the 2017 FDA Model Food Code is intended to provide operators with specific food safety guidance based on the process used by an operator for holding rice. It also includes information about permitting/licensing based on how it will be served/sold.



Appendix D: Food Flow and Hazard Analysis for Sushi Rice

Food Flow Diagram for Sushi Rice

This is an example of a food flow diagram that should be submitted with a sushi rice HACCP Plan. All steps related to the preparation and acidification of rice are included. Please note that food flow diagrams do not have to follow this format, they just must contain the appropriate information.



Hazard Analysis for Sushi Rice

This chart outlines the steps in sushi rice preparation and the hazards associated with them. The CCP has also been identified. This information can be used in assembling the HACCP Plan.

PROCESS	**RECOMMENDATIONS/POLICIES**	**HAZARDS**	**CCP? IF YES, CRITICAL LIMITS**
Receiving	●All food products received from approved suppliers/distributors	●B: Microbial pathogens ●C: Chemical contamination of products ●P: Pest contamination	●No; have prerequisite receiving program Rejection process/segregation of rejected products SOP
Food storage	●Any dry storage foods will be stored away from any chemicals and in a dry, clean, 6" off floor location that is not exposed to other contamination.	●B: Potential growth or survival of pathogens	●No; Food Code parameters met for cold storage and dry storage
Preparation	●Rinse/soak rice to remove any foreign debris ●Cook rice to desired temperature, 135°F for rice that will be hot held	●B: Potential growth of *B. cereus, S. aureus, C. perfringens*	●Follow Food Code parameters for proper cooking and holding of rice.
Acidification	●Acidify rice after cooking, prepare sample for pH measurement and take pH ●Calibrate pH meter according to manufacturer's specs	●B: Potential growth of *B. cereus, S. aureus* and *C. perfringens* if held at room temp	●CCP pH<4.2
Display/Serve	● Display and serve sushi using no bare hand contact with ready-to-eat foods. ● Food should be stored according to time/temperature requirements during display	●B: Potential growth or survival of pathogens	●Follow Food Code parameters for employee health, no bare hand contact, and holding temperatures for TCS ingredients

Appendix E: Checklist HACCP Plan Review and Verification

HACCP Plan Content Requirements	**Observed**
List of all ingredients, equipment, and packaging to be used including recipes and/or formulations	
Food flow diagram (page 15 Appendix D of guidance document)	
Hazard Analysis (*B. cereus, S. aureus* is pathogen of concern)	
Critical control points labeled (acidification step as CCP)	
Critical limit given (pH of rice below 4.2)	
Monitoring procedures (pg. 9-10)	
Corrective actions provided (pg. 7)	
Record keeping procedures (pg. 8)	
Employee training program	
Written prerequisite programs and SOPs	
Notes:	

Verification Activities	**Observed**
Approved equipment used	
Proper ingredients and formulation used	
Identification of employees involved in process	
Proper pH meter calibration observed	
Observation of pH sample preparation and pH meter use	
Corrective actions observed or discussed with trained employees	
Review of pH logs and corrective actions log	
Review and verification of adequate training program	
Observation of prerequisite programs/SOPs	
Notes:	

State	County	Acidified Rice	Variance Required	HACCP plan available	Lab test required for PH	Labelling	Are NIST Calibrated Thermometer required	Is 24 hours continuou monitoring required for Seafood items	Is the temp of the Seafood needs to be 38°F or 40°F or 41°F	Comment	Link
Arizona	Maricopa	4.2 or below	Yes for acidified rice	No	Yes					If the rice is acidified for the purposes of flavor enhancement and not preservation, and it is cooled in accordance with §3-501.14 and maintained at 41°F or below for no longer than 7 days, then neither a HACCP Plan or variance are required	https://conferenceforfoodprotection.sharepoint.com/:f:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/Arizona/Maricopa%20County?csf=1&web=1&e=xa25FC
California	Monterey	4.4 or less	Yes for acidified rice	Yes						If cooked rice is acidified by adding vinegar a HACCP plan is required to be submitted.	https://conferenceforfoodprotection.sharepoint.com/:f:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/California/Monterey%20County?csf=1&web=1&e=tizavD
California	Riverside	target ph <4.4 and must not reach critical limits >4.6	Yes for acidified rice	No	Yes						https://conferenceforfoodprotection.sharepoint.com/:b:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/California/Riverside%20County/Riverside%20-%20Guidelines%20for%20HACCP%20for%20Sushi%20Rice.pdf?csf=1&web=1&e=iLGogd
California	San Bernardino	4.6 or below	Yes for acidified rice	no	Yes					If cooked rice is acidified by adding vinegar a HACCP plan is required to be submitted.	https://conferenceforfoodprotection.sharepoint.com/:f:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/California/San%20Bernardino%20County?csf=1&web=1&e=tri7o7
California	San Francisco	4.1 or below	Yes for acidified rice	Yes							https://conferenceforfoodprotection.sharepoint.com/:f:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/California/San%20Francisco%20County?csf=1&web=1&e=3nLOMr
California	San Luis Obispo	4.6 or below	Yes for acidified rice	Yes	A verification letter from a naccredited laboratory indicating that the fina; pH of the sushi rice is less than 4.6.						https://conferenceforfoodprotection.sharepoint.com/:f:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/California/San%20Luis%20Obispo%20County?csf=1&web=1&e=yZjb3e
California	Sonoma	target ph <4.4 and must not reach critical limits >4.6	Yes for acidified rice	yes	Yes					Yes	https://conferenceforfoodprotection.sharepoint.com/:b:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/California/Sonoma%20County/Sonoma%20-%20Sushi%20Rice%20HACCP%20Plan%20Guidelines.pdf?csf=1&web=1&e=AfUtC3
California	Sutter	target ph <4.4 and must not reach critical limits >4.7	Yes for acidified rice	No	no						https://conferenceforfoodprotection.sharepoint.com/:b:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/California/Sutter%20County/Sutter%20-%20Sushi%20Rice%20HACCP%20Plan%20Guidelines.pdf?csf=1&web=1&e=kVNJ2G
Colorado		4.2 or below	Yes for acidified rice	Yes	Yes, if using the statewide variance option.					Can either obtain their own variance that may need a HACCP plan or can follow the statewide variance criteria (one sample, three different batches or onsite pH testing). Inspectors should be doing field verification for acidified rice.	https://conferenceforfoodprotection.sharepoint.com/sites/ConferenceforFoodProtection/Shared%20Documents/Forms/AllItems.aspx?FolderCTID=0x012000ZE08D3C88C78D24B9F6412D97F4C1B05&id=%2Fsites%2FConferenceforFoodProtection%2FShared%20Documents%2FCouncil%20Committees%2FCouncil%20III%2FRetail%20Sushi%20HACCP%20Committee%2FShared%20Documents%2FColorado%2FRF19%2D24%5FSushi%20Rice%5FApproval%20Letter%5FO40319%5Fmbrandt%2Epdf&parent=%2Fsites%2FConferenceforFoodProtection%2FShared%20Documents%2FCouncil%20Committees%2FCouncil%20III%2FRetail%20Sushi%20HACCP%20Committee%2FShared%20Documents%2FColorado
Delaware		4.1 or below	Yes for acidified rice	Yes							https://conferenceforfoodprotection.sharepoint.com/:b:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/Delaware/HACCP%20and%20Variance%20Template%20for%20Sushi%20Rice%20Acidification.pdf?csf=1&web=1&e=xLImBB
Michigan		4.2 below	Yes for acidified rice	Yes						Only if special process (Acidification of rice)	https://conferenceforfoodprotection.sharepoint.com/:b:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/Michigan/Sushi_Rice_Acidification_Application_715003_7.pdf?csf=1&web=1&e=vv1gJv
Wiconsin		4.3 or below (MN also)	Yes for acidified rice	Yes							https://conferenceforfoodprotection.sharepoint.com/:f:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/WI_DATCP?csf=1&web=1&e=feihqq
South Carolina DHEC		4.1	Yes for acidified rice	No	one-time product assessment from process authority or accredited food lab required to approve variance	For prepackaged "grab and go" foods only	No. Only pH meter and calibration required (sushi rice)	No.	41F	Variance based on approved SOP only if special process (Acidification of rice); Program offers options to use either temperature control or TPHC without control of pH. (SOP required for TPHC)	https://conferenceforfoodprotection.sharepoint.com/:b:/r/sites/ConferenceforFoodProtection/Shared%20Documents/Council%20Committees/Council%20III/Retail%20Sushi%20HACCP%20Committee/Shared%20Documents/SC%20DHEC%20Sushi%20Rice.pdf?csf=1&web=1&e=NdRSLL
Nevada	Washoe County	4.2 or below	Yes for acidified rice	Yes	Yes	For prepackage/manufactured foods only	No. Only pH meter and calibration required.	No.	41F	For sushi rice, TPHC or an approved HACCP plan and variance is required by all food establishments in Washoe County. Washoe County also has restrict SOP requirements such as training, employee health, and cleaning/sanitization for all HACCP plans. This often creates a lot of back and forth to get a plan approved from nationwide corp entities.	

COMMITTEE NAME: **Safe Use of Reusable Containers Committee (SURCC)**

DATE OF FINAL REPORT: *11/22/22*

COMMITTEE ASSIGNMENT: ☐ ***Council I*** ☐ ***Council II*** ***X*** ***Council III*** ☐ ***Executive Board***

REPORT SUBMITTED BY: **Carrie Pohjola (co-chair) and Dagny Tucker (co-chair)**

COMMITTEE CHARGE(S):

- Clarify the scenarios related to reusable containers within the scope of regulation
- Identify and analyze the scientific and other literature related to consumer-owned containers at retail
- Draft recommended guidance around those scenarios and create a definition of reusable container
- Provide recommended code language changes, if necessary, to FDA
- Report progress and report findings and recommendations at Biennial Meeting in 2023

Issue# 2020 I-024 (combined with 2020 I-022 and 2020 I-023)

1. Clarify the scenarios related to reusable containers within the scope of regulation.
2. Identify and analyze the scientific and other literature related to consumer-owned containers at retail.
3. Draft recommended guidance around those scenarios and create a definition of reusable container
4. Provide recommended Code language changes, if necessary, to FDA
5. Report progress back to the next Biennial Meeting in 2023 and the committee findings and recommendations may be presented at the subsequent Biennial Meeting if necessary.

COMMITTEE WORK PLAN AND TIMELINE:

COMMITTEE ACTIVITIES: **Dates of committee meetings or conference calls:** *11/16/2021, 11/30/2021, 12/14/2021, 1/11/2022, 2/8/2022, 2/22/2022, 3/22/2022, 4/5/2022, 4/19/2022, 5/3/2022, 6/14/2022, 7/12/2022, 10/04/2022, 10/28/2022, 11/01/2022, 11/15/2022, 11/22/2022, 11/29/2022*

1. ***Overview of committee activities:***

   The committee determined that subcommittee work would be best to accomplish the charges. The first subcommittee was the Regulatory Foundation Subcommittee that developed a flow chart of what is currently allowed in the Food Code for the safe use of re-usable containers. This will be used to address scenarios that were then addressed by sub-committees. Subcommittees then determined all types of scenarios that could possibly occur at the retail level based on types of sales of foods and finally a sub-committee is working on flows based on the packaging (consumer owned, business owned, third party owned) and when finalized will be used to determine which of the identified scenarios could be safely done with food code language changes. Once this is determined, guidance will be drafted based on identified literature and best practices to safely allow for the re-use of containers.

   The committee continues to work on a guidance document. A sub-committee is working on making the sections within the document more cohesive for review by the full committee on

September 20th, updated to 10/04/2022 due to FDA regional seminar. The final document is to be completed by the end of October for submission in November.

The committee will complete the final guidance document to be submitted to CFP by December 5th. It is currently in the formatting stage of completion.

Food code language and a definition of reuse was drafted based on jurisdictions that have adopted the reuse of containers and literature and documentation that was reviewed by the committee when drafting the guidance document.

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

A.a. Clarify the scenarios related to reusable containers within the scope of regulation. Scenario matrix developed demonstrating reusable/returnable containers currently being utilized in numerous scenarios where current regulatory code does not align with practice.

A.b. Identify and analyze the scientific and other literature related to consumer-owned containers at retail. Current scientific literature specific to consumer-owned containers is limited. Available relevant scientific literature, a precedents overview and other relevant examples and literature was reviewed and is compiled and referenced in the committee's guidance document.

A.c. Draft recommended guidance around those scenarios and create a definition of reusable container. Scenarios and opportunities for safe implementation of reusables/returnables were critically evaluated and a guidance document was drafted. Additionally food code was cross referenced for definitions of reuse, returnable, refillable along with allowable container types in current code and based on those examinations and current scenarios of use, a definition of reusable/refillable container was created.

A.d. Provide recommended code language changes, if necessary, to FDA. Based on the above work as well as current food code precedents at the state level, food code language changes are being recommended.

A.e. Both committee co-chairs plan to attend the Biennial meeting to report progress and report findings and recommendations at Biennial Meeting in 2023.

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

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

X ***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.

2.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

a. ***Issue #1:*** Report – Safe Use of Reusable Containers Committee Acknowledge the 2021-2023 Safe Use of Reusable Containers Committee final report, thanks the committee members for their work and disband the committee

b. **List of content documents submitted with this Issue:**

Committee Member Roster:

☐ ***See attached revised roster PDF*** x ***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) ***Committee Member Roster (see attached PDF)***

(2) ***Committee Generated guidance document entitled Guidance Document for Safe Use of Reusable Containers***

(3) ***Meeting Summations***

(4) ***Scenario Matrix***

c. List of supporting attachments: ☐ ***Not applicable***

1. ***Committee Issue #2***: SURCC 2-Approval and Posting of Guidance Document. Recommend acceptance of the Committee generated guidance document entitled "Guidance Document for the Safe Use of Reusable Containers" included in Issue #1: Report- Safe Use of Reusable Containers Committee and; inclusion of the guidance document on the CFP website in a downloadable PDF format.
2. ***Committee Issue #3***: SURCC 3-Amend Food Code Language to Include the Reuse of Containers
3. ***Committee Issue #4***: SURCC 4-Amend Food Code Language to Include a Reuse Definition

Committee Name: Council III-Use of Reusable Containers

Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Tucker	Dagny	Chair	Industry	Vessel	Lyon	CO	3039153079	dagny@threadcountcreative.com
Pohjola	Carrie	Vice- or Co-Chair	Regulatory-State	WI DATCP	Madison	WI	7155799487	carrie.pohjola@wi.gov
Oliker	Rayna	Member	Regulatory-State	Colorado Department of Public Health and the Environment	Denver	CO	7202138198	rayna.oliker@state.co.us
Salinas	Sabrina	Member	Regulatory - Local	Harris County Public Health	Houston	TX	832-840-5683	sabrina.salinas@phs.hctx.net
Shelton	Susan	Member	Regulatory-State	WA Dept of Health	Kennewick	WA	15092121206	susan.shelton@doh.wa.gov
Crabtree	Deborah	Member	Regulatory - Local	Fairfax Co	Fairfax	VA	5717223634	deborah.crabtree@fairfaxcounty.gov
Fells	Abeid	Member	Regulatory - Local	Houston Health Department	Houston	TX	7138557752	abeid.fells@houstontx.gov
Springer	Christina	Member	Regulatory - State	Oregon Dept. Agriculture	Salem	OR	9712826194	cspringer@oda.state.or.us
Olson	Kathryn	Member	Regulatory - Local	Washoe County	Reno	NV		kolson@washoecounty.us
Clark	Jeffrey	Member	Industry	National Restaurant Association	Washington DC			jclark@restaurant.org
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Hurysz	Alison	Member	Industry	Whole Foods Market	SARATOGA SPGS	NY	5853011612	Alison.hurysz@wholefoods.com
Kariri	Oren	Member	Industry	New Seasons Market	Portland	OR	15034738715	oren.kariri@newseasonsmarket.com
Strewler	Kaycee	Member	Industry	Ecolab Inc.	EAGAN	MN	651-236-0209	kaycee.strewler@ecolab.com
Wijesekera	Dilshika	Member	Industry	Instacart	Seattle	WA	4798793903	dilshika.wijesekera@instacart.com
Kantrowitz	Sarah	Member	Academia	Perkins & Will	Boston	MA	9145230757	sarah.e.kantrowitz@gmail.com
Bonatakis	Kristina	Member	Consumer		Red Bank	NJ	3478914072	kristinabonatakis@icloud.com

Non-Voting Members

Last Name	First Name	Position on Committee	Constituency	Employer	City	State	Phone	Email
Williams	Juhi	FDA Consultant	Regulatory- Federal	FDA				Juhi.Williams@fda.hhs.gov
Otto	Jessica	FDA Consultant	Regulatory - Federal	FDA				Jessica.Otto@fda.hhs.gov
Reddit	Dan	FDA Alternate	Regulatory - Federal	FDA				Joseph.Redditt@fda.hhs.gov
vacant		CDC Consultant	Regulatory - Federal					
Arbizu	Tom	Alternate	Industry	HEB, LP	San Antonio	TX	0	arbizu.thomas@heb.com
Curto	Frank	Alternate	Industry				7272361808	fcurto05@gmail.com
Ingle	Jordan	Alternate	Industry	Ecolab	Greensboro	NC	0	jordan.ingle@ecolab.com
Lux	Greg	Alternate	Industry	Retail Business Services supporting The Giant Company	Carlisle	PA	7175541726	glux@retailbusinessservices.com
Michelson	Traci	Alternate	Industry	McDonald's Corporation	THE COLONY	TX	2149842802	traci.michelson@us.mcd.com
Oswald	Steve	Alternate	Industry	Wakefern Food Corp.	Elizabeth	NJ	9085273624	steve.oswald@wakefern.com
Teclaw	Stephanie	Alternate	Industry	Festival Foods	De Pere	WI	9209643451	steclaw@festfoods.com
Puente	Eric	Alternate	Industry	Whole Foods Market	Austin	TX	2193918464	eric.puente@wholefoods.com
Pearson	Peri	Alternate	Regulatory-State	Virginia Dept of Health	Richmond	VA	8043047433	peri.pearson@vdh.virginia.gov

Note: *Minimum council committee size is 11 (as noted above): 1-Chair; 1-Vice Chair; 1-State; 1-Local; 2-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise;*
Maximum council committee size is 23 voting members: 1-Chair; 1-Vice Chair; 4-State; 4-Local; 8-Industry; 1-Academia; 1-Consumer; 3-Any constituency with emphasis on expertise; 36 -Non-voting alternates.
Membership on standing committees is defined by the Executive Board. On all CFP committees, the committee chair, co-chair(s), and vice chair(s) all count towards constituency balance.

GUIDANCE DOCUMENT
FOR SAFE USE OF REUSABLE CONTAINERS

CONFERENCE FOR FOOD PROTECTION

2020-2023

This page photo courtesy of Conscious Container
Cover photo courtesy of In Good Company

Prepared by the

SAFE USE OF REUSABLE CONTAINERS COMMITTEE 2020-2023 CONFERENCE FOR FOOD PROTECTION

VOTING MEMBERS	AT-LARGE, NON-VOTING MEMBERS
Dagny Tucker, Co-Chair	Tom Arbizu
Carrie Pohjola, Co-Chair	Frank Curto
Kristina Bonatakis	Beth Glynn
Jeffrey Clark	Michael Goscinski
Deborah Crabtree	Jordan Ingle
Abeid Fells	Greg Lux
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DEFINITIONS & ABBREVIATIONS

Terms not defined in the Food Code and shortened abbreviations used in this document.

TABLE 1: DEFINITION OF TERMS USED IN THIS GUIDANCE

Term	*Definition*
Contamination-free	A procedure for filling a consumer's container with food or beverage without directly or indirectly contaminating the source container of food or a food-contact surface.
Intermediate Utensil	A utensil used to prevent contamination from refillable containers to food or food-contact surfaces.
Origin	Source of the refillable container, such as the consumer, the food establishment, or a third-party provider.
Reusable Container	A product or primary packaging, to hold food, that is used repeatedly, refilled, or returned for multiple uses and conforms to characteristics of sanitary construction as defined in Chapter 4-1 and 4-2 of the Food Code.
Return Receptacles	Empty containers such as a bin, crate, or cart used to collect reusable containers returned to a food establishment for cleaning prior to refilling with food.
Secondary Reusable Container	Cooler, delivery bag or other container that is returned to a food establishment for reuse but is not a food-contact surface for ready-to-eat foods
Third-Party Providers	Person that provides warewashing services and/or refillable containers cleaned as specified under Parts 4-6 & 4-7 to the food establishment.
Verification	The cleaning, monitoring, or check procedure should be done by a food employee capable of affirming the cleaning process was completed properly.

TABLE 2: TABLE OF ABBREVIATIONS USED IN THIS GUIDANCE

Abbreviation	*Substituted Phrase*
CPG	Consumer Packaged Good
NON-TCS	Non-Time/Temperature Control for Safety Food
RTE	Ready-To-Eat
TCS	Time/Temperature Control for Safety Food
W/R/S	Wash/Rinse/Sanitize
LCA	Life Cycle Assessment
PR3	Partnership to Reuse, Refill, Replace Single-Use Packaging

II–DISCLAIMER

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 guide does not have the force and effect of law and thus is not subject to enforcement. This guide encourages food establishments to use the guidance herein to tailor food safety practices appropriate to their operations.

III–PREAMBLE

At the 2021 Conference for Food Protection (CFP) Biennial Meeting, Council III voted and approved the creation of the Safe Use of Reusable Containers Committee. This was in response to Issue #2020 I-024 (combined with 2022 I-022 and 2022 I-023), as presented at the CFP Biennial Meeting.

The following charges were given to the Committee:

1. *Clarify the scenarios related to reusable containers within the scope of regulation.*
2. *Identify and analyze the scientific and other literature related to consumer-owned containers at retail.*
3. *Draft recommended guidance around scenarios identified in the issue and create a definition of reusable container.*
4. *Provide recommended code language changes, if necessary, to the FDA.*

IV–SCOPE

This committee found there are numerous instances where current regulatory code does not align with practice in the field. To address this issue for CFP, the committee created this document around a scenario matrix, which offers an overview of how reusable/refillable/returnable containers are currently being used by the business community.

This document does not include: binding requirements unless adopted by the regulatory authority; nor does it describe W/R/S procedures for containers that are washed by food employees prior to refilling (which is spelled out in the Food Code).

This document will help clarify:

1. *Scenarios for refilling reusable containers in retail food establishments as listed in the 2017 FDA Model Food Code.*
2. *Best practice recommendations for filling reusable containers including those under a variance of the Food Code.*
3. *Reusable containers washed outside of the retail food establishment such as by a third-party provider.*
4. *Literature and local legislation related to refilling reusable containers.*

Photo courtesy of Dispatch Goods

V
INTRODUCTION

There are few pathways available in the 2017 FDA Food Code for refilling consumer-owned or third-party provided containers unless W/R/S in the food establishment or filled by the consumer at a water vending station (see Figure 1).

The CFP convened the 2020 Biennial Meeting using a virtual format in 2021 due to the ongoing coronavirus pandemic. Three issues related to refillable containers submitted to CFP Council I were transferred to Council III at the 2021 meeting. Issue 2020 I-024 Creation of a Committee to Address Reusable Scenarios in Food Retail was combined with 2020 I-022 Amend Food Code to Harmonize the Definition of Reusable Container and 2020 I-023 Amend Food Code to Address New Reusable Scenarios in Food Retail. Council III voted, and subsequently approved, to create the Safe Use of Reusable Containers Committee. The following charges were given to the new Committee:

1. *Clarify the scenarios related to reusable containers within the scope of regulation.*
2. *Identify and analyze the scientific and other literature related to consumer-owned containers at retail.*
3. *Draft recommended guidance around scenarios identified in the issue and create a definition of reusable container.*
4. *Provide recommended code language changes, if necessary, to the FDA.*

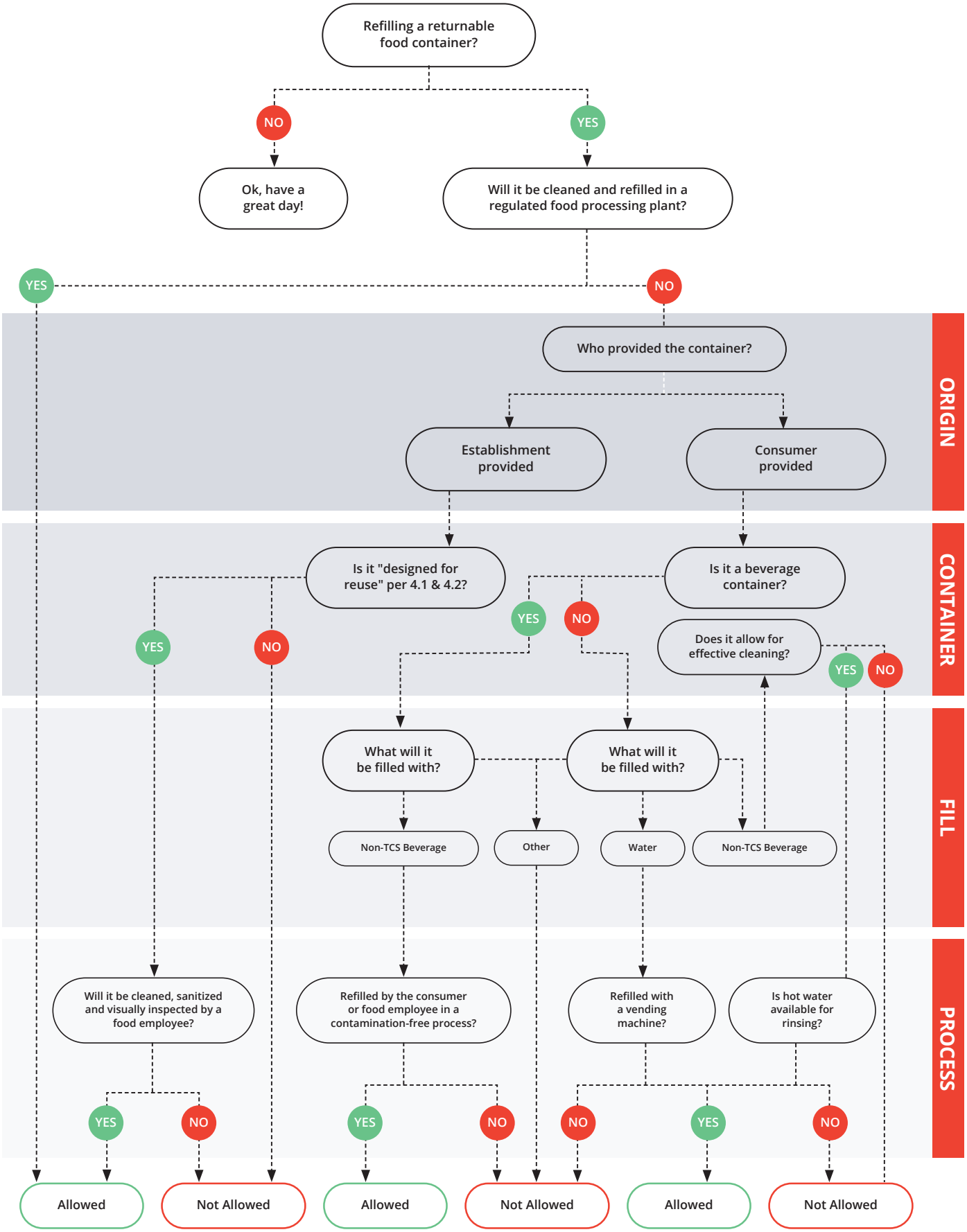
The committee was composed of representatives from academia, the food industry, and local, state, and federal regulatory agencies. Consultants from FDA and academic partners advised the committee throughout the entire process of guidance document preparation. The committee met biweekly with additional subcommittee meetings for approximately 12 months to fulfill its charges, including the completion of this guidance document.
Following a review of state and local codes, waste reduction bills, and the variety of current scenarios with reusable food containers in use, the committee identified several themes:

- *An increase in regulatory emphasis on the reduction of single-use articles to reduce solid waste.*
- *An increasing number of local ordinances that require (specifically for onsite dining) or expressly allow the use of reusable containers.*
- *An increase in the number of businesses that offer services to implement turnkey reusable container solutions for retail food establishments.*
- *The use of reusable containers in retail food establishments is common despite limited allowance in the food code.*
- *There is limited data on disease transmission related to the use of reusable containers.*
- *States recently modifying their food codes to increase the allowance of consumer-owned containers (see Appendix Table 1).*
- *Lack of understanding among industry, consumer, and regulatory partners for the existing allowances for reusable containers, such as those provided by the business for return*

The committee agreed the filling of customer-owned containers and third-party supplied reusable containers in retail food establishments was common despite limited allowance in the food code. The committee also agreed that local, national, and global legislation and movements to reduce solid waste from disposable food containers would increase reuse requirements and the demand for reusable container options from consumers, businesses, and environmental groups. In addition, legislative bodies will likely look toward reusable container options for food service packaging to help address issues of waste, human health, and climate change.

This document is designed to guide the safe use of reusable containers for retail food establishment operators intending to use these types of containers and to provide guidance to regulatory authorities evaluating or approving retail refilling operations. This document addresses scenarios where reusable containers are currently used, was informed by an analysis of literature and best practices related to consumer-owned containers at retail, identifies limitations in the 2017 FDA Food Code related to refilling operations, and highlights recommended guidance for potential food safety controls to help protect consumers, employees, and food if expanded reusable container and refilling operations are approved.

The document includes parameters for reducing potential contamination from direct and indirect contact when filling consumer-owned or third-party provided containers, options for a variety of foods and risk levels, and suggested equipment modifications to reduce risk. It also includes guidance for third-party providers that manage all or a portion of the circular movement of reusable containers for food retailers, such as nationally-distributed CPGs or locally-prepared food items. The committee members encourage regulatory and industry partners to refer to CFP-issued plan review guidance as future reduction of disposable food containers will potentially increase the warewashing and storage considerations for reusable serving containers.


Refilling a returnable food container?
NO
YES
Ok, have a great day!
Will it be cleaned and refilled in a regulated food processing plant?
YES
NO
ORIGIN
Who provided the container?
Establishment provided
Consumer provided
CONTAINER
Is it "designed for reuse" per 4.1 & 4.2?
Is it a beverage container?
YES
NO
YES
NO
Does it allow for effective cleaning?
YES
NO
FILL
What will it be filled with?
What will it be filled with?
Non-TCS Beverage
Other
Water
Non-TCS Beverage
PROCESS
Will it be cleaned, sanitized and visually inspected by a food employee?
Refilled by the consumer or food employee in a contamination-free process?
Refilled with a vending machine?
Is hot water available for rinsing?
YES
NO
YES
NO
NO
YES
NO
Allowed
Not Allowed
Allowed
Not Allowed
Allowed
Not Allowed

VI

CONTAINER CONSTRUCTION & CONDITION

CONTAINER CONSTRUCTION

Containers reused in a food service establishment need to meet the characteristics of sanitary construction as defined in Chapter 4-1 and 4-2 of the Food Code. They should be used as intended and temperature appropriate.

Regulators and retailers may allow for a broader array of refillable containers for raw agricultural commodities such as whole, unwashed fruits and vegetables that are intended to be washed before consumption. For example, a cloth bag may be an acceptable refillable container for produce provided it is clean and in good repair.

Consumers may fill containers such as insulated type vessels or other containers that do not support a reduced oxygen atmosphere with hot foods. Containers, such as lidded jars or heat-sealed bags, supporting a reduced oxygen atmosphere should not be refilled with hot foods. A reduced oxygen atmosphere may be created inside the container as the product cools, allowing pathogenic bacteria such as Clostridium botulinum to potentially grow in the container, presenting a significant hazard to the consumer.

Similarly, containers designed for use with cold foods should not be filled with hot foods. However, foods held at cold or ambient temperatures may be refilled into containers as the corresponding reduced oxygen environment is unlikely to occur.

CONTAINER CONDITION

In addition to multiuse construction, containers presented for reuse in a food service establishment must also be in good repair and condition as defined by Chapter 4 and 3-304.17(4)(c) of the Food Code.

Single-use articles are designed for a single, and often specific, use. Unless the food establishment has a variance of 4-502.13 to ensure damaged, cracked, or unsuitable single-use containers are not refilled, food employees may not refill a single-use container with food. However, the code does not explicitly prohibit a customer from refilling a clean container with their individual food using a contamination-free process. For example, a cleaned yogurt container might be used by a customer to fill with dry grains from a gravity-flow dispenser.

Due to the wide array of containers that may be presented for reuse, food establishments should have clear procedures to evaluate which customer owned refillable containers may be refilled in the food establishment and that single-use containers should not be refilled by a food employee without additional preventive controls as directed by the variance. Peer-reviewed scientific studies show that hazardous chemicals can migrate from plastic food packaging into food[1].

After an initial release of unbound chemicals, some refillable/reusable plastics have also been measured to migrate hazardous chemicals into food following multiple uses[2]. Current safety assessment approaches focus on a specific set of toxic endpoints (e.g. genotoxicity) and are not yet able to fully account for additional sensitive endpoints or for mixture toxicity[3]. Guidelines are therefore needed to ensure the safe reuse of plastic food packaging articles.

1. Yang et al. 2019, Qian et al. 2018
2. Tisler and Christensen 2022
3. Muncke et al. 2020v

VII

CONTAMINATION-FREE FILLING METHODS

Five methods for filling of reusable containers are included for either consumer or employee filling. Some of these methods are already common practice. These methods are examples and are not an exhaustive list of safe filling methods for reusable containers. Processes may vary and food establishments should consult with their regulatory authority to identify approval mechanisms.

METHOD 1

GRAVITY-FED DISPENSERS (SELF SERVICE, BULK GRAVITY FLOW)

Type of Equipment

Dispensers that protect bulk, unpackaged food using a baffle, chute, or other barrier to prevent access to the food. A handle or other mechanism allows the product to flow into the receiving container with no additional utensil needed.

Control Needed

Posted instructions for customer education to ensure proper use and clarity of which products may be refilled to a customer container.

Example

Continuous or portion-controlled flow dispensers used for free-flowing products like cereals, grains, nuts, ice cream and beverages. The customer would fill their refillable container by actuating a lever to allow food to flow. This would need to occur without contact between the refillable container and the dispenser.

METHOD 2

SELF SERVICE, NON-GRAVITY FED

Type of Equipment

Self-service scoop bins, spice containers, and non-TCS bulk foods that need utensils for food transfer.

Single-use articles

Such as a paper liners or utensils such as tray, scoop, or spoon may be used to ensure that customer-provided containers are not brought into food preparation areas, and that unpackaged foods do not come into contact with a contaminated utensil. Receptacles must be provided for both clean and dirty transfer utensils.

Control Needed

Displayed products shall be protected from contamination using packaging, guards, covered display containers or other effective means. Individual utensils must be provided for each bulk food storage bin and or container. Space to hold clean and dirty utensils. Staffing to wash utensils. Posted instructions for customer education to ensure proper use and clarity of which products may be refilled to a customer container.

Example

A customer provided container is filled from a bulk bin or other bulk storage container of non-TCS food. The customer would use a single-use article or transfer utensil to fill the consumer-owned container.

METHOD 3

INTERMEDIARY LINERS (FULL SERVICE, EMPLOYEE REFILLING)

Type of Equipment

Transfer liners such as a wax paper liner may be used to ensure that customer provided containers are not brought into kitchens or service areas, and that work spaces do not come into contact with containers that have not been sanitized according to FDA recommendations. Transfer liners are used on scales and to collect requested food for customers before being placed in the customer-provided container. Adhesive stickers can be provided for customer provided containers.

Control Needed

Intermediary liners shall be protected from contamination using proper storage or other effective means. Food service staff must be educated about proper handwashing procedures in the event of inadvertent hand contact with the customer provided container.

Example

A customer provided container is brought in for refill at a deli, seafood, meat counter, or similar full-service station. The employee would utilize a single-use liner to serve the food. The liner is then transferred to the customer owned container. This method limits waste significantly, while still maintaining existing food safety requirements.

METHOD 4

W/R/S FOR THE CUSTOMER (BEVERAGES & ALTERNATIVE METHOD FOR FULL SERVICE)

The customer presents a container to the food establishment for use, after any approved method for W/R/S service, or approved sanitization method, is completed prior to filling.

Control Needed

Staff must be educated on the defined acceptable condition/criteria of the customer returned container. Staff must be educated on proper cleaning, sanitizing and proper handwashing procedures associated with the handling of the customer returned containers. Intermediary container shall be protected from contamination using proper storage or other effective means.

Example A

Customer brings a container to the food establishment. The container is visually inspected to determine if they will W/R/S the container or use another approved sanitization method. The container is filled and returned to the customer.

Example B

Customer brings a beverage container in for beverages. The container is visually inspected to determine if they will W/R/S the container or use another approved sanitization method. The employee can fill an intermediary container (disposable or washable) with the beverage which is then transferred to their container.

METHOD 5

REUSABLE CONTAINER EXCHANGE — TRADE DIRTY FOR CLEAN, SANITIZED CONTAINERS

The business provides a pre-approved, exchangeable container program. Containers are provided either directly by the establishment, or by a contracted third-party vendor. Receptacles are provided for collection of used containers, and the customer is provided with (by the employee) a verified, sanitized container for use using the food establishment's process.

Control Needed

Staff must be educated about the defined acceptable condition/criteria of the customer returned container. Staff must be educated in proper W/R/S and proper handwashing procedures associated with the handling and cleaning of the customer returned container. Clean, sanitized containers shall be protected from contamination using proper storage or other effective means.

Example A

Customer returns a container provided by the food establishment in exchange for one that has been a W/R/S container. The customer will fill the clean container. The food establishment will W/R/S the returned container for a future exchange. Examples include multiuse to go boxes at a salad bar, beverage containers, lidded containers for bulk foods.

Example B

Customer brings a beverage container in for beverages. The container is visually inspected to determine if they will W/R/S the container or use another approved sanitization method. The employee can fill an intermediary container (disposable or washable) with the beverage which is then transferred to their container.

Photo top left

LOOP Haagen Daz

Photo top left

Tiffens To Go

VIII

THIRD PARTY REUSE PROVIDER

Reusing food contact packaging requires quality control measures that ensure safe and sanitary implementation.

Many food service providers do not have onsite facilities and/or capacity to adequately W/R/S reusable foodware, third party businesses have come to market providing these services as well as forward and reverse logistics services for the containers.

The following section addresses the emergence of third-party reusable foodware service providers beginning with an outline of the types of services provided and followed by considerations for ensuring safe and sanitary implementation of reusables with third-party providers.

Third-party reusables service providers are businesses that engage in any combination of the following activities:

- *Provide reusable food containers and complete circular management between sites (distribution of clean containers and collection of dirty containers);*
- *Clean and sanitize reusable containers at their site before returning to distribution inventory;*
- *Ensure sanitary handling transport for reusable containers between businesses; and*
- *Monitor reusable container condition and manage inventory accordingly.*

While there are many reusable food containers available, there are several critical differentiators between consumer provided reusable packaging, refillable packaging and reusable packaging designed for reuse service systems[4].

Reuse service systems are intentionally designed to incorporate:

- *The existence of infrastructure and reverse logistics for actual take-back, cleaning, refill and redistribution of the packaging (operated by the producers and/or a third party).*
- *A suitable incentive to return the packaging (usually a deposit, but can also be a system in which the consumer pays a fine when the packaging is not returned).*
- *A certain amount of minimum rotations (at least between 10-15 cycles with upwards of 1000+ the ideal[5])*
- *A collection rate of at least 90% of the packaging.*

THIRD-PARTY REUSE SERVICE PROVIDERS: EVALUATION AND CONSIDERATIONS

The rapidly changing third party reuse provider industry has seen exponential growth over the last several years in the number and type of reuse providers coming to market[6]. With any emerging industry it takes time for regulatory and other agencies to evaluate and implement regulations to ensure safe operations.

Currently, the degree of oversight into the reusable service provider space varies significantly across geographies. As such the following guidance offers an outline of considerations retailer's, food service providers and others contracting with a third-party reuse vendor may want to take into account.

REGULATORY OVERSIGHT (PERMIT/LICENSE/ INSPECTION)

It is critical third-party service providers follow state, county and local regulatory agency requirements. While service providers that do not handle food may not be considered a food preparation operation, they may be licensed by some agencies.

CUSTOMER OVERSIGHT (CONTRACTING BUSINESS CONSIDERATIONS)

As with any supplier consider a contract/agreement that ensures second or third-party assessments with onsite facility and/or procedural reviews including clear reporting/communication expectations and processes.

CONTAINER SELECTION

See guidance in VI of this document to evaluate the selection of reusable containers and conduct and/or use current life cycle assessments to ensure the number of reuse cycles provide the intended benefits. Setting individual minimum rotations for each packaging type would cause a very high administrative burden. According to a comparison of 32 LCA studies 10-15 rotations for all packaging materials already brings more benefits compared to single-use packaging.

4. Adopted from "Packaging Reuse vs. Packaging Prevention" Henriette Schneider, Senior Expert Circular Economy, Environmental Action Germany (DUH) Larissa Copello. Production and Consumption Campaigner, Zero Waste Europe. June 2022.2. Tisler and Christensen 2022
5. Reusable vs.Single-use Packaging. A review of environmental impacts. Downloadable at https://zerowasteeurope.eu/wp-content/uploads/2020/12/zwe_reloop_report_reusable-vs-single-use-packaging-a-review-of-environm ental-impact_en.pdf.pdf_v2.pdf

6. www.reuselandscape.org

STANDARD OPERATING PROCEDURES (SOPS)

All third-party service providers must have SOPs in place for the safe and sanitary handling of foodware throughout the container's entire journey. While SOPs for W/R/S are well known and have strong regulatory oversight and guidance, reuse service providers face a unique set of circumstances whereby many of their operations fall outside the normal bounds of regulated space yet still have implications for food safety. In particular, the reverse logistics of collecting dirty containers for transport to a facility for W/R/S, possibly in conjunction with the distribution of clean containers, requires specific attention and the development of SOPs in order to ensure minimal risk of cross-contamination and/or other health and hygiene concerns.

GENERAL CONSIDERATIONS

Well known industry standards exist for the following but we highlight them here so they are not overlooked simply because many of the third-party service providers operate outside of food handling facilities.

- *Employee health & hygiene*
- *Employee illness policy*
- *Hand washing and sinks*
- *Glove usage where appropriate (see example SOPs in appendix)*

WASHING, SANITIZING & HANDLING OF CONTAINERS

Clear guidance and regulations exist for the W/R/S and handling of containers. Please refer to local and federal food safety guidelines with particular attention to ensuring adequate space for stacking reusables after drying and storage of the reusables in secondary containers with lids for protection.

RECORD KEEPING, PROCEDURES AND PROTOCOLS

Third-party contractors and all food service operators must keep and retain adequate records related to their operation including SOP's, hazard control, audit/inspection reports, operational checklists, and if necessary for CPGs, market withdrawal and recall protocols.

REVERSE (COLLECTION) / FORWARD (DISTRIBUTION) LOGISTICS

In the appendix of this document, we offer guidance that addresses the expanded boundaries of food safety considerations required in open-network/offsite reusable foodware systems. This is an excerpt from the PR3 Washing, Sanitization & Handling of Foodware standard[7] which was designed to integrate and support diverse reuse initiatives. Below are some of the key takeaways from that extensive list.

For context it is important to note that several models have emerged for the collection of dirty containers including:

- *Staffed Returns Stations*
- *Automated/Machines*
- *Passive/Unstaffed Return Bins*

Each of these collection models will necessarily have a slightly different set of protocols but all need consistency in safe handling procedures.

All secondary and primary containers must be clearly labeled as clean or dirty. If any of the models being evaluated use the same bin for collection, storage and/or distribution, it is critical the bins and foodware are W/R/S between uses. The containers and bins should have the same level of W/R/S/ to ensure consumer safety and minimize cross contamination.

It is important to also take into account the following considerations:

- *Clean container handling procedures*
- *Storage of the foodware containers while in wash facility, during transportation, and onsite at the food service/restaurant location*

7. Partnership to Reuse, Refill, Replace Single-Use Packaging PR3 standards available for review online: PR3 Standards - RESOLVE

Photo courtesy of Boston Tea Party

IX
CONCLUSION

The above points of consideration and guidance are intended as a starting point for regulatory agencies, businesses, and other parties interested in the safe and sanitary implementation of reusable foodware systems.

While not designed to be comprehensive, this guidance offers key points of consideration when contracting with a third-party reuse provider.

As this new industry continues to mature, we encourage maintaining close contact with regulatory and industry peers on this topic, as well as monitoring for any updated food code and PR3 Reuse Industry Standards to stay abreast of and share emerging best practices.

X

RESOURCES

The following legislative activities, current reuse examples, scientific rationale, and existing guidance resources were evaluated when creating this document.

EXAMPLE MUNICIPALITY AND LEGISLATIVE REQUIREMENTS AFFECTING THE USE OF REUSABLES

California Assembly. (2019, July 12). Assembly Bill No. 619, CHAPTER 93, An Act to AMEND Sections 114121 and 114353 of the Health and Safety Code, relating to retail food facilities. California Legislative Information.

https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200AB619

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City of Berkeley, California. (2019, February 19). ORDINANCE NO. 7,639-N.S. Adding Chapter 11.64 to the Berkeley Municipal Code to Adopt a Single Use Foodware and Litter Reduction Ordinance. City of Berkeley's Records Online.
https://records.cityofberkeley.info/PublicAccess/paFiles/cqFiles/index.html and searching for "7639"

Nevada Legislature. (n.d.) CHAPTER 446 - FOOD ESTABLISHMENTS. Nevada Administrative Code.
https://www.leg.state.nv.us/NAC/NAC-446.html

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Pinsky, D. (2020, August 25). Reusables are Doable. Greenpeace.
https://www.greenpeace.org/usa/reports/reusables-are-doable

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https://drive.google.com/file/d/1QD8GufolsA7ZBFnRvt45g_BwCXD1Fea2/view

World Economic Forum. (2021, July). Future of Reusable Consumption.
https://www3.weforum.org/docs/WEF_IR_Future_of_Reusable_Consumption_2021.pdf

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Matthews, C., Moran, F., & Jaiswal, A. K. (2021, February 10). A review on European Union's strategy for plastics in a circular economy and its impact on food safety. Journal of Cleaner Production. Volume 283.
https://doi.org/10.1016/j.jclepro.2020.125263

Moss, E.,Gerken Kristina, Youngblood Kathryn, Jambeck Jenna R. (2022). Global landscape analysis of reuse and refill solutions. Frontiers in Sustainability. Volume 3.
https://www.frontiersin.org/articles/10.3389/frsus.2022.1006702

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GUIDANCE FOR REUSABLE CONTAINERS

Centers for Disease Control and Prevention. (n.d.). Retail Delis Can Address Gaps in Food Safety - Key Takeaways from 5 Scientific Articles.
https://www.cdc.gov/nceh/ehs/ehsnet/plain_language/retail-deli-food-safety-practices.html

Consumers Beyond Waste. (2021, September). Design Guidelines for Reuse: Working Document. World Economic Forum.
https://weforum.ent.box.com/siajeqni5jr8cuocoyouxmlmwi82hegov

Consumers Beyond Waste. (2021, September). Safety Guidelines for Reuse: Working Document. World Economic Forum.

https://weforum.ent.box.com/s/6f5192886e94cq5bluk68ltm8shjgwkn

Oceana. (2022). Taking Food or Drink To Go - Best practice and policy recommendations for a plastic-free future for take-away vendors and large events.
https://europe.oceana.org/wp-content/uploads/sites/26/d_files/factsheet_taking_food_or_drink_to_go.pdf

PR3 Partnership to Reuse, Refill, Replace Single-Use Packaging. (2021, September). Reusable Packaging System Design Standards - Specifications and recommendations. RESOLVE.
https://www.resolve.ngo/site-pr3standards.htm

Reusable Packaging Association. (2016). Guidelines and Best Practices for the Safe Use of Returnable Containers in Food Supply Chains.
https://www.reusables.org/wp-content/uploads/2016/06/RPA-Guidelines-Best-Practices-for-Safe-Use-of-Returnable-Containers-in-Food-Supply-Chain.pdf

HELPFUL REUSE EXAMPLES

Following is a short list of real-life examples of reuse in various scenarios in the U.S. For a comprehensive list of reuse in the U.S. and globally, in various applications see: Reuselandscape.org

U.S. Grocery — Retail and CPG
https://exploreloop.com
https://regrocery.co
Rootszerowastemarket.com
https://nudefoodsmarket.com
Trashless.com

U.S. Restaurants and Third-Party Providers
https://justsalad.com/reusablebowl
https://dispatchgoods.com/partners#restaurants
https://rcup.com
Boldreuse.com/find-bold-reuse-locations
Deliverzero.com
Planetozzi.com

Events
https://rcup.com/
https://turnsystems.co/
https://cupzero.com/

OTHER USEFUL WEBSITES

Refill.org.uk/resources
Reuseportal.org/case-studies

XI

APPENDIX

Filling Methods

Photos courtesy of Oren Kariri

Method 1

GRAVITY FLOW

Liquids/oils/honey/peanut butter

Method 2

SCOOPS / UTENSILS

Traditional bulk foods with scoop

Method 3

TRANSFER SHEETS (EMPLOYEE / DELI COUNTER)

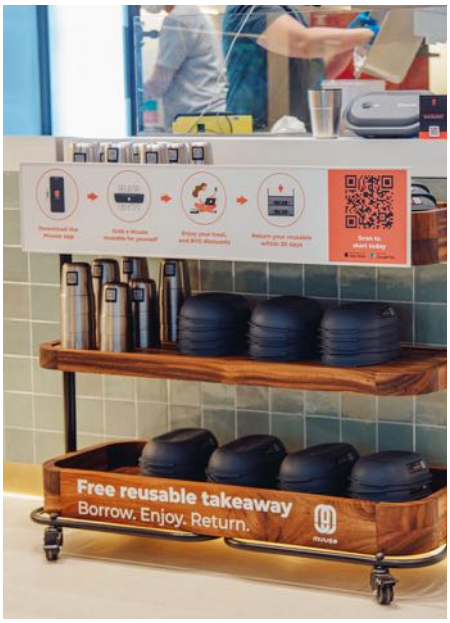
Use of a paper to prevent exposure of the equipment/packaging deli meat

Method 4

CONTAINER WASHED BY FOOD ESTABLISHMENT

Visual inspection/potential refusal of container

Method 5



CONTAINER WASHED BY A THIRD PARTY

Collection stations or transport of dirty containers/delivery of clean containers

CONSUMER OWNED CONTAINERS

WHAT CAN BE USED

Mason jar
Yogurt container
Canvas bag (produce)
Plastic bag
Metal foodware container
Plastic food storage container
Glass food storage container

WHAT CANNOT BE USED

Paper cup
Kitty litter bucket
Tin can
Styrofoam container
Pizza box

SAMPLE BEST PRACTICES FOR **SAFE HANDLING OF FOODWARE DURING REVERSE AND FORWARD LOGISTICS**

EXCERPT FROM PR3's "Washing, Sanitization & Handling of Foodware Standard."*

FOODWARE HANDLING DURING DISTRIBUTION AND COLLECTION

- Third-party employees should have food-handler certificates and receive additional training for safe container handling during collection and distribution.
- Handling procedures should be printed and kept in all vehicles, sorting, storage and washing facilities for reference.
- Distribution vehicles (trucks, vans, pedicabs, bikes, etc.) should have separated and designated dirty and clean areas or be used solely for distribution of clean containers or solely for collection of dirty containers.
- Vehicle operators that switch between collecting used foodware and distributing clean foodware should wash and sanitize vehicle storage areas between uses.
- Vehicle operators should seek further advice from local authorities on local requirements.
- Boxes of clean, food service gloves must be available in vehicles, at or near each collection point, and at the sorting, washing and warehousing facilities where employees drop off used foodware or pick up clean foodware.
- Handwashing should be provided at the receiving facility.
- Employees should use gloves to handle any used foodware or collection bins.
- Employees should wash hands and replace gloves if switching between collection and distribution roles, as detailed below.
- If a glove rips while handling dirty foodware, employee SHALL immediately wash hands and clean and sanitize any surfaces touched on the way to washing hands.
- If any clean foodware comes in contact with a dirty glove, ripped glove, or is dropped, or placed on an unsanitary surface, it SHALL be returned to a washing facility for re-washing and sanitization.

FOODWARE HANDLING DURING DISTRIBUTION

- Clean foodware must be stored and transported in FDA, EPA, NSF and/or other governing body agency approved, sealed storage/distribution containers.
- In the case that collections bins and storage/distribution containers are interchangeable, they SHALL be washed and sanitized between each use and clearly labeled as "clean" or "used.

PICKING UP CLEAN FOODWARE FOR DISTRIBUTION

Employees must follow the below steps in order.

- Employee must wash hands.
- Employee must wear gloves.
- Employee will collect cleaned, sanitized foodware that is packed and sealed in a distribution/storage container(s) from the warewashing provider.
- Employee will place distribution/storage container(s) into the designated clean section of the distribution vehicle(s).

DISTRIBUTING CLEAN FOODWARE

Employees must follow the below steps in order.

- Employee will distribute clean containers in sealed distribution/storage containers to vendors back of house.
- Employee will give storage/distribution container(s) directly to vendor employees or place it in designated areas in the back of house or behind the counter, away from customers and potential contamination until used.

** Partnership to Reuse, Refill, Replace Single-Use Packaging (PR3) standards are in the process of being accredited through the American National Standards Institute (ANSI) and are available for review online: https://www.resolve.ngo/site-pr3standards.htm*

FOODWARE HANDLING DURING COLLECTION

- Collection bins will be cleaned and sanitized with an FDA or other local governing body-approved sanitizing solution for nonfood-contact surface each time it is emptied by an employee.
- Collection bins will be cleaned and sanitized each time before being reused at a collection point.
- Collection bins will be fitted with a lid that seals the bin during collection.

NOTE: Nonfood-contact surfaces of equipment must be kept free of an accumulation of dust, dirt, food residue, and other debris. Timely cleaning and sanitizing prevent the growth of microorganisms on both food-contact surfaces of equipment and non-food contact surfaces. Additionally, proper cleaning frequency prevents the development of slime, mold, or other soil and related microorganisms on food-contact surfaces and equipment.

- Collection bins will be maintained by third-party employees, even if they are located within the vendor's space.

COLLECTING DIRTY BINS FROM COLLECTION POINTS

Employees must follow the below steps in order.

- When directly in front of the collection point, employee will wear gloves
- Employee will open the collection point housing unit and seal collection bin with lid.
- Employee will place the sealed collection bin into the designated dirty section of the collection/distribution vehicle.
- Employee will sanitize the collection point housing.
- Employee will repeat steps if multiple collection point housing units are in the same location.
- Employee will remove gloves and properly dispose of gloves in a nearby trash can and wash hands.

INSERTING CLEAN COLLECTION BINS INTO COLLECTION POINTS

- Employees will follow the below steps in order.
- o Employee will wear a new pair of clean
- o Employee will place sanitized collection bin from collection/distribution vehicle into collection point housing unit.
- o Employee will repeat steps above if multiple additional collection point housing units are in the same location.
- o Employee will remove gloves and properly dispose of gloves in a nearby trash can and wash hands.

RETURNING DIRTY FOODWARE TO SORTING OR WASHING FACILITY

- Employees will follow the below steps in order.
- o Employee will put on new gloves.
- o Employee will unload dirty reusable containers and receptacles for sorting and/or washing/sanitizing.

Photo courtesy of Muuse

SUMMARY OF RECENT FOOD CODE **ACTIVITY RELATED TO CONSUMER-OWNED FOOD CONTAINERS IN THE UNITED STATES**

After reviewing state and local codes, waste reduction bills, and a wide variety of reusable food containers commonly in use, the committee identified several themes:

Lack of awareness or enforcement of existing regulatory restrictions on reusable containers

- *The use of consumer-owned reusable containers, especially for beverages and bulk foods, is considered common practice.*
- *Lack of understanding among industry, consumer, and regulatory partners for the existing allowances for reusable containers, such as those provided by the business for return*

Increase in solid waste regulatory activities encourages consumer-owned reusable containers

- *Restrictions on single-use items are putting pressure on food establishments.*
- *Municipalities are passing regulations expressly allowing reusable food containers.*

Increase in the number businesses that support reusables in retail food services

- *Several businesses already offer services to implement turnkey reusable containers.*
- *Some jurisdictions do not consider these businesses to meet the definition of a "food establishment" and therefore do not provide regulatory oversight.*

Limited data on disease transmission related to the use of reusable containers

- *The existing requirement for filling reusable containers using contamination free process addresses any potential concerns with potential fomite transmission.*
- *Several states recently modified regulations, or are in the progress, to increase the allowance of consumer-owned containers (see Table 1).*

Table 1

Comparison of 2017 FDA Food Code, Recent State Code Modifications, and new CFP Guidance Document Related to Filling Consumer-Provided Reusable Food Containers Using a Contamination-free Procedure.

Allowances for Filling Consumer-Provided Reusable Containers

Shading indicates allowable filling options

	Method 1	***Method 2***	***Method 3***	***Method 4***	***Method 5***
	Bulk foods from protective dispensers	Bulk food using a utensil for transfer	Employee filling using intermediary liners	Employee filing washed or visually inspected container	Reusable container program washed by food establishment or third party
2017 FDA Food Code Section 3-304.17	Only non TCS beverages				No specific guidance for third party
California (2019) Section 114121(b)					Same as FDA Food Code
Illinois (2019) HB3440t					Same as FDA Food Code
Maine (2021) H.P. 641 - L.D. 885					Same as FDA Food Code
Oregon (2022) Proposed Rule for Public Comment					Same as FDA Food Code
Washington (2020) WAC 246-215-03348					Same as FDA Food Code
CFP Committee Guidance (2022)	Provides guidance	Provides guidance	Provides guidance	Provides guidance	Provides guidance for third party

SAFE USE OF REUSABLE CONTAINERS COMMITTEE

2020-2023 Conference for Food Protection

Website
www.foodprotect.org

Photo courtesy of Usefull

SURCC Meeting Summations

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

Date _11/16/2021_____

Recording on: Yes __X___ No____

Reminder of Anti-Trust Statement: Yes_X___ No ____

Roll Call: Dagny Tucker, Frank Cuarto, Eric Puente, Alison Hurysz, Jordan Ingle, Carrie Pohjola, Christina Springer, Kristina Bonatakis, Rayna Oliker, Steph Teclaw, Oren Kariri, Christina Applewhite, Susan Shelton, Gregory Lux, Jeff Clark, Kat Olson, Rayna Oliker, Sarah Kantrowitz, Steph Teclaw, Tom Arbizu, Sabrina Salinas, Traci Michelson

Quorum: Yes_X__ No___

Vote on previous conference call's Roll Call and Summation: APPROVE ____ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes_X___ No____

Summation of call proceedings

Clarifying Scenarios in which Reusable Containers may be used

- **Reusing personal containers for bulk**
- **Personal containers for take out**
- **A grocery might provide containers that are reusable**
- **Third party might be provide container**

Potential Platforms to be used during meetings (Tabled)

- Google Docs
- Food Shield Group
- Teams

Sub Committees to be created per Category

- **Before subcommittees are created per Category the Regulatory Committee will conduct foundation work to determine:**
    - What we want the recommendation to be
    - Proposed framework
    - Understanding where we are and wanting to go

- Review Food Code
    - **Regulatory Committee**
        - Susan Shelton
        - Kristina Bonatakis
        - Rayna Oliker
        - Gregory Lux

Categories to be reviewed:

- Bulk
- Delivery
    - Restaurant
    - Direct to consumer
    - Grocery (i.e. Instacart)
- Grocery
    - Ready to eat
        - TCS vs. Non TCS
    - Not ready to eat
        - TCS vs. Non TCS
- Institutional

    - Self Service Markets & Vending
- Events
    - Temporary & Mobile
    - Trade Shows
- Tabled- CPG (Consumer Product Goods)?

Meeting will be changed to 2:30 pm based on common consensus from group

ACTION ITEMS

Poll to be sent out in reference to Committee interest

- Christina Springer & Oren Kariri(expressed interest in Grocery)

Regulatory Committee will start work for next meeting

Safe Use of Reusable Containers

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

Date _____December 14th, 2021_____

Recording on: Yes __x___ No____

Reminder of Anti-Trust Statement: Yes_x___ No ____

Roll Call: ____Jeff Clark, Jessica Otto, Stephanie Teclaw, Jordan Ingle, Kat Olson, Traci Michelson, Oren Kariri, Susan Shelton, Dan Redditt, Mike Goscinski, Christina Springer, Steve Oswald, Ali Hurysz, Christine Applewhite, Kaycee Strewler, Dagny Tucker, Carrie Pohjola, Eric Puente, Sabrina Salinas, Gregory Lux, Abeid Fells, Rayna Oliker, Sarah Kantrowitz, Don Schnaffer

Quorum: Yes__x_ No___

Vote on previous conference call's Roll Call and Summation:

APPROVE _x___ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes_x___ No____

Summation of call proceedings__

1. Summation/notes are uploaded to TEAMS channel for review

2. Review of draft decision tree per current food code - Jessica Otto would like to take this back to the FDA team to validate it
3. Review of subcommittee meetings and actions
4. Discussion on how we should go about developing reusable container definitions/approvals - look for current definitions, use FDA Food Code definition - add to TEAMS any that the group comes across

(B) A take-home FOOD container returned to a FOOD ESTABLISHMENT may be refilled at a FOOD ESTABLISHMENT with FOOD if the FOOD container is:

(1) Designed and constructed for reuse and in accordance with the requirements specified under Part 4-1 and 4-2; P

5. Discussion on 12/28 meeting - cancel due to holidays - next meeting is 1/11/22

Action Items:

Jessica/FDA to review draft decision tree

Carrie/Dagny to look for reusable container definition - anyone else can upload as well

Subcommittees to continue to work and report out on the 1/11/22 meeting

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CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date __January 11, 2022_____

Recording on: Yes ___X__ No____

Reminder of Anti-Trust Statement: Yes_X__ No ____

Roll Call: In Chat

Jessica Otto, FDA
Traci Michelson - McDonald's
Jordan Ingle - Ecolab
Ali Hurysz - Whole Foods Market
stephanie teclaw- skogens festival foods
Susan Shelton, WaDOH
Bessie Politis Starbucks
Frank Curto, Territory Foods
Dilshika Wijesekera, Instacart

Christina Springer - Oregon Department of Agriculture
Sabrina Salinas- Harris County Public Health
Oren Kariri, New Seasons Market
Tom Arbizu - HEB LP
Debbie Crabtree - Fairfax County HD
Steve Oswald - Wakefern Food Corp.
Peri Pearson - Virginia Department of Health
Kristina Bonatakis - Customer
Sarah Kantrowitz - Perkins&Will
Mike Goscinski, NAMA
Christine Applewhite- future FDA :-)

Quorum: Yes_x__ No___

Vote on previous conference call's Roll Call and Summation: APPROVE ___x_ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes____ No_x___

Summation of call proceedings_____

FDA participant discussed the flow chart: Refilling Returnables 3-304.17. Container – (Food) Code doesn't care who owns the container but how it is used. Contextualize our work - needs to be food contact. Not talking about reusable bags. Filling a container with food. Q. Direct FC v. ?

Scope of diagram. Does the diagram take into account T/T in delivery

world? ___This is a great first step in helping to contextualize what this committee is trying to address. Direct to Consumer Guidance - will share for reference. Final version as a tool - may want to highlight what the rule is v the provision. Non TCS language? Annex 3. Food for thought (from FDA) scenario… can always apply for a variance for a use that is not allowed. _____Q. from committee membe Regarding the asterisk. Separate paragraphs are treated separately. They are distinct. Notes will be shared with the group who developed the diagram.

Subcommittee 1 Discussion:

Discussion around container definition. What's allowed v not allowed - decided to wait to address that. Grocery -identified departments, takeout v delivery, who would be filling a container with what - TCS v non TCS. Direct to consumer and ecommerce - compostable trays, insulation materials - want less packaging or reuse the materials. Suggestion to designate insulation materials as active or passive. Restaurants - same process of identifying who provides, who fills, etc… suggestion to use same terminology as DTC guidance._

Difficult to clean container - growlers, kombucha, etc. Salad food bars - self-service: olives, fruit, etc.

Subcommittee 2 has a bulleted list that will be added to the table that was shared by subcommittee 1. Literature review in process. Added scenarios from other countries (raw meat!) options available some grocery stores are already allowing refilling. Science articles - Norovirus outbreak traced back to reusable canvas bag that was in restroom during a vomiting (?) event.

Documents will be shared (Teams) suggestions for using other methods of sharing as well (in chat). Some subjects that didn't get a lot of interest - institution, mobile/temporary - is anyone interested in taking on those concepts. Sub committee 2 did talk about temp and mobile foods in their subcommittee meeting. _____Suggestion to change "Restaurant" to "Food Service" to incorporate more types of facilities. Let Co-chairs know if there are existing definitions in various state laws (legislated). _____Next meeting scheduled for Jan. 25 - ACTION ITEMS _____No additional action items identified.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

Date : 2/8/22

Recording on: Yes ___X__ No____

Reminder of Anti-Trust Statement: Yes_X_ No ____

In Attendance:

Dagny Tucker

Carrie Pohjola

Jessica Otto

Oren Kariri

Traci Michelson

Don Schaffner

Ali Hursyz

Rayna Oliker

Susan Shelton

Jeffrey Clark

Debbie Crabtree

Abeid Fells

Gregory Lux

Christina Springer

Frank Curto

Kat Olson

Sabrina Salinas

Sarah Kantrowitz

Kristina Bonatakis

Quorum: Yes_X_ No___

Vote on previous conference call's Roll Call and Summation:

APPROVE _X__ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes____ No_X__

Summation of call proceedings

- Dagny reiterated Committee member obligations - attendance etc.
- Approval of 1/11/22 summation
- Regulatory Sub-committee - Confirmed updates made to code visualization based on FDA comments. Will await further approval upon sharing.
- Discussion of shared scenario matrix for integration of sub-committee findings. Records sector, origin, collection, etc.
    - Traci elucidated intent for similar rows and desire to differentiate
    - Dagny explained Grocery/Manufacturer
    - Sarah K. - Raised issue of committee scope in e-commerce or grocery delivery. Does it include secondary packaging used in delivery (ex. dunnage).
    - Discussion of how to capture emerging scenarios, desire to document even if we will not make recommendations.
    - Expect some recent e-commerce, hospital, events/mobile, and "other" scenarios not yet documented
    - Noted call to add additional examples to "Literature Review"

- Reusable Container definition - first review
    - FDA code currently highlighted, but additional content is desired to accommodate other possibilities

- Governance and planning discussion
    - Assignment of small groups raised as a potential next step
    - Full group to decide scenarios for committee focus and recommendations

ACTION ITEMS

- Subcommittee members to contribute any undocumented scenarios to matrix
- Sarah K. to schedule a small-group session to visualize the documented scenarios, overlaps and patterns

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CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date __2/22/2022_____

Recording on: Yes X__ No____

Reminder of Anti-Trust Statement: Yes X__ No ____

Roll Call: In Chat

Oren Kariri, New Seasons Market

Jeff Clark, National Restaurant

Kaycee Strewler - Ecolab

Jessica Otto - FDA

Traci Michelson, McDonald's

Ali Hurysz - Whole Foods Market

Rayna Oliker - Colorado Department of Public Health & the Environment

Debbie Crabtree - Ffx HD

Abeid Fells - Houston Health Dept.

Dagny Tucker Co-chair

Christina Springer, Oregon Department of Agriculture

Sabrina Salinas- Harris County Public Health

Kat Olson - Washoe County Health District

Stephanie Teclaw - Skogen's Festival Foods

Quorum: Yes___ No___

Vote on previous conference call's Roll Call and Summation: APPROVE ___x_ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes _X_ No__

Summation of call proceedings

Note taking asssignment-

Antitrust statement – all accepted

Roll call- attendance discussion

Approval of meeting summation 2.8.2022 - Dagny Tucker 1st Rayna Oliker second approved.

Subcommittee 1 Discussion:

- Reusable refillable chart – discussion for needing revision or update.
    - Are there are FDA edits for this in teams folders
    - There is a version 3 for this chart

- FDA good with the version 3 which is most current in teams
- Used to how to use the decisions for reusables

- Scenarios – Primary Packaging
  - Based on packaging used. Consumer own, retail own, third party owned
  - Types of food (non TCS, TCS, TCS RTE); who fills (employeee, consumer)
  - Might direct fill if consumer to avoid contamination
  - Container uses (wax paper, etc) contact free manner
  - Labeling
  - Life cycle of the container -risk map
    - Moments where there are points of CCP
    - Weights and measures – more bet practices and other one for dirty and handling the clean containers.

Is there an opportunity maybe to align the language in the provision

decision tree and this scenario map? Just so we're using the same language where possible (and it's ok if there are places where it isn't possible/is different).

USDA did not supply a consultant for this committee.

ACTION ITEMS ____no additional action items identified.

Run through the scenrios with this scenario map to match of the language and see where they fall out. Which would work and ones that don't.

Align to clean up language for this scenarios and the decision tree.

1. 4 options in the "Type of Food" line... TCS -RTE (and nonRTE) and nonTCS-RTE (and nonRTE) – Susan Shelton.
2. Definition of reusable – or other definitions that need to be added for this type of setup. Example wash areas, cleaning areas.
3. Example salad, produce about literature on resusables, for deliverables
4. Draft report for committee

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date __3/22/2022_____

Recording on: Yes __X___ No____

Reminder of Anti-Trust Statement: Yes__X__ No ____

Roll Call:

Quorum: Yes___ No___

Vote on previous conference call's Roll Call and Summation: APPROVE

____ DISAPPROVE ____ (document date and results of email vote, if

applicable) APPROVE AS AMENDED ____

Agenda review: Yes____ No____

Summation of call proceedings

- Evaluation of scenarios -do we want to continue with all current

scenarios?

- Does container orientation need to be a point of emphasis?
    - Is this concern more psychological or are issues present?
- Should the cleaning guidelines for coffee mugs be implemented for all reusable food containers?
- Should we abandon the decision tree for a checklist?
- Section 114121 of the California Health & Safety Code

ACTION ITEMS: none

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date: 4/5/2022

Recording on: Yes __X___ No____

Reminder of Anti-Trust Statement: Yes___X_ No ____

Roll Call:

Frank Curto, Dagny Tucker, Jessica Otto, Tom Arbizu, Abeid Fells, Alison

Hurysz, Carrie Pohjola, Christina Springer, Debbie Crabtree, Dilshika Wijesekera, Don Schaffner, Gregory (from Iphone), Jeffery Clark, Jordan Ingle, Kat Olson, Kaycee Strewler, Kristina Bonatakis, Oren Oh-Wren, Payna Oliker, Sabrina Salinas, Susan Shelton, Traci Michelson

Quorum: Yes_X__ No___

Vote on previous conference call's Roll Call and Summation: APPROVE __X__ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes__X__ No____

Summation of call proceedings - Reviewed some of the current state guidance docs (reusable)

docs (reusable)

Discussed Filling Reusable Containers Proposed Regulatory Requirements by scenario - Question was posed by Dagy "do we go with

what we have”?

Don recommended that a “definitions” section be added.

Dagny proposed the formation of groups to focus on specific checklists and topics requiring further defining and scoping - 1. TCS 2. Non-TCS (existing) 3. Contamination-Free Process 4. Definitions (General)

Jessica shared FDA “5 Tips to Consider When Preparing Recommendations for Changes to Retail Policy”

Reviewed Committee Charges and discussed documents that will be needed to fulfill the charges (Draft Recommended Guidance Document) - 1. Categories of scenarios 2. Procedural guidelines & Performance Standards 3. Definitions 4. Recommended Code Changes (low priority)

Conducted working session to flesh out potential definitions needed (Reusable, 3rd Party Operator/washing facility, Intermediate tools, Return Receptacles (hold for further developments/clarity), Immediate

Origin, Sanitized, Validation of Cleaning,

Sanitized, Validation of Cleaning,

Discussed TCS vs. RTE scenarios and clarifying language

Discussed the efficacy of hot water rinsing requirements in respect to beverage food service practices as well as the differences in bulk dry cleaning applications - Tom noted the importance of citing existing FDA code and guidance

ACTION ITEMS:

Sub-committees to form and meeting starting next week - TCS Checklist Development (Oren, Susan, Gregory, Rayna, Debra, Dagny)

Definitions (General) - Traci (Lead), Gregory, Abeida)

Contamination-Free Process - Susan (Lead), Frank, Rayna, Dagny, Gregory, Kristina

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CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date _____May 3, 2022_____

Recording on: Yes __X___ No____

Reminder of Anti-Trust Statement: Yes__X__ No ____

Roll Call:

Carrie Pohjola, WI DATC,

Abeid Fells - Houston Health Dept.

Debbie Crabtree - Fairfax County HD

Oren Kariri, New Seasons Market OR

Dilshika Wijesekera, Instacart

Kat Olson, Washoe County

Steph Teclaw, Skogen's Festival Foods

Ali Hurysz, Whole Foods Market

Eric Puente, Whole Foods Market

Kaycee Strewler, Ecolab

Jeffrey Clark, National Restaurant Association

Greg Lux, Retail Business Services - The Giant Company

Susan Shelton WADOH

Dagny Tucker

Bessie Politis

Rayna Oliker - Colorado department of health and the environment

Tom Arbizu HEB LP - just log in and may have to leave early due to work conflict

Frank Curto, Territory Foods

Sabrina Salinas- Harris County Public Health

Donald Schaffner

Traci Michelson

Quorum: Yes__x_ No___

Vote on previous conference call's Roll Call and Summation: APPROVE

____ DISAPPROVE ____ (document date and results of email vote, if

applicable) APPROVE AS AMENDED ____

Agenda review: Yes__X__ No____

Summation of call proceedings

Carrie will cover the Guidance Doc for Safe Use of Reusable Containers

Dagny- Would we like a precedence in the document;

- Carrie suggested adding it to the Scope or Preamble/Preface;

- Don suggests writing it and determine the layout later

Add an Appendix to the document

Volunteers for the doc creation:

I

II - Susan

III – Abeid, Susan

IV – Steph, Sabrina

V – Susan, Kat

VI - Frank

VII – Rayna, Greg, Debbie, Oren, Eric, Bessie, Ali

VIII - Dagny

Due Date – Outline by next meeting in 2 weeks

Link to Team's Channel -

https://teams.microsoft.com/_#/FileBrowserTabApp/Safe%20Use%20of%20Returnable%20Containers%20Committee?groupId=8328d510-c3d3-

472b-9162-

24d7f910ebda&threadId=19:03a1c96865c945f5bb555f18a65b9834@thread.tacv2&ctx=channel

Jeff Clark Provided - Guidance for Reusable Packaging

https://sustainablepackaging.org/wp-content/uploads/2022/04/Guidance-for-Reusable-Packaging.pdf

ACTION ITEMS

Groups should work on the section they volunteered to write for the guidance doc.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

Date _5/17/2022_____

Recording on: Yes ___X__ No____

Reminder of Anti-Trust Statement: Yes__X__ No ____

Roll Call: __Gregory Lux, Sabrina Salinas, Tom Arbizu, Jessica Otto, Frank Curto, Rayna Oliker, Kat Olson, Abeid Falls, Dagny Tucker, Carrie Pohjola,

Susan Shelton, Eric Puente, Bessie Politis, Steph Teclaw, Christina Springer, Ali Hurysz, Don Schaffner, Christina Springer, Frank Curto, Jordon Ingle, Sarah Kantrowitz, Chip Manual, Beth Glenn

Quorum: Yes_X__ No___

Vote on previous conference call's Roll Call and Summation: APPROVE __X__ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes_X___ No____

Summation of call proceedings

Dagny and Bessie introduced a new member of the committee who is Beth Glenn from Starbucks.

Review of Guidance document work was discussed:

Section III-Susan and Abeid provided work done on the Introduction section which is in the Teams folder. They are relying on further sections to update the draft intro provided.

Section IV-Steph and Sabrina worked on the Definitions section based

on what was already worked on from committee work. They also included abbreviations. Steph requested if we wanted to continue to use returnable or reusable as definitions. Jessica did state the returnable was not defined in the food code. Dagny asked if there strong feelings from the group. Don Schaffner did state that we are not using a term, we don't need to define it. Dagny suggested that we continue with the term reusable.

Section V-Susan reviewed the draft language. Dagny suggested that we include containers not washed onsite what are provided by 3rd party providers.

Section VI-Frank reviewed Container construction and validation and the flow chart was developed and 3 scenarios that could present itself and the first discussed were the counter type scenario. The construction definition was also reviewed and it included some additions of complexity of the equipment. Rayna did suggest we may re-allocate the locations of decision trees and flow charts. Rayna suggested a decision tree for each of the methods provided.

Section VII-Eric reviewed the work on methods of contamination free process and discussed multiple scenarios. They were broken out into A, B, C.

Section VIII-Dagny reviewed the third party reusable containers and a document that was already developed which provided a distribution and collection. Beth did feel that this will provide some guidance for this type of activity. Dagny did review the outline for the Third party and asked if they needed to draft definitions in this section as well. The sub-committee did not come up with who would come up with the oversight of the 3rd party providers.

ACTION ITEMS:

Review the section assignments:

Group 3 no review

Group 4 review Group 5

Group 5 review Group 4

Group 6-no review

Group 7 review by Group 6

Group 8 no review

Next conference call-May 31st will be tentatively a working meeting and we will provide breakouts for the group.

Meeting was adjourned at 3:31 pm by Dagny.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date __6/14/2022_____

Recording on: Yes _____ No_X___

Reminder of Anti-Trust Statement: Yes__X__ No ____

Roll Call:

- Tom Arbizu, H-E-B
- Jeff Clark, National Restaurant Association
- Frank Curto, Territory Foods
- Abeid Fells, Houston Health Department
- Jordan Ingle, Ecolab

- Oren Kariri, New Seasons Market
- Chip Manuel, GOJO
- Rayna Oliker, Colorado Department of Public Health and Environment
- Eric Puente, Whole Foods Market
- Sabrina Salinas, Harris County Public Health
- Susan Shelton, Washington State Department of Health
- Dagny Tucker, Vessel Wrks

Quorum: Yes_X__ No___

Vote on previous conference call's Roll Call and Summation: APPROVE

__X__

Agenda review: Yes_x___ No____

Summation of call proceedings

- Reviewed guidance document and timeline. Each subcommittee chair or vice chair on call reported on status and updates.
- *Definition subcommittee*: edits were made as outlined from last meeting. Few questions remain and will be worked on by the group before the next call. After a discussion, some definitions

were kept in the section, such as “return receptacles,” and will be visited at a later date.

- *Methods of contamination subcommittee* (chapter 7): currently reviewing comments and outlining next steps now chapter. Requesting more feedback from Group 6 and will reach out for additional comments.

- *Container construction and condition subcommittee*: leveraged a lot of the existing code language but needed additional help with additional consumer-facing materials such as bags and non-ridged containers. In addition, needed to review: 1) the back-of-house decision tree when filling containers as well as a verification review; and 2) self-service for consumer product filling. Planning to coordinate with other teams for reviewing chapter.

- *Introduction subcommittee* (Group 3): a draft of the introduction is completed and will is available for review by the other groups.

- *Scope subcommittee* (Group 5): similar to the introduction subcommittee (Group 3), the scope is outlined and is requesting

review from other individuals/groups.

- Other comments/issues? None.

ACTION ITEMS

- Individuals to review other groups' language and suggest edits/changes before the next meeting.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date ____7/26/2022_____

Recording on: Yes _____ No____

Reminder of Anti-Trust Statement: Yes__x__ No ____

Roll Call: __Oren Kariri, Sabrina Salinas, Jessica Otto, Christina Springer, Jeff Clark, Juhi Williams, Kaycee Strewler, Rayna Oliker, Susan Shelton, Traci Michelson, Dagny Tucker, Tom Arbizu, Carrie Pohjola, Beth Glynn, Abeid Falls, Kristina Bonatakis, Bessie Politis, Eric Puente

Quorum: Yes__x_ No___

Vote on previous conference call's Roll Call and Summation:

APPROVE __x__ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes____ No__x__ (agenda not provided)

Summation of proceedings:

Definitions section reviewed-Sabrina had a question regarding return receptacle definition. Dagny did state in the 3rd party section 8 that it become "collection bin" instead of "return receptacle". Sabrina also suggested "origin" be changed to "source". She requested any other suggestions regarding the definitions section.

Carrie and Dagny will put the document together into one cohesive document on August 1st, which means any additions need to happen by July 31st. Please make comments so the groups know what is being asked.

Carrie did request that any reference to W/R/S in the construction

section be removed as it will be covered in the contamination free section.

Rayna asked for a review of the contamination free section and Dagny suggested a regulator review. Susan, Carrie and Christina will take a look from the regulator point. There are some concerns and conversations regarding the consumer self-serve area (buffets,etc.). Rayna did state that they did want to include more than less to put it out there.

Dagny covered the 3rd party section and made a suggestion for a pop out box on best practices and provide something more substantial. Dagny did request that folks go through the section to read through. Traci did ask Jessica for some language/verbiage protocol on recall of the container.

Dagny did acknowledge the Intro and Scope so they can read through the entire document to update the sections.

Provide illustrations, photos, precedence, etc. in you section folder and include where you would like them in the document with brackets or

highlights by August 9th. If this is provided, there will be no meeting on the 9th. Susan did suggest Kristina B.

Jessica did state that the new food code will be complete by the end of 2022. Anything that comes out of the 2023 CFP and approved will make it into the supplement.

Carrie did ask about proposing the charge of language change and asked if it is was ok to just request to align the food code language with the guidance document.

ACTION ITEMS:

- Comments for all sections are due **JULY 31st**
- Illustrations, pictures, etc. are due by **AUGUST 9th**

Next conference call: August 9th, unless the documents are provided by the committee members.

Meeting was adjourned by Dagny at 3:19 PM CT and seconded by Beth.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION

Date ____10/04/2022_____

Recording on: Yes _X____ No____

Reminder of Anti-Trust Statement: Yes_X___ No ____

Roll Call: ___Dagny Tucker, Carrie Pohjola, Jeff Clark, Bessie Politis, Kristina Bonatakis, Tom Arbizu, Abeid Fells, Ali, Hurysz, Jessica Otto, Debbie Crabtree, Greg Lux, Sabrina Salinas, Susan Shelton, Juhi Williams, Oren Kariri, Traci Michelson

Quorum: Yes_x__ No___

Vote on previous conference call's Roll Call and Summation:

APPROVE ____ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes__x__ No____

Summation of call proceedings__

Guidance document was reviewed and provided in the Teams folder. It was suggested to include the scenario matrix spreadsheet as an

appendix. Susan provided some background on the introduction changes for the group. Jessica suggested to circle back around to the charges in the introduction. The group thought it best to reference Figure 1.

Jessica did state some concerns with the number of uses or reclamation rate. But jurisdictions could include number of uses if they see fit. Origin was discussed and it was decided to swap supplier with source___

The FAQs were discussed in the container construction section VI. Jessica also suggested to not reference the food code language but perhaps cross reference to the appendix. There was some discussion on the yogurt reuse FAQ and Jessica will give it some thought. The committee left off at methods of filling.

ACTION ITEMS: Review guidance document for discussion at the next meeting.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM TEMPLATE

Date 10/18/22

Recording on: Yes _X_ No_

Reminder of Anti-Trust Statement: Yes: X No

Roll Call: In Chat

Carrie Pohjola- DATCP

Dagny Tucker-

Debbie Crabtree- Fairfax County Health

Oren Kariri- New Seasons Market

Ali Hurysz- Whole Foods

Frank Curto Alphia

Rayna Oliker- CDPHE

Kaycee Strewler- Ecolab

Traci Michelson (call in)

Susan Shelton- WADOH

Stephanie Teclaw- Festival Foods

Jeff Clark- National Restaurant Association

Greg Lux- RBS

Quorum: Yes_X__ No___

Vote on previous conference call's Roll Call and Summation: APPROVE

____ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes__X__ No____

SUMMATION OF CALL:

Review of FDA Comments:

Science Based Documentation

- Any places where we can make linkages to food safety will assist in strengthening the document
- Washington State may be the best resource for documentation
- Susan S. can provide code references to jurisdictions that allow these practices

3rd Party Delivered & Retail

- 3rd party delivered services are detailed, may need to include more on the retail side and how they handle containers/utensils, specific to collection of containers

- General consensus is that this is a routine concept for most retailers but there should be clarification on this in the document

Food Code Language Cited

- Reference of the language in the document is helpful, but not verbatim- vote determined to use references

Method 2

- Need to add control method. Greg will be adding language to account for the method to address this

FAQ's

- Lacks the safety literature back up, need full analysis for strong source citations, science behind why the recommendations we're making

- Move the FAQ's into the guidance

ACTION ITEMS:

- Put together a paragraph for retailers' collection and sanitation

document – Susan S will reach out to Starbucks Team for any pre established text they have on this

- Literature review from WA that can be placed in the document from Susan

NEXT CALL:

- Interim meeting may occur, Dagny & Carrie will meet prior and send out a note

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CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

Date __11/1/2022_____

Recording on: Yes __X___ No____

Reminder of Anti-Trust Statement: Yes__X__ No ____

Roll Call: Carrie Pohjola, Rayna Oliker, Stephanie Teclaw, Jessica Otto, Tom Arbizu, Kaycee Strewler, Gregory Lux, Jordan Ingle, Dan Redditt, Don Schaeffner, Beth Glynn, Kristina Bonatakis, Christina Springer,

Bessie Politis, Juhi, Williams, Traci Michelson, Susan Sheldon

Quorum: Yes_X__ No___

Vote on previous conference call's Roll Call and Summation:

APPROVE __X__ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes__X__ No____

Summation of call proceedings:

The committee discussed continuing and trying to complete the document for submission, overwhelming consensus was to move forward and provide the finished document to the conference. Meetings will be scheduled every Tuesday in November to complete the guidance document.

ACTION ITEMS:

Carrie will send out meeting invites to the committee for November 8th and the 22nd. In the interim, Carrie and Susan will work on including comments and edits made on the guidance document for the

committee review.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date __11/15/2022_____

Recording on: Yes _____ No____

Reminder of Anti-Trust Statement: Yes__x__ No ____

Roll Call:

Quorum: Yes___ No___

Vote on previous conference call's Roll Call and Summation:

APPROVE __X__ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes_x___ No____

Summation of call proceedings: Susan's changes to the document were reviewed and it was suggested that we also include language for the

scenarios into the introduction. The scenario matrix will be provided as an Issue to CFP. Dagny has a reference for container construction. Greg will work on Controls needed for Methods 3, 4 and 5. Photos provided from Orin will be included in the guidance by the individual formatting the guidance document. The committee will review other jurisdiction code language to provide as part of the charges.

ACTION ITEMS:

-Carrie will provide the current guidance document to Greg for review.

-Carrie will begin developing code language changes

-Greg will draft language for Methods 3.4 and 5.

-We will continue to hold weekly meetings.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

TEMPLATE

Date __11/22/2022_____

Recording on: Yes __X___ No____

Reminder of Anti-Trust Statement: Yes__X__ No ____

Roll Call: _Carrie Pohjola, Dagny Tucker, Jeff, Clark, Susan Shelton, Abeid Tucker, Christina Springer, Juhi Williams

Quorum: Yes___ No_X__

Vote on previous conference call's Roll Call and Summation: APPROVE ____ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes__X__ No____

Summation of call proceedings:

Dagny requested that folks who aware of code language for jurisdictions that currently allow for the reuse provide that reference within the document. CA does have language and other municipalities that have added it. It does not need to be at state level. Susan and Christina will provide an opening comment in the Contamination Free Filling Methods.

Jeff will review the guidance document and clean it up (removing comments, track changes, grammar, etc.)

The definition for reusable container definition was discussed and reviewed to replace refillable. Carrie will send out an email for comments for final vote on November 29th.

Code language was reviewed and an email will be sent out for comment for final vote on November 29th.

Actions Items:

-Carrie will send out an email for comments before final vote on the definition and proposed code language.

-Dagny will work with a designer on formatting final guidance document.

-Jeff will review the guidance document and make any needed edits.

CFP COMMITTEE CONFERENCE CALL DOCUMENTATION FORM

Date _11/29/2022_____

Recording on: Yes __X___ No____

Reminder of Anti-Trust Statement: Yes__X__ No ____

Roll Call: Carrie Pohjola, Dagny Tucker, Traci Michelson, Abeid Fells, Rayna Oliker, Debbie Crabtree, Jeff Clark, Jessica Otto, Oren Kariri, Don Schaffner, Sabrina Salinas, Steph Teclaw, Ali Hurtysz, Susan Shelton, Juhi Williams, Kristina Bonatakis, Beth Glynn

Quorum: Yes_X__ No___

Vote on previous conference call's Roll Call and Summation, November 22nd, 2022:

APPROVE __x__ DISAPPROVE ____ (document date and results of email vote, if applicable) APPROVE AS AMENDED ____

Agenda review: Yes_X__ No____

Summation of call proceedings:

-Guidance document reviewed with Jeff's editing. All edits were

reviewed and accepted.

-discussion regarding refillable v. reusable.

-Susan reviewed her language change regarding the jurisdictions that are currently or in the process of including language to allow for reusable containers. This was included in the introduction of the guidance document. Juhi suggested a table that listed each Method and what jurisdiction allows.

-Susan will work on a chart/table showing what jurisdictions allow reusables to support the food code language changes and Beth will provide background in the guidance document as well. Carrie and Dagny will include all changes in the final document.

-Rayna suggested a vote on the language and definition.

-Food code language was reviewed and approved by the committee.

ACTION ITEMS:

-Final Guidance document completion

-Beth-(1) Condense the language in the guidance document.

-Susan-(2) Add a table as an attachment to the issue OR add the table into the Public Health significance of the issue paper.

Next conference call: None, Committee has come to an end

COUNCIL III SAFE USE OF REUSEABLES COMMITTEE - REUSE SCENARIO MATRIX SAMPLE

The Council III "Safe Use of Reusables Committee" compiled an extensive matrix of scenarios in which reuseable conatiners are currently being utilized.
The following is intended as a representative sample and not an exhaustive list of all reusable container scenarios currently in practice.

GROCERY

Sector	Dept/Area	PKG Origin	PKG Collection	Cleaning Process	Filler	TCS/non-TCS	RTE/non-RTE	PRIMARY FOOD CONTACT PKG Form/Material(s)
Grocery/Delivery	Bulk Dry	Business	Return to Business	W,R,S (business)	Picker	Non-TCS	Both	Bag, box, plastic, glass
Grocery/Delivery	Produce	Business	Return to Business	W,R,S (business)	Picker	Both	Both	bag, box
Grocery/Delivery	Deli	Business	Return to Business	W,R,S (business)	Employee	TCS	RTE	plastic, glass
Grocery/Delivery	Bakery	Business	Return to Business	W,R,S (business)	Picker or Employee	Both	RTE	Bag, box, plastic, glass
Grocery/Delivery	Meat/Seafood Counter	Business	Return to Business	W,R,S (business)	Employee	TCS	Both	plastic, glass
Grocery/Delivery	Beverage/Coffe e Bar	Business	Return to Business	W,R,S (business)	Picker or Employee	TCS	RTE	plastic, glass
Grocery/Delivery	Salad/Food Bar	Business	Return to Business	W,R,S (business)	Picker or Employee	Both	RTE	plastic, glass
Grocery/Consumer	Bulk Dry - Scoop/	Consumer	Consumer	Off site (consumer)	Consumer	Non-TCS	Both	Bag, box, plastic, glass
Grocery/Consumer	Bulk Dry - Gravity	Consumer	Consumer	Off site (consumer)	Consumer	Non-TCS	Both	Bag, box, plastic, glass
Grocery/Consumer	Produce	Consumer	Consumer	Off site (consumer)	Consumer	Both	nonRTE	bag, box
Grocery/Consumer	Deli	Consumer	Consumer	Off site (consumer)	Employee	TCS	RTE	plastic, glass
Grocery/Consumer	Bakery	Consumer	Consumer	Off site (consumer)	Consumer or Employe	Both	RTE	Bag, box, plastic, glass
Grocery/Consumer	Meat/Seafood Counter	Consumer	Consumer	Off site (consumer)	Employee	TCS	Both	plastic, glass
Grocery/Consumer	Beverage/Coffe e Bar	Consumer	Consumer	Off site (consumer)	Consumer or Employe	TCS	RTE	plastic, glass
Grocery/Consumer	Salad/Food Bar	Consumer	Consumer	Off site (consumer)	Consumer or Employe	Both	RTE	plastic, glass
Grocery/Consumer	Honey/Oil/Visc ous Products	Consumer	Consumer	Off site (consumer)	Picker or Consumer	Non-TCS	Both	plastic, glass
Grocery/Manufacturer	Shelf stable retai	Manufacturer	Return to Business/Return Station	W,R,S (third party)	Manufacturer	Both	Both	Glass, aluminum, steel or plastic jars/bottles
Secondary Packaging	All areas	Consumer	Consumer	None	Consumer or Employe	Non-TCS	nonRTE	Canvas bags, single-use plastic bags, linen
Secondary Packaging	All areas	Manu/Distrib	Business/Distributor	None	Manu/Distrib	Both	Both (pack'd and unpackaged)	Generally nonFCS only - Wood, cardboard, metal

Grocery/Delivery - 3rd party would be picking the order for delivery to the consumer **Grocery/Consumer** - consumer would be at the store picking their own order and taking it home

Grocery/Manufacturer- manufacturer packages in reusable container, stocked in store per normal, consumer returns to store, manufacturer or 3rd party washes

RESTAURANT								
Sector	**Dept/Area**	**PKG Origin**	**PKG Collection**	**Cleaning Process**	**Filler**	**TCS/non-TCS**	**RTE/non-RTE**	**PKG Form/Material(s)**
Dine In/Leftovers	N/A	Consumer	Consumer	Cleaned off-site (consun	Consumer	Both	RTE	Plastic/Steel/Aluminum
Dine In/Leftovers	N/A	Business	Business	Cleaned on-site	Consumer or Business	Both	RTE	Plastic/Steel/Aluminum
Dine In/Leftovers	N/A	3rd Party	Business or 3rd Party	Cleaned off-Site (facility)	Consumer or Business	Both	RTE	Plastic/Steel/Aluminum
Consumer Take Out	N/A	Consumer	Consumer	Cleaned off-Site (consun	Consumer	Both	RTE	Plastic/Steel/Aluminum
Consumer Take Out	N/A	Business	Business	Cleaned on-site	Business	Both	RTE	Plastic/Steel/Aluminum
Consumer Take Out	N/A	3rd Party	3rd Party	Cleaned off-Site (facility)	Business	Both	RTE	Plastic/Steel/Aluminum
Delivery Take Out	N/A	Business	Business	Cleaned on-site	Business	Both	RTE	Plastic/Steel/Aluminum
Delivery Take Out	N/A	3rd Party	3rd Party	Cleaned off-Site (facility)	Business	Both	RTE	Plastic/Steel/Aluminum
Institutional: Campuses, Schools, Hospitals, other Large Dining Service Provider Institutions								
Sector	**Dept/Area**	**PKG Origin**	**PKG Collection**	**Cleaning Process**	**Filler**	**TCS/non-TCS**	**RTE/non-RTE**	**PKG Form/Material(s)**
Dine In/Leftovers	Dining Services	Consumer	Not Collected	Cleaned off-Site (consumer)	Consumer	Both	RTE	Plastic/Steel/Aluminum/Glass
Dine In/Leftovers	Dining Services	Business	Business	Cleaned on-site	Consumer or Business	Both	RTE	Plastic/Steel/Aluminum
Dine In/Leftovers	Dining Services	3rd Party	Business	Cleaned off-Site (facility)	Consumer or Business	Both	RTE	Plastic/Steel/Aluminum
Consumer Take Out	Dining Services	Consumer	Not Collected	Cleaned off-Site (consumer)	Consumer	Both	RTE	Plastic/Steel/Aluminum
Consumer Take Out	Dining Services	Business	Business	Cleaned on-site	Business	Both	RTE	Plastic/Steel/Aluminum
Consumer Take Out	Dining Services	3rd Party	Business	Cleaned off-Site (facility)	Business	Both	RTE	Plastic/Steel/Aluminum
Vending Distribution	Dining Services	3rd Party	Business	Cleaned off-Site (facility)	3rd Party	Both	Both	Plastic/Steel/Aluminum
Convenience Store Distribut	Dining Services	Business	Business	Cleaned on-site	Business	Both	Both	Plastic/Steel/Aluminum
Convenience Store Distribut	Dining Services	3rd Party	Business	Cleaned off-Site (facility)	3rd Party	Both	Both	Plastic/Steel/Aluminum
Micro-kitchen	Dining Services	Business	Business	Cleaned on-site	Consumer	Both	Both	Plastic/Steel/Aluminum
Micro-kitchen	Dining Services	3rd Party	3rd Party	Cleaned off-Site (3rd Party facility)	Consumer	Both	Both	Plastic/Steel/Aluminum
K-12 Schools	School nutrition staff	School kitchen staff	Business	stays on site or goes to centralized washing facility	school staff or outside vendor	Both	Both	Plastic/Steel/Aluminum
K-12 Schools	Outside vendor	School kitchen staff or outside vendor	3rd Party Onsite	3rd Party	Reuse service provider	Both	Both	Plastic/Steel/Aluminum
College/ University	School nutrition	School kitchen staff or outside vendor	Business	stays on site or goes to centralized washing facility	school staff or outside vendor	Both	Both	Plastic

EVENTS & MOBILE								
Sector	**Dept/Area**	**PKG Origin**	**PKG Collection**	**Cleaning Process**	**Filler**	**TCS/non-TCS**	**RTE/non-RTE**	**PKG Form/Material(s)**
Food Trucks	N/A	3rd Party	Truck/3rd Party	Cleaned off-Site (facility)	Employee	Both	RTE	
Farmers Markets	N/A	Consumer	N/A	Cleaned off-Site (consumer)	Consumer /Employee	Both	Both	Glass, aluminum, steel or plastic jars/bottles
Farmers Markets	N/A	3rd Party	3rd Party	Cleaned off-Site (facility)	Consumer /Employee	Both	Both	Glass, aluminum, steel or plastic jars/bottles
Farmers Markets	N/A	Vendor/ Farmers	Vendor/ Farmers Mark	Cleaned off-Site (facility)	Consumer /Employee	Both	Both	Glass, aluminum, steel or plastic jars/bottles
Festivals Live Events	N/A	Event Producer/\	Event Producer/Venue	On-site	Employee	Both	RTE	Plastic/Steel/Aluminum
Festivals Live Events	N/A	3rd Party	3rd Party	Cleaned On or off-Site (facility)	Employee	Both	RTE	Plastic/Steel/Aluminum
Festivals Live Events	N/A	Event Producer/\	Event Producer/Venue	On-site	Employee	Both	RTE	Plastic/Steel/Aluminum
Festivals Live Events	N/A	3rd Party	3rd Party	Cleaned On or off-Site (facility)	Employee	Both	RTE	Plastic/Steel/Aluminum
Stadiums	N/A	Venue	Venue	Cleaned off-Site (facility)	Employee	Both	RTE	Plastic/Steel/Aluminum
Stadiums		3rd Party	Venue	Cleaned On or off-Site (facility)	Employee	Both	RTE	Plastic/Steel/Aluminum
E-COMMERCE								
Sector	**Dept/Area**	**PKG Origin**	**PKG Collection**	**Cleaning Process**	**Filler**	**TCS/non-TCS**	**RTE/non-RTE**	**Primary Food Contact Materials/Secondary Packaging**
Home Delivery - Meal Prep	N/A	Producer - Online Sales	3PL Delivery person	3rd party	Producer	TCS	RTE	Bags, Boxes, Jars / Dunnage, Insulated Bags, Ice Packs, Active Refrigeration
Delivery - Corp/Home	N/A	Producer - Online Sales	Producer	3rd Party	Producer	TCS	RTE	Pans/Dunnage, Insulated Bags, Ice Packs, Active Refrigeration
Meal Prep - Storefront/HD	N/A	Producer - Commissary	Driver/Consumer	Internal	Producer	TCS	RTE	Bags, Boxes, Jars/Dunnage, Insulated Bags, Ice Packs, Active Refrigeration
Manufacturer CPGs	N/A	Manufacturer	Driver/Consumer	3rd party	Manufacturer/Producer	Both	Both	Glass, aluminum, steel or plastic jars, bottles/Dunnage, Insulated Bags, Ice Packs, Active Refrigeration
Home Delivery - Meal Prep	N/A	Producer	Driver	Internal	Procucer	Both	Both	Glass, aluminum, steel or plastic jars, bottles/Dunnage, Insulated Bags, Ice Packs, Active Refrigeration
Grocery Home Deliver	N/A	Business	Driver/In-store	Internal/3rd Party	Business	Both	Both	Glass, aluminum, steel or plastic jars, bottles/Dunnage, Insulated Bags, Ice Packs, Active Refrigeration

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
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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]

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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	• Broad spectrum of activity • Good hard water tolerance	• 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	• Broad spectrum of activity • Compatible with most surfaces • Very stable with	• 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 • Less reactive with soil	reducing active levels in a solution • Food Code requires use above 24°C (75°F)
Peroxides	Vegetative bacteria and enveloped and nonenveloped viruses	• Minimal residue • Formulated for hard water tolerance	• 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	• Broad spectrum of activity (note that antifungal activity may require a mixture of peracid) • Compatible with most surfaces • Minimal residue	• 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	• Compatible with residual cleaners if rinsing is incomplete • Good cleaning performance • Good material compatibility • Good hard water tolerance	• May be incompatible with some soft metals and some plastic surfaces • Can generate chlorine gas if mixed with chlorine products
Alcohol	Vegetative	• Can be used in	• High flammability

ACTIVE INGREDIENT	SPECTRUM OF ACTIVITY[A]	ADVANTAGES	DISADVANTAGES
	bacteria and enveloped viruses	environments where aqueous SANITIZERS or DISINFECTANTS are undesirable • No residue • Limited impact on organic matter	• 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.

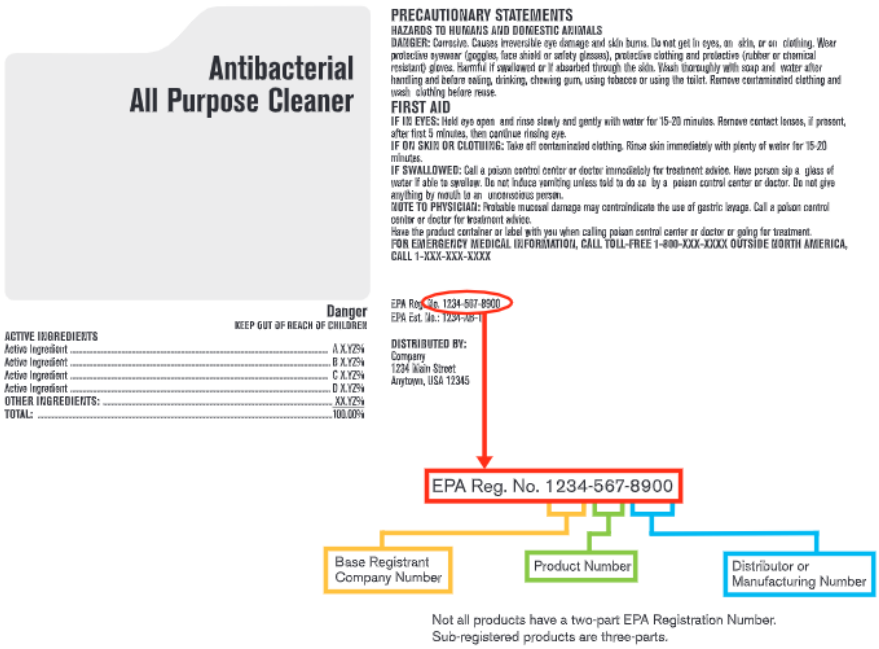
Phone number

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]



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 µm. 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.

- <u>Disposable DISINFECTANT wipes.</u>
  - 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 trips 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.

<u>At a minimum</u> 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/scraper
    - 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 ft^2 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.

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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

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Daily Breeze Article

SpaceX’s Inspiration4 update: Cold pizza, zero-gravity flips and a ukulele solo

Hawthorne-based SpaceX's crew of amateur astronauts will return to Earth on Saturday evening

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This photo provided by SpaceX shows the passengers of Inspiration4 in the Dragon capsule on Friday, Sept. 17. They are, from left, Chris Sembroski, Jared Isaacman, Sian Proctor and Hayley Arceneaux. SpaceX got them into a 363-mile (585-kilometer) orbit following Wednesday night’s launch from NASA’s Kennedy Space Center. That’s 100 miles (160 kilometers) higher than the International Space Station. (SpaceX)

By **TYLER SHAUN EVAINS** | tevains@scng.com |

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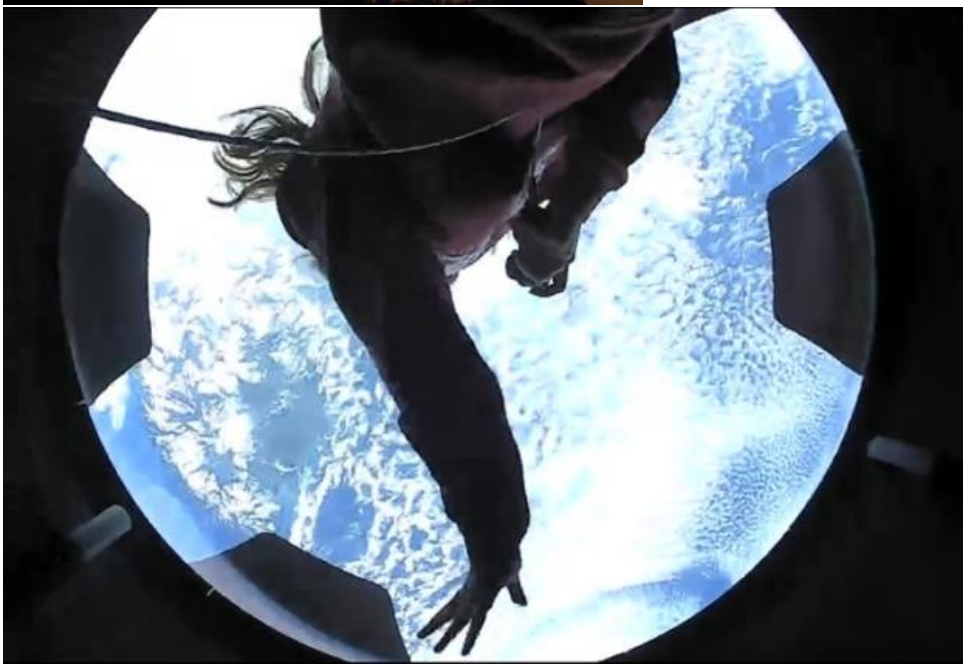
- 

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1 of 4

This photo provided by SpaceX shows Hayley Arceneaux, one of the passengers of Inspiration4 in the Dragon capsuleon Friday, Sept. 17. (SpaceX)

Two days into Hawthorne-based SpaceX’s Inspiration4 mission, the Earth-orbiting crew of amateur astronauts provided a lively livecast update on its journey on Friday, Sept. 17, 24 hours before they’re due to splash down off the Florida coast.

The event included zero-gravity tumbles, lots of high spirits, displays of artwork created in space and an interstellar ukulele solo.

During the livestream, the crew announced that the quartet was scheduled to return to Earth at 4:06 p.m. PDT Saturday, splashing down into the Atlantic Ocean off the coast of Florida.

SpaceX's Dragon capsule was scheduled to perform two burns Friday night to reduce the spacecraft's altitude to 365 kilometers, SpaceX tweeted Friday, to align the craft with its landing site.

Dragon reached as high as 590 kilometers, or 367 miles, above earth's surface before the astronauts took off their space suits, said Andy Tran, quality engineer at SpaceX, during the update.

Dragon lifted off Wednesday at NASA's Kennedy Space Center in Florida.

Aboard the history-making, fund-raising flight are the four amateur astronauts: mission commander Jared Isaacman, billionaire CEO of payment processing company Shift4 Payments, who funded the trip; mission pilot Sian Proctor, a geoscientist and community college professor in Arizona; mission medical officer Hayley Arceneaux, a physician's assistant at St. Jude Children's Research Center in Memphis, TN; and mission specialist Chris Sembroski, an aerospace data engineer.

Their first meal in space was cold pizza, which the crew said, Tran relayed. And it was extraordinary, he added.

On Friday, Proctor turned the camera to the Dragon's cupola window, trying to share a view the stars and an aurora around Earth amid the dark atmosphere.

"We've been spending so much time in this cupola, the largest window flown into space," Arceneaux said. "We could see the entire perimeter of the Earth, which gives such incredible perspective; the views, I have to say, are out of this world."

Well, they literally are just that.

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The crew floated above Europe during the update, Proctor said, as Proctor showed her marker illustration of the Dragon being carried by an actual dragon off of Earth, Sembroski played his ukulele and Arceneaux turned flips in the zero-gravity environment.

The crew only had 10 minutes of connectivity to Earth on Friday, Tran said, as SpaceX can only communicate with a spacecraft travelling 17,500 mph when it is flying over a designated ground station.

They've been taking swabs of different body parts to evaluate the microbiome and how that changes in those three days in space, Arceneaux said. The crew has also been taking blood samples for research teams back on Earth to study, as well as cognitive tests.

Aside from scientific research, the mission's biggest goal is to raise $200 million for St. Jude Children's Research Hospital. Isaacman looks to the greater community to match the $100 million he's pledging to the hospital.

Axiom Article

4 days in, Axiom Space's crew makes history for private space flight at ISS
Axiom-1 is the first all-private mission to the International Space Station.

*BY***DORIS ELÍN URRUTIA**

APRIL 12, 2022

SpaceX/Axiom

Over the weekend, the Axiom-1 mission carried four rich guys and philanthropists, a celebrity-chef menu, and biomedical experiments to the International Space Station (ISS).

On Friday (April 8) at 11:17 a.m. Eastern, Axiom-1 launched atop a reused SpaceX Falcon 9 rocket from NASA's Kennedy Space Center in Cape Canaveral, Florida. This flight began the 10-day mission for the first all-private mission for Axiom Space, a company based in Houston near NASA's Johnson Space Center that seeks to place the first commercial space station into low-Earth orbit sometime this decade.

Everything leading up to the flight went smoothly for the most part. Personnel noticed a slight loss of pressure after the hatch was first sealed, so a ground crew reopened and resealed it about two hours prior to takeoff.

Two minutes and 45 seconds after launch, the pre-flown first stage — the bottom two-thirds of the rocket — separated from the upper stage and successfully navigated back to Earth's surface, landing on a SpaceX drone ship floating in the Atlantic Ocean.

A SpaceX Falcon 9 rocket launched on Friday (April 8) shortly before noon local time with the four crewmembers of the Axiom-1 mission.

ANADOLU AGENCY/ANADOLU AGENCY/GETTY IMAGES

Axiom-1's crew were meanwhile "hooting and hollering" during the ride, Axiom-1 pilot and American real-estate investor Larry Connor said during a video message to SpaceX headquarters the following day. Commander and former NASA Space Shuttle astronaut Michael López-Alegría remained "diplomatic" during the cheers, Connor added.

They rode within a SpaceX Dragon Endeavour crew capsule, which is now on its third mission to the ISS. Once this robotic cocoon reached its targeted orbit about 12 minutes after launch, the crew got comfortable and had their first meals for the mission. The Axiom-1 mission menu includes Iberian ham and chicken paella, according to a video segment that SpaceX aired during its pre-launch broadcast. The food was prepared by the non-profit organization World Central Kitchen, helmed by celebrity chef José Andrés.

A "Caramel the Dog" stuffed animal traveled to space with Axiom-1. This is the mascot for the Montreal Children's Hospital in Canada.

AXIOM SPACE

Caramel the Dog, the mascot for the Montreal Children's Hospital Foundation, made an appearance after launch. Astronauts typically use stuffed animals as zero-G indicators, which lets them see whether or not weightlessness has kicked in while remaining safely strapped into their seats. A camera inside Endeavour aired the first microgravity flight of Axiom-1's zero-G indicator. The toy was selected because Mission Specialist and Canadian entrepreneur Mark Pathy collaborates with Canadian health centers as part of his philanthropic work.

The 21-hour trip to the space station suffered a snag at the end. When Endeavor reached the ISS and attempted to dock, the astronauts on the space station couldn't see the feed from an Endeavour camera that was necessary for the docking procedure. Docking was delayed about 45 minutes as teams figured out a solution, which was eventually reached through support from SpaceX Headquarters and NASA.

The SpaceX Dragon Endeavour carrying the Axiom-1 astronauts approaches the International Space Station on April 9, 2022.

NASA/FLICKR

At 10:13 a.m. on Saturday (April 9), the Axiom-1 crew successfully docked to the ISS, bringing the orbiting laboratory's population up to 11. The space station was already housing Expedition 67, a mission made up of three NASA astronauts, one European astronaut, and three Roscosmos cosmonauts.

A NASA blog post published on Monday (April 11) details the science work they will be assisting during their eight days on the space station. The experiments will tackle questions about genetic markers in cellular aging, changes to brain activity in microgravity, and a DNA editing system.

Monday marked Flight Day 4 of Axiom-1.

2-million-dollar bacon sando Article

Heston Blumenthal's Canned Bacon Sandwich Cost $2.8 Million

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Is it the priciest sandwich in the galaxy?

by Dana Hatic@DanaHatic Mar 15, 2016, 4:30pm EDT

Via TV chef Heston Blumenthal creates bacon sandwich costing 'a couple of million pounds' [The Mirror], Heston, we have a problem... the top chef cooks for Tim Peake [The Guardian], and All Heston Blumenthal Coverage [E]

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Stuart C. Wilson/Getty Images

British chef, TV personality, and proprietor of the many-starred Fat Duck in Bray, England, Heston Blumenthal is known for innovative and elaborate cooking styles, but his latest production takes the cake. Blumenthal designed a canned bacon

sandwich for Major Tim Peake, a British astronaut stationed at the International Space Station, and transport of the expensive sandwich cost "a couple million pounds," according to *The Mirror*. That's over $2.8 million.

The chef, who often makes use of molecular gastronomy techniques in his kitchens, curated a handful of meals for Peake, all of which were was designed to hold up under zero-gravity situations. The meal also had to abide by the strict regulations of the world's space agencies which had to approve the meal. Heston spent two years working on the sandwich, eventually landing on canning as the best method of preservation. Though canning cut the risks, it still left Blumenthal in of fear of giving Peake food poisoning, *The Guardian* reported.

In addition to the bacon sandwich, Blumenthal created a red Thai curry, beef stew with truffles, Alaskan salmon, and apple crumble, among other items. These dishes were sent to the International Space Station on a rocket from Cape Canaveral and were waiting for Peake when he arrived in December. Back then we didn't know Blumenthal was the chef, though we did know Peake was excited about having a bacon sandwich in space.

Most expensive bacon sandwich ever? Probably. Worth it? Peake will be the judge, and the world will find out in a TV special called, "Dinner in Space," featuring a video-chat dinner with Peake and Blumenthal, which airs on March 20.

Kimchi Article New York Times

Kimchi goes to space, along with first Korean astronaut

- Give this article

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By [Choe Sang-Hun]

- Feb. 22, 2008

SEOUL — Koreans say they must eat kimchi wherever they are. When South Korea dispatched troops to the Vietnam War in the 1960s, tearful mothers sent off their sons with clay pots containing homemade kimchi. Soon troopships were filled with the pungent smell of the fermenting cabbage slathered with pepper and garlic.

So it was only natural for Koreans to think that their first astronaut must have the beloved national dish when he goes on his historic space mission in April. Three top government research institutes went to work. Their mission: to create "space kimchi."

"If a Korean goes to space, kimchi must go there, too," said Kim Sung Soo, a Korea Food Research Institute scientist. "Without kimchi, Koreans feel flabby. Kimchi first came to our mind when we began discussing what Korean food should go into space."

Ko San, a 30-year-old computer science engineer who beat 36,000 contestants to become the first South Korean space traveler, will blast off April 8 on board a Russian-made Soyuz rocket, together with two Russian cosmonauts. He will stay in the International Space Station for 10 days conducting scientific experiments.

Ko's trip will be an occasion for national celebration. Since 1961, 34 countries, including Vietnam, Mongolia and Afghanistan, have sent more than 470 astronauts into space, but none of them was Korean - something South Koreans have found humiliating, given their country's economic stature. So when their government finally decided to finance Ko's trip, they wanted him well prepared for his momentous journey. Which means he must take kimchi with him.

After millions of dollars and years of research, South Korean scientists successfully engineered kimchi and nine other Korean recipes fit for space travel. When the Russian space authorities this month approved them for Ko's trip, the South Korean food companies that participated in the research took out full-page newspaper ads.

The other space food Koreans created include the national instant noodle called ramyeon, hot pepper paste, fermented soybean soup and sticky rice.

But kimchi - a must-have side dish at every Korean meal - was the toughest to turn into space food.

"The key was how to make a bacteria-free kimchi while retaining its unique taste, color and texture," said Lee Ju Woon at the Korean Atomic Energy Research Institute, who began working on the newfangled kimchi in 2003 with samples provided by his mother.

Ordinary kimchi is teeming with microbes, like lactic acid bacteria, which help fermentation. On Earth they are harmless, but scientists fear they could turn dangerous in space if cosmic rays cause them to mutate. Another problem is that kimchi has a short shelf life, especially when temperatures fluctuate rapidly, as they do in space.

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"Imagine if a bag of kimchi starts fermenting and bubbling out of control and bursts all over the sensitive equipment of the spaceship," Lee said.

Lee's team found a way to kill the bacteria with radiation while retaining 90 percent of the original taste. Lee's space kimchi comes in cans, whereas the Korea Food Research Institute's version, developed by Kim's team using a different technology to control the fermentation process, comes in a plastic package.

"This will greatly help my mission. When you're working in space-like conditions and aren't feeling too well, you miss Korean food," Ko, who is training in Russia, said in a statement transmitted through the Korea Aerospace Research Institute, which is overseeing his mission. "Since I am taking kimchi with me, this will help cultural exchanges in space."

Ko plans to be host of a Korean dinner in the space station on April 12 to celebrate the 47th anniversary of the day the Soviet cosmonaut Yuri Gagarin became the first human in space. The dinner will conclude with Korean ginseng and green tea.

What about kimchi's strong aroma, which often keeps non-Koreans from trying it?

"We managed to reduce the smell by one-third or by half," Kim said. "So the other astronauts will feel comfortable trying our space kimchi."

Sea moss has recently seen increasing popularity for use in “healthy” smoothie beverages, with some products formulated with sea moss appearing to be a major ingredient. Despite the unpermitted vendors selling in various local venues, there are several safety concerns associated with sea moss (*Chondrus crispus*) that require specific controls to ensure the safety of consumers. The production process requires regulatory approval, and the producer must operate from a commercial kitchen under a Retail Food Establishment permit.

Here are the safety concerns:

1. The spores of *Clostridium botulinum* are present in the marine environment and may be present on the product. These bacteria, often referred to as “**C. bot**.”, produce the toxin that causes botulism poisoning. In producing the sea moss gel, growth and toxin formation by C. bot. must be controlled by one of two methods:
    a. Use of a scientifically backed cooking process to destroy the spores and bacteria, or
    b. Acidification of the product to a pH of 4.6 or lower to prevent growth and toxin formation by any C. bot that may be present.

    A written procedure must be submitted to the regulatory authority for approval of the production process using one of the two options above as the safety control. The “Fish and Fishery Products Hazards and Controls Guidance,” March 2020 includes validated guidance on cooking processes for destruction of the spores of C. bot. If the product will be acidified, an initial product assessment for pH must be obtained from a recognized Process Authority. That report must be provided to the regulatory authority as one requirement for approval of the production process. The retail producer will be required to do their own pH testing of each process batch, and must maintain batch production records that include the pH test results for each batch.
2. The supplier of raw sea moss must harvest from an area free from contaminants such as heavy metals, agricultural or industrial chemicals and microorganisms associated with septic waste, which are commonly associated with runoff water from populated and industrial areas. An approved harvester/producer of the sea moss must be able to provide a letter to the retail establishment attesting that their harvesting practices meet this requirement. This letter must be made available to retail food inspectors, and a copy of the letter must be supplied to the regulatory authority as another requirement for approval of the production process.
3. Sea moss and seaweed are natural sources of iodine. Maximum serving sizes must consider the maximum daily allowance of dietary iodine. The concentration of iodine in the sea moss gel will depend on factors such as the local source of the raw material as well as the processing of the gel. The National Institutes of Health (NIH) have published a study of various seaweed products showing, anecdotally, that sea moss had the lowest concentration of iodine of all types of seaweed in the study (see Table 4 of the study). For the sample tested, an 8 gram serving of sea moss would provide 85% of the NIH recommended 150 micrograms daily intake of iodine. NIH recommended a tolerable upper limit of 650 micrograms of daily iodine intake, corresponding to approximately 40 grams of sea moss. NIH further reports that iodine toxicity can occur with more than 1100 micrograms iodine intake per day, resulting in a variety of thyroid health problems. The best guidance is to maintain a balanced diet and moderate consumption of sea moss products.

4. Sea moss is the natural source from which the thickener/emulsifier carrageenan is refined. Use of carrageenan is regulated as a food additive under 21 CFR 172.620. Additional information on allowed use is found at 21 CFR 172.623. The FDA Food Additive Status List provides maximum allowed concentrations of food additives in food.

The above requested documentation should be submitted to foodvariances@dhec.sc.gov for review and approval.

Be aware that if the sea moss gel will be processed using the acidification option, you will need a pH meter with which to test each production batch to be sure the critical pH value is met.

The topic of health claims is one that requires specific FDA guidance to navigate the fine details of what is allowed or not allowed. No health claims can be approved by local agencies such as SC DHEC, and the use of health claims renders the associated product as a dietary supplement, and not a food. As such, the product would be regulated by FDA, not by any local regulatory agency. Here are resources to assist you:
FDA Customer Service Hotline: 1-888-463-6332
FDA Office of Nutritional Products, Labeling and Dietary Supplements 240-402-2375
CFSAN Industry Assistance Information

Additional Resources:
FDA Warning Letter – Everything Health LLC 05-24-2021
FDA Warning Letter – Red's Kitchen Sink 03-02-2021
Consumer Advisory – Michigan Dept. of Agriculture and Rural Development
Sea Moss Fact Sheet – Ohio Department of Agriculture
Iodine Intake from Sea Moss – National Institutes of Health

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Connect: www.scdhec.gov Facebook Twitter

Consumer Advisory: MDARD Urges Consumers to Dispose of Royalty Sea Moss Lemonade and Gel Products Because of Possible Health Risk

Michigan Dept of Agriculture & Rural Development sent this bulletin at 10/17/2022 10:30 AM EDT

For immediate release: October 17, 2022
MDARD Program Contact: Tom Tederington, 517-749-5849
MDARD Media Contact: Jennifer Holton, 517-284-5724

Consumer Advisory: MDARD Urges Consumers to Dispose of Royalty Sea Moss Lemonade and Gel Products Because of Possible Health Risk

LANSING - The Michigan Department of Agriculture and Rural Development (MDARD) is advising consumers not to eat, drink, or consume any sea moss lemonade or gel products produced by Royalty Sea Moss of Mt. Pleasant, MI.

MDARD initiated the investigation after receiving a complaint from the Maryland Department of Health, Office of Food Protection. During the investigation, MDARD identified the firm produced these products with inadequate processing controls required to stop the growth of deadly foodborne pathogens including botulism. In addition to inadequate process controls the firm does not hold a license to manufacture, hold, or sell food products, which is a violation of the Michigan Food Law of 2000, P.A. 92, MCL 289.5101(1).

Improperly processed beverages and food products may have the potential to be contaminated with Clostridium botulinum, a tasteless and odorless bacterium which can cause life-threatening illness or death.

Botulism, a potentially fatal form of food poisoning, can cause the following symptoms: general weakness, dizziness, double-vision and trouble with speaking or swallowing. Difficulty in breathing, weakness of other muscles, abdominal distension and constipation may also be common symptoms. People experiencing these problems should seek immediate medical attention.

No illnesses have been reported at this time. Consumers are warned not to use the product even if it does not look or smell spoiled.

Products were primarily distributed across the U.S. through the firm's website, and social media platforms. Products advertised on their website lack adequate and consistent labeling including but not limited to ingredient statements, lot codes, and sell by dates.

- Regular Sea Moss Gel
- Fruit Flavored Sea Moss Gel:
  - Mixed Berry with Blueberry Strawberry Raspberry
  - Pineapple Cherry Strawberry
  - Peach Strawberry Flavor
  - Strawberry Dragon fruit
  - Mango Pineapple
  - Strawberry Banana
- Sea Moss Lemonade:
  - Blue Raspberry

- Mango
- Lemonade
- Watermelon
- Strawberry Peach
- Green Apple
- Pink Strawberry
- Strawberry Lemonade
- Grape
- Pineapple
- Strawberry Kiwi
- Cherry
- Fruit Punch

If consumers have additional questions or concerns, they may contact MDARD at 800-292-3939, Monday through Friday between 8 am and 5 pm.

###

Michigan Department of AGRICULTURE & Rural Development
QUESTIONS?
Contact Us
Phone: 800-292-3939

STAY CONNECTED:

[Picture of seaweed removed due to file size constraints]

The identification of potential food safety hazards in seaweed

Words by Clare Winkel

The consumption of seaweed has many health and nutritional benefits and Australia currently imports a significant amount of seaweed for human consumption.

Between 2017-2018, seaweed imports were worth $40 million and 85% of that was for human consumption. Every year there are at least 36 recalls or import alerts worldwide for seaweed-based foods. In 2019, Australia instigated at least 50% of these recalls or rejections.

There are currently only a small number of domestic harvesters, growers and processors producing and selling seaweed for human consumption, but given the food safety concerns with imported seaweed, how does the local product compare?

AgriFutures

To assist this small industry, AgriFutures has funded Integrity Compliance Solutions (ICS) to undertake a project to identify potential food safety hazards and develop HACCP Plans (Hazard Analysis Critical Control Point) for two seaweed case studies. These documents will provide the basis of a readily adaptable program for seaweed processors and guidance for regulators in terms of minimising risks in the processing of seaweed for human consumption.

The project is focused on two seaweed species: one grown and one wild harvested. The first case study is *Phyco Health & Venus Shell Systems,* run by Dr Pia Weinberg. This business grows sea lettuce in large 'swimming pools' which is then heat dried and processed. The second case study is *Sea Health Products,* run by Jo Lane. This business harvests kelp from the beach which it then sun dries and processes.

The end-products from both businesses in the case studies are similar dried flaked products that can then be further processed into almost any type of processed foods including pasta, seasonings, chips, cheese, chocolate and coated snacks such as roasted nuts.

To start the hazard identification process, a literature review was undertaken. One study by the European Union Rapid Alert System[1] identified 22 food safety hazards in European seaweed - four were considered major, five moderate and thirteen minor.

The four major hazards identified were: arsenic, cadmium, iodine and Salmonella. Some of the minor hazards included pesticide residues, dioxins, polychlorinated biphenyls, brominated flame retardants, polycyclic aromatic hydrocarbons, pharmaceuticals, marine bio toxins, allergens, nano plastics, pathogenic bacteria and viruses. The pathogenic bacteria include Salmonella and viruses include norovirus and hepatitis B.

These minor hazards are organisms or chemicals that are found within the European environment. Some are naturally occurring, such as marine biotoxins, and some are clearly a result of human activities such as nano plastics, pesticides, dioxins and flame retardants. There are safety concerns related to adverse events associated with seaweed consumption, particularly the variable and potentially dangerously high concentrations of iodine and heavy metals (including inorganic arsenic) in certain seaweeds.[2,3]

Only one publication by the University of Connecticut[4] focused on seaweed sold to the consumer (including raw and chilled), whether in restaurants or as a processed product. The food safety hazards identified

[Picture of person collecting seaweed removed due to file size constraints]

Jo Lane collecting Golden Kelp (Ecklonia radiata) at dawn from case study 2. Photo taken by Honey Atkinson and supplied by Jo Lane.

were pathogens from the harvest area, which were potentially significant because the seaweed may be consumed as a raw product, without any additional processing kill step.

Pathogens of concern include *Vibrio, Salmonella, E.coli* O157:H7, *Shigella, Norovirus* and Hepatitis. Environmental chemical contaminants were considered potentially significant as certain species of seaweeds exhibit a high affinity for accumulating heavy metals and other contaminants in their tissues. Natural toxins from the harvest area including outbreaks related to the consumption of several *Gracilaria* species. These toxins are often heat-stable and even if seaweed is cooked before consumption, the toxin will remain in the final product.

The spores of *Clostridium botulinum,* that form botulinum toxin, are naturally occurring in the marine and estuarine environment. It could be considered for seaweed products that are raw or blanched and then packaged in a modified/reduced atmosphere package (e.g. vacuum packed). Almost all papers reviewed were based on Northern hemisphere seaweed species and environments.

In addition to the literature review, the project reviewed 20 years of worldwide recall notices and border rejections using the Horizon Scan database.[5] This process identified the following food safety hazards:

- Iodine: 262 incidents between 2000 – 2022
- Inorganic arsenic: 64 incidents between 2000 – 2022
- USA Import refusals: 35 incidents between 2002 – 2021 including labelling failure, processing failure, 'filth' and unauthorised colours
- Cadmium: 13 incidents between 2005 – 2020
- Salmonella: 11 incidents between 2011 – 2018
- E. coli O7:H4: 3,000 school students and staff in Japan in 2020 (red seaweed salad)
- Chemical hazards: Nitrofurans, sulphites, benzopyrene and aluminium
- Unauthorised colours
- Unauthorised irradiation
- Microbiological organisms: Listeria, mould and coliforms
- Allergens: soy, gluten and sesame
- Fraud: documentation (labelled as organic from Nth Korea in 2020) and species substitution (Vietnam 2021).

The process steps undertaken in the case studies were reviewed for actual food safety hazards, control measures and critical control points (CCP). The hazards identified were quite different to those identified in most of the publications. These were:

- Allergens: crustaceans and molluscs - controlled by washing in fresh water
- Physical contamination: sand and marine debris - controlled by washing in fresh water
- Micro contamination: Salmonella - controlled by the drying process resulting in a final product of Aw below 0.83 and salt content
- Chemical contamination: iodine – possibly controlled by blanching of raw material
- Almost all hazards were controlled or eliminated by growing seaweed in controlled tank conditions.

Variables that need to be considered to identify further controls for the identified food safety hazards include:

- Species specific hazards in local seaweed species
- Seaweed plant age and which parts of the plants are used
- Local harvest environmental conditions
- Rainfall levels in the local harvest area and harvest water temperature
- Blanching process.

Project partners:

1. Sea Health Products: https://www.seahealthproducts.com.au/
2. Phyco Health & Venus Shell Systems: https://www.venusshell-systems.com.au/

References

1. *Banach, JL, Hoek-van den Hil, EF, van der Fels-Klerx, HL. Food safety hazards in the European seaweed chain. Compr Rev Food Sci Food Saf. 2020; 19: 332– 364. https://doi.org/10.1111/1541-4337.12523*
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3. *Suleria HA, Osborne S, Masci P, Gobe G. Marine-based nutraceuticals: an innovative trend in the food and supplement industries. Mar Drugs. 2015;13:6336–6351.*
4. University of Connecticut, USA https://seagrant.uconn.edu/
5. Horizon Scan Database of worldwide recalls and border rejections https://horizon-scan.fera.co.uk/

Clare Winkel is the Executive Manager – Technical Solutions for Integrity Compliance Solutions (ICS).

[Picture of seaweed removed due to file size constraints]

Photo supplied by Pia Winberg: finished product (dried farmed seaweed- Ulvophyceae) from case study 1.

NATIONAL COFFEE ASSOCIATION USA EST. 1911

January 23, 2023

Dr. David McSwane, REHS, CP-FS
Executive Director
Conference for Food Protection
30 Elliott Court
Martinsville, IN 46151-1331
Dmcswane.cfp@gmail.com

Cc: Sharon Farrell, MS, RD,
Indiana Department of Health

Dear Dr. McSwane:

The NCA appreciates the opportunity to comment and submit an Issue to the Conference for Food Protection on retail cold brew coffee to consider for recommendation to the Food Code. We provide this supporting document to summarily describe justification, current enforcement practices, and a comprehensive challenge study currently underway, to help inform the creation of a standard on retail cold brew coffee for the Food Code.

The National Coffee Association (NCA), established in 1911, is the nation's leading coffee trade organization, representing more than 200 member organizations across all segments of the U.S. coffee industry, including growers, importers, traders, roasters, retailers, and allied organizations. Coffee plays a key role in the U.S. economy, supporting more than 1.6 million jobs and contributing more than $225 billion to the economy annually. Most Americans (66% of those over 18) drink coffee each day, more than any other beverage, including water[1].

While "traditional" coffee is recognized as a safe food, cold brew coffee involves a different preparation method, one that exchanges a heat-based extraction method for one that takes place over a longer period of time at ambient or cooler temperature, and results in a beverage that tastes less acidic and is smoother than traditionally prepared coffee. Given a lack of consistent and clear regulations regarding safe preparation, storage, and dispensing of cold brew coffee, coupled with its rapidly growing popularity, state and local health departments as well as coffee retailers (such as coffee shops) are in need of guidance in the form of regulations that provide clarity for food safety enforcement and compliance, as well as consumer safety.

As a result, there is a pressing need for the creation of a Food Code standard on cold brew coffee prepared for retail sale to help provide uniformity of food safety enforcement and compliance across the many enforcement agencies across the country.

[1] National Coffee Data Trends Report Fall 2022, National Coffee Association USA, Inc. https://www.ncausa.org/Portals/56/PDFs/Communication/Fall-2022-media-highlights.pdf

Outlined below is a summary of some safety concerns and enforcement considerations that have been brought to our attention via prominent health departments and businesses. In addition, we have summarized the objectives, outcomes and timing for a comprehensive cold brew challenge study that the NCA has commissioned with a leading national third-party accredited laboratory, currently underway, intended to result in empirical data to support the creation of safety standards.

Summary of Justification, Enforcement, and Challenge Study Research Objectives

Safety concerns in retail cold brew coffee, existing food code enforcement, and research objectives for a cold brew coffee challenge study designed to resolve regulators' concerns and inform the Food Code.

Safety concerns for retail cold brew coffee:

1. Temperature abuse or ambient brewing allowing for increased microbial growth.
2. Extended shelf-life increases risk of microbial growth
3. Sanitation concerns
4. Reduced oxygen packaging (ROP)

Health inspector enforcement of existing food code:

Health inspector enforcement of existing food code standards on retail cold brew has varied significantly across state and local jurisdictions. Some of the most rigorous and prominent enforcement has included (excerpted from Maricopa County Environmental Services Department):

1. Cold brew coffee has been regarded by various jurisdictions as a time/temperature control for safety (TCS) food unless evidence has been provided to health departments to indicate it is a non-TCS food.
    a. A food that because of its pH or a_w (water activity) value, or interaction of a_w and pH values, is designated as a non-TCS food.
    b. If the interaction of the product's pH and a_w indicates a product assessment is required, then a challenge study will need to be conducted in accordance with National Advisory Committee on Microbiological Criteria for Foods (NACMCF) standards and provided to departments of health for consideration.
2. HACCP plans and variances are not required if cold brew coffee is handled in accordance with all applicable parameters of the food code:
    a. Brew, hold, and dispense at 41°F or below.
    b. Date marked for no more than 7 days from the date of production.
3. Kegging cold brew coffee, or using a similar packaging method, such as bottling, is a reduced oxygen packaging (ROP) process. With the exceptions identified below, a HACCP plan and a variance may be required.
4. HACCP plans and variances are NOT required for non-TCS food.
5. HACCP plans and variances are NOT required if sealing the product using ROP methods and holding the product in package for less than 48 hours (after 48 hours product must be discarded, removed from package or unsealed) in accordance with §3-502.12 (F) and if handled in accordance with all other applicable parameters of the food code.

6. When packaging (packaged at 41°F or below) is conducted in accordance with §3-502.12, only a HACCP plan will be required. If processes deviate from §3-502.12, a variance will also be required.

Research Objectives:

1. NCA has commissioned a nationally accredited third-party laboratory to determine the ability of proteolytic and non-proteolytic *Clostridium botulinum* (*C. bot.*) and non-*C. bot.* pathogens (*Bacillus cereus* spores, *Escherichia coli* O157:H7, *Listeria monocytogenes*, *Salmonella*, and *Staphylococcus aureus*) to grow in cold brew coffee concentrate prepared by the bucket method (4-6° Brix) at ambient temperature for 12-18 hours and single-strength cold brew (1.5-2° Brix) packaged into bag-in-box (BIB) and stored at 85°F for up to 11 days of storage.

Outcomes & Timing:

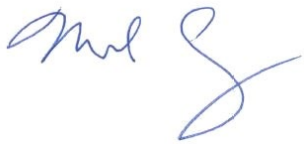
The NCA anticipates that the research study will be completed in the Spring with completion of a white paper by June 2023. The results can be used to inform creation of a standard for the Food Code.

Conclusion:

On behalf of the coffee sector, we are interested in participating and supporting a process to create science-based, practical guidance to support creation and enforcement of cold brew coffee related food safety regulations to protect consumers.

Sincerely,

William (Bill) Murray, CAE
President & CEO
National Coffee Association
wmurray@ncausa.org



Mark Corey, Ph.D.
Director Science & Policy
National Coffee Association
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Comprehensive Reviews in Food Science and Food Safety

Evaluation and Definition of Potentially Hazardous Foods

A Report of the Institute of Food Technologists
for the Food and Drug Administration
of the United States Department of Health and Human Services

December 31, 2001

IFT/FDA Contract No. 223-98-2333
Task Order No. 4

Table of Contents

Comprehensive Reviews in Food Science and Food Safety

Chapter VIII
Framework Developed to Determine Whether Foods Need Time/ Temperature Control for Safety

1. Description of framework

The variety and novelty of the foods currently available to consumers has resulted in a complex situation when determining whether a food needs time/temperature control for safety. Although there are many foods that need time/temperature control for safety (TCS), other foods require specific evaluation in order to determine their status as TCS or non-TCS foods. To facilitate the decision as to whether a food needs time/temperature control for safety, the panel developed a framework based on: in-depth evaluation of criteria used by industry, government, and trade organizations; survey data collected by the panel (see Appendix B); available scientific literature; and the panelists' own experience on this subject. The framework provides a stepwise process that considers holding time and temperature, product description, pH and a_w interaction, product assessment, challenge testing, and mathematical models. Decisions as to whether or not a food should be designated as TCS can be made at various steps of the framework. Performing the initial steps requires only limited experience and/or minimum training, while subsequent steps require knowledge of the product's pH and a_w. More technical expertise is needed for the analysis step which is based on product assessment, challenge studies, and predictive modeling. If it is determined that the product needs (or may need) time/temperature control for safety, a number of alternatives are presented in the framework that might be considered. For example, a decision might be made that a challenge study is so costly that the best alternative is to reformulate the product or control the time or temperature.

The following is a description of the proposed framework that the panel has developed to determine whether a food needs time/temperature control for safety (see section 2 of this chapter).

Before proceeding with Step 1 of the evaluation process, the evaluator needs to make a succinct review of the food product in question, including intrinsic and extrinsic factors that may affect microbial growth and potential hazards. (Detailed descriptions of factors and potential hazards that will help with this review are presented in Chapters 3 and 4.) The food may already be held hot or cold for safety reasons. In this case, and if there is no desire to store the food at ambient temperature, the trained decision-maker need not proceed any further. Product history, in combination with a robust scientific rationale that justifies such safe history of use, may also be used as criteria to designate a food as a non-TCS food not requiring further evaluation (see also Chapter 3, section 4.2.).

Step 1. The panel concluded that the appropriate scientific evidence exists to allow for the evaluation of a food according to its pH, water activity, and pH/a_w interaction. The panel also agreed that a product that is processed to eliminate vegetative cells needs to be addressed differently than an unprocessed product that received no treatment or a less robust treatment. The concern of possible post-process contamination also needs to be addressed. If a food is processed to inactivate bacteria and packaged so that there is no post-process contamination, the tolerable range conditions of a_w and pH are more permissive, since spores would become the only microbial hazard. For these reasons, the panel designed two pH/a_w tables: one for the control of spores (Table A), and one for the control of spores and vegetative cells (Table B). The rationale for the ranges of pH and a_w in determining whether a food is non-TCS versus TCS is based on minimum pH and a_w requirements for the pathogens of concern; that is, *Bacillus cereus* and *Clostridium botulinum* toxin production when controlling spores, and *Listeria monocytogenes*, *Staphylococcus aureus, Salmonella* spp*, C. botulinum*, and *B. cereus* when controlling both vegetative cells and spores (see Chapter 3, sections 2.1. and 2.2. and Appendix C). If process technologies other than heat are applied, then the effectiveness of the process needs to be validated. For this decision, the evaluator needs to have an understanding of both the process and the validation of its effectiveness in reducing pathogens of concern. It should be noted that for some products, the analysis of pH and a_w may be inaccurate, especially in the case of combination products (see Chapter 4, section 10). Consequently, for these products the pH and a_w would not be considered as controlling factors without supporting data from challenge studies.

Step 2. After the product's assignment to a box inside one of the tables, if the product is designated as non-TCS, it may be safely stored at room temperature. If the product is placed in a box indicating with a question mark (?) that it may require temperature control for safety, an analysis may be performed to assess the microbial risk of holding the product at ambient temperature. The evaluator may also decide not to perform the analysis, in which case the time and temperature of the product should be controlled for safety.

Product assessment. A comprehensive description of the product is the first task in this product assessment. This entails a detailed description of such factors as (1) potential pathogens, (2) intrinsic factors (for example, preservatives, antimicrobials, humectants, acidulants, and nutrients), (3) extrinsic factors (for example, packaging, atmosphere (MAP), use/shelf life, and temperature range of storage and use), (4) effectiveness of the processing for control of pathogens, and (5) possible post-process recontamination opportunities that may be present. If any of the factors precludes the growth of pathogens (for example, acetic acid as an acidulant at a reasonably low pH), the product may be designated non-TCS. Historical information regarding product safety should be considered by determining whether the food in question, or

any of its ingredients, has been previously implicated as a common vehicle of foodborne disease after temperature abuse. Of particular importance are the microbiological agents that are responsible for illnesses associated with the food and the reported contributing factors that have led to documented illnesses. Has adequate temperature control been clearly documented as a factor that can prevent or reduce the risk of illness associated with the food? Lastly, product history alone should not be used as the sole factor in determining whether or not a food needs time/temperature control for safety, unless a scientific basis for such safe use could be rationalized. As intrinsic or extrinsic factors change (for example, MAP or greatly extended shelf life), historical evidence alone is not appropriate in determining potential risk. Therefore, for a product to be identified as non-TCS based on history, the intrinsic and extrinsic factors affecting microbial growth need to have remained constant, and a scientific rationale needs to have been provided for the product's safe use (see also Chapter 3, section 4.2.).

Microbial growth models and challenge studies. In addition to the usual considerations, time of expected storage and display might also play a significant role in determining the classification of the food. Foods that have combinations of pH, a_w, preservatives, or other factors that are restrictive (but not prohibitive) to microbial growth and/or toxin production may not require refrigeration to protect public health. For example, if the duration of storage and/or display is less than that needed for microbial growth and/or toxin production, adequate control may be achieved through a variety of time and temperature combinations. Under certain circumstances, time alone at ambient temperatures can be used to control product safety. These factors can be considered in light of the product assessment and the microbial hazards of concern. The following is an example of how storage or holding time alone at ambient temperatures could be used to control product safety. If the microbiological concern for a specific food is the growth of *S. aureus*, the USDA Pathogen Modeling Program v. 5.1 could be used to estimate the time of storage where pathogen growth could occur. Using Table 8-1 with data generated from the model, a product with an $a_w = 0.88$ and pH = 5.5 could be safely stored at ambient temperature for weeks, assuming *S. aureus* would be the only microbial concern.

Table 8-1—Time estimates required for 3-log growth of *Staphylococcus aureus* at various pH and water activities (a_w) based on the USDA Pathogen Modeling Program v. 5.1

	PH			
a_w	6.0	5.5	5.0	4.6
0.94	Hours	Hours	Hours	Hours
0.92	Hours	Hours	Days	Days
0.90	Hours	Days	Days	Weeks
0.88	Days	Weeks	Months	Months
0.86	Weeks	Months	Months	Months

Days = 2–13 days
Weeks = 13–60 days
Months = > 60 days

It must be emphasized, however, that general growth models such as the USDA Pathogen Modeling Program must be restricted in use because of limitations of the model parameters, microorganisms of concern, or other factors. Consequently, unless used conservatively, it is often more appropriate to use them in combination with challenge testing. Nevertheless, a general model can assist, for example, in selecting pathogens of concern for a challenge test. In the absence of an appropriate model, a challenge test alone could be used to determine whether pathogens of concern could grow under specified storage conditions (see Chapter 6 for guidelines on challenge testing). On the other hand, if an in-house model has been developed and validated for a particular food, it could be used to make such an assessment by itself or with challenge testing. At this point, a final decision needs to be made about the product's need to be time/temperature controlled. If the hazard analysis indicates that the product should be designated as non-TCS, the product can be stored at room temperature. If, on the contrary, the product is identified as TCS, the evaluator can either decide to modify the product, change the processing and handling it undergoes, control pathogen growth with time/temperature, or revisit the commercial feasibility of the product.

(See "2. Framework for determining if time/temperature control is required for safety" on next page)

2. Framework for determining if time/temperature conrol is required for safety

The food in question may already be held hot or cold for safety reasons. In this case, and if there is no desire for ambient temperature storage, an analysis using this framework is not needed. If the need to control the temperature of the product for safety reasons is unknown, a review of the food, its ingredients, and general methods of preparation should precede the evaluation of the food. If the food, as described, has a substantial and extensive history of safe use without time/temperature control, and there is enough scientific rationale that supports such safe history of use, then the food may continue to be classified as not requiring temperature control for safety, or non-TCS (see also Chapter 3, section 4.2.).

If there is no known history of safe use, proceed with Step 1.

Step 1—Was the food treated to destroy vegetative cells of potential pathogens and packaged to avoid recontamination? If yes, position your product in Table A according to its pH and water activity (a_w). If not, position your product in Table B according to its pH and a_w.

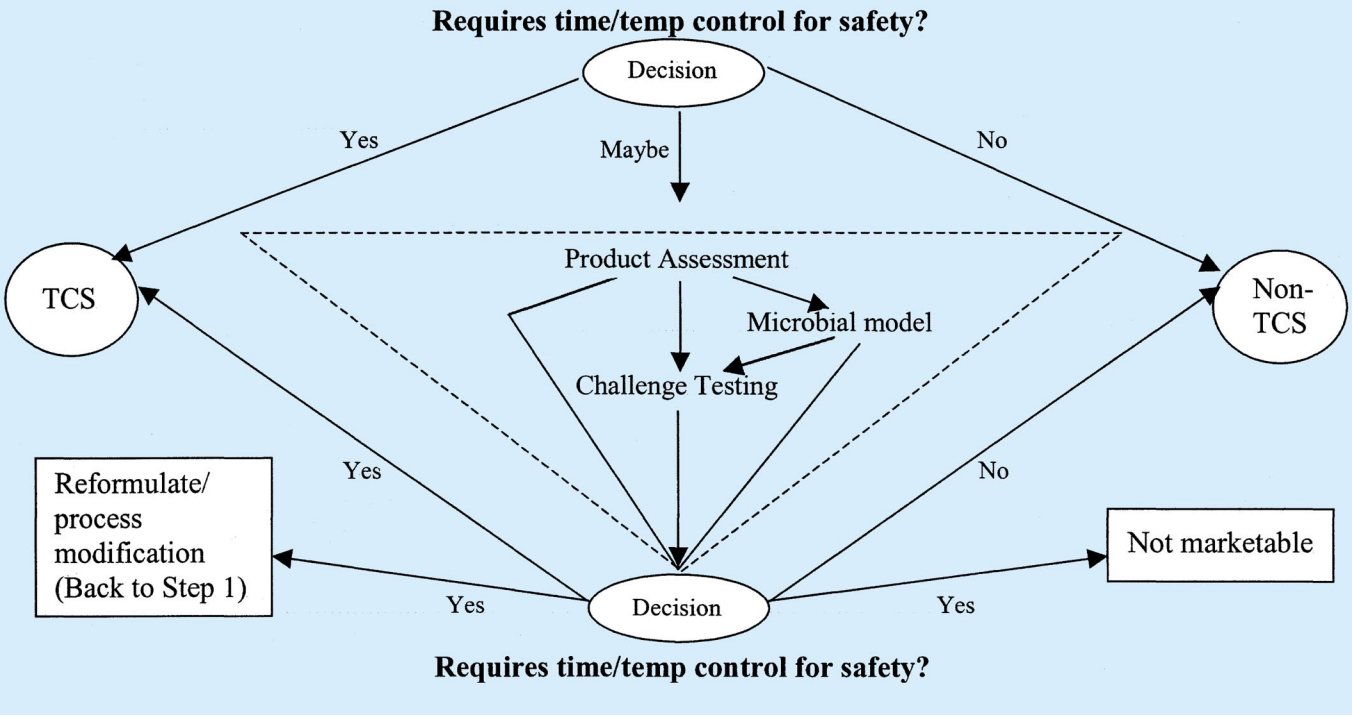
Table A—Control of spores: Product treated to control vegetative cells and protected from recontamination.

Critical a_w values	Critical pH values		
	4.6 or less	> 4.6 to 5.6	> 5.6
0.92 or less	Non-TCS	Non-TCS	Non-TCS
> 0.92 to .95	Non-TCS	Non-TCS	?
> 0.95	Non-TCS	?	?

Table B—Control of vegetative cells and spores: Product not treated or treated but not protected from recontamination

Critical a_w values	Critical pH values			
	< 4.2	4.2 to 4.6	> 4.6 to 5.0	> 5.0
< 0.88	Non-TCS	Non-TCS	Non-TCS	Non-TCS
0.88 to 0.90	Non-TCS	Non-TCS	Non-TCS	?
> 0.90 to .92	Non-TCS	Non-TCS	?	?
> 0.92	Non-TCS	?	?	?

Step 2—If the food is classified as a non-TCS food according to Step 1 above, it may be stored and held safely without regard to time or temperature. If the need for time/temperature control is questionable, the food should be held either hot or cold for safety, or subjected to a product assessment as the next step in determining the appropriate classification.



3. Critique of framework. Application of framework to foods.

The panel's framework on time/temperature control of foods for safety was applied to the following foods as examples. Each step of the framework has been described as it applies to the food under consideration. Most of the data presented were from industry studies submitted to the panel in response to a survey of industry practices to determine whether a food needs time/temperature control (see Appendix B).

3.1. Salad dressings

Product: Viscous, non-particulate[1] pourable salad dressing.

The product is not held hot or cold. The ingredients of the product are eggs, soybean oil, buttermilk, tomato paste, onion, garlic, spices, lemon juice, vinegar (2.5 – 5.4% salt), and potassium sorbate. Microbial hazards: *Clostridium botulinum*. The product is intended to be distributed and stored at ambient temperature for 7 to 9 mo. New product, so there is no history of use.

Step 1. Processing: Cold blended and filled in plastic or glass bottle. No heat applied.

Go to Table B.

Table: pH maximum of 4.2 and "high" (not specified) a_w.

Step 2. Decision: Product may be a temperature controlled for safety (TCS) food.

Product Assessment: Salad dressing is acidified with acetic acid. No microbiological hazard at pH 4.2.

Decision: Product is a Non-TCS.

[1]If salad dressing had particulate matter, then this product would need to be reevaluated.

3.2. Condiments: Mustard

Product: Viscous, non-particulate[1] mustard.

The product is not held hot or cold. The ingredients of the product are mustard seeds and vinegar (acetic acid). The product is intended to be distributed and stored at ambient temperature for extended shelf life. Microbial hazards: *Listeria monocytogenes, Salmonella* spp.*, Escherichia coli* O157:H7, *C. botulinum.* There is history of safe use without time/temperature control[2].

Step 1. Processing: Ground and blended. Go to Table B.

Table: pH maximum of 4.0 and "high" (not specified) a_w.

Decision: Product is a Non-TCS.

[1] If mustard had particulate matter, then this product needs to be reevaluated.

[2] If pH of mustard was above 4.2 or if acidulant was not acetic acid, then this product would need to be reevaluated.

3.3. Butter

Example 1

Product: Salted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution product is held at low temperatures for quality reasons. The ingredients of the product are cream and salt. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There is no history of safety problems when the consumer does not control time/temperature of commercial salted butter.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 5.41 and a_w 0.897.

Step 2. Decision: Product may be a TCS food.

Product Assessment: Product characteristics prevent *L. monocytogenes* growth. Predictive model (p 8-3) suggests that holding the product for hours at ambient temperature is safe.

Decision: Challenge testing, predictive microbial model, reformulation to decrease a_w, refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or product is not marketable.

Example 2

Product: Salted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution product is held at low temperatures for quality reasons. The ingredients of the product are cream and salt. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There is no history of safety problems when the consumer does not control time/temperature of commercial salted butter.

Step 1. Processing: Pasteurization of cream. Acidified by fermentation. No heat applied after butter is churned. Go to Table B.

Table: pH 4.25 and a_w 0.897.

Step 2. Decision: Product is a Non-TCS food.

Example 3

Product: Salted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution product is held at low temperatures for quality reasons. The ingredients of the product are cream and salt. The product is intended to be stored at ambient temperature. Microbiological hazard: *S. aureus, L. monocytogenes*. There is no history of safety problems when the consumer does not control time/temperature of commercial salted butter.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 5.94 and a_w 0.847.

Step 2. Decision: Product is a Non-TCS food.

Example 4

Product: Salted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution product is held at low temperatures for quality reasons. The ingredients of the product are cream, lactic acid bacteria, and salt. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There is no history of safety problems when the consumer does not control time/temperature of commercial salted butter.

Step 1. Processing: Pasteurization of cream. Acidified by fermentation. No heat applied after butter is churned. Go to Table B.

Table: pH 4.78 and a_w 0.863.

Step 2. Decision: Product is a Non-TCS.

Example 5

Product: Unsalted whipped butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution, the product is held at low temperatures for quality reasons. The ingredients of the product are cream and acidified natural flavoring. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There has been a report of unsafe handling of a whipped butter product.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 4.91 and a_w 0.921.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision: Challenge testing, predictive microbial model, reformulation to decrease a_w, refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or product is not marketable.

Example 6

Product: Unsalted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution , the product is held at low temperatures for quality

reasons. The ingredients of the product are cream and natural flavoring. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There is no history of unsafe use without time/temperature control.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 5.98 and a_w 0.941.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision: Challenge testing, predictive microbial model, reformulation to decrease a_w, refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or product is not marketable.

Example 7

Product: Unsalted butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution , the product is held at low temperatures for quality reasons. The ingredients of the product are cream and natural flavoring. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There is no history of unsafe use without time/temperature control.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned. Go to Table B.

Table: pH 5.42 and a_w 0.907.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision: Challenge testing, predictive microbial model, reformulation to decrease a_w, refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or product is not marketable.

Example 8

Product: Salted light whipped butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution, the product is held at low temperatures for quality reasons. The ingredients of the product are cream, salt, water, tapioca, modified food starch, beta carotene, vitamin A, natural flavoring, lactic acid, vegetable mono and diglycerides, potasium sorbate, sodium benzoate. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There has been a report of unsafe handling of a whipped butter product.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 4.48 and a_w 0.985.

Step 2. Product may be a TCS food.

Product Assessment: Sodium benzoate and potassium sorbate may prevent pathogen growth.

Decision: Challenge testing, predictive microbial model, reformulation to decrease a_w, refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or product is not marketable.

Example 9

Product: Salted whipped butter. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution, the product is held at low temperatures for quality reasons. The ingredients of the product are cream and acidified natural flavoring. The product is intended to be stored at ambient temperature. Microbiological hazards: *S. aureus, L. monocytogenes*. There has been a report of unsafe handling of a whipped butter product.

Step 1. Processing: Pasteurization of cream. No heat applied after butter is churned.

Go to Table B.

Table: pH 4.14 and a_w 0.822.

Step 2. Decision: Product is a Non-TCS food.

3.4. Margarine

Product: Margarine. The product is not held hot or cold for safety. However, during commercial handling, storage, and distribution, the product is held at low temperatures for quality reasons. The ingredients of the product are soybean oil (80%), water and milk protein (19%), salt (0.9%), and potassium sorbate (.1%). The product is intended to be distributed and stored at ambient temperature for 3 mo. Microbiological hazards: *S. aureus, L. monocytogenes*. There is history of safe use without time/temperature control.

Step 1. Processing: Emulsification of oil blend/water preservative mixture. No heat applied. Go to Table B.

Table: pH 4.8 and a_w unknown.

Step 2. Product may be a TCS food.

Product Assessment: Sorbic acid in formulation prevents pathogen growth. Historically product is safe and stable.

Decision: Product is a Non-TCS.

3.5. Garlic-in-oil[1]

Product: Garlic-in-oil. The product is not held hot or cold. The ingredients of the product are chopped fresh garlic and oil. The product is intended to be distributed and stored at ambient temperature for extended shelf life. Outbreaks have been associated with *C. botulinum* toxin in garlic-in-oil. Microbiological hazards: *C. botulinum* toxin production.

Step 1. Processing: Oil poured into chopped garlic in a bottle. Although no heat is applied, vegetative pathogens are not associated with this food. Go to Table A.

Table: pH > 4.6 and high a_w (not specified).

Step 2. Decision: Product may be a TCS food.

Product Assessment: No identified product characteristic that prevents spore-forming pathogen growth. Antimicrobial properties of garlic will prevent the growth of vegetative pathogens.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic or phosphoric acid to < 4.6, refrigerate (TCS food), store hot (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

[1]Flavored oil will present negligible hazard due to lack of *C. botulinum* survival or growth in 100% oil.

3.6. Cheeses

Example 1

Product: Cream cheese. The product is not held hot or cold during use. The ingredients of the product are milk, cream, salt, gums. The product is intended to be distributed and stored

at ≤ 7 °C (45 °F) for a maximum of 120 d. When in use, the tempered unopened product can be kept up to 48 h at ambient temperature. There is no history of botulism associated with cream-cheese products. Microbiological hazard: *C. botulinum.*

Step 1. Processing: Full fat, plain cream cheese, bulk packed and hot-filled > 68 °C (155 °F) in 3 lb/30 lb/ 50 lb tubs/blocks. Ready-to-eat after opening or baked. Go to Table A

Table: pH 4.7 to 5.1, $a_w > 0.97$.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic acid or phosphoric acid to < 4.6, keep refrigerated—that is, eliminate tempering at ambient (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: Separate products were inoculated with 100 – 500 spores/g of either proteolytic A & B or non-proteolytic B cocktails of *C. botulinum* and held at 30 °C (86 °F) for 10 d. No toxin was detected throughout the study. Conclusion is that the unopened product can be stored safely at ambient temperature for up to 7 d based on a safety factor of 1.3 times shelf life of the product. However, loss of product quality dictates storage at ambient temperature for no longer than 48 h. Without additional challenge studies on vegetative pathogens, opened product requires time/temperature control.

Example 2

Product: Process cheese sauce packed in 40 lb bag-in-box containers. The product is not held hot or cold during use. The ingredients of the product are cheddar cheese, milk, whey, milk fat, water, salt, sodium phosphate, sorbic acid, artificial color. The product is intended to be distributed and stored at ≤ 7 °C (45 °F) for a maximum of 9 mo. The tempered unopened product can be kept 24 h at ambient temperature in foodservice establishments prior to use. New product, so there is no history of use. Microbiological hazards: C*. botulinum.*

Step 1. Processing: Heated to 85 °C (185 °F) for 1 to 2 min and hot-filled at 68 to 69 °C (155 to 165 °F) into bag-in-box containers. Ready-to-eat or heated prior to consumption. Go to Table A.

Table: pH 5.7 (target) and $a_w > 0.95$.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No apparent product characteristic that prevents spore outgrowth. Possibly certain ingredients such as sodium phosphate and sorbic acid may inhibit pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic, lactic or phosphoric acid, refrigerate (that is, eliminate tempering at ambient temperature [TCS food]), or store at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Run formulation through a validated microbial model.

Predictive microbial modeling: Microbial model showed that the product would support the growth and toxigenesis of *C. botulinum.* A decision was made to reformulate by optimizing the controlling factors and their interactions. In this case, sorbic acid levels were adjusted from 0.08 % to 0.15 %. The reformulated product was run through the microbial model which gave a prediction of safety. Conclusion is that the reformulated unopened product may be tempered at room temperature for 24 h maximum. Without additional challenge studies on vegetative pathogens, opened product requires time/temperature control.

Example 3

Product: Pasteurized process cheese slices, bulk packaged. The product is not held hot or cold during use. The ingredients of the product are milk, whey, cheese, milk fat, water, salt, sodium citrate, sorbic acid, artificial color. The product is intended to be distributed and stored at ≤ 7 °C (45 °F) for a maximum of 8 mo. The tempered 96-slice pack can be kept for an 8 h shift at ambient temperature prior to use near to the grill in foodservice establishments to facilitate peeling of slices and melting on sandwiches. No history of pathogenic growth associated with commercial pasteurized process cheese slices. Product is subject to recontamination after opening. Microbial hazards: *L. monocytogenes, S. aureus, Salmonella* spp*., E. coli* O157:H7, *C. botulinum* (product does not receive a proteolytic botulinal cook).

Step 1. Processing: Heated to ≥ 66 °C (150 °F) for ≥ 30 s and cooled over a chill roll. Slices are then bulk packed in units of 96 slices. Ready-to-eat directly out of package or used in melt applications. Go to Table B.

Table: pH 5.7 to 5.8 and $a_w > 0.92$.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No apparent product characteristic that prevents spore outgrowth. Possibly sorbic acid may inhibit pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic, lactic, or phosphoric acid, refrigerate (that is, eliminate tempering at ambient temperature [TCS food]), or store at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: Product was inoculated with 10^3 CFU/g *L. monocytogenes, S. aureus, E. coli* O157:H7, *Salmonella* spp*.,* and *C. botulinum* (proteolytic strains only). Cocktails of each challenge organism were inoculated into separate samples. Inoculated product was incubated at 30°C (86°F) for 96 h. Results showed that *Salmonella* spp*, E. coli* O157:H7, and *L. monocytogenes* decreased in populations over the challenge period. *Staphylococcus aureus* levels remained constant during the challenge period, but were below levels that supported detectable enterotoxin production. No botulinal toxin was detected over the challenge period. From a safety perspective the opened product could be stored for 67 h at room temperature, based on a safety factor of 1.3 times shelf life of the product. Loss of product quality dictates that slices be tempered for no longer than 8 h.

Example 4

Product: Cheese blend for pizza topping. The product is not held hot or cold during use. The ingredients of the product are cheese, sodium chloride 1.81%, nitrite level < 1ppm. The product is intended to be stored at ambient temperature for a maximum of 10 h before being baked. This is a new intended use, so there is no history of safe use. The microbiological hazards are the heat-stable toxins of *S. aureus* and *B. cereus.*

Step 1. Processing: Baked, but heat-stable toxins may remain. Go to Table B.

Table: pH 5.56 and a_w 0.978.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic, lactic, or phosphoric acid, refrigerate (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: 1,000 CFU/g of product inoculated with *S. aureus* and *B. cereus* and incubated at 27 °C (80 °F) for various lengths of time: No toxin was detected at 10 h. Product can be stored safely at room temperature for 7 h, based on a safety factor of 1.3 shelf life of the product.

Example 5

Description: Cheese-filled bread. The product is not held hot or cold during use. The ingredients of the product are process cheese, pastry covering, salt, glycerol. The product is intended to be distributed and stored at 4.4 to 7.3 °C (40 to 45 °F) for a maximum of 90 d, and then stored at ambient temperature for sale. New product, so there is no history of use. Microbiological hazard: *Bacillus cereus* and *Clostridium botulinum* toxin production.

Step 1. Processing: Baked to internal temperature of 88 °C (190 °F) and MAP packed with 100% N_2. Go to Table B.

Table: pH 5.6 to 5.7 and a_w 0.93.

Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic acid or phosphoric acid, refrigerate (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: Separated inocula of 500 spores of *C. botulinum* and 500 spores of *B. cereus* incubated at 13, 18.5, 30 °C (55, 65, 86 °F) for various lengths of time. No toxin production or *B. cereus* growth at 30°C (86 °F) for 14 d. Product can be stored safely at room temperature for at least 10 d, based on a safety factor of 1.3 times shelf life of the product.

Example 6

Product : Monterey cheese slices. The product is not held hot or cold during use. The ingredients of the product are Monterey Jack cheese, milk fat, water, citrate and phosphate emulsifiers, salt (1.9 to 2.5%), sorbic acid (2000 ppm max), color. The product is intended to be distributed and stored refrigerated for 180 to 210 d, but used at room temperature in food service. New product, so there is no history of use. Microbiological hazards: *L. monocytogenes, S. aureus, Salmonella* spp.*, E. coli* O157:H7.

Step 1. Processing: 71 °C (160 °F) for 30 s, hot filled, and sliced, but recontamination is possible. Go to Table B.

Table: pH 5.7 to 6.0, and a_w 0.94 to 0.95.

Step 2. Decision: Product may be a TCS food.

Product Assessment: Sorbic acid as a preservative may prevent pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic acid or phosphoric acid, refrigerate (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: Inoculum with 1,000 CFU/g of *L. monocytogenes, S. aureus, Salmonella* spp.*, E. coli* O157:H7 incubated at 30 °C (86 °F) for various lengths of time: No growth of any pathogen tested at 24 h, no *S. aureus* toxin, *E. coli, L. monocytogenes* and *Salmonella* spp. were detected at 48 h. Although *E. coli, L. monocytogenes* and *Salmonella* spp. levels remain the same up to 72 h, *S. aureus* toxin was detected at 72 h. Product can be stored safely at room temperature for no more than 33 h, based on a safety factor of 1.3 times shelf life of the product.

3.7. Filled bakery product

Product: Cream-filled éclairs. The product is not held hot or cold during use. The ingredients of the product are pastry shell (water, eggs, flour, hydrogenated vegetable oil, baking powder, sodium acid pyrophosphate, baking soda, corn starch, monocalcium phosphate, salt, malted barley); filling (water, sugar, modified corn starch, dextrose, vegetable oil, cottonseed, mono and diglycerides, salt, carrageenan, glucono delta lactone, sodium benzoate and potassium sorbate (0.02%), polysorbate 60, soy lecithin, natural and artificial flavors colored w/Yellow). The product is intended to be distributed at = 0 °C (32 °F) or refrigerated for a maximum of 180 d or 3 d, respectively, and stored at room temperature for a maximum of 4 h. This is a new product, so there is no history of use. Microbiological hazards: *L. monocytogenes, S. aureus, Salmonella* spp.

Step 1. Processing: Filling 88 °C (190 °F), cooled to 5 °C (41 °F) in 4 h; shell > 93 °C (200 °F), cooled to ambient but recontamination is possible. Go to Table B.

Table: pH 7.2 (shell), 5.1 to 5.8 (filling), a_w 0.87 (shell), 0.96 to 0.98 (filling).

Step 2. Decision: Product may be a TCS food.

Product Assessment: Benzoate, sorbate, and glucono delta lactone as preservatives may prevent pathogen growth.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic acid or phosphoric acid, refrigerate (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

Decision: Challenge test.

Microbial Challenge Testing: Filling inoculated (and placed in shell) with 100 to 1,000 CFU/g with *L. monocytogenes, S. aureus, Salmonella* spp. incubated at 7, 12 and 26 °C (44.6, 53.6 and 78.8 °F) for various lengths of time. There was pathogen growth at 1 d. Product as processed and formulated cannot be stored safely at room temperature.

3.8. Breads

Example 1

Product: Pepper focaccia. The product is not held hot or cold during use. The ingredients of the product are bread, roasted sliced red peppers, oil, Romano cheese, garlic powder, oregano. This is a new product, so there is no history of use. The microbiological hazards are: *S. aureus, Salmonella* spp, and *C. botulinum*.

Step 1. Processing: Baked, but recontamination is possible. Go to Table B.

Table: pH (pepper and bread) 3.9 to 4.1[1] and a_w 0.99.

Step 2. Decision: Product is a non-TCS food.

[1]If only the bread or the peppers have low pH, then a challenge study should be performed.

Example 2

Product: Plain focaccia. The product is not held hot or cold during use. The ingredients of the product are bread, oil, Romano cheese, garlic powder, oregano. This is a new product, so there is no history of use. The microbiological hazards are: *S. aureus, Salmonella* spp.

Step 1. Processing: Baked, but recontamination is possible. Go to Table B.

Table: pH 5.5 to 5.3, and a_w 0.95 to 0.97.

Step 2. Decision: Product may be a TCS food.

Product Assessment: No product characteristic that prevents pathogen growth. Although product has properties similar to white bread, with a long history of safe use, some ingredients would not be in the formulation of white bread; therefore, the product may be a TCS food and should be further analyzed.

Decision options: Challenge testing, predictive microbial model, reformulation to lower pH with acetic acid or phosphoric acid, refrigerate (TCS food), or at ambient temperature for a limited time less than the estimated lag phase for the pathogens of concern, or not marketable.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

Reference Document: 2013 FDA Food Code

Provision: 1-201.10

Document Name: Heat sealing without a vacuum v03

Date: January 4, 2017, Editorial change September 12, 2017, December 20, 2019

Question: When packaging food in a retail food establishment, does the 2013 Food Code definition of reduced oxygen packaging apply to the use of plastic bags or plastic films that have been heat sealed without drawing a vacuum?

Response:

No. The process of heat sealing a time temperature control for safety (TCS) food in packaging (a plastic bag or a plastic film on trays) without drawing a vacuum or otherwise modifying the atmosphere inside the package would not meet the 2013 Food Code definition of reduced oxygen packaging (ROP), provided the food being packaged has NOT been heated, just prior to packaging.

The 2013 FDA Food Code defines "Reduced Oxygen Packaging" (ROP) as:

- "The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and . . . .."

A reduced oxygen environment occurs in a package when less oxygen is present in the package relative to the amount of oxygen expected to be present in the atmosphere (typically 21% at sea level). The Food Code definition of reduced oxygen packaging is limited to the intentional or purposeful methods used by food establishments to create a reduced oxygen environment within a packaged TCS food product at the time of packaging.

The packaging and sealing, without drawing a vacuum, of a TCS food that has not been heated, just prior to packaging, is not considered to be removing oxygen to the degree that you are: 1) reducing the amount of oxygen in a package at the time of packaging, or 2) using an intentional or purposeful method to create a reduced oxygen environment within a packaged TCS food product at the time of packaging.

Heat sealing a hot TCS food (which includes TCS foods cooked as specified in relevant Sections of Part 3-401 of the Food Code and TCS foods heated to hot holding temperatures) without modifying the atmosphere or drawing a vacuum raises a concern of *C. botulinum* growth in the packaged TCS food. This is because the process of cooking food drives off oxygen from the food thereby lowering the oxygen level in that food. After the bag is sealed, the oxygen level in the headspace and the oxygen level in the hot TCS food will begin to equilibrate. This results in a package with an oxygen level below what is normally found in the atmosphere, thereby creating a process that aligns with the Food Code definition of ROP.

The model Food Code is neither federal law nor federal regulation and is not preemptive. It represents FDA's best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented. The model Food Code provisions are designed to be consistent with federal food laws and regulations and are written for ease of legal adoption at all levels of government.

References:

1. 2013 FDA Food Code, 1-202.10 Statement of Application and Listing of Terms.

SGR 129

Fish and Fishery Products Hazards and Controls Guidance

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
OFFICE OF FOOD SAFETY

CHAPTER 13: **Clostridium botulinum Toxin Formation**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

UNDERSTAND THE POTENTIAL HAZARD.

Clostridium botulinum (*C. botulinum*) toxin formation can result in consumer illness and death. It is the toxin responsible for botulism. About 10 outbreaks of foodborne botulism occur annually in the United States, from all sources. Symptoms include: weakness, vertigo, double vision, difficulty in speaking, swallowing and breathing, abdominal swelling, constipation, paralysis, and death. Symptoms start from 18 hours to 36 hours after consumption. Everyone is susceptible to intoxication by *C. botulinum* toxin; only a few micrograms of the toxin can cause illness in a healthy adult. Mortality is high; without the antitoxin and respiratory support, death is likely.

This chapter covers the hazard of *C. botulinum* growth and toxin formation as a result of time and temperature abuse during processing, storage, and distribution.

- **Strategies for controlling pathogen growth**

There are a number of strategies for the control of pathogens in fish and fishery products. They include:

- Controlling the level of acidity (pH) in the product (covered by the Acidified Foods regulation, 21 CFR 114, for shelf-stable acidified products, and by this chapter for refrigerated acidified products);
- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product (covered in this chapter);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by formulation (covered in this chapter);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by drying (covered in Chapter 14);
- Controlling the introduction of pathogenic bacteria after the pasteurization process and after the cooking process performed immediately before reduced oxygen packaging (covered in Chapter 18);
- Controlling the source of molluscan shellfish and the time from exposure to air (e.g., by harvest or receding tide) to refrigeration to control pathogens from the harvest area (covered in Chapter 4);
- Managing the amount of time that food is exposed to temperatures that are favorable for pathogenic bacteria growth and toxin production (covered generally in Chapter 12; for *C. botulinum*, in this chapter; and for *Staphylococcus aureus (S. aureus)* in hydrated batter mixes, in Chapter 15);
- Killing pathogenic bacteria by cooking or pasteurization (covered in Chapter 16), or retorting (covered by the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation, 21 CFR 113 (hereinafter, the Low-Acid Canned Foods (LACF) Regulation));
- Killing pathogenic bacteria by processes that retain the raw product characteristics (covered in Chapter 17).

- **Formation of *C. botulinum* toxin**

When *C. botulinum* grows, it can produce a potent toxin, one of the most poisonous naturally occurring substances known. The toxin can be destroyed by heat (e.g., boiling for 10 minutes), but, because of its potency, you should not rely on this as a means of control.

The strains of *C. botulinum* can be divided into two groups, the proteolytic group (i.e., those that break down proteins) and the non-proteolytic group (i.e., those that do not break down proteins). The proteolytic group includes *C. botulinum* type A and some of types B and F. The non-proteolytic group includes *C. botulinum* type E and some of types B and F.

The vegetative cells of all types of *C. botulinum* are easily killed by heat. However, *C. botulinum* is able to produce spores. In this state, the pathogen is very resistant to heat. The spores of the proteolytic group are much more resistant to heat than are those of the non-proteolytic group (i.e., they require a canning process to be destroyed). Table A-4 (Appendix 4) provides guidance about the conditions under which the spores of the most heat-resistant form of non-proteolytic *C. botulinum*, type B, are killed. However, there are some indications that substances that may be naturally present in some products (e.g., dungeness crabmeat), such as lysozyme, may enable non-proteolytic *C. botulinum* to more easily recover after heat damage, resulting in the need for a considerably more stringent process to ensure destruction.

C. botulinum is able to produce toxin when a product in which it is present is exposed to temperatures favorable for growth for sufficient time. Table A-1 (Appendix 4) provides guidance about the conditions under which *C. botulinum* and other pathogenic bacteria are able to grow. Table A-2 (Appendix 4) provides guidance about the time necessary at various temperatures for toxin formation to occur.

Packaging conditions that reduce the amount of oxygen present in the package (e.g., vacuum packaging and modified atmosphere packaging) extend the shelf life of a product by inhibiting the growth of aerobic spoilage bacteria. There is a safety concern with these products because there is an increased potential for the formation of *C. botulinum* toxin before spoilage makes the product unacceptable to consumers.

C. botulinum forms toxin more rapidly at higher temperatures than at lower temperatures. The minimum temperature for growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F is 38°F (3.3°C). For type A and proteolytic types B and F, the minimum temperature for growth is 50°F (10°C). As the shelf life of refrigerated foods is increased, more time is available for *C. botulinum* growth and toxin formation. As storage temperatures increase, the time required for toxin formation is significantly shortened. You should expect that at some point during storage, distribution, display, or consumer handling of refrigerated foods, safe refrigeration temperatures will not be maintained (especially for the non-proteolytic group). Surveys of retail display cases indicate that temperatures of 45 to 50°F (7 to 10°C) are not uncommon. Surveys of home refrigerators indicate that temperatures can exceed 50°F (10°C).

In reduced oxygen packaged products in which the spores of non-proteolytic *C. botulinum* are inhibited or destroyed (e.g., smoked fish, pasteurized crabmeat, and pasteurized surimi), a normal refrigeration temperature of 40°F (4.4°C) is appropriate because it will limit the growth of proteolytic *C. botulinum* and other pathogens that may be present. Even in pasteurized products where non-proteolytic *C. botulinum* is the target organism for the pasteurization process, and vegetative pathogens, such as *Listeria monocytogenes*, are not likely to be present (e.g., pasteurized crabmeat and pasteurized surimi), a storage temperature of 40°F (4.4°C) is still appropriate because of the potential for survival through the pasteurization process and recovery of spores of non-proteolytic *C. botulinum*, aided by naturally occurring

substances, such as lysozyme. In this case, refrigeration serves as a prudent second barrier.

However, in reduced oxygen packaged products in which refrigeration is the sole barrier to outgrowth of non-proteolytic *C. botulinum* and the spores have not been destroyed (e.g., vacuum-packaged refrigerated raw fish, vacuum-packaged refrigerated unpasteurized crayfish meat, and reduced oxygen packaged unpasteurized dungeness crabmeat), the temperature should be maintained below 38°F (3.3°C) from packing to consumption. Ordinarily you, as a processor, can ensure that temperatures are maintained below 38°F (3.3°C) while the product is in your control. However, the current U.S. food distribution system does not ensure the maintenance of these temperatures after the product leaves your control.

The use of a Time-Temperature Indicator (TTI) on each consumer package may be an appropriate means of overcoming these problems in the distribution system for reduced oxygen packaged products in which refrigeration is the sole barrier to outgrowth of non-proteolytic *C. botulinum* and in which the spores have not been destroyed. A TTI is a device that monitors the time and temperature of exposure of the package and alerts the consumer or end user if a safe exposure limit has been exceeded. If a TTI is used, it should be validated to ensure that it is fit for its intended purpose and verified that it is functional at the time of use. It should be designed to alert the consumer (e.g., a color change) that an unsafe time and temperature exposure has occurred that may result in *C. botulinum* toxin formation. Additionally, the alert should remain perpetually visible after it has been triggered, regardless of environmental conditions that could reasonably be expected to occur thereafter. Skinner, G. E., and J. W. Larkin in "Conservative prediction of time to *Clostridium botulinum* toxin formation for use with time-temperature indicators to ensure the safety of foods," Journal of Food Protection, 61:1154-1160 (1998), describe a safe time and temperature exposure curve ("Skinner-Larkin curve") that may be useful in evaluating the suitability of a TTI for control of *C. botulinum* toxin formation in reduced oxygen packaged fish and fishery products.

Alternatively, products of this type may be safely marketed frozen, with appropriate labeling to ensure that it is held frozen throughout distribution. For some reduced oxygen packaged products, control of *C. botulinum* can be achieved by breaking the vacuum seal before the product leaves the processor's control.

The guidance in this chapter emphasizes preventive measures for the control of non-proteolytic strains of *C. botulinum* in products that are contained in reduced oxygen packaging. As was previously described, this emphasis is because such an environment extends the shelf life of a refrigerated product in a way that, under moderate temperature abuse, favors *C. botulinum* growth and toxin formation over aerobic spoilage. It is also possible for both non-proteolytic and proteolytic *C. botulinum* to grow and produce toxin in a product that is not reduced oxygen packaged and is subjected to severe temperature abuse. This is the case because of the development within the product of microenvironments that support its growth. However, this type of severe temperature abuse of refrigerated products is not reasonably likely to occur in the processing environment of most fish or fishery products and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulation, 21 CFR 110, requires refrigeration of foods that support the growth of pathogenic microorganisms.

- **Sources of *C. botulinum***

C. botulinum can enter the process on raw materials. The spores of *C. botulinum* are very common. They have been found in the gills and viscera of finfish, crabs, and shellfish. *C. botulinum* type E is the most common form found in freshwater and marine environments. Types A and B are generally found on land but may also be occasionally found in water. It should be assumed that *C. botulinum* will be present in any raw fishery product, particularly in the viscera.

Because spores are known to be present in the viscera, any product that will be preserved by salting, drying, pickling, or fermentation should be eviscerated prior to processing (see the "Compliance Policy Guide," Sec. 540.650). Without evisceration, toxin formation is possible during the process, even with strict control of temperature. Evisceration of fish is the careful and complete removal of all internal organs in the body cavity without puncturing or cutting them, including gonads. If even a portion of the viscera or its contents is left behind, the risk of toxin formation by *C. botulinum* remains. Uneviscerated small fish, less than 5 inches in length (e.g., anchovies and herring sprats), for which processing eliminates preformed toxin, prevents toxin formation during processing and that reach a water phase salt content of 10% in refrigerated finished products, or a water activity of below 0.85 in shelf-stable finished products, or a pH of 4.6 or less in shelf-stable finished products, are not subject to the evisceration recommendation.

Note: The water phase salt content of 10% is based on the control of *C. botulinum* type A and proteolytic types B and F.

Note: The water activity value of below 0.85 is based on the minimum water activity for toxin production of *S. aureus*.

- **Reduced oxygen packaging**

A number of conditions can result in the creation of a reduced oxygen environment in packaged fish and fishery products. They include:

- Vacuum, modified, or controlled atmosphere packaging. These packaging methods generally directly reduce the amount of oxygen in the package;
- Packaging in hermetically sealed containers (e.g., double-seamed cans, glass jars with sealed lids, and heat-sealed plastic containers), or packing in deep containers from which the air is expressed (e.g., caviar in large containers), or packing in oil. These and similar processing and packaging techniques prevent the entry of oxygen into the container. Any oxygen present at the time of packaging (including oxygen that may be added during modified atmosphere packaging) may be rapidly depleted by the activity of spoilage bacteria, resulting in the formation of a reduced oxygen environment.

Packaging that provides an oxygen transmission rate (in the final package) of at least 10,000 cc/m^2/24 hours at 24ºC can be regarded as an oxygen-permeable packaging material for fishery products. The oxygen transmission rate of packaging material is listed in the packaging specifications that can be obtained from the packaging manufacturer.

An oxygen-permeable package should provide sufficient exchange of oxygen to allow aerobic spoilage organisms to grow and spoil the product before toxin is produced under moderate abuse temperatures. Particular care should be taken in determining the safety of a packaging material for a product in which the spoilage organisms have been eliminated or significantly reduced by processes such as high pressure processing. The generally recommended 10,000 cc/m^2/24 hours at 24ºC transmission rate may not be suitable in this case.

Use of an oxygen-permeable package may not compensate for the restriction to oxygen exchange created by practices such as packing in oil or in deep containers from which the air is expressed or the use of oxygen scavengers in the packaging.

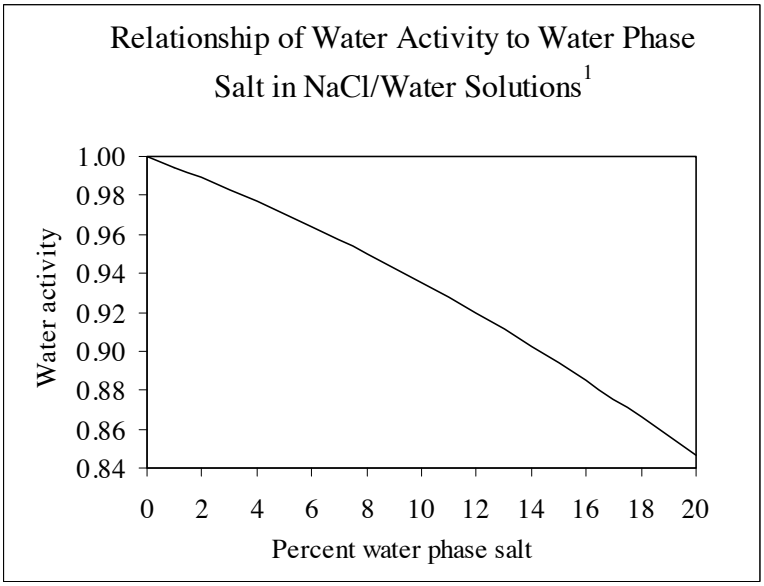
- **Control of *C. botulinum***

There are a number of strategies to prevent *C. botulinum* growth and toxin formation during processing, storage, and distribution of finished fish and fishery products. They include:

For products that do not require refrigeration (i.e., shelf-stable products):

- Heating the finished product in its final container sufficiently by retorting to destroy the spores of *C. botulinum* types A B, E, and F (e.g., canned fish). This strategy is covered by the LACF Regulation, 21 CFR 113, and these controls are not required to be included in your Hazard Analysis Critical Control Point (HACCP) plan;

- Controlling the level of acidity (pH) in the finished product to 4.6 or below, to prevent growth and toxin formation by *C. botulinum* types A, B, E, and F (e.g., shelf-stable acidified products). This strategy is covered by the Acidified Foods regulation, 21 CFR 114, and these controls are not required to be included in your HACCP plan;
- Controlling the amount of moisture that is available in the product (water activity) to 0.85 or below by drying, to prevent growth and toxin formation by *C. botulinum* types A, B, E, and F and other pathogens that may be present in the product (e.g., shelf-stable dried products). This strategy is covered by Chapter 14;
- Controlling the amount of salt in the product to 20% water phase salt (wps) or more, to prevent the growth of *C. botulinum* types A, B, E, and F and other pathogens that may be present in the product (e.g., shelf-stable salted products). This strategy is covered in this chapter. Water phase salt is the concentration of salt in the water-portion of the fish flesh and calculated as follows: (% NaCl X 100)/(% NaCl + % moisture) = % NaCl in water phase. The relationship between percent water phase salt and water activity in fish is described in the following graph.



1. This relationship is generally valid for fish products when salt (sodium chloride) is the primary means of binding water. The specific food matrix and the use of other salts or water binding agents could affect the exact relationship. If you intend to use this relationship in your control strategy, you should determine the exact relationship in your product by conducting a study.

For products that require refrigeration:

- Heating the finished product in its final container sufficiently by pasteurization to destroy the spores of *C. botulinum* type E and non-proteolytic types B and F, and then minimizing the risk of recontamination by controlling seam closures and cooling water, and next controlling the growth of the surviving *C. botulinum* type A and proteolytic types B and F in the finished product with refrigerated storage (e.g.. pasteurized crabmeat and some pasteurized surimi-based products). Pasteurization is covered in Chapter 16, controlling recontamination after pasteurization is covered in Chapter 18, and controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter;
- Heating the product sufficiently to destroy the spores of *C. botulinum* type E and non-proteolytic types B and F, and then minimizing the risk of recontamination by hot filling the product into the final container in a sanitary, continuous, closed filling system and controlling seam closures and cooling water, and next controlling the growth of the surviving *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product with refrigerated storage (e.g., vacuum packed soups, chowders, and sauces). Specialized cooking processes are covered in Chapter 16, prevention of recontamination after specialized cooking processes is covered in Chapter 18, controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12;
- Controlling the amount of moisture that is available in the product (water activity) to 0.97 or below to inhibit the growth of *C. botulinum* type E and non-proteolytic types B and F by drying, and then controlling the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product through refrigerated storage (e.g., refrigerated dried fish). Drying is covered in Chapter 14, controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12;
- Controlling the level of pH to 5 or below, salt to 5% wps or more, moisture (water activity) to 0.97 or below, or some combination of these barriers, in the finished product sufficiently to prevent the growth of *C. botulinum* type E and non-proteolytic types B and F by formulation, and then controlling the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product with refrigerated storage (e.g., refrigerated acidified (pickled) products). Controlling the growth of non-proteolytic *C. botulinum* through formulation is covered in this chapter, controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12;
- Controlling the amount of salt and preservatives, such as sodium nitrite, in the finished product, in combination with other barriers, such as smoke, heat damage, and competitive bacteria, sufficiently to prevent the growth of *C. botulinum* type E and non-proteolytic types B and F, and then controlling the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product with refrigerated storage (e.g., salted, smoked, or smoke-flavored fish). Controlling the growth of non-proteolytic *C. botulinum* through salting and smoking is covered in this chapter, controlling the growth of proteolytic *C. botulinum* through

refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12;

- Controlling the amount of salt in the finished product, in combination with heat damage from pasteurization in the finished product container, sufficiently to prevent the growth of *C. botulinum* type E and nonproteolytic types B and F, and then controlling the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in the finished product with refrigerated storage (e.g., some pasteurized surimi-based products). Controlling the growth of non-proteolytic *C. botulinum* through a combination of salt and heat damage is covered in this chapter, controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12.

Examples of *C. botulinum* control in specific products:

- **Refrigerated (not frozen), reduced oxygen packaged smoked and smoke-flavored fish**

  Achieving the proper concentration of salt and nitrite in the flesh of refrigerated, reduced oxygen packaged smoked and smoke-flavored fish is necessary to prevent the formation of toxin by *C. botulinum* type E and non-proteolytic types B and F during storage and distribution. Salt works along with smoke and any nitrites that are added to prevent growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F. Note that nitrites should be used only in salmon, sable, shad, chubs, and tuna, according to 21 CFR 172.175 and 21 CFR 172.177 , and should not exceed a level of 200 ppm in salmon, sable, shad, chubs and 10 ppm in tuna.

  In hot-smoked products, heat damage to the spores of *C. botulinum* type E and non-proteolytic types B and F also helps prevent toxin formation. In these products, control of the heating process is critical to the safety of the finished product. It is important to note, however, that this same heating process also reduces the numbers of naturally occurring spoilage organisms. The spoilage organisms would otherwise have competed with, and inhibited the growth of, *C. botulinum*.

  In cold-smoked fish, it is important that the product does not receive so much heat that the numbers of spoilage organisms are significantly reduced. This is important because spoilage organisms must be present to inhibit the growth and toxin formation of *C. botulinum* type E and non-proteolytic types B and F. This inhibition is important in cold-smoked fish because the heat applied during this process is not adequate to weaken the *C. botulinum* spores. Control of the temperature during the cold-smoking process to ensure survival of the spoilage organisms is, therefore, critical to the safety of the finished product.

  The interplay of these inhibitory effects (i.e., salt, temperature, smoke, and nitrite) is complex. Control of the brining or dry salting process is clearly critical to ensure that there is sufficient salt in the finished product. However, preventing toxin formation by *C. botulinum* type E and non-proteolytic types B and F is made even more complex by the fact that adequate salt levels are not usually achieved during brining. Proper drying during smoking is also critical in order to achieve the finished product water phase salt level (i.e., the concentration of salt in the water portion of the fish flesh) needed to inhibit growth and toxin formation by *C. botulinum*.

  This chapter covers the control procedures described above.

You should ordinarily restrict brining, dry salting, and smoking loads to single species and to fish portions of approximately uniform size. This restriction minimizes the complexity of controlling the operation. You should treat brine to minimize microbial contamination or periodically replace it as a good manufacturing practice control.

The combination of inhibitory effects that are present in smoked and smoke-flavored fish are not adequate to prevent toxin formation by *C. botulinum* type A and proteolytic types B and F. Strict refrigeration control (i.e., at or below 40°F (4.4°C)) during storage and distribution should be maintained to prevent growth and toxin formation by *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in these products. Controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the growth of other pathogenic bacteria through refrigeration is covered in Chapter 12.

- **Refrigerated (not frozen), reduced oxygen packaged, pasteurized fishery products**

  Refrigerated, reduced oxygen packaged, pasteurized fishery products fall into two categories: (1) those which are pasteurized in the final container; and (2) those which are cooked in a kettle and then hot filled into the final container in a continuous, closed filling system (e.g., heat-and-fill soups, chowders, and sauces). In both cases, ordinarily the heating process should be sufficient to destroy the spores of *C. botulinum* type E and non-proteolytic types B and F. In neither case is it likely that the heating process will be sufficient to destroy the spores of *C. botulinum* type A and proteolytic types B and F. Therefore, strict refrigeration control (i.e., at or below 40°F (4.4°C)) should be maintained during storage and distribution to prevent growth and toxin formation by *C. botulinum* type A and proteolytic types B and F. Refrigeration also serves as a prudent second barrier because of the potential survival through the pasteurization process and recovery of spores of non-proteolytic *C. botulinum*, aided by naturally occurring substances, such as lysozyme. Cooking and pasteurization are covered in Chapter 16, and controlling the growth of *C. botulinum* through refrigeration is covered in this chapter.

  In the second category of products, filling the product into the final container while it is still hot in a continuous, closed filling system (i.e., hot filling) is also critical to the safety of the finished product because it minimizes the risk of recontamination of the product with pathogens, including *C. botulinum* type E and non-proteolytic types B and F. This control strategy applies to products such as soups, chowders, and sauces that are filled directly from the cooking kettle, where the risk of recontamination is minimized. It may not apply to products such as crabmeat, lobster meat, or crayfish meat or to other products that are handled between cooking and filling. Control of hot filling is covered in Chapter 18.

  Chapter 18 also covers other controls that may be necessary to prevent recontamination, including controlling container sealing and controlling contamination of container cooling water. These controls may be critical to the safety of both categories of products.

  Examples of properly pasteurized products follow: fish and fishery products generally (e.g., surimi-based products, soups, or sauces) pasteurized to a minimum cumulative total lethality of $F_{194°F}$ ($F_{90°C}$) = 10 minutes, where z = 12.6°F (7°C) for temperatures less than 194°F (90°C), and z = 18°F (10°C) for temperatures above 194°F (90°C); blue crabmeat pasteurized to a minimum cumulative total lethality of $F_{185°F}$ ($F_{85°C}$) = 31 minutes, where z = 16°F (9°C); and dungeness crabmeat pasteurized to a minimum cumulative total lethality of $F_{194°F}$ ($F_{90°C}$) = 57 minutes, where z = 15.5°F

(8.6°C). Equivalent processes at different temperatures can be calculated using the z values provided.

EXAMPLES OF PROPERLY PASTEURIZED PRODUCTS

PRODUCT	MINIMUM CUMULATIVE TOTAL LETHALITY	Z VALUE
Fish and fishery products generally (e.g., surimi-based products, soups, or sauces)	$F_{194°F}$ ($F_{90°C}$) = 10 minutes	12.6°F (7°C), for temperatures less than 194°F (90°C) 18°F (10°C) for temperatures above 194°F (90°C)
Blue crabmeat	$F_{185°F}$ ($F_{85°C}$) = 31 minutes	16°F (9°C)
Dungeness crabmeat	$F_{194°F}$ ($F_{90°C}$) = 57 minutes	15.5°F (8.6°C)

In some pasteurized surimi-based products, salt, in combination with a milder pasteurization process, in the finished product container works to prevent growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F. An example of a properly pasteurized surimi-based product in which 2.4% wps is present is one that has been pasteurized at an internal temperature of 185°F (85°C) for at least 15 minutes. This process may not be suitable for other types of products because of the unique formulation and processing involved in the manufacture of surimi-based products.

- **Refrigerated (not frozen), reduced oxygen packaged pickled fish, salted fish, caviar, and similar products**

  In pickled fish, salted fish, caviar, and similar products that have not been preserved sufficiently for them to be shelf stable, growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F is controlled by one of the following:

  - Adding sufficient salt to produce a water phase salt level (i.e., the concentration of salt in the water portion of the fish flesh) of at least 5%;
  - Adding sufficient acid to reduce the acidity (pH) to 5.0 or below;
  - Reducing the amount of moisture that is available for growth (water activity) to below 0.97 (e.g., by adding salt or other substances that "bind" the available water); or
  - Making a combination of salt, pH, and/or water activity adjustments that, when combined, prevents the growth of *C. botulinum* type E and non-proteolytic types B and F (to be established by a scientific study).

  Much like smoked products, in some of these products the interplay of these inhibitory effects (i.e., salt, water activity, and pH) can be complex. Control of the brining, pickling, or formulation steps is, therefore, critical to ensure that there are sufficient barriers in the finished product to prevent the growth and toxin formation of *C. botulinum* type E and non-proteolytic types B and F during storage and distribution. These control procedures are covered in this chapter.

  You should ordinarily restrict brining and pickling loads to single species and to fish portions of approximately uniform size. This restriction minimizes the complexity of controlling the operation. You should treat brine to minimize microbial contamination or periodically replace it as a good manufacturing practice control.

  The controls discussed above are not sufficient to prevent toxin formation by *C. botulinum* type A and proteolytic types B and F. Strict refrigeration control (i.e., at or below 40°F (4.4°C)) during storage and distribution should, therefore, be maintained to prevent growth and toxin formation by *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present in these products. Controlling the growth of proteolytic *C. botulinum* through refrigeration is covered in this chapter, and controlling the

growth of other pathogenic bacteria through refrigeration is covered in Chapter 12.

- **Refrigerated (not frozen), reduced oxygen packaged raw, unpreserved fish and unpasteurized, cooked fishery products**

  For refrigerated, reduced oxygen packaged raw, unpreserved fish (e.g., refrigerated, vacuum-packaged fish fillets) and refrigerated, reduced oxygen packaged, unpasteurized, cooked fishery products (e.g., refrigerated, vacuum-packaged, unpasteurized crabmeat, lobster meat, or crayfish meat), the sole barrier to toxin formation by *C. botulinum* type E and non-proteolytic types B and F during finished product storage and distribution is refrigeration. These types of *C. botulinum* will grow at temperatures as low as 38°F (3.3°C). As was previously noted, maintenance of temperatures below 38°F (3.3°C) after the product leaves your control and enters the distribution system cannot normally be ensured. The use of a TTI on the smallest unit of packaging (i.e., the unit of packaging that will not be distributed any further, usually consumer or end-user package) may be an appropriate means of overcoming these problems in the distribution system. This chapter provides controls for the application of TTIs for packaging.

  If you intend to package these products in a reduced oxygen package and you do not intend to apply a TTI on each consumer package, you should evaluate the effectiveness of other preventive measures, either singularly, or in combination, that may be effective in preventing growth and toxin formation by *C. botulinum*. Such evaluation is customarily accomplished by conducting an inoculated pack study under moderate abuse conditions. A suitable protocol for the performance of such studies is contained in a 1992 publication by the National Advisory Committee on Microbiological Criteria for Foods, "Vacuum or modified atmosphere packaging for refrigerated, raw fishery products."

- **Frozen, reduced oxygen packaged raw, unpreserved fish and unpasteurized, cooked fishery products**

  For frozen, reduced oxygen packaged raw, unpreserved fish (e.g., frozen, vacuum-packaged fish fillets) and frozen, reduced oxygen packaged, unpasteurized, cooked fishery products (e.g., frozen, vacuum-packaged, unpasteurized crabmeat, lobster meat, or crayfish meat), the sole barrier to toxin formation by *C. botulinum* type E and non-proteolytic types B and F during finished product storage and distribution is freezing. Because these products may appear to the retailer, consumer, or end user to be intended to be refrigerated, rather than frozen, labeling to ensure that they are held frozen throughout distribution is critical to their safety.

  Controls should be in place to ensure that such products are immediately frozen after processing, maintained frozen throughout storage in your facility, and labeled to be held frozen and to be thawed under refrigeration immediately before use (e.g., "Important, keep frozen until used, thaw under refrigeration immediately before use"). Frozen, reduced oxygen packaged products that are customarily cooked by the consumer or end user in the frozen state (e.g., boil-in-bag products and frozen fish sticks) need not be labeled to be thawed under refrigeration. For purposes of hazard analysis, other frozen products that do not contain the "keep frozen" statement should be evaluated as if they will be stored refrigerated because the consumer or end user would not have been warned to keep them frozen.

  Control procedures to ensure that product is properly labeled with "keep frozen" instructions are covered in this chapter.

- **Control in unrefrigerated (shelf-stable), reduced oxygen packaged fishery products**

  Examples of shelf-stable, reduced oxygen packaged fishery products are dried fish, acidified fish, canned fish, and salted fish. Because these products are marketed without refrigeration, either (1) the spores of *C. botulinum* types A, B, E, and F should be destroyed after the product is placed in the finished product container (covered by the LACF Regulation, 21 CFR 113) or (2) a barrier, or combination of barriers, should be in place that will prevent growth and toxin formation by *C. botulinum* types A, B, E, and F, and other pathogens that may be present in the product. Suitable barriers include:

  - Adding sufficient salt to produce a water phase salt level (i.e., the concentration of salt in the water portion of the fish flesh) of at least 20%. Note that this value is based on the maximum salt level for growth of *S. aureus*, covered in this chapter;
  - Reducing the amount of moisture that is available for growth (water activity) to below 0.85 (e.g., by adding salt or other substances that bind the available water). Note that this value is based on the minimum water activity for growth and toxin formation of *S. aureus*, covered in this chapter;
  - Adding sufficient acid to reduce the pH to 4.6 or below. This barrier is covered by the Acidified Foods regulation, 21 CFR 114, and these controls are not required to be included in your HACCP plan;
  - Drying the product sufficiently to reduce the water activity to 0.85 or below. Note that this value is based on the minimum water activity for growth and toxin formation of *S. aureus*, covered in Chapter 14.

  Note: A heat treatment, addition of chemical additives, or other treatment may be necessary to inhibit or eliminate spoilage organisms (e.g., mold) in shelf-stable products.

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether *C. botulinum* toxin formation is a significant hazard at a processing step:

1. Is it reasonably likely that *C. botulinum* will grow and produce toxin during finished product storage and distribution?

   The factors that make *C. botulinum* toxin formation during finished product storage and distribution reasonably likely to occur are those that may result in the formation of a reduced oxygen packaging environment. These are discussed in the section "Understand the potential hazard," under the heading, "Reduced oxygen packaging."

2. Can growth and toxin formation by *C. botulinum* that is reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step?

   C. botulinum toxin formation should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur.

   Preventive measures for *C. botulinum* toxin formation during finished product distribution and storage are discussed in the section, "Understand the potential hazard," under the heading, "Control of *C. botulinum*."

- **Intended use**

Because of the extremely toxic nature of *C. botulinum* toxin, it is unlikely that the significance of the hazard will be affected by the intended use of your product.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for *C. botulinum* toxin formation:

1. Is there an acidification step (equilibrium pH of 4.6 or below), a drying step, an in-package pasteurization step, a combination of cook and hot-fill steps, or a retorting step (commercial sterility) in the process?

    a. If there is, you should in most cases identify the acidification step, drying step, pasteurization step, cook and hot-fill steps, or retorting step as the CCP(s) for this hazard. Other processing steps where you have identified *C. botulinum* toxin formation as a significant hazard will then not require control and will not need to be identified as CCPs for the hazard. However, control should be provided for time and temperature exposure during finished product storage and distribution of the following products:

    - Products pasteurized in the final container to kill *C. botulinum* type E and non-proteolytic types B and F and refrigerated to control the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present (e.g., pasteurized crabmeat and pasteurized surimi);
    - Products cooked to kill *C. botulinum* type E and non-proteolytic types B and F, and then hot filled into the final container, and next refrigerated to control the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present;
    - Products dried to control the growth of *C. botulinum* type E and non-proteolytic types B and F and refrigerated to control the growth of *C. botulinum* type A and proteolytic types B and F and other pathogens that may be present.

In these cases, you should also identify the finished product storage step as a CCP for the hazard. Control of refrigeration is covered in this chapter for *C. botulinum* and in Chapter 12 for other pathogenic bacteria.

Additionally, some pasteurized surimi-based products rely on a combination of salt and a relatively mild pasteurization process in the finished product container for the control of *C. botulinum* type E and non-proteolytic types B and F. In these products, you should also identify the formulation step as a CCP for the hazard. Guidance provided in "Control Strategy Example 4 - Pickling and Salting" may be useful in developing controls at this step.

Guidance for the *C. botulinum* control strategies listed above is contained in the following locations:

- Control of cooking and hot-filling is covered in Chapters 16 and 18;
- Control of pasteurization is covered in Chapters 16 and 18;
- Control of drying is covered in Chapter 14;
- Control of acidification is covered in the Acidified Foods regulation, 21 CFR 114;
- Control of retorting is covered in the LACF Regulation, 21 CFR 113.

Note: Acidification and retorting controls for *C. botulinum* required by 21 CFRs 113 and 114 need not be included in your HACCP plan.

b. If there is no acidification step (equilibrium pH of 4.6 or below), drying step, pasteurization step, cooking and hot-filling, or retorting (commercial sterility) step in the process, then decide which of the following categories best describes your product and refer to the guidance below:

- Smoked and smoke-flavored fish;
- Fishery products in which refrigeration is the sole barrier to prevent toxin formation;
- Fishery products in which freezing is the sole barrier to toxin formation;
- Pickled fish and similar products.

- **Smoked and smoke-flavored fish**

1. Is the water phase salt level and, when permitted, the nitrite level, important to the safety of the product?

   For all products in this category, the water phase salt level is critical to the safety of the product, and the brining, dry salting and, where applicable, drying steps should be identified as CCPs. Nitrite, when permitted, allows a lower level of salt to be used. Salt and nitrite are the principal inhibitors to *C. botulinum* type E and non-proteolytic types B and F toxin formation in these products. The water phase salt level needed to inhibit toxin formation is partially achieved during brining or dry salting and is partially achieved during drying. Control should be exercised over both operations.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Smoking (1a - Brining, Dry Salting, and Drying)."

2. Is the temperature of the heating or smoking process important to the safety of the product?

   For both cold-smoked and hot-smoked fish products, the temperature of smoking is critical, and the smoking step should be identified as a CCP for this hazard. The smoking step for hot-smoked fish should be sufficient to damage the spores and make them more susceptible to inhibition by salt. The smoking step for cold-smoked fish should not be so severe that it kills the natural spoilage bacteria. These bacteria are necessary so that the product will spoil before toxin production occurs. It is likely that they will also produce acid, which will further inhibit *C. botulinum* growth and toxin formation.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Smoking (1b - Cold Smoking and 1c - Hot Smoking)."

3. Is the storage temperature important to the safety of the product?

   Refrigerated (not frozen) finished product storage is critical to the safety of all products in this category and should be identified as a CCP. Toxin formation by *C. botulinum* type A and proteolytic types B and F is not inhibited by water phase salt levels below 10%, nor by the combination of inhibitors present in most smoked or smoke-flavored fish. *Bacillus cereus* can grow and form toxin at water phase salt concentrations as high as 18%.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Smoking (1d - Refrigerated Finished Product Storage)."

   In some cases, salted, smoked, or smoke-flavored fish are received as ingredients for assembly into another product, such as a salmon paté. In other cases, they are received simply for storage and further distribution (e.g., by a warehouse). In either case, the refrigerated (not frozen) storage step is critical to the safety of the product and should be identified as a CCP. Control is the same as that provided under "Control Strategy Example 1 - Smoking (1d - Refrigerated

Finished Product Storage)." Additionally, receiving of these products should be identified as a CCP, where control can be exercised over the time and temperature during transit.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Smoking (1e - Receipt of Products by Secondary Processor)."

- **Fishery products in which refrigeration is the sole barrier to prevent toxin formation**

1. Is the storage temperature important to the safety of the product?

Refrigerated finished product storage is critical to the safety of all products in this category and should be identified as a CCP. These products contain no barriers (other than refrigeration) to toxin formation by *C. botulinum* type E and non-proteolytic types B and F during finished product storage and distribution. These types of *C. botulinum* will grow at temperatures as low as 38°F (3.3°C), necessitating particularly stringent temperature control.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 2 - Refrigeration With TTI (2d - Refrigerated Finished Product Storage)."

In some cases, these products are received as ingredients for assembly into another product. In other cases, they are received simply for storage and further distribution (e.g., by a warehouse). In either case, the refrigerated storage step is critical to the safety of the product and should be identified as a CCP. Control is the same as that provided under "Control Strategy Example 2 - Refrigeration With a TTI (2d - Refrigerated Finished Product Storage)." Additionally, receiving of these products should be identified as a CCP, where control can be exercised over the time and temperature during transit.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 2 - Refrigeration With a TTI (2e - Receipt of Product by Secondary Processor)."

As previously noted, maintenance of temperatures below 38°F (3.3°C) after the product leaves your control and enters the distribution system cannot normally be ensured. The use of a TTI on the smallest unit of packaging (i.e., the unit of packaging that will not be distributed any further, usually consumer or end-user package) may be an appropriate means of overcoming these problems in the distribution system. When TTIs are used in this manner, their receipt, storage, and application and activation should be identified as CCPs.

This control approach is a control strategy referred to as "Control Strategy Example 2 - Refrigeration With TTI (2a - Unactivated TTI Receipt, 2b - Unactivated TTI Storage, and 2c - Application and Activation of TTI)."

- **Fishery products in which freezing is the sole barrier to toxin formation**

1. Is the storage temperature important to the safety of the product?

Frozen finished product storage is critical to the safety of all products in this category. These products contain no barriers (other than freezing) to toxin formation by *C. botulinum* type E and non-proteolytic types B and F during finished product storage and distribution. As previously noted, because these products may appear to the retailer, consumer, or end user to be intended to be refrigerated, rather than frozen, labeling to ensure that they are held frozen throughout distribution is critical to their safety and should be identified as a CCP.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 3 - Frozen With Labeling."

- **Pickled and salted fish and similar products**

1. Is the water phase salt level, water activity, and/or pH level important to the safety of the product?

   For all products in this category, the water phase salt level, water activity, and/or pH level are critical to the safety of the product because they are the principal inhibitors to growth and toxin formation by *C. botulinum* type E and non-proteolytic type B and F. The levels of these inhibitors needed to inhibit toxin formation are achieved during the pickling, brining, or formulation step. Control should be exercised over the relevant step.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 4 - Pickling and Salting (4a - Brining, Pickling, Salting, and Formulation)."

2. Is the storage temperature important to the safety of the product?

   Unless pickling, brining, or formulation results in a water phase salt level of at least 20% (note that this value is based on the maximum salt concentration for growth of *S. aureus*), a pH of 4.6 or below, or a water activity of 0.85 or below (note that this value is based on the minimum water activity for growth of *S. aureus*), refrigerated finished product storage is critical to ensure the safety of the product and should be identified as a CCP.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 4 - Pickling and Salting (4b - Refrigerated Finished Product Storage)."

   In some cases, pickled fish or similar products are received as ingredients for assembly into another product. In other cases, they are received simply for storage and further distribution (e.g., by a warehouse). In either case, the refrigerated storage step is critical to the safety of the product and should be identified as a CCP. Control is the same as that provided under "Control Strategy Example 4 - Pickling and Salting (4b - Refrigerated Finished Product Storage)." Additionally, receiving of these products should be identified as a CCP, where control can be exercised over time and temperature during transit.

   This control approach is a control strategy referred to in this chapter as "Control Strategy Example 4 - Pickling and Salting (4c - Receipt of Product by Secondary Processor)."

DEVELOP A CONTROL STRATEGY.

The following guidance provides four control strategies for *C. botulinum* toxin formation. You may select a control strategy that is different from those which are suggested, provided it complies with the requirements of the applicable food safety laws and regulations. Control strategies contain several elements that may need to be used in combination to result in an effective control program.

The following are examples of control strategies included in this chapter:

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Smoking	✓	✓
Refrigeration with TTI	✓	✓
Frozen with labeling	✓	✓
Pickling and salting	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 - SMOKING**

This control strategy should include the following elements, as appropriate:

a. Brining, dry salting, and drying;

b. Cold smoking;

c. Hot smoking;

d. Refrigerated finished product storage;

e. Receipt of products by secondary processor.

1A. BRINING, DRY SALTING, AND DRYING

Set Critical Limits.

- The minimum or maximum values for the critical factors of the brining, dry salting, and/or drying processes established by a scientific study. The critical factors are those that are necessary to ensure that the finished product has not less than 3.5% wps or, where permitted, the combination of 3% wps and not less than 100 ppm nitrite. The critical factors may include: brine strength; brine to fish ratio; brining time; brining temperature; thickness, texture, fat content, quality, and species of fish; drying time; input/output air temperature, humidity, and velocity; smoke density; and drier loading.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The critical factors of the established brining, dry salting, and/or drying processes. These may include: brine strength; brine to fish ratio; brining time; brining temperature; thickness, texture, fat content, quality, and species of fish; drying time; input/output air temperature, humidity, and velocity; smoke density; and drier loading;

  OR

- The water phase salt and, where appropriate, nitrite level of the finished product.

» **How Will Monitoring Be Done?**

- For monitoring critical factors:
  - Monitor brine strength with a salinometer;

    AND

  - Monitor brine time with a clock;

    AND

  - Monitor brine temperature using:
    - A temperature-indicating device (e.g., a thermometer);

      OR

    - Monitor brine temperature at the start of the brining process with a temperature- indicating device (e.g., a thermometer), and then monitor ambient air temperature using a continuous temperature-recording device (e.g., a recording thermometer);

      AND

  - Monitor the drying time and the input/output air temperature (as specified by the study) using a continuous temperature-recording device (e.g., a recording thermometer);

    AND

  - Monitor all other critical factors specified by the study with equipment appropriate for the measurement;

  OR

- Collect a representative sample of the finished product and conduct water phase salt analysis and, when appropriate, nitrite analysis.

» **How Often Will Monitoring Be Done (Frequency)?**

- For brine strength:
  - At least at the start of the brining process;

  AND

- For brine time:
  - Once per batch;

  AND

- For manual brine temperature monitoring:
  - At the start of the brining process and at least every 2 hours thereafter;

  AND

- For continuous temperature-recording devices:
  - Continuous monitoring by the device itself, with a visual check of the recorded data at least once per batch;

AND

- For brine to fish ratio:
  - At the start of the brining process;

AND

- For time requirements of the drying process:
  - Each batch;

AND

- For all other critical factors specified by the study:
  - As often as necessary to maintain control;

OR

- For water phase salt and, when appropriate, nitrite:
  - Each lot or batch of finished product.

» **Who Will Do the Monitoring?**

- For continuous temperature-recording devices:
  - Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have been met consistently, may be performed by any person who has an understanding of the nature of the controls;

OR

- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Chill and hold the product until its safety can be evaluated;

OR

- Reprocess the product;

OR

- Divert the product to a use in which the critical limit is not applicable (e.g., packaging that is not hermetically sealed, or an LACF, or a frozen product);

OR

- Destroy the product;

OR

- Divert the product to a non-food use.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Adjust the salt and/or nitrite concentration in the brine;

OR

- Adjust the air velocity or input air temperature to the drying chamber;

OR

- Extend the drying process to compensate for a reduced air velocity or temperature or elevated humidity;

OR

- Adjust the brine strength or brine to fish ratio;

OR

- Cool the brine;

OR

- Move some or all of the product to another drying chamber;

OR

- Make repairs or adjustments to the drying chamber as necessary.

Establish a Recordkeeping System.

- Printouts, charts, or readings from continuous temperature-recording devices;

AND

- Record of visual checks of recorded data;

AND

- Appropriate records (e.g., processing record showing the results of the brine strength and temperature, brine to fish ratio, size

and species of fish, and time of brining) as necessary to document the monitoring of the critical factors of the brining, dry salting, and/or drying process, as established by a study;

OR

- Results of the finished product water phase salt determination and, when appropriate, nitrite determination.

Establish Verification Procedures.

- Process validation study (except where water phase salt analysis and, where appropriate, nitrite analysis of the finished product are the monitoring procedure):
    - The adequacy of the brining, dry salting, and drying processes should be established by a scientific study. It should be designed to consistently achieve a water phase salt level of 3.5% or 3% with not less than 100 ppm nitrite. Expert knowledge of salting and/or drying processes may be required to establish such a process. Such knowledge can be obtained by education or experience, or both. Process validation study for establishment of brining, dry salting, and drying processes may require access to adequate facilities and the application of recognized methods. The drying equipment should be designed, operated, and maintained to deliver the established drying process to every unit of product. In some instances, brining, dry salting, and/or drying studies may be required to establish minimum processes. In other instances, existing literature, which establishes minimum processes or adequacy of equipment, is available. Characteristics of the process, product, and/or equipment that affect the ability of the established minimum salting, dry salting, and drying process to deliver the desired finished product water phase salt and, where applicable, nitrite levels should be taken into consideration in the process establishment. A record of the process establishment should be maintained;

AND

- Before a temperature-indicating device (e.g., a thermometer) or temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
    - Immersing the sensor in an ice slurry (32°F (0°C)), if the device will be used at or near refrigeration temperature;

      OR
    - Immersing the sensor in boiling water (212°F (100°C)) if the device will be used at or near the boiling point. Note that the temperature should be adjusted to compensate for altitude, when necessary;

      OR
    - Doing a combination of the above if the device will be used at or near room temperature;

      OR
    - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a thermometer traceable to National Institute of Standards and Technology (NIST) standards) under conditions that are similar to how it will be used (e.g., air temperature, brine temperature, product internal temperature) within the temperature range at which it will be used;

AND

- Once in service, check the temperature-indicating device or temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended

by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

AND

- Calibrate the temperature-indicating device or temperature recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Devices subjected to high temperatures for extended periods of time may require more frequent calibration. Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- Perform other calibration procedures as necessary to ensure the accuracy of the monitoring instruments;

AND

- Do finished product sampling and analysis to determine water phase salt and, where appropriate, nitrite analysis at least once every 3 months (except where such testing is performed as part of monitoring);

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

1B. COLD SMOKING

Set Critical Limits.

- The smoker temperature must not exceed 90°F (32.2°C).

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The smoker temperature.

» **How Will Monitoring Be Done?**

- Measure ambient smoker chamber temperature using a continuous temperature-recording device (e.g., a recording thermometer).

» **How Often Will Monitoring Be Done (Frequency)?**

- Continuous monitoring by the device itself, with a visual check of the recorded data at least once per batch.

» **Who Will Do the Monitoring?**

- Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have been met consistently, may be performed by any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Chill and hold the product until its safety can be evaluated;

OR

- Divert the product to a use in which the critical limit is not applicable (e.g., packaging that is not hermetically sealed, or an LACF, or a frozen product);

OR

- Destroy the product;

  OR

- Divert the product to a non-food use.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Make repairs or adjustments to the smoking chamber;

  AND/OR

- Move some or all of the product to another smoking chamber.

Establish a Recordkeeping System.

- Printouts, charts, or readings from continuous temperature-recording devices;

  AND

- Record of visual checks of recorded data.

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR

  - Immersing the sensor in boiling water (212°F (100°C)) if the device will be used at or near the boiling point. Note that the temperature should be adjusted to compensate for altitude, when necessary;

    OR

  - Doing a combination of the above if the device will be used at or near room temperature;

    OR

  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

  AND

- Once in service, check the temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

  AND

- Calibrate the temperature-recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

  AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

1C. HOT SMOKING

Set Critical Limits.

- The internal temperature of the fish must be maintained at or above 145°F (62.8°C) throughout the fish for at least 30 minutes.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The internal temperature at the thickest portion of three of the largest fish in the smoking chamber.

» **How Will Monitoring Be Done?**

- Use a continuous temperature-recording device (e.g., a recording thermometer) equipped with three temperature-sensing probes.

» **How Often Will Monitoring Be Done (Frequency)?**

- Continuous monitoring by the device itself, with visual check of the recorded data at least once per batch.

» **Who Will Do the Monitoring?**

- Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have been met consistently, may be performed by any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Chill and hold the product until its safety can be evaluated;

  OR

- Reprocess the product;

  OR

- Divert the product to a use in which the critical limit is not applicable (e.g., packaging that is not hermetically sealed, or a LACF, or a frozen product);

  OR

- Destroy the product;

  OR

- Divert the product to a non-food use.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Make repairs or adjustments to the heating chamber;

  OR

- Move some or all of the product to another heating chamber.

Establish a Recordkeeping System.

- Printouts, charts, or readings from continuous temperature-recording devices;

  AND

- Record of visual checks of recorded data.

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR

  - Immersing the sensor in boiling water (212°F (100°C)) if the device will be used at or near the boiling point. Note that the temperature should be adjusted to compensate for altitude, when necessary;

    OR

  - Doing a combination of the above if the device will be used at or near room temperature;

    OR

- Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

AND

- Once in service, check the temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

AND

- Calibrate the temperature-recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

1D. REFRIGERATED FINISHED PRODUCT STORAGE

Set Critical Limits.

- For refrigerated (not frozen) finished product storage:
  - The product is held at a cooler temperature of 40°F (4.4°C) or below. Note that allowance for routine refrigeration defrost cycles may be necessary. Also note that you may choose to set a critical limit that specifies a time and temperature of exposure to temperatures above 40°F (4.4°C);

OR

- For finished product stored under ice:
  - The product is completely and continuously surrounded by ice throughout the storage time.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- For refrigerated finished product storage:
  - The temperature of the cooler;

OR

- For finished product storage under ice:
  - The adequacy of ice surrounding the product.

» **How Will Monitoring Be Done?**

- For refrigerated finished product storage:
  - Use a continuous temperature-recording device (e.g., a recording thermometer);

OR

- For finished product storage under ice:
  - Make visual observations of the adequacy of ice in a representative number of containers (e.g., cartons and totes) from throughout the cooler.

» **How Often Will Monitoring Be Done (Frequency)?**

- For continuous temperature-recording devices:
  - Continuous monitoring by the device itself, with a visual check of the recorded data at least once per day;

  OR
- For finished product storage under ice:
  - Sufficient frequency to ensure control.

» **Who Will Do the Monitoring?**

- For continuous temperature-recording devices:
  - Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have been met consistently, may be performed by any person who has an understanding of the nature of the controls;

  OR
- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Chill and hold the affected product until an evaluation of the total time and temperature exposure is performed;

  OR
- Destroy the product;

  OR
- Divert the product to a non-food use.

AND

Take the following corrective actions to regain control over the operation after a critical limit deviation:

- Prevent further deterioration:
  - Add ice to the product;

    OR
  - Move some or all of the product in the malfunctioning cooler to another cooler;

    OR
  - Freeze the product;

  AND
- Address the root cause:
  - Make repairs or adjustments to the malfunctioning cooler;

    OR
  - Make adjustments to the ice application operations.

Establish a Recordkeeping System.

- For refrigerated finished product storage:
  - Printouts, charts, or readings from continuous temperature-recording devices;

    AND
  - Record of visual checks of recorded data;

  OR
- For finished product storage under ice:
  - Results of ice checks:
    - The number of containers examined and the sufficiency of ice for each;

      AND
    - The approximate number of containers in the cooler.

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR

- Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

AND

- Once in service, check the temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

AND

- Calibrate the temperature-recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- When visual checks of ice are used, periodically measure internal temperatures of fish to ensure that the ice is sufficient to maintain product temperatures at 40°F (4.4°C) or less;

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

1E. RECEIPT OF PRODUCTS BY SECONDARY PROCESSOR

Set Critical Limits.

- For fish or fishery products delivered refrigerated (not frozen):
  - All lots received are accompanied by transportation records that show that the product was held at or below 40°F (4.4°C) throughout transit. Note that allowance for routine refrigeration defrost cycles may be necessary;

OR

- For products delivered under ice:
  - Product is completely surrounded by ice at the time of delivery;

OR

- For products delivered under chemical cooling media, such as gel packs:
  - There is an adequate quantity of cooling media that remain frozen to have maintained product at 40°F (4.4°C) or below throughout transit;

AND

  - The internal temperature of the product at the time of delivery is 40°F (4.4°C) or below;

OR

- For products delivered refrigerated (not frozen) with a transit time (including all time outside a controlled temperature environment) of 4 hours or less (optional control strategy):

- Time of transit does not exceed 4 hours;

  AND

- Temperature of the product at the time of delivery does not exceed 40°F (4.4°C).

Note: Processors receiving product with transit times of 4 hours or less may elect to use one of the controls described for longer transit times.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- For products delivered refrigerated (not frozen):
  - The internal temperature of the product throughout transportation;

    OR

  - The temperature within the truck or other carrier throughout transportation;

  OR
- For products delivered under ice:
  - The adequacy of ice surrounding the product at the time of delivery;

  OR
- For products held under chemical cooling media, such as gel packs:
  - The quantity and frozen status of cooling media at the time of delivery;

    AND

  - The internal temperature of a representative number of product containers (e.g., cartons and totes) at time of delivery;

  OR
- For products delivered refrigerated (not frozen) with a transit time of 4 hours or less:
  - The date and time fish were removed from a controlled temperature environment before shipment and the date and time delivered;

    AND

  - The internal temperature of a representative number of product containers (e.g., cartons and totes) at the time of delivery.

» **How Will Monitoring Be Done?**

- For products delivered refrigerated (not frozen):
  - Use a continuous temperature-recording device (e.g., a recording thermometer) for internal product temperature or ambient air temperature monitoring during transit;

  OR
- For products delivered under ice:
  - Make visual observations of the adequacy of ice in a representative number of containers (e.g., cartons and totes) from throughout the shipment, at delivery;

  OR
- For products delivered under chemical cooling media, such as gel packs:
  - Make visual observations of the adequacy and frozen state of the cooling media in a representative number of containers (e.g., cartons and totes) from throughout the shipment, at delivery;

    AND

  - Use a temperature-indicating device (e.g., a thermometer) to determine internal product temperatures in a representative number of product containers from throughout the shipment, at delivery;

  OR
- For products delivered refrigerated (not frozen) with a transit time of 4 hours or less:
  - Review carrier records to determine the date and time the product was removed from a controlled temperature environment before shipment and the date and time delivered;

    AND

- Use a temperature-indicating device (e.g., a thermometer) to determine internal product temperatures in a representative number of product containers (e.g., cartons and totes) randomly selected from throughout the shipment, at delivery. Measure a minimum of 12 product containers, unless there are fewer than 12 product containers in a lot, in which case measure all of the containers. Lots that show a high level of temperature variability may require a larger sample size.

» **How Often Will Monitoring Be Done (Frequency)?**

- Each lot received.

» **Who Will Do the Monitoring?**

- For continuous temperature-recording devices:
  - Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have been met consistently, may be performed by any person who has an understanding of the nature of the controls;

  OR
- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Chill and hold the affected product until an evaluation of the total time and temperature exposure is performed;

  OR
- Reject the lot.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Discontinue use of the supplier or carrier until evidence is obtained that the identified transportation-handling practices have been improved.

Establish a Recordkeeping System.

- Receiving records showing:
  - Results of continuous temperature monitoring:
    - Printouts, charts, or readings from continuous temperature-recording devices;

      AND
    - Visual check of recorded data;

    OR
  - Results of ice checks, including:
    - The number of containers examined and the sufficiency of ice for each;

      AND
    - The number of containers in the lot;

    OR
  - Results of the chemical media checks, including:
    - The number of containers examined and the frozen status of the media for each;

      AND
    - The number of containers in the lot;

    AND/OR
  - Results of internal product temperature monitoring, including:
    - The number of containers examined and the internal temperatures observed for each;

      AND
    - The number of containers in the lot;

      AND
    - Date and time fish were initially removed from a controlled

temperature environment and date and time fish were delivered, when applicable.

Establish Verification Procedures.

- Before a temperature-indicating device (e.g., a thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
    - Immersing the sensor in an ice slurry (32°F (0°C)), if the device will be used at or near refrigeration temperature;

      OR
    - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., product internal temperature) within the temperature range at which it will be used;

  AND
- Once in service, check the temperature-indicating device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational;

  AND
- Calibrate the temperature-indicating device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

  AND
- Check the accuracy of temperature-recording devices that are used for monitoring transit conditions, for all new suppliers and at least quarterly for each supplier thereafter. Additional checks may be warranted based on observations at receipt (e.g., refrigeration units appear to be in poor repair or readings appear to be erroneous). The accuracy of the device can be checked by comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

  AND
- When visual checks of ice are used, periodically measure internal temperatures of fish to ensure that the ice or is sufficient to maintain product temperatures at 40°F (4.4°C) or less;

  AND
- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 13-1

CONTROL STRATEGY EXAMPLE 1 - SMOKING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1 - Smoking." This example illustrates how a processor of vacuum-packaged hot-smoked salmon can control C. botulinum toxin formation. It is provided for illustrative purposes only.

C. botulinum toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, growth of other pathogenic bacteria, survival of other pathogenic bacteria through the cook step, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE*	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Brining	C. botulinum toxin formation in the finished product	Minimum brining time: 6 hours Maximum brine temperature: 40°F	Start time and end time of the brining process Brine temperature	Clock Dial thermometer	Every batch Every 2 hours	Brine room employee	Extend the brining process Hold and evaluate the product Cool the brine	Production record	Establish a brining and drying process Check the dial thermometer for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Monthly calibration of the scale Quarterly water phase salt analysis of the finished product Review monitoring, corrective action, and verification records within 1 week of preparation
		Minimum salt concentration of brine at the start of brining: 60° salinometer	Salt concentration of brine	Salinometer	Start of each brining process	Brine room employee	Add salt	Production record	
		Minimum ratio of brine to fish: 2:1	Weight of brine (as determined by volume)	Visual, to mark on the tank	Start of each brining process	Brine room employee	Add brine	Production record	
			Weight of fish	Scale	Each batch		Remove some fish and reweigh		
		Maximum fish thickness 1½ in. Note: To produce a minimum water phase salt level in the loin muscle of 3.5%	Fish thickness	Caliper	Each batch (10 largest fish)	Brine room employee	Hold and evaluate based on finished product water phase salt analysis	Production record	

TABLE 13-1

CONTROL STRATEGY EXAMPLE 1 - SMOKING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 1 - Smoking." This example illustrates how a processor of vacuum-packaged hot-smoked salmon can control C. botulinum toxin formation. It is provided for illustrative purposes only.

C. botulinum toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, growth of other pathogenic bacteria, survival of other pathogenic bacteria through the cook step, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE*	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Smoking and drying	C. botulinum toxin formation in finished product	Minimum time open vent: 2 hours	Time of open vent	Clock	Each batch	Smoker employee	Extend the drying process Hold and evaluate based on finished product water phase salt analysis	Production record	Establish a brining and drying process Quarterly water phase salt analysis of the finished product Review monitoring, corrective action, and verification records within 1 week of preparation
Heating	C. botulinum toxin formation in the finished product	Internal temperature of fish held at or above 145°F for at least 30 minutes	Internal temperature of fish and time at that temperature	Digital data logger with three probes in thickest fish in cold spot of smoking chamber	Continuous, with visual check of recorded data at the end of the batch	Smoker employee	Extend the heating process Make repairs or adjustments to the smoking chamber Hold and evaluate the product	Data logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation
Finished product storage	C. botulinum toxin formation during finished product storage	Maximum cooler temperature: 40°F (based on growth of vegetative pathogens)	Cooler air temperature	Digital data logger	Continuous, with visual check of recorded data once per day	Production employee	Adjust or repair the cooler Hold and evaluate the product based on time and temperature of exposure	Digital data logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation

*Note: The critical limits in this example are for illustrative purposes only and are not related to any recommended process.

- **CONTROL STRATEGY EXAMPLE 2 - REFRIGERATION WITH TTI**

This control strategy should include the following elements, as appropriate:

a. Unactivated TTI receipt;

b. Unactivated TTI storage;

c. Application and activation of TTI;

d. Refrigerated finished product storage;

e. Receipt of product by secondary processor.

2A. UNACTIVATED TTI RECEIPT

Set Critical Limits.

- The TTI is suitable for use. It should be designed to perform properly under the conditions that it will be used. It should also be designed to produce an alert indicator (e.g., a color change of the device) at a combination of time and temperature exposures that will prevent the formation of non-proteolytic *C. botulinum* toxin formation (e.g., consistent with the "Skinner-Larkin curve");

  AND

- Where transportation conditions (e.g., temperature) could affect the functionality of the TTI, all lots of TTIs are accompanied by transportation records that show that they were held at conditions that do not result in loss of functionality throughout transit;

  AND

- The TTI functions (i.e., produces an alert indicator, such as a color change of the device, when exposed to time and temperature abuse) at time of receipt.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- For suitability of use:
  - Performance data from the manufacturer;

  AND

- For transportation conditions:
  - The temperature within the truck or other carrier throughout transportation;

    OR
  - Other conditions that affect the functionality of the TTI, where applicable;

  AND

- For functionality at receipt:
  - The ability of the TTI to produce an alert indicator, such as a color change of the device, when exposed to time and temperature abuse at time of receipt.

» **How Will Monitoring Be Done?**

- For suitability of use:
  - Review performance data;

  AND

- For transportation conditions:
  - Use a continuous temperature-recording device (e.g., a recording thermometer) for ambient air temperature monitoring during transit;

  AND

- For functionality at receipt:
  - Activate and then expose a TTI from the lot to ambient air temperature for sufficient time to determine whether it is functional (i.e., produces an alert indicator, such as a color change of the device).

» **How Often Will Monitoring Be Done (Frequency)?**

- For suitability of use:
  - The first shipment of a TTI model;

  AND

- For transportation conditions and functionality at receipt:
  - Every shipment.

» **Who Will Do the Monitoring?**

- For suitability of use:
  - Anyone with an understanding of TTI validation studies and of the intended conditions of use;

  AND
- For transportation conditions and functionality at receipt:
  - Anyone with an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Reject or return the shipment.

AND

Take the following corrective actions to regain control over the operation after a critical limit deviation:

- For suitability of use:
  - Discontinue use of the supplier until documentation of validation has been provided;

  AND
- For transportation conditions and functionality at receipt:
  - Discontinue use of the supplier or carrier until evidence is obtained that the identified production or transportation practices have been improved.

Establish a Recordkeeping System.

- For suitability of use:
  - Manufacturer's performance data;

  AND
- For transportation conditions:
  - Printouts, charts, or readings from continuous temperature-recording devices;

    AND
  - Records of visual checks of recorded data;

  AND
- For functionality at receipt:
  - Results of a TTI challenge test (i.e., whether the TTI produces an alert indicator, such as a color change of the device, when exposed to time and temperature abuse).

Establish Verification Procedures.

- Check the accuracy of temperature-recording devices that are used for monitoring transit conditions, for all new suppliers and at least quarterly for each supplier thereafter. Additional checks may be warranted based on observations at receipt (e.g., refrigeration units appear to be in poor repair or readings appear to be erroneous). The accuracy of the device can be checked by comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

  AND
- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

2B. UNACTIVATED TTI STORAGE

Set Critical Limits.

- The combination of storage conditions (e.g., temperature) that prevent loss of functionality throughout storage (based on manufacturer's specifications).

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Storage air temperature, where temperature affects functionality of the TTI;

  AND/OR

- Other storage conditions that affect functionality of the TTI.

» **How Will Monitoring Be Done?**

- For temperature:
  - Use a continuous temperature-recording device (e.g., a recording thermometer);

  AND/OR

- For other conditions:
  - Use instruments appropriate for the purpose.

» **How Often Will Monitoring Be Done (Frequency)?**

- For temperature:
  - Continuous monitoring by the device itself, with a visual check of the recorded data at least once per day;

  AND/OR

- For other conditions:
  - With sufficient frequency to ensure control.

» **Who Will Do the Monitoring?**

- With continuous temperature-recording devices:
  - Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have been met consistently, may be performed by any person who has an understanding of the nature of the controls;

  AND

- For other checks:
  - Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a TTI involved in a critical limit deviation:

- Destroy the lot of TTIs.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Make repairs or adjustments to the malfunctioning cooler;

  AND/OR

- Make other repairs or adjustment appropriate for the condition.

Establish a Recordkeeping System.

- For refrigerated storage:
  - Printouts, charts, or readings from continuous temperature-recording devices;

    AND
  - Record of visual checks of recorded data;

  AND/OR

- Storage record showing the results of monitoring of other conditions.

Establish Verification Procedures.

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR
  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

AND

- Once in service, check the temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

AND

- Calibrate the temperature-recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- Perform other instrument calibration, as appropriate;

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

2C. APPLICATION AND ACTIVATION OF TTI

Set Critical Limits.

- Each consumer package has an activated TTI.

Establish Monitoring Procedures.

» What Will Be Monitored?

- Packages for the presence of an activated TTI.

» How Will Monitoring Be Done?

- Visual examination.

» How Often Will Monitoring Be Done (Frequency)?

- Representative number of packages from each lot of product.

» Who Will Do the Monitoring?

- Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Hold the lot below 38°F (3.3°C) until TTIs are applied and activated.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Identify and correct the cause of the TTI application or activation deficiency.

Establish a Recordkeeping System.

- Packaging control record that shows the results of the TTI checks.

Establish Verification Procedures.

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

2D. REFRIGERATED FINISHED PRODUCT STORAGE

Follow the guidance for "Control Strategy Example 1 - Smoking (1d - Refrigerated Finished Product Storage)," except that the where the critical limits list 40°F (4.4°C), they should list 38°F (3.3°C).

2E. RECEIPT OF PRODUCTS BY SECONDARY PROCESSOR

Follow the guidance for "Control Strategy Example 1 - Smoking (1e - Receipt of Products by Secondary Processor)," except that the where the critical limits list 40°F (4.4°C), they should list 38°F (3.3°C).

TABLE 13-2

CONTROL STRATEGY EXAMPLE 2 - REFRIGERATION WITH TTI

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Refrigeration With TTI." This example illustrates how a processor of refrigerated, vacuum-packaged, raw fish fillets can control C. botulinum toxin formation. It is provided for illustrative purposes only.

C. Botulinum toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, growth of other pathogenic bacteria, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receipt of TTI	C. botulinum toxin formation in the finished product	TTI is suitable for use	Performance data from the manufacturer	Review of performance data	First shipment of a TTI model	Quality assurance supervisor	Reject the shipment Discontinue use of the supplier until appropriate validation documentation is provided	Manufacturer's performance data	Review monitoring, corrective action records within 1 week of preparation
		All lots received are accompanied by truck records that show temperature was maintained at or below 40°F	Truck temperature	Digital time and temperature data logger	Continuous, with visual review and evaluation of temperature-monitoring records for each shipment	Receiving employee	Discontinue use of the supplier or carrier until evidence is obtained that the identified transportation- handling practices have been improved Reject the shipment	Receiving record	Check the data logger for all new suppliers and for all suppliers at least quarterly thereafter Review monitoring, corrective action records within 1 week of preparation
		The TTI functions at receipt	The ability of the TTI to change color when exposed to room air temperature	Expose a TTI from the lot to room air temperature for sufficient time to determine whether it changes color	Every shipment	Quality assurance staff	Discontinue use of the supplier or carrier until evidence is obtained that the identified production or transportation-handling practices have been improved	TTI challenge record	Review monitoring, corrective action records within 1 week of preparation

TABLE 13-2

CONTROL STRATEGY EXAMPLE 2 - REFRIGERATION WITH TTI

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Refrigeration With TTI." This example illustrates how a processor of refrigerated, vacuum-packaged, raw fish fillets can control C. botulinum toxin formation. It is provided for illustrative purposes only.

C. Botulinum toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, growth of other pathogenic bacteria, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
TTI storage	C. botulinum toxin formation in the finished product	Cooler maintained below 38°F	Cooler temperature	Digital time and temperature data logger	Continuous, with visual check of recorded data once per day	Quality assurance staff	Repair or adjust cooler Destroy the lot of TTIs	Data logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation
TTI attachment and activation	C. botulinum toxin formation in the finished product	Each package has an activated TTI	Packages for the presence of an activated TTI	Visual examination	Representative number of packages from each lot of product	Production employee	Hold lot below 38°F, and apply and activate TTIs Identify and correct the cause of TTI application deviation	Packaging control record	Review monitoring, and corrective action and verification records within 1 week of preparation

TABLE 13-2

CONTROL STRATEGY EXAMPLE 2 - REFRIGERATION WITH TTI

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Refrigeration With TTI." This example illustrates how a processor of refrigerated, vacuum-packaged, raw fish fillets can control C. botulinum toxin formation. It is provided for illustrative purposes only.

C. Botulinum toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, growth of other pathogenic bacteria, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Finished product storage	C. botulinum toxin formation during finished product storage	Maximum cooler temperature 38°F	Cooler air temperature	Digital data logger	Continuous, with visual check of recorded data once per day	Production employee	Adjust or repair cooler Hold and evaluate the product based on time and temperature of exposure	Digital logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation

*Note: The critical limits in this example are for illustrative purposes only and are not related to any recommended process.

- **CONTROL STRATEGY EXAMPLE 3 - FROZEN WITH LABELING**

Set Critical Limits.

- All finished product labels must contain a "keep frozen" statement (e.g., "Important, keep frozen until used, thaw under refrigeration immediately before use").

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Finished product labels for the presence of a "keep frozen" statement.

» **How Will Monitoring Be Done?**

- Visual examination.

» **How Often Will Monitoring Be Done (Frequency)?**

- Representative number of packages from each lot of product.

» **Who Will Do the Monitoring?**

- Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Segregate and relabel any improperly labeled product.

AND

Take the following corrective actions to regain control over the operation after a critical limit deviation:

- Segregate and return or destroy any label stock or pre-labeled packaging stock that does not contain the proper statement;

  AND

- Determine and correct the cause of improper labels.

Establish a Recordkeeping System.

- Record of labeling checks.

Establish Verification Procedures.

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 13-3

CONTROL STRATEGY EXAMPLE 3 - FROZEN WITH LABELING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 3 - Frozen With Labeling." This example illustrates how a processor of frozen, vacuum-packaged, raw fish fillets can control C. botulinum toxin formation. It is provided for illustrative purposes only.

C. Botulinum toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receipt of labeling	C. botulinum toxin formation during finished product storage	All finished product labels must contain a "keep frozen" statement	Finished product labels for the presence of a "keep frozen" statement	Visual examination	Representative number of packages from each lot of product	Receiving employee	Segregate and relabel any improperly labeled product Segregate and destroy any label stock that does not contain the proper statement Determine and correct the cause of improper labels	Label receiving record	Review monitoring and correction action records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 4 - PICKLING AND SALTING**

This control strategy should include the following elements, as appropriate:

a. Brining, pickling, salting, and formulation;

b. Refrigerated finished product storage;

c. Receipt of Product by secondary processor.

4A. BRINING, PICKLING, SALTING, AND FORMULATION

Set Critical Limits.

- The minimum or maximum values for the critical factors of the brining, pickling, or formulation process established by a scientific study. The critical factors are those that are necessary to ensure that the finished product has:

For refrigerated, reduced oxygen-packaged fishery products:

- A water phase salt level of at least 5%;

  OR

- A pH of 5.0 or below;

  OR

- A water activity of below 0.97;

  OR

- A water phase salt level of at least 2.4% in surimi-based products, when combined with a pasteurization process in the finished product container of 185°F (85°C) for 15 minutes (pasteurization controls are covered in Chapter 16);

  OR

- A combination of water phase salt, pH, and/or water activity that, when combined, have been demonstrated to prevent the growth of *C. botulinum* type E and non-proteolytic types B and F.

For unrefrigerated (shelf-stable), reduced oxygen-packaged products:

- A water phase salt level of at least 20% (based on the maximum salt level for growth of *S. aureus*);

  OR

- A pH of 4.6 or below;

  OR

- A water activity of 0.85 or below (based on the minimum water activity for growth and toxin formation of *S. aureus*).

A heat treatment, addition of chemical additives, or other treatment may be necessary to inhibit or eliminate spoilage organisms (e.g., mold) in shelf-stable products.

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- The critical factors of the established pickling, brining, or formulation process. These may include: brine and acid strength; brine or acid to fish ratio; brining and pickling time; brine and acid temperature; thickness, texture, fat content, quality, and species of fish;

  OR

- The water phase salt, pH, and/or water activity of the finished product.

» **How Will Monitoring Be Done?**

- For brine strength:
  - Use a salinometer;

  AND

- For acid strength:
  - Use a pH meter or titrate for acid concentration;

  AND

- For brine/acid temperature:
  - Use a temperature-indicating device (e.g., a thermometer);

  AND

- For all other critical factors specified by the study:
  - Use equipment appropriate for the measurement;

  OR
- For water phase salt, pH, and/or water activity:
  - Collect a representative sample of the finished product, and conduct water phase salt, pH, and/or water activity analysis, as appropriate.

» **How Often Will Monitoring Be Done (Frequency)?**

- For brine and acid strength:
  - At the start of each brining, pickling, and formulation process;

  AND
- For brine and acid temperature:
  - At the start of each brining, pickling, and formulation process and at least every 2 hours thereafter;

  AND
- For brine or acid to fish ratio:
  - At the start of each brining, pickling, and formulation process;

  AND
- For other critical factors specified by the study:
  - As often as necessary to maintain control;

  OR
- Water phase salt, pH, and/or water activity analysis should be determined for each batch of finished product.

» **Who Will Do the Monitoring?**

- For water activity:
  - Any person with sufficient training to perform the analysis;

  OR
- For other checks:
  - Any person with an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Chill and hold the product until it can be evaluated based on its water phase salt, pH, and/or water activity level;

  OR
- Reprocess the product (if reprocessing does not jeopardize the safety of the product);

  OR
- Divert the product to a use in which the critical limit is not applicable (e.g., packaging that is not hermetically sealed, or a LACF, or a frozen product);

  OR
- Divert the product to a non-food use;

  OR
- Destroy the product.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Adjust the brine or acid strength or brine or acid to fish ratio;

  OR
- Extend the brining or pickling time to compensate for an improper brine or acid temperature.

Establish a Recordkeeping System.

- Records, as necessary, to document the monitoring of the critical factors of the brining or pickling process, as established by a study (e.g., a processing record showing the results of the brine or acid strength and temperature, brine or acid to fish ratio, size and species of fish, time of brining or pickling);

  OR
- Record of determinations of the finished product water phase salt, pH, or water activity.

Establish Verification Procedures.

- Process validation study (except where water phase salt, pH, or water activity analysis of the finished product is the monitoring procedure):
    - The adequacy of the pickling, brining, and formulation process steps should be established by a scientific study. For refrigerated, reduced oxygen-packaged products, it should be designed to consistently achieve: a water phase salt level of at least 5%; a pH of 5.0 or below; a water activity of below 0.97; a water phase salt level of at least 2.4% in surimi-based products, when combined with a pasteurization process in the finished product container of 185°F (85°C) for at least 15 minutes; or a combination of salt, pH, and/or water activity that, when combined, prevent the growth of *C. botulinum* type E and non-proteolytic types B and F (established by a scientific study). For unrefrigerated (shelf-stable), reduced oxygen-packaged products, it should be designed to consistently achieve: a water phase salt level of at least 20% (based on the maximum water phase salt level for the growth of *S. aureus*); a pH of 4.6 or below; or a water activity of 0.85 or below (based on the minimum water activity for the growth of *S. aureus*). Expert knowledge of pickling, brining, and formulation processes may be required to establish such a process. Such knowledge can be obtained by education or experience, or both. Establishment of pickling, brining, and formulation processes may require access to adequate facilities and the application of recognized methods. In some instances, pickling, brining, and formulation studies may be required to establish minimum processes. In other instances, existing literature, which establishes minimum processes, is available. Characteristics of the process and/or product that affect the ability of the established minimum pickling, brining, and formulation process should be taken into consideration in the process establishment. A record of the process establishment should be maintained;

AND

- Before a temperature-indicating device (e.g., a thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
    - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

      OR
    - Immersing the sensor in boiling water (212°F (100°C)) if the device will be used at or near the boiling point. Note that the temperature should be adjusted to compensate for altitude, when necessary);

      OR
    - Doing a combination of the above if the device will be used at or near room temperature;

      OR
    - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a NIST-traceable thermometer) under conditions that are similar to how it will be used (e.g., brine temperature) within the temperature range at which it will be used;

  AND
- Once in service, check the temperature-indicating device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your

facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational;

AND

- Calibrate the temperature-indicating device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable device). Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- Perform daily calibration of pH meters against standard buffers;

AND

- Perform other calibration procedures as necessary to ensure the accuracy of the monitoring instruments;

AND

- Do finished product sampling and analysis to determine water phase salt, pH, or water activity level, as appropriate, at least once every 3 months (except where such testing is performed as part of monitoring);

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

4B. REFRIGERATED FINISHED PRODUCT STORAGE

Follow the guidance for "Control Strategy Example 1 - Smoking (1d - Refrigerated Finished Product Storage)."

4C. RECEIPT OF PRODUCT BY SECONDARY PROCESSOR

Follow the guidance for "Control Strategy Example 1 - Smoking (1e - Receipt of Product by Secondary Processor)."

TABLE 13-4

CONTROL STRATEGY EXAMPLE 4 - PICKLING AND SALTING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 4 - Pickling and Salting." This example illustrates how a pickled herring processor can control C. botulinum toxin formation. It is provided for illustrative purposes only.

C. botulinum toxin formation may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., histamine, environmental and chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Pickling	C. botulinum toxin formation in the finished product	Maximum finished product pH in the loin muscle of 5.0	Finished product pH in the loin muscle	Collect a sample of the product from each pickling tank at the end of each pickling cycle and analyze for pH using a pH meter	Each pickling tank, each cycle	Quality control personnel	Continue the pickling process until pH meets the critical limit	Pickling control record	Daily calibration of the pH meter Review monitoring, corrective action, and verification records within 1 week of preparation
Finished product storage	C. botulinum toxin formation during finished product storage	Maximum cooler temperature: 40°F (based on growth of vegetative pathogens)	Cooler air temperature	Time and temperature data logger	Continuous, with visual check of recorded data once per day	Production employee	Adjust or repair cooler Hold and evaluate the product based on time and temperature of exposure	Data logger printout	Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Review monitoring, corrective action, and verification records within 1 week of preparation

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We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of March 29, 2011, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after March 29, 2011.

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NOTES:

CHAPTER 14: **Pathogenic Bacteria Growth and Toxin Formation as a Result of Inadequate Drying**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

UNDERSTAND THE POTENTIAL HAZARD.

Pathogenic bacteria growth and toxin formation in the finished product as a result of inadequate drying of fishery products can cause consumer illness. The primary pathogens of concern are *Staphylococcus aureus* (*S. aureus*) and *Clostridium botulinum* (*C. botulinum*). See Appendix 7 for a description of the public health impacts of these pathogens.

- **Control by Drying**

Dried products are usually considered shelf stable and are, therefore, often stored and distributed unrefrigerated. Examples of shelf-stable dried fish products are salmon jerky, octopus chips, dried shrimp, stock fish, and shark cartilage. The characteristic of dried foods that makes them shelf stable is their low water activity (A_w). Water activity is the measure of the amount of water in a food that is available for the growth of microorganisms, including pathogenic bacteria. A water activity of 0.85 or below will prevent the growth and toxin production of all pathogenic bacteria, including *S. aureus* and *C. botulinum*, and is critical for the safety of a shelf-stable dried product. *S. aureus* grows at a lower water activity than other pathogenic bacteria, and should, therefore, be considered the target pathogen for drying for shelf-stable products.

You should select a packaging material that will prevent rehydration of the product under the expected conditions of storage and distribution. Additionally, finished product package closures should be free of gross defects that could expose the product to moisture during storage and distribution. Chapter 18 provides guidance on control of container closures.

Some dried products that are reduced oxygen packaged (e.g., vacuum packaged, modified atmosphere packaged) are dried only enough to control growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F (i.e., types that will not form toxin with a water activity of below 0.97). These dried products are then refrigerated to control growth and toxin formation by *C. botulinum* type A and proteolytic types B and F and by other pathogenic bacteria that may be present in the product, including *S. aureus*. The products might have the appearance of a fully dried product. Therefore, their packaging should include "keep refrigerated" labeling to ensure that temperature controls are applied throughout distribution.

Distributing partially dried, reduced oxygen packaged products frozen also could be used to control these pathogens. However, labeling with "keep frozen" instructions would then be important to ensure food safety. More information on *C. botulinum* and reduced oxygen packaging is contained in Chapter 13.

This chapter does not cover the growth of pathogenic bacteria, including *S. aureus*, which may occur as a result of time and temperature

abuse during processing, including before or during the drying process. That hazard is covered in Chapter 12. It also does not cover the control of *C. botulinum* type A and proteolytic types B and F and that of other pathogenic bacteria that may be present, including *S. aureus,* during refrigerated storage of reduced oxygen packaged, partially dried products. That hazard is covered in Chapters 12 and 13, respectively.

Controlling pathogenic bacteria growth and toxin formation by drying is best accomplished by:

- Scientifically establishing a drying process that reduces the water activity to 0.85 or below if the product will be stored and distributed unrefrigerated (shelf stable). Note that a heat treatment, addition of chemical additives, further drying, or other treatment may be necessary to inhibit or eliminate spoilage organisms, for example, mold;
- Scientifically establishing a drying process that reduces the water activity to below 0.97 if the product will be stored refrigerated (not frozen) in reduced oxygen packaging;
- Designing and operating the drying equipment so that every unit of a product receives at least the established minimum process;
- Packaging the finished product in a container that will prevent rehydration.

The drying operation used in the production of smoked or smoke-flavored fish is not designed to result in a finished product water activity of 0.85 or below. The controls for these products are described in Chapter 13.

Because spores of *C. botulinum* are known to be present in the viscera of fish, any product that will be preserved by salting, drying, pickling, or fermentation should be eviscerated prior to processing (see the "Compliance Policy Guide," Sec. 540.650). Without evisceration, toxin formation is possible during the process even with strict control of temperature. Evisceration should be thorough and performed to minimize contamination of the fish flesh. If even a portion of the viscera or its contents is left behind, the risk of toxin formation by *C. botulinum* remains. Small fish, less than 5 inches in length, that are processed in a manner that eliminates preformed toxin and prevents toxin formation and that reach (1) a water phase salt content of 10%, a value based on the control of *C. botulinum* type A and proteolytic types B and F, in refrigerated products; or (2) a water activity of 0.85 or below (note that this is a value based on the minimum water activity for toxin production by *S. aureus*, in shelf-stable products); or (3) a pH (acidity) level of 4.6 or less in shelf-stable products are not subject to the evisceration recommendation.

- **Strategies for controlling pathogenic bacteria growth**

Pathogens can enter the process on raw materials. They can also be introduced into foods during processing, from the air, unclean hands, insanitary utensils and equipment, contaminated water, and sewage. There are a number of strategies for the control of pathogenic bacteria in fish and fishery products. They include:

- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by drying (covered in this chapter);
- Controlling the amount of moisture that is available for pathogenic bacteria growth (water activity) in the product by formulation (covered in Chapter 13);
- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product (covered in Chapter 13);
- Controlling the pH in the product (covered by the Acidified Foods regulation, 21 CFR 114, for shelf-stable acidified products, and by Chapter 13 for refrigerated acidified products);
- Controlling the source of molluscan shellfish and the time from exposure to air (e.g., by harvest or receding tide) to refrigeration to control pathogens from the harvest area (covered in Chapter 12);

- Controlling the introduction of pathogenic bacteria after the pasteurization process (covered in Chapter 18);
- Managing the amount of time that food is exposed to temperatures that are favorable for pathogenic bacteria growth and toxin production (covered generally in Chapter 12; for *C. botulinum*, in Chapter 13; and for *S. aureus* in hydrated batter mixes, in Chapter 15);
- Killing pathogenic bacteria by cooking or pasteurization (covered in Chapter 16) or by retorting (covered by the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulation, 21 CFR 113 (called the Low-Acid Canned Foods Regulation in this guidance document));
- Killing pathogenic bacteria by processes that retain raw product characteristics (covered in Chapter 17).

DETERMINE WHETHER THE POTENTIAL HAZARD IS SIGNIFICANT.

The following guidance will assist you in determining whether pathogenic bacteria growth and toxin formation as a result of inadequate drying is a significant hazard at a processing step:

1. For shelf-stable, dried products, is it reasonably likely that *S. aureus* will grow and form toxin in the finished product if the product is inadequately dried?

   Table A-1 (Appendix 4) provides information on the conditions under which *S. aureus* will grow. If your food that is not distributed refrigerated or frozen and meets these conditions (i.e., in Table A-1) before drying, then drying will usually be important to the safety of the product, because it provides the barrier to *S. aureus* growth and toxin formation. Under ordinary circumstances, it would be reasonably likely that *S. aureus* will grow and form toxin in such products during finished product storage and distribution if drying is not properly performed. Note that drying to control toxin formation by *S. aureus* will also control toxin formation by *C. botulinum* in these products.

2. For shelf-stable, dried products, can *S. aureus* toxin formation that is reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step?

   Pathogenic bacteria growth and toxin formation as a result of inadequate drying should also be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard of *S. aureus* toxin formation (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. The preventive measure that can be applied for pathogenic bacteria growth and toxin formation as a result of inadequate drying are:

   - Proper design and control of the drying process (covered in this chapter);

3. For refrigerated or frozen, partially dried (i.e., not shelf stable) products, is it reasonably likely that *C. botulinum* type E and nonproteolytic types B and F will grow and form toxin in the finished product if the product is inadequately dried?

   Table A-1 (Appendix 4) provides information on the conditions under which *C. botulinum* type E and non-proteolytic types B and F will grow. Because of the need to prevent rehydration of dried products, these products generally will be contained in a reduced oxygen package. If your refrigerated (not frozen), reduced oxygen packaged food meets these conditions (i.e., Table A-1) before drying, then drying will usually be important to the safety of the product, because it provides the barrier to growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F. Note that refrigeration will control toxin formation by *S. aureus* and *C. botulinum* type A and non-proteolytic types B and F in these products. Under ordinary

circumstances, it would be reasonably likely that *C. botulinum* type E and non-proteolytic types B and F will grow and form toxin in such products during finished product storage and distribution if drying is not properly performed. In addition, controlling labeling (e.g., "keep refrigerated" labeling) to ensure that the product is held refrigerated throughout distribution may be important to the safety of the product, because the product may appear to retailers, consumers, and end users to be shelf stable.

However, if your dried, reduced oxygen packaged product is distributed frozen, then freezing may provide the barrier to growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F, rather than drying. In this case, labeling to ensure that the product is distributed frozen may be important to the safety of the product. Chapter 13 provides guidance on labeling controls to ensure that frozen product that supports the growth of non-proteolytic *C. botulinum* is distributed frozen.

4. For refrigerated or frozen, partially dried, reduced oxygen packaged dried products, can growth and toxin formation by *C. botulinum* type E and non-proteolytic types B and F that are reasonably likely to occur be eliminated or reduced to an acceptable level at this processing step?

   Pathogenic bacteria growth and toxin formation as a result of inadequate drying should be considered a significant hazard at any processing step where a preventive measure is, or can be, used to eliminate the hazard (or reduce the likelihood of its occurrence to an acceptable level) if it is reasonably likely to occur. The preventive measures that can be applied for pathogenic bacteria growth and toxin formation as a result of inadequate drying for refrigerated or frozen, partially dried, reduced oxygen packaged products are:

   - Proper design and control of the drying process (covered in this chapter);
   - Refrigeration (covered in Chapter 12) and labeling to ensure that the product is held refrigerated throughout distribution (covered in this chapter);
   - Freezing (Chapter 13 provides guidance on labeling controls to ensure that a frozen product that otherwise supports the growth of non-proteolytic *C. botulinum* is distributed frozen).

- **Intended use**

Because of the highly stable nature of *S. aureus* toxin and the extremely toxic nature of *C. botulinum* toxin, it is unlikely that the intended use will affect the significance of the hazard.

IDENTIFY CRITICAL CONTROL POINTS.

The following guidance will assist you in determining whether a processing step is a critical control point (CCP) for pathogenic bacteria growth and toxin formation as a result of inadequate drying:

1. If you identified the hazard of pathogenic bacteria growth and toxin formation as a result of inadequate drying as significant because drying (rather than, or in addition to, refrigeration) is important to the safety of the product, you should identify the drying step as a CCP for this hazard.

   Example:

   A salmon jerky processor that distributes the product unrefrigerated should set the CCP for controlling the hazard of pathogenic bacteria growth and toxin formation as a result of inadequate drying at the drying step. The processor would not need to identify the processing steps prior to drying as CCPs for that hazard. However, these steps may be CCPs for the control of other hazards, such as the growth of pathogenic bacteria as a result of time and temperature abuse during processing, covered by Chapter 12.

This control approach is a control strategy referred to in this chapter as "Control Strategy Example 1 - Control by Drying."

2. If you identified the hazard of pathogenic bacteria growth and toxin formation as a result of inadequate drying as significant because refrigeration (in addition to drying) is important to the safety of the product, you should identify the finished product storage step and the labeling step, where you will ensure that the "keep refrigerated" labeling is included on every package, as a CCP, for this hazard.

   Example:

   A partially dried catfish processor that distributes the product refrigerated and reduced oxygen packaged should set the CCPs for controlling the hazard of pathogenic bacteria growth and toxin formation as a result of inadequate drying at the drying step, finished product labeling step, and finished product storage step. The processor would not need to identify the processing steps prior to drying as CCPs for that hazard. However, these steps may be CCPs for the control of other hazards, such as the growth of pathogenic bacteria as a result of time and temperature abuse during processing, covered by Chapter 12.

The control by drying is covered in "Control Strategy Example 1 - Control by Drying." Control of labeling is referred to in this chapter as "Control Strategy Example 2 - Control by Refrigeration With Labeling." It should be used along with "Control Strategy Example 1 - Control by Drying." Note that control of refrigerated finished product storage is covered in Chapter 12. Note also that Chapter 13 provides guidance on labeling controls to ensure that a frozen product that otherwise supports the growth of non-proteolytic *C. botulinum* is distributed frozen.

DEVELOP A CONTROL STRATEGY.

The following guidance provides examples of two control strategies for pathogenic bacteria growth and toxin formation that occurs as a result of inadequate drying. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation. It is important to note that you may select a control strategy that is different from those that are suggested, provided it complies with the requirements of the applicable food safety laws and regulations.

The following are examples of control strategies included in this chapter:

CONTROL STRATEGY	MAY APPLY TO PRIMARY PROCESSOR	MAY APPLY TO SECONDARY PROCESSOR
Control by drying	✓	✓
Control by refrigeration with labeling	✓	✓

- **CONTROL STRATEGY EXAMPLE 1 - CONTROL BY DRYING**

It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Set Critical Limits.

- The minimum or maximum values for the critical factors established by a scientific study (i.e., for shelf-stable products, those which must be met in order to ensure that the finished product has a water activity of 0.85 or below; for refrigerated (not frozen), reduced oxygen packaged products, those which must be met in order to ensure that the finished product has a water activity of less than 0.97). These will likely include drying time, input/output air temperature, humidity, and velocity, as well as flesh thickness. Other critical factors that affect the rate of drying of the product may also be established by the study;

OR

- The minimum percent weight loss established by a scientific study (i.e., for shelf-stable products, that which must be met in order to ensure that the finished product has a water activity of 0.85 or below; for refrigerated (not frozen), reduced oxygen packaged products, that which must be met in order to ensure that the finished product has a water activity of less than 0.97);

OR

- For shelf-stable products:
  - Maximum finished product water activity of 0.85 or above;

OR

- For refrigerated (not frozen), reduced oxygen packaged products:
  - Maximum finished product water activity of less than 0.97.

Note: A heat treatment, addition of chemical additives, further drying, or other treatment may be necessary to inhibit or eliminate spoilage organisms (e.g., mold) in shelf-stable products.

Establish Monitoring Procedures.

» What Will Be Monitored?

- Critical factors of the established drying process that affect the ability of the process to ensure the desired finished product water activity (i.e., 0.85 or below for shelf-stable products, less than 0.97 for refrigerated (not frozen), reduced oxygen packaged products). These may include drying time, air temperature, humidity, and velocity, as well as flesh thickness;

OR

- Percent weight loss;

OR

- Water activity of the finished product.

» How Will Monitoring Be Done?

For batch drying equipment:

- For drying time and input/output air temperature:
  - Use a continuous temperature-recording device (e.g., a recording thermometer);

AND

- For all other critical factors specified by the study:
  - Use equipment appropriate for the measurement;

OR

- For percent weight loss:
  - Weigh all, or a portion, of the batch before and after drying;

OR

- For water activity analysis:
  - Collect a representative sample of the finished product and conduct water activity analysis.

For continuous drying equipment:

- For input/output air temperature:
  - Use a continuous temperature-recording device (e.g., a recording thermometer);

AND

- For drying time:
  - Measure:
    - The revolutions per minute (RPM) of the belt drive wheel, using a stopwatch or tachometer;

    OR

    - The time necessary for a test unit or belt marking to pass through the equipment, using a stopwatch;

AND

- For all other critical factors specified by the study:
  - Use equipment appropriate for the measurement;

OR

- For percent weight loss:
  - Weigh all, or a portion, of the batch before and after drying;

OR

- For water activity:
  - Collect a representative sample of the finished product and conduct water activity analysis.

» **How Often Will Monitoring Be Done (Frequency)?**

For batch drying equipment:

- For time and temperature:
  - Continuous monitoring, with a visual check of the recorded data at least once during each batch;

  AND
- For all other critical factors specified by the study:
  - As often as necessary to maintain control;

  OR
- For percent weight loss:
  - Each batch;

  OR
- For water activity:
  - Each batch.

For continuous drying equipment:

- For temperature:
  - Continuous monitoring, with a visual check of the recorded data at least once per day;

  AND
- For time:
  - At least once per day, and whenever any changes in belt speed are made;

  AND
- For all other critical factors specified by the study:
  - As often as necessary to maintain control;

  OR
- For percent weight loss:
  - Each lot of finished product;

  OR
- For water activity:
  - Each lot of finished product.

» **Who Will Do the Monitoring?**

- For continuous temperature-recording devices:
  - Monitoring is performed by the equipment itself. The visual check of the data generated by this equipment, to ensure that the critical limits have consistently been met, may be performed by any person who has an understanding of the nature of the controls;

  AND
- For all other critical factors specified by the study:
  - Any person who has an understanding of the nature of the controls;

  OR
- For percent weight loss:
  - Any person who has an understanding of the nature of the controls;

  OR
- For water activity:
  - Any person with sufficient training to perform the analysis.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Redry the product (provided that redrying does not present an unacceptable opportunity for pathogenic bacteria growth);

  OR
- Chill and hold the product for an evaluation of the adequacy of the drying process. The evaluation may involve water activity determination on a representative sample of the finished product. If the evaluation shows that the product has not received an adequate drying process, the product should be destroyed, diverted to a use in which

pathogenic bacteria growth in the finished product will be controlled by means other than drying, diverted to a non-food use, or redried;

OR

- Divert the product to a use in which the critical limit is not applicable because pathogenic bacteria growth in the finished product will be controlled by means other than drying (e.g., divert inadequately dried fish to a frozen fish operation);

OR

- Divert the product to a non-food use;

OR

- Destroy the product.

AND

Take the following corrective action to regain control over the operation after a critical limit deviation:

- Adjust the air temperature or velocity;

OR

- Adjust the length of the drying cycle to compensate for a temperature or velocity drop, humidity increase, or inadequate percent weight loss;

OR

- Adjust the belt speed to increase the length of the drying cycle.

Establish a Recordkeeping System.

For batch drying equipment:

- Record of continuous temperature monitoring;

AND

- Record of visual checks of recorded data;

AND

- Record of notation of the start time and end time of the drying periods;

AND

- Records that are appropriate for the other critical factors (e.g., a drying log that indicates input/output air humidity and/or velocity);

OR

- Record of weight before and after drying;

OR

- Record of water activity analysis.

For continuous drying equipment:

- Record of continuous temperature monitoring;

AND

- Record of visual checks of recorded data;

AND

- Drying log that indicates the RPM of the belt drive wheel or the time necessary for a test unit or belt marking to pass through the drier;

AND

- Records that are appropriate for the other critical factors (e.g., a drying log that indicates input/output air humidity and/or velocity);

OR

- Record of weight before and after drying;

OR

- Record of water activity analysis.

Establish Verification Procedures.

- Process validation study (except where a water activity analysis of the finished product is the monitoring procedure):
    - The adequacy of the drying process should be established by a scientific study. For shelf-stable products, the drying process should be designed to ensure the production of a shelf-stable product with a water activity of 0.85. For refrigerated (not frozen), reduced oxygen packaged products, it should be designed to ensure a finished product water activity of less than 0.97. Expert knowledge of drying process calculations and the dynamics of mass transfer in processing equipment may be required

to establish such a drying process. Such knowledge can be obtained by education or experience or both. Establishment of drying processes may require access to adequate facilities and the application of recognized methods. The drying equipment should be designed, operated, and maintained to deliver the established drying process to every unit of a product. In some instances, drying studies may be required to establish the minimum process. In other instances, existing literature that establishes minimum processes or adequacy of equipment is available. Characteristics of the process, product, and/or equipment that affect the ability to achive the established minimum drying process should be taken into consideration in the process establishment. A record of the process establishment should be maintained;

AND

- Finished product sampling and analysis to determine water activity at least once every 3 months (except where such testing is performed as part of monitoring);

  AND

- Before a temperature-recording device (e.g., a recording thermometer) is put into service, check the accuracy of the device to verify that the factory calibration has not been affected. This check can be accomplished by:
  - Immersing the sensor in an ice slurry (32°F (0°C)) if the device will be used at or near refrigeration temperature;

    OR
  - Immersing the sensor in boiling water (212°F (100°C)) if the device will be used at or near the boiling point. Note that the temperature should be adjusted to compensate for altitude, when necessary;

    OR
  - Doing a combination of the above if the device will be used at or near room temperature;

    OR
  - Comparing the temperature reading on the device with the reading on a known accurate reference device (e.g., a thermometer traceable to National Institute of Standards and Technology (NIST) standards) under conditions that are similar to how it will be used (e.g., air temperature) within the temperature range at which it will be used;

  AND

- Once in service, check the temperature-recording device daily before the beginning of operations. Less frequent accuracy checks may be appropriate if they are recommended by the instrument manufacturer and the history of use of the instrument in your facility has shown that the instrument consistently remains accurate for a longer period of time. In addition to checking that the device is accurate by one of the methods described above, this process should include a visual examination of the sensor and any attached wires for damage or kinks. The device should be checked to ensure that it is operational and, where applicable, has sufficient ink and paper;

  AND

- Calibrate the temperature-recording device against a known accurate reference device (e.g., a NIST-traceable thermometer) at least once a year or more frequently if recommended by the device manufacturer. Optimal calibration frequency is dependent upon the type, condition, past performance, and conditions of use of the device. Consistent temperature variations away from the actual value (drift) found during checks and/or calibration may show a need for more frequent calibration or the need to replace the device (perhaps with a more durable

device). For example, devices subjected to high temperatures for extended periods of time may require more frequent calibration. Calibration should be performed at a minimum of two temperatures that bracket the temperature range at which it is used;

AND

- Calibrate other instruments as necessary to ensure their accuracy;

AND

- Review monitoring, corrective action, and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 14-1

CONTROL STRATEGY EXAMPLE 1 - CONTROL BY DRYING

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 1 - Control by Drying." This example illustrates how a processor of shelf-stable salmon jerky can control pathogenic bacteria growth and toxin formation as a result of inadequate drying. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Drying (forced convection oven)	Pathogenic bacteria growth and toxin formation	Maximum product thickness: ¼ inch	Product thickness	Preset slicer to just less than ¼ inch	Once per day before operations	Slicer operator	Re-adjust slicer	Processing log	Documentation of drying process establishment Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Analyze the finished product sample once every 3 months for water activity Review of monitoring, corrective action and verification, records within 1 week of preparation

TABLE 14-1

CONTROL STRATEGY EXAMPLE 1 - CONTROL BY DRYING

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 1 - Control by Drying." This example illustrates how a processor of shelf-stable salmon jerky can control pathogenic bacteria growth and toxin formation as a result of inadequate drying. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Drying (forced convection oven)	Pathogenic bacteria growth and toxin formation	Minimum drying time: 5 hours	Drying time	Digital time and temperature data logger	Continuous, with visual check of recorded data each batch	Oven operator	Continue drying	Data logger printout	Documentation of drying process establishment Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Analyze the finished product sample once every 3 months for water activity Review of monitoring, corrective action and verification, records within 1 week of preparation

TABLE 14-1

CONTROL STRATEGY EXAMPLE 1 - CONTROL BY DRYING

This table is an example of a portion of a Hazard Analysis Critical Control Point (HACCP) plan using "Control Strategy Example 1 - Control by Drying." This example illustrates how a processor of shelf-stable salmon jerky can control pathogenic bacteria growth and toxin formation as a result of inadequate drying. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., aquaculture drugs, environmental chemical contaminants and pesticides, parasites, and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Drying (forced convection oven)	Pathogenic bacteria growth and toxin formation	Minimum oven temperature: 140°F To achieve a final water activity of 0.85 or less	Oven air input temperature	Digital time and temperature data logger	Continuous, with visual check of recorded data each batch	Oven operator	Extend drying process Segregate the product and hold under refrigeration for evaluation Evaluate by performing water activity analysis on finished product Redry if less than 0.85	Data logger printout	Documentation of drying process establishment Check the data logger for accuracy and damage and to ensure that it is operational before putting into operation; check it daily, at the beginning of operations; and calibrate it once per year Analyze the finished product sample once every 3 months for water activity Review of monitoring, corrective action and verification, records within 1 week of preparation

- **CONTROL STRATEGY EXAMPLE 2 - CONTROL BY REFRIGERATION WITH LABELING**

It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Set Critical Limits.

- All finished product labels must contain a "keep refrigerated" statement (e.g., "Important, keep refrigerated until used").

Establish Monitoring Procedures.

» **What Will Be Monitored?**

- Finished product labels for presence of "keep refrigerated" statement.

» **How Will Monitoring Be Done?**

- Visual examination.

» **How Often Will Monitoring Be Done (Frequency)?**

- Representative number of packages from each lot of a finished product.

» **Who Will Do the Monitoring?**

- Any person who has an understanding of the nature of the controls.

Establish Corrective Action Procedures.

Take the following corrective action to a product involved in a critical limit deviation:

- Segregate and relabel any improperly labeled product.

AND

Take the following corrective actions to regain control over the operation after a critical limit deviation:

- Segregate and return or destroy any label stock or pre-labeled packaging stock that does not contain the proper statement;

AND

- Determine and correct the cause of improper labels.

Establish a Recordkeeping System.

- Record of labeling checks.

Establish Verification Procedures.

- Review monitoring and corrective action records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

TABLE 14-2

CONTROL STRATEGY EXAMPLE 2 - CONTROL BY REFRIGERATION WITH LABELING

This table is an example of a portion of a HACCP plan using "Control Strategy Example 2 - Control by Refrigeration With Labeling." This example illustrates how a processor of refrigerated, partially dried catfish can control pathogenic bacteria growth and toxin formation as a result of inadequate drying. It is provided for illustrative purposes only. It may be necessary to select more than one control strategy in order to fully control the hazard, depending upon the nature of your operation.

Pathogenic bacteria growth and toxin formation as a result of inadequate drying may be only one of several significant hazards for this product. Refer to Tables 3-2 and 3-4 (Chapter 3) for other potential hazards (e.g., environmental chemical contaminants and pesticides and metal fragments).

Example Only
See Text for Full Recommendations

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CRITICAL CONTROL POINT	SIGNIFICANT HAZARD(S)	CRITICAL LIMITS FOR EACH PREVENTIVE MEASURE	MONITORING				CORRECTIVE ACTION(S)	RECORDS	VERIFICATION
			WHAT	HOW	FREQUENCY	WHO			
Receipt of labeling	C. botulinum toxin formation during finished product storage	All finished product labels must contain a "keep refrigerated" statement	Finished product labels for the presence of the "keep refrigerated" statement	Visual examination	One label from each case of labels at receipt	Receiving employee	Segregate and re-label any improperly labeled product Segregate and return or destroy any label stock that does not contain the proper statement Determine and correct the cause of improper labels	Label receiving record	Review monitoring and correction action records within 1 week of preparation

*Note: Chapter 12 covers control of pathogenic bacteria growth at the CCP of finished product storage.

BIBLIOGRAPHY.

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of March 29, 2011, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after March 29, 2011.

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APPENDIX 1: **FORMS**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

This appendix contains the following templates:

- Hazard Analysis Worksheet;

And

- Hazard Analysis Critical Control Point (HACCP) Plan Form.

HAZARD ANALYSIS WORKSHEET

Product Name

Firm Name:	Product Description:
Firm Address:	Method of Distribution and Storage:
	Intended Use and Consumer:

(1)	(2)	(3)	(4)	(5)	(6)
Ingredient/Processing Step	**Identify Potential Biological, Chemical, and Physical Hazards Associated with this Product and Process**	**Are Any Potential Food Safety Hazards Significant at this Step? (Yes/No)**	**Justify Your Decision for Column 3**	**What Preventive Measure(s) can be Applied for the Significant Hazards?**	**Is this Step a Critical Control Point? (Yes/No)**

HAZARD ANALYSIS WORKSHEET

(1)	(2)	(3)	(4)	(5)	(6)
Ingredient/Processing Step	**Identify Potential Biological, Chemical, and Physical Hazards Associated with this Product and Process**	**Are Any Potential Food Safety Hazards Significant at this Step? (Yes/No)**	**Justify Your Decision for Column 3**	**What Preventive Measure(s) can be Applied for the Significant Hazards?**	**Is this Step a Critical Control Point? (Yes/No)**

HACCP PLAN FORM

HACCP PLAN NAME

Firm Name:	Product Description:
Firm Address:	Method of Distribution and Storage:
	Intended Use and Consumer:

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	Significant Hazard(s)	Critical Limits	What	How	Frequency	Who	Corrective Action(s)	Records	Verification

Signature of Company Official: _____ Date: _____

HACCP PLAN FORM

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
			Monitoring						
Critical Control Point	Significant Hazard(s)	Critical Limits	What	How	Frequency	Who	Corrective Action(s)	Records	Verification

Signature of Company Official: _____ Date: _____

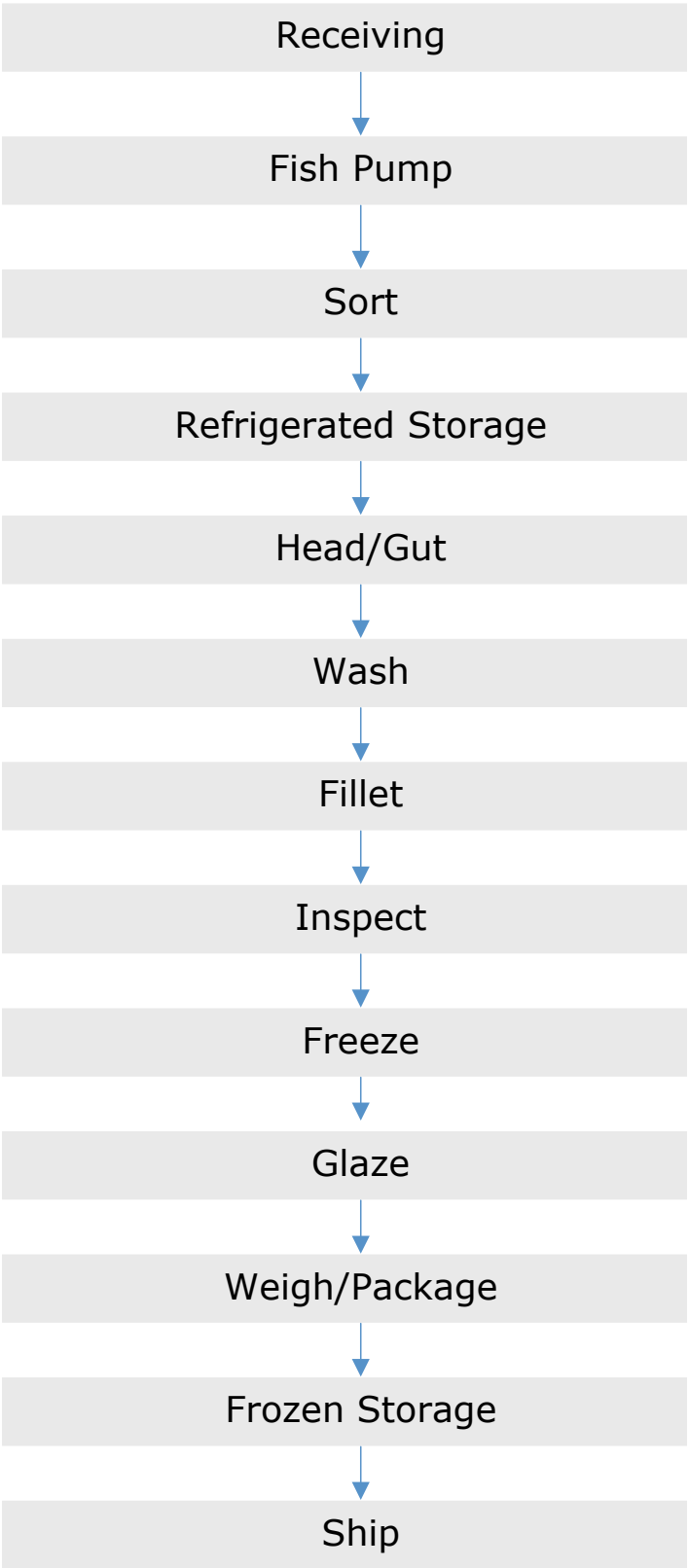
NOTES:

APPENDIX 2: **PRODUCT FLOW DIAGRAM - EXAMPLE**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

This appendix contains a product flow diagram that can be used as an example when you develop your own flow diagram.

FIGURE A-1:
PRODUCT FLOW DIAGRAM EXAMPLE:
FROZEN SALMON FILLETS



NOTES:

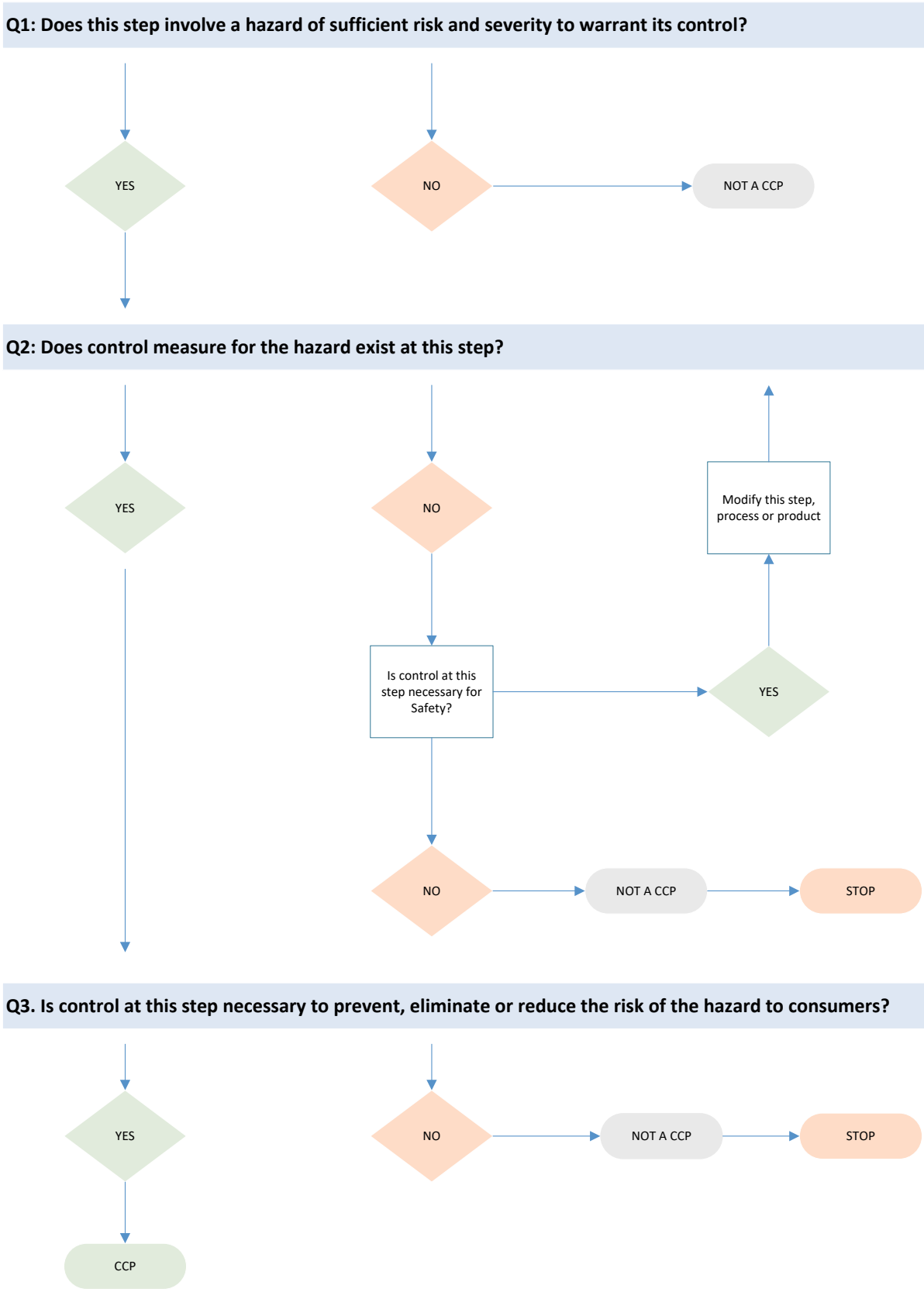
APPENDIX 3: **CRITICAL CONTROL POINT DECISION TREE**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

This appendix contains a decision tree that may be used to assist you with the identification of critical control points (CCPs). You should not rely exclusively on the decision tree, because error may result.

The following decision tree is derived from one that was developed by the National Advisory Committee on Microbiological Criteria for Foods.

FIGURE A-2: CCP DECISION TREE



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- National Advisory Committee on Microbiological Criteria for Foods. 1992. *Hazard Analysis and Critical Control Point System.* Intl. J. Food Microbiol. 16:1-23.

NOTES:

APPENDIX 4: **Bacterial Pathogen Growth and Inactivation**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

This appendix contains information on the growth and inactivation of bacterial pathogens.

Table A-1 contains information on the minimum water activity (a_w), acidity (pH), and temperature; the maximum, pH, water phase salt, and temperature; and oxygen requirements that will sustain growth for the bacterial pathogens that are of greatest concern in seafood processing. Data shown are the minimum or maximum values, the extreme limits reported among the references cited. These values may not apply to your processing conditions.

Table A-2 contains information on maximum, cumulative time and internal temperature combinations for exposure of fish and fishery products that, under ordinary circumstances, will be safe for the bacterial pathogens that are of greatest concern in seafood processing. These maximum, cumulative exposure times are derived from published scientific information.

Because the nature of bacterial growth is logarithmic, linear interpolation using the time and temperature guidance may not be appropriate. Furthermore, the food matrix effects bacterial growth (e.g., presence of competing microorganisms, available nutrients, growth restrictive agents). Consideration of such attributes is needed when using the information in Tables A-1 and A-2.

In summary, Table A-2 indicates that:

For raw, ready-to-eat products:

- If at any time the product is held at internal temperatures above 70°F (21.1°C), exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135ºF (57.2ºC)) should be limited to 2 hours (3 hours if *Staphylococcus aureus* (*S. aureus*) is the only pathogen of concern),

  OR

  Alternatively, exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135ºF (57.2ºC)) should be limited to 4 hours, as long as no more than 2 of those hours are between 70°F (21.1°C) and 135ºF (57.2ºC);

OR

- If at any time the product is held at internal temperatures above 50°F (10°C) but never above 70°F (21.1°C), exposure time at internal temperatures above 50°F (10°C) should be limited to 5 hours (12 hours if *S. aureus* is the only pathogen of concern);

OR

- The product is held at internal temperatures below 50°F (10°C) throughout processing,

  OR

  Alternatively, the product is held at ambient air temperatures below 50°F (10°C) throughout processing.

For cooked, ready-to-eat products:

- If at any time the product is held at internal temperatures above 80°F (26.7°C), exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135ºF (57.2ºC)) should be limited to 1 hour (3 hours if *S. aureus* is the only pathogen of concern),

  OR

Alternatively, if at any time the product is held at internal temperatures above 80°F (26.7°C), exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135°F (57.2°C)) should be limited to 4 hours, as long as no more than 1 of those hours is above 70°F (21.1°C);

OR

- If at any time the product is held at internal temperatures above 70°F (21.1°C) but never above 80°F (26.7°C), exposure time at internal temperatures above 50°F (10°C) should be limited to 2 hours (3 hours if *S. aureus* is the only pathogen of concern),

  OR

  Alternatively, if the product is never held at internal temperatures above 80°F (26.7°C), exposure times at internal temperatures above 50°F (10°C) should be limited to 4 hours, as long as no more than 2 of those hours are above 70°F (21.1°C);

OR

- If at any time the product is held at internal temperatures above 50°F (10°C) but never above 70°F (21.1°C), exposure time at internal temperatures above 50°F (10°C) should be limited to 5 hours (12 hours if *S. aureus* is the only pathogen of concern);

OR

- The product is held at internal temperatures below 50°F (10°C) throughout processing,

  OR

  Alternatively, the product is held at ambient air temperatures below 50°F (10°C) throughout processing.

Note that the preceding recommended critical limits do not address internal product temperatures between 40°F (4.4°C), the recommended maximum storage temperature for refrigerated fish and fishery products, and 50°F (10°C). That is because growth of foodborne pathogenic bacteria is very slow at these temperatures and the time necessary for significant growth is longer than would be reasonably likely to occur in most fish and fishery product processing steps. However, if you have processing steps that occur at these temperatures that approach the maximum cumulative exposure times listed in Table A-2 below for the pathogenic bacteria of concern in your product, you should consider development of a critical limit for control at these temperatures.

It is not possible to furnish recommendations for each pathogenic bacteria, process, type of fish and fishery product, and temperature or combination of temperatures. Programmable models to predict growth rates for certain pathogens associated with various foods under differing conditions have been developed by the U.S. Department of Agriculture's (Pathogen Modeling Program (PMP)) and the United Kingdom's (Food MicroModel (FMM) program). These programs can provide growth curves for selected pathogens. You indicate the conditions, such as pH, temperature, and salt concentration that you are interested in and the models provide pathogen growth predictions (e.g., growth curve, time of doubling, time of lag phase, and generation time). FDA does not endorse or require the use of such modeling programs, but recognizes that the predictive growth information they provide may be of assistance to some processors. However, you are cautioned that significant deviations between actual microbiological data in specific products and the predictions do occur, including those for the lag phase of growth. Therefore, you should validate the time and temperature limits derived from such predictive models.

Table A-3 contains information on the destruction of *Listeria monocytogenes* (*L. monocytogenes*). Lethal rate, as used in this table, is the relative lethality of 1 minute at the designated internal product temperature as compared with the lethality of 1 minute at the reference internal product temperature of 158°F (70°C) (i.e., z = 13.5°F (7.5°C)). For example, 1

minute at 145°F (63°C) is 0.117 times as lethal as 1 minute at 158°F (70°C). The times provided are the length of time at the designated internal product temperature necessary to deliver a 6D process for *L. monocytogenes*. The length of time at a particular internal product temperature needed to accomplish a six logarithm reduction in the number of *L. monocytogenes* (6D) is, in part, dependent upon the food in which it is being heated. The values in the table are generally conservative and apply to all foods. You may be able to establish a shorter process time for your food by conducting scientific thermal death time studies. Additionally, lower degrees of destruction may be acceptable in your food if supported by a scientific study of the normal initial levels in the food. It is also possible that higher levels of destruction may be necessary in some foods, if especially high initial levels are anticipated.

Table A-4 contains information on the destruction of *Clostridium botulinum* (*C. botulinum*) type B (the most heat- resistant form of non-proteolytic *C. botulinum*). Lethal rate, as used in this table, is the relative lethality of 1 minute at the designated internal product temperature as compared with the lethality of 1 minute at the reference product internal temperature of 194°F (90°C) (i.e., for temperatures less than 194°F (90°C), z = 12.6°F (7.0°C); for temperatures above 194°F (90°C), z = 18°F (10°C)). The times provided are the length of time at the designated internal product temperature necessary to deliver a 6D process for *C. botulinum*. The values in the table are generally conservative. However, these values may not be sufficient for the destruction of non-proteolytic *C. botulinum* in dungeness crabmeat because of the potential protective effect of lysozyme. You may be able to establish a shorter process time for your food by conducting scientific thermal death time studies. Additionally, lower degrees of destruction may be acceptable in your food if supported by a scientific study of the normal innoculum in the food.

TABLE A-1
LIMITING CONDITIONS FOR PATHOGEN GROWTH

PATHOGEN	MIN. A_W (USING SALT)	MIN. pH	MAX. pH	MAX. % WATER PHASE SALT	MIN. TEMP.	MAX. TEMP.	OXYGEN REQUIREMENT
BACILLUS CEREUS	0.92	4.3	9.3	10	39.2°F 4°C	131°F[1] 55°C	facultative anaerobe[4]
CAMPYLOBACTER JEJUNI	0.987	4.9	9.5	1.7	86°F 30°C	113°F 45°C	micro-aerophile[2]
CLOSTRIDIUM BOTULINUM, TYPE A, AND PROTEOLYTIC TYPES B AND F	0.935	4.6	9	10	50°F 10°C	118.4°F 48°C	anaerobe[3]
CLOSTRIDIUM BOTULINUM, TYPE E, AND NON-PROTEOLYTIC TYPES B AND F	0.97	5	9	5	37.9°F 3.3°C	113°F 45°C	anaerobe[3]
CLOSTRIDIUM PERFRINGENS	0.93	5	9	7	50°F 10°C	125.6°F 52°C	anaerobe[3]
PATHOGENIC STRAINS OF ESCHERICHIA COLI	0.95	4	10	6.5	43.7°F 6.5°C	120.9°F 49.4°C	facultative anaerobe[4]
LISTERIA MONOCYTOGENES	0.92	4.4	9.4	10	31.3°F -0.4°C	113°F 45°C	facultative anaerobe[4]
SALMONELLA SPP.	0.94	3.7	9.5	8	41.4°F 5.2°C	115.2°F 46.2°C	facultative anaerobe[4]
SHIGELLA SPP.	0.96	4.8	9.3	5.2	43°F 6.1°C	116.8°F 47.1°C	facultative anaerobe[4]
STAPHYLOCOCCUS AUREUS GROWTH	0.83	4	10	20	44.6°F 7°C	122°F 50°C	facultative anaerobe[4]
STAPHYLOCOCCUS AUREUS TOXIN FORMATION	0.85	4	9.8	10	50°F 10°C	118°F 48°C	facultative anaerobe[4]
VIBRIO CHOLERAE	0.97	5	10	6	50°F 10°C	109.4°F 43°C	facultative anaerobe[4]
VIBRIO PARAHAEMOLYTICUS	0.94	4.8	11	10	41°F 5°C	113.5°F 45.3°C	facultative anaerobe[4]
VIBRIO VULNIFICUS	0.96	5	10	5	46.4°F 8°C	109.4°F 43°C	facultative anaerobe[4]
YERSINIA ENTEROCOLITICA	0.945	4.2	10	7	29.7°F -1.3°C	107.6°F 42°C	facultative anaerobe[4]

1. Has significantly delayed growth (>24 hours) at 131°F (55°C).
2. Requires limited levels of oxygen.
3. Requires the absence of oxygen.
4. Grows either with or without oxygen.

TABLE A-2 TIME AND TEMPERATURE GUIDANCE FOR CONTROLLING PATHOGEN GROWTH AND TOXIN FORMATION IN FISH AND FISHERY PRODUCTS		
POTENTIALLY HAZARDOUS CONDITION	PRODUCT TEMPERATURE	MAXIMUM CUMULATIVE EXPOSURE TIME
GROWTH AND TOXIN FORMATION BY ***BACILLUS CEREUS***	39.2-43°F (4-6°C) 44-59°F (7-15°C) 60-70°F (16-21°C) Above 70°F (21°C)	5 days 1 day 6 hours 3 hours
GROWTH OF ***CAMPYLOBACTER JEJUNI***	86-93°F (30-34°C) Above 93°F (34°C)	48 hours 12 hours
GERMINATION, GROWTH, AND TOXIN FORMATION BY ***CLOSTRIDIUM BOTULINUM*** TYPE A, AND PROTEOLYTIC TYPES B AND F	50-70°F (10-21°C) Above 70°F (21°C)	11 hours 2 hours
GERMINATION, GROWTH, AND TOXIN FORMATION BY ***CLOSTRIDIUM BOTULINUM*** TYPE E, AND NON-PROTEOLYTIC TYPES B AND F	37.9-41°F (3.3-5°C) 42-50°F (6-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	7 days 2 days 11 hours 6 hours
GROWTH OF ***CLOSTRIDIUM PERFRINGENS***	50-54°F (10-12°C) 55-57°F (13-14 °C) 58-70°F (15-21°C) Above 70°F (21°C)	21 days 1 day 6 hours[1] 2 hours
GROWTH OF PATHOGENIC STRAINS OF ***ESCHERICHIA COLI***	43.7-50°F (6.6-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
GROWTH OF ***LISTERIA MONOCYTOGENES***	31.3-41°F (-0.4-5°C) 42-50°F (6-10°C) 51-70°F (11-21°C) 71-86°F (22-30°C) Above 86°F (30°C)	7 days 1 day 7 hours 3 hours 1 hour
GROWTH OF ***SALMONELLA*** SPECIES	41.4-50°F (5.2-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
GROWTH OF ***SHIGELLA*** SPECIES	43-50°F (6.1-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
GROWTH AND TOXIN FORMATION BY ***STAPHYLOCOCCUS AUREUS***	50°F (7-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	14 days 12 hours[1] 3 hours
GROWTH OF ***VIBRIO CHOLERAE***	50°F (10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80ºF (27ºC)	21 days 6 hours 2 hours 1 hour[2]
GROWTH OF ***VIBRIO PARAHAEMOLYTICUS***	41-50°F (5-10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80ºF (27ºC)	21 days 6 hours 2 hours 1 hour[2]
GROWTH OF ***VIBRIO VULNIFICUS***	46.4-50°F (8-10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80ºF (27ºC)	21 days 6 hours 2 hours 1 hour[2]
GROWTH OF ***YERSINIA ENTEROCOLITICA***	29.7-50°F (-1.3-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	1 day 6 hours 2.5 hours

1. Additional data needed.
2. Applies to cooked, ready-to-eat foods only.

TABLE A-3 INACTIVATION OF LISTERIA MONOCYTOGENES			
INTERNAL PRODUCT TEMPERATURE (°F)	INTERNAL PRODUCT TEMPERATURE (°C)	LETHAL RATE	TIME FOR 6D PROCESS (MINUTES)
145	63	0.117	17.0
147	64	0.158	12.7
149	65	0.215	9.3
151	66	0.293	6.8
153	67	0.398	5.0
154	68	0.541	3.7
156	69	0.736	2.7
158	70	1.000	2.0
160	71	1.359	1.5
162	72	1.848	1.0
163	73	2.512	0.8
165	74	3.415	0.6
167	75	4.642	0.4
169	76	6.310	0.3
171	77	8.577	0.2
172	78	11.659	0.2
174	79	15.849	0.1
176	80	21.544	0.09
178	81	29.286	0.07
180	82	39.810	0.05
182	83	54.116	0.03
183	84	73.564	0.03
185	85	100.000	0.02
Note: z = 13.5°F (7.5°C).			

TABLE A-4 INACTIVATION OF NON-PROTEOLYTIC CLOSTRIDIUM BOTULINUM TYPE B			
INTERNAL PRODUCT TEMPERATURE (°F)	INTERNAL PRODUCT TEMPERATURE (°C)	LETHAL RATE*	TIME FOR 6D PROCESS (MINUTES)
185	85	0.193	51.8
187	86	0.270	37.0
189	87	0.370	27.0
190	88	0.520	19.2
192	89	0.720	13.9
194	90	1.000	10.0
196	91	1.260	7.9
198	92	1.600	6.3
199	93	2.000	5.0
201	94	2.510	4.0
203	95	3.160	3.2
205	96	3.980	2.5
207	97	5.010	2.0
208	98	6.310	1.6
210	99	7.940	1.3
212	100	10.000	1.0

Note: For temperatures less than 194°F (90°C), z = 12.6°F (7.0°C); for temperatures above 194°F (90°C), z = 18°F (10°C).

*Note: These lethal rates and process times may not be sufficient for the destruction of non-proteolytic C. botulinum in dungeness crabmeat because of the potential that substances that may be naturally present, such as lysozyme, may enable the pathogen to more easily recover from heat damage.

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NOTES:

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

Reference Document: 2013 FDA Food Code

Provision: 1-201.10

Document Name: Heat sealing without a vacuum v03

Date: January 4, 2017, Editorial change September 12, 2017, December 20, 2019

Question: When packaging food in a retail food establishment, does the 2013 Food Code definition of reduced oxygen packaging apply to the use of plastic bags or plastic films that have been heat sealed without drawing a vacuum?

Response:

No. The process of heat sealing a time temperature control for safety (TCS) food in packaging (a plastic bag or a plastic film on trays) without drawing a vacuum or otherwise modifying the atmosphere inside the package would not meet the 2013 Food Code definition of reduced oxygen packaging (ROP), provided the food being packaged has NOT been heated, just prior to packaging.

The 2013 FDA Food Code defines "Reduced Oxygen Packaging" (ROP) as:

- "The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and . . . .."

A reduced oxygen environment occurs in a package when less oxygen is present in the package relative to the amount of oxygen expected to be present in the atmosphere (typically 21% at sea level). The Food Code definition of reduced oxygen packaging is limited to the intentional or purposeful methods used by food establishments to create a reduced oxygen environment within a packaged TCS food product at the time of packaging.

The packaging and sealing, without drawing a vacuum, of a TCS food that has not been heated, just prior to packaging, is not considered to be removing oxygen to the degree that you are: 1) reducing the amount of oxygen in a package at the time of packaging, or 2) using an intentional or purposeful method to create a reduced oxygen environment within a packaged TCS food product at the time of packaging.

Heat sealing a hot TCS food (which includes TCS foods cooked as specified in relevant Sections of Part 3-401 of the Food Code and TCS foods heated to hot holding temperatures) without modifying the atmosphere or drawing a vacuum raises a concern of *C. botulinum* growth in the packaged TCS food. This is because the process of cooking food drives off oxygen from the food thereby lowering the oxygen level in that food. After the bag is sealed, the oxygen level in the headspace and the oxygen level in the hot TCS food will begin to equilibrate. This results in a package with an oxygen level below what is normally found in the atmosphere, thereby creating a process that aligns with the Food Code definition of ROP.

The model Food Code is neither federal law nor federal regulation and is not preemptive. It represents FDA's best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented. The model Food Code provisions are designed to be consistent with federal food laws and regulations and are written for ease of legal adoption at all levels of government.

References:

1. 2013 FDA Food Code, 1-202.10 Statement of Application and Listing of Terms.

Reference Document: 2013 Food Code

Provision(s): 1-201.10; 3-502.12; 8-103.10; 8-103.11

Document Name: Vacuum packaging and oxygen transfer rate of the packaging material

Date: October 6, 2016

Question: Does the Food Code definition for "Reduced Oxygen Packaging" apply to fish, not frozen, that is vacuum packaged using packaging material with a greater than or equal to oxygen transfer rate (OTR) of 10,000 cc/m^2/24 hours at 24°C (10K)?

Response:

Vacuum packaging by definition is a reduced oxygen packaging process. The oxygen transfer rate (OTR) of the packaging material used in vacuum packaging a food item does not change this designation.

Paragraph 3-502.12 (C) of the 2013 FDA Food Code specifically states, "except for fish that is frozen before, during, and after packaging, a food establishment may not package fish using a reduced oxygen packaging method." This provision is intended to apply irrespective of the oxygen transfer rate of the packaging material used.

The 2013 FDA Food Code defines "Reduced Oxygen Packaging" (ROP) as:

a) The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and

b) A process as specified in (a) of this definition that involves a food for which the hazards *Clostridium botulinum* or *Listeria monocytogenes* require control in the final packaged form. "Reduced oxygen packaging" includes Vacuum packaging, in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package…"

Unfrozen raw fish and other seafood are excluded from being reduced oxygen packaged at retail because of these products' natural association with non-proteolytic *Clostridium botulinum* (primarily type E) which grows at 3.3°C (38°F). If a food establishment wants to employ a reduced oxygen packaging method for fish that is not frozen before, during and after packaging it is recommended that the food establishment seek a variance (8-103.10 Modifications and

Waivers) from the regulatory authority that has jurisdiction.

FDA acknowledges that the reduced oxygen environment created in a reduced oxygen packaged product at the time of packaging can be impacted over time by the oxygen-permeability of the packaging material. As such, the FDA-CFSAN Retail Food Policy Team would not object to a variance request being approved based upon information that shows the OTR of the packaging material provides sufficient exchange of oxygen to allow naturally occurring, aerobic spoilage organisms on the fishery product to grow and spoil the product (under moderate abuse temperatures) before *Clostridium botulinum* toxin is produced.

Food Code Section 8-103.10 Modifications and Waivers, provides the regulatory authority the means to grant a variance by modifying or waiving the requirements of the Code, if in the opinion of the regulatory authority a health hazard or nuisance will not result from the variance. Food Code Section 8-103.11 Documentation of Proposed Variance and Justification, provides a means for the regulatory authority to obtain information from the operator regarding the proposed variance prior to approval. If the operator intends to produce and package the product for wholesale, it would be subject to federal and state food manufacturing regulations.

The FDA Food Code is neither federal law nor federal regulation and is not preemptive. It represents FDA's best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented. The FDA Food Code provisions are designed to be consistent with federal food laws and regulations, and are written for ease of legal adoption at all levels of government.

References:

1. 2013 Food Code, Section 3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria; Section 1-201.10 Statement of Application and Listing of Terms; Section 8-103.10 Modifications and Waivers; Section 8-103.11 Documentation of Proposed Variance and Justification

Controlling the Hazard of *Clostridium botulinum* Growth and Toxin Formation in Reduced Oxygen Packaged Fish and Fishery Products Including Refrigerated, Vacuum-Packed Crawfish Tail Meat

It has come to FDA's attention that processors of refrigerated, vacuum-packed crawfish tail meat may not be controlling the hazard of *Clostridium botulinum* growth and toxin formation. FDA considers the hazard of *C. botulinum* growth and toxin formation reasonably likely to occur in reduced oxygen packaged (ROP) fish and fishery products including refrigerated, vacuum-packed crawfish tail meat. All seafood processors are required to conduct a hazard analysis and implement a written HACCP plan to control hazards that are reasonably likely to occur within and outside the processing plant according to 21 CFR Part 123.6. FDA's Fish and Fishery Products Hazards and Controls Guidance provides recommendations to assist processors with assessing hazards and developing HACCP plans.

FDA considers ROP fish and fishery products including refrigerated, vacuum-packed crawfish tail meat to be adulterated under section 402 (a)(4) of the Food, Drug and Cosmetic Act when the hazard of *C. botulinum* growth and toxin formation is not controlled. Specific sections addressing primary processors and secondary processors including distributors are provided below in this document.

Background

ROP encompasses a large variety of packaging methods including vacuum packaging, modified atmosphere packaging, hermetically sealed containers, sealed plastic or laminated packaging, packing in oil, and using a material that is not considered oxygen-permeable. Packaging that is not considered oxygen-permeable restricts the exchange of oxygen and can lead to any oxygen present in the packaging being utilized by spoilage organisms resulting in a reduced oxygen environment. By reducing or preventing the exchange of oxygen, a processor introduces the hazard of *C. botulinum* growth and toxin formation.

C. botulinum is an anaerobic bacterium, meaning it can grow in low oxygen conditions, that is widely distributed in nature, in soil, the sediment of streams, lakes, and coastal waters, and in the intestinal tracts of fish and mammals. The toxin produced by *C. botulinum* is considered one of the most poisonous naturally occurring substances known and when ingested can result in paralysis, leading to death from asphyxiation. There are two major groups of *C. botulinum*, the proteolytic and non-proteolytic. Proteolytic strains can grow at 50°F and above. Non-proteolytic strains, commonly found in seafood, can grow at 38°F and above to render a food toxic without any apparent signs of spoilage.

Primary Processors

1. When refrigeration below 38°F is the sole control for the hazard *C. botulinum,* processors should use a Time-Temperature Indicator (TTI) on each reduced oxygen package of product and maintain the product below 38°F. Since product will likely not be maintained below 38°F during distribution, TTIs are needed to monitor time and temperatures exposures throughout distribution until consumption. TTIs should be designed specifically for *C. botulinum* and alert consumers and end users of potentially unsafe time and temperature exposures that could result in toxin formation.

Processors that use a TTI on each ROP package and maintain the product below 38°F should have a HACCP plan that, at a minimum, lists critical control points for finished product storage below 38°F, and TTI use and application. The critical control points and critical limits for the TTIs should be based on the TTI manufacturer's specifications.

2. For seafood, packaging that has an oxygen transmission rate (OTR) of 10,000 cc/m^2/24 hours at 24°C, or higher (often referred to as 10K OTR and occasionally printed on the packaging) is considered oxygen permeable and not ROP by FDA. Oxygen permeable packaging should provide a sufficient exchange of oxygen to allow naturally occurring aerobic spoilage organisms on the fishery product to grow and spoil the product before *C. botulinum* toxin is produced under moderate abuse temperatures.

3. Product can be frozen with proper labeling. The product should be immediately frozen after being placed in a reduced oxygen package. The HACCP plan should list a labeling critical control point for each package to be labeled "Important, keep frozen until used, thaw under refrigeration immediately before use."

Secondary Processors Including Distributors

The term secondary processor includes distributors that hold or store product because holding and storing is defined as processing in 21 CFR Part 123.3 (k)(1). Secondary processors should assess the hazard of *C. botulinum* when receiving ROP products and ensure the product is received with proper controls, in addition to implementing proper controls within their own facility, as necessary. For example, distributors of refrigerated ROP products including vacuum-packed crawfish tail meat, should receive product below 38°F with TTIs and have a HACCP plan that lists critical control points for receiving and storage with critical limits that maintain the product below 38°F.

For more information on *C. botulinum* and controls see Chapter 13 of FDA's Fish and Fishery Products Hazards and Controls Guidance (4th ed.) and FDA's Seafood HACCP Video titled "Time-Temperature Indicators" available at www.fda.gov/seafood.

STATE OF COLORADO

Huffman - CDPHE, Troy <troy.huffman@state.co.us>

Response to your Case 299700: Food Code [ref:_00D60KbN0._5003d5N9HNAA0:ref]

1 message

"FCIC Inquiry" <fcicinquiry@fda.hhs.gov> <fcicinquiry@fda.hhs.gov> Thu, Nov 17, 2022 at 10:02 AM
To: "troy.huffman@state.co.us" <troy.huffman@state.co.us>

This message is being sent in response to the following submitted inquiry:

When packaging food that has been heated just prior to packaging in a retail food establishment using a breathable plastic bag or plastic film and then allowing that product to cool, does the 2017 Food Code definition of reduced oxygen packaging apply? Does the film or bag have to be 10K OTR or greater to be considered breathable?

The Food and Drug Administration's (FDA) Food and Cosmetic Information Center (FCIC)/Technical Assistance Network (TAN) has prepared a response for case number 299700.

Response:

Thank you for your inquiry on the 2017 Food code definition of reduced oxygen packaging. The Food Code defines Reduced oxygen packaging (ROP) as:

(a) The reduction of the amount of oxygen in a PACKAGE by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and

(b) A process as specified in Subparagraph (1)(a) of this definition that involves a FOOD for which the HAZARDS Clostridium botulinum or Listeria monocytogenes require control in the final PACKAGED form.

ROP also includes:

1. Vacuum packaging
2. Modified atmosphere packaging
3. Controlled atmosphere packaging
4. Cook chill packaging
5. Sous Vide packaging

Based on the information provided in this inquiry, the trays are sealed with a film that allows oxygen transmission and the trays contain ambient air (no removal of oxygen by vacuum or displacement with another gas such as nitrogen), therefore, it is not considered ROP. It seems like the film is a measure to protect the food contents from contamination. Barrier properties of a container are not used to define what we mean by ROP. With the information provided, this practice would not be considered ROP as defined in the Food Code.

It is important to note that although it appears based on the information provided that this is not considered an ROP process, it can potentially create a ROP environment depending on the temperature at which the product is packaged (which is the case with many foods in many different storage containers). Heating temperatures were not provided in the inquiry. Heating a food drives off the oxygen. Also, when hot food cools in a package, it can draw a slight vacuum, thereby reducing oxygen, although oxygen can reenter the package once the food cools if the package material is oxygen permeable. In addition, there can be areas in a packaged food that have reduced oxygen capable of supporting growth of pathogens such as Clostridium botulinum if the food is not maintained at a temperature to prevent such growth.

We do not have a definition of "breathable." Note also that breathable packaging is usually designed to provide oxygen levels that will allow spoilage organisms to grow and spoil food before it becomes toxic, not as a measure to prevent growth of C. botulinum.

The Food Code is a model for adoption by state, local, tribal, territorial regulatory jurisdictions although some local laws may differ from the model Food Code.

For the most up to date information on the FDA Food Code, please go to: https://www.fda.gov/food/fda-food-code/food-code-2017.

Thank you for contacting FDA's FCIC/TAN.

View popular Food Safety Modernization Act (FSMA) questions and answers identified by the Technical Assistance Network (TAN), on our website.

This communication is intended for the exclusive use of the inquirer and does not constitute an advisory opinion (21 CFR 10.85(k)). Also note that this response is not intended to be a comprehensive list of all applicable requirements. Please check FDA's web page (www.fda.gov) regularly for guidance reflecting our current thinking. Additional information on FSMA can be found on FDA's FSMA web page (www.fda.gov/fsma). This communication may contain information that is protected, privileged, or confidential. If you have received it in error, please immediately delete all copies.

**Please do not reply to this email box. If you would like to submit a follow-up question or need clarification to this inquiry, please click here www.fda.gov/fcic and reference this inquiry's case number.

In order to improve our service, we'd like your opinion about your experiences using the FSMA TAN - http://cfsan.force.com/Responsesurvey

FSMA
TECHNICAL ASSISTANCE
NETWORK

Response to your Case 301854: Food Code [ref:_00D60KbN0._5003d5tAlMAAU:ref]

1 message

"FCIC Inquiry" <fcicinquiry@fda.hhs.gov> <fcicinquiry@fda.hhs.gov>
To: "troy.huffman@state.co.us" <troy.huffman@state.co.us>

Fri, Nov 18, 2022 at 5:29 AM

This message is being sent in response to the following submitted inquiry:

This is a follow-up to assigned case number 299700. The package is sealed with the breathable film and the product temperature is above 135F and then allowed to cool while still sealed with a breathable film. Would that be considered ROP if sealed hot then allowed to cool?

The Food and Drug Administration's (FDA) Food and Cosmetic Information Center (FCIC)/Technical Assistance Network (TAN) has prepared a response for case number 301854.

Response:

As explained in our response to case #299700, based on the limited information provided in your inquiry, the trays are sealed with a film that allows oxygen transmission and the trays contain ambient air (no removal of oxygen by vacuum or displacement with another gas such as nitrogen), therefore, it is not considered ROP as defined in the Food Code.

Thank you for contacting FDA's FCIC/TAN.

View popular Food Safety Modernization Act (FSMA) questions and answers identified by the Technical Assistance Network (TAN), on our website.

this response is not intended to be a comprehensive list of all applicable requirements. Please check FDA's web page (www.fda.gov) regularly for guidance reflecting our current thinking. Additional information on FSMA can be found on FDA's FSMA web page (www.fda.gov/fsma). This communication may contain information that is protected, privileged, or confidential. If you have received it in error, please immediately delete all copies.

**Please do not reply to this email box. If you would like to submit a follow-up question or need clarification to this inquiry, please click here www.fda.gov/fcic and reference this inquiry's case number.

In order to improve our service, we'd like your opinion about your experiences using the FSMA TAN - http://cfsan.force.com/Responsesurvey

January 16, 2023

Revised January 17, 2023

Lodge Cast Iron

Research & Development Report

VGSRN: 434

Cleaning Effectiveness of Cast Iron Pans and Glass and Plastic Plates when Machine Washed

Prepared For:

David Fletcher

QA Supervisor/Metallurgist

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Prepared By:

Rachel Corken

Scientist, Research & Development

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OBJECTIVE

The objective of this study was to validate the reduction of *E. coli* and *Staphylococcus aureus* on cast iron pans and plates when place and cycled through a machine dishwasher.

MATERIAL AND METHODS

Test Product

Lodge Cast Iron provided a sufficient amount of product for inoculation to pass through a machine dishwasher. SGS North America provided all other testing supplies.

Test Organisms

A strain of generic *Escherichia coli* (ATCC 25922) and *Staphylococcus aureus* (ATCC 6538) was used to inoculate the products. The cultures were grown overnight in Brain Heart Infusion Broth (BHI) individually and diluted to achieve an inoculum level of approximately 8 log CFU/g sample.

Inoculation of Product

The product was inoculated with freshly prepared inoculum. The inoculum was combined with a 1% solution of reconstituted non-fat dry milk that served as a "soil". The pan surfaces were inoculated with a concentration between $1.0x10^8$ to $9.9x10^8$ cells/ml on the product. The inoculum was then allowed to dry overnight at room temperature.

Product Processing

Twelve of each Pioneer Woman 13.5" cast iron skillets, Mainstays 12" cast iron skillets, Lodge 8" cast iron skillets, Lodge cast iron oval servers pre-own and used by Chattanooga State University Culinary program, Corelle Pioneer Women Blue plates, and Mainstays black plastic plates were inoculated and tested for generic *E. coli* and *S. aureus*. For each test organism, three of each product were used to measure the viable bacteria after overnight drying without washing to serve as the untreated controls for each microorganism. The other nine of each pan type for each test organism were washed in triplicate in 3 separate wash cycles. After the wash cycle were complete, the products were tested for residual bacterial count. For both the treated and untreated products, the level of organisms remaining on the products was determined by swabbing the product surfaces with EZ-10NB-PUR swabs.

Microbial Analyses

Each of the swabs was serially diluted to obtain a countable range and plated in duplicate using 15 mL to 20 mL of TSA agar. The plates were incubated at 35±1°C for 48±2h. All typical colonies were enumerated.

DATA ANALYSIS AND REPORT

The cleaning effectiveness of cast iron pans, glass plates, and plastic plates was determined by comparing the level of organisms on the washed product to that of the unwashed product.

After the inoculation and drying of *Staphylococcus aureus,* the untreated Pioneer Woman Cast Iron had an average of 6.977 log CFU/g, Mainstays Cast Iron of 6.854 log CFU/g, Lodge 8in Cast Iron of 6.700 log CFU/g, Lodge Cast Iron Oval Server (pre-own and used by Chattanooga State University Culinary program) of 6.767 log CFU/g, Corelle Plate of 6.585 log CFU/g and Mainstays Plate of 6.729 log CFU/g (Table 1). Once the products where washed (treated) the Pioneer Woman Cast Iron had an average of 0.300 log CFU/g, Mainstays Cast Iron of 0.978 log CFU/g, Lodge 8in Cast Iron of 0.487 log CFU/g, Lodge Cast Iron Oval Server of 1.120 log CFU/g, Corelle Plate of 0.689 log CFU/g and Mainstays Plate of 1.034 log CFU/g.

For the inoculation of *Escherichia coli*, the untreated Pioneer Woman Cast Iron had an average of 4.472 log CFU/g, Mainstays Cast Iron of 2.867 log CFU/g, Lodge 8in Cast Iron of 4.000 log CFU/g, Lodge Cast Iron Oval Server (pre-own and used by Chattanooga State University Culinary program) of 4.667 log CFU/g, Corelle Plate of 2.767 log CFU/g and Mainstays Plate of 4.460 log CFU/g (Table 2). Ones the products where washed(treated) the Pioneer Woman Cast Iron had an average of 0.942 log CFU/g, Mainstays Cast Iron of 0.622 log CFU/g, Lodge 8in Cast Iron of 1.115 log CFU/g, Lodge Cast Iron Oval Server of 0.817 log CFU/g, Corelle Plate of 0.589 log CFU/g and Mainstays Plate of 0.742 log CFU/g.

The washing process effectively reduced the level of inoculated *Staphylococcus aureus* in Pioneer Woman Cast Iron by at least 6.677 log CFU/g, Mainstays Cast Iron by 5.876 log CFU/g, Lodge 8in Cast Iron by 6.213 log CFU/g, Lodge Cast Iron Oval Server (pre-own and used by Chattanooga State University Culinary program) by 5.647 log CFU/g, Corelle Plate by 5.896 log CFU/g and Mainstays Plate by 5.695 log CFU/g.

The washing process effectively reduced the level of inoculated *Escherichia coli* in Pioneer Woman Cast Iron by at least 3.530 log CFU/g, Mainstays Cast Iron by 2.245 log CFU/g, Lodge 8in Cast Iron by 2.885 log CFU/g, Lodge Cast Iron Oval Server (pre-own and used by Chattanooga State University Culinary program) by 3.850 log CFU/g, Corelle Plate by 2.178 log CFU/g and Mainstays Plate by 3.718log CFU/g.

Consumer dishwashing of cast iron, Correlle, and plastic plates, effectively reduced the level of inoculated *S. aureus* and *E. coli* on all three surface types.

Table 1: Comparison of level of *Staphylococcus aureus* in treated and untreated products.

Sample	Average Untreated (Log CFU/g)	Average Treated (Log CFU/g)	Reduction (Log CFU/g)
Pioneer Woman Cast Iron	6.977 (σ=0.046)	0.300 (σ=0.585)	6.677
Mainstays Cast Iron	6.854 (σ=0.052)	0.978 (σ=0.593)	5.876
Lodge 8in Cast Iron	6.700 (σ=0.062)	0.487 (σ=0.692)	6.213
Lodge Cast Iron Oval Server	6.767 (σ=0.087)	1.120 (σ=0.454)	5.647
Corelle Plate	6.585 (σ=0.108)	0.689 (σ=0.655)	5.896
Mainstays Plate	6.729 (σ=0.027)	1.034 (σ=0.765)	5.695

Table 2: Comparison of level of *Escherichia coli* in treated and untreated products.

Sample	Average Untreated (Log CFU/g)	Average Treated (Log CFU/g)	Reduction (Log CFU/g)
Pioneer Woman Cast Iron	4.472 (σ=0.470)	0.942 (σ=0.555)	3.530
Mainstays Cast Iron	2.867 (σ=2.042)	0.622 (σ=0.585)	2.245
Lodge 8in Cast Iron	4.000 (σ=0.000)	1.115 (σ=0.555)	2.885
Lodge Cast Iron Oval Server	4.667 (σ=0.046)	0.817 (σ=0.847)	3.850
Corelle Plate	2.767 (σ=1.960)	0.589 (σ=0.694)	2.178
Mainstays Plate	4.460 (σ=0.225)	0.742 (σ=0.681)	3.718

Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel

Final Report

December 18, 2019

Version 1

Project Identification Number

QL # 19269-2B

Test Articles

Cast Iron Cookware and Food Grade Stainless Steel Carriers

Study Director

Benjamin J. Bastin

Study Sponsor

Lodge Manufacturing
204 East 5th Street
South Pittsburgh, TN 37380

Performing Laboratory

Q Laboratories
1930 Radcliff Drive
Cincinnati, OH 45204

Table of Contents

Test Summary

Title: Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel

Study Design: This study was designed to demonstrate that microorganisms can be removed from cast iron cookware with similar effectiveness as from stainless steel surfaces. The equivalence of recovery was demonstrated by inoculating both materials with equivalent numbers of each microorganism. For this study the following microorganisms were used: *Staphylococcus aureus*, *Escherichia coli*, *Salmonella* Enteritidis, *Listeria monocytogenes*, and *Clostridium perfringens*. Following inoculation, surfaces were sampled.

Test Articles:

The test articles evaluated were provided to the testing facility by the study sponsor, complete with appropriate documentation. Test articles were sterilized via autoclave upon receipt and stored at ambient temperature (20 - 25 °C) in autoclaved aluminum foil.

1. Cast Iron Cookware
   - 1.1 14 Ounce Round Cast Iron Mini Server (SKU: HMSRD)
   - 1.2 12 Ounce Cast Iron Mini Serving Bowl (SKU: HMSB)
   - 1.3 16 Ounce Oval Cast Iron Mini Server (SKU: HM16OS)
   - 1.4 9 Ounce Oval Cast Iron Mini Server (SKU: HMSOV)
   - 1.5 14 Ounce Rectangular Cast Iron Mini Server (SKU: HMS14RC)
   - 1.6 10 Ounce Square Cast Iron Mini Server (SKU: HMSS)
2. Food Grade Stainless Steel Carriers (18 GA 300 series, brush finish)

Sponsor: Lodge Manufacturing
204 East 5th Street
South Pittsburgh, TN 37380

Testing Conditions

Challenge Microorganisms:

1. *Staphylococcus aureus* American Type Culture Collection (ATCC) 6538
2. *Escherichia coli* ATCC 8739
3. *Salmonella* Enteritidis ATCC 13076
4. *Listeria monocytogenes* ATCC 7644
5. *Clostridium perfringens* ATCC 12915

Note: Appropriate laboratory safety conditions was employed while working with enriched culture suspensions. These conditions included, but were not limited to, the use of appropriate PPE (including disposable gloves, beard nets, hair nets, and lab coats), Biological Safety Cabinets, and protective eyewear.

Testing Conditions:

The evaluation was conducted at ambient temperature (20 - 25 °C).

Media/Reagents:

1. Tryptic Soy Agar with 5% Sheep Blood (SBA) (Fisher Scientific, PN 221261) or equivalent
2. Microbial Content Test (MCT) agar MP107
3. Tryptic Soy Broth (TSB) MP058
4. Phosphate Buffered Saline (PBS) MP416
5. Columbia Blood Agar (CBA) with 5% Sheep Blood MP086
6. Reinforced Clostridial Medium (RCM) MP158

Equipment/Supplies:

1. Incubator, temperature range 35 ± 1 °C
2. Incubator thermometer, NIST traceable
3. Sterile containers
4. Steam autoclave
5. Vortex mixer
6. Calibrated, traceable minute/second timer
7. Refrigerator, temperature range 2 - 8 °C
8. Refrigerator thermometer, NIST traceable
9. Traceable thermometer/clock/humidity monitor
10. Adjustable pipettor, 1 µL - 200 µL capacity
11. Adjustable pipettor, 100 µL - 1000 µL capacity
12. Sterile serological pipettes
13. Sterile 100 µL and 1000 µL micropipette tips
14. Reichert Quebec® Colony Counter, or equivalent
15. Hand tally

16. Test tubes, sterilized
17. Sterile disposable Petri dishes, 100 x 15 mm
18. Sterile polyurethane tip swabs
19. Sterile disposable loops
20. Rotator/shaker
21. Anaerobic Sachets, BBL GasPaks or equivalent

Study Dates and Facility

The analysis phase of this test was conducted at Q Laboratories in the Microbiology Research and Development Laboratory, 1930 Radcliff Drive, Cincinnati, Ohio 45204, from 10-28-19 to 11-11-19. The study sponsor and study director signed the protocol on 10-31-19. The final report was released 12-16-19.

Records to be Maintained

All testing data, protocol, protocol modifications, test material records, the final report, and correspondence between Q Laboratories and the sponsor will be stored in the archives at Q Laboratories, 1930 Radcliff Drive, Cincinnati, Ohio 45204 for a period of at least seven (7) years.

Test Procedure

Test Microorganism Preparation:

Staphylococcus aureus ATCC 6538, *Escherichia coli* ATCC 8739, *Salmonella* Enteritidis ATCC 13076, and *Listeria monocytogenes* ATCC 7644 were propagated on Tryptic Soy Agar with 5% Sheep Blood (SBA) from a Q Laboratories frozen stock culture stored at -70 °C. SBA plates were incubated aerobically at 35 ± 1 °C for 24 ± 2 hours. After incubation, an isolated colony was picked to Tryptic Soy Broth (TSB) and incubated at 35 ± 1 °C for 24 ± 2 hours. Test articles were inoculated with the 24 hour TSB culture.

Clostridium perfringens ATCC 12915 was propagated on SBA from a Q Laboratories frozen stock culture stored at -70 °C. The SBA plate was incubated anaerobically at 35 ± 1 °C for 24 ± 2 hours. After incubation, an isolated colony was transferred to pre-reduced Reinforced Clostridial Medium (RCM) and incubated anaerobically at 35 ± 1 °C for 24 ± 2 hours. Test articles were inoculated with the 24 hour RCM culture.

Pre-Inoculation Preparation:

The study sponsor reported that the test articles were pre-cleaned using one cycle in an industrial dishwasher prior to shipping.

Test articles and stainless-steel control carriers were placed in a sterile container and autoclaved after receipt by the testing facility. This step was done to ensure there is no residual bioburden prior to inoculation.

Using sterile gloves, the test article was placed on a disinfected flat surface. One (1) 1” x 1” location on each test article was marked for evaluation, depicted as red squares in Figures 1 - 4.

Inoculation of Test Articles:

A 100 µL aliquot of each test culture was applied to the 1” x 1” marked areas. The culture was uniformly spread over the sample area using 100 - 1000 µL micropipette tip to prevent areas of pooling.

After inoculation, the test articles were allowed to dry for 18 - 24 hours at ambient temperature (20 - 25 °C). After 18-24 hours, the test article was visually inspected to ensure the test culture suspension was uniformly dried and testing was initiated.

The inoculation steps above were repeated for the stainless-steel control carriers.

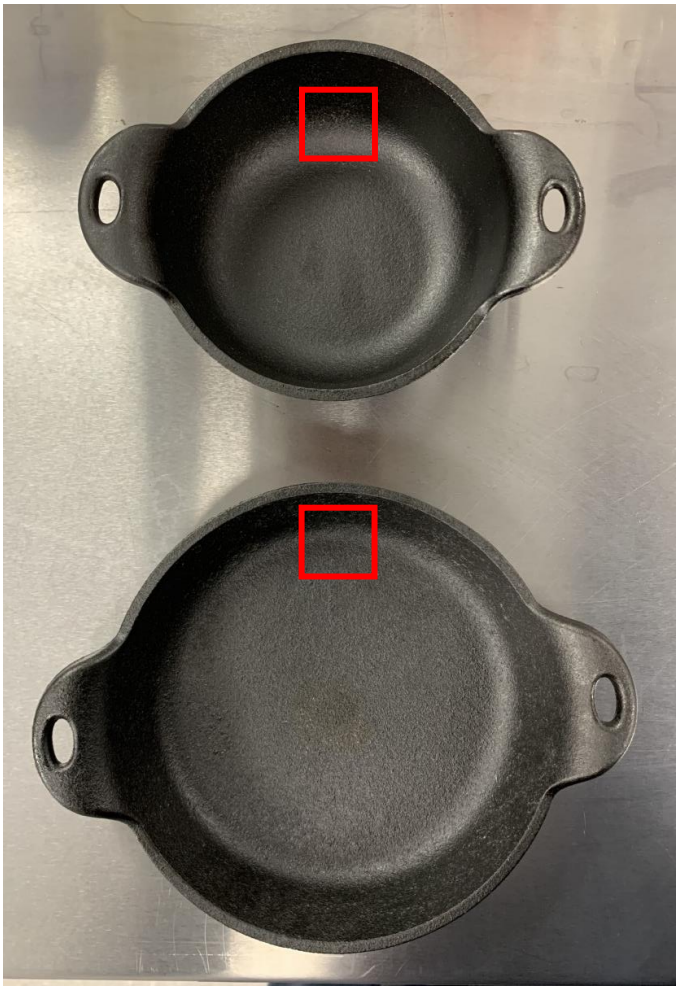

Figure 1. 12 Ounce Cast Iron Mini Serving Bowl and 14 Ounce Round Cast Iron Mini Server Sample Areas.

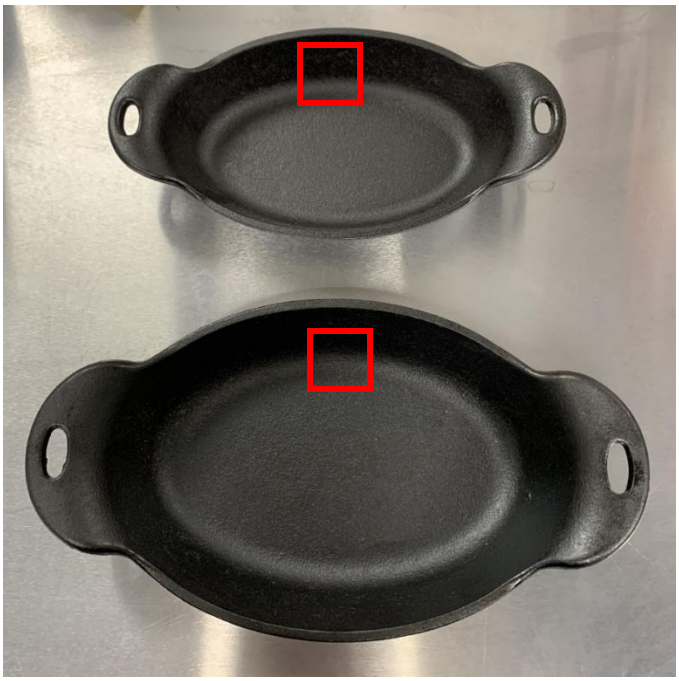

Figure 2. 9 Ounce Oval Cast Iron Mini Server and 16 Ounce Oval Cast Iron Mini Server Sample Areas.

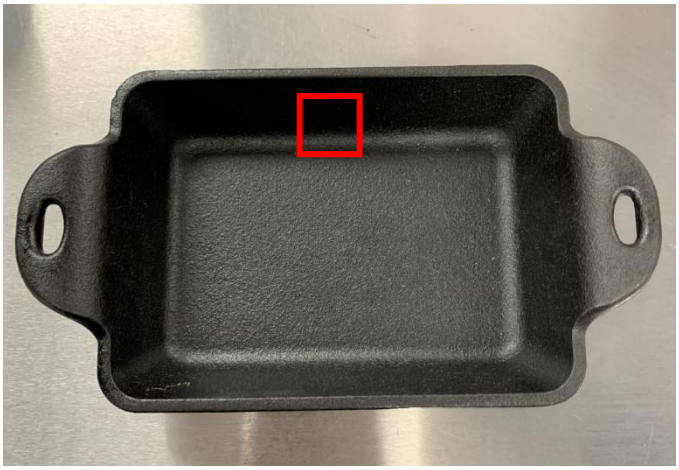

Figure 3. 14 Ounce Rectangular Cast Iron Mini Server Sample Area.

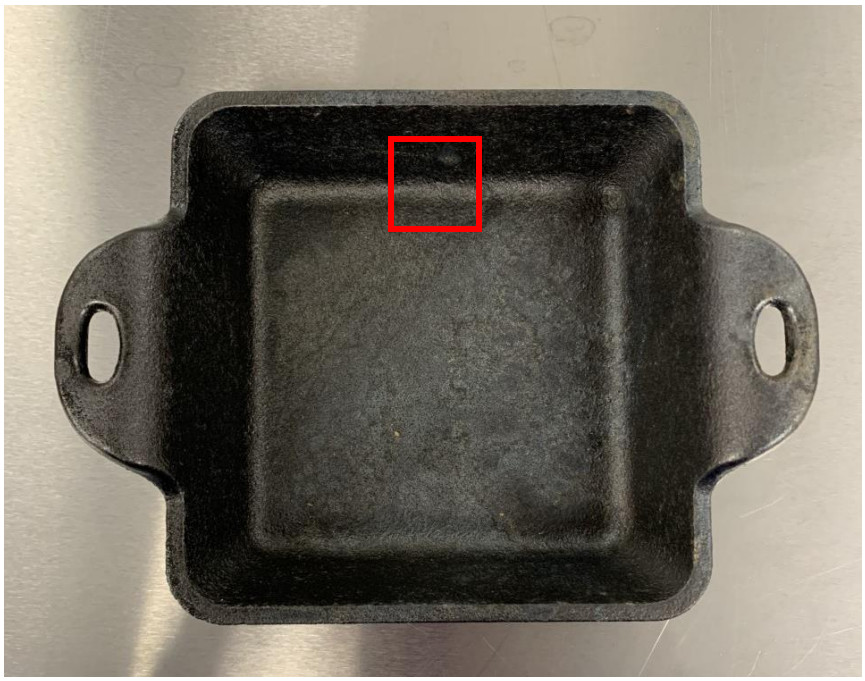

Figure 4. 10 Ounce Square Cast Iron Mini Server Sample Area.

Three (3) replicates of the test articles and three (3) replicates using food grade stainless steel carries were evaluated for each microorganism. A summary of the recovery study parameters is presented in Table 1.

Table 1. Summary of Recovery Study Parameters

Test Organisms	Test Article	No. of Test Replicates	No. of Stainless-Steel Control Replicates
S. aureus, *E. coli*, *S.* Enteritidis, *L. monocytogenes*, *C. perfringens*	14 Ounce Round Cast Iron Mini Server	3	3
	12 Ounce Cast Iron Mini Serving Bowl	3	3
	16 Ounce Oval Cast Iron Mini Server	3	3
	9 Ounce Oval Cast Iron Mini Server	3	3
	14 Ounce Rectangular Cast Iron Mini Server	3	3
	10 Ounce Square Cast Iron Mini Server	3	3

Recovery and Enumeration Procedure:

A 1.0 mL aliquot of PBS was added to a sterile swab. The marked 1" x 1" sample area was thoroughly swabbed in an up and down vertical motion and a left and right horizontal motion. This process was designed to remove viable microorganisms from the surface of the test article for enumeration.

The swab was placed in a test tube containing 9.0 mL of PBS. The swab was expressed into the test tube and thoroughly vortexed for 30 ± 5 seconds. Ten-fold serial dilutions of the sample were prepared by transferring 1.0 mL from the initial dilution into 9.0 mL of PBS.

For *S. aureus*, *E. coli*, *S.* Enteritidis and *L. monocytogenes*, each dilution was plated into duplicate sterile Petri dishes and 12 - 15 mL of tempered MCT was added. Plates were mixed thoroughly and allowed to solidify. Plates were inverted and incubated at 35 ± 1 °C for 48 ± 2 hours.

For *C. perfringens* each dilution was spread plated with sterile plating beads onto duplicate pre-poured plates of Columbia Blood Agar (CBA) with 5% Sheep Blood (CBA). Plates were inverted and incubated anaerobically at 35 ± 1 °C for 48 ± 2 hours.

After incubation, typical colonies were enumerated, and raw data was recorded as CFU/plate. Duplicate plates were averaged and multiplied by the dilution factor to arrive at CFU/test article. Raw values were recorded and used for the calculations in Tables 2-6.

Study Controls:

Food Grade Stainless Steel Controls – Three (3) 4" x 4" food grade stainless steel test articles were inoculated according to the test procedure. The recovered microorganisms were determined following the procedures found in Recovery and Enumeration. In order for the testing to be considered acceptable, the recovery data from the cast iron test articles had to be comparable to the food grade stainless steel.

Statistical Analysis

A logarithmic transformation measuring surviving microbial populations of the positive control article and test replicates for each microorganism were performed.

Equivalence of Recovery was calculated as follows:

ΔLog10 = Equivalence Recovery
TR1 = Test Article Replicate 1
TR2 = Test Article Replicate 2
TR3 = Test Article Replicate 3
SS1 = Stainless Steel 1
SS2 = Stainless Steel 2
SS3 = Stainless Steel 3

$$\left(\frac{TR1 + TR2 + TR3}{3}\right) - \left(\frac{SS1 + SS2 + SS3}{3}\right) = \Delta\text{Log10}$$

Media Quality Controls

The MCT plating media was inoculated with an aliquot of each *S. aureus, E. coli, S.* Enteritidis, and *L. monocytogenes* suspension and incubated at 35 ± 1 °C for 48 ± 2 hours. These plates served as positive growth controls for the media.

The CBA and RCM media were inoculated with an aliquot of the *C. perfringens* suspension and incubated anaerobically at 35 ± 1 °C for 48 ± 2 hours. These served as positive growth controls for the media.

The acceptance criterion for these bacterial media controls was "typical growth" of the organisms.

For negative sterility controls, two tubes each of TSB, PBS, and three plates of MCT were incubated at 35 ± 2 °C for 48 ± 2 hours.

The acceptance criterion for these uninoculated media controls was "negative for growth".

References

U. S. Food and Drug Administration *Bacteriological Analytical Manual*, Chapter 3 *Aerobic Plate Count* (January 2001). (Accessed October 2019)
http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm063346.htm

Summary of Results

The results of the initial microorganism recovery comparison are presented in Tables 2-6. The results of the retested test articles are presented in Tables 7-10. The mean Log values were obtained from duplicate plates. The Equivalence of Recovery was calculated as follows:

ΔLog10 = Equivalence Recovery
TR1 = Test Article Replicate 1
TR2 = Test Article Replicate 2
TR3 = Test Article Replicate 3
SS1 = Stainless Steel 1
SS2 = Stainless Steel 2
SS3 = Stainless Steel 3

$$\left(\frac{TR1 + TR2 + TR3}{3}\right) - \left(\frac{SS1 + SS2 + SS3}{3}\right) = \Delta\text{Log10}$$

Results

Table 2: *Staphylococcus aureus* ATCC 6538 Recovery Comparison
Reported in CFU/mL recovered.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
14 Ounce Round Cast Iron Mini Server	CFU/mL	2.6E+05	3.2E+05	3.8E+05	1.1E+05	2.6E+05	1.1E+05	0.3340
	Log CFU/mL	5.4150	5.5051	5.5798	5.0414	5.4150	5.0414	
12 Ounce Cast Iron Mini Serving Bowl	CFU/mL	3.3E+05	4.2E+05	2.8E+05	1.2E+05	1.2E+05	1.1E+05	0.4630
	Log CFU/mL	5.5185	5.6232	5.4472	5.0792	5.0792	5.0414	
16 Ounce Oval Cast Iron Mini Server	CFU/mL	3.0E+05	2.4E+05	2.1E+05	1.7E+05	1.5E+05	1.4E+05	0.2090
	Log CFU/mL	5.4771	5.3802	5.3222	5.2304	5.1761	5.1461	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	4.2E+05	5.0E+05	1.2E+05	1.6E+05	1.1E+05	1.2E+05	0.3589
	Log CFU/mL	5.6232	5.6990	5.0792	5.2041	5.0414	5.0792	
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	4.6E+05	5.0E+05	4.9E+05	1.5E+05	8.4E+04	1.5E+05	0.5918
	Log CFU/mL	5.6628	5.6990	5.6902	5.1761	4.9243	5.1761	
10 Ounce Square Cast Iron Mini Server	CFU/mL	2.7E+05	3.0E+05	2.8E+05	7.4E+04	1.2E+05	1.3E+05	0.4311
	Log CFU/mL	5.4314	5.4771	5.4472	4.8692	5.0792	5.1139	

Table 3: *Escherichia coli* ATCC 8739 Recovery Comparison
Reported in CFU/mL recovered.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
14 Ounce Round Cast Iron Mini Server	CFU/mL	1.2E+04	1.7E+04	6.0E+03	5.0E+03	1.6E+04	5.6E+03	0.1455
	Log CFU/mL	4.0792	4.2304	3.7782	3.6990	4.2041	3.7482	
12 Ounce Cast Iron Mini Serving Bowl	CFU/mL	6.6E+03	3.0E+03	9.2E+03	4.4E+03	6.6E+03	7.0E+03	-0.0159
	Log CFU/mL	3.8195	3.4771	3.9638	3.6435	3.8195	3.8451	
16 Ounce Oval Cast Iron Mini Server	CFU/mL	5.4E+03	1.0E+04	5.8E+03	2.6E+04	2.6E+04	3.0E+04	-0.6038
	Log CFU/mL	3.7324	4.0000	3.7634	4.4150	4.4150	4.4771	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	6.4E+03	8.0E+03	8.4E+03	1.7E+04	2.7E+04	3.6E+04	-0.5282
	Log CFU/mL	3.8062	3.9031	3.9243	4.2304	4.4314	4.5563	
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	4.7E+03	4.1E+03	4.2E+03	4.0E+03	5.6E+03	4.6E+03	-0.0350
	Log CFU/mL	3.6721	3.6128	3.6232	3.6021	3.7482	3.6628	
10 Ounce Square Cast Iron Mini Server	CFU/mL	5.4E+03	6.0E+03	1.0E+04	3.1E+03	9.2E+03	8.3E+03	0.0454
	Log CFU/mL	3.7324	3.7782	4.0000	3.4914	3.9638	3.9191	

Table 4: *Salmonella* Enteritidis ATCC 13076 Recovery Comparison
Reported in CFU/mL recovered.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
14 Ounce Round Cast Iron Mini Server	CFU/mL	7.0E+04	7.2E+04	3.9E+04	1.4E+04	3.6E+04	3.8E+04	0.3371
	Log CFU/mL	4.8451	4.8573	4.5911	4.1461	4.5563	4.5798	
12 Ounce Cast Iron Mini Serving Bowl	CFU/mL	2.6E+04	1.3E+04	1.4E+04	8.9E+03	5.2E+04	4.6E+04	-0.2177
	Log CFU/mL	4.4150	4.1139	4.1461	3.9494	4.7160	4.6628	
16 Ounce Oval Cast Iron Mini Server	CFU/mL	9.9E+03	8.7E+03	2.8E+04	4.6E+03	1.3E+04	8.8E+03	0.2204
	Log CFU/mL	3.9956	3.9395	4.4472	3.6628	4.1139	3.9445	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	3.2E+04	4.2E+04	3.4E+04	2.8E+04	1.2E+04	1.4E+04	0.3291
	Log CFU/mL	4.5051	4.6232	4.5315	4.4472	4.0792	4.1461	
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	4.3E+04	3.4E+04	3.8E+04	1.2E+04	1.4E+04	2.7E+04	0.3627
	Log CFU/mL	4.6335	4.5315	4.5798	4.0792	4.1461	4.4314	
10 Ounce Square Cast Iron Mini Server	CFU/mL	6.3E+04	4.9E+04	5.8E+04	1.1E+04	1.7E+04	2.0E+04	0.5600
	Log CFU/mL	4.7993	4.6902	4.7634	4.0414	4.2304	4.3010	

Table 5: *Listeria monocytogenes* ATCC 7644 Recovery Comparison
Reported in CFU/mL recovered.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
14 Ounce Round Cast Iron Mini Server	CFU/mL	1.1E+04	5.6E+03	1.6E+04	4.6E+03	1.3E+04	6.8E+03	0.1282
	Log CFU/mL	4.0414	3.7482	4.2041	3.6628	4.1139	3.8325	
12 Ounce Cast Iron Mini Serving Bowl	CFU/mL	1.5E+04	5.8E+03	1.0E+03	6.3E+03	1.0E+03	6.4E+03	0.1133
	Log CFU/mL	4.1761	3.7634	3.0000	3.7993	3.0000	3.8062	
16 Ounce Oval Cast Iron Mini Server	CFU/mL	1.1E+04	8.2E+03	1.3E+04	7.0E+02	3.2E+03	2.6E+03	0.7680
	Log CFU/mL	4.0414	3.9138	4.1139	2.8451	3.5051	3.4150	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	2.6E+04	3.0E+04	2.6E+04	1.2E+03	2.1E+03	3.4E+03	1.1247
	Log CFU/mL	4.4150	4.4771	4.4150	3.0792	3.3222	3.5315	
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	1.2E+04	5.4E+03	5.5E+03	3.8E+03	3.0E+03	2.8E+03	0.3493
	Log CFU/mL	4.0792	3.7324	3.7404	3.5798	3.4771	3.4472	
10 Ounce Square Cast Iron Mini Server	CFU/mL	2.4E+03	1.7E+03	4.3E+03	1.8E+03	9.6E+02	1.7E+03	0.2587
	Log CFU/mL	3.3802	3.2304	3.6335	3.2553	2.9823	3.2304	

Table 6: *Clostridium perfringens* ATCC 12915 Recovery Comparison
Reported in CFU/mL recovered.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
14 Ounce Round Cast Iron Mini Server	CFU/mL	2.3E+05	2.7E+05	3.9E+05	1.0E+05	1.3E+05	1.6E+05	0.3554
	Log CFU/mL	5.3617	5.4314	5.5911	5.000	5.1139	5.2041	
12 Ounce Cast Iron Mini Serving Bowl	CFU/mL	2.9E+05	4.5E+04	2.9E+05	9.0E+04	1.0E+05	1.2E+05	0.1815
	Log CFU/mL	5.4624	4.6532	5.4624	4.9542	5.0000	5.0792	
16 Ounce Oval Cast Iron Mini Server	CFU/mL	2.5E+05	2.7E+05	1.5E+05	1.6E+05	1.9E+05	1.6E+05	0.1061
	Log CFU/mL	5.3979	5.4314	5.1761	5.2041	5.2788	5.2041	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	3.7E+05	4.7E+05	2.6E+05	1.1E+05	1.8E+05	1.7E+05	0.3761
	Log CFU/mL	5.5682	5.6721	5.4150	5.0414	5.2553	5.2304	
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	5.2E+05	3.8E+05	3.9E+05	1.7E+05	1.0E+05	2.6E+05	0.4138
	Log CFU/mL	5.7160	5.5798	5.5911	5.2304	5.0000	5.4150	
10 Ounce Square Cast Iron Mini Server	CFU/mL	1.9E+05	3.2E+05	2.6E+05	1.1E+05	8.0E+04	1.9E+05	0.3252
	Log CFU/mL	5.2788	5.5051	5.4150	5.0414	4.9031	5.2788	

Table 7: *Staphylococcus aureus* ATCC 6538 Recovery Comparison
Reported in CFU/mL recovered – Retested.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
14 Ounce Rectangular Cast Iron Mini Server	CFU/mL	2.1E+05	2.9E+05	4.5E+05	5.3E+05	4.1E+05	3.9E+05	-0.1635
	Log CFU/mL	5.3222	5.4624	5.6532	5.7243	5.6128	5.5911	

Table 8: *Escherichia coli* ATCC 8739 Recovery Comparison
Reported in CFU/mL recovered - Retested.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
16 Ounce Oval Cast Iron Mini Server	CFU/mL	1.3E+04	1.8E+04	2.4E+04	1.2E+04	3.4E+04	2.6E+04	-0.0921
	Log CFU/mL	4.1139	4.2553	4.3802	4.0792	4.5315	4.4150	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	1.5E+04	2.3E+04	2.7E+04	3.3E+04	2.9E+04	2.4E+04	-0.1306
	Log CFU/mL	4.1761	4.3617	4.4314	4.5185	4.4624	4.3802	

Table 9: *Salmonella* Enteritidis ATCC 13076 Recovery Comparison
Reported in CFU/mL recovered - Retested.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
10 Ounce Square Cast Iron Mini Server	CFU/mL	5.5E+04	3.2E+04	6.2E+04	2.2E+04	2.5E+04	3.4E+04	0.2554
	Log CFU/mL	4.7404	4.5051	4.7924	4.3424	4.3979	4.5315	

Table 10: *Listeria monocytogenes* ATCC 7644 Recovery Comparison
Reported in CFU/mL recovered - Retested.

Test Article	Units	Cast Iron Replicate A	Cast Iron Replicate B	Cast Iron Replicate C	Stainless Steel Control A	Stainless Steel Control B	Stainless Steel Control C	Equivalence Recovery (ΔLog10)
16 Ounce Oval Cast Iron Mini Server	CFU/mL	1.8E+04	2.6E+04	1.1E+04	3.4E+04	2.3E+04	3.8E+04	-0.2538
	Log CFU/mL	4.2553	4.4150	4.0414	4.5315	4.3617	4.5798	
9 Ounce Oval Cast Iron Mini Server	CFU/mL	2.8E+04	3.9E+04	1.7E+04	2.0E+04	1.4E+04	4.5E+05	-0.2772
	Log CFU/mL	4.4472	4.5911	4.2304	4.3010	4.1461	5.6532	

Conclusion

Based on the results presented in this study report, the microorganism recovery equivalence from cast iron products and food grade stainless met the performance criteria for 2 of the 6 test articles. The performance criteria states that for equivalent recovery, the cast iron test articles must be within 0.5 Log of the stainless-steel carrier controls. Both 14 Ounce Round Cast Iron Mini Server and 12 Ounce Cast Iron Mini Serving Bowl met the performance criteria for each inoculum. The 9 Ounce Oval Cast Iron and 16 Ounce Oval Cast Iron did not meet the performance criteria for *Listeria monocytogenes,* and *Escherichia coli.* The 14 Ounce Rectangle Cast Iron Mini Server did not meet the performance criteria for *Staphylococcus aureus.* The 10 Ounce Square Cast Iron Mini server did not meet the performance criteria for *Salmonella* Enteritidis.

Since failure to meet the performance criteria could have been caused by variable inoculum levels due to homogenization of the test culture or by variable die off rate during the overnight drying, any test articles that did not meet the performance criteria were retested. Upon retesting all test articles met the performance criteria. The performance criteria states that for equivalent recovery, the cast iron test articles must be within 0.5 Log of the stainless-steel carrier controls.

Appendix 1

Signed Protocol

Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel

Protocol # QL19269-2B

Version 2

Prepared for:

Lodge Manufacturing (Study Sponsor)
204 East 5th Street
South Pittsburgh, TN 37380

Prepared by:

Q Laboratories (Testing Facility)
1930 Radcliff Drive
Cincinnati, OH 45204
(513) 471-1300

Table of Contents

1.0 **Title:** Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel

2.0 **Sponsor:** Lodge Manufacturing
204 East 5th Street
South Pittsburgh, TN 37380

3.0 **Testing Facility:** Q Laboratories
1930 Radcliff Drive
Cincinnati, OH 45204

4.0 **Study Director:** Benjamin J. Bastin

5.0 **Purpose:**

This study is designed to demonstrate that microorganisms can be removed from cast iron cookware with similar effectiveness as from stainless steel surfaces.

6.0 **Scope:**

The equivalence of recovery will be demonstrated by inoculating both materials with equivalent numbers of each microorganism. For this study the following microorganisms will be used: *Staphylococcus aureus, Escherichia coli, Salmonella* Enteritidis, *Listeria monocytogenes,* and *Clostridium perfringens*. Following inoculation, surfaces will be sampled.

7.0 **Test Articles:**

The test articles to be evaluated will be provided to the testing facility by the study sponsor, complete with appropriate documentation. Test articles will be sterilized via autoclave upon receipt.

7.1 Cast Iron Cookware
- 7.1.1 14 Ounce Round Cast Iron Mini Server (SKU: HMSRD)
- 7.1.2 12 Ounce Cast Iron Mini Serving Bowl (SKU: HMSB)
- 7.1.3 16 Ounce Oval Cast Iron Mini Server (SKU: HM16OS)
- 7.1.4 9 Ounce Oval Cast Iron Mini Server (SKU: HMSOV)
- 7.1.5 14 Ounce Rectangular Cast Iron Mini Server (SKU: HMS14RC)
- 7.1.6 10 Ounce Square Cast Iron Mini Server (SKU: HMSS)

7.2 Food Grade Stainless Steel Carriers (18 GA 300 series, brush finish)

8.0 **Testing Conditions:**

8.1 The evaluation will be conducted at ambient temperature (20 - 25 °C).

9.0 Test Microorganisms:

9.1 *Staphylococcus aureus* American Type Culture Collection (ATCC) 6538
9.2 *Escherichia coli* ATCC 8739
9.3 *Salmonella* Enteritidis ATCC 13076
9.4 *Listeria monocytogenes* ATCC 7644
9.5 *Clostridium perfringens* ATCC 12915

Note: Appropriate laboratory safety conditions will be employed while working with enriched culture suspensions. These conditions will include, but are not limited to, the use of appropriate PPE (including disposable gloves, beard nets, hair nets, and lab coats), Biological Safety Cabinets, and protective eyewear.

10.0 Media/Reagents:

10.1 Tryptic Soy Agar with 5% Sheep Blood (SBA) Commercially available from BD 221261 or equivalent
10.2 Microbial Content Test (MCT) agar MP107
10.3 Tryptic Soy Broth (TSB) MP058
10.4 Phosphate Buffered Saline (PBS) MP416
10.5 Columbia Blood Agar (CBA) with 5% Sheep Blood MP086
10.6 Reinforced Clostridial Medium (RCM) MP158

11.0 Equipment/Supplies:

11.1 Incubator, temperature range 35 ± 1 °C
11.2 Incubator thermometers, NIST traceable
11.3 Sterile containers
11.4 Steam autoclave
11.5 Vortex mixer
11.6 Calibrated, traceable minute/second timer
11.7 Refrigerator, temperature range 2 - 8 °C
11.8 Refrigerator thermometer, NIST traceable
11.9 Traceable thermometer/clock/humidity monitor
11.10 Adjustable pipettor, 1 µL - 200 µL capacity
11.11 Adjustable pipettor, 100 µL - 1000 µL capacity
11.12 Sterile serological pipettes
11.13 Sterile 100 µL and 1000 µL micropipette tips
11.14 Reichert Quebec® Colony Counter, or equivalent
11.15 Hand tally
11.16 Test tubes, sterilized
11.17 Sterile disposable Petri dishes, 100 x 15 mm
11.18 Sterile polyurethane tip swabs
11.19 Sterile disposable loops
11.20 Rotator/shaker
11.21 Anaerobic Sachets, BBL GasPaks or equivalent

12.0 Test Microorganism Preparation:

12.1 *Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 8739, *Salmonella* Enteritidis ATCC 13076, and *Listeria monocytogenes* ATCC 7644 will be propagated on Tryptic Soy Agar with 5% Sheep Blood (SBA) from a Q Laboratories frozen stock culture stored at -70 °C. SBA plates will be incubated aerobically at 35 ± 1 °C for 24 ± 2 hours. After incubation, an isolated colony will be picked to Tryptic Soy Broth (TSB) and incubated at 35 ± 1 °C for 24 ± 2 hours.

12.2 *Clostridium perfringens* ATCC 12915 will be propagated on SBA from a Q Laboratories frozen stock culture stored at -70 °C. The SBA plate will be incubated anaerobically at 35 ± 1 °C for 24 ± 2 hours. After incubation, an isolated colony will be transferred to pre-reduced Reinforced Clostridial Medium (RCM) and incubated anaerobically at 35 ± 1 °C for 24 ± 2 hours.

13.0 Microorganism Recovery Study Parameters:

13.1 Three (3) total replicates of the test articles will be evaluated for each microorganism. A summary of the recovery study parameters is presented in Table 1.

13.2 Three (3) total replicates using food grade stainless steel carries will be evaluated for each microorganism as controls. A summary of the antimicrobial activity study parameters is presented in Table 1.

Table 1. Summary of Recovery Study Parameters.

Test Organisms	Test Article	No. of Test Replicates	No. of Stainless-Steel Control Replicates
S. aureus, *E. coli*, *S.* Enteritidis, *L. monocytogenes*, *C. perfringens*	14 Ounce Round Cast Iron Mini Server	3	3
	12 Ounce Cast Iron Mini Serving Bowl	3	3
	16 Ounce Oval Cast Iron Mini Server	3	3
	9 Ounce Oval Cast Iron Mini Server	3	3
	14 Ounce Rectangular Cast Iron Mini Server	3	3
	10 Ounce Square Cast Iron Mini Server	3	3

14.0 Test Procedure:

Preconditioning:

14.1 The study sponsor reported that the test articles were pre-cleaned using one cycle in an industrial dishwasher prior to shipping.

14.2 Test articles and stainless-steel control carriers will be placed in a sterile container and autoclaved after receipt by the testing facility. This step will be done to ensure there is no residual bioburden prior to inoculation.

Inoculation:

14.3 Using sterile gloves, place the test article on a disinfected flat surface. One (1) 1" x 1" location on the test article will be marked for evaluation as depicted in Figures 1 - 4.

14.4 Apply 100 µL of each test culture to the 1" x 1" marked areas. The culture will be uniformly spread over the sample area using 100 - 1000 µL micropipette tip to prevent areas of pooling.

14.5 After inoculation, the test articles will be allowed to dry for 18 - 24 hours at ambient temperature (20 - 25 °C). After 18-24 hours, the test article will be visually inspected to ensure the test culture suspension is uniformly dried and testing will be initiated.

14.6 Repeat inoculation steps 14.2 to 14.4 for the stainless-steel control carriers.

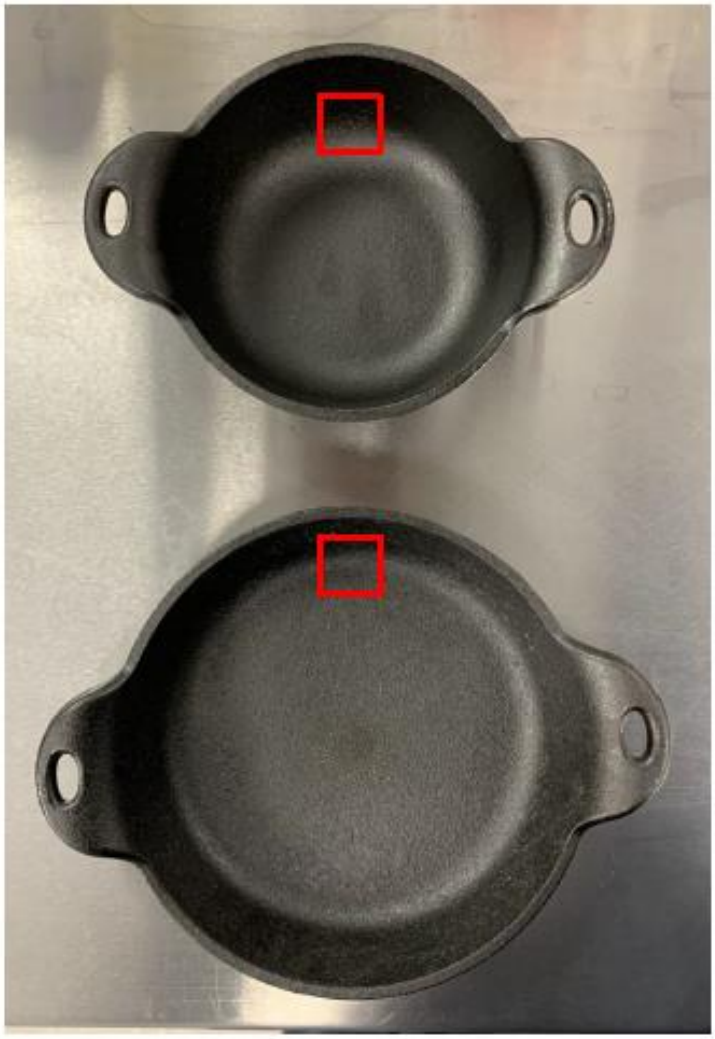

Figure 1. 12 Ounce Cast Iron Mini Serving Bowl and 14 Ounce Round Cast Iron Mini Server Sample Areas.

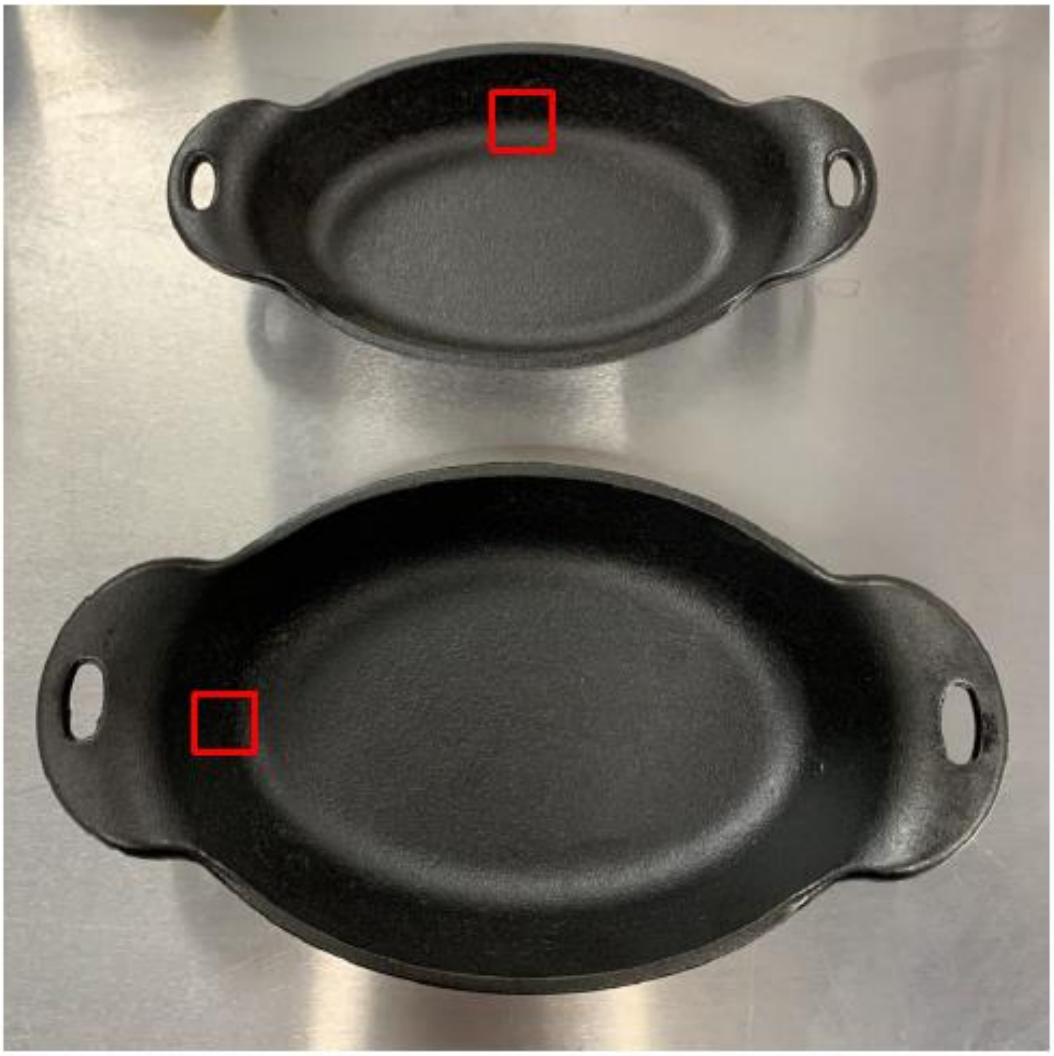

Figure 2. 9 Ounce Oval Cast Iron Mini Server and 16 Ounce Oval Cast Iron Mini Server Sample Areas.

Figure 3. 14 Ounce Rectangular Cast Iron Mini Server Sample Area.

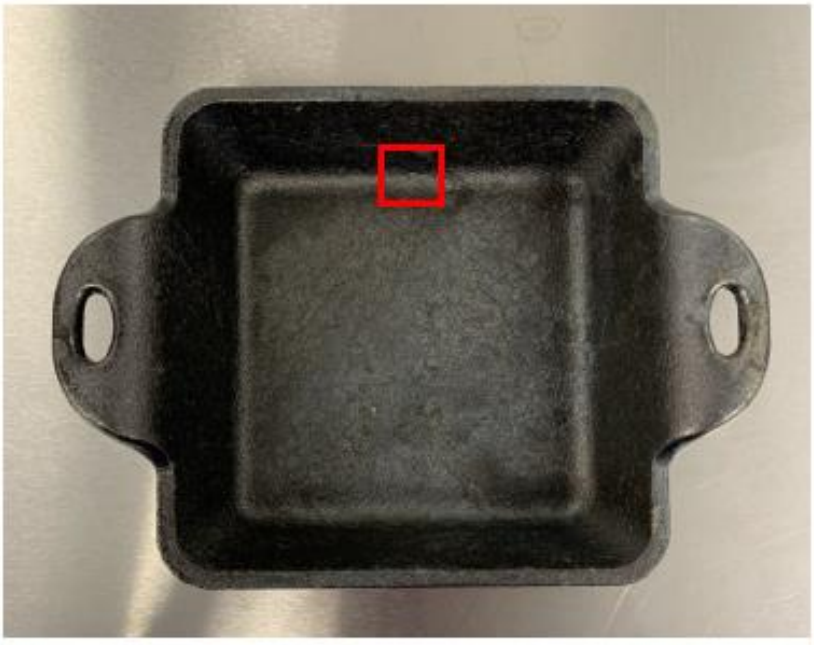

Figure 4. 10 Ounce Square Cast Iron Mini Server Sample Area.

15.0 Recovery and Enumeration Procedure:

15.1 Add 1.0 mL of PBS to a sterile swab. Thoroughly swab the 1" x 1" sample area in a both an up and down vertical motion and in a left and right horizontal motion. This process is designed to remove viable microorganisms from the surface of the test article for enumeration.

15.2 Place the swab in a test tube containing 9.0 mL of PBS. Express the swab into the test tube and thoroughly vortex. Prepare ten-fold serial dilutions of the sample by transferring 1.0 mL from the initial dilution into 9.0 mL of PBS.

15.3 For *S. aureus, E. coli, S.* Enteritidis and *L. monocytogenes*, plate each dilution into duplicate sterile Petri dishes and add 12 - 15 mL of tempered MCT to the Petri dishes. Mix thoroughly and allow the plates to solidify. Invert plates and incubate at 35 ± 1 °C for 48 ± 2 hours.

15.4 For *C. perfringens* spread plate each dilution on duplicate pre-poured plates of CBA. Spread inoculum with a sterile L-shaped spreader or sterile plating beads. Invert plates and incubate anaerobically at 35 ± 1 °C for 48 ± 2 hours.

15.5 After incubation, typical colonies will be enumerated and raw data recorded as CFU/plate. Duplicate plates will be averaged and multiplied by the dilution factor to arrive at CFU/test article. Raw values will be recorded and used for the calculations in section 18.0.

16.0 Study Controls:

16.1 Food Grade Stainless Steel Controls – Three (3) 4" x 4" food grade stainless steel test articles will be inoculated according to the procedures outlined in Section 14.0. The recovered microorganisms will be determined following the procedures in Section 15.0. In order for the testing to be considered acceptable, recovery data comparable to the cast iron test articles much be achieved.

17.0 Statistical Analysis:

17.1 A logarithmic transformation measuring surviving microbial populations of the positive control article and test replicates for each microorganism will be performed.

17.2 Equivalence of Recovery will be calculated as follows:
ΔLog10 = Equivalence Recovery
TR1 = Test Article Replicate 1
TR2 = Test Article Replicate 2
TR3 = Test Article Replicate 3
SS1 = Stainless Steel 1
SS2 = Stainless Steel 2
SS3 = Stainless Steel 3

$$\left(\frac{TR1 + TR2 + TR3}{3}\right) - \left(\frac{SS1 + SS2 + SS3}{3}\right) = \Delta\text{Log10}$$

18.0 Media Quality Controls:

18.1 The MCT plating media will be inoculated with an aliquot of each *S. aureus, E. coli, S.* Enteritidis, and *L. monocytogenes* suspension. The MCT plates will be incubated at 35 ± 1 °C for 48 ± 2 hours. These plates will serve as positive growth controls for the media.

18.2 The CBA and RCM media will be inoculated with an aliquot of the *C. perfringens* suspension. The CBA and RCM will be incubated anaerobically at 35 ± 1 °C for 48 ± 2 hours. These will serve as positive growth controls for the media.

18.3 The acceptance criterion for these bacterial media controls is "typical growth" of the organisms.

18.4 For negative sterility controls, two tubes each of TSB, PBS, and three plates of MCT will be incubated at 35 ± 2 °C for 48 ± 2 hours.

The acceptance criterion for these uninoculated media controls is "negative for growth".

19.0 Performance Criteria:

19.1 In order to demonstrate equivalent recovery the cast iron test articles must be within 0.5 Log of the stainless-steel carrier controls.

20.0 Acceptance Criteria:

20.1 The study controls below must perform according to the criteria detailed for the data to be considered acceptable.

20.1.1 Comparable growth acceptance will be within 50 - 200 % between the media. Sterility acceptance is no growth.

20.1.2 The acceptance criteria are growth from inoculated streaks and no growth from the sterility controls.

21.0 References:

21.1 U. S. Food and Drug Administration *Bacteriological Analytical Manual*, Chapter 3 *Aerobic Plate Count (*January 2001). (Accessed October 2019) http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm063346.htm

22.0 Final Report:

A final validation report will be prepared upon completion of the study, including a tabularized summary of data and a description of results of the study.

23.0 Documentation and Record-Keeping:

All documentation and records will be compiled, analyzed, and retained by Q Laboratories at its facility in Cincinnati, Ohio. All raw data for this study, as well as the final report, will be sent to the study sponsor and retained in safe storage by the testing facility for a period of at least seven (7) years (20 –ADMN-ISO-008D, Control of Records).

24.0 Quality Compliance:

Q Laboratories has developed and implemented a quality management system that enhances our ability to provide testing services that consistently meet client expectations and regulatory requirements. Q Laboratories quality documentation requirements are defined by ISO 17025, FDA Quality System Regulations (QSR), FDA Current Good Manufacturing Practices (cGMPs), FDA Good Laboratory Practices (GLP), and EPA Good Laboratory Practices standards (GLPs).
Q Laboratories applies the following standards as applicable:

- ISO 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories
- FDA 21 CFR Part 820 Quality System Regulation
- FDA 21 CFR Part 58 Good Laboratory Practice for Non Clinical Laboratory Studies
- FDA 21 CFR Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals
- FDA 21 CFR Part 210 Current Good Manufacturing Practice in Manufacturing Processing, Packing or Holding of Drugs; General
- EPA 40 CFR Part 160 FIFRA Good Laboratory Practice Standards

25.0 Protocol Modifications:

During the testing phase, changes to the protocol may be required. The study sponsor will be notified immediately of any modifications to the protocol. Approval of the modifications is required before any additional analysis is conducted. The modifications will be added to the protocol as an amendment and approved by both the study director and study sponsor.

26.0 Test Article Disposition:

All unused test material will be offered for return to the Study Sponsor at expense of Study Sponsor. If not desired by Study Sponsor, all unused test material to be disposed of within 90 days following the study completion.

27.0 Acceptance of Study Protocol:

Microorganism Recovery Equivalence from Cast Iron and Food Grade Stainless Steel

Q Laboratories (Testing Facility)
1930 Radcliff Drive
Cincinnati, OH 45204

Laboratory Supervisor: _____ 10/31/19
Benjamin J. Bastin — Date
Microbiology R&D Laboratory Supervisor

Lodge Manufacturing (Study Sponsor)
204 East 5th Street
South Pittsburgh, TN 37380

David Fletcher — 10/31/19
Representative — Date

QA Supervisor
Title

Literature Demonstrating Microbial Growth in Cut Fruits/Vegetables

TYPE OF FOOD	PATHOGEN	TITLE	MICROBIAL GROWTH (≥ 1 log @RT)	REFERENCES
Cantaloupe flesh / Avocado pulp	*Listeria monocytogenes*	Growth kinetics of *Listeria monocytogenes* in cut produce.	Avocado pulp reached 1 log growth in 5.2-7.7 hrs. at 25°C and Cantaloupe reached 1 log growth in 7.3-10.7 hrs. at 25°C	(Salazar et al., 2017)
Avocado pulp and processed Guacamole	*Listeria monocytogenes*	Behavior of *Listeria monocytogenes* in Avocado Pulp and Processed Guacamole	1 log growth at approximately 8 hours at 22°C	(Iturriaga et al., 2002)
Cantaloupe flesh and Avocado pulp, green Olives, and Broccoli	*Listeria monocytogenes*	Growth kinetics of *Listeria monocytogenes* in cut produce.	At 25°C storage temp., growth rates of *L.* monocytogenes in Cantaloupe flesh and Avocado pulp were ≥ 0.1 log CFU/g/h	(Salazar et al., 2017)
Fresh-cut Celery	*Escherichia coli* O157:H7	Fate of *Escherichia coli* O157: H7, *Listeria monocytogenes*, and *Salmonella* on fresh-cut celery.	*E. coli* O157:H7 populations on fresh cut celery increased by 1.0 log CFU/g over the 2-day storage period at 22° C. The most growth occurred over the first 17 hours.	(Vandamm et al., 2013)
	Listeria monocytogenes		*L. monocytogenes* populations on fresh cut celery increased by 0.5 log CFU/g over the 2-day storage period at 22°C	
	Salmonella		*Salmonella* populations on fresh cut celery increased by 2.0 log CFU/g over the 2-day storage period at 22°C. The most growth occurred over the first 17 hours.	
Highbush blueberries	*Listeria monocytogenes*	Survival of *Listeria monocytogenes* on Fresh Blueberries (Vaccinium corymbosum) Stored under Controlled Atmosphere and Ozone.	Estimated initial inoculum per sample was approximately 10^7 CFU/mL. Blueberries inoculated with *L. monocytogenes* and stored in regular air conditions at 12°C for 10 days had bacterial recovery of 5.15 CFU/mL.	(Concha-Meyer et al., 2014)
Cut red round tomatoes	*Salmonella* (Includes four serotypes, Typhimurium, Newport, Javiana, and Braenderup)	Modeling the Growth of *Salmonella* in Cut Red Round Tomatoes as a Function of Temperature	Starting concentration on cut tomato was 10^2 CFU/g. Cut tomato was inoculated at 10, 12.5, 15, 17.5, 20, 22.5, 25, 27.5, 30, and 35°C for five to twelve hours. Concentration increased throughout incubation time to a final concentration of 10^7 to 10^8 CFU/g of tomato. Growth has little to no lag time which is in contrast to FDA research that indicates that *Salmonella* will	(Pan and Schaffner, 2010)

			have a growth lag time between 3 to 7 hours at 22.2˚C depending on tomato variety.	
Peaches	*Escherichia coli* O157:H7	Fate of *Escherichia coli* O157:H7, *Salmonella* and *Listeria innocua* on minimally processed peaches under different storage conditions	Initial population was 5.2 $\log_{10}$ cfu plug^{-1}. Population after 6 days at 20˚C was approximately 6.0 $\log_{10}$ cfu plug^{-1}. Peak growth was 8.0 $\log_{10}$ cfu plug^{-1} after 2 days at 20˚C. Population after 6 days at 25˚C was 7.7 $\log_{10}$ cfu plug^{-1}. Peak growth was 8.0 $\log_{10}$ cfu plug^{-1} after 24 hours at 25˚C.	(Alegre et al., 2010)
	Salmonella choleraesuis		Initial population was approximately 5.3 $\log_{10}$ cfu plug^{-1} Population after 6 days at 20˚C was approximately 7.5 $\log_{10}$ cfu plug^{-1}. Peak growth was 7.7 $\log_{10}$ cfu plug^{-1} after 3 days at 20˚C. Population after 6 days at 25˚C was approximately 7.7 $\log_{10}$ cfu plug^{-1}. Peak growth was 8.2 $\log_{10}$ cfu plug^{-1} after 3 days at 25˚C.	
	Listeria innocua		Initial population was 5.3 $\log_{10}$ cfu plug^{-1}. Population after 6 days at 20˚C was approximately 7.5 $\log_{10}$ cfu plug^{-1}. Peak growth was 7.9 $\log_{10}$ cfu plug^{-1} after 3 days at 20˚C. Peak growth was 8.1 $\log_{10}$ cfu plug^{-1} after 6 days at 25˚C.	
Fresh cut mangoes and papayas	*Escherichia coli* O157:H7	Fate of *Escherichia coli* O157:H7 and *Salmonella* spp. on fresh and frozen cut mangoes and papayas	**Mangoes:** Initial population of 2.9 log CFU/g on day 0 at 23˚C. Peak growth was 4.7 log CFU/g on day 1 at 23˚C. Population after 7 days at 23˚C was 4.0 log CFU/g. Cut mango was visually determined to be spoiled on day 3 at 23˚C.	(Strawn and Danyluk, 2010)
			Papayas: Initial population was 2.6 log CFU/g on day 0 at 23˚C. Peak growth was 7.1 log CFU/g on day 3 at 23˚C. Population after 7 days at 23˚C was 6.3 log CFU/g. Initial population was 3.9 log CFU/g on day 0 at 12˚C. Peak growth was 6.9 log CFU/g on day 5 at	

			12˚C. Population after 7 days at 12˚C was 6.8 log CFU/g.	
	Salmonella spp.		**Mangoes:** Initial population was 2.9 CFU/g on day 0 at 23˚C. Peak growth was 6.2 CFU/g on day 3 at 23˚C. Population after 7 days at 23˚C was 2.4 CFU/g. Initial population was 4.5 CFU/g on day 0 at 12˚C. Peak growth was 5.9 CFU/g on day 1 at 12˚C. Population after 7 days at 12˚C was 4.5 CFU/g.	
			Papayas: Initial population was 2.6 CFU/g on day 0 at 23˚C. Peak growth was 7.4 CFU/g on day 3 at 23˚C. Population after 7 days at 23˚C was 6.6 CFU/g. Initial population was 4.1 CFU/g on day 0 at 12˚C. Peak growth was 7.7 CFU/g on day 5 at 12˚C. Population after 7 days at 12˚C was 7.6 CFU/g.	
Fresh cut Golden Delicious apple plugs	*Listeria monocytogenes*	Biocontrol of the Food-Borne Pathogens *Listeria monocytogenes* and *Salmonella enterica* Serovar Poona on Fresh-Cut Apples with Naturally Occurring Bacterial and Yeast Antagonists	Initial population was 2.8 log CFU/plug. Without antagonistic treatment, population increased to 5.3 log CFU/plug when stored at 10˚C for 5 days. Without antagonistic treatment, population increased to 6.0 log CFU/plug when stored at 25˚C for 7 days.	(Leverentz et al., 2006)
	Salmonella enterica		Initial population was 2.3 log CFU/plug. Without antagonistic treatment, population increased to 5.3 log CFU/plug when stored at 25˚C for 7 days.	
Sliced cucumbers	*Listeria monocytogenes*	Growth and Survival of *Listeria monocytogenes* and *Salmonella* on Whole and Sliced Cucumbers	**Non-selective Media:** Initial population was 4.3 log CFU/g on hour/day 0. Population after 24 hours at 23˚C was 6.0 log CFU/g (increase of 1.7 log CFU/g). Peak population growth was 6.5 log CFU/g at 23˚C on day 2. After day 2 populations declined. **Selective Media:** Initial population was 4.1 log CFU/g on hour/day 0. Population after 24 hours at 23˚C was 5.8 log CFU/g (increase of 1.7 log CFU/g). Peak population growth was 6.4 log CFU/g at 23˚C on day 2. After day 2 populations declined.	(Bardsley et al., 2019)
	Salmonella		**Non-selective Media:** Initial population was 2.8 log CFU/g on hour/day 0. Population after 8 hours at	

			23˚C was 5.9 log CFU/g (increase of 3.1 log CFU/g). Peak population growth was 6.3 log CFU/g at 23˚C at hour 17. After day 1 populations declined. **Selective Media:** Initial population was 2.7 log CFU/g on hour/day 0. Population after 8 hours at 23˚C was 5.7 log CFU/g (increase of 3.0 log CFU/g). Peak population growth was 6.1 log CFU/g at 23˚C at hour 17. After day 1 populations declined.	
Rocha fresh-cut pears	*Escherichia coli*	Growth of *Escherichia coli*, *Salmonella enterica* and *Listeria* spp., and their inactivation using ultraviolet energy and electrolyzed water, on 'Rocha' fresh-cut pears	At 12˚C maximum growth rate was 1.9±0.193 day^{-1} At 20˚C maximum growth rate was 2.98±0.258 day^{-1}	(Graça et al., 2017)
	Salmonella enterica		At 12˚C maximum growth rate was 2.2±0.23 day^{-1} At 20˚C maximum growth rate was 2.7±0.322 day^{-1}	
	Listeria spp.		At 12˚C maximum growth rate was 2.6± 0.636 day^{-1} At 20˚C maximum growth rate was 3.1±0.296 day^{-1}	
Various fresh cut produce items (summary of early literature findings)	*Shigella*	Outbreaks Fresh Produce Incidence, Growth, and Survival of Pathogens in Fresh and Fresh- Cut Produce	Populations of *S. sonnei, S. flexneri, and S. dysenteriae* inoculated on fresh cut cubes of papaya, jicama, and watermelon increased substantially within 4 to 6 hours at 22˚C - 27˚C. (Table G/S2, G/S4. GS1)	(Harris et al., 2003)
	Listeria monocytogenes		Chopped tomato stored at 21˚C with initial population of 5 log_{10} CFU/g. After 8 days, population was between 1.0 to 3.5 log_{10} CFU/g with survival slightly better in chlorine treated samples. Butternut squash cubes stored in a sealed bag at 10˚C had an initial concentration of 3.0 log_{10} CFU/g. After 9 days of storage at 10˚C population increased to approximately 8.5 log_{10} CFU/g. Shredded cabbage stored in plastic impermeable bags with ambient air had an initial concentration of 4.1 log_{10} CFU/g. For the first 24 hours, package was stored in refrigerator, afterwards stored at 25˚C. After 2 days at 25˚C, population increased to approximately 6.0 log_{10} CFU/g. Shredded cabbage stored in plastic impermeable bag with 70% CO_2 and 30% N_2 at 25˚C had an initial	

			concentration of 4.0 log_{10} CFU/g. After 2 days at 25˚C population increased to approximately 4.5 log_{10} CFU/g. Shredded carrots held at 15˚C had initial concentration of <1.0 log_{10} CFU/g. After 7 days of storage at 15˚C population increased to 3.4 - 5.8 log_{10} CFU/g. Sliced onion stored at 10˚C had initial concentration of 3.5 log_{10} CFU/g. After 9 days of storage at 10˚C population increased to approximately 4.8 log_{10} CFU/g. Rutabaga sticks stored at 10˚C had initial concentration of 3.0 log_{10} CFU/g. After 9 days of storage at 10˚C population increased to approximately 6.0 log_{10} CFU/g.	
	Salmonella		Cut tomato was stored at 22˚C with initial population of 1.1 log_{10} CFU/g. After 24 hours population increased to 6.3-6.9 log_{10} CFU/g.	
	Salmonella Typhi		Papaya cubes stored between 25-27˚C with initial population of 2.9 log_{10} CFU/cube (pH 5.69) and 3.0 log_{10} CFU/cube (pH 3.59). After 6 hours of incubation, population increased to 4.3 log_{10} CFU/cube (pH 5.69) and 3.8 log_{10} CFU/cube (pH 3.59). Jicama cubes stored between 25-27˚C with initial population of 3.1 log_{10} CFU/cube (pH 3.30) and 3.2 log_{10} CFU/cube (pH 5.97). After 6 hours of incubation, population increased to 3.4 log_{10} CFU/cube (pH 3.30) and 4.7 log_{10} CFU/cube (pH 5.97).	
	Salmonella Baildon		Diced tomatoes stored at 21˚C with initial population of 3.4 log_{10} CFU/g. After 72 hours, population was 8.1 log_{10} CFU/g.	

	Salmonella Montevideo		Slices of tomato stored at 25°C with initial counts of 3.4 $\log_{10}$ CFU/slice and 4.4 $\log_{10}$ CFU/slice. After 12 hours, population was approximately 7.5 and 8.0 $\log_{10}$ CFU/slice respectively.	
	Clostridium botulinum		Butternut squash cubes inoculated with 2.0 $\log_{10}$ spores/g of 10 strains of proteolytic *C. botulinum* stored at 15°C and 25°C for 14 days and 3 days respectively. Toxin was detected at for both temperatures after storage for 14 days and 3 days respectively.	
	Escherichia coli O157:H7		Shredded carrot stored in 3% O_2 97% N_2 polyolefin L-bags with initial concentration of 2.5 $\log_{10}$ CFU/g at 21°C. After 7 days population increased to 4.2 $\log_{10}$ CFU/g. Shredded carrot stored in air in polyolefin L-bags with initial concentration of 5.3 $\log_{10}$ CFU/g at 12°C and 21°C. After 14 days at 12°C population increased to 6.3 $\log_{10}$ CFU/g. After 7 days at 21°C population increased to 6.0 $\log_{10}$ CFU/g. Shredded carrot stored in polyolefin L-bags with initial concentration of 2.5 $\log_{10}$ CFU/g at 21°C. After 7 days population increased to 3.8 $\log_{10}$ CFU/g. Sliced cucumber stored in 3% O_2 97% N_2 in polyolefin L-bags with initial concentration of 2.3 $\log_{10}$ CFU/g at 21°C. After 7 days at 21°C population increased to 2.6 $\log_{10}$ CFU/g. Sliced cucumber stored in air in polyolefin L-bags with initial concentration of 5.1 $\log_{10}$ CFU/g at 12°C. After 10 days at 12°C population increased to 5.7 $\log_{10}$ CFU/g. Sliced cucumber stored in air in polyolefin L-bags with initial concentration of 2.3 $\log_{10}$ CFU/g at 21°C.	

			After 7 days at 21°C population increased to 3.1 log_{10} CFU/g.	
Cut turnips	*Listeria monocytogenes*	Growth of *Listeria monocytogenes* Inoculated on Packaged Fresh-Cut Turnips Stored at 4 and 10°C	Initial population was 3.40 log CFU/g (LOT 1) and 3.51 log CFU/g (LOT 2) on day 0 at 10°C. Peak growth was 4.7 log CFU/g (LOT 1) and 5.10 log CFU/g (LOT 2) on day 10 at 10°C.	(Brierley et al., 2020)
Cut red cabbage	*Listeria monocytogenes*	Growth Kinetics of *Listeria monocytogenes* on Cut Red Cabbage	Initial population on cut red cabbage was 3.67 log CFU/g. After 3 days of storage at 10°C, population increased to 4.25 log CFU/g. Maximum growth rate was 0.27 log CFU/g/day. After 3 days of storage at 25°C, population increased to 4.74 log CFU/g. Maximum growth rate was 1.15 log CFU/g/day.	(Salazar et al., 2022)
Sliced zucchini squash	*Salmonella* Typhimurium, Gaminara, Typhi, Montevideo	Incidence and Behavior of *Salmonella* and *Escherichia coli* on Whole and Sliced Zucchini Squash (Cucurbita pepo) Fruit	Initial populations were approximately 2.5 log CFU/slice. After two days at 25°C, populations increased to approximately 6.0 log CFU/slice.	(Castro-Rosas et al., 2010)
	Escherichia coli		Initial population was approximately 2.5 log CFU per slice. After two days at 25°C, population increased to approximately 7.0 log CFU/slice.	
Tomato and cucumber salad without lemon juice or salt (Arabic salad)	*Listeria monocytogenes*	Survival and growth of *Listeria monocytogenes* and *Staphylococcus aureus* in ready-to-eat Mediterranean vegetable salads: Impact of storage temperature and food matrix	Initial population was approximately 5.5 log CFU/g. After 1 day stored at 24°C, population increased to 7.2 log CFU/g. After 5 days stored at 10°C, population increased to 7.5 log CFU/g.	(Olaimat et al., 2021)
	Staphylococcus aureus		Initial population was approximately 5.7 log CFU/g. After 2 days stored at 24°C, population increased to 7.5 log CFU/g. After 5 days stored at 10°C, population increased to 6.7 log CFU/g.	

Fresh-cut canary melon and papaya	*Listeria monocytogenes*	Effect of citral nanoemulsion on the inactivation of *Listeria monocytogenes* and sensory properties of fresh-cut melon and papaya during storage	Initial population was 5.0 log CFU/g. After 7 days stored at 12˚C, population on cut melon increased to approximately 7.5 log CFU/g. After 7 days stored at 16˚C, population on cut melon increased to approximately 8.7 log CFU/g. After 7 days stored at 12˚C, population on cut papaya increased to approximately 7.3 log CFU/g. After 7 days stored at 16˚C, population on cut papaya increased to approximately 7.8 log CFU/g.	(Luciano et al., 2023)
Cut grapes, tomato, white cabbage, red cabbage	*Listeria monocytogenes*	Evaluating the growth potential of *Listeria monocytogenes* in Ready to Eat Vegetables	All cut produce was inoculated and stored at 5˚C for two days then 10˚C until a few days after shelf-life. Initial population on grapes was 4.2 log CFU/g. Two days after shelf life (9 days total), population on cut grapes increased to 4.9 log CFU/g. Initial population on tomatoes was 4.0 log CFU/g. Two days after shelf life (8 days total), population on cut tomatoes increased to 4.1 log CFU/g. Initial population on white cabbage was 4.1 log CFU/g. Two days after shelf life (9 days total), population on cut white cabbage increased to 4.2 log CFU/g. Initial population on red cabbage was 3.6 log CFU/g. Two days after shelf life (9 days total), population on cut red cabbage increased to 4.0 log CFU/g.	(Shoja Gharehbagh et al., 2023)

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Chapter 1. Purpose and Definitions

- Page 20 *(page 49 in PDF)* –
  - "Time/temperature control for safety food" included:
    a. An animal FOOD that is raw or heat-treated; a plant FOOD that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation

Annex 2. References

- Page 281 *(page 313 in PDF)* –
  - N. Retail Food Protection Program Information Manual: Storage and Handling of Tomatoes, 2007.

    This document can be found at the web site: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm

    The Retail Food Protection Program Information Manual, Storage and Handling of Tomatoes provides safe storage and handling practices for cut tomatoes and additional rationale for including cut tomatoes in the definition of time/temperature control for safety food in the 2005 Food Code. Historically, uncooked fruits and vegetables have been considered non-TCS food unless they were epidemiologically implicated in foodborne illness outbreaks and are capable of supporting the growth of pathogenic bacteria in the absence of temperature control. Since 1990, at least 12 multi-state foodborne illness outbreaks have been associated with different varieties of tomatoes. From 1998 – 2006, outbreaks associated with tomatoes made up 17% of the produce-related outbreaks reported to FDA. Salmonella has been the pathogen of concern most often associated with tomato outbreaks. Recommendations are being offered to prevent contamination in food service facilities and retail food stores and to reduce the growth of pathogenic bacteria when contamination of fresh tomatoes may have already occurred (regardless of the location where the contamination occurred).

- Page 281-282 *(page 313-314 in PDF)* –
  - O. Retail Food Protection Program Information Manual: Recommendations to Food Establishments for Serving or Selling Cut Leafy Greens.

    This document can be found at: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm.

    Following 24 multi-state outbreaks between 1998 and 2008, cut leafy greens was added to the definition of time/temperature for safety food requiring time-temperature control for safety (TCS). The term used in the definition includes a variety of cut lettuces and leafy greens. Raw agricultural commodities (RACs) that are not processed or cut on-site are excluded from the definition of cut leafy greens. Herbs such as cilantro or parsley are also not considered cut leafy greens. The pH, water activity, available

moisture and nutrients of cut leafy greens supports the growth of foodborne pathogens and refrigeration at 41ºF (5ºC) or less inhibits growth and promotes general die off in some pathogens such as E. coli O157:H7. Salmonella, E. coli O157:H7 and Listeria monocytogenes, once attached to the surface or internalized into cut surfaces of leafy greens, are only marginally affected by chemical sanitizers. Recommended handling instructions for leafy greens during purchasing and receiving, storage, food employee handling fresh produce, washing fresh produce, preparation for sale or service and display for sale or service are attached to the document.

Annex 3. Public Health Reasons/Administrative Guidelines

- Page 295-297 *(page 327-329 in PDF)* –
    - **Time/Temperature Control for Safety Food**

      Time Temperature Control for Safety Food (TCS) is defined in terms of whether or not it requires time/temperature control for safety to limit pathogen growth or toxin formation. The term does not include foods that do not support growth but may contain a pathogenic microorganism or chemical or physical food safety hazard at a level sufficient to cause foodborne illness or injury. The progressive growth of all foodborne pathogens is considered whether slow or rapid.

      The definition of TCS food takes into consideration pH, aw, pH and aw interaction, heat treatment, and packaging for a relatively simple determination of whether the food requires time/temperature control for safety. If the food is heat-treated to eliminate vegetative cells, it needs to be addressed differently than a raw product with no, or inadequate, heat treatment. In addition, if the food is packaged after heat treatment to destroy vegetative cells and subsequently packaged to prevent re-contamination, higher ranges of pH and/or aw can be tolerated because remaining spore-forming bacteria are the only microbial hazards of concern. While foods will need to be cooled slightly to prevent condensation inside the package, they must be protected from contamination in an area with limited access and packaged before temperatures drop below 57°C (135°F). In some foods, it is possible that neither the pH value nor the aw value is low enough by itself to control or eliminate pathogen growth; however, the interaction of pH and aw may be able to accomplish it. This is an example of a hurdle technology. Hurdle technology involves several inhibitory factors being used together to control or eliminate pathogen growth, when they would otherwise be ineffective if used alone. When no other inhibitory factors are present and the pH and/or aw values are unable to control or eliminate bacterial pathogens which may be present, growth may occur and foodborne outbreaks result. Cut melons, cut tomatoes, and cut leafy greens are examples where intrinsic factors are unable to control bacterial growth once pathogens are exposed to the cellular fluids and nutrients after cutting.

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      The Food Code definition designates certain raw plant foods as TCS food because they have been shown to support the growth of foodborne pathogens in the absence of temperature control and to lack intrinsic factors that would inhibit pathogen growth. Unless product assessment shows otherwise, these designations are supported by Tables A and B. For example:

For cut cantaloupe (pH 6.2-7.1, aw > 0.99, not heat-treated),. fresh sprouts (pH > 6.5, aw > 0.99, not heat-treated), and cut tomatoes (pH 4.23 – 5.04, aw > 0.99, not heat-treated), Table B indicates that they are considered TCS Foods unless a product assessment shows otherwise. Maintaining these products under the temperature control requirements prescribed in this code for TCS food will limit the growth of pathogens that may be present in or on the food and may help prevent foodborne illness.

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More information can be found in the Institute of Food Technologists (IFT) Report, "Evaluation and Definition of Potentially Hazardous Foods" at http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm094141.htm

- Page 389 *(page 421 in PDF)* –
  - 3-302.15 Washing Fruits and Vegetables

    After being cut, certain produce such as melons, leafy greens and tomatoes are considered time/temperature control for safety food (TCS) requiring time/temperature control for safety and should be refrigerated at 41°F or lower to prevent any pathogens that may be present from multiplying. For more retail food guidance on the storage and handling of tomatoes, leafy greens, and other produce, you may consult the FDA Program Information Manual, Retail Food Protection Storage and Handling of Tomatoes, dated October 5, 2007, available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm, the document, Time as a Public Health Control for Cut Tomatoes, dated June 8, 2010 available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm215053.htm and the FDA Program Information Manual, Recommendations for the Temperature Control of Cut Leafy Greens during Storage and Display in Retail Food Establishments dated July 7, 2010 available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm218750.htm

- Page 427 (*page 459 in PDF)* –
  - At the 2018 meeting of the CFP it was recommended that Section 3-501.19 be amended to allow raw agricultural commodities (RACs) that are cut on-site (such as tomatoes, melons, or leafy greens) or shelf-stable hermetically sealed containers (such as canned tuna) opened on-site have an initial temperature of 21°C (70°F) or less when time without temperature control is used as a public health control for a maximum of 4 hours. Peer-reviewed scientific literature and the above-mentioned pathogen modeling has shown Salmonella spp. and L. monocytogenes will not exceed a 1-log increase in growth when started and maintained at 21°C (70°F) or less for up to 4 hours.

STATE OF COLORADO

Warwick - CDPHE, Robert <robert.warwick@state.co.us>

Fwd: Issue Edited | Conference for Food Protection

1 message

Warwick - CDPHE, Robert <robert.warwick@state.co.us> Wed, Feb 22, 2023 at 8:46 AM
To: Robert Warwick - CDPHE <robert.warwick@state.co.us>

From: **Patrick Guzzle** <pguzzle@restaurant.org>
Date: Tue, Feb 21, 2023 at 2:43 PM
Subject: RE: Issue Edited | Conference for Food Protection
To: Huffman - CDPHE, Troy <troy.huffman@state.co.us>
Cc: Kate Piche <KPiche@restaurant.org>

Let me know if this doesn't work and I'll edit as appropriate. I've copied Kate Piche from my team as a heads up.

The National Restaurant Association Food Safety/Compliance team supports this Issue. With continually decreasing time and resources in the face of increasing demands, the recommended solution reduces the regulatory burden without jeopardizing public health and food safety. As indicated in the Issue, several States are now relying on the more recent technology of culture independent diagnostic tests to help determine an appropriate time frame to allow a restricted or excluded food employee to return to work. We add our voice to those asking FDA to consider this change to the Food Code.

Patrick L. Guzzle | Vice President, Food Science

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Research Paper

Influence of Soap Characteristics and Food Service Facility Type on the Degree of Bacterial Contamination of Open, Refillable Bulk Soaps

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ABSTRACT

Concern has been raised regarding the public health risks from refillable bulk-soap dispensers because they provide an environment for potentially pathogenic bacteria to grow. This study surveyed the microbial quality of open refillable bulk soap in four different food establishment types in three states. Two hundred ninety-six samples of bulk soap were collected from food service establishments in Arizona, New Jersey, and Ohio. Samples were tested for total heterotrophic viable bacteria, *Pseudomonas,* coliforms and *Escherichia coli,* and *Salmonella*. Bacteria were screened for antibiotic resistance. The pH, solids content, and water activity of all soap samples were measured. Samples were assayed for the presence of the common antibacterial agents triclosan and parachlorometaxylenol. More than 85% of the soap samples tested contained no detectable microorganisms, but when a sample contained any detectable microorganisms, it was most likely contaminated at a very high level (~7 log CFU/mL). Microorganisms detected in contaminated soap included *Klebsiella oxytoca, Serratia liquefaciens, Shigella sonnei, Enterobacter gergoviae, Serratia odorifera,* and *Enterobacter cloacae*. Twenty-three samples contained antibiotic-resistant organisms, some of which were resistant to two or more antibiotics. Every sample containing less than 4% solids had some detectable level of bacteria, whereas no samples with greater than 14% solids had detectable bacteria. This finding suggests the use of dilution and/or low-cost formulations as a cause of bacterial growth. There was a statistically significant difference ($P = 0.0035$) between the fraction of bacteria-positive samples with no detected antimicrobial agent (17%) and those containing an antimicrobial agent (7%). Fast food operations and grocery stores were more likely to have detectable bacteria in bulk-soap samples compared with convenience stores ($P < 0.05$). Our findings underscore the risk to public health from use of refillable bulk-soap dispensers in food service establishments.

Key words: Bulk soap; Coliforms; Contamination; Hand washing

Washing hands with soap and water is a universally accepted practice to reduce cross-contamination and the incidence of nosocomial infections *(9, 12–14, 16, 18, 20, 26, 29, 33)*. The U.S. Food and Drug Administration (FDA), the U.S. Centers for Disease Control and Prevention (CDC), and the World Health Organization (WHO) suggest proper hand hygiene with soap and water and/or an alcohol-based hand sanitizer in health care and food preparation settings *(3, 35, 39)*. The CDC and WHO recommend alcohol-based hand sanitizer as the primary means for hand hygiene at key moments in health care settings *(3, 31, 39),* whereas food handling guidance from FDA *(35)* supports gloving or hand washing for primary prevention. The respective hand hygiene guidance documents from these three public health agencies all have language that indicates that a hand wash is not complete without the use of soap *(3, 35, 39)*. However, concern has been raised that the use of refillable bulk-soap dispensers is a public health risk because they provide an environment for potentially pathogenic bacteria to grow, especially if the bulk soap is diluted with water to reduce cost *(8, 21, 25, 30, 40)*.

Outbreaks associated with contaminated soap have been extensively documented in health care settings *(1, 2, 5, 24, 27, 30, 38),* but none to date have been connected to food service settings. Organisms found in bulk soaps are primarily gram-negative bacteria *(8),* and these bacteria include microorganisms that are commonly associated with nosocomial infection in hospitals *(3, 19)*. *Klebsiella pneumonia,* a bacterium associated with contaminated bulk soaps, can cause community-acquired pneumonia; proper hand hygiene is a good way of preventing cross-contamination by these bacteria because health care workers' hands can be vectors for these organisms *(7)*. Outbreaks of *Serratia marcescens* have also been traced to contaminated soap *(2, 5, 27, 30, 37)*. Although no outbreaks in food service have been directly linked to contaminated bulk-soap dispensers, roughly 50% of food service–linked outbreaks can be traced to food workers' hands as the source of pathogens *(16)*. Whereas soaps and other cosmetics are not required to be

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sterile, good manufacturing practices for soaps and cosmetics require that any bacteria present should not constitute a hazard to consumers during regular use *(32)*.

Several factors contribute to bulk-soap contamination, including design of dispenser, soap formulation, and economically motivated dilution of soap *(5, 25)*. To refill sealed dispensers, new cartridges, which contain soap sealed inside with a new nozzle, are placed into the dispenser; in contrast, open refillable bulk-soap dispensers reuse a permanent nozzle and are refilled with soap from a larger bottle. A top-fill reservoir design allows for "topping-off" the soap. Although this potentially reduces soap waste, it also allows mixing of multiple soap lots and types and exposes the soap to an open-air environment, which increases the risk of contamination *(3, 25, 40)*. Furthermore, top-fill design dispensers may never thoroughly be rinsed out, as commonly recommended by dispenser manufacturers. The CDC recommends that bulk liquid soap dispensers be thoroughly cleaned every time before fresh soap is added *(3, 8, 14)*. However, as pointed out by Lorenz et al. *(21)*, no data exist to show that cleanings in between soap refills actually prevent contamination of soap. Regardless, bulk soap can quickly become contaminated due to biofilm formation inside the dispenser (up to 9 log CFU/mL) and can support growth in as little as 24 h *(25)*. Once pump mechanisms are colonized with bacteria, cells from the biofilm continue to contaminate soap, even if completely new bacteria-free soap is used to fill the container *(15)*. Soap formulations will often include preservatives to prevent growth, but because these preservatives are concentration dependent, dilution (as a cost savings measure) can render them ineffective. There has been no evidence of contamination in soap samples collected from dispensers in sealed disposable refills to date.

Potentially harmful bacteria will remain on hands after using contaminated soap *(8, 30, 40)*. Although the bacteria may not be a health concern for the hand washer, these bacteria can transfer from hands to food, objects, and surfaces *(6, 9, 12, 13, 16, 17, 22, 29)*. Hands are one of the main sources of cross-contamination in both health care and food service *(12, 20)*.

The purpose of this study was to survey the microbial quality of open refillable bulk soap sampled in four different food establishment types, within three different states, and to determine the influence of formulation factors on the degree of contamination.

MATERIALS AND METHODS

Sample collection. Samples were acquired from food service establishments around New Brunswick, NJ; Tucson, AZ; and Akron, OH. The categories of merchants from which soap samples were collected were convenience stores, grocery stores, "sit-down" restaurants, and fast food (quick-service) restaurants. Categories were sampled based on the prevalence of the types of establishment in each area and on the likelihood of finding bulk soap in the establishment. Soap was collected from the bathrooms of these establishments. Men's and women's restrooms were sampled in approximately equal frequency. Although soap color was noted, no attempt was made to sample specific colors.

Samples were shipped to the University of Arizona for microbiological analysis, and to GOJO Industries, Inc. (Akron, OH) for physical and chemical analysis. One hundred samples each were collected from Arizona and New Jersey, and 96 samples were collected from Ohio.

Soap samples were collected in a 50-mL sterile conical tube (Corning, Union City, CA), with a minimum volume goal of 45 mL. Two tubes of soap were collected from most establishments, except in a few instances in which a facility only had enough soap for one tube. Soap was collected in the tube by catching the soap released when the dispenser lever was pressed. We used this method to ensure that the soap collected was representative of what would be dispensed onto a customer's hands. Foaming soap was not sampled because bulk refillable foam soap dispensers are uncommon, and challenges in collecting an adequate mass of foaming soap made sampling impractical. Samples were sealed using parafilm (Bemis NA, Neenah, WI) and were placed in an ice pack–chilled cooler after collection.

Microbiological analysis. Total heterotrophic viable bacteria were assayed on Reasoner's 2A agar (R2A; EMD Chemicals, Inc., Gibbstown, NJ), using serial dilutions of 10^{-1} through 10^{-3} of the soap samples, with colonies counted after 5 days of incubation at 22 ± 2°C. R2A agar was originally developed as a rapid method for fecal coliforms in water *(28)*; however, since its development, it has been used in a wide variety of applications, including screening of bulk soap for contaminants *(8)* because it may be especially suitable for culturing slower growing organisms from stressed environments *(36)*. Colonies of the three most predominant morphologies were streaked onto plates of Trypticase soy agar (TSA; EMD Chemicals, Inc.) for isolation and identification. R2A plates were also examined for the presence of *Pseudomonas,* which was then isolated and confirmed.

Coliforms and *E. coli* were quantified using the IDEXX Quanti-Tray/2000 system (IDEXX Laboratories, Westbrook, MA). A 10-mL aliquot of the sample was added to 90 mL of sterile water containing the Quanti-Tray reagent, poured into the Quanti-Tray, and then sealed and incubated at 35°C for 24 h. Coliforms were identified by yellow pigmentation and *E. coli* by fluorescence under UV light. The number of positive yellow and fluorescing wells were quantified, and the IDEXX most-probable-number (MPN) generator program was used for quantification.

Randomly selected coliform-positive wells from the IDEXX Colilert Quanti-Tray/2000 (IDEXX Laboratories) were spread plated on MacConkey agar (EMD Chemicals, Inc.) to select for lactose fermenters. These isolates were then spread plated to TSA (EMD Chemicals, Inc.) and subjected to an oxidase test (BD, Sparks, MD) and API 20E identification biochemical test strips (bioMérieux, Durham, NC) for confirmation as coliforms. Twenty-eight isolates were identified as coliforms and tested for antibiotic resistance by placing antibiotic disks for vancomycin, ampicillin, gentamicin, and ciprofloxacin (Sigma Chemical, St. Louis, MO) onto bacterial lawns of the individual bacteria.

Salmonella preenrichment started by placing a 5-mL aliquot of the soap sample into a tube that contained 10 mL of tryptic soy broth (TSB; EMD), followed by incubation at 35°C for 24 h. After 24 h, 1 mL of the TSB was transferred to a tube that contained 10 mL of Rappaport-Vassiliadis broth (Hardy Diagnostics, Santa Maria, CA), followed by incubation at 41.5°C for 24 h. One milliliter of TSB was also added to a tube that contained 10 mL of selenite cystine broth (EMD Chemicals, Inc.) and was incubated at 35.0°C for 24 h. Each tube showing turbidity was streaked onto plates of Hektoen (EMD Chemicals, Inc.) and xylose lysine desoxycholate (XLD; EMD Chemicals, Inc.) agars and incubated

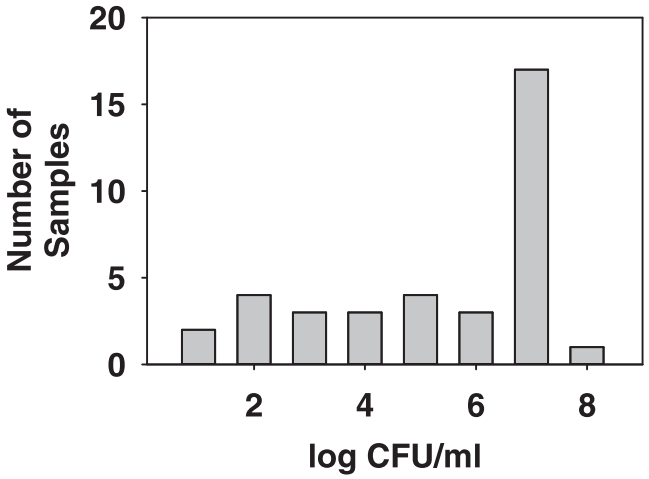

FIGURE 1. *The distribution of microbial counts in contaminated soap samples.*

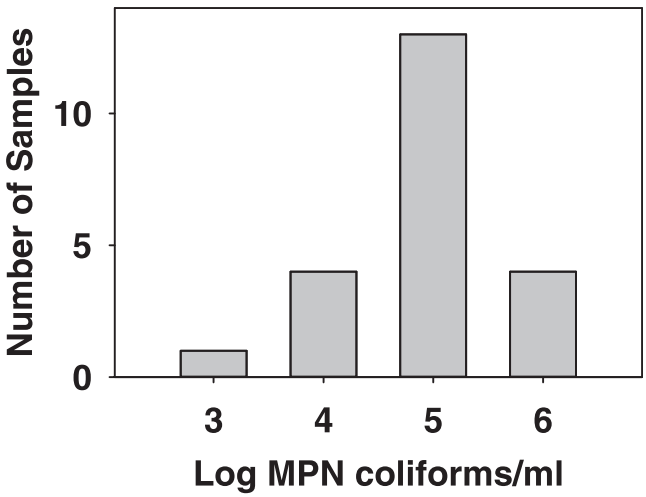

FIGURE 2. *The distribution of coliform counts in contaminated soap samples.*

at 35°C for 24 h. Presumptive *Salmonella* isolates were transferred to TSA for biochemical identification using the API 20E (bioMérieux). If the isolate was presumptively identified as *Salmonella,* the isolated colonies were sent to the National Veterinary Services Laboratories (Ames, IA) for serotyping.

pH and water activity. The pH of all samples was evaluated using a Thermo Orion 720A+ pH with the Thermo Scientific Orion ROSS Sure-Flow pH electrode (Thermo Fisher Scientific, Pittsburgh, PA). Five grams of each test sample was evaluated using the Ohaus standard moisture analyzer (model MB45, Ohaus, Pine Brook, NJ).

A water activity meter (Rotronic Instrument Corp., Hauppauge, NY) was used to measure the water activity of soap samples. Distilled water and glycerol solutions were used as standards. Each sample cup was filled with about 10 mL of soap sample, and after 4 to 5 min the temperature and water activity were recorded. The sample cup was rinsed using distilled water and was dried completely using a Kimwipe (Kimberly-Clark, New York, NY) after each test.

Antimicrobial analysis. All samples were evaluated for the presence and quantity of triclosan using the Waters (Milford, MA) e2695 Alliance high-performance liquid chromatography system with a UV/Visible Detector (Waters 2489) and a Waters μBondapak C18 column (125Å, 10 μm, 3.9 by 150 mm; Waters no. WAT086684). All samples that tested negative for the presence of triclosan were evaluated for the presence and quantity of parachlorometaxylenol, using the same system, detector, and column as used for triclosan.

RESULTS

Most of the soap samples tested (>85%) contained no detectable microorganisms (10 CFU/mL detection limit). The distribution of microbial counts found in contaminated soap samples is shown in Figure 1. Samples containing detectable microorganisms were most often contaminated at a very high level (~7 log CFU/mL), with counts on the remaining samples ranging uniformly from 1 to 6 log CFU/mL. Although not all bacteria recovered were identified, microorganisms detected in contaminated soap included *Klebsiella oxytoca, Serratia liquefaciens, Shigella sonnei, Enterobacter gergoviae, Serratia odorifera,* and *Enterobacter cloacae*. Four of the soap samples were positive for *Salmonella* by API 20E, but were not confirmed as *Salmonella* by the National Veterinary Services Laboratories. Twenty-three samples contained vancomycin-resistant organisms. Seven of these were also resistant to ampicillin, and two of those, in turn, were resistant to gentamicin. One sample contained an organism resistant to vancomycin, ampicillin, gentamicin, and ciprofloxacin (antibiotic resistance data not shown).

When a sample contained detectable coliforms, similarly, the population was likely to be high, as shown in Figure 2. The distribution of coliforms is likely higher than what is shown in Figure 2, because the two highest populations were at the upper limit of quantification (i.e., >241,960 MPN/mL or >24,196 MPN/mL).

Figure 3 shows that higher coliform counts tended to be associated with samples that contained higher bacterial counts overall. Coliform counts at the upper limits of the MPN method are especially associated with high total bacterial counts.

Figure 4 shows the relationship between sample pH and the population of detectable microorganisms. Of samples with a pH less than 7.0, 18% had detectable contamination, whereas only 10% of samples with a pH of 7 and above had detectable contamination. Note, however, that contaminated soap samples with a pH ≥7.0 are more likely to result in contamination at a relatively higher level (i.e., >1,000 CFU/mL), perhaps because pH influences bacterial growth or survival.

Figure 5 shows the relationship between the measured percent solids (top panel) or water activity (bottom panel) of a sample and the bacterial count. Note that every sample containing less than 4% solids had some detectable level of bacteria, whereas only two samples with greater than 14% solids had detectable bacteria. A similar pattern is shown with water activity (Fig. 5, bottom panel), and samples with water activities between 0.99 and 1.0 were associated with a range of bacterial populations, including the highest populations observed. As the measured water activity

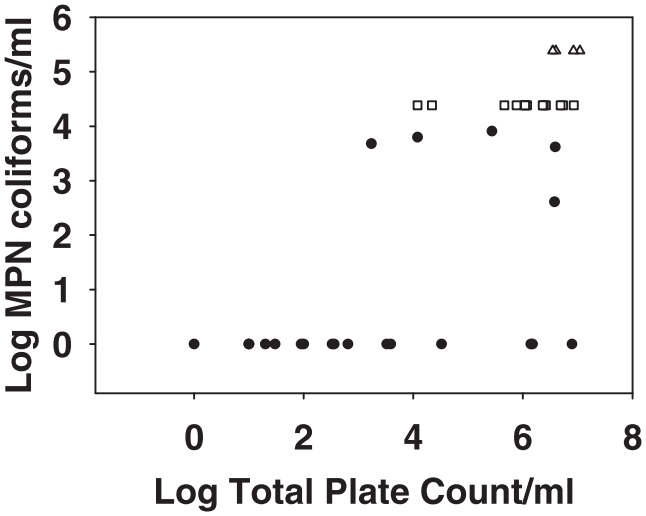

FIGURE 3. *Relationship between coliform counts and total plate counts in contaminated soap samples. Coliform counts above 4.4 log MPN or above 5.4 log MPN are shown using open squares and open triangles, respectively. Counts below the detection limit (10 CFU/mL) are plotted as 0 log CFU or MPN.*

decreased, the occurrence of higher bacterial populations declined, although there was a low population of bacteria in the soap with the lowest water activity measured. There was no clear relationship between the solids content and the water activity (data not shown).

Figure 6 expands upon the analysis of the relationships between percent solids (top panel) or water activity (bottom panel) and bacterial count. As percent solids increases, the fraction of samples with a bacterial count above the detection limit (10 CFU/mL) decreases (Fig. 6, top panel). Note that the two leftmost bars in the figure are associated with very few observations (three and six observations, respectively), whereas all other points are always associated with 30 or more observations. The bottom panel of Figure 6 shows the number of samples associated with different water

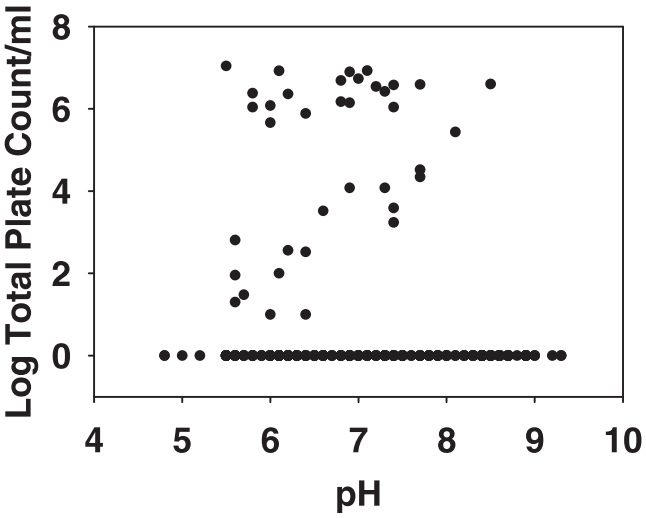

FIGURE 4. *Relationship between sample pH and the population of detectable microorganisms. Counts below the detection limit (10 CFU/mL) are plotted as 0 log CFU.*

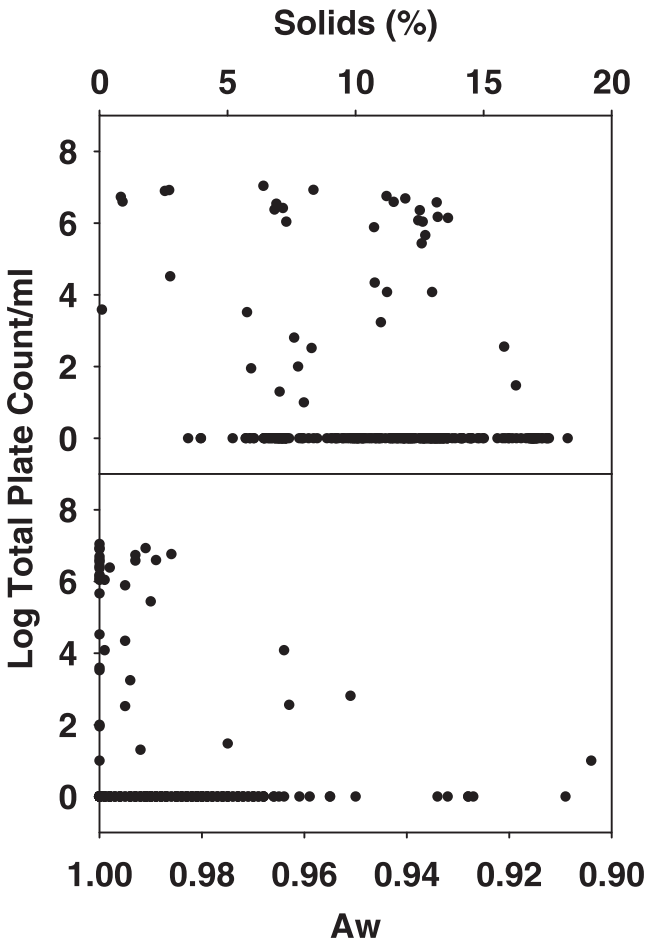

FIGURE 5. *Relationship between soap sample percent solids (top panel) or water activity (bottom panel) and bacterial count. Counts below the detection limit (10 CFU/mL) are plotted as 0 log CFU.*

activities, with the number of samples generally decreasing as water activity increases. The number of contaminated (gray) versus uncontaminated (black) samples are shown by shading on the bars. Clearly the greatest number, as well as the greatest fraction, of samples containing detectable bacteria is associated with higher (0.99 to 1.00) water activities, although even soaps with lower water activity can also contain detectable bacteria.

Figure 7 shows the relationship between the measured population of antimicrobial agent in the soap and the bacterial count. Samples containing no detected antimicrobial agent have widely distributed contamination levels. Although samples containing triclosan were contaminated regardless of the triclosan level (~0.15 to 0.65%), only one sample containing parachlorometaxylenol was contaminated, and that was at a relatively low level (0.15%).

Table 1 shows a summary of these antimicrobial data. Most of the samples tested contained no detected antimicrobial, and these samples contained the greatest fraction with countable microorganisms, almost 17%. There was a statistically significant difference between the fraction of bacteria-positive samples with no detected antimicrobial agent and those containing an antimicrobial agent ($P = 0.0035$). There was not a statistically significant difference between the fractions of bacteria-positive samples for the two types of

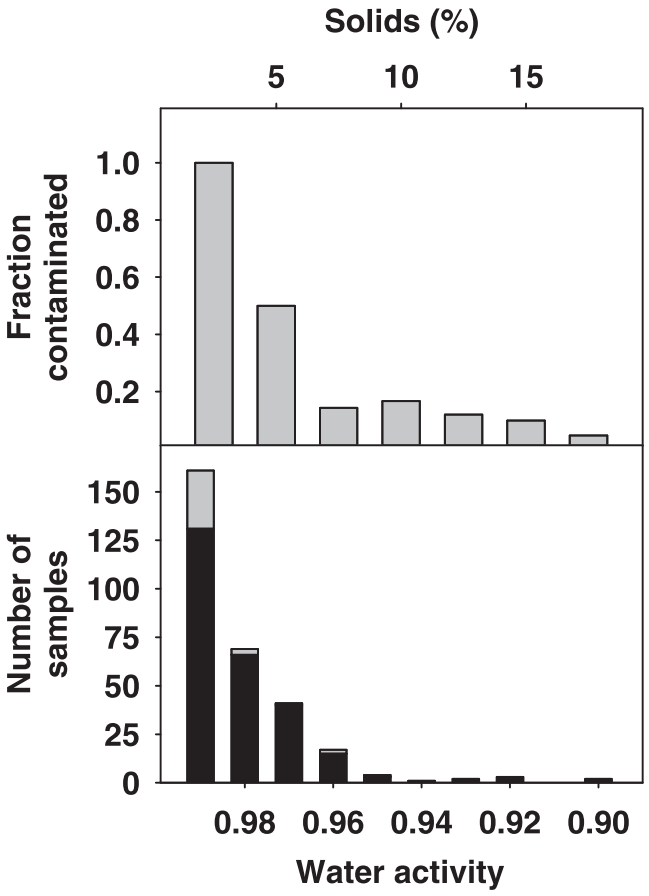

FIGURE 6. *Relationship between fraction of soap samples with bacterial counts above the detection limit (10 CFU/mL) and percent solids (top panel) or number of soap samples contaminated (gray) or uncontaminated (black) and soap water activity (bottom panel).*

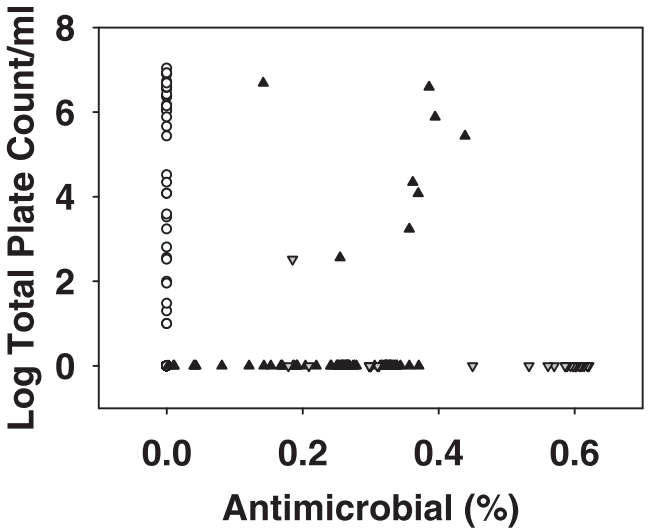

FIGURE 7. *Relationship between the measured concentration of the antimicrobial agent triclosan (black triangle) or parachlorometaxylenol (gray downward triangle) or no detectable antimicrobial agent (open circles) and total bacterial count. Counts below the detection limit (10 CFU/mL) are plotted as 0 log CFU.*

TABLE 1. *Comparison of the fraction of samples containing detectable bacteria for soap samples with detectable antimicrobial agents*[a]

	No. sampled	No. countable	% total samples	% countable
None	166	28	56.1	16.9 A
Triclosan	97	8	32.8	8.2 B
Parachlorometaxylenol	33	1	11.1	3.0 B
Total	296	37	100.0	12.5

[a] Percent countable values followed by a different letter are significantly different ($P < 0.05$).

antimicrobial agents ($P = 0.1022$). The fraction contaminated in total for all soap samples collected was 12.5%.

The relationship between the type of location sampled and the fraction of the time that samples contained detectable microorganisms is shown in Table 2. Grocery stores and fast food operations each had more than 10% bulk-soap samples positive. Grocery stores, fast food restaurants, and sit-down restaurants did not have significantly different fractions of contaminated samples from one another ($P > 0.05$), but grocery stores and fast food restaurants had significantly more ($P < 0.05$) contaminated bulk-soap samples than convenience stores.

The breakdown of bulk-soap samples in Table 3 shows that both men's and women's bathrooms have contaminated soap >10% of the time. Although samples collected from men's restrooms have a slightly higher frequency of detectable bacteria, the difference was not significant ($P = 0.29$).

The relationship between soap color and the presence of detectable bacteria is shown in Table 4. There are differences in the fraction of samples containing detectable bacteria, by soap color. However, given the wide array of soap colors observed, and the small number of samples containing detectable microorganisms, no differences were statistically significant.

Table 5 shows the fraction of samples containing detectable microorganisms by state, with >10% of soap contaminated in all three states. There were not statistically significant differences among the three states where soap samples were collected ($P > 0.05$).

DISCUSSION

This study identified gram-negative organisms as the primary organisms that colonize bulk-soap dispensers,

TABLE 2. *Fraction of samples containing detectable bacteria by store type*[a]

Type	No. sampled	No. of times bacteria detected	% detected
Grocery	30	5	16.7 A
Fast food	122	19	15.6 A
Sit down	113	11	9.7 AB
Convenience	28	1	3.6 B

[a] Percent detected values followed by a different letter are significantly different ($P < 0.05$).

TABLE 3. *Fraction of samples containing detectable bacteria by restroom gender type*

Type	No. sampled	No. of times bacteria detected	% detected
Men	169	23	13.6
Women	114	13	11.4
Other[a]	13	1	7.7

[a] Includes unknown, not recorded, and unisex bathrooms.

consistent with past outbreaks *(1, 2, 24, 38)* and screening studies *(8, 25)*. We identified gram-negative organisms at a broad range of populations (1 to 7 log CFU/mL), as reported by Momeni et al. (2 to 9 log CFU/mL *(25)*). Whereas Momeni et al. found detectable bacteria in ~60% of their samples, we found detectable bacteria in 15% of samples. This may be owing to differences in sample size (our 296 versus their 14), locations (three states versus two institutes), and type of facility (food service versus dental institute). Chattman et al. *(8)* collected 541 bulk-soap samples from five U.S. cities (Boston, Atlanta, Columbus, Los Angeles, Dallas), from liquid soap dispensers in a wide variety of public settings: offices, health clubs, restaurants, and retail stores. These authors found heterotrophic and coliform populations greater than ~2 log CFU/mL in ~19% of the sink area dispensers, similar to what we found (>2 log CFU/mL in ~15% of dispensers).

Specifically relevant to the food industry was the identification of *S. sonnei* from a contaminated soap dispenser in Arizona. According to the CDC, *S. sonnei* is the predominant cause of shigellosis in industrialized countries (and is the most common species in the United States). Consumption of ready-to-eat food contaminated due to handling by an infected worker could be a significant contributor to the spread of *S. sonnei (4)*.

The published literature reports that bacteria are more commonly isolated from plain soaps *(1, 5, 27, 30)* and are less frequently isolated from antimicrobial soaps *(1, 2, 24)*, which is consistent with the findings from our study. Although fewer bacteria are generally isolated from antimicrobial soaps (as they were in our study), it is a major technical challenge to maintain the activity of active ingredients, such as triclosan, so that they are not bound by the surfactant micelles *(11, 34)*. Our research clearly shows that the presence of an antimicrobial agent is not a safeguard

TABLE 4. *Fraction of samples containing detectable bacteria by soap color*

Color	No. sampled	No. of times bacteria detected	% detected
Green	11	5	45.5
Clear	24	7	29.2
Orange	37	8	21.6
Pink	120	12	10.0
White	41	3	7.3
Blue	42	3	7.1
Yellow	16	0	0.0
Unknown	6	0	0.0

TABLE 5. *Fraction of samples containing detectable bacteria by state*

State	No. of samples	No. of times bacteria detected	% detected
AZ	100	14	14.0
NJ	100	11	11.0
OH	96	12	12.5

against the colonization of bulk soap by bacteria. This is consistent with Archibald et al. *(1)*, who detected *S. marcescens* in 1% chloroxylenol soap (parachlorometaxylenol), and with Barry et al. *(2)* and McNaughton et al. *(24)*, who isolated bacteria from soap that contained triclosan.

It is well understood by chemists that formulation affects the performance of hand hygiene products *(10, 23)*. Our study is a reminder that quality also matters in soap development. For example, high water–low solids formulations may be less expensive to manufacture, but they are more likely to be contaminated. Soap delivery systems designed to allow mixing (or dilution of soaps to save money) promote colonization and lead to less-stable formulations. We also observed differences among types of food establishments. Fast food and grocery stores are more likely to be contaminated than convenience stores; this may be because, in the former, there is less maintenance and management oversight of the bathrooms, whereas convenience stores typically have small bathrooms that are cleaned frequently. Fast food restaurants should be of the greatest concern because food handlers often use the bathrooms we sampled that were located in the "front of the house" and then often return directly from the bathroom into the kitchen. This finding warrants strong consideration of Food Code restrictions on the use of bulk soap in restaurants, analogous to rules that discourage their use in health care *(3, 31, 39)*.

We believe this work is generalizable across the United States. Samples were obtained from a variety of food handling environments in three states spread across the country, with a wide range of weather (temperature and humidity); we found no significant differences in level of microbial contamination among states. Our findings show that the design of open refillable systems for dispensing bulk soap is fundamentally flawed and creates opportunities for contamination and biofilm development, independent of geographic location. Future needs and opportunities include better understanding the relationship of bathroom design (e.g., toilet proximity to the soap dispenser, size of bathroom) and further assessment of the risk of antibiotic-resistant bacteria in bulk soaps. Alternative approaches to achieve a lower or acceptable cost to the food service provider are also important, because low cost is the primary attraction to bulk-soap systems. Changing this practice will require good policy development, analogous to what happened in health care *(3)*.

Use of refillable bulk-soap dispensers is a clear public health concern because they provide an environment for bacteria to grow, often to high populations *(8, 21, 25, 30, 40)*, and their use has led to non–foodborne disease outbreaks *(1, 2, 5, 24, 27, 30, 38)*. In our study, most soap

samples had no detectable bacteria; however, those soap samples that did have detectable bacteria (12.5%) had populations that would be considered highly risky if the bacteria present were pathogenic (~7 log CFU/mL). Whereas the CDC recommends that bulk liquid soap dispensers be thoroughly cleaned before adding fresh soap *(3, 8, 14),* cleanings in between soap refills might not prevent recontamination *(21),* and difficult-to-clean biofilms may develop. Bulk soap has been proven to cause infection outbreaks in health care settings. It has been difficult to document outbreaks in food service settings to date; however, our findings show that the use of bulk soap presents a clear risk in food service facilities.

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Original Article

A survey of public restrooms microbial contamination in Tehran city, capital of Iran, during 2019

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Abstract

Introduction: Daily use of public restrooms may have a significant impact on spreading infectious diseases. Human society could be affected by spreading of transitional infectious diseases through feces, urinary tract infection and poor personal hygiene. According to the World Health Organization reports, plenty of people's developed diseases caused by contaminated public restrooms that may result in severe health problems. **Methods:** This descriptive cross-sectional study was conducted on 7,482 samples that were collected randomly in 6 months (spring and summer 2019) in different regions of Tehran. The Data were obtained by analyzing 804 restroom's indoor and outdoor handles, 1062 toilet faucet, 826 washbasin taps, 1,062 toilet hoses, 804 flush tank levers, 643 soap dispenser bottoms, 643 liquid soaps, 99 bar soaps, 169 toilet papers and paper towels, and 50 hand dryer machines. Samples which were tested, based on bacteriology standard methods. **Result:** 7,482 samples were gathered of which 6,678 contaminated cases (89.25%) were observed and 804 cases (10.75%) were found non-contaminated. *Escherichia coli* with 28.48% and *Pseudomonas* with 0.39% were the most and the least common bacteria, respectively, in this study. **Conclusion:** The required tests to identify the bacteria that cause contamination through the use of public restrooms have been done. It is essential to inform the public of the mentioned items and teach how to prevent infectious diseases.

Keywords: Bacterial contamination, hand dryer soaps, public restrooms

Introduction

Using public restrooms on a regular basis could have a significant effect on the transmission and diffusion of infectious diseases and other bacterial contamination. Due to many people using public toilets or washbasins and touching doorknobs several times a day, it can cause transmission of such contamination and pathogenic infectious disease. Therefore, the importance of toilets and washbasins as a source of transmission of bacterial contamination becomes more evident. It's obvious that if people's awareness of transitional contamination and related diseases enhances, it can be good for better social health and prevention of various infections. The purpose of this research is to boost health care in public services. In this study, by the

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survey of bacteriology and sampling of every facility that exist in restrooms and public services, we have measured the kind and amount of contamination that may be transferred by one to another people while they are using this places.

It seems that public services and home services must be more sanitized; absolutely in order to use public services and preventing problem for public health, more care of these services are recommended. Public services such as cinemas, hotels, hospitals, libraries, parks, etc., are more intended to be polluted because of severe public usage this should be done repeatedly to prevent transmission of disease and not to establish various illnesses such as skin disease, digestive disease, genital and venereal disease to the public. Such diseases are commonly transferable to public services because of sharing the same spaces of usage. All the points that are touchable for publics such as door handles, toilet paper, flush tanks, water hoses, valve handles, sink, liquid and solid soap, tissues, electrical driers, etc., subjects to be cleaned properly. The ventilation of public services areas is a very important factor to keep health care for public services.[1] Per annum, many cases of disease from public places occur to the people who are using these services, because of lack of sanitizing procedure; furthermore, by being infected with multidrug-resistant (MDR) bacteria or a harmful one, the process of recovery will become more complicated; this causes many economic and mental consequences to these people. Knowing the variety of contamination and checking infected facilities (such as an important one, toilet papers) that are existing in such services and have an important role in publishing the infection, McCusky *et al.*[2] and Robinton *et al.*[3] can help us to find means of preventing or diminishing infectious diffusion.

Recognizing the transmittal ways of"germs" and the means, help us to prevent establishing of contamination and to decrease the prevalence rate of disease that we expect to come after use of these facilities. . Also, making people aware of the bad consequences of poor health services and encouraging them to keep their personal belongings clean will cause social behavior more confident in their health. This study examines whether electric driers, liquid or solid soaps, toilet paper and toilet valves, outdoor, and indoor handles etc., and whether they can play a positive or negative role in the transmission of diseases. In this article, we tried to answer this question by determining the type of microorganisms that we presume to exist. By the 7,482 samples we had taken from different points of many services, we get rich to achieve the trustful answer to the question. Definitely, by the numerous numbers of samples taken, its precision, accuracy, and reliability would be also higher.

Materials and Methods

This descriptive cross-sectional study was conducted in different areas of Tehran during 2019. The subjects which were sampled are indoor and outdoor handles, taps, flush tank bottoms and levers, liquid and bar soaps. For bacterial type detecting, we have used of principals scientific sources and standard methods of bacteriology.

For a bacterial sampling of cases mentioned above, first provided wet sterile swabs which after sampling, transported on transport culture media and then as soon as possible it was transferred to the laboratory for passaging them on culture medias such as nutrient agar (HIMEDIA, LOT45114591), blood agar (HIMEDIA, LOT45114591), MacConkey agar (HIMEDIA, LOTWe215), and EMB (HIMEDIA, LOT00000015320) which had been prepared before and were keeping on the refrigerator. Before passaging the samples on culture media, the prepared media were brought out from the refrigerator in order to reach room temperature. After passage, in order to bacterial growth, the culture media which were passaged on were put into the incubator on 37 centigrade degrees (for 24–48 h). Finally, in order to assess the bacterial growth and colony-formation, the preserved culture media were examined precisely. When it manifested that the bacterial colonies had been grown on culture media, the Gram-staining method used to determine Gram-positive and Gram-negative bacteria.

Generally, all the species with their bacterial load of up to 100,000 CFU/g were designated detrimental even though those between 50,000 and 100,000 CFU/g were repeated for sampling and reassessed. Although, less than 50,000 colonies of bacteria/g are also considered normal and were excluded from the samples.

We realized that all the bacteria (whether Gram-positive and Gram-negative) could be able to grow on Nutrient agar media; also Gram-positive bacteria were grown on blood agar media and Gram-negative bacteria were grown on EMB and MacConkey agar media. For determining the specious of bacteria, these biochemical tests had been done; as mentioned below: For detecting the specious of Gram-negative bacilli such as *Shigella*, *Salmonella*, *Pseudomonas*, etc., Catalase, oxidase, urease test and triple sugar iron agar (TSI) (HIMEDIA, LOT00000015312) culture media were used. For detecting the specious of Gram-positive bacteria such as *Enterococcus faecalis*, *Staphylococcus aureus*, etc., Catalase, coagulase, and MSA culture media (HIMEDIA, LOT0000287212) were used, too.

Result

In the above study, we sampled 1,062 restrooms that in this survey: 2,124 restroom indoor and outdoor handles, 1,062 toilet faucet, 826 washbasin taps, 1,062 toilet hoses, 804 flush bottoms, 643 soap dispenser bottoms, 643 liquid soaps, 99 bar soaps, 169 toilet papers and paper towels, and 50 hand dryer machines. In total 7482 samples were tested from which 6,678 samples (89.25%) were contaminated and 804 samples (10.75%) uncontaminated.

Discussion

In this study, 7,482 samples were taken from various cases. According to Table 1, there were 6,678 contaminated specimens, of which the highest rate was found in toilet hoses and taps with 99.72% (Out of 1,062 samples, 1,058 specimens were contaminated), followed by toilet outdoor handles with 99.62% (out of 1,062 samples, 1,058 specimens were

contaminated). Flush tank levers with 99.14% (out of 804 samples, 781 samples were contaminated), toilet indoor handles with 95.52%, soap dispenser bottoms with 97.82%, washbasin taps with 95.52%, bar soaps with 91.92%, hand dryer with 56% and towel papers with 20.12% were placed in terms of the amount of contamination.

According to results of Table 2. *E. coli* (28.5%) and Klebsiella (1.51%) were the most and least present bacteria in toilet indoor handles, respectively. On toilet outdoor handles, *E. coli* was the most (28.54%) and *Pseudomonas* was the least (1.32%). On flush tank levers, maximum bacteria was *E. coli* (35.08%) and *Pseudomonas* (0.26%) was the minimum. *E. coli* (30.6%) and *Salmonella* (1.52%) were the most and the least bacteria on

Table 1: Absolute and relative frequency table of contaminated and non-contaminated public restrooms

Sample items	Contaminated items		Non-contaminated items		Total
	n.	Percentage	*n*	Percentage	
Restroom indoor handles	1042	98.12	20	1.88	1062
Restroom outdoor handles	1058	99.62	4	0.38	1062
Toilet faucet	1059	99.72	3	0.28	1062
Toilet hose	1059	99.72	3	0.28	1062
Flush bottoms and levers	781	99.14	23	2.86	804
Washbasin tap	789	95.52	37	4.48	826
Liquid Soap dispenser bottoms	629	97.82	14	2.18	643
Liquid soaps	108	16.80	535	83.2	643
Solid soaps and bar soaps	91	91.92	8	8.08	99
Toilet paper and paper towels	34	20.12	135	79.88	169
Hand dryer machines	28	56	22	44	50
Total	6678	89.25	804	10.75	7482

* *n.*=number * %=Percent

Table 2: Absolute and relative frequency table of microorganisms isolated from public restrooms

Microorganisms / Sampl items	S.epidermidis	S.aureus	salmonella	Entrococcus faecalis	Basillus subtilis	E.coli	Klebsiella	Citrobacter	Entrobacter	Pseudomonas	Proteus vulgaris	Shigella	Mix	Contaminating cases	
	N. (%)	N. (%)	N.(%)	N.(%)	N.(%)	N.(%)	N.(%)	N.(%)	N.(%)	N.(%)	N.(%)	N.(%)	N.(%)	N.(%)	
Restroom indoor handles	138 (13.24%)	105 (10.08%)		16 (1.54%)	186 (17.85%)	297 (28.5%)	12 (1.15%)	18 (1.73%)	14 (1.34%)		128 (12.28%)	14 (1.44%)	114 (10.94%)	1042	
Restroom outdoor handles	130 (12.29%)	98 (9.26%)	24 (2.27%)	38 (3.59%)	191 (18.05%)	302 (28.54%)	14(1.32%)	21 (1.98%)	28 (2.65%)		80 (7.56%)	14 (1.44%)	112 (10.59%)	1058	
Toilet faucet	61 (5.76%)	59 (5.57%)	26 (2.46%)	40 (3.78%)	189 (17.85%)	365 (34.47%)	16 (1.51%)	30 (2.83%)	35 (3.31%)		98 (9.25%)	20 (1.89%)	108 (10.2%)	1059	
Toilet hose	107 (10.1%)	101 (9.54%)	18 (1.7%)	81 (7.65%)	197 (18.6%)	217 (20.49%)	22 (2.08%)	34 (3.21%)	38 (3.59%)	4 (0.38%)	109 (10.29%)	32 (3.02%)	110 (10.39%)	1059	
Flush bottom and levers	90 (11.52%)	62 (7.94%)	24 (3.07%)	73 (9.35%)	60 (7.68%)	274 (35.08%)	67 (8.57%)	29 (3.71%)	22 (2.82%)	2 (0.26%)	45 (5.76%)	21 (1.98%)	8 (1.21%)	781	
Whashbasin tap	76 (9.63%)	94 (11.91%)	12 (1.52%)	49 (6.21%)	128 (16.22%)	238 (30.6%)			46 (5.83%)		86 (10.9%)	25 (3.2%)	48 (6.08%)	789	
Liquid soap dispenser bottoms	48 (7.63%)	38 (6.04%)	10 (1.59%)	92 (14.63%)	111 (17.65%)	187 (29.73%)		12 (1.91%)	9 (1.43%)	2 (0.32%)	63 (10.02%)	12 (1.52%)	40 (6.36%)	629	
Liquid soaps				2 (1.85%)	22 (20.27%)			10 (9.26%)		18 (16.67%	30 (27.78%)	17 (2.7%)	26 (24.07%)	108	
Solid soaps and bar soaps	14 (15.83%)	10 (10.99%)	10 (10.99%)		10 (10.99%)	16 (17.58%)	1 (1.1%)	2 (2.2%)			14 (15.38%)		14 (15.38%)	91	
Toilet paper and paper towels	10 (29.41%)				4 (11.76%)	6 (17.65%)					4 (11.76%)		10 (29.41%)	34	
Hand dryer	10 (35.71%)	2 (7.14%)			2 (7.14%)						6 (21.43%)		8 (28.57%)	28	
Total	684 (10.24%)	569 (8.52%)	124 (1.86%)	391 (5.86%)	1100 (16.47%)	1902 (28.84%	132 (1.98%	156 (2.34%)	192 (2.86)	26 (0.39%)	663 (9.93%)	141 (2.11%)	598 (8.95%)	6678	c

washbasin taps, respectively. In soap dispenser bottoms, *E. coli* was the most (29.73%) and *Pseudomonas* was the least (0.32%). The most and the least bacteria that were found in liquid soaps were *Proteus vulgaris* (27.78%) and *Enterococcus* (1.85%). The most bacteria in bar soaps was *E. coli* (17.58%) and the least was *Klebsiella (1.1%)*. On toilet papers, *Staphylococcus epidermidis* and mix bacteria were the most with (29.41%) and *Proteus spp.* and *Bacillus spp.* with (11.76%) were the least and finally in hand dryer machines *S. epidermidis* (35.71%) was the most and *S. aureus* and *Bacillus spp.* (7.14%) were the least.

In general, *E. coli* is the highest rate of contamination related to flush tank levers or bottoms and *Pseudomonas* is the lowest rate of contamination. It seems that after using the bathroom, flush tank levers can be effective in transmitting bacterial infectious diseases due to non-adherence in health care. It seems that *E. coli*, which is an intestinal bacteria, causes various parts of restroom contamination during the use of toilets, which is a sign of non-adherence in health care. Also, *E. coli* bacteria are very sensitive to drying on the contaminated hands; so the high potential of this bacteria for cross-contamination is expected due to soppy hands.[4] *Pseudomonas* in liquid soap and the other parts of restrooms, which were contaminated by these bacteria, is a sign that subjects and materials are not used correctly. People are infected, and they transmit diseases.

A study performed by Buffet-Bataillon *et al.*,[5] has questioned the outbreak of *Serratia marcescens* and its investigation and control in the neonatal intensive care unit (NICU). In this study, during 3 months period, five infants were colonized by a single strain of *Serratia marcescens*. The researchers of this study achieved that a bottle soap dispenser can be a reservoir of this nosocomial pathogenic bacteria. So, these microorganisms can be easily transferred to newborns by healthcare workers. Conversely, *P. vulgaris* (27.78%) were the most bacteria sampled from liquid soaps as well as *E. coli* (29.73%), *Bacillus subtilis* (17.65%), and *Entrococcus faecalis* (14.63%) liquid soap dispenser bottoms. Although some researchers have proved that washing hands with non-antibacterial soaps and water are more effective than with water alone, Burton *et al.*,[6] basically by regarding the contamination of soap dispensers, we suggest using of alcoholic hand antiseptic instead of liquid or solid soaps.

In the study of microbial biogeography of public restroom surfaces which have been done by Flores *et al.*,[7] the communities were clustered into three general categories: those found on surfaces associated with toilets, those on the restroom floor, and those found on the surface routinely touched with hands. However, by comparison to our study, the sample items and bacterial diversity were almost alike, also vagina-associated *Lactobacillaceae* were wildly distributed in female restrooms.

In the study of Kanayama *et al.*,[8] 252 samples were contaminated from 292 specimens, taken from toilets and warm water taps. *S. aureus*, *Streptococcus spp*, *Enterococcus spp*, *Enterobacteriaceae* and other negative bacteria had been found. From the above items, *Enterobacteriaceae* were isolated as 84 (%28.8) bidets and *E. coli*, *Enterobacter spp. Klebsiella, Citrobacter spp, and Enterobacteriaceae* by 38 (13.0%), 22 (7.5%), 13 (4.5%), 5 (1.7%) and 6 (2.1%) were isolated in toilet bidets warm water, respectively.

In the study of McCusky *et al.*, *Bacillus licheniformis* was the most isolated bacteria with 20.2% that shows a remarkable difference to compare with our study.[2] Also, in the study of Harrison *et al.*, *Micrococcus luteus* and some strains of *Serratia marcescens* were the two specious of bacteria found in paper towel specimens.[9] In addition, Robinton *et al.*,[3] showed that paper towels have substantially fewer viable bacteria on them than cloth towels, although in the opposite of cloth towels, the number of bacteria found on paper towels does not seem to be a variable appreciably influenced by geographic and/or climatic differences. In the above study, *Bacillus spp* were the most bacterial species found in both kinds of towels. This is in contrast to our results in which *S. epidermidis* was common. There is no difference in the type of infectious bacteria in the above study compared with our study, but there is a significant difference in the percentage of contamination.[10] In a study by Sabra in Egypt in 2011,[11] the contamination of the women's public toilets were examined. 71.9% of the samples being positively infected. Toilets door handles (91.3%), toilet doors (73.8%), toilet sinks (63.3%), and flush tank levers (50%) were contaminated. *S. aureus* (40.6%) and *E. coli* (22.5%) were the most isolated bacteria from positive samples and *P. vulgaris* was the least one. There is no significant difference to compare with our study.

In the study of Alharbi *et al.*,[12] five different bacterial isolations were sampled from the airflow of 15 warm air dryers used in washrooms; including *Staphylococcus haemolyticus*, *Micrococcus luteus*, *Pseudomonas alcaligenes*, *Bacillus cereus,* and *Brevandimonad diminuta (vascularis)*. In this survey, the most bacterial isolates were due to *S. haemolyticus* with 95% pathogenicity; however, in our study, hand dryer machines were highly contaminated by *S. epidermidis* (35.71%). It is obvious that hot air dryers can deposit the pathogenic bacteria onto the hands and body of users as well as distributing them into the general environment whenever dryers are running. Also, some microorganisms could be inhaled by users and nonusers alike. So, it is imperative to recommend the sanitization of this machines several times a day. It is notable that in some studies it's manifested by which using warm air dryers or some jet dryers, we actually have augmented the aerosolization of bacteria and facilitating the microbial cross-contamination via airborne dissemination to the environment.[1] Best *et al.* reported that higher levels of contamination were due to washrooms using a jet air dryers compared with those using paper towels.[13] The hand-drying method can affect the risk of (airborne) dissemination of bacteria in real-world settings. JADs may not be suitable for settings where microbial cross-contamination risks are high, including hospitals.

The study that was conducted by Zapka *et al.*, in 2011,[14] the *K. pneumoniae* was isolated from samples after the bacteria were recovered and transferred by hand after washing with liquid soap which had been spontaneously infused and liquid soaps which were contaminated without control.

A study of bacteriological assessment of door handles/knobs of toilets and washrooms was conducted by Frank Ngonda in a hospital setting in 2017,[15] which revealed some bacteriological similar results. Among the total of 442 samples, 184 cases (41.6%) were contaminated and also *S. aureus* was the most bacteria had isolated. The male toilet handles were most contaminated than the females (35.5% beside 19.4%), followed by general sets (9.7%). Whilst the washroom was less contaminated in general, the highest contamination being observed in the male washroom 19.4% as compared to the female washroom at 9.7%.

In the study of Ogba *et al.*,[16] the researchers have checked on 151 samples of public toilet seats. Out of the 151 samples examined, *E. coli* 70 (46.4%) was the most prevalent isolate followed by *Salmonella spp.* 45 (29.8%) while *Staphylococcus aureus* 15 (9.9%) was the least encountered isolate. Nevertheless, most of the samples and isolates were from hostels 41 (44.0%). This study demonstrates that public toilet seats that have been washed still harbor a high number of bacterial organisms and may serve as a potential source of infections.

Conclusion

The results of this study and other similar related studies, that have been presented, demonstrate that illnesses such as genitourinary tract infections as well as gastrointestinal diseases can be found in children and adults by using contaminated services. In females, some genitourinary tract disorders such as vulvovaginocistitis, acute and chronic pregnancy, premature rupture of membrane (PROM), and acute pyelonephritis would arise mostly due to *E. coli*. In males, acute and chronic urethritis, cystitis, and prostatitis are most likely. Also, *E. coli* contamination is principally qualified to lead on Infertility in males and females. Acute cystitis, urethritis, and vaginal discharges are the main problems that occur in children are affected by this bacteria, therefore, enhancing personal hygiene, sanitizing public restrooms regularly and correctly, and using public toilets safely can prevent the transmission, diffusion, and spread of bacterial infections.

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Conflicts of interest

There are no conflicts of interest.

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Bacterial Hand Contamination and Transfer after Use of Contaminated Bulk-Soap-Refillable Dispensers▽†

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Bulk-soap-refillable dispensers are prone to extrinsic bacterial contamination, and recent studies demonstrated that approximately one in four dispensers in public restrooms are contaminated. The purpose of this study was to quantify bacterial hand contamination and transfer after use of contaminated soap under controlled laboratory and in-use conditions in a community setting. Under laboratory conditions using liquid soap experimentally contaminated with 7.51 $\log_{10}$ CFU/ml of *Serratia marcescens*, an average of 5.28 $\log_{10}$ CFU remained on each hand after washing, and 2.23 $\log_{10}$ CFU was transferred to an agar surface. In an elementary-school-based field study, Gram-negative bacteria on the hands of students and staff increased by 1.42 $\log_{10}$ CFU per hand (26-fold) after washing with soap from contaminated bulk-soap-refillable dispensers. In contrast, washing with soap from dispensers with sealed refills significantly reduced bacteria on hands by 0.30 $\log_{10}$ CFU per hand (2-fold). Additionally, the mean number of Gram-negative bacteria transferred to surfaces after washing with soap from dispensers with sealed-soap refills (0.06 $\log_{10}$ CFU) was significantly lower than the mean number after washing with contaminated bulk-soap-refillable dispensers (0.74 $\log_{10}$ CFU; $P < 0.01$). Finally, significantly higher levels of Gram-negative bacteria were recovered from students (2.82 $\log_{10}$ CFU per hand) than were recovered from staff (2.22 $\log_{10}$ CFU per hand) after washing with contaminated bulk soap ($P < 0.01$). These results demonstrate that washing with contaminated soap from bulk-soap-refillable dispensers can increase the number of opportunistic pathogens on the hands and may play a role in the transmission of bacteria in public settings.

Hand washing with soap and water is a universally accepted practice for reducing the transmission of potentially pathogenic microorganisms. However, liquid soap can become contaminated with bacteria and poses a recognized health risk in health care settings. In particular, bulk-soap-refillable dispensers (ones in which new soap is poured into a dispenser) are prone to bacterial contamination, and several outbreaks linked to the use of contaminated soap in health care settings have been reported (2, 3, 5, 15, 18, 22–24). The Centers for Disease Control and Prevention (CDC) "Guideline for Hand Hygiene in Health-Care Settings" addresses this risk in a recommendation: "Do not add soap to a partially empty soap dispenser. This practice of 'topping off' dispensers can lead to bacterial contamination of soap" (4). This "category IA recommendation" was "strongly supported by well-designed experimental, clinical, and epidemiologic studies." (4) Sealed-soap-dispensing systems, in contrast, are typically refilled by inserting into the dispenser a new bag or cartridge of soap that usually includes a new nozzle.

Bulk-soap-refillable dispensers are the predominant dispenser type in community settings, such as public restrooms. However, few studies have been conducted to evaluate the occurrence of microbial soap contamination in community settings. One study, conducted in Japan, examined bacterial contamination of hand washing soaps obtained from restrooms of various public use facilities. The authors found 17 different species of bacteria, many of which were opportunistic pathogens, including *Klebsiella pneumoniae*, *Serratia marcescens*, *Enterobacter* species, and *Pseudomonas* species (1). Recent studies conducted in the United States demonstrated that 25% of bulk-soap-refillable dispensers in public restrooms were excessively contaminated (8). Bacterial loads averaged more than 10^6 CFU/ml of soap, and 16% of the samples contained coliform bacteria. Interestingly, of the 15 different species isolated in this study, 7 were identical to those found in the Japanese study, including both *K. pneumoniae* and *S. marcescens.* Both *S. marcescens* and *K. pneumoniae* are opportunistic pathogens known to transmit via the hands (7, 17, 21).

Despite these findings, the public health risk associated with the use of contaminated bulk-soap-refillable dispensers in community settings is unclear. It would be very difficult if not impossible to trace the source of a community-acquired infection back to contaminated soap in a public restroom. Therefore, to better understand this risk, a greater understanding of the potential for bacteria from contaminated soap to remain on the hands and to be transferred to secondary surfaces after washing with contaminated soap is needed. The objectives of this study were to (i) quantify the levels of bacteria remaining on hands after washing with contaminated soap; (ii) quantify the transfer of contaminating bacteria from the hands to a secondary surface; and (iii) collect microbiological data in a field setting under actual use conditions. To our knowledge this is the first study of its kind in any setting.

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MATERIALS AND METHODS

Controlled hand washing studies. (i) Test articles. The liquid test soap contained a surfactant system representative of soaps found in public restrooms but did not contain preservatives. Soap was prepared by mixing 1,648 g of soft water, 17 g of ammonium chloride, 330 g of surfactant blends (Lubrizol Advanced Materials, Cleveland, OH; and Rhodia, Inc., Mississauga, Ontario, Canada), 2 g of fragrance (Flavorchem Orchidia, Downers Grove, IL), and 2 g of citric acid. Contaminated-soap samples were prepared by 8 successive inoculations with 300-μl to 10-ml aliquots of overnight tryptic soy broth (TSB) cultures of the marker organism *S. marcescens* ATCC 14756 or *K. pneumoniae* ATCC 13883 over the 3-week period prior to the hand wash test date. Populations of marker organisms were determined by standard plating on tryptic soy agar (TSA) and monitored over time to achieve the target contamination level.

(ii) Subjects. Eighteen subjects participated in controlled study I, and 16 participated in study II. Subjects recruited from the Bozeman, MT, area were at least 18 years of age, and the study demographics were mixed for age, sex, and race. Exclusion criteria included dermatoses or other injuries to the skin of the hands or forearms or any other conditions that would have compromised the subjects and the study.

(iii) Study design. Two controlled studies (study I and study II) assessed bacterial hand contamination and transfer post-hand washing with contaminated or uncontaminated soap. Protocols were approved by the Gallatin Institutional Review Board (Bozeman, MT). In study I, 6 subjects washed with uncontaminated test soap, 6 subjects washed with soap contaminated with *K. pneumoniae* (5.85 $\log_{10}$ CFU/ml), and 6 subjects washed with soap contaminated with *S. marcescens* (3.72 $\log_{10}$ CFU/ml). Following the hand wash, hands were sampled for residual *S. marcescens* and/or *K. pneumoniae* as described below. In study II, 8 subjects washed with soap contaminated with a low level of *S. marcescens* (4.51 $\log_{10}$ CFU/ml), and 8 subjects washed with soap contaminated with a high level of *S. marcescens* (7.51 $\log_{10}$ CFU/ml). Following the hand wash, the hands of 6 random subjects per test soap were sampled for residual *S. marcescens*. Two subjects per test soap touched agar plates to create hand imprints of bacteria transferred to the agar surfaces.

(iv) Hand washing procedure. Water used for wetting and rinsing the hands was maintained at a temperature of 40°C ± 2°C. In study I, subjects washed with 5 ml of test soap for 30 s, followed by a 30-s water rinse. In study II, subjects washed with 1.5 ml of test soap for 10 s followed by a 10-s rinse.

(v) Bacterial recovery and enumeration. To recover bacteria from the hands, powder-free, sterile, latex gloves were placed on subjects' hands, 75 ml of a recovery solution (0.4 g KH_2PO_4, 10.1 g Na_2HPO_4, and 1.0 g isooctylphenoxypolyethoxyethanol [Triton X-100] in 1 liter distilled water [pH adjusted to 7.8]) was transferred into each glove, and gloves were secured above the wrist. Technicians massaged the hands through the gloves for 60 s. Within 1 min of completing the massage, a 5-ml aliquot of the "glove juice" sample was removed and serially diluted in Butterfield's phosphate buffer solution containing lecithin and polysorbate 80 (BPB+). Dilutions were plated in duplicate onto appropriate agar plates by spread plating 1.0 ml of the recovery solution manually and spiral plating 50-μl aliquots of all dilutions (Spiral Biotech Autoplate; Advanced Instruments, Inc., Norwood, MA). *S. marcescens* was recovered on TSA with lecithin and polysorbate 80 (TSA+) and incubated for 24 to 48 h at 25°C. *K. pneumoniae* was recovered on MacConkey agar and incubated for 24 to 48 h at 35°C (7). Colonies with a morphology qualitatively similar to that of the marker organism were counted (i.e., red pigment on TSA+ for *S. marcescens* and pink mucoid on MacConkey agar for *K. pneumoniae*) with a plate-counting system (QCount model 510; Advanced Instruments, Inc., Norwood, MA). For the hand-stamp sampling procedure, subjects pressed the palms of the hands onto TSA+-containing polystyrene bioassay trays for 15 s. Trays were placed in laminar flow hoods to remove residual moisture and then incubated for 24 to 48 h at 25°C.

Field hand washing study. (i) Study site and test site. The field study was conducted in the restrooms of an elementary school in Ohio. Twenty-two subjects participated, including 12 adult staff members (teachers, administration, and janitorial staff) and 10 students (fourth and fifth grades). Exclusion criteria included cuts, rashes, or other skin conditions that would have compromised the subjects and the study. All adult subjects signed an informed consent form preapproved by Chesapeake Research Review, Inc. (Columbia, MD). All students participated only after signed parental consent, which was also preapproved by Chesapeake Research Review, Inc.

(ii) Test articles and assessment of microbial contamination. The contaminated soap used in the field study was a commercially available antimicrobial soap formulation that had been in use in the school for years prior to this study. Samples were obtained from all 14 bulk-soap-refillable soap dispensers used in the school restrooms. Approximately 10 ml of soap was aseptically collected from the dispenser nozzle into sterile 50-ml conical centrifuge tubes. The sealed-soap dispensers contained a foam soap which was sampled by filling a 120-ml sterile cup with foam. Samples were vortexed for at least 30 s and placed at rest until all bubbles dissipated. An aliquot of soap was removed with a positive displacement pipette and serially diluted in BPB+. One hundred microliters of each dilution was spiral plated onto R2A agar plates in duplicate. R2A agar is a nonselective medium designed for heterotrophic plate counts from potable water and has been previously used to quantify levels of bacteria in contaminated soap (8). Plates were incubated for 96 h at 37°C, and colonies were enumerated by hand by the standard spiral plate count methodology. The number of CFU/ml of bacteria in the original soap sample was determined based on the average colony count and the dilution factor. Soaps were considered to be contaminated if the level exceeded 1,000 CFU/ml, which is the level typically considered acceptable in nonsterile cosmetic products (13). Representatives of each dominant colony type were streak purified by multiple passages on TSA. Bacterial species were identified by using AP120E strips (bioMérieux, Marcy-l'Etoile, France). Contamination levels were monitored in the bulk-soap dispensers for 3 months prior to the hand washing trials (data not shown). All soap samples used in hand washing trials were also collected and tested for the presence of contaminating bacteria on the same days that the hand washing trials were conducted.

(iii) Study design. The study protocol was approved by Chesapeake Research Review, Inc., and was conducted in compliance with procedures approved under this protocol. Hand wash trials were conducted in 14 different restroom locations throughout the school. Technicians executing the study were of the gender indicated by the restroom. In phase I of the study, the contaminated bulk soap and uncontaminated bulk soap trials were conducted over a 4-day period. The bulk dispensers were then replaced with sealed-system dispensers. Phase II of the study, which evaluated the sealed system, was conducted 6 months later and was completed in 1 day. Each subject participated in up to 6 hand washes total for the entire study. No subject participated in more than 2 hand washes on a single day, and a minimum of 30 min was required between each hand wash. Each subject's visit consisted of a pre-hand wash (baseline) sampling, a hand wash, and a post-hand wash sampling. Right and left hands were randomized for glove juice or hand-stamp sampling at the first wash for each participant and alternated at each subsequent wash.

(iv) Hand washing and decontamination procedures. Subjects were asked to wash their hands with soap as they normally would do when washing after using the restroom facilities. The amount of soap and the length and technique of washing, rinsing, and towel drying were at the discretion of each test subject. The temperature of the water used was not controlled. The participants' hands were decontaminated at the end of each visit by washing with soap from a bottle of commercially available uncontaminated soap and then sanitizing with an ethanol-based hand sanitizer.

(v) Bacterial recovery and enumeration. The glove juice sampling method was performed similarly to the controlled study method, except for a few modifications designed to improve the detection limit of the method. Fifty milliliters of recovery solution was added to each glove, and all of the solution recovered from each hand sample was transferred to a sterile 50-ml centrifuge tube. The solution was centrifuged (10 min at 5,000 × *g*) to concentrate the bacteria. Pilot testing verified the effectiveness of the concentration method. All but 5 ml of recovery solution supernatant was removed, and the pellet was vortexed for 1 min to resuspend the cells back into the remaining 5 ml. One milliliter of the concentrated recovery solution was pour plated in duplicate, and 0.1 ml of 10-fold dilutions prepared in BPB+ was spiral plated. All plating was conducted in duplicate on both MacConkey and Chromagar orientation agar (BD, Franklin Lakes, NJ). MacConkey agar was used to select for Gram-negative bacteria. Chromagar orientation results are not presented here, but were used to qualitatively verify that MacConkey plates were adequately selective for contaminants in the soap (versus normal skin microbiota). For the hand-stamp method, subjects placed the palms of their hands and fingers onto MacConkey agar plates for 10 s. All agar plates were incubated for 96 h at 37°C and photographed for archiving. Colonies present on the MacConkey plates were counted.

Data analysis and statistical considerations. For the controlled studies, the estimated $\log_{10}$ number of viable *S. marcescens* or *K. pneumoniae* cells recovered from each hand (the "*R* value") was determined with the formula $R = \log_{10}(75 \times C_i \times 10^D)$, where 75 is the amount (ml) of recovery solution instilled in each glove, C_i is the arithmetic average colony count of the 2 plate counts at a particular dilution, and D is dilution factor. The limit of detection for the controlled studies was 1.57 $\log^{10}$ CFU/hand. For the field study, the total number of Gram-negative bacteria recovered from each hand was determined by the

TABLE 1. Bacteria recovered from hands after washing with contaminated liquid soap

Bacterial contaminant (marker organism)	Bacterial load		Postwash bacterial recovery (mean $\log_{10}$ CFU/hand ± SD [n = 12])
	Test soap ($\log_{10}$ CFU/ml)	Applied ($\log_{10}$ CFU/hand)	
None	0.00	0.00	<1.57[a]
Klebsiella pneumoniae	5.85	6.25	2.74 ± 0.5
Serratia marcescens	3.72	4.12	3.60 ± 0.2[b]

[a] Limit of detection.
[b] Greater bacterial recovery per hand after washing with soap contaminated with *Serratia marcescens* versus washing with soap contaminated with *Klebsiella pneumoniae.* $P < 0.0001$ by unpaired two-sample t test.

TABLE 2. Bacteria recovered and transferred from hands after washing with soap contaminated with *S. marcescens*

Bacterial load in test soap ($\log_{10}$ CFU/ml)	Bacterial load applied ($\log_{10}$ CFU/hand)	Postwash bacterial recovery (n = 12)		Postwash bacterial transfer (n = 4)	
		Mean $\log_{10}$ CFU/hand ± SD	P value	Mean $\log_{10}$ CFU/hand ± SD	P value
4.51	4.39	1.70 ± 0.27		0.30 ± 0.42	
7.51	7.39	5.28 ± 0.47	<0.0001[a]	2.23 ± 0.49	0.001[a]

[a] Unpaired two-sample t test.

formula $R = \log_{10}(5 \times C_i \times 10^D)$. The limit of detection for the field studies was 0.40 $\log_{10}$ CFU/hand. The total numbers of bacteria transferred to MacConkey agar hand-stamp plates were counted directly from the agar plates. Results were obtained by analysis of 91 hand wash trials that yielded usable results for all four measurements taken (CFU recovered before, CFU recovered after, CFU transferred before, and CFU transferred after). Raw CFU values were converted to $\log_{10}$ CFU values, and statistical comparisons were performed by using paired and unpaired t tests on GraphPad Prism version 5.04 for Windows (GraphPad Software, San Diego, CA).

RESULTS

Recovery and transfer of bacteria from hands after washing with experimentally contaminated liquid soap. Human subjects washed for 30 s with 5 ml of soap experimentally contaminated with either *K. pneumoniae* (5.85 $\log_{10}$ CFU/ml) or *S. marcescens* (3.72 $\log_{10}$ CFU/ml) followed by a 30-s rinse. Neither test organism was recovered from the hands of subjects prior to washing hands or from the subjects that washed with uncontaminated control soap. In contrast, for *K. pneumoniae*, a mean of 2.74 $\log_{10}$ CFU/hand was recovered from subjects after washing with *K. pneumoniae*-contaminated soap, and for *S. marcescens*, a mean of 3.60 $\log_{10}$ CFU/hand was recovered from subjects after washing with *S. marcescens*-contaminated soap (Table 1). Interestingly, more bacteria were recovered from hands washed with *S. marcescens*-contaminated soap than from those washed with *K. pneumoniae*-contaminated soap ($P < 0.0001$), even though the level of *K. pneumoniae* contamination was 100-fold higher.

In a second experiment, subjects performed a 10-s hand wash with 1.5 ml of liquid soap experimentally contaminated with either a high level of *S. marcescens* (7.51 $\log_{10}$ CFU/ml) or with a low level of *S. marcescens* (4.51 $\log_{10}$ CFU/ml) followed by a 10-s rinse. It is known that when soap that is not contaminated is used for hand washing, it is more effective at removing transient bacteria when greater volumes of soap and longer wash times are used (11). Therefore, the second controlled study was conducted under conditions chosen to be more representative of the hand washing behaviors typically observed (6, 12, 14, 16, 19). The mean numbers of *S. marcescens* cells recovered after washing with high- and low-level-contaminated soap were 5.28 $\log_{10}$ CFU and 1.70 $\log_{10}$ CFU per hand, respectively (Table 2) ($P < 0.0001$). The number of bacteria transferred to an agar surface after washing were 2.23 $\log_{10}$ CFU and 0.30 $\log_{10}$ CFU per hand for the high- and low-level-contaminated soap, respectively (Table 2 and Fig. 1) ($P = 0.001$).

Recovery and transfer of bacteria from hands after washing with contaminated liquid soap in an elementary school. An elementary school was identified in which all (14/14) of the bulk-soap-refillable dispensers being used in the restrooms were found to be contaminated with bacteria at levels ranging from 6.0 to 7.0 $\log_{10}$ CFU/ml of soap (Table 3). A variety of Gram-negative species from the *Citrobacter*, *Providencia*, *Pseudomonas*, and *Serratia* genera were identified among the recovered contaminants. All of the contaminated dispensers were replaced with sealed-soap-dispensing systems after the first phase of the field hand washing study. After 1 year postinstallation, all of the soap dispensed from the sealed-soap dispensers was confirmed to be contamination free.

A study was conducted with students and staff to assess the levels of Gram-negative bacteria remaining on or transferred from hands after washing with contaminated soap from these dispensers or with uncontaminated control soaps (Table 4). Prior to washing with contaminated bulk soap, uncontaminated bulk soap, and uncontaminated soap from sealed refills, the mean numbers of bacteria recovered from hands of subjects were 1.17, 0.99, and 1.67 $\log_{10}$ CFU per hand, respectively. The mean number of bacteria recovered from the hands after hand washing with the contaminated soap (2.59 $\log_{10}$ CFU per hand) was significantly higher than the pre-hand-washing value ($P < 0.0001$). Gram-negative bacteria were detected in 97% (60/62) of hands tested after washing with bulk soap compared to 52% (32/62) before washing. In contrast, the mean number of bacteria recovered from hands after washing with uncontaminated bulk soap (0.82 $\log_{10}$ CFU per hand) was reduced compared to the prewashing numbers. When hands were washed with uncontaminated soap from the new replacement sealed-system dispensers, the mean numbers of bacteria recovered from hands after washing (1.37 $\log_{10}$ CFU per hand) were also reduced compared to the prewashing numbers and were statistically lower than those recovered from hands washed with contaminated soap ($P < 0.0001$). The mean number of Gram-negative bacteria recovered from the hands after washing with contaminated soap was significantly higher for students (2.82 $\log_{10}$ CFU per hand) than that for staff (2.22 $\log_{10}$ CFU per hand; $P = 0.008$) (Table 5).

Figure 2 compiles $\log_{10}$ CFU changes after individual hand washes into a histogram in which the bars represent the number of times each reduction or increase was observed. When contaminated soap was used, an increase was observed for 55 of 62 hand washes (89%), and the mean change was a 1.42-$\log_{10}$ CFU increase. In contrast, when uncontaminated soap (bulk or sealed) was used, an increase was observed for only 3

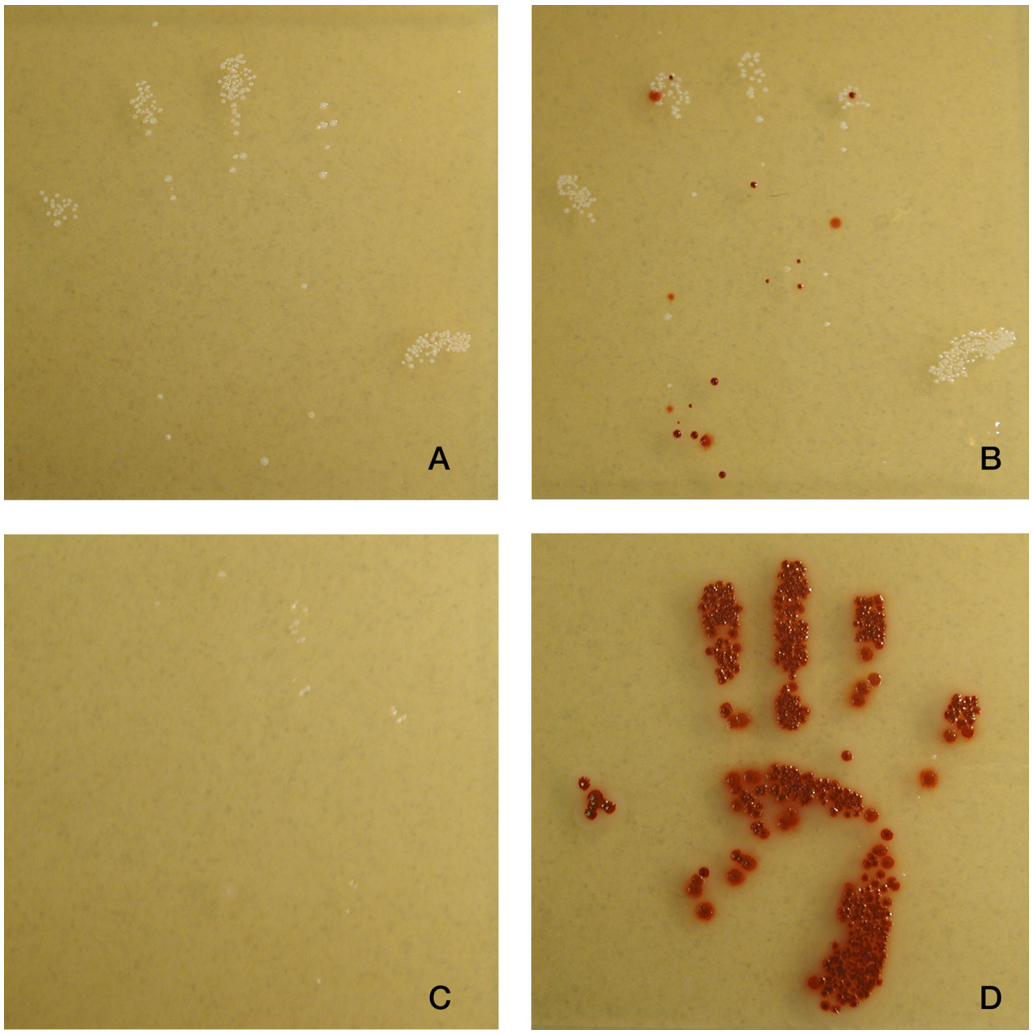

FIG. 1. Sample images from a controlled study (Table 2) to determine the number of bacteria from contaminated hands transferred to an agar surface before (A and C) and after (B and D) hand washing with soap containing 4.51 $\log_{10}$ CFU/ml (A and B) or 7.51 $\log_{10}$ CFU/ml (C and D) of *S. marcescens*.

of 29 hand washes (10%), and the mean change was a 0.26-$\log_{10}$ CFU decrease.

Prior to washing, subjects transferred on average 0.10, 0.10, and 0.18 $\log_{10}$ CFU/hand of Gram-negative bacteria to touched agar surfaces. This number increased significantly after washing with soap from the contaminated dispensers (0.74 $\log_{10}$ CFU/hand; $P < 0.0001$) (Table 4). Washing with uncontaminated-soap controls did not significantly change the mean number of transferred Gram-negative bacteria ($P = 0.945$, uncontaminated bulk soap; $P = 0.100$, uncontaminated sealed soap). Furthermore, fewer bacteria were transferred from subjects' hands after washing with uncontaminated sealed soap (0.06 versus 0.74 $\log_{10}$ CFU; $P = 0.0004$) or uncontaminated bulk soap (0.09 versus 0.74 $\log_{10}$ CFU; $P = 0.012$), compared to bacteria that were transferred from subjects' hands after washing with contaminated soap. Transfer of at least 1 CFU of Gram-negative bacteria after washing was observed in 61% (38/62) of hands washed with contaminated soap versus 21% (4/19) of hands washed with uncontaminated sealed soap. In addition, significantly more Gram-negative bacteria were transferred to agar surfaces touched by students (0.98 $\log_{10}$ CFU per hand) after using contaminated soap than by the adult staff (0.37 $\log_{10}$ CFU per hand; $P = 0.003$) (Table 5).

A comparison of the pre- and postwash recoveries of bacteria for the individual bulk-soap-refillable dispensers tested in the field study is shown in Fig. 3. The number of bacteria recovered from hands postwash increased significantly relative to the prewash recoveries for all of the contaminated dispensers, and the increase was significant for 8 of the 14 contaminated dispensers (P values ranging from 0.0003 to 0.03). In contrast, the number of bacteria recovered from hands after washing with the uncontaminated control soaps decreased relative to the prewash recoveries, but was not significant ($P = 0.199$ for control 1, and $P = 0.324$ for control 2).

DISCUSSION

The purpose of hand washing is to remove soil and to reduce the level of potentially pathogenic transient microorganisms. This is the first study to quantitatively demonstrate that wash-

TABLE 3. Identification of bacteria isolated from bulk-soap-refillable soap dispensers in an elementary school

Soap dispenser tested	Total bacterial contamination in soap (log_{10} CFU/ml)	Presence of:							
		Unknown species	*Citrobacter freundii*	*Citrobacter youngae*	*Providencia rettgeri*	*Providencia stuartii*	*Pseudomonas aeruginosa*	*Pseudomonas fluorescens*	*Serratia rubidaea*
1	6.9				+				+
2	6.8				+				
3	6.3		+				+		
4	6.4				+		+		
5	6.0		+				+		
6	6.4		+			+			
7	6.0						+		
8	6.7			+	+				
9	6.2				+				
10	6.2		+		+				
11	6.4						+		
12	6.2	+						+	
13	7.0				+		+		
14	6.0		+		+				

ing hands with contaminated liquid soap actually increases the number of Gram-negative bacteria on hands. Furthermore, the results directly demonstrate that bacteria from contaminated hands can be transferred to secondary surfaces. We therefore conclude that washing with contaminated soap not only defeats the purpose of hand washing but may contribute to the transmission of potentially harmful bacteria. The results of the two laboratory hand washing studies were corroborated by the elementary school field study, which demonstrated a 26-fold increase in the number of Gram-negative bacteria present on the hands (Table 4) after washing with contaminated soap from bulk-soap-refillable dispensers, demonstrating a potential public health risk in public, non-health-care settings. Importantly, when the contaminated dispensers in the school were replaced with dispensers containing sealed-soap refills, none were found to be contaminated after 12 months of use. Furthermore, washing hands with soap from the sealed-soap system reduced the number of bacteria on hands of the study participants (Table 4). Taken together, these results indicate that use of dispensers with sealed refills instead of open bulk-soap-refillable dispensers can lower the risk of extrinsic microbial contamination and can reduce the spread of potentially pathogenic bacteria.

Previous studies have demonstrated an association between the use of bulk-soap-refillable dispensers and bacterial contamination of the liquid soap. Contamination rates in these studies ranged from 20% to 25% (8; C. A. Zapka, M. Chattman, S. L. Maxwell, D. R. Macinga, M. J. Dolan, and C. P. Gerba, unpublished data). In the present study, we found that 100% (Table 3) of bulk soap dispensers in one elementary school were contaminated. A single soap formulation was used in the school and was dispensed from two similar bulk-soap dispensers. In previous studies, multiple sites using different soap formulations and different dispensers were surveyed. These differences may account for the higher rate of contamination in this facility. Further analysis of the factors contributing to the unusually high prevalence of contaminated soap in this school will be presented elsewhere (C. A. Zapka, unpublished data). Many of the bacteria isolated from the bulk soap in the elementary school are considered to be opportunistic pathogens and can cause infections in compromised populations (10, 15). In fact, use of a shampoo contaminated with *Pseudomonas aeruginosa*, an organism found in 43% (6/14) of the dispensers in this elementary school (Table 3), has been reported to have led to a fatality (9).

The levels of bacteria in the soaps tested in the two laboratory hand washing studies (3.72 to 7.51 log_{10} CFU/ml) were representative of those encountered in this and our previous field studies (2.77 to 7.81 log_{10} CFU/ml) (8; C.A. Zapka, unpublished data). Significantly higher levels of *S. marcescens* were recovered from the hands despite a lower level of contamination in the test soap compared to *K. pneumoniae* (Table 1). These results suggest that the two organisms may interact with human skin in qualitatively different ways. Both organisms have been reported to contaminate soaps and lead to infections in health care settings (5, 18, 20, 22). Even a brief contact

TABLE 4. Gram-negative bacteria recovered and transferred from the hands of students and staff in an elementary school before and after hand washing

Test soap type	No. of hand washes	Bacteria recovered/hand			Bacteria transferred/hand		
		Mean log_{10} CFU ± SD		*P* value[a]	Mean log_{10} CFU ± SD		*P* value[a]
		Before hand wash	After hand wash		Before hand wash	After hand wash	
Contaminated bulk soap	62	1.17 ± 0.70	2.59 ± 0.89	<0.0001	0.10 ± 0.31	0.74 ± 0.81	<0.0001
Uncontaminated bulk soap	10	0.99 ± 0.39	0.82 ± 0.19	0.084	0.10 ± 0.32	0.09 ± 0.28	0.945
Uncontaminated sealed soap	19	1.67 ± 0.98	1.37 ± 0.81	0.025	0.18 ± 0.37	0.06 ± 0.20	0.100

[a] Log_{10} CFU before versus after by paired two-sample *t* test.

TABLE 5. Influence of gender and age on Gram-negative bacteria recovered and transferred from hands washed with contaminated bulk soap in an elementary school

Participant type	No. of hand washes	Bacteria recovered/hand				Bacteria transferred/hand			
		Before hand wash (mean $\log_{10}$ CFU ± SD)	*P* value[a]	After hand wash (mean $\log_{10}$ CFU ± SD)	*P* value[a]	Before hand wash (mean $\log_{10}$ CFU ± SD)	*P* value[a]	After hand wash (mean $\log_{10}$ CFU ± SD)	*P* value[a]
Students									
Male	19	0.95 ± 0.52	0.222	2.49 ± 1.01	0.024	0.10 ± 0.37	0.575	0.71 ± 0.89	0.047
Female	19	1.22 ± 0.78		3.15 ± 0.69		0.17 ± 0.37		1.25 ± 0.71	
Staff									
Male	13	1.53 ± 0.91	0.134	2.37 ± 0.72	0.253	0.08 ± 0.23	0.450	0.42 ± 0.61	0.688
Female	11	1.06 ± 0.44		2.03 ± 0.70		0.03 ± 0.09		0.32 ± 0.61	
All									
Students	38	1.09 ± 0.66	0.218	2.82 ± 0.91	0.008	0.13 ± 0.37	0.344	0.98 ± 0.84	0.003
Staff	24	1.31 ± 0.76		2.22 ± 0.71		0.06 ± 0.18		0.37 ± 0.60	

[a] Male versus female or students versus staff by unpaired two-sample *t* test.

(10 s) with contaminated soap resulted in detectable levels of bacteria on hands (Table 2). Significantly higher levels of *S. marcescens* were recovered from the hands and were transferrable to a secondary surface when the liquid soap was contaminated with a higher bacterial load. These results demonstrate that both the identity of the microbial contaminant and the level of contamination are important factors influencing the public health risk associated with the use of contaminated soap.

The elementary school field study revealed that students retained more bacteria on the hands and transferred significantly more after washing with contaminated bulk soap than the adult staff (Table 4). Although the reasons for these observed differences are not clear, we hypothesize that differences in hand size, skin condition, and/or hand washing technique (e.g., thoroughness of water rinsing and paper towel drying) may be contributing factors. Children represent a vulnerable population with potentially a greater susceptibility to bacterial infections due to their less developed immune systems. Hence, further studies to identify these factors are warranted.

The number of bacteria transferred to agar surfaces was directly proportional to the number of bacteria recovered from subjects' hands post-hand washing in both laboratory studies and in the field study. Analysis of the combined data set showed the concentration of bacteria in contaminated soap correlated positively with both the number of CFU recovered from the hands ($P < 0.0001$) and the number of CFU transferred from the hands ($P < 0.0001$) post-hand washing (data not shown). Based on the observed correlations, washing with soap containing less than 3.7 $\log_{10}$ CFU of bacteria/ml would not lead to detectable bacteria on the hands, and washing with soap with less than 5.4 $\log_{10}$ CFU/ml would not result in detectable transfer of the bacteria to touched surfaces. Coincidentally, this observation confirms the appropriateness of a current industry guideline that recommends that cosmetic products contain less than 3.0 $\log_{10}$ CFU of bacteria/g (13).

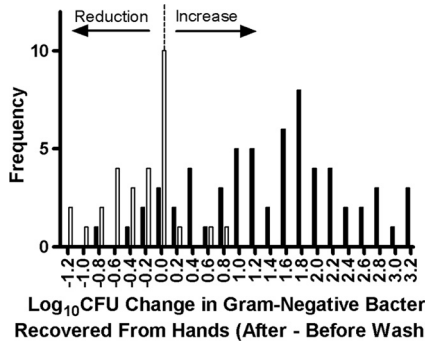

FIG. 2. $\log_{10}$ CFU change in Gram-negative bacteria recovered from hands of elementary school students and staff as a result of hand washing with contaminated soap (solid bars) versus uncontaminated control soaps (open bars).

In summary, this study is the first to quantify the levels of bacteria remaining on hands after washing with contaminated soap and to quantify the transfer of contaminating bacteria from the hands to a secondary surface. This research confirms previous work demonstrating a strong association between open bulk-soap-refillable soap dispensers and extrinsic bacterial soap contamination and demonstrates that washing with contaminated soap poses a potential public health risk in community settings. Our findings further show that extrinsic contamination of hand soap can be eliminated or considerably reduced through the use of sealed-soap-dispensing systems.

Limitations of our study that future studies should be designed to address include species identification of the entire microbial communities present on the hands before and after washing, comparison of results between dominant and nondominant hands, and correlation of hand washing techniques (volume of soap used, length of washing and rinsing, paper towel use behaviors, etc.) employed by participants with the observed results. Further studies to confirm these preliminary findings and to develop accurate risk models should be considered. Epidemiological studies of the causal relationship between contaminated soap and disease would be very useful to quantify the risk; however, they may be impractical to execute. The lack of such study data, however, should not preclude proactive efforts to reduce the

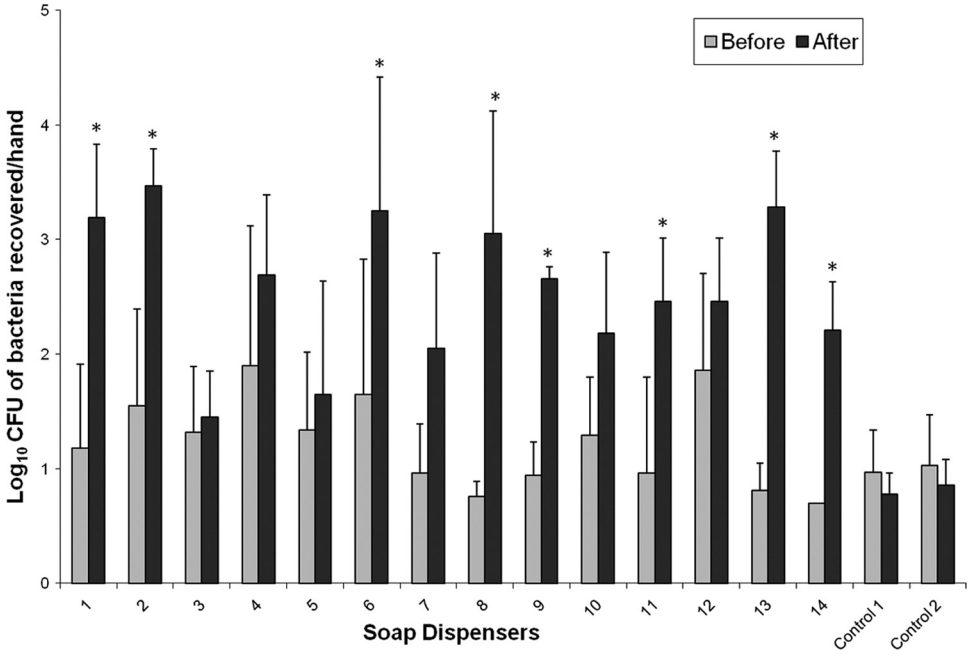

FIG. 3. Gram-negative bacteria recovered from the hands of elementary school students and staff before and after washing with contaminated bulk soap. Fourteen contaminated soap dispensers and 2 uncontaminated soap controls were used by students and staff. $n = 4$ for dispensers 2 to 5 and 12, and $n = 2$ for dispenser 10; $n = 5$ for all other dispensers. *, $P < 0.05$ for bacteria recovered per hand before versus after hand washing by paired two-sample t test.

unnecessary public health risks posed by open bulk-soap-refillable dispensers.

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Evaluation and remediation of bulk soap dispensers for biofilm

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Evaluation and remediation of bulk soap dispensers for biofilm

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Recent studies evaluating bulk soap in public restroom soap dispensers have demonstrated up to 25% of open refillable bulk-soap dispensers were contaminated with * 6 $\log_{10}$(CFU ml^{71}) heterotrophic bacteria. In this study, plastic counter-mounted, plastic wall-mounted and stainless steel wall-mounted dispensers were analyzed for suspended and biofilm bacteria using total cell and viable plate counts. Independent of dispenser type or construction material, the bulk soap was contaminated with 4–7 $\log_{10}$(CFU ml^{71}) bacteria, while 4–6 $\log_{10}$(CFU cm^{72}) biofilm bacteria were isolated from the inside surfaces of the dispensers (n ¼ 6). Dispenser remediation studies, including a 10 min soak with 5000 mg l^{71} sodium hypochlorite, were then conducted to determine the efficacy of cleaning and disinfectant procedures against established biofilms. The testing showed that contamination of the bulk soap returned to pre-test levels within 7–14 days. These results demonstrate biofilm is present in contaminated bulk-soap dispensers and remediation studies to clean and sanitize the dispensers are temporary.

Keywords: biofilm; bulk soap; soap dispensers; efficacy testing

Introduction

Hand washing has long been recognized to play an important role in public health (Garner and Favero 1986), and is generally accepted as an important practice to help prevent the spread of infectious microorganisms, which is especially significant in the healthcare industry. Hand washing sinks and liquid soap are generally provided to patrons of public restrooms to encourage good hand hygiene. Shared public bathrooms, however, can be a vector, con-tributing to the spread of pathogenic microorganisms (Mokhtari and Jaykus 2009). As early as the 1960s, studies were published regarding significant surface contamination of bar soap (Bannan and Judge 1965; Kabara and Brady 1983). Liquid soap was eventually recommended to be a more hygienic solution, and dispensers were developed to distribute liquid soaps (Graf et al. 1988; Chattman et al. 2011).

Like bar soaps, liquid soap dispensers have been associated with microbial contamination issues. Reports dating back to the 1960s have linked bulk liquid hand soap and hand lotion contamination to nosocomial infections in hospital operating rooms and neonatal units (Morse et al. 1967; Archibald et al. 1997; Sartor et al. 2000; Rabier et al. 2008; Buffet-Bataillon et al. 2009). Washing with contaminated soap can leave more bacteria present on the hands after the washing event than before, which undermines the effectiveness of hand washing (Sartor et al. 2000; Zapka et al. 2011). In 1986, the healthcare industry hand hygiene guidelines recognized that 'since liquid-soap containers can become contaminated and might serve as reservoirs of microorganisms, reusable liquid containers need to be cleaned when empty and refilled with fresh soap. Completely disposable containers obviate the need to empty and clean dispensers.' (Garner and Favero 1986). In response to this guideline, the use of bulk hand soap dispensers is now rare in US healthcare settings. How-ever, these types of dispensers are still common in public restrooms. Recent research has demonstrated that up to 25% of bulk hand soap dispensers from office buildings, health clubs, schools, food service centers, retail spaces and other locations are contaminated. Heterotrophic bacteria in contaminated soap averages 6 $\log_{10}$(CFU ml^{71}), which is approximately 1000 times in excess of what industry guidelines recommend (Krowka and Bailey 2007; Chattman et al. 2011).

There are numerous unique dispenser designs but all include a reservoir area to store the soap, a mechanism to pump the soap out of the reservoir onto hands, and a way to refill the dispenser with new soap. Dispensers are constructed of metal or plastic and are typically semi-permanently mounted to the wall or under the counter near the sink. Dispensers are

designed to be refilled by one of two methods: bulk refill and sealed soap refill. Bulk refill dispensers are manually refilled by pouring soap through an opening in the top from a separate bulk soap refill bottle, commonly supplied in a 1 gallon volume. These bulk soap dispenser models typically have a built-in permanent nozzle through which soap is dispensed and is not replaced under normal circumstances. Sealed soap dispensing systems, in contrast, are typically refilled by inserting a new bag or cartridge of soap that contains a new built-in nozzle. As such, the nozzles in these systems are replaced regularly and the soap does not come into contact with the dispenser itself. Empty cartridges are then either disposed or recycled.

Personal care and cosmetic products, such as soap, are not expected to be sterile, but US manufacturers are required by law to ensure that their products do not present a hazard to consumers when they are used as directed (Steinberg 2006). The Federal Food, Drug, and Cosmetic Act 'requires that successful preservation can only be established if one considers all aspects of development from concept and design through manufacturing to the last consumer use before disposal' (Geis 2006). Industry guidelines suggest that to be safe, a product should not contain any pathogens and that the bacterial load should not exceed 1000 total bacteria per gram or milliliter of product (Krowka and Bailey 2007). In order to protect products from contamination during use, soap manufacturers include preservatives in their formulations and verify their performance by testing that each newly-developed formulation effectively inhibits the growth of a range of microorganisms (Sutton 2006). Liquid hand soaps, however, are perishable and can become contaminated with microorganisms under certain adverse circumstances, particularly when consumers use or store the product in unintended ways that are hostile to preservative efficacy (Geis 2006). Occasionally, products are sold that are either already contaminated (intrinsic contamination) or that are inherently susceptible to becoming contaminated because of poor formulation design. However, the primary cause of failure of even a robust, well-preserved formulation is the introduction of contamination during use of the product when a consumer intentionally adds water, mixes products, or stores the product in inhospitable conditions, such as in warm or humid places (extrinsic contamination) (Geis 2006). The design of packaging and dispensing mechanisms used to store and deliver products affects the probability that a product will become contaminated. Systems that have an open design and that allow for increased opportunity for consumers to manipulate the product inside are inherently at greater risk of becoming contaminated as compared to products with a closed design (Garner and Favero 1986; Brannan and Dille 1990; Geis 2006).

Dispenser design and construction of soap packaging is a critical factor to both the occurrence of contamination and the challenge of contamination remediation. The likelihood of extrinsic contamination is greatest when products are packaged, stored, or used in a manner that allows for repeated introduction of microorganisms from the consumer or the surrounding environment (Brannan and Dille 1990; Geis 2006). Dispenser designs, particularly those for wall-mounted dispensers, do not take into consideration the potential for microbial contamination, thus, cleaning is impractical because the dispensers are often securely bolted into walls, making them difficult to remove. For this reason, the same dispensers often remain in facilities for many years. Some wall-mounted dispensers are designed with a nozzle that is located centimeters above the bottom of the dispenser, rather than dispensing the soap from the bottom of the dispenser. This design flaw ensures that the dispenser will never completely drain. Once the soap becomes contaminated, this serves to provide a reservoir of bacteria that are uniquely adapted to survive in the soap environment. Also, some counter-mounted dispensers are sold with one dispensing pump to be reused between bottles (Sartor et al. 2000). Once the pump becomes contaminated, it can transfer the bacteria between bottles (Graf et al. 1988).

Remediation of contaminated dispensers is one option for reducing potential health risks to the general public. There are no published research studies to date that have determined if there is an effective way to eliminate or reduce the contamination problem by washing and/or sanitizing the dispenser. Furthermore, even as far back as the late 1980s, biofilm was suspected of being present in bulk soap dispensers (Graf et al. 1988). Given that bacterial biofilm is known to be more tolerant to disinfectants (Stewart et al. 2000; Donlan and Costerton 2002; Smith and Hunter 2008; Peeters et al. 2008), biofilms likely survive on internal surfaces in contact with soap. While most published studies only tested the bulk soap coming out of the dispenser for bacterial contamination, the entire soap dispenser could be considered a microbial habitat and should be examined. This examination should include both the bulk soap for planktonic contamination and the inner dispenser surfaces to test for the presence of biofilm.

The objectives of this study were to test for the presence of biofilm within dispensers collected from public restrooms and to determine which organisms were present, to understand the efficacy of cleaning and disinfection procedures against established biofilm, and to examine the recurrence of bulk soap contamination following cleaning. Plastic counter-mounted, plastic wall-mounted, and stainless steel (SS) wall-mounted

dispensers were analyzed for planktonic and biofilm heterotrophic and coliform bacteria using viable plate counts (VPC) and total cell counts (TCC). Isolated bacterial colonies were identified using biochemical and molecular profiling. Once the presence of biofilm within dispensers was confirmed, several washing and sanitizing procedures were evaluated for their ability to remediate contamination using both plastic and SS wall-mounted dispensers.

Methods

Sampling dispensers for biofilm

Test dispenser information

Three counter-mounted plastic dispensers from a shopping complex, two plastic wall-mounted dispensers from an elementary school, and two SS wall-mounted dispensers from a middle school and high school, all located in Ohio, USA were evaluated. The dispensers were sampled in the field and determined to be contaminated prior to being sent to the Center for Biofilm Engineering (CBE) for analysis. The plastic dispensers tested were designed with a top lid that completely lifted open for refilling the dispenser with new soap. The SS dispensers were designed with a small, hinged lid that is lifted to refill the dispenser with soap.

Experimental design

A schematic of the process used to sample the refillable soap dispensers for viable and total cells is found in Figure 1. Dispensers were visually inspected and imaged after arrival from the collection site. Three samples were collected from each dispenser: bulk soap to enumerate viable, planktonic bacteria (CFU ml^{-1}); rinse water to enumerate loosely-attached, surface-associated bacteria (CFU cm^{-2}); and inner surface scrapings to determine the density of attached, biofilm bacteria (CFU cm^{-2}). In addition, TCC were determined for each sample type collected, as described below.

Determination of planktonic bacteria

For the plastic counter- and wall-mounted dispensers, the soap was drained through the nozzle into a sterile beaker containing 220 g of 3 mm glass beads. For the SS dispensers, the soap was drained into a sterile glass beaker, and after vigorous mixing, a 10 ml aliquot was added to a 50 ml conical vial containing 10 g of glass beads.

Determination of loosely-attached bacteria

After the soap was removed from the dispenser, 100 ml of sterile phosphate buffered water was added to the dispenser and swirled around to remove any loosely-attached bacteria. For the plastic dispensers, the rinse water was drained into a sterile beaker containing 60 g of glass beads. For the SS dispensers, the rinse water was drained into a beaker and a 10 ml aliquot was collected for culturing.

Determination of strongly-attached bacteria

For the plastic dispensers, the entire inside of the dispenser was scraped with a Teflon scraper and then rinsed with 100 ml of DeyEngley (D/E) Neutralizing Broth.

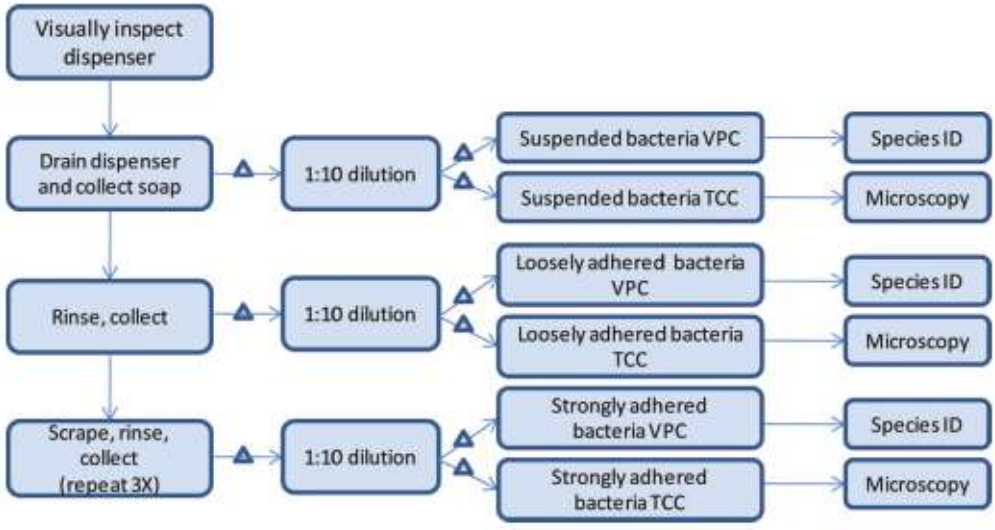

Figure 1. Schematic of the experimental design used to analyze bacteria suspended in the soap and loosely- or strongly-attached to the inside surfaces of contaminated bulk soap dispensers. Three samples were collected and analyzed for viable cells (VPC) and total cells (TCC). Δ = sample disaggregation steps.

The D/E broth was poured into a beaker containing 185 g of glass beads. The scrape and rinse procedure was completed three times and all rinses were combined.

For the SS dispensers, 150 ml of cold phosphate buffered water were added to the dispenser. The dispenser was shaken vigorously for 5 min and the inside surfaces of the dispenser that were accessible were scraped with a sterile Teflon scraper.

Disaggregation and plating methods

All samples were neutralized with D/E broth. Three cycles of sonication and vortexing (1 min each) followed to disaggregate the biofilm. Sterile glass beads were included to aid in biofilm disaggregation. The efficiency of this method was confirmed microscopically. Samples were serially diluted and 1 ml aliquots were plated on both R2A and MacConkey agar. The R2A plates were incubated at room temperature for 7 days and the MacConkey plates were incubated at 36°C for a period of 24–72 h. In addition, 1 ml of the disaggregated, undiluted soap was plated.

For TCC, an additional 1 ml aliquot from the diluted sample was pipetted onto a 0.2 μm membrane. LIVE/DEAD *Bac*Light Bacterial Viability Kit stain (Invitrogen #L7012, Carlsbad, CA) was added, incubated for 15 min in the dark, and after rinsing, the membrane was placed on a glass slide. The total cell count slides were imaged on a Nikon Eclipse E800 microscope with a FITC cube (ex 480/15, DM 505, em 535/20) for the green and a TRITC cube (ex 546/5, DM 575, em 590 LP) for the red. Images were analyzed for total cells regardless of the color the cell stained. A scan of 20 fields per slide was performed and this information was processed for total counts per sample dilution using Metamorph, v7.6.4 Software (MDS Analytical Technologies, Sunnyvale, CA).

Identification of bacterial isolates

Colonies collected from the three sample types that expressed a unique morphology were streaked for isolation and sent to an outside laboratory (Medical Laboratory Services, Inc., Bozeman, MT) for bacterial identification based upon biochemical profiling. Identification of bacterial isolates was confirmed by sequence determination of the V1–V3 region of the SSU rRNA gene. The SSU rRNA gene was amplified with previously described primers FD1 and 1540R and sequenced with 529R via capillary Sanger sequencing (Ye et al. 2004; Hwang et al. 2009). Sequences were identified using the BLASTn algorithm through NCBI (http://ncbi.nlm.nih.gov/blast).

For the plastic wall-mounted dispensers, the field identifications (from historical data) and laboratory identifications were determined using biochemical profiling and molecular analysis. For the SS wall-mounted dispensers, the laboratory identifications were determined biochemically and the isolated colonies used in the biochemical identifications were sent in for molecular testing to provide direct comparisons between the two methods.

Molecular analysis of whole biofilm community

Using separate dispensers from above, two plastic wall-mounted and two SS wall-mounted dispensers were sampled to determine microbial diversity of biofilm within the dispensers. For each dispenser tested, bulk soap was removed and 100 ml cold, sterile 1X PBS were added. The inside surfaces of the dispenser were scraped into the PBS and transferred to 50 ml conical centrifuge tubes. Biomass was collected *via* centrifugation and multiple pellets from the same dispenser were combined until all biomass was in a single pellet for each sample. Pellets were resuspended in 10 ml of PowerBead solution and transferred into sterile mortars with sand. Samples were flash frozen with liquid nitrogen and ground with pestles three times. The whole sample was collected into PowerBead tubes and nucleic acid extraction was done according to the manufacturer's instructions with the PowerMax Soil DNA Extraction Kit (MO BIO, Inc., Carlsbad, CA). The extracted DNA was amplified as above with primers FD1 and 1540R using PCR program 80°C 1:30, 94°C 2:00, 25 cycles of (94°C 0:30, 58°C 1:00, 72°C 1:00), 72°C 7:00 followed by 4°C hold. Appropriately-sized DNA was cloned into plasmid pCR2.1-TOPO (plastic) or pCR4-TOPO (SS), transformed into competent *E.coli* DH5α and plated on LB-Kan50 plates as per the manufacturer's instructions (Invitrogen, Inc., Carlsbad, CA). Transformants were screened for appropriately-sized inserts using primers M13F and M13R. Ninety-six M13 amplicons were submitted from each dispenser for Sanger sequencing using primer 529R. Sequence libraries were checked for chimeras and identified as described above.

Dispenser imaging

Prior to any sampling steps, the dispensers were visually inspected and various outside and/or removable dispenser pieces were imaged using a Nikon SMZ1500 stereo zoom microscope.

Experimental design of remediation study

Washing studies were conducted on plastic and SS wall-mounted dispensers. Five plastic wall-mounted dispensers from an elementary school in Ohio were used in the first set of experiments. Some of these

dispensers were previously used to investigate hand transfer of contaminants in a different study (Zapka et al. 2011). Eight SS wall-mounted dispensers from a school district in New Jersey were used in the second set of experiments. Each experiment included a positive control (randomly chosen dispenser that had tested positive for contamination in the bulk soap) and a negative control (a new dispenser that had never tested positive for bacteria in the bulk soap). The experiments were performed in triplicate and control dispensers remained the same for each of three experimental repeats. The remaining dispensers used in the studies had all tested positive for viable bacteria (at least 3 $\log_{10}$(CFU ml^{-1})) in the bulk soap prior to commencing each washing experiment. The washing procedure tested on each dispenser was randomly assigned before every experiment.

The washing procedures were designed to vary in difficulty and to utilize products that would be readily available to any cleaning personnel, including the use of tap water. Just prior to washing the dispenser, a sample of the bulk soap was collected and analyzed for heterotrophic bacteria. Samples from plastic dispensers were neutralized with D/E Neutralizing Broth and disaggregated and plated on R2A, while samples from SS dispensers were neutralized with a modified Butterfield's phosphate buffer solution containing lecithin, polysorbate 80, KH_2PO_4, K_2HPO_4, $Na_2S_2O_3 \cdot 5H_2O$, Tamol SN, and Triton X-100 (BPB^+ Neutralizer) (Beausoleil 1999), followed by disaggregation and plating on TSA. The control dispensers were then drained and refilled with an antibacterial soap labeled to contain triclosan (percent triclosan not listed on the label) for the plastic dispensers or a bland (non-antimicrobial) soap for the SS dispensers. The soap formulation used to fill each dispenser was consistent with the formulation used to fill that dispenser in the field. The test dispensers were washed with sodium hypochlorite (5000 mg l^{-1}), a quaternary ammonium compound-containing disinfectant (Ecolab Oasis 146 Multi-Quat Sanitizer, 8 ml l^{-1}), or a mildew remover (Tilex Mildew Root Penetrator & Remover, 24,000 mg l^{-1} sodium hypochlorite, active ingredient), as depicted in Figure 2. They were then filled with the appropriate soaps as described above. The bulk soap from all the dispensers was then sampled immediately after filling and for up to 2 weeks or until the population reached pre-test levels. Both the fresh soap and tap water were plated and tested on each experiment day for viable cells.

Results

Planktonic and biofilm contamination

Bulk soap from contaminated dispensers harbored between 3.7 to 6.7 $\log_{10}$(CFU ml^{-1}) of viable coliform and heterotrophic bacteria and between 6.9 to 8.0 $\log_{10}$(CFU ml^{-1}) total cells (Figure 3). Soap from plastic wall-mount dispensers had the highest density of viable planktonic bacteria (5.4 to 6.7 $\log_{10}$(CFU ml^{-1})) while plastic counter-mounted dispensers contained the lowest density (3.7 to 4.9 $\log_{10}$(CFU ml^{-1})) and SS wall-mounted dispensers contained an intermediate density (4.9 to 5.2 $\log_{10}$(CFU ml^{-1})). The TCC in the soap were $\sim$ 1 to 3 logs greater than the viable counts for all of the dispensers.

Loosely- and strongly-adhered viable coliform or heterotrophic cells were present at densities between 3.3 to 6.4 $\log_{10}$(CFU cm^{-2}) in all dispensers (Figure 4). The SS wall-mounted dispensers had the highest density of surface-associated viable bacteria (5.1 to 6.4 $\log_{10}$(CFU cm^{-2})) as compared to the plastic counter-mounted and wall-mounted (3.3-5.8 $\log_{10}$(CFU cm^{-2})) dispensers. The TCC from the loosely- and strongly adhered bacteria were generally greater than the loosely- and strongly-adhered viable bacteria, except for the strongly-adhered bacteria from the plastic wall-mounted dispenser. For the majority of dispensers, slightly more strongly-adhered and total cell count bacteria were recovered than loosely-adhered bacteria, except for the plastic counter-mounted dispensers, in which much higher densities of loosely-attached bacteria and TCC were recovered (6.3 to 6.9 as compared to the strongly-associated bacteria at 4.6 to 5.1).

Bacterial identification

The colonies recovered from the plastic counter-mounted dispensers were identified through biochemical profiles as *Klebsiella oxytoca* and *Kluyvera ascorbata*, both of which are Gram-negative opportunistic pathogens. The bacteria identified in the plastic wall-mounted dispensers were commonly Gram-negative, presumptive opportunistic pathogens (eg *Providencia, Citrobacter, Klebsiella, Serratia*, and *Pseudomonas*) (Table 1). Bacterial populations were also identified *via* clone libraries of SSU rRNA gene sequences. The isolates identified with both biochemical and molecular techniques revealed similar identifications at the genus level, although not surprisingly the clone library data identified potential organisms that were not cultivated. The bacteria identified in the SS wall-mounted dispensers were consistent with that observed for the other dispensers (Table 2). In total, the SS dispensers contained bacteria from five unique genera that included *Pseudomonas, Providencia, Serratia, Stenotrophomonas* and *Acinetobacter*. Interestingly, the molecular data did not reveal additional sequences that were not cultivated from the SS dispensers. In previous unpublished work, historical data indicated

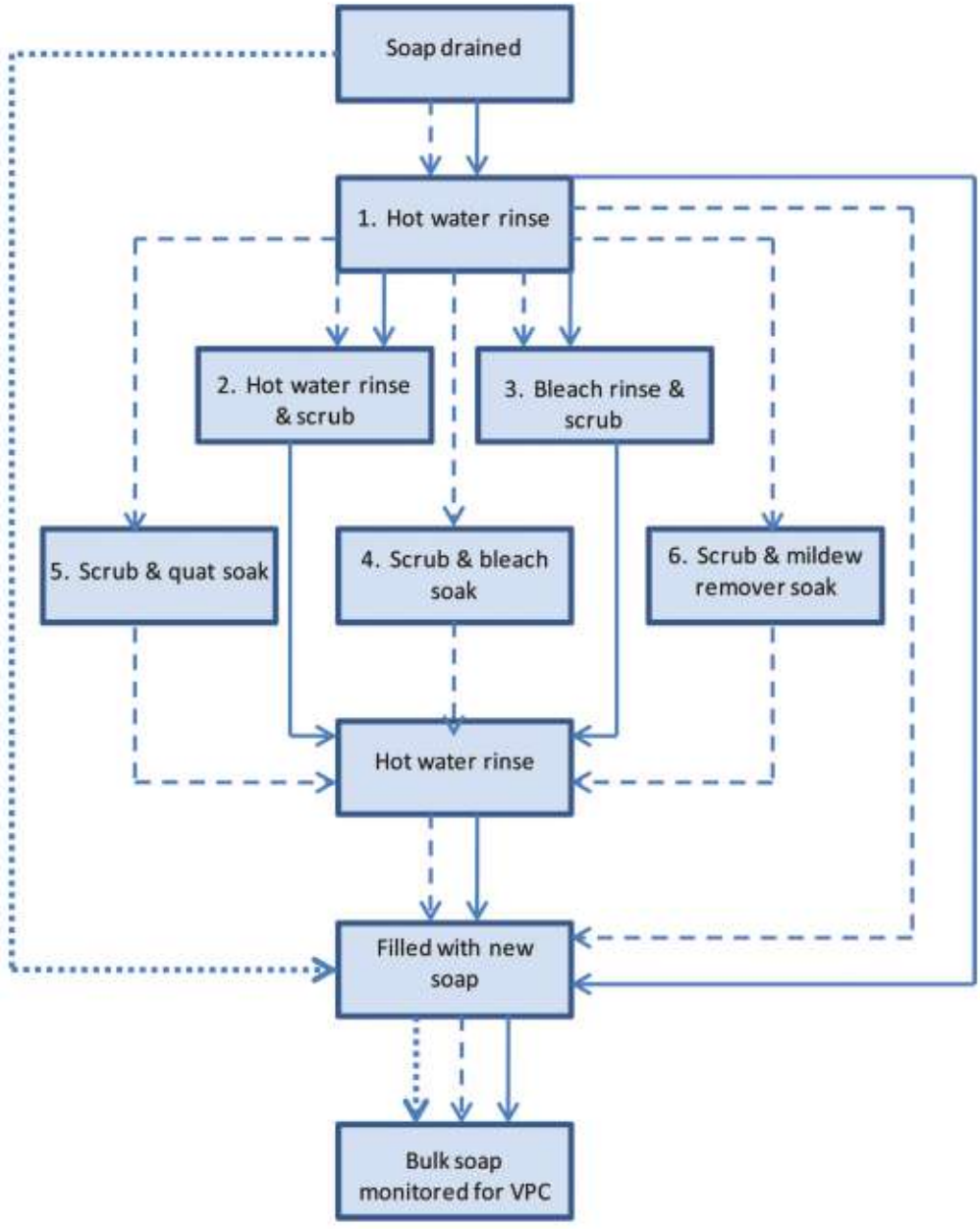

Figure 2. Schematic of the experimental design used to evaluate the effectiveness of dispenser remediation procedures. Procedures 1, 2, and 3 were followed for plastic wall-mounted dispensers (solid lines). Procedures 1–6 were tested for the SS dispensers (dashed lines). The dotted line denotes the control dispenser protocol.

that the dominant colony types in each dispenser were *Pseudomonas aeruginosa* and *Serratia liquefaciens*. This research confirmed that these genera were present in the respective dispensers but did not confirm that they were the dominant colony types. Bacterial isolates obtained from SS dispensers were also identified using both SSU rRNA gene sequencing biochemical profiling to compare the two techniques. The results from the comparison revealed equivalent identities at the genus level for all but one of 14 isolates.

Effectiveness of dispenser remediation techniques

The heterotrophic plate count results of the dispenser washing experiments are shown in Figures 5 and 6 for the plastic wall-mounted and SS wall-mounted dispensers, respectively. In Figure 5, the standard error of the mean (SEM) for the hot water rinse procedure was 0.10 and 0.47 on day 0 and day 4, as averaged over the three experiments. The SEM for the hot water rinse and scrub procedure on day 0 was 0.28 and ranged from 0.07 to 0.53 on days 0, 4, and 7 for the scrub and

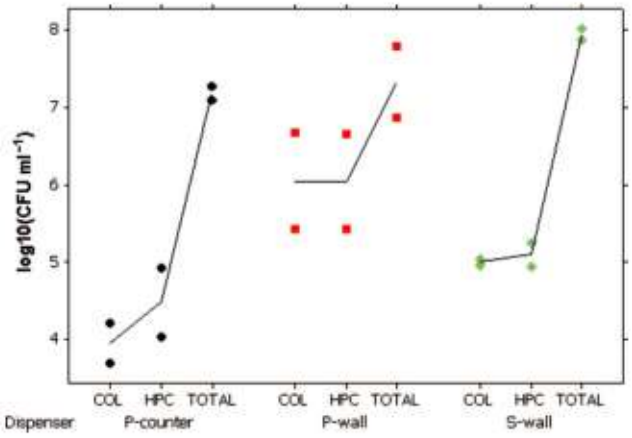

Figure 3. Coliform (COL), heterotrophic (HPC), and total cell count (TOTAL) results from the bulk soap for plastic counter-mount, plastic wall-mount, and SS wall-mount dispensers ($n = 2$ of each). The black solid line connects the mean $\log_{10}$(CFU ml^{-1}) of the data points.

sodium hypochlorite rinse washing procedure, over the three experiments. The triplicate experiments for these dispensers were not conducted consistently with respect to the frequency of plating. In experiment 1, the dispensers were only plated on day 0 and 14, whereas in experiment 2, they were plated on days 0, 2, 4, 7, and 10. The dispensers were plated on days 0, 1, 4, and 7 for experiment 3 and for all experiments, plating was discontinued once the bacterial counts returned to pre-test contamination levels. For these reasons, the SEM could not be calculated for all dispensers and all experiments for each day.

In Figure 6, the SEM for the hot water rinse procedure over the three experiments was 0.30, 0.14, and 0.20 for days 0, 2, and 4. The SEM could not be calculated for day 7 because some of the dispensers had reached their pre-test contamination levels and plating was discontinued. The SEM for the hot water rinse and scrub procedure was 0.27, 0.25, 0.15, and 0.15 for days 0, 2, 4, and 7 averaged over three experiment replicates. For the scrub and sodium hypochlorite rinse procedure, the SEM was 0.25, 0.52, 1.01, and 0.34 for days 0, 2, 4, and 7. The SEM could not be calculated on day 10 because some of the dispensers had already reached their pre-test contamination levels. For the 10 min sodium hypochlorite soak procedure and for the 10 min quat soak procedure, the SEM was 0.26, 0.31, 0.71, and 0.22, and 0.28, 0.15, 0.87, and 0.16 on days 0, 2, 4, and 7, respectively. For the 10 min mildew remover soak washing procedure, the SEM was 0.34, 0.63, 1.55, and 1.24 for days 0, 2, 4, and 7. The SEM could not be calculated for days 10 and 14 because some of the dispensers had already reached their pre-test contamination levels and plating was discontinued.

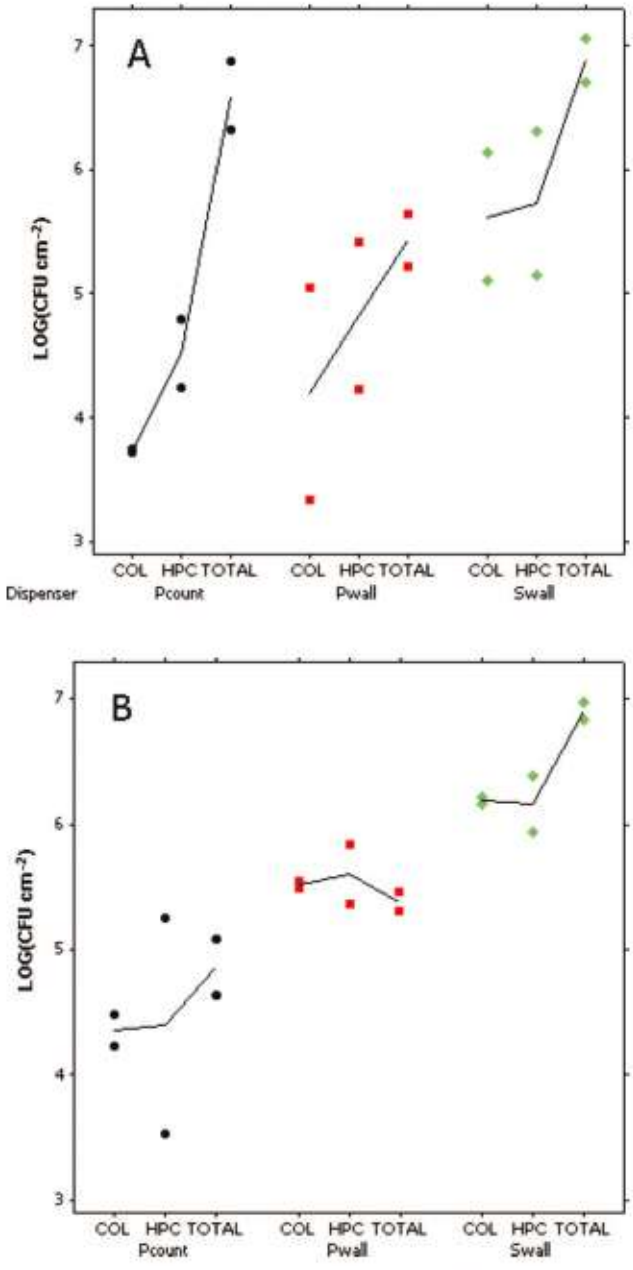

Figure 4. Coliform (COL), heterotrophic (HPC), and total cell count (TOTAL) results from the loosely-attached (Panel A) and strongly-adhered (Panel B) sampling steps for plastic counter-mounted, plastic wall-mounted, and SS wall-mounted dispensers ($n = 2$ of each). The black solid line connects the mean $\log_{10}$(CFU cm^{-2}) of the data points.

The dispensers initially contained 4.3 to 6.0 $\log_{10}$(CFU ml^{-1}) in the bulk soap dispensed after cleaning. Rinsing the dispenser with hot water, with or without scrubbing, did little to reduce the contamination levels in the soap. Based upon industry guidelines that suggest a microbial load limit of 1000 CFU ml^{-1}, these soaps would be considered contaminated within 1–2 days after performing the remediation procedures.

Table 1. Bacteria identified in wall-mounted plastic dispensers.

Organisms identified	Field identified	Lab identified	Clone library analysis
Providencia rettgeri	+	+	+
Pseudomonas sp.			
P. aeruginosa	+	+	+
P. fluorescens	+		
P. luteola	+		
P. stuzeri	+		
Citrobacter sp.			+
C. koseri	+		
C. freundii		+	
Serratia sp.			
S. oderifera	+		
S. liquefaciens		+	
S. rubidae	+		+
Stenotrophomonas sp.			+
S. maltophilia	+		
Klebsiella pneumoniae		+	
Aeromonas hydrophilia	+		
Burkholderia cepacia		+	
Enterobacter sp.			+
E. cloacae		+	
Achromobacter xylosoxidans			+
Alcaligenes xylosoxidans			+
Curvibacter sp.			+
Leptothrix sp.			+
Pelomonas sp.			+
Delftia acidovorans			+
Rubribacter xylanophilus			+

Table 2. Bacteria identified in SS wall-mounted dispensers.

Organisms identified	16S ID of isolates	Biochemical ID of isolates	Clone library analysis
Pseudomonas sp.			+
P. aeruginosa	+	+	
P. fluorescens/putida		+	
Providencia sp.	+		+
P. vericola	+		
P. rettgeri	+	+	
Serratia sp.	+		+
S. marcescens		+	
S. liquefaciens		+	
Stenotrophomonas sp.	+		+
S. maltophilia		+	
Acinetobacter lwoffii		+	
Alcaligenes/ Achromobacter sp.			+

The most effective remediation treatments were the sodium hypochlorite soak, sodium hypochlorite rinse and scrub, and the mildew remover soak, which were all able to reduce the bacterial contamination densities to below the 1000 CFU ml^{-1} threshold for $\sim$ 4 to 5 days after treatment. However, the levels in the soap continued to increase and returned to pre-remediation

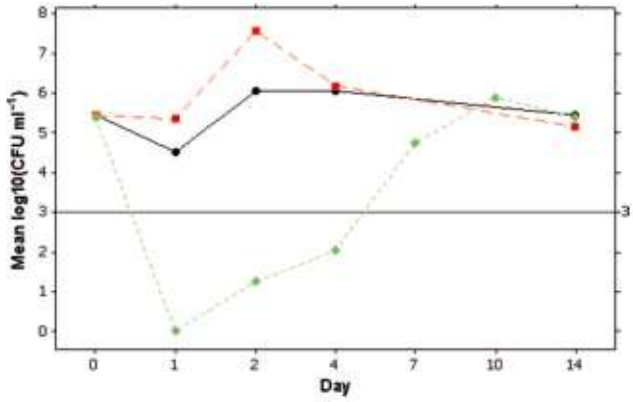

Figure 5. HPC results for plastic wall-mounted dispenser washing studies, averaged over three experiments. ● = hot water rinse procedure; ■ = hot water rinse and scrub procedure; ♦ = scrub and sodium hypochlorite rinse washing procedure. The solid horizontal line at 3 $\log_{10}$(CFU ml^{-1}) depicts the cosmetic industry guideline recommendation.

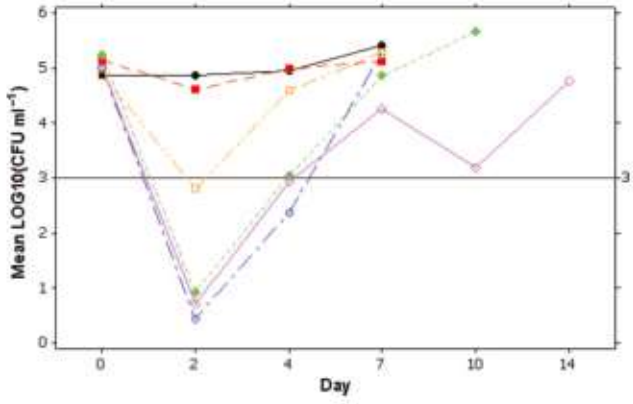

Figure 6. HPC results for SS wall-mounted dispenser washing studies, averaged over three experiments. ● = hot water rinse procedure; ■ = hot water rinse and scrub procedure; ♦ = scrub and sodium hypochlorite rinse washing procedure, ○ = 10 min sodium hypochlorite soak procedure; □ = 10 min quat soak procedure; ◇ = 10 min mildew remover soak washing procedure. The dispenser bulk soap was sampled until the populations reached pre-test contamination levels. The solid horizontal line at 3 $\log_{10}$(CFU ml^{-1}) depicts the cosmetic industry guideline recommendation.

levels after only 7 to 14 days post-remediation. The quat soak did little to decrease contamination levels, and on average, only decreased levels below the 3 $\log_{10}$(CFU ml^{-1}) microbial load limit for 2 days, post-treatment.

When considering the individual data points, the 10 min mildew remover soap procedure in experiment 3 took 10 days to recover beyond a 3 $\log_{10}$(CFU ml^{-1}) level. Interestingly, it had reached that level after 4 days in the first two experiments.

The effectiveness of the three remediation methods performed on both the plastic and SS dispensers (hot water rinse, hot water rinse and scrub, and sodium hypochlorite rinse and scrub) was not significantly different depending on dispenser type. Positive control dispensers, which were simply drained of soap and refilled with fresh soap, maintained their contamination levels at approximately 5 $\log_{10}$(CFU ml^{-1}), and no bacteria were detected from the negative control dispensers throughout the experiments (data not shown).

Discussion

The results of this study demonstrate that open, bulk-refillable soap dispensers found to contain contaminated soap also contained bacterial biofilms. Three samples were collected from each dispenser to assess the bacterial contamination, viz. bulk soap, loosely-attached cells, and biofilm. Analyzing the soap for bacteria in addition to the surface samples allowed for comparisons between historical findings, field data, and the present laboratory evaluation.

The density of surface-associated bacteria in SS wall-mounted dispensers was up to ten-fold greater than that seen for the other two dispenser types. This is interesting because the bacterial density in the soap was slightly greater than that recovered in the plastic counter-mounted dispensers and slightly less than the bacteria recovered from the soap in the plastic wall-mounted dispensers. This result suggests that there is no direct correlation between biofilm density in a dispenser and the level of contamination in the bulk soap.

Previous reports suggest that bulk liquid samples are not necessarily predictive of the microbial health of the system (Goeres 2010). In general, if the bulk soap is contaminated, then biofilm is also most likely present in the dispenser. Perhaps the most interesting case would be to determine whether dispensers containing no bulk soap contamination still contain biofilm. Additional factors that would be interesting to include in a correlation study are the type of soap, the location of dispenser, and the use pattern.

For this study, the type of dispenser (plastic wall-mounted, plastic counter-mounted and SS wall-mounted) did not appear to be a significant factor, although a slightly greater diversity of organisms was detected in the plastic dispensers. This is an interesting result given the design of the SS dispensers, which does not allow for the dispenser to ever completely empty.

Bacterial isolates from the soap were almost exclusively Gram-negative. While isolates were identified to at least the genus level, the identifications provided a qualitative description of organisms contaminating the dispensers but did not serve to quantify each species. In most cases, molecular typing of the isolates provided similar results to the biochemical typing. Identifications from both methods are limited to matching the biochemical profile or the sequence to an organism already in the database. Biochemical profiling of environmental isolates is particularly limited due to the extremely great diversity of organisms which have not yet been characterized as well as those multiple species which are similar, if not identical, in the limited size of the array used for profiling. While the bacterial diversity was relatively low compared to other environments, 16S rRNA gene sequencing demonstrated the presence of organisms not detected *via* cultivation-based techniques in plastic dispensers. The same was not true for the SS dispensers. Identified isolates are consistent with organisms previously reported to have been isolated from liquid soap (Chattman et al. 2011; Zapka et al. 2011). The molecular data can be used to further direct cultivation methods in order to isolate a broader diversity of the present microbiota, which could be useful information when crafting new formulations of soap. Intentional incubation of isolates already known to be well-suited for survival in soaps during the formulation phase would give insight into the ability of the new formulation to resist bacterial growth. Future work could include molecular techniques that differentiate bacterial populations in the bulk soap *vs* biofilm populations.

Inclusion of microscopy in these experiments proved to be useful for two reasons. First, the TCC demonstrated that only a fraction of the bacteria were recovered by the VPC. On average, the TCC were 1 to 2 $\log_{10}$(CFU ml^{-1}) higher than the VPC, indicating the presence of a population that was either non-viable or non-culturable by the plating techniques used in this study. Second, microscopy demonstrated whether or not the disaggregation method was adequate (Figure 7).

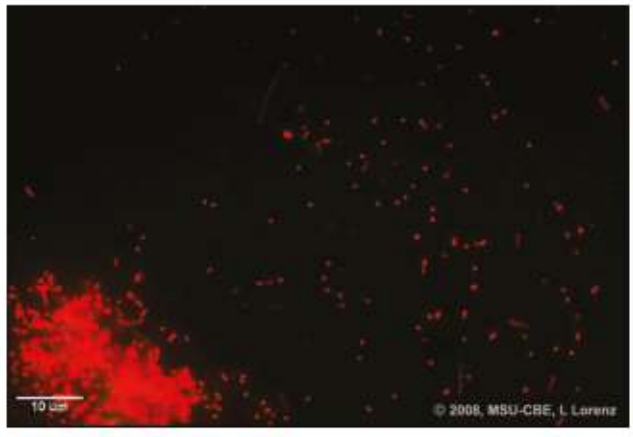

Figure 7. Total cell count image displaying biofilm clumping when disaggregation was inadequate. X100. Bar = 10 um.

The physical properties of soap makes it challenging to disaggregate cell clusters; it foams when homogenized and is difficult to vortex vigorously, so microscopy was an important means by which to assess the disaggregation method used. Improper disaggregation will result in an underestimate of the viable cells present in a sample (Hamilton et al. 2009). Previously published results obtained without using disaggregation techniques showed that contaminated bulk soap in public restrooms contains an average of 6 $\log_{10}$(CFU ml^{-1}) of heterotrophic bacteria, therefore, they may have underestimated the true levels of viable bacteria in the soaps (Chattman et al. 2011). Another interesting use of the imaging from the dispensers was to visually record that the dispensers often contained substances that presumably did not originate from the soap (Figure 8).

Once a biofilm has established on a surface, cleaning and eradicating the biofilm from that surface becomes a challenge, as the dispenser remediation experiments demonstrated. The ineffectiveness of washing soap bottles dates back to the 1960s, so these findings are not surprising (Burdon and Whitby 1967). The present study showed that even soaking the dispensers with sodium hypochlorite, a quat, or with a full strength mildew remover for 10 min before adding new soap, was ineffective at eradicating biofilm. Because the soap used to refill each dispenser contained no detectable bacteria, the results demonstrated that the recovery of bacterial populations in the bulk soap resulted from dispersal of bacteria from biofilms present inside the dispensers. The rate of recolonization was inconsistent between replicates and likely represents a host of different factors including density of the biofilm, age of the biofilm, species composition of the biofilm, and quality of disruption of the biofilm during disinfection. The slowest recovery took 14 days to reach pre-test contamination levels. This particular dispenser received the mildew remover treatment in experiment 3, where the recovery was 14 days, but this dispenser also received that treatment in experiment 1 and received the sodium hypochlorite rinse treatment in experiment 2. The mildew remover contains 24,000 mg l^{-1} sodium hypochlorite. It is conceivable that the two mildew sodium hypochlorite treatments, coupled with an approximate 5,000 mg l^{-1} sodium hypochlorite rinse treatment, all occurring within just under 2 months, were able to decrease the biofilm counts and delay regrowth and contamination, but still failed to completely eradicate the biofilm.

Figure 8. Stereoscope image of inner dispensing tube of a plastic counter-mounted dispenser coated with unknown brown substance. 7.5X.

The soap dispenser remediation procedures evaluated in this study were very time and labor intensive and would not realistically be utilized by a custodial staff, especially in a facility with multiple dispensers to maintain. Furthermore, the trials conducted in triplicate were completed in rather quick succession, sometimes with just a week between replicate experiments. A custodian would be very unlikely to add an every-other-week soap dispenser cleaning regimen to an already long list of cleaning duties. Finally, the design of the dispenser systems contributes to the challenges of keeping them clean. They are composed of intricate pieces that are difficult to reach with a scrubbing brush. For instance, some of the top openings are quite small, making it difficult to use a scrubbing brush or to get into them at all. Bulk soap dispensers are constructed of many materials including plastics, SS, and rubber (gaskets). SS and rubber are incompatible with high level concentrations of sodium hypochlorite, which makes continuous cleaning of these materials with such disinfectants impractical, as the dispenser components will begin to corrode or deteriorate.

It is possible that dispenser design guidelines could be written to facilitate easier cleaning and disinfecting protocols for bulk soap dispensers. The SS wall-mounted dispensers, for example, had an inefficient valve placement on the front of the dispenser, about 2.5 cm above the bottom, leaving a constant reservoir of soap. Valve systems that are both easily replaceable and not economically prohibitive would eliminate the need to clean intricate and delicate valve components. It is important to consider both the potential for contamination and the ease of cleaning a system as design parameters for a dispenser. As with any environment where microbial contamination could be a concern, including dispenser systems, these considerations must be evaluated in the engineering design.

Conclusions

Bulk soap dispensers were shown to be highly contaminated, both by bacteria in the soap, and also

by biofilm bacteria attached to the inner dispenser surfaces. The bacteria identified were consistent with those typically found in cosmetics/soap environments, as determined by both culture- and molecular-based identification analyses. The remediation effectiveness experiments demonstrated that, due to biofilm attached to the dispenser surfaces, even cleaning with highly concentrated disinfectants does not eliminate the bacterial populations that are adapted to live in the soap environment.

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Outbreak of *Serratia marcescens* in a neonatal intensive care unit: contaminated unmedicated liquid soap and risk factors

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Soap

Summary This study describes an outbreak of *Serratia marcescens* and its investigation and control in a neonatal intensive care unit (NICU). During a three-month period, five infants were colonised or infected by a single strain of *S. marcescens*. A case–control study, culture surveys and pulse-field gel electrophoresis analysis implicated a bottle soap dispenser as a reservoir of *S. marcescens* ($P = 0.032$). Infants with *S. marcescens* colonisation or infection were also more likely to have been exposed to a central or percutaneous venous catheter ($P = 0.05$) and had had longer exposure to endotracheal intubation ($P = 0.05$). Soap dispensers are used in many hospitals and may be an unrecognised source of nosocomial infections. This potential source of infection could be reduced by using 'airless' dispensers which have no air intake for the distribution of soap. Prompt intervention and strict adherence to alcoholic hand disinfection were the key factors that led to the successful control of this outbreak.

Introduction

Serratia marcescens is a nosocomial pathogen involved in many outbreaks and endemic nosocomial infections.[1] Outbreaks of *S. marcescens* have been traced to several sources, such as

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contaminated antiseptic solution or soap, tap water, hand soap, fluid tanks of nebulisers, breast pumps, milk bottles, laryngoscopes, bronchoscopes, heparin—saline solution, and recently, contaminated intravenous magnesium sulphate solution.[2–16] No source was identified in other studies.[17,18]

This study describes an outbreak of *S. marcescens* that occurred over a three-month period in a neonatal intensive care unit (NICU), in which a retrospective case—control study was performed to identify risk factors for infection or colonisation with *S. marcescens*.

Methods

Hospital

The study was carried out in an 1819-bed, tertiary care, university teaching hospital in Rennes, France. The neonatal intensive care unit (NICU) is a 12-bed unit with 10 rooms.

Epidemic investigation

Each week, all bacteriological positive results from the NICU are routinely discussed by a neonatologist and a bacteriologist. In early June 2006, four infants were identified with cultures of *S. marcescens*, and so all neonates on the unit were screened for respiratory and gastrointestinal carriage. This screening was repeated weekly and for each new admission. An audit of hygiene practices and infection control of the healthcare environment was carried out. Environmental samples were collected based on the results of the audit.

Culture surveys

Water samples (1000 mL) from each room were filtered, and the filters were cultured on blood agar. Samples of unmedicated soap (1 mL) were plated onto chocolate agar plates (bioMérieux, Marcy l'Etoile, France). All the plates were incubated for 48 h at 37 °C and for 72 h at 22 °C. Bacterial colonies were identified using a commercial identification strip (API 20E Systems, bioMérieux).

Antimicrobial susceptibility testing

S. marcescens isolates were tested for susceptibility to a panel of 23 antimicrobial agents: amoxicillin, amoxicillin/clavulanate, ticarcillin, ticarcillin/clavulanate, piperacillin/tazobactam, imipenem, aztreonam, cefalotin, cefoxitin, cefamandole, cefotaxime, ertapenem, ceftazidime, cefepime, amikacin, tobramycin, gentamicin, nalidixic acid, ciprofloxacin, norfloxacin, fosfomycin, colistin, co-trimoxazole.

Susceptibility testing was performed by using an agar diffusion method according to current recommendations of the French Society for Microbiology.

Pulsed-field gel electrophoresis (PFGE)

Chromosomal DNA was extracted from stored *S. marcescens* isolates (Cryobeds, AES Laboratoires, Bruz, France). DNA was digested with *Xba*I (Promega, Charbonnières, France) and PFGE was performed.[19] The pulse time was ramped from 10—90 s and gels were run for 24 h.

The gels were stained with ethidium bromide and photographed under ultraviolet light. Isolates were considered to be the same strain if all bands matched, to be subtypes of the same strain if one to three bands differed, and to be different strains if more than three bands differed.[20]

Case—control study

The infection control team reviewed the medical records to identify possible risk factors for colonisation or infection. Previously reported risk factors include: female gender, lower gestational age, birthweight, preterm birth, prolonged respiratory therapy, prolonged use of antibiotics, maternal antimicrobial therapy with β-lactams prior to delivery, and oral cleaning care.[7,21–25] Based on these studies, each case infant was matched to three randomly selected control infants by four criteria.

A case was defined as any patient who had the epidemic *S. marcescens* strain isolated from a clinical specimen. Controls were infants who: (a) were hospitalised in the NICU during the same period but whose clinical specimens did not yield the epidemic strain; (b) were hospitalised in the NICU for at least as long as the time from admission to infection for the matched case patient (i.e. exposure time); (c) had a primary diagnosis that was similar to that of the affected patient; and (d) were within two weeks of age of the case patient. If an exact match could not be identified, the selection criteria were prioritised in the order listed above.

Data on risk factors were taken from the patients' medical records and were analysed using Epi-Info, version 6.04 (CDC). Potential risk factors, represented by continuous variables, were assessed using Student's *t*-test or Wilcoxon test. Categorical variables were assessed using χ^2-test or

Fisher's exact test. $P \leq 0.05$ was considered to be statistically significant.

Results

Description of the epidemic

On 8 June 2006, the neonatologist and the bacteriologist in the NICU notified the infection control practitioner that two hospitalised infants were colonised (patients B, D; Figure 1) and two were infected (patients A, C; Figure 1) by *S. marcescens*. All the isolates were the same antibiotype (resistant to amoxicillin, amoxicillin/clavulanate, cefalotin, cefamandole and colistin; intermediate to cefoxitin; susceptible to ticarcillin, ticarcillin/clavulanate, piperacillin/tazobactam, imipenem, aztreonam, cefotaxime, ertapenem, ceftazidime, cefepime, amikacin, tobramycin, gentamicin, nalidixic acid, ciprofloxacin, norfloxacin, fosfomycin and cotrimoxazole). The infection control team implemented isolation precautions for the four infants. Screening for both respiratory and gastrointestinal carriage of all infants in the NICU was undertaken. Despite these precautions, a fifth patient (patient E; Figure 1) was identified as being infected with a strain of *S. marcescens* having a similar antibiotype. PFGE results indicated that all five patients were infected or colonised with the same strain of *S. marcescens*. The results of the infection control audit suggested that it was unlikely that devices, drugs or incubators were an environmental source. Devices used for multiple patients such as breast pumps, milk bottles, and bronchoscope were used with appropriate disinfection. Each bottle of antiseptic had been dated, and was discarded after each infant's discharge. The daily cleaning of incubators, and their periodic disinfection were observed to comply with infection control guidelines. Based on these observations, the investigation of the outbreak was extended, and tap water and liquid soap samples were analysed. However, the infection control audit also showed that alcohol-based hand rubbing and use of gloves between infants were not being performed adequately.

Environmental culture surveys

None of the water samples collected from the 10 patients' rooms was contaminated with *S. marcescens*. However, samples of the single soap dispenser collected from room no. 10 grew *S. marcescens*. This isolate had the same antibiotype and PFGE pattern as the epidemic strain of *S. marcescens*.

Intervention

Following the positive result from the soap sample, the unmedicated soap was removed from patient

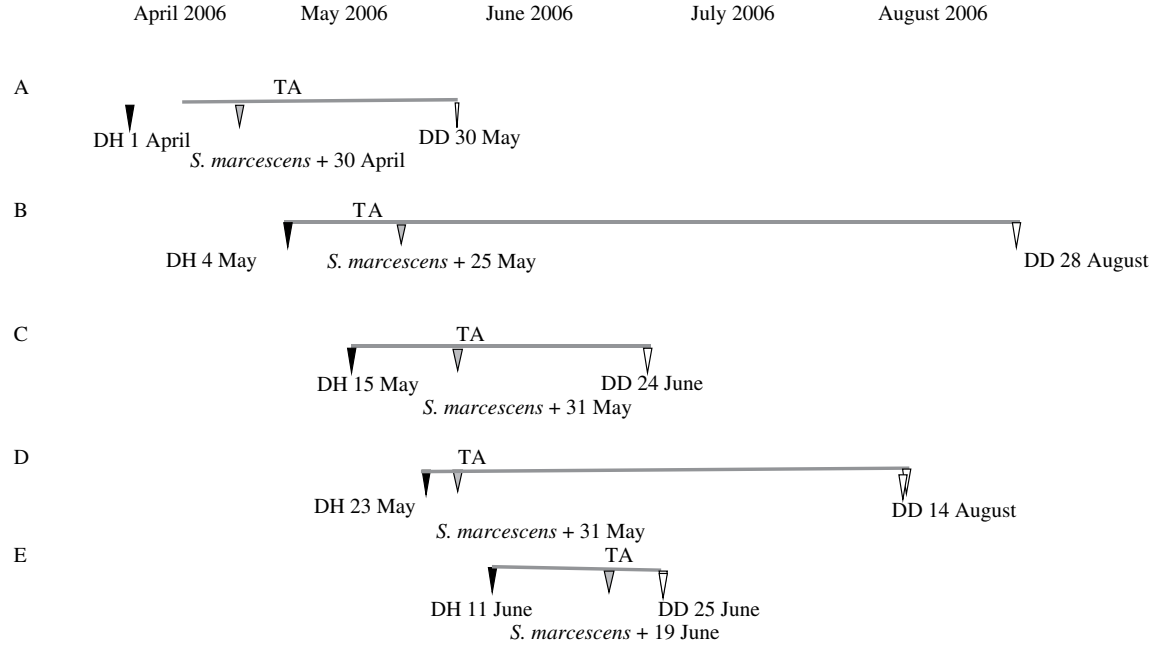

Figure 1 Graphic representation of *Serratia marcescens* outbreak. TA, transtracheal aspirate specimen positive for *S. marcescens*; DH, date of hospitalisation in the neonatal intensive care unit (NICU); DD, date of departure from the NICU.

rooms after each discharge. Before the outbreak, staff in the affected unit changed the soap only when the bottle soap dispenser was empty. The soap bottle dispensers were replaced with 'airless' dispensers in every room. These have a flexible bag as the reservoir and an internal pump, and were wall-mounted.

An education program was instituted to reinforce adherence to universal precautions, and the use of alcohol-based hand rub for all care. Despite these measures, a sixth case (patient F) was identified in November 2006. The infection control staff reinforced the use of alcohol-based hand rub for all care, and nearly one year later, no further epidemic cases have been identified.

Case–control study

All the case and control patients were matched for exposure time, primary diagnosis and age (Table I). As indicated in Table II, cases were more likely to be exposed to central or percutaneous venous catheters than controls ($P = 0.05$). However, the mean duration of exposure to central or percutaneous venous catheter was nine days for case patients and 12 days for control patients ($P = 0.46$) (Table II). Cases had longer exposure to endotracheal intubation (median of nine days), than controls (six days) ($P = 0.05$) (Table II). The case–control analysis confirmed that hospitalisation in the room contaminated by the unmedicated soap was a risk factor for infection or colonisation with *S. marcescens*. Three of the five cases were nursed in room no. 10 compared with one of 15 controls ($P = 0.032$) (Table II).

Table I Demographic and clinical characteristics of case and control patients

	Cases ($N = 5$)	Controls ($N = 15$)	*P* value
Male	4 (80)	8 (53)	0.6
Age of admission (days), median (range)	10 (1–23)	1 (1–30)	0.31
Birthweight (g), mean ± SD	924 ± 920	1689 ± 950	0.12
Weight on admission (g), median (range)	1892 (445–8160)	1225 (610–3280)	0.84
Reason for hospitalisation			
Prematurity	3 (60)	9 (60)	1
Congenital malformations	1 (20)	2 (13)	1
Respiratory distress syndrome	0 (0)	3 (20)	0.54
Operative procedures	0 (0)	1 (7)	1

ND, not done.
Data are no. (%) of patients, unless otherwise indicated.

Discussion

Serratia marcescens has been reported to cause 5% of nosocomial infections in pediatric intensive care and 15% in neonatal units.[26] Different contaminated

Table II Drugs and other treatments to which case and control patients were exposed

	Cases ($N = 5$)	Controls ($N = 15$)	*P* value
Antepartum corticosteroid therapy	3 (60)	9 (60)	1
β-Lactam	2 (40)	6 (40)	1
β-Lactam and aminoglycoside	1 (20)	3 (20)	1
β-Lactam and vancomycin	1 (20)	4 (27)	1
Bottlefeeding	1 (20)	1 (7)	0.45
Nasogastric feeding tube	5 (100)	15 (100)	ND
Median days (range)	14 (9–30)	6 (1–63)	0.15
Parenteral nutrition	4 (80)	13 (87)	1
Median days (range)	13 (3–29)	6 (2–43)	0.50
Arterial catheter	0 (0)	1 (7)	1
Central, percutaneous venous catheter	5 (100)	7 (47)	0.05
Median days (range)	9 (2–23)	12 (3–34)	0.46
Umbilical venous catheter	2 (40)	9 (60)	0.61
Median days (range)	5 (3–7)	4 (2–12)	0.81
Endotracheal intubation	5 (100)	10 (67)	0.13
Median days (range)	9 (8–11)	6 (1–39)	0.05
Continuous positive airway pressure	3 (60)	9 (60)	0.63
Median days (range)	7 (1–12)	6 (2–64)	0.64
Hospitalisation in room no. 10 (with contaminated unmedicated soap)	3 (60)	1 (7)	0.032

ND, not done.
Data are no. (%) of patients, unless otherwise indicated.

sources have been implicated in outbreaks with *S. marcescens*.[2–16] To our knowledge, this is the first reported outbreak in which a case–control study, culture surveys and PFGE implicated unmedicated soap from a dispenser as a reservoir.

We hypothesise that the soap dispenser acted as a continuous source of *S. marcescens*, facilitating handborne transmission of *S. marcescens* by healthcare workers (HCWs). Several facts support this proposed mechanism.

First, three of the five infants who became infected or colonised with the epidemic strain were nursed in the room with the contaminated soap dispenser (room no. 10). HCWs who were in charge of those three infants also looked after different infants in the neonatal unit.

Second, the infants who were infected or colonised with the epidemic strain were more likely to have been exposed to a central or percutaneous venous catheter ($P = 0.05$) and endotracheal intubation ($P = 0.05$). All cases had *S. marcescens* cultured from transtracheal aspirates. Oral cleaning care has been recognised as a risk factor.[7]

Third, it was unlikely that the outbreak strain was selected by antibiotic use. There was no significant difference between the five cases and 15 controls with regard to antimicrobial therapy with β-lactams, β-lactam and aminoglycoside combination or β-lactam and vancomycin combination (Table II).

We believe that the design of the soap dispenser was an important factor in the spread of the epidemic *S. marcescens* strain. Contamination of the soap was probably due to a retrograde contamination during hand washing. The 'airless' soap dispenser reduced this risk of soap contamination, and was probably an important part of controlling the outbreak.

Potential limitations of this study include the fact that the sixth *S. marcescens* epidemic strain was detected five months after replacement of the contaminated soap. This may be explained by prolonged carriage by HCWs. DeVries *et al.* sampled the hands of 100 HCWs and showed colonisation of a single HCW with the epidemic strain of *S. marcescens*.[27] Although this HCW went on leave, repeated culture surveys found prolonged carriage of the epidemic strain on the hands of the other HCWs for three months. This hypothesis cannot be proved in our study, as in France legal agreement is required for sampling HCWs' hands and this was not allowed in the unit. However, nearly one year later, no further cases with the epidemic strain of *S. marcescens* have been identified.

Our results suggest that the soap dispenser acted as the source of *S. marcescens* which facilitated handborne transmission of *S. marcescens* by HCWs.

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Conflict of interest statement
None declared.

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Guideline for Hand Hygiene in Health-Care Settings

Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force

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Summary

The Guideline for Hand Hygiene in Health-Care Settings provides health-care workers (HCWs) with a review of data regarding handwashing and hand antisepsis in health-care settings. In addition, it provides specific recommendations to promote improved hand-hygiene practices and reduce transmission of pathogenic microorganisms to patients and personnel in health-care settings. This report reviews studies published since the 1985 CDC guideline (Garner JS, Favero MS. CDC guideline for handwashing and hospital environmental control, 1985. Infect Control 1986;7:231–43) *and the 1995 APIC guideline* (Larson EL, APIC Guidelines Committee. APIC guideline for handwashing and hand antisepsis in health care settings. Am J Infect Control 1995;23:251–69) *were issued and provides an in-depth review of hand-hygiene practices of HCWs, levels of adherence of personnel to recommended handwashing practices, and factors adversely affecting adherence. New studies of the in vivo efficacy of alcohol-based hand rubs and the low incidence of dermatitis associated with their use are reviewed. Recent studies demonstrating the value of multidisciplinary hand-hygiene promotion programs and the potential role of alcohol-based hand rubs in improving hand-hygiene practices are summarized. Recommendations concerning related issues (e.g., the use of surgical hand antiseptics, hand lotions or creams, and wearing of artificial fingernails) are also included.*

Part I. Review of the Scientific Data Regarding Hand Hygiene

Historical Perspective

For generations, handwashing with soap and water has been considered a measure of personal hygiene (*1*). The concept of cleansing hands with an antiseptic agent probably emerged in the early 19th century. As early as 1822, a French pharmacist demonstrated that solutions containing chlorides of lime or soda could eradicate the foul odors associated with human corpses and that such solutions could be used as disinfectants and antiseptics (*2*). In a paper published in 1825, this pharmacist stated that physicians and other persons attending patients with contagious diseases would benefit from moistening their hands with a liquid chloride solution (*2*).

In 1846, Ignaz Semmelweis observed that women whose babies were delivered by students and physicians in the First Clinic at the General Hospital of Vienna consistently had a higher mortality rate than those whose babies were delivered by midwives in the Second Clinic (*3*). He noted that physicians who went directly from the autopsy suite to the obstetrics ward had a disagreeable odor on their hands despite washing their hands with soap and water upon entering the obstetrics clinic. He postulated that the puerperal fever that affected so many parturient women was caused by "cadaverous particles" transmitted from the autopsy suite to the obstetrics ward via the hands of students and physicians. Perhaps because of the known deodorizing effect of chlorine compounds, as of May 1847, he insisted that students and physicians clean their hands with a chlorine solution between each patient in the clinic. The maternal mortality rate in the First Clinic subsequently dropped dramatically and remained low for years. This intervention by Semmelweis represents the first evidence indicating that cleansing heavily contaminated hands with an antiseptic agent between patient contacts may reduce health-care–associated transmission of contagious diseases more effectively than handwashing with plain soap and water.

In 1843, Oliver Wendell Holmes concluded independently that puerperal fever was spread by the hands of health personnel (*1*). Although he described measures that could be taken to limit its spread, his recommendations had little impact on

The material in this report originated in the National Center for Infectious Diseases, James M. Hughes, M.D., Director; and the Division of Healthcare Quality Promotion, Steve Solomon, M.D., Acting Director.

obstetric practices at the time. However, as a result of the seminal studies by Semmelweis and Holmes, handwashing gradually became accepted as one of the most important measures for preventing transmission of pathogens in health-care facilities.

In 1961, the U. S. Public Health Service produced a training film that demonstrated handwashing techniques recommended for use by health-care workers (HCWs) (*4*). At the time, recommendations directed that personnel wash their hands with soap and water for 1–2 minutes before and after patient contact. Rinsing hands with an antiseptic agent was believed to be less effective than handwashing and was recommended only in emergencies or in areas where sinks were unavailable.

In 1975 and 1985, formal written guidelines on handwashing practices in hospitals were published by CDC (*5,6*). These guidelines recommended handwashing with nonantimicrobial soap between the majority of patient contacts and washing with antimicrobial soap before and after performing invasive procedures or caring for patients at high risk. Use of waterless antiseptic agents (e.g., alcohol-based solutions) was recommended only in situations where sinks were not available.

In 1988 and 1995, guidelines for handwashing and hand antisepsis were published by the Association for Professionals in Infection Control (APIC) (*7,8*). Recommended indications for handwashing were similar to those listed in the CDC guidelines. The 1995 APIC guideline included more detailed discussion of alcohol-based hand rubs and supported their use in more clinical settings than had been recommended in earlier guidelines. In 1995 and 1996, the Healthcare Infection Control Practices Advisory Committee (HICPAC) recommended that either antimicrobial soap or a waterless antiseptic agent be used for cleaning hands upon leaving the rooms of patients with multidrug-resistant pathogens (e.g., vancomycin-resistant enterococci [VRE] and methicillin-resistant *Staphylococcus aureus* [MRSA]) (*9,10*). These guidelines also provided recommendations for handwashing and hand antisepsis in other clinical settings, including routine patient care. Although the APIC and HICPAC guidelines have been adopted by the majority of hospitals, adherence of HCWs to recommended handwashing practices has remained low (*11,12*).

Recent developments in the field have stimulated a review of the scientific data regarding hand hygiene and the development of new guidelines designed to improve hand-hygiene practices in health-care facilities. This literature review and accompanying recommendations have been prepared by a Hand Hygiene Task Force, comprising representatives from HICPAC, the Society for Healthcare Epidemiology of America (SHEA), APIC, and the Infectious Diseases Society of America (IDSA).

Normal Bacterial Skin Flora

To understand the objectives of different approaches to hand cleansing, a knowledge of normal bacterial skin flora is essential. Normal human skin is colonized with bacteria; different areas of the body have varied total aerobic bacterial counts (e.g., 1×10^6 colony forming units (CFUs)/cm^2 on the scalp, 5×10^5 CFUs/cm^2 in the axilla, 4×10^4 CFUs/cm^2 on the abdomen, and 1×10^4 CFUs/cm^2 on the forearm) (*13*). Total bacterial counts on the hands of medical personnel have ranged from 3.9×10^4 to 4.6×10^6 (*14–17*). In 1938, bacteria recovered from the hands were divided into two categories: transient and resident (*14*). Transient flora, which colonize the superficial layers of the skin, are more amenable to removal by routine handwashing. They are often acquired by HCWs during direct contact with patients or contact with contaminated environmental surfaces within close proximity of the patient. Transient flora are the organisms most frequently associated with health-care–associated infections. Resident flora, which are attached to deeper layers of the skin, are more resistant to removal. In addition, resident flora (e.g., coagulase-negative staphylococci and diphtheroids) are less likely to be associated with such infections. The hands of HCWs may become persistently colonized with pathogenic flora (e.g., *S. aureus*), gram-negative bacilli, or yeast. Investigators have documented that, although the number of transient and resident flora varies considerably from person to person, it is often relatively constant for any specific person (*14,18*).

Physiology of Normal Skin

The primary function of the skin is to reduce water loss, provide protection against abrasive action and microorganisms, and act as a permeability barrier to the environment. The basic structure of skin includes, from outer- to innermost layer, the superficial region (i.e., the stratum corneum or horny layer, which is 10- to 20-µm thick), the viable epidermis (50- to 100-µm thick), the dermis (1- to 2-mm thick), and the hypodermis (1- to 2-mm thick). The barrier to percutaneous absorption lies within the stratum corneum, the thinnest and smallest compartment of the skin. The stratum corneum contains the corneocytes (or horny cells), which are flat, polyhedral-shaped nonnucleated cells, remnants of the terminally differentiated keratinocytes located in the viable epidermis. Corneocytes are composed primarily of insoluble bundled keratins surrounded by a cell envelope stabilized by cross-linked proteins and covalently bound lipid. Interconnecting the corneocytes of the stratum corneum are polar structures (e.g., corneodesmosomes), which contribute to stratum corneum cohesion.

The intercellular region of the stratum corneum is composed of lipid primarily generated from the exocytosis of lamellar bodies during the terminal differentiation of the keratinocytes. The intercellular lipid is required for a competent skin barrier and forms the only continuous domain. Directly under the stratum corneum is a stratified epidermis, which is composed primarily of 10–20 layers of keratinizing epithelial cells that are responsible for the synthesis of the stratum corneum. This layer also contains melanocytes involved in skin pigmentation; Langerhans cells, which are important for antigen presentation and immune responses; and Merkel cells, whose precise role in sensory reception has yet to be fully delineated. As keratinocytes undergo terminal differentiation, they begin to flatten out and assume the dimensions characteristic of the corneocytes (i.e., their diameter changes from 10–12 µm to 20–30 µm, and their volume increases by 10- to 20-fold). The viable epidermis does not contain a vascular network, and the keratinocytes obtain their nutrients from below by passive diffusion through the interstitial fluid.

The skin is a dynamic structure. Barrier function does not simply arise from the dying, degeneration, and compaction of the underlying epidermis. Rather, the processes of cornification and desquamation are intimately linked; synthesis of the stratum corneum occurs at the same rate as loss. Substantial evidence now confirms that the formation of the skin barrier is under homeostatic control, which is illustrated by the epidermal response to barrier perturbation by skin stripping or solvent extraction. Circumstantial evidence indicates that the rate of keratinocyte proliferation directly influences the integrity of the skin barrier. A general increase in the rate of proliferation results in a decrease in the time available for 1) uptake of nutrients (e.g., essential fatty acids), 2) protein and lipid synthesis, and 3) processing of the precursor molecules required for skin-barrier function. Whether chronic but quantitatively smaller increases in rate of epidermal proliferation also lead to changes in skin-barrier function remains unclear. Thus, the extent to which the decreased barrier function caused by irritants is caused by an increased epidermal proliferation also is unknown.

The current understanding of the formation of the stratum corneum has come from studies of the epidermal responses to perturbation of the skin barrier. Experimental manipulations that disrupt the skin barrier include 1) extraction of skin lipids with apolar solvents, 2) physical stripping of the stratum corneum using adhesive tape, and 3) chemically induced irritation. All of these experimental manipulations lead to a decreased skin barrier as determined by transepidermal water loss (TEWL). The most studied experimental system is the treatment of mouse skin with acetone. This experiment results in a marked and immediate increase in TEWL, and therefore a decrease in skin-barrier function. Acetone treatment selectively removes glycerolipids and sterols from the skin, which indicates that these lipids are necessary, though perhaps not sufficient in themselves, for barrier function. Detergents act like acetone on the intercellular lipid domain. The return to normal barrier function is biphasic: 50%–60% of barrier recovery typically occurs within 6 hours, but complete normalization of barrier function requires 5–6 days.

Definition of Terms

Alcohol-based hand rub. An alcohol-containing preparation designed for application to the hands for reducing the number of viable microorganisms on the hands. In the United States, such preparations usually contain 60%–95% ethanol or isopropanol.

Antimicrobial soap. Soap (i.e., detergent) containing an antiseptic agent.

Antiseptic agent. Antimicrobial substances that are applied to the skin to reduce the number of microbial flora. Examples include alcohols, chlorhexidine, chlorine, hexachlorophene, iodine, chloroxylenol (PCMX), quaternary ammonium compounds, and triclosan.

Antiseptic handwash. Washing hands with water and soap or other detergents containing an antiseptic agent.

Antiseptic hand rub. Applying an antiseptic hand-rub product to all surfaces of the hands to reduce the number of microorganisms present.

Cumulative effect. A progressive decrease in the numbers of microorganisms recovered after repeated applications of a test material.

Decontaminate hands. To Reduce bacterial counts on hands by performing antiseptic hand rub or antiseptic handwash.

Detergent. Detergents (i.e., surfactants) are compounds that possess a cleaning action. They are composed of both hydrophilic and lipophilic parts and can be divided into four groups: anionic, cationic, amphoteric, and nonionic detergents. Although products used for handwashing or antiseptic handwash in health-care settings represent various types of detergents, the term "soap" is used to refer to such detergents in this guideline.

Hand antisepsis. Refers to either antiseptic handwash or antiseptic hand rub.

Hand hygiene. A general term that applies to either handwashing, antiseptic handwash, antiseptic hand rub, or surgical hand antisepsis.

Handwashing. Washing hands with plain (i.e., non-antimicrobial) soap and water.

Persistent activity. Persistent activity is defined as the prolonged or extended antimicrobial activity that prevents or inhibits the proliferation or survival of microorganisms after application of the product. This activity may be demonstrated by sampling a site several minutes or hours after application and demonstrating bacterial antimicrobial effectiveness when compared with a baseline level. This property also has been referred to as "residual activity." Both substantive and nonsubstantive active ingredients can show a persistent effect if they substantially lower the number of bacteria during the wash period.

Plain soap. Plain soap refers to detergents that do not contain antimicrobial agents or contain low concentrations of antimicrobial agents that are effective solely as preservatives.

Substantivity. Substantivity is an attribute of certain active ingredients that adhere to the stratum corneum (i.e., remain on the skin after rinsing or drying) to provide an inhibitory effect on the growth of bacteria remaining on the skin.

Surgical hand antisepsis. Antiseptic handwash or antiseptic hand rub performed preoperatively by surgical personnel to eliminate transient and reduce resident hand flora. Antiseptic detergent preparations often have persistent antimicrobial activity.

Visibly soiled hands. Hands showing visible dirt or visibly contaminated with proteinaceous material, blood, or other body fluids (e.g., fecal material or urine).

Waterless antiseptic agent. An antiseptic agent that does not require use of exogenous water. After applying such an agent, the hands are rubbed together until the agent has dried.

Food and Drug Administration (FDA) product categories. The 1994 FDA Tentative Final Monograph for Health-Care Antiseptic Drug Products divided products into three categories and defined them as follows (*19*):

- *Patient preoperative skin preparation.* A fast-acting, broad-spectrum, and persistent antiseptic-containing preparation that substantially reduces the number of microorganisms on intact skin.
- *Antiseptic handwash or HCW handwash*. An antiseptic-containing preparation designed for frequent use; it reduces the number of microorganisms on intact skin to an initial baseline level after adequate washing, rinsing, and drying; it is broad-spectrum, fast-acting, and if possible, persistent.
- *Surgical hand scrub*. An antiseptic-containing preparation that substantially reduces the number of microorganisms on intact skin; it is broad-spectrum, fast-acting, and persistent.

Evidence of Transmission of Pathogens on Hands

Transmission of health-care–associated pathogens from one patient to another via the hands of HCWs requires the following sequence of events:

- Organisms present on the patient's skin, or that have been shed onto inanimate objects in close proximity to the patient, must be transferred to the hands of HCWs.
- These organisms must then be capable of surviving for at least several minutes on the hands of personnel.
- Next, handwashing or hand antisepsis by the worker must be inadequate or omitted entirely, or the agent used for hand hygiene must be inappropriate.
- Finally, the contaminated hands of the caregiver must come in direct contact with another patient, or with an inanimate object that will come into direct contact with the patient.

Health-care–associated pathogens can be recovered not only from infected or draining wounds, but also from frequently colonized areas of normal, intact patient skin (*20– 31*). The perineal or inguinal areas are usually most heavily colonized, but the axillae, trunk, and upper extremities (including the hands) also are frequently colonized (*23,25,26,28,30–32*). The number of organisms (e.g., *S. aureus*, *Proteus mirabilis*, *Klebsiella* spp., and *Acinetobacter* spp.) present on intact areas of the skin of certain patients can vary from 100 to $10^6/cm^2$ (*25,29,31,33*). Persons with diabetes, patients undergoing dialysis for chronic renal failure, and those with chronic dermatitis are likely to have areas of intact skin that are colonized with *S. aureus* (*34–41*). Because approximately 10^6 skin squames containing viable microorganisms are shed daily from normal skin (*42*), patient gowns, bed linen, bedside furniture, and other objects in the patient's immediate environment can easily become contaminated with patient flora (*30,43–46*). Such contamination is particularly likely to be caused by staphylococci or enterococci, which are resistant to dessication.

Data are limited regarding the types of patient-care activities that result in transmission of patient flora to the hands of personnel (*26,45–51*). In the past, attempts have been made to stratify patient-care activities into those most likely to cause hand contamination (*52*), but such stratification schemes were never validated by quantifying the level of bacterial contamination that occurred. Nurses can contaminate their hands with 100–1,000 CFUs of *Klebsiella* spp. during "clean" activities (e.g., lifting a patient; taking a patient's pulse, blood pressure, or oral temperature; or touching a patient's hand, shoulder, or groin) (*48*). Similarly, in another study, hands were cultured of nurses who touched the groins of patients heavily colonized with *P. mirabilis* (*25*); 10–600 CFUs/mL of this

organism were recovered from glove juice samples from the nurses' hands. Recently, other researchers studied contamination of HCWs' hands during activities that involved direct patient-contact wound care, intravascular catheter care, respiratory-tract care, and the handling of patient secretions (*51*). Agar fingertip impression plates were used to culture bacteria; the number of bacteria recovered from fingertips ranged from 0 to 300 CFUs. Data from this study indicated that direct patient contact and respiratory-tract care were most likely to contaminate the fingers of caregivers. Gram-negative bacilli accounted for 15% of isolates and *S. aureus* for 11%. Duration of patient-care activity was strongly associated with the intensity of bacterial contamination of HCWs' hands.

HCWs can contaminate their hands with gram-negative bacilli, *S. aureus*, enterococci, or *Clostridium difficile* by performing "clean procedures" or touching intact areas of the skin of hospitalized patients (*26,45,46,53*). Furthermore, personnel caring for infants with respiratory syncytial virus (RSV) infections have acquired RSV by performing certain activities (e.g., feeding infants, changing diapers, and playing with infants) (*49*). Personnel who had contact only with surfaces contaminated with the infants' secretions also acquired RSV by contaminating their hands with RSV and inoculating their oral or conjunctival mucosa. Other studies also have documented that HCWs may contaminate their hands (or gloves) merely by touching inanimate objects in patient rooms (*46,53–56*). None of the studies concerning hand contamination of hospital personnel were designed to determine if the contamination resulted in transmission of pathogens to susceptible patients.

Other studies have documented contamination of HCWs' hands with potential health-care–associated pathogens, but did not relate their findings to the specific type of preceding patient contact (*15,17,57–62*). For example, before glove use was common among HCWs, 15% of nurses working in an isolation unit carried a median of 1 x 10^4 CFUs of *S. aureus* on their hands (*61*). Of nurses working in a general hospital, 29% had *S. aureus* on their hands (median count: 3,800 CFUs), whereas 78% of those working in a hospital for dermatology patients had the organism on their hands (median count: 14.3 x 10^6 CFUs). Similarly, 17%–30% of nurses carried gram-negative bacilli on their hands (median counts: 3,400–38,000 CFUs). One study found that *S. aureus* could be recovered from the hands of 21% of intensive-care–unit personnel and that 21% of physician and 5% of nurse carriers had >1,000 CFUs of the organism on their hands (*59*). Another study found lower levels of colonization on the hands of personnel working in a neurosurgery unit, with an average of 3 CFUs of *S. aureus* and 11 CFUs of gram-negative bacilli (*16*). Serial cultures revealed that 100% of HCWs carried gram-negative bacilli at least once, and 64% carried *S. aureus* at least once.

Models of Hand Transmission

Several investigators have studied transmission of infectious agents by using different experimental models. In one study, nurses were asked to touch the groins of patients heavily colonized with gram-negative bacilli for 15 seconds — as though they were taking a femoral pulse (*25*). Nurses then cleaned their hands by washing with plain soap and water or by using an alcohol hand rinse. After cleaning their hands, they touched a piece of urinary catheter material with their fingers, and the catheter segment was cultured. The study revealed that touching intact areas of moist skin of the patient transferred enough organisms to the nurses' hands to result in subsequent transmission to catheter material, despite handwashing with plain soap and water.

The transmission of organisms from artificially contaminated "donor" fabrics to clean "recipient" fabrics via hand contact also has been studied. Results indicated that the number of organisms transmitted was greater if the donor fabric or the hands were wet upon contact (*63*). Overall, only 0.06% of the organisms obtained from the contaminated donor fabric were transferred to recipient fabric via hand contact. *Staphylococcus saprophyticus, Pseudomonas aeruginosa,* and *Serratia* spp. were also transferred in greater numbers than was *Escherichia coli* from contaminated fabric to clean fabric after hand contact (*64*). Organisms are transferred to various types of surfaces in much larger numbers (i.e., >10^4) from wet hands than from hands that are thoroughly dried (*65*).

Relation of Hand Hygiene and Acquisition of Health-Care–Associated Pathogens

Hand antisepsis reduces the incidence of health-care–associated infections (*66,67*). An intervention trial using historical controls demonstrated in 1847 that the mortality rate among mothers who delivered in the First Obstetrics Clinic at the General Hospital of Vienna was substantially lower when hospital staff cleaned their hands with an antiseptic agent than when they washed their hands with plain soap and water (*3*).

In the 1960s, a prospective, controlled trial sponsored by the National Institutes of Health and the Office of the Surgeon General demonstrated that infants cared for by nurses who did not wash their hands after handling an index infant colonized with *S. aureus* acquired the organism more often and more rapidly than did infants cared for by nurses who used hexachlorophene to clean their hands between infant

contacts *(68)*. This trial provided evidence that, when compared with no handwashing, washing hands with an antiseptic agent between patient contacts reduces transmission of health-care–associated pathogens.

Trials have studied the effects of handwashing with plain soap and water versus some form of hand antisepsis on health-care–associated infection rates (*69,70*). Health-care–associated infection rates were lower when antiseptic handwashing was performed by personnel (*69*). In another study, antiseptic handwashing was associated with lower health-care–associated infection rates in certain intensive-care units, but not in others (70).

Health-care–associated infection rates were lower after antiseptic handwashing using a chlorhexidine-containing detergent compared with handwashing with plain soap or use of an alcohol-based hand rinse (*71*). However, because only a minimal amount of the alcohol rinse was used during periods when the combination regimen also was in use and because adherence to policies was higher when chlorhexidine was available, determining which factor (i.e., the hand-hygiene regimen or differences in adherence) accounted for the lower infection rates was difficult. Investigators have determined also that health-care–associated acquisition of MRSA was reduced when the antimicrobial soap used for hygienic handwashing was changed (*72,73*).

Increased handwashing frequency among hospital staff has been associated with decreased transmission of *Klebsiella* spp. among patients (*48*); these studies, however, did not quantitate the level of handwashing among personnel. In a recent study, the acquisition of various health-care–associated pathogens was reduced when hand antisepsis was performed more frequently by hospital personnel (*74*); both this study and another (*75*) documented that the prevalence of health-care–associated infections decreased as adherence to recommended hand-hygiene measures improved.

Outbreak investigations have indicated an association between infections and understaffing or overcrowding; the association was consistently linked with poor adherence to hand hygiene. During an outbreak investigation of risk factors for central venous catheter-associated bloodstream infections (*76*), after adjustment for confounding factors, the patient-to-nurse ratio remained an independent risk factor for bloodstream infection, indicating that nursing staff reduction below a critical threshold may have contributed to this outbreak by jeopardizing adequate catheter care. The understaffing of nurses can facilitate the spread of MRSA in intensive-care settings (*77*) through relaxed attention to basic control measures (e.g., hand hygiene). In an outbreak of *Enterobacter cloacae* in a neonatal intensive-care unit (*78*), the daily number of hospitalized children was above the maximum capacity of the unit, resulting in an available space per child below current recommendations. In parallel, the number of staff members on duty was substantially less than the number necessitated by the workload, which also resulted in relaxed attention to basic infection-control measures. Adherence to hand-hygiene practices before device contact was only 25% during the workload peak, but increased to 70% after the end of the understaffing and overcrowding period. Surveillance documented that being hospitalized during this period was associated with a fourfold increased risk of acquiring a health-care–associated infection. This study not only demonstrates the association between workload and infections, but it also highlights the intermediate cause of antimicrobial spread: poor adherence to hand-hygiene policies.

Methods Used To Evaluate the Efficacy of Hand-Hygiene Products

Current Methods

Investigators use different methods to study the in vivo efficacy of handwashing, antiseptic handwash, and surgical hand antisepsis protocols. Differences among the various studies include 1) whether hands are purposely contaminated with bacteria before use of test agents, 2) the method used to contaminate fingers or hands, 3) the volume of hand-hygiene product applied to the hands, 4) the time the product is in contact with the skin, 5) the method used to recover bacteria from the skin after the test solution has been used, and 6) the method of expressing the efficacy of the product (i.e., either percent reduction in bacteria recovered from the skin or log reduction of bacteria released from the skin). Despite these differences, the majority of studies can be placed into one of two major categories: studies focusing on products to remove transient flora and studies involving products that are used to remove resident flora from the hands. The majority of studies of products for removing transient flora from the hands of HCWs involve artificial contamination of the volunteer's skin with a defined inoculum of a test organism before the volunteer uses a plain soap, an antimicrobial soap, or a waterless antiseptic agent. In contrast, products tested for the preoperative cleansing of surgeons' hands (which must comply with surgical hand-antisepsis protocols) are tested for their ability to remove resident flora from without artificially contaminating the volunteers' hands.

In the United States, antiseptic handwash products intended for use by HCWs are regulated by FDA's Division of Over-the-Counter Drug Products (OTC). Requirements for in vitro and in vivo testing of HCW handwash products and surgical

hand scrubs are outlined in the FDA Tentative Final Monograph for Healthcare Antiseptic Drug Products (TFM) (*19*). Products intended for use as HCW handwashes are evaluated by using a standardized method (*19*). Tests are performed in accordance with use directions for the test material. Before baseline bacterial sampling and before each wash with the test material, 5 mL of a standardized suspension of *Serratia marcescens* are applied to the hands and then rubbed over the surfaces of the hands. A specified volume of the test material is dispensed into the hands and is spread over the hands and lower one third of the forearms. A small amount of tap water is added to the hands, and hands are completely lathered for a specified time, covering all surfaces of the hands and the lower third of the forearms. Volunteers then rinse hands and forearms under 40°C tap water for 30 seconds. Ten washes with the test formulation are required. After the first, third, seventh, and tenth washes, rubber gloves or polyethylene bags used for sampling are placed on the right and left hands, and 75 mL of sampling solution is added to each glove; gloves are secured above the wrist. All surfaces of the hand are massaged for 1 minute, and samples are obtained aseptically for quantitative culture. No neutralizer of the antimicrobial is routinely added to the sampling solution, but if dilution of the antimicrobial in the sampling fluid does not result in demonstrable neutralization, a neutralizer specific for the test formulation is added to the sampling solution. For waterless formulations, a similar procedure is used. TFM criteria for efficacy are as follows: a 2-$\log_{10}$ reduction of the indicator organism on each hand within 5 minutes after the first use, and a 3-$\log_{10}$ reduction of the indicator organism on each hand within 5 minutes after the tenth use (*19*).

Products intended for use as surgical hand scrubs have been evaluated also by using a standardized method (*19*). Volunteers clean under fingernails with a nail stick and clip their fingernails. All jewelry is removed from hands and arms. Hands and two thirds of forearms are rinsed with tap water (38°C–42°C) for 30 seconds, and then they are washed with a nonantimicrobial soap for 30 seconds and are rinsed for 30 seconds under tap water. Baseline microbial hand counts can then be determined. Next, a surgical scrub is performed with the test formulation using directions provided by the manufacturer. If no instructions are provided with the formulation, two 5-minute scrubs of hands and forearms followed by rinsing are performed. Reduction from baseline microbial hand counts is determined in a series of 11 scrubs conducted during 5 days. Hands are sampled at 1 minute, 3 hours, and 6 hours after the first scrubs on day 1, day 2, and day 5. After washing, volunteers wear rubber gloves; 75 mL of sampling solution are then added to one glove, and all surfaces of the hands are massaged for 1 minute. Samples are then taken aseptically and cultured quantitatively. The other glove remains on the other hand for 6 hours and is sampled in the same manner. TFM requires that formulations reduce the number of bacteria 1 $\log_{10}$ on each hand within 1 minute of product application and that the bacterial cell count on each hand does not subsequently exceed baseline within 6 hours on day 1; the formulation must produce a 2-$\log_{10}$ reduction in microbial flora on each hand within 1 minute of product application by the end of the second day of enumeration and a 3-$\log_{10}$ reduction of microbial flora on each hand within 1 minute of product use by the end of the fifth day when compared with the established baseline (*19*).

The method most widely used in Europe to evaluate the efficacy of hand-hygiene agents is European Standard 1500–1997 (EN 1500—Chemical disinfectants and antiseptics. Hygienic hand-rub test method and requirements) (*79*). This method requires 12–15 test volunteers and an 18- to 24-hour growth of broth culture of *E. coli* K12. Hands are washed with a soft soap, dried, and then immersed halfway to the metacarpals in the broth culture for 5 seconds. Hands are removed from the broth culture, excess fluid is drained off, and hands are dried in the air for 3 minutes. Bacterial recovery for the initial value is obtained by kneading the fingertips of each hand separately for 60 seconds in 10 mL of tryptic soy broth (TSB) without neutralizers. The hands are removed from the broth and disinfected with 3 mL of the hand-rub agent for 30 seconds in a set design. The same operation is repeated with total disinfection time not exceeding 60 seconds. Both hands are rinsed in running water for 5 seconds and water is drained off. Fingertips of each hand are kneaded separately in 10 mL of TSB with added neutralizers. These broths are used to obtain the final value. Log_{10} dilutions of recovery medium are prepared and plated out. Within 3 hours, the same volunteers are tested with the reference disinfectant (60% 2-propanol [isopropanol]) and the test product. Colony counts are performed after 24 and 48 hours of incubation at 36°C. The average colony count of both left and right hand is used for evaluation. The log-reduction factor is calculated and compared with the initial and final values. The reduction factor of the test product should be superior or the same as the reference alcohol-based rub for acceptance. If a difference exists, then the results are analyzed statistically using the Wilcoxon test. Products that have log reductions substantially less than that observed with the reference alcohol-based hand rub (i.e., approximately 4 $\log_{10}$ reduction) are classified as not meeting the standard.

Because of different standards for efficacy, criteria cited in FDA TFM and the European EN 1500 document for establishing alcohol-based hand rubs vary (*1,19,79*). Alcohol-based

hand rubs that meet TFM criteria for efficacy may not necessarily meet the EN 1500 criteria for efficacy (*80*). In addition, scientific studies have not established the extent to which counts of bacteria or other microorganisms on the hands need to be reduced to minimize transmission of pathogens in health-care facilities (*1,8*); whether bacterial counts on the hands must be reduced by 1 $\log_{10}$ (90% reduction), 2 $\log_{10}$ (99%), 3 $\log_{10}$ (99.9%), or 4 $\log_{10}$ (99.99%) is unknown. Several other methods also have been used to measure the efficacy of antiseptic agents against various viral pathogens (*81–83*).

Shortcomings of Traditional Methodologies

Accepted methods of evaluating hand-hygiene products intended for use by HCWs require that test volunteers wash their hands with a plain or antimicrobial soap for 30 seconds or 1 minute, despite the observation in the majority of studies that the average duration of handwashing by hospital personnel is <15 seconds (*52,84–89*). A limited number of investigators have used 15-second handwashing or hygienic hand-wash protocols (*90–94*). Therefore, almost no data exist regarding the efficacy of plain or antimicrobial soaps under conditions in which they are actually used by HCWs. Similarly, certain accepted methods for evaluating waterless antiseptic agents for use as antiseptic hand rubs require that 3 mL of alcohol be rubbed into the hands for 30 seconds, followed by a repeat application for the same duration. This type of protocol also does not reflect actual usage patterns among HCWs. Furthermore, volunteers used in evaluations of products are usually surrogates for HCWs, and their hand flora may not reflect flora found on the hands of personnel working in health-care settings. Further studies should be conducted among practicing HCWs using standardized protocols to obtain more realistic views of microbial colonization and risk of bacterial transfer and cross-transmission (*51*).

Review of Preparations Used for Hand Hygiene

Plain (Non-Antimicrobial) Soap

Soaps are detergent-based products that contain esterified fatty acids and sodium or potassium hydroxide. They are available in various forms including bar soap, tissue, leaflet, and liquid preparations. Their cleaning activity can be attributed to their detergent properties, which result in removal of dirt, soil, and various organic substances from the hands. Plain soaps have minimal, if any, antimicrobial activity. However, handwashing with plain soap can remove loosely adherent transient flora. For example, handwashing with plain soap and water for 15 seconds reduces bacterial counts on the skin by 0.6–1.1 $\log_{10}$, whereas washing for 30 seconds reduces counts by 1.8–2.8 $\log_{10}$ (*1*). However, in several studies, handwashing with plain soap failed to remove pathogens from the hands of hospital personnel (*25,45*). Handwashing with plain soap can result in paradoxical increases in bacterial counts on the skin (*92,95–97*). Non-antimicrobial soaps may be associated with considerable skin irritation and dryness (*92,96,98*), although adding emollients to soap preparations may reduce their propensity to cause irritation. Occasionally, plain soaps have become contaminated, which may lead to colonization of hands of personnel with gram-negative bacilli (*99*).

Alcohols

The majority of alcohol-based hand antiseptics contain either isopropanol, ethanol, n-propanol, or a combination of two of these products. Although n-propanol has been used in alcohol-based hand rubs in parts of Europe for many years, it is not listed in TFM as an approved active agent for HCW handwashes or surgical hand-scrub preparations in the United States. The majority of studies of alcohols have evaluated individual alcohols in varying concentrations. Other studies have focused on combinations of two alcohols or alcohol solutions containing limited amounts of hexachlorophene, quaternary ammonium compounds, povidone-iodine, triclosan, or chlorhexidine gluconate (*61,93,100–119*).

The antimicrobial activity of alcohols can be attributed to their ability to denature proteins (*120*). Alcohol solutions containing 60%–95% alcohol are most effective, and higher concentrations are less potent (*120–122*) because proteins are not denatured easily in the absence of water (*120*). The alcohol content of solutions may be expressed as percent by weight (w/w), which is not affected by temperature or other variables, or as percent by volume (vol/vol), which can be affected by temperature, specific gravity, and reaction concentration (*123*). For example, 70% alcohol by weight is equivalent to 76.8% by volume if prepared at 15°C, or 80.5% if prepared at 25°C (*123*). Alcohol concentrations in antiseptic hand rubs are often expressed as percent by volume (*19*).

Alcohols have excellent in vitro germicidal activity against gram-positive and gram-negative vegetative bacteria, including multidrug-resistant pathogens (e.g., MRSA and VRE), *Mycobacterium tuberculosis*, and various fungi (*120–122,124–129*). Certain enveloped (lipophilic) viruses (e.g., herpes simplex virus, human immunodeficiency virus [HIV], influenza virus, respiratory syncytial virus, and vaccinia virus) are susceptible to alcohols when tested in vitro (*120,130,131*) (Table 1). Hepatitis B virus is an enveloped virus that is somewhat less susceptible but is killed by 60%–70% alcohol; hepatitis C virus also is likely killed by this percentage of alcohol (*132*). In a porcine tissue carrier model used to study antiseptic activity, 70% ethanol and 70% isopropanol were found to

TABLE 1. Virucidal activity of antiseptic agents against enveloped viruses

Ref. no.	Test method	Viruses	Agent	Results
(*379*)	Suspension	HIV	19% EA	LR = 2.0 in 5 minutes
(*380*)	Suspension	HIV	50% EA 35% IPA	LR > 3.5 LR > 3.7
(*381*)	Suspension	HIV	70% EA	LR = 7.0 in 1 minute
(*382*)	Suspension	HIV	70% EA	LR = 3.2B 5.5 in 30 seconds
(*383*)	Suspension	HIV	70% IPA/0.5% CHG 4% CHG	LR = 6.0 in 15 seconds LR = 6.0 in 15 seconds
(*384*)	Suspension	HIV	Chloroxylenol Benzalkonium chloride	Inactivated in 1 minute Inactivated in 1 minute
(*385*)	Suspension	HIV	Povidone-iodine Chlorhexidine	Inactivated Inactivated
(*386*)	Suspension	HIV	Detergent/0.5% PCMX	Inactivated in 30 seconds
(*387*)	Suspension/dried plasma chimpanzee challenge	HBV	70% IPA	LR = 6.0 in 10 minutes
(*388*)	Suspension/plasma chimpanzee challenge	HBV	80% EA	LR = 7.0 in 2 minutes
(*389*)	Suspension	HSV	95% EA 75% EA 95% IPA 70% EA + 0.5% CHG	LR > 5.0 in 1 minute LR > 5.0 LR > 5.0 LR > 5.0
(*130*)	Suspension	RSV	35% IPA 4% CHG	LR > 4.3 in 1 minute LR > 3.3
(*141*)	Suspension	Influenza Vaccinia	95% EA 95% EA	Undetectable in 30 seconds Undetectable in 30 seconds
(*141*)	Hand test	Influenza Vaccinia	95% EA 95% EA	LR > 2.5 LR > 2.5

Note: HIV = human immunodeficiency virus, EA = ethanol, LR = Log_{10} reduction, IPA = isopropanol, CHG = chlorhexidine gluconate, HBV = hepatitis B virus, RSV = respiratory syncitial virus, HSV = herpes simplex virus, HAV = hepatitis A virus, and PCMX = chloroxylenol.

reduce titers of an enveloped bacteriophage more effectively than an antimicrobial soap containing 4% chlorhexidine gluconate (*133*). Despite its effectiveness against these organisms, alcohols have very poor activity against bacterial spores, protozoan oocysts, and certain nonenveloped (nonlipophilic) viruses.

Numerous studies have documented the *in vivo* antimicrobial activity of alcohols. Alcohols effectively reduce bacterial counts on the hands (*14,121,125,134*). Typically, log reductions of the release of test bacteria from artificially contaminated hands average 3.5 log_{10} after a 30-second application and 4.0–5.0 log_{10} after a 1-minute application (*1*). In 1994, the FDA TFM classified ethanol 60%–95% as a Category I agent (i.e., generally safe and effective for use in antiseptic handwash or HCW hand-wash products) (*19*). Although TFM placed isopropanol 70%–91.3% in category IIIE (i.e., insufficient data to classify as effective), 60% isopropanol has subsequently been adopted in Europe as the reference standard against which alcohol-based hand-rub products are compared (*79*). Alcohols are rapidly germicidal when applied to the skin, but they have no appreciable persistent (i.e., residual) activity. However, regrowth of bacteria on the skin occurs slowly after use of alcohol-based hand antiseptics, presumably because of the sublethal effect alcohols have on some of the skin bacteria (*135,136*). Addition of chlorhexidine, quaternary ammonium compounds, octenidine, or triclosan to alcohol-based solutions can result in persistent activity (*1*).

Alcohols, when used in concentrations present in alcohol-based hand rubs, also have in vivo activity against several nonenveloped viruses (Table 2). For example, 70% isopropanol and 70% ethanol are more effective than medicated soap or nonmedicated soap in reducing rotavirus titers on fingerpads (*137,138*). A more recent study using the same test methods evaluated a commercially available product containing 60%

TABLE 2. Virucidal activity of antiseptic agents against nonenveloped viruses

Ref. no.	Test method	Viruses	Antiseptic	Result
(*390*)	Suspension	Rotavirus	4% CHG	LR < 3.0 in 1 minute
			10% Povidone-Iodine	LR > 3.0
			70% IPA/0.1% HCP	LR > 3.0
(*141*)	Hand test	Adenovirus	95% EA	LR > 1.4
		Poliovirus	95% EA	LR = 0.2–1.0
		Coxsackie	95% EA	LR = 1.1–1.3
	Finger test	Adenovirus	95% EA	LR > 2.3
		Poliovirus	95% EA	LR = 0.7–2.5
		Coxsackie	95% EA	LR = 2.9
(*389*)	Suspension	ECHO virus	95% EA	LR > 3.0 in 1 minute
			75% EA	LR $\leq$ 1.0
			95% IPA	LR = 0
			70% IPA + 0.5% CHG	LR = 0
(*140*)	Finger pad	HAV	70% EA	87.4% reduction
			62% EA foam	89.3% reduction
			plain soap	78.0% reduction
			4% CHG	89.6% reduction
			0.3% Triclosan	92.0% reduction
(*105*)	Finger tips	Bovine	n-propanol + IPA	LR = 3.8 in 30 seconds
		Rotavirus	70% IPA	LR = 3.1
			70% EA	LR = 2.9
			2% triclosan	LR = 2.1
			water (control)	LR = 1.3
			7.5% povidone-iodine	LR = 1.3
			plain soap	LR = 1.2
			4% CHG	LR = 0.5
(*137*)	Finger pad	Human	70% IPA	98.9% decrease in 10 seconds
		Rotavirus	plain soap	77.1%
(*138*)	Finger pad	Human	70% IPA	99.6% decrease in 10 seconds
		Rotavirus	2% CHG	80.3%
			plain soap	72.5%
(*81*)	Finger pad	Rotavirus	60% EA gel	LR > 3.0 in 10 seconds
		Rhinovirus	60% EA gel	LR > 3.0
		Adenovirus	60% EA gel	LR > 3.0
(*139*)	Finger pad	Poliovirus	70% EA	LR = 1.6 in 10 seconds
			70% IPA	LR = 0.8
(*200*)	Finger tips	Poliovirus	Plain soap	LR = 2.1
			80% EA	LR = 0.4

Note: HIV = human immunodeficiency virus, EA = ethanol, LR = Log_{10} reduction, IPA = isopropanol, CHG = chlorhexidine gluconate, HBV = hepatitis B virus, RSV = respiratory syncitial virus, HSV = herpes simplex virus, and HAV = hepatitis A virus.

ethanol and found that the product reduced the infectivity titers of three nonenveloped viruses (i.e., rotavirus, adenovirus, and rhinovirus) by >3 logs (*81*). Other nonenveloped viruses such as hepatitis A and enteroviruses (e.g., poliovirus) may require 70%–80% alcohol to be reliably inactivated (*82,139*). However, both 70% ethanol and a 62% ethanol foam product with emollients reduced hepatitis A virus titers on whole hands or fingertips more than nonmedicated soap; both were equally as effective as antimicrobial soap containing 4% chlorhexidine gluconate in reducing reduced viral counts on hands (*140*). In the same study, both 70% ethanol and the 62% ethanol foam product demonstrated greater virucidal activity against poliovirus than either non-antimicrobial soap or a 4% chlorhexidine gluconate-containing soap (*140*). However, depending on the alcohol concentration, the amount of time that hands are exposed to the alcohol, and viral variant, alcohol may not be effective against hepatitis A and other nonlipophilic viruses. The inactivation of nonenveloped viruses is influenced by temperature, disinfectant-virus volume ratio, and protein load (*141*). Ethanol has greater activity against viruses than isopropanol. Further in vitro and in vivo studies of both alcohol-based formulations and antimicrobial soaps are warranted to establish the minimal level of virucidal activity that is required to interrupt direct contact transmission of viruses in health-care settings.

Alcohols are not appropriate for use when hands are visibly dirty or contaminated with proteinaceous materials. However, when relatively small amounts of proteinaceous material (e.g., blood) are present, ethanol and isopropanol may reduce viable bacterial counts on hands more than plain soap or antimicrobial soap (*142*).

Alcohol can prevent the transfer of health-care–associated pathogens (*25,63,64*). In one study, gram-negative bacilli were transferred from a colonized patient's skin to a piece of catheter material via the hands of nurses in only 17% of experiments after antiseptic hand rub with an alcohol-based hand rinse (*25*). In contrast, transfer of the organisms occurred in 92% of experiments after handwashing with plain soap and water. This experimental model indicates that when the hands of HCWs are heavily contaminated, an antiseptic hand rub using an alcohol-based rinse can prevent pathogen transmission more effectively than can handwashing with plain soap and water.

Alcohol-based products are more effective for standard handwashing or hand antisepsis by HCWs than soap or antimicrobial soaps (Table 3) (*25,53,61,93,106–112,119,143–152*). In all but two of the trials that compared alcohol-based solutions with antimicrobial soaps or detergents, alcohol reduced bacterial counts on hands more than washing hands with soaps or detergents containing hexachlorophene, povidone-iodine, 4% chlorhexidine, or triclosan. In studies examining antimicrobial-resistant organisms, alcohol-based products reduced the number of multidrug-resistant pathogens recovered from the hands of HCWs more effectively than did handwashing with soap and water (*153–155*).

Alcohols are effective for preoperative cleaning of the hands of surgical personnel (*1,101,104,113–119,135,143,147,156–159*) (Tables 4 and 5). In multiple studies, bacterial counts on the hands were determined immediately after using the product and again 1–3 hours later; the delayed testing was performed to determine if regrowth of bacteria on the hands is inhibited during operative procedures. Alcohol-based solutions were more effective than washing hands with plain soap in all studies, and they reduced bacterial counts on the hands more than antimicrobial soaps or detergents in the majority of experiments (*101,104,113–119,135,143,147,157–159*). In addition, the majority of alcohol-based preparations were more effective than povidone-iodine or chlorhexidine.

The efficacy of alcohol-based hand-hygiene products is affected by several factors, including the type of alcohol used, concentration of alcohol, contact time, volume of alcohol used, and whether the hands are wet when the alcohol is applied. Applying small volumes (i.e., 0.2–0.5 mL) of alcohol to the hands is not more effective than washing hands with plain soap and water (*63,64*). One study documented that 1 mL of alcohol was substantially less effective than 3 mL (*91*). The ideal volume of product to apply to the hands is not known

TABLE 3. Studies comparing the relative efficacy (based on log_{10} reductions achieved) of plain soap or antimicrobial soaps versus alcohol-based antiseptics in reducing counts of viable bacteria on hands

Ref. no.	Year	Skin contamination	Assay method	Time (sec)	Relative efficacy
(*143*)	1965	Existing hand flora	Finger-tip agar culture	60	Plain soap < HCP < 50% EA foam
(*119*)	1975	Existing hand flora	Hand-rub broth culture	—	Plain soap < 95% EA
(*106*)	1978	Artificial contamination	Finger-tip broth culture	30	Plain soap < 4% CHG < P-I < 70% EA = alc. CHG
(*144*)	1978	Artificial contamination	Finger-tip broth culture	30	Plain soap < 4% CHG < 70% EA
(*107*)	1979	Existing hand flora	Hand-rub broth culture	120	Plain soap < 0.5% aq. CHG < 70% EA < 4% CHG < alc.CHG
(*145*)	1980	Artificial contamination	Finger-tip broth culture	60–120	4% CHG < P-I < 60% IPA
(*53*)	1980	Artificial contamination	Finger-tip broth culture	15	Plain soap < 3% HCP < P-I < 4% CHG < 70% EA
(*108*)	1982	Artificial contamination	Glove juice test	15	P-I < alc. CHG
(*109*)	1983	Artificial contamination	Finger-tip broth culture	120	0.3–2% triclosan = 60% IPA = alc. CHG < alc. triclosan
(*146*)	1984	Artificial contamination	Finger-tip agar culture	60	Phenolic < 4% CHG < P-I < EA < IPA < n-P
(*147*)	1985	Existing hand flora	Finger-tip agar culture	60	Plain soap < 70% EA < 95% EA
(*110*)	1986	Artificial contamination	Finger-tip broth culture	60	Phenolic = P-I < alc. CHG < n-P
(*93*)	1986	Existing hand flora	Sterile-broth bag technique	15	Plain soap < IPA < 4% CHG = IPA-E = alc. CHG
(*61*)	1988	Artificial contamination	Finger-tip broth culture	30	Plain soap < triclosan < P-I < IPA < alc. CHG < n-P
(*25*)	1991	Patient contact	Glove-juice test	15	Plain soap < IPA-E
(*148*)	1991	Existing hand flora	Agar-plate/image analysis	30	Plain soap < 1% triclosan < P-I < 4% CHG < IPA
(*111*)	1992	Artificial contamination	Finger-tip agar culture	60	Plain soap < IPA < EA < alc. CHG
(*149*)	1992	Artificial contamination	Finger-tip broth culture	60	Plain soap < 60% n-P
(*112*)	1994	Existing hand flora	Agar-plate/image analysis	30	Plain soap < alc. CHG
(*150*)	1999	Existing hand flora	Agar-plate culture	N.S.	Plain soap < commercial alcohol mixture
(*151*)	1999	Artificial contamination	Glove-juice test	20	Plain soap < 0.6% PCMX < 65% EA
(*152*)	1999	Artificial contamination	Finger-tip broth culture	30	4% CHG < plain soap < P-I < 70% EA

Note: Existing hand flora = without artificially contaminatiing hands with bacteria, alc. CHG = alcoholic chlorhexidine gluconate, aq. CHG = aqueous chlorhexidine gluconate, 4% CHG = chlorhexidine gluconate detergent, EA = ethanol, HCP = hexachlorophene soap/detergent, IPA = isopropanol, IPA-E = isopropanol + emollients, n-P = n-propanol, PCMX = chloroxylenol detergent, P-I = povidone-iodine detergent, and N.S. = not stated.

TABLE 4. Studies comparing the relative efficacy of plain soap or antimicrobial soap versus alcohol-containing products in reducing counts of bacteria recovered from hands immediately after use of products for pre-operative cleansing of hands

Ref. no.	Year	Assay method	Relative efficacy
(*143*)	1965	Finger-tip agar culture	HCP < 50% EA foam + QAC
(*157*)	1969	Finger-tip agar culture	HCP < P-I < 50% EA foam + QAC
(*101*)	1973	Finger-tip agar culture	HCP soap < EA foam + 0.23% HCP
(*135*)	1974	Broth culture	Plain soap < 0.5% CHG < 4% CHG < alc. CHG
(*119*)	1975	Hand-broth test	Plain soap < 0.5% CHG < 4% CHG < alc. CHG
(*118*)	1976	Glove-juice test	0.5% CHG < 4% CHG < alc. CHG
(*114*)	1977	Glove-juice test	P-I < CHG < alc. CHG
(*117*)	1978	Finger-tip agar culture	P-I = 46% EA + 0.23% HCP
(*113*)	1979	Broth culture of hands	Plain soap < P-I < alc. CHG < alc. P-I
(*116*)	1979	Glove-juice test	70% IPA = alc. CHG
(*147*)	1985	Finger-tip agar culture	Plain soap < 70% - 90% EA
(*115*)	1990	Glove-juice test, modified	Plain soap < triclosan < CHG < P-I < alc. CHG
(*104*)	1991	Glove-juice test	Plain soap < 2% triclosan < P-I < 70% IPA
(*158*)	1998	Finger-tip broth culture	70% IPA < 90% IPA = 60% n-P
(*159*)	1998	Glove-juice test	P-I < CHG < 70% EA

Note: QAC = quaternary ammonium compound, alc. CHG = alcoholic chlorhexidine gluconate, CHG = chlorhexidine gluconate detergent, EA = ethanol, HCP = hexachlorophene detergent, IPA = isopropanol, and P-I = povidone-iodine detergent.

TABLE 5. Efficacy of surgical hand-rub solutions in reducing the release of resident skin flora from clean hands

Study	Rub	Concentration* (%)	Time (min)	Mean log reduction	
				Immediate	Sustained (3 hr)
1	n-Propanol	60	5	2.9†	1.6†
2			5	2.7†	NA
3			5	2.5†	1.8†
4			5	2.3†	1.6†
5			3	2.9§	NA
4			3	2.0†	1.0†
4			1	1.1†	0.5†
6	Isopropanol	90	3	2.4§	1.4§
6		80	3	2.3§	1.2§
7		70	5	2.4†	2.1†
4			5	2.1†	1.0†
6			3	2.0§	0.7§
5			3	1.7[c]	NA
4			3	1.5†	0.8†
8			2	1.2	0.8
4			1	0.7†	0.2
9			1	0.8	NA
10		60	5	1.7	1.0
7	Isopropanol + chlorhexidine gluc. (w/v)	70 + 0.5	5	2.5†	2.7†
8			2	1.0	1.5
11	Ethanol	95	2	2.1	NA
5		85	3	2.4§	NA
12		80	2	1.5	NA
8		70	2	1.0	0.6
13	Ethanol + chlorhexidine gluc. (w/v)	95 + 0.5	2	1.7	NA
14		77 + 0.5	5	2.0	1.5¶
8		70 + 0.5	2	0.7	1.4
8	Chlorhexidine gluc. (aq. Sol., w/v)	0.5	2	0.4	1.2
15	Povidone-iodine (aq. Sol., w/v)	1.0	5	1.9†	0.8†
16	Peracetic acid (w/v)	0.5	5	1.9	NA

Note: NA = not available.

Source: Rotter M. Hand washing and hand disinfection [Chapter 87]. In: Mayhall CG, ed. Hospital epidemiology and infection control. 2nd ed. Philadelphia, PA: Lippincott Williams & Wilkins, 1999. Table 5 is copyrighted by Lippincott Williams & Wilkins; it is reprinted here with their permission and permission from Manfred Rotler, M.D., Professor of Hygiene and Microbiology, Klinisches Institute für Hygiene der Universitat Wien, Germany.

* Volume/volume unless otherwise stated.

† Tested according to Deutsche Gesellschaft fur Hygiene, and Mikrobiologic (DGHM)-German Society of Hygiene and Microbiology method.

§ Tested according to European Standard prEN.

¶ After 4 hours.

and may vary for different formulations. However, if hands feel dry after rubbing hands together for 10–15 seconds, an insufficient volume of product likely was applied. Because alcohol-impregnated towelettes contain a limited amount of alcohol, their effectiveness is comparable to that of soap and water (*63,160,161*).

Alcohol-based hand rubs intended for use in hospitals are available as low viscosity rinses, gels, and foams. Limited data are available regarding the relative efficacy of various formulations. One field trial demonstrated that an ethanol gel was slightly more effective than a comparable ethanol solution at reducing bacterial counts on the hands of HCWs (*162*). However, a more recent study indicated that rinses reduced bacterial counts on the hands more than the gels tested (*80*). Further studies are warranted to determine the relative efficacy of alcohol-based rinses and gels in reducing transmission of health-care–associated pathogens.

Frequent use of alcohol-based formulations for hand antisepsis can cause drying of the skin unless emollients, humectants, or other skin-conditioning agents are added to the formulations. The drying effect of alcohol can be reduced or eliminated by adding 1%–3% glycerol or other skin-conditioning agents (*90,93,100,101,106,135,143,163,164*). Moreover, in several recent prospective trials, alcohol-based rinses or gels containing emollients caused substantially less skin irritation and dryness than the soaps or antimicrobial detergents tested (*96,98,165,166*). These studies, which were conducted in clinical settings, used various subjective and objective methods for assessing skin irritation and dryness. Further studies are warranted to establish whether products with different formulations yield similar results.

Even well-tolerated alcohol hand rubs containing emollients may cause a transient stinging sensation at the site of any broken skin (e.g., cuts and abrasions). Alcohol-based hand-rub preparations with strong fragrances may be poorly tolerated by HCWs with respiratory allergies. Allergic contact dermatitis or contact urticaria syndrome caused by hypersensitivity to alcohol or to various additives present in certain alcohol hand rubs occurs only rarely (*167,168*).

Alcohols are flammable. Flash points of alcohol-based hand rubs range from 21°C to 24°C, depending on the type and concentration of alcohol present (*169*). As a result, alcohol-based hand rubs should be stored away from high temperatures or flames in accordance with National Fire Protection Agency recommendations. In Europe, where alcohol-based hand rubs have been used extensively for years, the incidence of fires associated with such products has been low (*169*). One recent U.S. report described a flash fire that occurred as a result of an unusual series of events, which included an HCW applying an alcohol gel to her hands, immediately removing a polyester isolation gown, and then touching a metal door before the alcohol had evaporated (*170*). Removing the polyester gown created a substantial amount of static electricity that generated an audible static spark when the HCW touched the metal door, igniting the unevaporated alcohol on her hands (*170*). This incident emphasizes the need to rub hands together after application of alcohol-based products until all the alcohol has evaporated.

Because alcohols are volatile, containers should be designed to minimize evaporation. Contamination of alcohol-based solutions has seldom been reported. One report documented a cluster of pseudoinfections caused by contamination of ethyl alcohol by *Bacillus cereus* spores (*171*).

Chlorhexidine

Chlorhexidine gluconate, a cationic bisbiguanide, was developed in England in the early 1950s and was introduced into the United States in the 1970s (*8,172*). Chlorhexidine base is only minimally soluble in water, but the digluconate form is water-soluble. The antimicrobial activity of chlorhexidine is likely attributable to attachment to, and subsequent disruption of, cytoplasmic membranes, resulting in precipitation of cellular contents (*1,8*). Chlorhexidine's immediate antimicrobial activity occurs more slowly than that of alcohols. Chlorhexidine has good activity against gram-positive bacteria, somewhat less activity against gram-negative bacteria and fungi, and only minimal activity against tubercle bacilli (*1,8,172*). Chlorhexidine is not sporicidal (*1,172*). It has in vitro activity against enveloped viruses (e.g., herpes simplex virus, HIV, cytomegalovirus, influenza, and RSV) but substantially less activity against nonenveloped viruses (e.g., rotavirus, adenovirus, and enteroviruses) (*130,131,173*). The antimicrobial activity of chlorhexidine is only minimally affected by the presence of organic material, including blood. Because chlorhexidine is a cationic molecule, its activity can be reduced by natural soaps, various inorganic anions, nonionic surfactants, and hand creams containing anionic emulsifying agents (*8,172,174*). Chlorhexidine gluconate has been incorporated into a number of hand-hygiene preparations. Aqueous or detergent formulations containing 0.5% or 0.75% chlorhexidine are more effective than plain soap, but they are less effective than antiseptic detergent preparations containing 4% chlorhexidine gluconate (*135,175*). Preparations with 2% chlorhexidine gluconate are slightly less effective than those containing 4% chlorhexidine (*176*).

Chlorhexidine has substantial residual activity (*106,114–116,118,135,146,175*). Addition of low concentrations (0.5%–1.0%) of chlorhexidine to alcohol-based preparations results in greater residual activity than alcohol alone (*116,135*). When used as recommended, chlorhexidine has a good safety

record (*172*). Minimal, if any, absorption of the compound occurs through the skin. Care must be taken to avoid contact with the eyes when using preparations with ≥1% chlorhexidine, because the agent can cause conjunctivitis and severe corneal damage. Ototoxicity precludes its use in surgery involving the inner or middle ear. Direct contact with brain tissue and the meninges should be avoided. The frequency of skin irritation is concentration-dependent, with products containing 4% most likely to cause dermatitis when used frequently for antiseptic handwashing (*177*); allergic reactions to chlorhexidine gluconate are uncommon (*118,172*). Occasional outbreaks of nosocomial infections have been traced to contaminated solutions of chlorhexidine (*178–181*).

Chloroxylenol

Chloroxylenol, also known as parachlorometaxylenol (PCMX), is a halogen-substituted phenolic compound that has been used as a preservative in cosmetics and other products and as an active agent in antimicrobial soaps. It was developed in Europe in the late 1920s and has been used in the United States since the 1950s (*182*).

The antimicrobial activity of PCMX likely is attributable to inactivation of bacterial enzymes and alteration of cell walls (*1*). It has good in vitro activity against gram-positive organisms and fair activity against gram-negative bacteria, mycobacteria, and certain viruses (*1,7,182*). PCMX is less active against *P. aeruginosa*, but addition of ethylenediaminetetraacetic acid (EDTA) increases its activity against *Pseudomonas* spp. and other pathogens.

A limited number of articles focusing on the efficacy of PCMX-containing preparations intended for use by HCWs have been published in the last 25 years, and the results of studies have sometimes been contradictory. For example, in studies in which antiseptics were applied to abdominal skin, PCMX had the weakest immediate and residual activity of any of the agents studied (*183*). However, when 30-second handwashes were performed using 0.6% PCMX, 2% chlorhexidine gluconate, or 0.3% triclosan, the immediate effect of PCMX was similar to that of the other agents. When used 18 times per day for 5 consecutive days, PCMX had less cumulative activity than did chlorhexidine gluconate (*184*). When PCMX was used as a surgical scrub, one report indicated that 3% PCMX had immediate and residual activity comparable to 4% chlorhexidine gluconate (*185*), whereas two other studies demonstrated that the immediate and residual activity of PCMX was inferior to both chlorhexidine gluconate and povidone-iodine (*176,186*). The disparity between published studies may be associated with the various concentrations of PCMX included in the preparations evaluated and with other aspects of the formulations tested, including the presence or absence of EDTA (*7,182*). PCMX is not as rapidly active as chlorhexidine gluconate or iodophors, and its residual activity is less pronounced than that observed with chlorhexidine gluconate (*7,182*). In 1994, FDA TFM tentatively classified PCMX as a Category IIISE active agent (i.e., insufficient data are available to classify this agent as safe and effective) (*19*). Further evaluation of this agent by the FDA is ongoing.

The antimicrobial activity of PCMX is minimally affected by the presence of organic matter, but it is neutralized by nonionic surfactants. PCMX, which is absorbed through the skin (*7,182*), is usually well-tolerated, and allergic reactions associated with its use are uncommon. PCMX is available in concentrations of 0.3%–3.75%. In-use contamination of a PCMX-containing preparation has been reported (*187*).

Hexachlorophene

Hexachlorophene is a bisphenol composed of two phenolic groups and three chlorine moieties. In the 1950s and early 1960s, emulsions containing 3% hexachlorophene were widely used for hygienic handwashing, as surgical scrubs, and for routine bathing of infants in hospital nurseries. The antimicrobial activity of hexachlorophene results from its ability to inactivate essential enzyme systems in microorganisms. Hexachlorophene is bacteriostatic, with good activity against *S. aureus* and relatively weak activity against gram-negative bacteria, fungi, and mycobacteria (*7*).

Studies of hexachlorophene as a hygienic handwash and surgical scrub demonstrated only modest efficacy after a single handwash (*53,143,188*). Hexachlorophene has residual activity for several hours after use and gradually reduces bacterial counts on hands after multiple uses (i.e., it has a cumulative effect) (*1,101,188,189*). With repeated use of 3% hexachlorophene preparations, the drug is absorbed through the skin. Infants bathed with hexachlorophene and personnel regularly using a 3% hexachlorophene preparation for handwashing have blood levels of 0.1–0.6 ppm hexachlorophene (*190*). In the early 1970s, certain infants bathed with hexachlorophene developed neurotoxicity (vacuolar degeneration) (*191*). As a result, in 1972, the FDA warned that hexachlorophene should no longer be used routinely for bathing infants. However, after routine use of hexachlorophene for bathing infants in nurseries was discontinued, investigators noted that the incidence of health-care–associated *S. aureus* infections in hospital nurseries increased substantially (*192,193*). In several instances, the frequency of infections decreased when hexachlorophene bathing of infants was reinstituted. However, current guidelines still recommend against the routine bathing of neonates with hexachlorophene because of its potential neurotoxic effects (*194*). The agent is classified by FDA TFM as not

generally recognized as safe and effective for use as an antiseptic handwash (*19*). Hexachlorophene should not be used to bathe patients with burns or extensive areas of susceptible, sensitive skin. Soaps containing 3% hexachlorophene are available by prescription only (*7*).

Iodine and Iodophors

Iodine has been recognized as an effective antiseptic since the 1800s. However, because iodine often causes irritation and discoloring of skin, iodophors have largely replaced iodine as the active ingredient in antiseptics.

Iodine molecules rapidly penetrate the cell wall of microorganisms and inactivate cells by forming complexes with amino acids and unsaturated fatty acids, resulting in impaired protein synthesis and alteration of cell membranes (*195*). Iodophors are composed of elemental iodine, iodide or triiodide, and a polymer carrier (i.e., the complexing agent) of high molecular weight. The amount of molecular iodine present (so-called "free" iodine) determines the level of antimicrobial activity of iodophors. "Available" iodine refers to the total amount of iodine that can be titrated with sodium thiosulfate (*196*). Typical 10% povidone-iodine formulations contain 1% available iodine and yield free iodine concentrations of 1 ppm (*196*). Combining iodine with various polymers increases the solubility of iodine, promotes sustained release of iodine, and reduces skin irritation. The most common polymers incorporated into iodophors are polyvinyl pyrrolidone (i.e., povidone) and ethoxylated nonionic detergents (i.e., poloxamers) (*195,196*). The antimicrobial activity of iodophors also can be affected by pH, temperature, exposure time, concentration of total available iodine, and the amount and type of organic and inorganic compounds present (e.g., alcohols and detergents).

Iodine and iodophors have bactericidal activity against gram-positive, gram-negative, and certain spore-forming bacteria (e.g., clostridia and *Bacillus* spp.) and are active against mycobacteria, viruses, and fungi (*8,195,197–200*). However, in concentrations used in antiseptics, iodophors are not usually sporicidal (*201*). In vivo studies have demonstrated that iodophors reduce the number of viable organisms that are recovered from the hands of personnel (*113,145,148,152,155*). Povidone-iodine 5%–10% has been tentatively classified by FDA TFM as a Category I agent (i.e., a safe and effective agent for use as an antiseptic handwash and an HCW handwash) (*19*). The extent to which iodophors exhibit persistent antimicrobial activity after they have been washed off the skin is unclear. In one study, persistent activity was noted for 6 hours (*176*); however, several other studies demonstrated persistent activity for only 30–60 minutes after washing hands with an iodophor (*61,117,202*). In studies in which bacterial counts were obtained after gloves were worn for 1–4 hours after washing, iodophors have demonstrated poor persistent activity (*1,104,115,189,203–208*). The in vivo antimicrobial activity of iodophors is substantially reduced in the presence of organic substances (e.g., blood or sputum) (*8*).

The majority of iodophor preparations used for hand hygiene contain 7.5%–10% povidone-iodine. Formulations with lower concentrations also have good antimicrobial activity because dilution can increase free iodine concentrations (*209*). However, as the amount of free iodine increases, the degree of skin irritation also may increase (*209*). Iodophors cause less skin irritation and fewer allergic reactions than iodine, but more irritant contact dermatitis than other antiseptics commonly used for hand hygiene (*92*). Occasionally, iodophor antiseptics have become contaminated with gram-negative bacilli as a result of poor manufacturing processes and have caused outbreaks or pseudo-outbreaks of infection (*196*).

Quaternary Ammonium Compounds

Quaternary ammonium compounds are composed of a nitrogen atom linked directly to four alkyl groups, which may vary in their structure and complexity (*210*). Of this large group of compounds, alkyl benzalkonium chlorides are the most widely used as antiseptics. Other compounds that have been used as antiseptics include benzethonium chloride, cetrimide, and cetylpyridium chloride (*1*). The antimicrobial activity of these compounds was first studied in the early 1900s, and a quaternary ammonium compound for preoperative cleaning of surgeons' hands was used as early as 1935 (*210*). The antimicrobial activity of this group of compounds likely is attributable to adsorption to the cytoplasmic membrane, with subsequent leakage of low molecular weight cytoplasmic constituents (*210*).

Quaternary ammonium compounds are primarily bacteriostatic and fungistatic, although they are microbicidal against certain organisms at high concentrations (*1*); they are more active against gram-positive bacteria than against gram-negative bacilli. Quaternary ammonium compounds have relatively weak activity against mycobacteria and fungi and have greater activity against lipophilic viruses. Their antimicrobial activity is adversely affected by the presence of organic material, and they are not compatible with anionic detergents (*1,210*). In 1994, FDA TFM tentatively classified benzalkonium chloride and benzethonium chloride as Category IIISE active agents (i.e., insufficient data exists to classify them as safe and effective for use as an antiseptic handwash) (*19*). Further evaluation of these agents by FDA is in progress.

Quaternary ammonium compounds are usually well tolerated. However, because of weak activity against

gram-negative bacteria, benzalkonium chloride is prone to contamination by these organisms. Several outbreaks of infection or pseudoinfection have been traced to quaternary ammonium compounds contaminated with gram-negative bacilli (*211–213*). For this reason, in the United States, these compounds have been seldom used for hand antisepsis during the last 15–20 years. However, newer handwashing products containing benzalkonium chloride or benzethonium chloride have recently been introduced for use by HCWs. A recent study of surgical intensive-care unit personnel found that cleaning hands with antimicrobial wipes containing a quaternary ammonium compound was about as effective as using plain soap and water for handwashing; both were less effective than decontaminating hands with an alcohol-based hand rub (*214*). One laboratory-based study reported that an alcohol-free hand-rub product containing a quaternary ammonium compound was efficacious in reducing microbial counts on the hands of volunteers (*215*). Further studies of such products are needed to determine if newer formulations are effective in health-care settings.

Triclosan

Triclosan (chemical name: 2,4,4' –trichloro-2'-hydroxydiphenyl ether) is a nonionic, colorless substance that was developed in the 1960s. It has been incorporated into soaps for use by HCWs and the public and into other consumer products. Concentrations of 0.2%–2% have antimicrobial activity. Triclosan enters bacterial cells and affects the cytoplasmic membrane and synthesis of RNA, fatty acids, and proteins (*216*). Recent studies indicate this agent's antibacterial activity is attributable to binding to the active site of enoyl-acyl carrier protein reductase (*217,218*).

Triclosan has a broad range of antimicrobial activity, but it is often bacteriostatic (*1*). Minimum inhibitory concentrations (MICs) range from 0.1 to 10 ug/mL, whereas minimum bactericidal concentrations are 25–500 ug/mL. Triclosan's activity against gram-positive organisms (including MRSA) is greater than against gram-negative bacilli, particularly *P. aeruginosa* (*1,216*). The agent possesses reasonable activity against mycobacterial and *Candida* spp., but it has limited activity against filamentous fungi. Triclosan (0.1%) reduces bacterial counts on hands by 2.8 $\log_{10}$ after a 1-minute hygienic handwash (*1*). In several studies, log reductions have been lower after triclosan is used than when chlorhexidine, iodophors, or alcohol-based products are applied (*1,61,149,184,219*). In 1994, FDA TFM tentatively classified triclosan ≤1.0% as a Category IIISE active agent (i.e., insufficient data exist to classify this agent as safe and effective for use as an antiseptic handwash) (*19*). Further evaluation of this agent by the FDA is underway. Like chlorhexidine, triclosan has persistent activity on the skin. Its activity in hand-care products is affected by pH, the presence of surfactants, emollients, or humectants and by the ionic nature of the particular formulation (*1,216*). Triclosan's activity is not substantially affected by organic matter, but it can be inhibited by sequestration of the agent in micelle structures formed by surfactants present in certain formulations. The majority of formulations containing <2% triclosan are well-tolerated and seldom cause allergic reactions. Certain reports indicate that providing hospital personnel with a triclosan-containing preparation for hand antisepsis has led to decreased MRSA infections (*72,73*). Triclosan's lack of potent activity against gram-negative bacilli has resulted in occasional reports of contamination (*220*).

Other Agents

Approximately 150 years after puerperal-fever–related maternal mortality rates were demonstrated by Semmelweis to be reduced by use of a hypochlorite hand rinse, the efficacy of rubbing hands for 30 seconds with an aqueous hypochlorite solution was studied once again (*221*). The solution was demonstrated to be no more effective than distilled water. The regimen used by Semmelweis, which called for rubbing hands with a 4% [w/w] hypochlorite solution until the hands were slippery (approximately 5 minutes), has been revisited by other researchers (*222*). This more current study indicated that the regimen was 30 times more effective than a 1-minute rub using 60% isopropanol. However, because hypochlorite solutions are often irritating to the skin when used repeatedly and have a strong odor, they are seldom used for hand hygiene.

Certain other agents are being evaluated by FDA for use in health-care-related antiseptics (*19*). However, the efficacy of these agents has not been evaluated adequately for use in handwashing preparations intended for use by HCWs. Further evaluation of these agents is warranted. Products that use different concentrations of traditional antiseptics (e.g., low concentrations of iodophor) or contain novel compounds with antiseptic properties are likely to be introduced for use by HCWs. For example, preliminary studies have demonstrated that adding silver-containing polymers to an ethanol carrier (i.e., Surfacine®) results in a preparation that has persistent antimicrobial activity on animal and human skin (*223*). New compounds with good in vitro activity must be tested in vivo to determine their abilities to reduce transient and resident skin flora on the hands of HCWs.

Activity of Antiseptic Agents Against Spore-Forming Bacteria

The widespread prevalence of health-care–associated diarrhea caused by *Clostridium difficile* and the recent occurrence

in the United States of human *Bacillus anthracis* infections associated with contaminated items sent through the postal system has raised concern regarding the activity of antiseptic agents against spore-forming bacteria. None of the agents (including alcohols, chlorhexidine, hexachlorophene, iodophors, PCMX, and triclosan) used in antiseptic handwash or antiseptic hand-rub preparations are reliably sporicidal against *Clostridium* spp. or *Bacillus* spp. (*120,172,224,225*). Washing hands with non-antimicrobial or antimicrobial soap and water may help to physically remove spores from the surface of contaminated hands. HCWs should be encouraged to wear gloves when caring for patients with *C. difficile*-associated diarrhea (*226*). After gloves are removed, hands should be washed with a non-antimicrobial or an antimicrobial soap and water or disinfected with an alcohol-based hand rub. During outbreaks of *C. difficile*-related infections, washing hands with a non-antimicrobial or antimicrobial soap and water after removing gloves is prudent. HCWs with suspected or documented exposure to *B. anthracis*-contaminated items also should be encouraged to wash their hands with a non-antimicrobial or antimicrobial soap and water.

Reduced Susceptibility of Bacteria to Antiseptics

Reduced susceptibility of bacteria to antiseptic agents can either be an intrinsic characteristic of a species or can be an acquired trait (*227*). Several reports have described strains of bacteria that appear to have acquired reduced susceptibility (when defined by MICs established in vitro) to certain antiseptics (e.g., chlorhexidine, quaternary ammonium compounds, and triclosan) (*227–230*). However, because the antiseptic concentrations that are actually used by HCWs are often substantially higher than the MICs of strains with reduced antiseptic susceptibility, the clinical relevance of the in vitro findings is questionable. For example, certain strains of MRSA have chlorhexidine and quaternary ammonium compound MICs that are several-fold higher than methicillin-susceptible strains, and certain strains of *S. aureus* have elevated MICs to triclosan (*227,228*). However, such strains were readily inhibited by the concentrations of these antiseptics that are actually used by practicing HCWs (*227,228*). The description of a triclosan-resistant bacterial enzyme has raised the question of whether resistance to this agent may develop more readily than to other antiseptic agents (*218*). In addition, exposing *Pseudomonas* strains containing the MexAB-OprM efflux system to triclosan may select for mutants that are resistant to multiple antibiotics, including fluoroquinolones (*230*). Further studies are needed to determine whether reduced susceptibility to antiseptic agents is of epidemiologic significance and whether resistance to antiseptics has any influence on the prevalence of antibiotic-resistant strains (*227*).

Surgical Hand Antisepsis

Since the late 1800s, when Lister promoted the application of carbolic acid to the hands of surgeons before procedures, preoperative cleansing of hands and forearms with an antiseptic agent has been an accepted practice (*231*). Although no randomized, controlled trials have been conducted to indicate that surgical-site infection rates are substantially lower when preoperative scrubbing is performed with an antiseptic agent rather than a non-antimicrobial soap, certain other factors provide a strong rationale for this practice. Bacteria on the hands of surgeons can cause wound infections if introduced into the operative field during surgery (*232*); rapid multiplication of bacteria occurs under surgical gloves if hands are washed with a non-antimicrobial soap. However, bacterial growth is slowed after preoperative scrubbing with an antiseptic agent (*14,233*). Reducing resident skin flora on the hands of the surgical team for the duration of a procedure reduces the risk of bacteria being released into the surgical field if gloves become punctured or torn during surgery (*1,156,169*). Finally, at least one outbreak of surgical-site infections occurred when surgeons who normally used an antiseptic surgical scrub preparation began using a non-antimicrobial product (*234*).

Antiseptic preparations intended for use as surgical hand scrubs are evaluated for their ability to reduce the number of bacteria released from hands at different times, including 1) immediately after scrubbing, 2) after wearing surgical gloves for 6 hours (i.e., persistent activity), and 3) after multiple applications over 5 days (i.e., cumulative activity). Immediate and persistent activity are considered the most important in determining the efficacy of the product. U.S. guidelines recommend that agents used for surgical hand scrubs should substantially reduce microorganisms on intact skin, contain a nonirritating antimicrobial preparation, have broad-spectrum activity, and be fast-acting and persistent (*19,235*).

Studies have demonstrated that formulations containing 60%–95% alcohol alone or 50%–95% when combined with limited amounts of a quaternary ammonium compound, hexachlorophene, or chlorhexidine gluconate, lower bacterial counts on the skin immediately postscrub more effectively than do other agents (Table 4). The next most active agents (in order of decreasing activity) are chlorhexidine gluconate, iodophors, triclosan, and plain soap (*104,119,186,188, 203,204,206,208,236*). Because studies of PCMX as a surgical scrub have yielded contradictory results, further studies are needed to establish how the efficacy of this compound compares with the other agents (*176,185,186*).

Although alcohols are not considered to have persistent antimicrobial activity, bacteria appear to reproduce slowly on the hands after a surgical scrub with alcohol, and bacterial counts on hands after wearing gloves for 1–3 hours seldom exceed baseline (i.e., prescrub) values (*1*). However, a recent study demonstrated that a formulation containing 61% ethanol alone did not achieve adequate persistent activity at 6 hours postscrub (*237*). Alcohol-based preparations containing 0.5% or 1% chlorhexidine gluconate have persistent activity that, in certain studies, has equaled or exceeded that of chlorhexidine gluconate-containing detergents (*1,118,135,237*).*

Persistent antimicrobial activity of detergent-based surgical scrub formulations is greatest for those containing 2% or 4% chlorhexidine gluconate, followed by hexachlorophene, triclosan, and iodophors (*1,102,113–115,159,189,203, 204,206–208,236*). Because hexachlorophene is absorbed into the blood after repeated use, it is seldom used as a surgical scrub.

Surgical staff have been traditionally required to scrub their hands for 10 minutes preoperatively, which frequently leads to skin damage. Several studies have demonstrated that scrubbing for 5 minutes reduces bacterial counts as effectively as a 10-minute scrub (*117,238,239*). In other studies, scrubbing for 2 or 3 minutes reduced bacterial counts to acceptable levels (*156,205,207,240,241*).

Studies have indicated that a two-stage surgical scrub using an antiseptic detergent, followed by application of an alcohol-containing preparation, is effective. For example, an initial 1- or 2-minute scrub with 4% chlorhexidine gluconate or povidone-iodine followed by application of an alcohol-based product has been as effective as a 5-minute scrub with an antiseptic detergent (*114,242*).

Surgical hand-antisepsis protocols have required personnel to scrub with a brush. But this practice can damage the skin of personnel and result in increased shedding of bacteria from the hands (*95,243*). Scrubbing with a disposable sponge or combination sponge-brush has reduced bacterial counts on the hands as effectively as scrubbing with a brush (*244–246*). However, several studies indicate that neither a brush nor a sponge is necessary to reduce bacterial counts on the hands of surgical personnel to acceptable levels, especially when alcohol-based products are used (*102,117,159,165,233,237, 247,248*). Several of these studies performed cultures immediately or at 45–60 minutes postscrub (*102,117, 233,247,248*), whereas in other studies, cultures were obtained 3 and 6 hours postscrub (*159,237*). For example, a recent laboratory-based study using volunteers demonstrated that brushless application of a preparation containing 1% chlorhexidine gluconate plus 61% ethanol yielded lower bacterial counts on the hands of participants than using a sponge/brush to apply a 4% chlorhexidine-containing detergent preparation (*237*).

Relative Efficacy of Plain Soap, Antiseptic Soap/Detergent, and Alcohols

Comparing studies related to the in vivo efficacy of plain soap, antimicrobial soaps, and alcohol-based hand rubs is problematic, because certain studies express efficacy as the percentage reduction in bacterial counts achieved, whereas others give $\log_{10}$ reductions in counts achieved. However, summarizing the relative efficacy of agents tested in each study can provide an overview of the in vivo activity of various formulations intended for handwashing, hygienic handwash, antiseptic hand rub, or surgical hand antisepsis (Tables 2–4).

Irritant Contact Dermatitis Resulting from Hand-Hygiene Measures

Frequency and Pathophysiology of Irritant Contact Dermatitis

In certain surveys, approximately 25% of nurses report symptoms or signs of dermatitis involving their hands, and as many as 85% give a history of having skin problems (*249*). Frequent and repeated use of hand-hygiene products, particularly soaps and other detergents, is a primary cause of chronic irritant contact dermatitis among HCWs (*250*). The potential of detergents to cause skin irritation can vary considerably and can be ameliorated by the addition of emollients and humectants. Irritation associated with antimicrobial soaps may be caused by the antimicrobial agent or by other ingredients of the formulation. Affected persons often complain of a feeling of dryness or burning; skin that feels "rough;" and erythema, scaling, or fissures. Detergents damage the skin by causing denaturation of stratum corneum proteins, changes in intercellular lipids (either depletion or reorganization of lipid moieties), decreased corneocyte cohesion, and decreased stratum corneum water-binding capacity (*250,251*). Damage

* In a recent randomized clinical trial, surgical site infection rates were monitored among patients who were operated on by surgical personnel who cleaned their hands preoperatively either by performing a traditional 5-minute surgical hand scrub using 4% povidone-iodine or 4% antisepsis antimicrobial soap, or by washing their hands for 1 minute with a non-antimicrobial soap followed by a 5-minute hand-rubbing technique using an alcohol-based hand rinse containing 0.2% mecetronium etilsulfate. The incidence of surgical site infections was virtually identical in the two groups of patients. (**Source:** Parienti JJ, Thibon P, Heller R, et al. for Members of the Antisepsie Chirurgicale des Mains Study Group. Hand-rubbing with an aqueous alcoholic solution vs traditional surgical hand-scrubbing and 30-day surgical site infection rates: a randomized equivalence study. JAMA 2002;288:722–7).

to the skin also changes skin flora, resulting in more frequent colonization by staphylococci and gram-negative bacilli (*17,90*). Although alcohols are among the safest antiseptics available, they can cause dryness and irritation of the skin (*1,252*). Ethanol is usually less irritating than n-propanol or isopropanol (*252*).

Irritant contact dermatitis is more commonly reported with iodophors (*92*). Other antiseptic agents that can cause irritant contact dermatitis (in order of decreasing frequency) include chlorhexidine, PCMX, triclosan, and alcohol-based products. Skin that is damaged by repeated exposure to detergents may be more susceptible to irritation by alcohol-based preparations (*253*). The irritancy potential of commercially prepared hand-hygiene products, which is often determined by measuring transepidermal water loss, may be available from the manufacturer. Other factors that can contribute to dermatitis associated with frequent handwashing include using hot water for handwashing, low relative humidity (most common in winter months), failure to use supplementary hand lotion or cream, and the quality of paper towels (*254,255*). Shear forces associated with wearing or removing gloves and allergy to latex proteins may also contribute to dermatitis of the hands of HCWs.

Allergic Contact Dermatitis Associated with Hand-Hygiene Products

Allergic reactions to products applied to the skin (i.e., contact allergies) may present as delayed type reactions (i.e., allergic contact dermatitis) or less commonly as immediate reactions (i.e., contact urticaria). The most common causes of contact allergies are fragrances and preservatives; emulsifiers are less common causes (*256–259*). Liquid soaps, hand lotions or creams, and "udder ointments" may contain ingredients that cause contact allergies among HCWs (*257,258*).

Allergic reactions to antiseptic agents, including quaternary ammonium compounds, iodine or iodophors, chlorhexidine, triclosan, PCMX, and alcohols have been reported (*118,167,172,256,260–265*). Allergic contact dermatitis associated with alcohol-based hand rubs is uncommon. Surveillance at a large hospital in Switzerland, where a commercial alcohol hand rub has been used for >10 years, failed to identify a single case of documented allergy to the product (*169*). In late 2001, a Freedom of Information Request for data in the FDA's Adverse Event Reporting System regarding adverse reactions to popular alcohol hand rubs in the United States yielded only one reported case of an erythematous rash reaction attributed to such a product (John M. Boyce, M.D., Hospital of St. Raphael, New Haven, Connecticut, personal communication, 2001). However, with increasing use of such products by HCWs, true allergic reactions to such products likely will be encountered.

Allergic reactions to alcohol-based products may represent true allergy to alcohol, allergy to an impurity or aldehyde metabolite, or allergy to another constituent of the product (*167*). Allergic contact dermatitis or immediate contact urticarial reactions may be caused by ethanol or isopropanol (*167*). Allergic reactions can be caused by compounds that may be present as inactive ingredients in alcohol-based hand rubs, including fragrances, benzyl alcohol, stearyl or isostearyl alcohol, phenoxyethanol, myristyl alcohol, propylene glycol, parabens, and benzalkonium chloride (*167,256,266–270*).

Proposed Methods for Reducing Adverse Effects of Agents

Potential strategies for minimizing hand-hygiene–related irritant contact dermatitis among HCWs include reducing the frequency of exposure to irritating agents (particularly anionic detergents), replacing products with high irritation potential with preparations that cause less damage to the skin, educating personnel regarding the risks of irritant contact dermatitis, and providing caregivers with moisturizing skin-care products or barrier creams (*96,98,251,271–273*). Reducing the frequency of exposure of HCWs to hand-hygiene products would prove difficult and is not desirable because of the low levels of adherence to hand-hygiene policies in the majority of institutions. Although hospitals have provided personnel with non-antimicrobial soaps in hopes of minimizing dermatitis, frequent use of such products may cause greater skin damage, dryness, and irritation than antiseptic preparations (*92,96,98*). One strategy for reducing the exposure of personnel to irritating soaps and detergents is to promote the use of alcohol-based hand rubs containing various emollients. Several recent prospective, randomized trials have demonstrated that alcohol-based hand rubs containing emollients were better tolerated by HCWs than washing hands with non-antimicrobial soaps or antimicrobial soaps (*96,98,166*). Routinely washing hands with soap and water immediately after using an alcohol hand rub may lead to dermatitis. Therefore, personnel should be reminded that it is neither necessary nor recommended to routinely wash hands after each application of an alcohol hand rub.

Hand lotions and creams often contain humectants and various fats and oils that can increase skin hydration and replace altered or depleted skin lipids that contribute to the barrier function of normal skin (*251,271*). Several controlled trials have demonstrated that regular use (e.g., twice a day) of such products can help prevent and treat irritant contact dermatitis caused by hand-hygiene products (*272,273*). In one study, frequent and scheduled use of an oil-containing lotion improved skin condition, and thus led to a 50% increase in

handwashing frequency among HCWs (273). Reports from these studies emphasize the need to educate personnel regarding the value of regular, frequent use of hand-care products.

Recently, barrier creams have been marketed for the prevention of hand-hygiene–related irritant contact dermatitis. Such products are absorbed to the superficial layers of the epidermis and are designed to form a protective layer that is not removed by standard handwashing. Two recent randomized, controlled trials that evaluated the skin condition of caregivers demonstrated that barrier creams did not yield better results than did the control lotion or vehicle used (*272,273*). As a result, whether barrier creams are effective in preventing irritant contact dermatitis among HCWs remains unknown.

In addition to evaluating the efficacy and acceptability of hand-care products, product-selection committees should inquire about the potential deleterious effects that oil-containing products may have on the integrity of rubber gloves and on the efficacy of antiseptic agents used in the facility (*8,236*).

Factors To Consider When Selecting Hand-Hygiene Products

When evaluating hand-hygiene products for potential use in health-care facilities, administrators or product-selection committees must consider factors that can affect the overall efficacy of such products, including the relative efficacy of antiseptic agents against various pathogens (Appendix) and acceptance of hand-hygiene products by personnel (*274,275*). Soap products that are not well-accepted by HCWs can be a deterrent to frequent handwashing (*276*). Characteristics of a product (either soap or alcohol-based hand rub) that can affect acceptance by personnel include its smell, consistency (i.e., "feel"), and color (*92,277,278*). For soaps, ease of lathering also may affect user preference.

Because HCWs may wash their hands from a limited number of times per shift to as many as 30 times per shift, the tendency of products to cause skin irritation and dryness is a substantial factor that influences acceptance, and ultimate usage (*61,98,274,275,277,279*). For example, concern regarding the drying effects of alcohol was a primary cause of poor acceptance of alcohol-based hand-hygiene products in hospitals in the United States (*5,143*). However, several studies have demonstrated that alcohol-based hand rubs containing emollients are acceptable to HCWs (*90,93,98,100,101,106, 143,163,164,166*). With alcohol-based products, the time required for drying may also affect user acceptance.

Studies indicate that the frequency of handwashing or antiseptic handwashing by personnel is affected by the accessibility of hand-hygiene facilities (*280–283*). In certain health-care facilities, only one sink is available in rooms housing several patients, or sinks are located far away from the door of the room, which may discourage handwashing by personnel leaving the room. In intensive-care units, access to sinks may be blocked by bedside equipment (e.g., ventilators or intravenous infusion pumps). In contrast to sinks used for handwashing or antiseptic handwash, dispensers for alcohol-based hand rubs do not require plumbing and can be made available adjacent to each patient's bed and at many other locations in patient-care areas. Pocket carriage of alcohol-based hand-rub solutions, combined with availability of bedside dispensers, has been associated with substantial improvement in adherence to hand-hygiene protocols (*74,284*). To avoid any confusion between soap and alcohol hand rubs, alcohol hand-rub dispensers should not be placed adjacent to sinks. HCWs should be informed that washing hands with soap and water after each use of an alcohol hand rub is not necessary and is not recommended, because it may lead to dermatitis. However, because personnel feel a "build-up" of emollients on their hands after repeated use of alcohol hand gels, washing hands with soap and water after 5–10 applications of a gel has been recommended by certain manufacturers.

Automated handwashing machines have not been demonstrated to improve the quality or frequency of handwashing (*88,285*). Although technologically advanced automated handwashing devices and monitoring systems have been developed recently, only a minimal number of studies have been published that demonstrate that use of such devices results in enduring improvements in hand-hygiene adherence among HCWs. Further evaluation of automated handwashing facilities and monitoring systems is warranted.

Dispenser systems provided by manufacturers or vendors also must be considered when evaluating hand-hygiene products. Dispensers may discourage use by HCWs when they 1) become blocked or partially blocked and do not deliver the product when accessed by personnel, and 2) do not deliver the product appropriately onto the hands. In one hospital where a viscous alcohol-based hand rinse was available, only 65% of functioning dispensers delivered product onto the caregivers' hands with one press of the dispenser lever, and 9% of dispensers were totally occluded (*286*). In addition, the volume delivered was often suboptimal, and the product was sometimes squirted onto the wall instead of the caregiver's hand.

Only limited information is available regarding the cost of hand-hygiene products used in health-care facilities (*165,287*). These costs were evaluated in patient-care areas at a 450-bed community teaching hospital (*287*); the hospital spent $22,000 ($0.72 per patient-day) on 2% chlorhexidine-containing preparations, plain soap, and an alcohol hand rinse. *(287)* When

hand-hygiene supplies for clinics and nonpatient care areas were included, the total annual budget for soaps and hand antiseptic agents was $30,000 (approximately $1 per patient-day). Annual hand-hygiene product budgets at other institutions vary considerably because of differences in usage patterns and varying product prices. One researcher (*287*) determined that if non-antimicrobial liquid soap were assigned an arbitrary relative cost of 1.0, the cost per liter would be 1.7 times as much for 2% chlorhexidine gluconate detergent, 1.6–2.0 times higher for alcohol-based hand-rub products, and 4.5 times higher for an alcohol-based foam product. A recent cost comparison of surgical scrubbing with an antimicrobial soap versus brushless scrubbing with an alcohol-based hand rub revealed that costs and time required for preoperative scrubbing were less with the alcohol-based product (*165*). In a trial conducted in two critical-care units, the cost of using an alcohol hand rub was half as much as using an antimicrobial soap for handwashing ($0.025 versus $0.05 per application, respectively) (*166*).

To put expenditures for hand-hygiene products into perspective, health-care facilities should consider comparing their budget for hand-hygiene products to estimated excess hospital costs resulting from health-care–associated infections. The excess hospital costs associated with only four or five health-care–associated infections of average severity may equal the entire annual budget for hand-hygiene products used in inpatient-care areas. Just one severe surgical site infection, lower respiratory tract infection, or bloodstream infection may cost the hospital more than the entire annual budget for antiseptic agents used for hand hygiene (*287*). Two studies provided certain quantitative estimates of the benefit of hand-hygiene–promotion programs (*72,74*). One study demonstrated a cost saving of approximately $17,000 resulting from reduced use of vancomycin after the observed decrease in MRSA incidence in a 7-month period (*72*). In another study that examined both direct costs associated with the hand-hygiene promotion program (increased use of hand-rub solution and poster production) and indirect costs associated with health-care–personnel time (*74*), costs of the program were an estimated $57,000 or less per year (an average of $1.42 per patient admitted). Supplementary costs associated with the increased use of alcohol-based hand-rub solution averaged $6.07 per 100 patient-days. Based on conservative estimates of $2,100 saved per infection averted and on the assumption that only 25% of the observed reduction in the infection rate was associated with improved hand-hygiene practice, the program was substantially cost-effective. Thus, hospital administrators must consider that by purchasing more effective or more acceptable hand-hygiene products to improve hand-hygiene practices, they will avoid the occurrence of nosocomial infections; preventing only a limited number of additional health-care–associated infections per year will lead to savings that will exceed any incremental costs of improved hand-hygiene products.

Hand-Hygiene Practices Among HCWs

In observational studies conducted in hospitals, HCWs washed their hands an average of five times per shift to as many as 30 times per shift (Table 6) (*17,61,90,98,274,288*); certain nurses washed their hands ≤100 times per shift (*90*). Hospitalwide surveillance of hand hygiene reveals that the average number of handwashing opportunities varies markedly between hospital wards. For example, nurses in pediatric wards had an average of eight opportunities for hand hygiene per hour of patient care compared with an average of 20 for nurses in intensive-care units (*11*). The duration of handwashing or hygienic handwash episodes by HCWs has averaged 6.6–24.0 seconds in observational studies (Table 7) (*17,52,59,84–87,89,249,279*). In addition to washing their

TABLE 6. Handwashing frequency among health-care workers

Ref. no.	Year	Avg. no./ time period	Range	Avg. no./hr
(*61*)	1988	5/8 hour	N.S.	
(*89*)	1984	5–10/shift	N.S.	
(*96*)	2000	10/shift	N.S.	
(*273*)	2000	12–18/day	2–60	
(*98*)	2000	13–15/8 hours	5–27	1.6–1.8/hr
(*90*)	1977	20–42/8 hours	10–100	
(*391*)	2000	21/12 hours	N.S.	
(*272*)	2000	22/day	0–70	
(*88*)	1991			1.7–2.1/hr
(*17*)	1998			2.1/hr
(*279*)	1978			3/hr
(*303*)	1994			3.3/hr

Note: N.S. = Not Stated.

TABLE 7. Average duration of handwashing by health-care workers

Ref. no.	Year	Mean/median time
(*392*)	1997	4.7–5.3 seconds
(*303*)	1994	6.6 seconds
(*52*)	1974	8–9.3 seconds
(*85*)	1984	8.6 seconds
(*86*)	1994	<9 seconds
(*87*)	1994	9.5 seconds
(*88*)	1991	<10 seconds
(*294*)	1990	10 seconds
(*89*)	1984	11.6 seconds
(*300*)	1992	12.5 seconds
(*59*)	1988	15.6–24.4 seconds
(*17*)	1998	20.6 seconds
(*279*)	1978	21 seconds
(*293*)	1989	24 seconds

hands for limited time periods, personnel often fail to cover all surfaces of their hands and fingers (*288*).

Adherence of HCWs to Recommended Hand-Hygiene Practices

Observational Studies of Hand-Hygiene Adherence. Adherence of HCWs to recommended hand-hygiene procedures has been poor, with mean baseline rates of 5%–81% (overall average: 40%) (Table 8) (*71,74,86,87,276,280,281,283,285, 289–313*). The methods used for defining adherence (or nonadherence) and those used for conducting observations vary considerably among studies, and reports do not provide detailed information concerning the methods and criteria used. The majority of studies were conducted with hand-hygiene adherence as the major outcome measure, whereas a limited number measured adherence as part of a broader investigation. Several investigators reported improved adherence after implementing various interventions, but the majority of studies had short follow-up periods and did not confirm whether behavioral improvements were long-lasting. Other studies established that sustained improvements in handwashing behavior occurred during a long-term program to improve adherence to hand-hygiene policies (*74,75*).

TABLE 8. Hand-hygiene adherence by health-care workers (1981–2000)

Ref. no.	Year	Setting	Before/ after	Adherence baseline	Adherence after intervention	Invervention
(*280*)	1981	ICU	A	16%	30%	More convenient sink locations
(*289*)	1981	ICU	A	41%	—	
		ICU	A	28%	—	
(*290*)	1983	All wards	A	45%	—	
(*281*)	1986	SICU	A	51%	—	
		MICU	A	76%	—	
(*276*)	1986	ICU	A	63%	92%	Performance feedback
(*291*)	1987	PICU	A	31%	30%	Wearing overgown
(*292*)	1989	MICU	B/A	14%/28%*	73%/81%	Feedback, policy reviews, memo, and posters
		MICU	B/A	26%/23%	38%/60%	
(*293*)	1989	NICU	A/B	75%/50%	—	
(*294*)	1990	ICU	A	32%	45%	Alcohol rub introduced
(*295*)	1990	ICU	A	81%	92%	Inservices first, then group feedback
(*296*)	1990	ICU	B/A	22%	30%	
(*297*)	1991	SICU	A	51%	—	
(*298*)	1991	Pedi OPDs	B	49%	49%	Signs, feedback, and verbal reminders to physicians
(*299*)	1991	Nursery and NICU	B/A†	28%	63%	Feedback, dissemination of literature, and results of environmental cultures
(*300*)	1992	NICU/others	A	29%	—	
(*71*)	1992	ICU	N.S.	40%	—	
(*301*)	1993	ICUs	A	40%	—	
(*87*)	1994	Emergency Room	A	32%	—	
(*86*)	1994	All wards	A	32%	—	
(*285*)	1994	SICU	A	22%	38%	Automated handwashing machines available
(*302*)	1994	NICU	A	62%	60%	No gowning required
(*303*)	1994	ICU Wards	AA	30%29%	—	
(*304*)	1995	ICU Oncol Ward	A	56%	—	
(*305*)	1995	ICU	N.S.	5%	63%	Lectures, feedback, and demonstrations
(*306*)	1996	PICU	B/A	12%/11%	68%/65%	Overt observation, followed by feedback
(*307*)	1996	MICU	A	41%	58%	Routine wearing of gowns and gloves
(*308*)	1996	Emergency Dept	A	54%	64%	Signs/distributed review paper
(*309*)	1998	All wards	A	30%	—	
(*310*)	1998	Pediatric wards	B/A	52%/49%	74%/69%	Feedback, movies, posters, and brochures
(*311*)	1999	MICU	B/A	12%/55%	—	
(*74*)	2000	All wards	B/A	48%	67%	Posters, feedback, administrative support, and alcohol rub
(*312*)	2000	MICU	A	42%	61%	Alcohol hand rub made available
(*283*)	2000	MICU	B/A	10%/22%	23%/48%	Education, feedback, and alcohol gel made available
		CTICU	B/A	4%/13%	7%/14%	
(*313*)	2000	Medical wards	A	60%	52%	Education, reminders, and alcohol gel made available

Note: ICU = intensive care unit, SICU = surgical ICU, MICU = medical ICU, PICU = pediatric ICU, NICU = neonatal ICU, Emerg = emergency, Oncol = oncology, CTICU = cardiothoracic ICU, and N.S. = not stated.

* Percentage compliance before/after patient contact.

† After contact with inanimate objects.

Factors Affecting Adherence. Factors that may influence hand hygiene include those identified in epidemiologic studies and factors reported by HCWs as being reasons for lack of adherence to hand-hygiene recommendations. Risk factors for poor adherence to hand hygiene have been determined objectively in several observational studies or interventions to improve adherence (*11,12,274,292,295,314–317*). Among these, being a physician or a nursing assistant, rather than a nurse, was consistently associated with reduced adherence (Box 1).

In the largest hospitalwide survey of hand-hygiene practices among HCWs *(11),* predictors of poor adherence to recommended hand-hygiene measures were identified. Predictor variables included professional category, hospital ward, time of day/week, and type and intensity of patient care, defined as the number of opportunities for hand hygiene per hour of patient care. In 2,834 observed opportunities for hand hygiene, average adherence was 48%. In multivariate analysis, nonadherence was lowest among nurses and during weekends

BOX 1. Factors influencing adherence to hand-hygiene practices*

Observed risk factors for poor adherence to recommended hand-hygiene practices

- Physician status (rather than a nurse)
- Nursing assistant status (rather than a nurse)
- Male sex
- Working in an intensive-care unit
- Working during the week (versus the weekend)
- Wearing gowns/gloves
- Automated sink
- Activities with high risk of cross-transmission
- High number of opportunities for hand hygiene per hour of patient care

Self-reported factors for poor adherence with hand hygiene

- Handwashing agents cause irritation and dryness
- Sinks are inconveniently located/shortage of sinks
- Lack of soap and paper towels
- Often too busy/insufficient time
- Understaffing/overcrowding
- Patient needs take priority
- Hand hygiene interferes with health-care worker relationships with patients
- Low risk of acquiring infection from patients
- Wearing of gloves/beliefs that glove use obviates the need for hand hygiene
- Lack of knowledge of guidelines/protocols
- Not thinking about it/forgetfulness
- No role model from colleagues or superiors
- Skepticism regarding the value of hand hygiene
- Disagreement with the recommendations
- Lack of scientific information of definitive impact of improved hand hygiene on health-care–associated infection rates

Additional perceived barriers to appropriate hand hygiene

- Lack of active participation in hand-hygiene promotion at individual or institutional level
- Lack of role model for hand hygiene
- Lack of institutional priority for hand hygiene
- Lack of administrative sanction of noncompliers/rewarding compliers
- Lack of institutional safety climate

* **Source:** Adapted from Pittet D. Improving compliance with hand hygiene in hospitals. Infect Control Hosp Epidemiol 2000;21:381–6.

(Odds Ratio [OR]: 0.6; 95% confidence interval [CI] = 0.4–0.8). Nonadherence was higher in intensive-care units compared with internal medicine wards (OR: 2.0; 95% CI = 1.3–3.1), during procedures that carried a high risk of bacterial contamination (OR: 1.8; 95% CI = 1.4–2.4), and when intensity of patient care was high (21–40 handwashing opportunities — OR: 1.3; 95% CI = 1.0-1.7; 41–60 opportunities — OR: 2.1; 95% CI = 1.5-2.9; >60 opportunities — OR: 2.1; 95% CI = 1.3–3.5). The higher the demand for hand hygiene, the lower the adherence; on average, adherence decreased by 5% (± 2%) for each increase of 10 opportunities per hour when the intensity of patient care exceeded 10 opportunities per hour. Similarly, the lowest adherence rate (36%) was found in intensive-care units, where indications for hand hygiene were typically more frequent (on average, 20 opportunities per patient-hour). The highest adherence rate (59%) was observed in pediatrics wards, where the average intensity of patient care was lower than in other hospital areas (an average of eight opportunities per patient-hour). The results of this study indicate that full adherence to previous guidelines may be unrealistic, and that facilitated access to hand hygiene could help improve adherence (*11,12,318*).

Perceived barriers to adherence with hand-hygiene practice recommendations include skin irritation caused by hand-hygiene agents, inaccessible hand-hygiene supplies, interference with HCW-patient relationships, priority of care (i.e., the patients' needs are given priority over hand hygiene), wearing of gloves, forgetfulness, lack of knowledge of the guidelines, insufficient time for hand hygiene, high workload and understaffing, and the lack of scientific information indicating a definitive impact of improved hand hygiene on health-care–associated infection rates (*11,274,292,295,315–317*). Certain perceived barriers to adherence with hand-hygiene guidelines have been assessed or quantified in observational studies (*12,274,292,295,314–317*) (Box 1).

Skin irritation by hand-hygiene agents constitutes a substantial barrier to appropriate adherence (*319*). Because soaps and detergents can damage skin when applied on a regular basis, HCWs must be better informed regarding the possible adverse effects associated with hand-hygiene agents. Lack of knowledge and education regarding this subject is a barrier to motivation. In several studies, alcohol-based hand rubs containing emollients (either isopropanol, ethanol, or n-propanol in 60%–90% vol/vol) were less irritating to the skin than the soaps or detergents tested. In addition, the alcohol-based products containing emollients that were tested were at least as tolerable and efficacious as the detergents tested. Also, studies demonstrate that several hand lotions have reduced skin scaling and cracking, which may reduce microbial shedding from the hands (*67,272,273*).

Easy access to hand-hygiene supplies, whether sink, soap, medicated detergent, or alcohol-based hand-rub solution, is essential for optimal adherence to hand-hygiene recommendations. The time required for nurses to leave a patient's bedside, go to a sink, and wash and dry their hands before attending the next patient is a deterrent to frequent handwashing or hand antisepsis (*11,318*). Engineering controls could facilitate adherence, but careful monitoring of hand-hygiene behavior should be conducted to exclude the possible negative effect of newly introduced handwashing devices (*88*).

The impact of wearing gloves on adherence to hand-hygiene policies has not been definitively established, because published studies have yielded contradictory results (*87,290,301,320*). Hand hygiene is required regardless of whether gloves are used or changed. Failure to remove gloves after patient contact or between "dirty" and "clean" body-site care on the same patient must be regarded as nonadherence to hand-hygiene recommendations (*11*). In a study in which experimental conditions approximated those occurring in clinical practice (*321*), washing and reusing gloves between patient contacts resulted in observed bacterial counts of 0–4.7 log on the hands after glove removal. Therefore, this practice should be discouraged; handwashing or disinfection should be performed after glove removal.

Lack of 1) knowledge of guidelines for hand hygiene, 2) recognition of hand-hygiene opportunities during patient care, and 3) awareness of the risk of cross-transmission of pathogens are barriers to good hand-hygiene practices. Furthermore, certain HCWs believe they have washed their hands when necessary, even when observations indicate they have not (*89,92,295,296,322*).

Perceived barriers to hand-hygiene behavior are linked not only to the institution, but also to HCWs' colleagues. Therefore, both institutional and small-group dynamics need to be considered when implementing a system change to secure an improvement in HCWs' hand-hygiene practice.

Possible Targets for Hand-Hygiene Promotion

Targets for the promotion of hand hygiene are derived from studies assessing risk factors for nonadherence, reported reasons for the lack of adherence to recommendations, and additional factors perceived as being important to facilitate appropriate HCW behavior. Although certain factors cannot be modified (Box 1), others can be changed.

One factor that must be addressed is the time required for HCWs to clean their hands. The time required for traditional handwashing may render full adherence to previous guidelines unrealistic (*11,12,318*) and more rapid access to hand-hygiene materials could help improve adherence. One study conducted in an intensive-care unit demonstrated that it took

nurses an average of 62 seconds to leave a patient's bedside, walk to a sink, wash their hands, and return to patient care (*318*). In contrast, an estimated one fourth as much time is required when using alcohol-based hand rub placed at each patient's bedside. Providing easy access to hand-hygiene materials is mandatory for appropriate hand-hygiene behavior and is achievable in the majority of health-care facilities (*323*). In particular, in high-demand situations (e.g., the majority of critical-care units), under hectic working conditions, and at times of overcrowding or understaffing, HCWs may be more likely to use an alcohol-based hand rub than to wash their hands (*323*). Further, using alcohol-based hand rubs may be a better option than traditional handwashing with plain soap and water or antiseptic handwash, because they not only require less time (*166,318*) but act faster (*1*) and irritate hands less often (*1,67,96,98,166*). They also were used in the only program that reported a sustained improvement in hand-hygiene adherence associated with decreased infection rates (*74*). However, making an alcohol-based hand rub available to personnel without providing ongoing educational and motivational activities may not result in long-lasting improvement in hand-hygiene practices (*313*). Because increased use of hand-hygiene agents might be associated with skin dryness, the availability of free skin-care lotion is recommended.

Education is a cornerstone for improvement with hand-hygiene practices. Topics that must be addressed by educational programs include the lack of 1) scientific information for the definitive impact of improved hand hygiene on health-care–associated infection and resistant organism transmission rates; 2) awareness of guidelines for hand hygiene and insufficient knowledge concerning indications for hand hygiene during daily patient care; 3) knowledge concerning the low average adherence rate to hand hygiene by the majority of HCWs; and 4) knowledge concerning the appropriateness, efficacy, and understanding of the use of hand-hygiene and skin-care–protection agents.

HCWs necessarily evolve within a group that functions within an institution. Possible targets for improvement in hand-hygiene behavior not only include factors linked to individual HCWs, but also those related to the group(s) and the institution as a whole (*317,323*). Examples of possible targets for hand-hygiene promotion at the group level include education and performance feedback on hand-hygiene adherence; efforts to prevent high workload, downsizing, and understaffing; and encouragement and provision of role models from key members in the work unit. At the institutional level, targets for improvement include 1) written guidelines, hand-hygiene agents, skin-care promotions and agents, or hand-hygiene facilities; 2) culture or tradition of adherence; and 3) administrative leadership, sanction, support, and rewards. Several studies, conducted in various types of institutions, reported modest and even low levels of adherence to recommended hand-hygiene practices, indicating that such adherence varied by hospital ward and by type of HCW. These results indicate educational sessions may need to be designed specifically for certain types of personnel (*11,289,290,294,317,323)*.

Lessons Learned from Behavioral Theories

In 1998, the prevailing behavioral theories and their applications with regard to the health professions were reviewed by researchers in an attempt to better understand how to target more successful interventions (*317*). The researchers proposed a hypothetical framework to enhance hand-hygiene practices and stressed the importance of considering the complexity of individual and institutional factors when designing behavioral interventions.

Although behavioral theories and secondary interventions have primarily targeted individual workers, this practice might be insufficient to produce sustained change (*317,324,325*). Interventions aimed at improving hand-hygiene practices must account for different levels of behavior interaction (*12,317,326*). Thus, the interdependence of individual factors, environmental constraints, and the institutional climate must be taken into account in the strategic planning and development of hand-hygiene campaigns. Interventions to promote hand hygiene in hospitals should consider variables at all these levels. Various factors involved in hand-hygiene behavior include intention, attitude towards the behavior, perceived social norm, perceived behavioral control, perceived risk for infection, hand-hygiene practices, perceived role model, perceived knowledge, and motivation (*317*). The factors necessary for change include 1) dissatisfaction with the current situation, 2) perception of alternatives, and 3) recognition, both at the individual and institutional level, of the ability and potential to change. Although the latter implies education and motivation, the former two necessitate a system change.

Among the reported reasons for poor adherence with hand-hygiene recommendations (Box 1), certain ones are clearly associated with the institution or system (e.g., lack of institutional priority for hand hygiene, administrative sanctions, and a safety climate). Although all of these reasons would require a system change in the majority of institutions, the third requires management commitment, visible safety programs, an acceptable level of work stress, a tolerant and supportive attitude toward reported problems, and belief in the efficacy

of preventive strategies (*12,317,325,327*). Most importantly, an improvement in infection-control practices requires 1) questioning basic beliefs, 2) continuous assessment of the group (or individual) stage of behavioral change, 3) intervention(s) with an appropriate process of change, and 4) supporting individual and group creativity (*317*). Because of the complexity of the process of change, single interventions often fail. Thus, a multimodal, multidisciplinary strategy is likely necessary (*74,75,317,323,326*).

Methods Used To Promote Improved Hand Hygiene

Hand-hygiene promotion has been challenging for >150 years. In-service education, information leaflets, workshops and lectures, automated dispensers, and performance feedback on hand-hygiene adherence rates have been associated with transient improvement (*291,294–296,306,314*).

Several strategies for promotion of hand hygiene in hospitals have been published (Table 9). These strategies require education, motivation, or system change. Certain strategies are based on epidemiologic evidence, others on the authors' and other investigators' experience and review of current knowledge. Some strategies may be unnecessary in certain circumstances, but may be helpful in others. In particular, changing the hand-hygiene agent could be beneficial in institutions or hospital wards with a high workload and a high demand for hand hygiene when alcohol-based hand rubs are not available (*11,73,78,328*). However, a change in the recommended hand-hygiene agent could be deleterious if introduced during winter, at a time of higher hand-skin irritability, and if not accompanied by the provision of skin-care products (e.g., protective creams and lotions). Additional specific elements should be considered for inclusion in educational and motivational programs (Box 2).

Several strategies that could potentially be associated with successful promotion of hand hygiene require a system change (Box 1). Hand-hygiene adherence and promotion involve factors at both the individual and system level. Enhancing individual and institutional attitudes regarding the feasibility of making changes (self-efficacy), obtaining active participation of personnel at both levels, and promoting an institutional safety climate represent challenges that exceed the current perception of the role of infection-control professionals.

Whether increased education, individual reinforcement technique, appropriate rewarding, administrative sanction, enhanced self-participation, active involvement of a larger number of organizational leaders, enhanced perception of health threat, self-efficacy, and perceived social pressure (*12,317,329,330*), or combinations of these factors can improve HCWs' adherence with hand hygiene needs further investigation. Ultimately, adherence to recommended hand-hygiene practices should become part of a culture of patient safety where a set of interdependent quality elements interact to achieve a shared objective (*331*).

On the basis of both these hypothetical considerations and successful, actual experiences in certain institutions, strategies to improve adherence to hand-hygiene practices should be both multimodal and multidisciplinary. However, strategies must be further researched before they are implemented.

TABLE 9. Stategies for successful promotion of hand hygiene in hospitals

Strategy	Tool for change*	Selected references†
Education	E (M, S)	(*74,295,306,326,393*)
Routine observation and feedback	S (E, M)	(*74,294,306,326,393*)
Engineering control		
Make hand hygiene possible, easy, and convenient	S	(*74,281,326,393*)
Make alcohol-based hand rub available	S	(*74*)
(at least in high-demand situations)	S	(*74,283,312*)
Patient education	S (M)	(*283,394*)
Reminders in the workplace	S	(*74,395*)
Administrative sanction/rewarding	S	(*12,317*)
Change in hand-hygiene agent	S (E)	(*11,67,71,283,312*)
Promote/facilitate skin care for health-care–workers' hands	S (E)	(*67,74,274,275*)
Obtain active participation at individual and institutional level	E, M, S	(*74,75,317*)
Improve institutional safety climate	S (M)	(*74,75,317*)
Enhance individual and institutitional self-efficacy	S (E, M)	(*74,75,317*)
Avoid overcrowding, understaffing, and excessive workload	S	(*11,74,78,297,396*)
Combine several of above strategies	E, M, S	(*74,75,295,306,317,326*)

* The dynamic of behavioral change is complex and involves a combination of education (E), motivation (M), and system change (S).
† Only selected references have been listed; readers should refer to more extensive reviews for exhaustive reference lists (*1,8,317,323,397*).

BOX 2. Elements of health-care worker educational and motivational programs

Rationale for hand hygiene
- Potential risks of transmission of microorganisms to patients
- Potential risks of health-care worker colonization or infection caused by organisms acquired from the patient
- Morbidity, mortality, and costs associated with health-care–associated infections

Indications for hand hygiene
- Contact with a patient's intact skin (e.g., taking a pulse or blood pressure, performing physical examinations, lifting the patient in bed) (*25,26,45,48,51,53*)
- Contact with environmental surfaces in the immediate vicinity of patients (*46,51,53,54*)
- After glove removal (*50,58,71*)

Techniques for hand hygiene
- Amount of hand-hygiene solution
- Duration of hand-hygiene procedure
- Selection of hand-hygiene agents
  - — Alcohol-based hand rubs are the most efficacious agents for reducing the number of bacteria on the hands of personnel. Antiseptic soaps and detergents are the next most effective, and non-antimicrobial soaps are the least effective (*1,398*).
  - — Soap and water are recommended for visibly soil hands.
  - — Alcohol-based hand rubs are recommended for routine decontamination of hands for all clinical indications (except when hands are visibly soiled) and as one of the options for surgical hand hygiene.

Methods to maintain hand skin health
- Lotions and creams can prevent or minimize skin dryness and irritation caused by irritant contact dermatitis
- Acceptable lotions or creams to use
- Recommended schedule for applying lotions or creams

Expectations of patient care managers/administrators
- Written statements regarding the value of, and support for, adherence to recommended hand-hygiene practices
- Role models demonstrating adherence to recommended hand hygiene practices (*399*)

Indications for, and limitations of, glove use
- Hand contamination may occur as a result of small, undetected holes in examination gloves (*321,361*)
- Contamination may occur during glove removal (50)
- Wearing gloves does not replace the need for hand hygiene (58)
- Failure to remove gloves after caring for a patient may lead to transmission of microorganizations from one patient to another *(373).*

Efficacy of Promotion and Impact of Improved Hand Hygiene

The lack of scientific information of the definitive impact of improved hand hygiene on health-care–associated infection rates is a possible barrier to appropriate adherence with hand-hygiene recommendations (Box 1). However, evidence supports the belief that improved hand hygiene can reduce health-care–associated infection rates. Failure to perform appropriate hand hygiene is considered the leading cause of health-care–associated infections and spread of multiresistant organisms and has been recognized as a substantial contributor to outbreaks.

Of nine hospital-based studies of the impact of hand hygiene on the risk of health-care–associated infections (Table 10) (*48,69–75,296*), the majority demonstrated a temporal relationship between improved hand-hygiene practices and reduced infection rates.

In one of these studies, endemic MRSA in a neonatal intensive-care unit was eliminated 7 months after introduction of a new

TABLE 10. Association between improved adherence with hand-hygiene practice and health-care–associated infection rates

Year	Ref. no.	Hospital setting	Results	Duration of follow-up
1977	(*48*)	Adult ICU	Reduction in health-care–associated infections caused by endemic *Klebsiella* spp.	2 years
1982	(*69*)	Adult ICU	Reduction in health-care-associated infection rates	N.S.
1984	(*70*)	Adult ICU	Reduction in health-care–associated infection rates	N.S.
1990	(*296*)	Adult ICU	No effect (average hand hygiene adherence improvement did not reach statistical significance)	11 months
1992	(*71*)	Adult ICU	Substantial difference between rates of health-care–associated infection between two different hand-hygiene agents	8 months
1994	(*72*)	NICU	Elimination of MRSA, when combined with multiple other infection-control measures. Reduction of vancomycin use	9 months
1995	(*73*)	Newborn nursery	Elimination of MRSA, when combined with multiple other infection-control measures	3.5 years
2000	(*75*)	MICU/NICU	85% relative reduction of VRE rate in the intervention hospital; 44% relative reduction in control hospital; no change in MRSA	8 months
2000	(*74*)	Hospitalwide	Substantial reduction in the annual overall prevalence of health-care–associated infections and MRSA cross-transmission rates. Active surveillance cultures and contact precautions were implemented during same period	5 years

Note: ICU = intensive care unit, NICU = neonatal ICU, MRSA = methicillin-resistant *Staphylococcus aureus*, MICU = medical ICU, and N.S. = not stated.

hand antiseptic (1% triclosan); all other infection-control measures remained in place, including the practice of conducting weekly active surveillance by obtaining cultures (*72*). Another study reported an MRSA outbreak involving 22 infants in a neonatal unit (*73*). Despite intensive efforts, the outbreak could not be controlled until a new antiseptic was added (i.e., 0.3% triclosan); all previously used control measures remained in place, including gloves and gowns, cohorting, and obtaining cultures for active surveillance.

The effectiveness of a longstanding, hospitalwide program to promote hand hygiene at the University of Geneva hospitals was recently reported (*74*). Overall adherence to hand-hygiene guidelines during routine patient care was monitored during hospitalwide observational surveys. These surveys were conducted biannually during December 1994–December 1997, before and during implementation of a hand-hygiene campaign that specifically emphasized the practice of bedside, alcohol-based hand disinfection. Individual-sized bottles of hand-rub solution were distributed to all wards, and custom-made holders were mounted on all beds to facilitate access to hand disinfection. HCWs were also encouraged to carry bottles in their pockets, and in 1996, a newly designed flat (instead of round) bottle was made available to further facilitate pocket carriage. The promotional strategy was multimodal and involved a multidisciplinary team of HCWs, the use of wall posters, the promotion of antiseptic hand rubs located at bedsides throughout the institution, and regular performance feedback to all HCWs (see http://www.hopisafe.ch for further details on methodology). Health-care–associated infection rates, attack rates of MRSA cross-transmission, and consumption of hand-rub disinfectant were measured. Adherence to recommended hand-hygiene practices improved progressively from 48% in 1994 to 66% in 1997 ($p < 0.001$). Whereas recourse to handwashing with soap and water remained stable, frequency of hand disinfection markedly increased during the study period ($p < 0.001$), and the consumption of alcohol-based hand-rub solution increased from 3.5 to 15.4 liters per 1,000 patient-days during 1993–1998 ($p < 0.001$). The increased frequency of hand disinfection was unchanged after adjustment for known risk factors of poor adherence. During the same period, both overall health-care–associated infection and MRSA transmission rates decreased (both $p < 0.05$). The observed reduction in MRSA transmission may have been affected by both improved hand-hygiene adherence and the simultaneous implementation of active surveillance cultures for detecting and isolating patients colonized with MRSA (*332*). The experience from the University of Geneva hospitals constitutes the first report of a hand-hygiene campaign with a sustained improvement over several years. An additional multimodal program also yielded sustained improvements in hand-hygiene practices over an extended period (*75*); the majority of studies have been limited to a 6- to 9-month observation period.

Although these studies were not designed to assess the independent contribution of hand hygiene on the prevention of health-care–associated infections, the results indicate that

improved hand-hygiene practices reduce the risk of transmission of pathogenic microorganisms. The beneficial effects of hand-hygiene promotion on the risk of cross-transmission also have been reported in surveys conducted in schools and day care centers (*333–338*), as well as in a community setting (*339–341*).

Other Policies Related to Hand Hygiene

Fingernails and Artificial Nails

Studies have documented that subungual areas of the hand harbor high concentrations of bacteria, most frequently coagulase-negative staphylococci, gram-negative rods (including *Pseudomonas* spp.), Corynebacteria, and yeasts (*14,342,343*). Freshly applied nail polish does not increase the number of bacteria recovered from periungual skin, but chipped nail polish may support the growth of larger numbers of organisms on fingernails (*344,345*). Even after careful handwashing or the use of surgical scrubs, personnel often harbor substantial numbers of potential pathogens in the subungual spaces (*346–348*).

Whether artificial nails contribute to transmission of health-care–associated infections is unknown. However, HCWs who wear artificial nails are more likely to harbor gram-negative pathogens on their fingertips than are those who have natural nails, both before and after handwashing (*347–349*). Whether the length of natural or artificial nails is a substantial risk factor is unknown, because the majority of bacterial growth occurs along the proximal 1 mm of the nail adjacent to subungual skin (*345,347,348*). Recently, an outbreak of *P. aeruginosa* in a neonatal intensive care unit was attributed to two nurses (one with long natural nails and one with long artificial nails) who carried the implicated strains of *Pseudomonas* spp. on their hands (*350*). Patients were substantially more likely than controls to have been cared for by the two nurses during the exposure period, indicating that colonization of long or artificial nails with *Pseudomonas* spp. may have contributed to causing the outbreak. Personnel wearing artificial nails also have been epidemiologically implicated in several other outbreaks of infection caused by gram-negative bacilli and yeast (*351–353*). Although these studies provide evidence that wearing artificial nails poses an infection hazard, additional studies are warranted.

Gloving Policies

CDC has recommended that HCWs wear gloves to 1) reduce the risk of personnel acquiring infections from patients, 2) prevent health-care worker flora from being transmitted to patients, and 3) reduce transient contamination of the hands of personnel by flora that can be transmitted from one patient to another (*354*). Before the emergence of the acquired immunodeficiency syndrome (AIDS) epidemic, gloves were worn primarily by personnel caring for patients colonized or infected with certain pathogens or by personnel exposed to patients with a high risk of hepatitis B. Since 1987, a dramatic increase in glove use has occurred in an effort to prevent transmission of HIV and other bloodborne pathogens from patients to HCWs (*355*). The Occupational Safety and Health Administration (OSHA) mandates that gloves be worn during all patient-care activities that may involve exposure to blood or body fluids that may be contaminated with blood (*356*).

The effectiveness of gloves in preventing contamination of HCWs' hands has been confirmed in several clinical studies (*45,51,58*). One study found that HCWs who wore gloves during patient contact contaminated their hands with an average of only 3 CFUs per minute of patient care, compared with 16 CFUs per minute for those not wearing gloves (*51*). Two other studies, involving personnel caring for patients with *C. difficile* or VRE, revealed that wearing gloves prevented hand contamination among the majority of personnel having direct contact with patients (*45,58*). Wearing gloves also prevented personnel from acquiring VRE on their hands when touching contaminated environmental surfaces (*58*). Preventing heavy contamination of the hands is considered important, because handwashing or hand antisepsis may not remove all potential pathogens when hands are heavily contaminated (*25,111*).

Several studies provide evidence that wearing gloves can help reduce transmission of pathogens in health-care settings. In a prospective controlled trial that required personnel to routinely wear vinyl gloves when handling any body substances, the incidence of *C. difficile* diarrhea among patients decreased from 7.7 cases/1,000 patient discharges before the intervention to 1.5 cases/1,000 discharges during the intervention (*226*). The prevalence of asymptomatic *C. difficile* carriage also decreased substantially on "glove" wards, but not on control wards. In intensive-care units where VRE or MRSA have been epidemic, requiring all HCWs to wear gloves to care for all patients in the unit (i.e., universal glove use) likely has helped control outbreaks (*357,358*).

The influence of glove use on the hand-hygiene habits of personnel is not clear. Several studies found that personnel who wore gloves were less likely to wash their hands upon leaving a patient's room (*290,320*). In contrast, two other studies found that personnel who wore gloves were substantially more likely to wash their hands after patient care (*87,301*).

The following caveats regarding use of gloves by HCWs must be considered. Personnel should be informed that gloves

do not provide complete protection against hand contamination. Bacterial flora colonizing patients may be recovered from the hands of ≤30% of HCWs who wear gloves during patient contact (*50,58*). Further, wearing gloves does not provide complete protection against acquisition of infections caused by hepatitis B virus and herpes simplex virus (*359,360*). In such instances, pathogens presumably gain access to the caregiver's hands via small defects in gloves or by contamination of the hands during glove removal (*50,321,359,361*).

Gloves used by HCWs are usually made of natural rubber latex and synthetic nonlatex materials (e.g., vinyl, nitrile, and neoprene [polymers and copolymers of chloroprene]). Because of the increasing prevalence of latex sensitivity among HCWs and patients, FDA has approved several powdered and powder-free latex gloves with reduced protein contents, as well as synthetic gloves that can be made available by health-care institutions for use by latex-sensitive employees. In published studies, the barrier integrity of gloves varies on the basis of type and quality of glove material, intensity of use, length of time used, manufacturer, whether gloves were tested before or after use, and method used to detect glove leaks (*359,361–366*). In published studies, vinyl gloves have had defects more frequently than latex gloves, the difference in defect frequency being greatest after use (*359,361,364,367*). However, intact vinyl gloves provide protection comparable to that of latex gloves (*359*). Limited studies indicate that nitrile gloves have leakage rates that approximate those of latex gloves (*368–371*). Having more than one type of glove available is desirable, because it allows personnel to select the type that best suits their patient-care activities. Although recent studies indicate that improvements have been made in the quality of gloves (*366*), hands should be decontaminated or washed after removing gloves (*8,50,58,321,361*). Gloves should not be washed or reused (*321,361*). Use of petroleum-based hand lotions or creams may adversely affect the integrity of latex gloves (*372*). After use of powdered gloves, certain alcohol hand rubs may interact with residual powder on the hands of personnel, resulting in a gritty feeling on the hands. In facilities where powdered gloves are commonly used, various alcohol-based hand rubs should be tested after removal of powdered gloves to avoid selecting a product that causes this undesirable reaction. Personnel should be reminded that failure to remove gloves between patients may contribute to transmission of organisms (*358,373*).

Jewelry

Several studies have demonstrated that skin underneath rings is more heavily colonized than comparable areas of skin on fingers without rings (*374–376*). One study found that 40% of nurses harbored gram-negative bacilli (e.g., *E. cloacae*, *Klebsiella*, and *Acinetobacter*) on skin under rings and that certain nurses carried the same organism under their rings for several months (*375*). In a more recent study involving >60 intensive care unit nurses, multivariable analysis revealed that rings were the only substantial risk factor for carriage of gram-negative bacilli and *S. aureus* and that the concentration of organisms recovered correlated with the number of rings worn (*377*). Whether the wearing of rings results in greater transmission of pathogens is unknown. Two studies determined that mean bacterial colony counts on hands after handwashing were similar among persons wearing rings and those not wearing rings (*376,378*). Further studies are needed to establish if wearing rings results in greater transmission of pathogens in health-care settings.

Hand-Hygiene Research Agenda

Although the number of published studies concerning hand hygiene has increased considerably in recent years, many questions regarding hand-hygiene products and strategies for improving adherence of personnel to recommended policies remain unanswered. Several concerns must still be addressed by researchers in industry and by clinical investigators (Box 3).

Web-Based Hand-Hygiene Resources

Additional information regarding improving hand hygiene is available at http://www.hopisafe.ch
University of Geneva Hospitals, Geneva, Switzerland
http://www.cdc.gov/ncidod/hip
CDC, Atlanta, Georgia
http://www.jr2.ox.ac.uk/bandolier/band88/b88-8.html
Bandolier journal, United Kingdom
http://www.med.upenn.edu
University of Pennsylvania, Philadelphia, Pennsylvania

BOX 3. Hand-hygiene research agenda

Education and promotion

- Provide health-care workers (HCWs) with better education regarding the types of patient care activities that can result in hand contamination and cross-transmission of microorganisms.
- Develop and implement promotion hand-hygiene programs in pregraduate courses.
- Study the impact of population-based education on hand-hygiene behavior.
- Design and conduct studies to determine if frequent glove use should be encouraged or discouraged.
- Determine evidence-based indications for hand cleansing (considering that it might be unrealistic to expect HCWs to clean their hands after every contact with the patient).
- Assess the key determinants of hand-hygiene behavior and promotion among the different populations of HCWs.
- Develop methods to obtain management support.
- Implement and evaluate the impact of the different components of multimodal programs to promote hand hygiene.

Hand-hygiene agents and hand care

- Determine the most suitable formulations for hand-hygiene products.
- Determine if preparations with persistent antimicrobial activity reduce infection rates more effectively than do preparations whose activity is limited to an immediate effect.
- Study the systematic replacement of conventional handwashing by the use of hand disinfection.
- Develop devices to facilitate the use and optimal application of hand-hygiene agents.
- Develop hand-hygiene agents with low irritancy potential.
- Study the possible advantages and eventual interaction of hand-care lotions, creams, and other barriers to help minimize the potential irritation associated with hand-hygiene agents.

Laboratory-based and epidemiologic research and development

- Develop experimental models for the study of cross-contamination from patient to patient and from environment to patient.
- Develop new protocols for evaluating the in vivo efficacy of agents, considering in particular short application times and volumes that reflect actual use in health-care facilities.
- Monitor hand-hygiene adherence by using new devices or adequate surrogate markers, allowing frequent individual feedback on performance.
- Determine the percentage increase in hand-hygiene adherence required to achieve a predictable risk reduction in infection rates.
- Generate more definitive evidence for the impact on infection rates of improved adherence to recommended hand-hygiene practices.
- Provide cost-effectiveness evaluation of successful and unsuccessful promotion campaigns.

Part II. Recommendations

Categories

These recommendations are designed to improve hand-hygiene practices of HCWs and to reduce transmission of pathogenic microorganisms to patients and personnel in health-care settings. This guideline and its recommendations are not intended for use in food processing or food-service establishments, and are not meant to replace guidance provided by FDA's Model Food Code.

As in previous CDC/HICPAC guidelines, each recommendation is categorized on the basis of existing scientific data, theoretical rationale, applicability, and economic impact. The CDC/HICPAC system for categorizing recommendations is as follows:

Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.

Category IB. Strongly recommended for implementation and supported by certain experimental, clinical, or epidemiologic studies and a strong theoretical rationale.

Category IC. Required for implementation, as mandated by federal or state regulation or standard.

Category II. Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale.

No recommendation. Unresolved issue. Practices for which insufficient evidence or no consensus regarding efficacy exist.

Recommendations

1. Indications for handwashing and hand antisepsis
   - A. When hands are visibly dirty or contaminated with proteinaceous material or are visibly soiled with blood or other body fluids, wash hands with either a non-antimicrobial soap and water or an antimicrobial soap and water (IA) (*66*).
   - B. If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands in all other clinical situations described in items 1C–J (IA) (*74,93,166,169,283,294,312,398*). Alternatively, wash hands with an antimicrobial soap and water in all clinical situations described in items 1C–J (IB) (*69-71,74*).
   - C. Decontaminate hands before having direct contact with patients (IB) (*68,400*).
   - D. Decontaminate hands before donning sterile gloves when inserting a central intravascular catheter (IB) (*401,402*).
   - E. Decontaminate hands before inserting indwelling urinary catheters, peripheral vascular catheters, or other invasive devices that do not require a surgical procedure (IB) (*25,403*).
   - F. Decontaminate hands after contact with a patient's intact skin (e.g., when taking a pulse or blood pressure, and lifting a patient) (IB) (*25,45,48,68*).
   - G. Decontaminate hands after contact with body fluids or excretions, mucous membranes, nonintact skin, and wound dressings if hands are not visibly soiled (IA) (*400*).
   - H. Decontaminate hands if moving from a contaminated-body site to a clean-body site during patient care (II) (*25,53*).
   - I. Decontaminate hands after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient (II) (*46,53,54*).
   - J. Decontaminate hands after removing gloves (IB) (*50,58,321*).
   - K. Before eating and after using a restroom, wash hands with a non-antimicrobial soap and water or with an antimicrobial soap and water (IB) (*404-409*).
   - L. Antimicrobial-impregnated wipes (i.e., towelettes) may be considered as an alternative to washing hands with non-antimicrobial soap and water. Because they are not as effective as alcohol-based hand rubs or washing hands with an antimicrobial soap and water for reducing bacterial counts on the hands of HCWs, they are not a substitute for using an alcohol-based hand rub or antimicrobial soap (IB) (*160,161*).
   - M. Wash hands with non-antimicrobial soap and water or with antimicrobial soap and water if exposure to *Bacillus anthracis* is suspected or proven. The physical action of washing and rinsing hands under such circumstances is recommended because alcohols, chlorhexidine, iodophors, and other antiseptic agents have poor activity against spores (II) (*120,172, 224,225*).
   - N. No recommendation can be made regarding the routine use of nonalcohol-based hand rubs for hand hygiene in health-care settings. Unresolved issue.
2. Hand-hygiene technique
   - A. When decontaminating hands with an alcohol-based hand rub, apply product to palm of one hand and rub hands together, covering all surfaces of hands and fingers, until hands are dry (IB) (*288,410*). Follow the manufacturer's recommendations regarding the volume of product to use.
   - B. When washing hands with soap and water, wet hands first with water, apply an amount of product recommended by the manufacturer to hands, and rub hands together vigorously for at least 15 seconds, covering all surfaces of the hands and fingers. Rinse hands with water and dry thoroughly with a disposable towel. Use towel to turn off the faucet (IB) (*90-92,94,411*). Avoid using hot water, because repeated exposure to hot water may increase the risk of dermatitis (IB) (*254,255*).
   - C. Liquid, bar, leaflet or powdered forms of plain soap are acceptable when washing hands with a non-antimicrobial soap and water. When bar soap is used, soap racks that facilitate drainage and small bars of soap should be used (II) (*412-415*).
   - D. Multiple-use cloth towels of the hanging or roll type are not recommended for use in health-care settings (II) (*137,300*).
3. Surgical hand antisepsis
   - A. Remove rings, watches, and bracelets before beginning the surgical hand scrub (II) (*375,378,416*).
   - B. Remove debris from underneath fingernails using a nail cleaner under running water (II) (*14,417*).

C. Surgical hand antisepsis using either an antimicrobial soap or an alcohol-based hand rub with persistent activity is recommended before donning sterile gloves when performing surgical procedures (IB) (*115,159,232,234,237,418*).

D. When performing surgical hand antisepsis using an antimicrobial soap, scrub hands and forearms for the length of time recommended by the manufacturer, usually 2–6 minutes. Long scrub times (e.g., 10 minutes) are not necessary (IB) (*117,156,205, 207,238-241*).

E. When using an alcohol-based surgical hand-scrub product with persistent activity, follow the manufacturer's instructions. Before applying the alcohol solution, prewash hands and forearms with a non-antimicrobial soap and dry hands and forearms completely. After application of the alcohol-based product as recommended, allow hands and forearms to dry thoroughly before donning sterile gloves (IB) (*159,237*).

4. Selection of hand-hygiene agents

A. Provide personnel with efficacious hand-hygiene products that have low irritancy potential, particularly when these products are used multiple times per shift (IB) (*90,92,98,166,249*). This recommendation applies to products used for hand antisepsis before and after patient care in clinical areas and to products used for surgical hand antisepsis by surgical personnel.

B. To maximize acceptance of hand-hygiene products by HCWs, solicit input from these employees regarding the feel, fragrance, and skin tolerance of any products under consideration. The cost of hand-hygiene products should not be the primary factor influencing product selection (IB) (*92,93,166, 274,276-278*).

C. When selecting non-antimicrobial soaps, antimicrobial soaps, or alcohol-based hand rubs, solicit information from manufacturers regarding any known interactions between products used to clean hands, skin care products, and the types of gloves used in the institution (II) (*174,372*).

D. Before making purchasing decisions, evaluate the dispenser systems of various product manufacturers or distributors to ensure that dispensers function adequately and deliver an appropriate volume of product (II) (*286*).

E. Do not add soap to a partially empty soap dispenser. This practice of "topping off" dispensers can lead to bacterial contamination of soap (IA) (*187,419*).

5. Skin care

A. Provide HCWs with hand lotions or creams to minimize the occurrence of irritant contact dermatitis associated with hand antisepsis or handwashing (IA) (*272,273*).

B. Solicit information from manufacturers regarding any effects that hand lotions, creams, or alcohol-based hand antiseptics may have on the persistent effects of antimicrobial soaps being used in the institution (IB) (*174,420,421*).

6. Other Aspects of Hand Hygiene

A. Do not wear artificial fingernails or extenders when having direct contact with patients at high risk (e.g., those in intensive-care units or operating rooms) (IA) (*350–353*).

B. Keep natural nails tips less than 1/4-inch long (II) (*350*).

C. Wear gloves when contact with blood or other potentially infectious materials, mucous membranes, and nonintact skin could occur (IC) (*356*).

D. Remove gloves after caring for a patient. Do not wear the same pair of gloves for the care of more than one patient, and do not wash gloves between uses with different patients (IB) (*50,58,321,373*).

E. Change gloves during patient care if moving from a contaminated body site to a clean body site (II) (*50,51,58*).

F. No recommendation can be made regarding wearing rings in health-care settings. Unresolved issue.

7. Health-care worker educational and motivational programs

A. As part of an overall program to improve hand-hygiene practices of HCWs, educate personnel regarding the types of patient-care activities that can result in hand contamination and the advantages and disadvantages of various methods used to clean their hands (II) (*74,292,295,299*).

B. Monitor HCWs' adherence with recommended hand-hygiene practices and provide personnel with information regarding their performance (IA) (*74,276,292,295,299,306,310*).

C. Encourage patients and their families to remind HCWs to decontaminate their hands (II) (*394,422*).

8. Administrative measures

A. Make improved hand-hygiene adherence an institutional priority and provide appropriate

administrative support and financial resources (IB) (*74,75*).

B. Implement a multidisciplinary program designed to improve adherence of health personnel to recommended hand-hygiene practices (IB) (*74,75*).

C. As part of a multidisciplinary program to improve hand-hygiene adherence, provide HCWs with a readily accessible alcohol-based hand-rub product (IA) (*74,166,283,294,312*).

D. To improve hand-hygiene adherence among personnel who work in areas in which high workloads and high intensity of patient care are anticipated, make an alcohol-based hand rub available at the entrance to the patient's room or at the bedside, in other convenient locations, and in individual pocket-sized containers to be carried by HCWs (IA) (*11,74,166,283,284,312,318,423*).

E. Store supplies of alcohol-based hand rubs in cabinets or areas approved for flammable materials (IC).

Part III. Performance Indicators

1. The following performance indicators are recommended for measuring improvements in HCWs' hand-hygiene adherence:

   A. Periodically monitor and record adherence as the number of hand-hygiene episodes performed by personnel/number of hand-hygiene opportunities, by ward or by service. Provide feedback to personnel regarding their performance.

   B. Monitor the volume of alcohol-based hand rub (or detergent used for handwashing or hand antisepsis) used per 1,000 patient-days.

   C. Monitor adherence to policies dealing with wearing of artificial nails.

   D. When outbreaks of infection occur, assess the adequacy of health-care worker hand hygiene.

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Appendix

Antimicrobial Spectrum and Characteristics of Hand-Hygiene Antiseptic Agents*

Group	Gram-positive bacteria	Gram-negative bacteria	Mycobacteria	Fungi	Viruses	Speed of action	Comments
Alcohols	+++	+++	+++	+++	+++	Fast	Optimum concentration 60%–95%; no persistent activity
Chlorhexidine (2% and 4% aqueous)	+++	++	+	+	+++	Intermediate	Persistent activity; rare allergic reactions
Iodine compounds	+++	+++	+++	++	+++	Intermediate	Causes skin burns; usually too irritating for hand hygiene
Iodophors	+++	+++	+	++	++	Intermediate	Less irritating than iodine; acceptance varies
Phenol derivatives	+++	+	+	+	+	Intermediate	Activity neutralized by nonionic surfactants
Tricolsan	+++	++	+	—	+++	Intermediate	Acceptability on hands varies
Quaternary ammonium compounds	+	++	—	—	+	Slow	Used only in combination with alcohols; ecologic concerns

Note: +++ = excellent; ++ = good, but does not include the entire bacterial spectrum; + = fair; — = no activity or not sufficient.
* Hexachlorophene is not included because it is no longer an accepted ingredient of hand disinfectants.

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Continuing Education Activity Sponsored by CDC
Guideline for Hand Hygiene in Health-Care Settings

Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force

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Goal and Objectives

This *MMWR* provides evidence-based recommendations for hand hygiene in health-care settings. These recommendations were developed by the Healthcare Infection Control Practices Advisory Committee (HICPAC), the Society for Healthcare Epidemiology of America, the Association for Professionals in Infection Control and Epidemiology, and the Infectious Diseases Society of America Hand Hygiene Task Force. The goal of this report is to provide guidance for clinicians and other health-care practitioners regarding strategies to improve hand-hygiene practices and reduce transmission of microorganisms in health-care settings. Upon completion of this educational activity, the reader should be able to 1) describe the indications for hand hygiene in health-care settings; 2) list the advantages of alcohol-based hand rubs; and 3) describe the barriers to hand hygiene in health-care settings.

To receive continuing education credit, please answer all of the following questions.

1. Hand hygiene refers to . . .
- A. handwashing using plain soap and water.
- B. using an antiseptic hand rub (e.g alcohol, chlorhexidine, iodine).
- C. handwashing using antimicrobial soap and water.
- D. all of the above.

2. Hand hygiene adherence in health-care facilities might be improved by . . .
- A. providing personnel with individual containers of alcohol-based hand rubs.
- B. providing personnel with hand lotions or creams.
- C. providing personnel with feedback regarding hand-hygiene adherence/performance.
- D. all of the above.

3. Alcohol-based hand rubs have good or excellent antimicrobial activity against all of the following except . . .
- A. viruses.
- B. fungi.
- C. mycobacteria.
- D. bacterial spores.
- E. gram-positive and gram-negative bacteria.

4. Alcohol-based hand rubs are indicated for all of the following clinical situations except . . .
- A. when the hands are visibly soiled.
- B. preoperative cleaning of hands by surgical personnel.
- C. before inserting urinary catheters, intravascular catheters, or other invasive devices.
- D. after removing gloves.

5. Each of the following statements regarding alcohol-based hand rubs is true except . . .
- A. alcohol-based hand rubs reduce bacterial counts on the hands of health-care personnel more effectively than plain soaps.
- B. alcohol-based hand rubs can be made more accessible than sinks or other handwashing facilities.
- C. alcohol-based hand rubs require less time to use than traditional handwashing.
- D. alcohol-based hand rubs have been demonstrated to cause less skin irritation and dryness than handwashing using soap and water.
- E. alcohol-based hand rubs are only effective if they are applied for ≥60 seconds.

6. Which of the following statements regarding preoperative surgical hand antisepsis is true?
- A. Antimicrobial counts on hands are reduced as effectively with a 5-minute scrub as with a 10-minute scrub.
- B. A brush or sponge must be used when applying the antiseptic agent to adequately reduce bacterial counts on hands.
- C. Alcohol-based hand rubs for preoperative surgical scrub have been associated with increased surgical site infection rates.
- D. A and B are true.
- E. A and C are true.

7. Antimicrobial-impregnated wipes (i.e., towelettes) . . .
- A. might be considered as an alternative to handwashing with plain soap and water.
- B. are as effective as alcohol-based hands rubs.
- C. are as effective as washing hands with antimicrobial soap and water.
- D. A and C.

8. The following statements regarding hand hygiene in health-care settings are true except . . .
- A. Overall adherence among health-care personnel is approximately 40%.
- B. Poor adherence to hand-hygiene practice is a primary contributor to health-care–associated infection and transmission of antimicrobial-resistant pathogens.
- C. Personnel wearing artificial nails or extenders have been linked to nosocomial outbreaks.
- D. Hand hygiene is not necessary if gloves are worn.

9. Indicate your work setting.
- A. State/local health department.
- B. Other public health setting.
- C. Hospital clinic/private practice.
- D. Managed care organization.
- E. Academic institution.
- F. Other.

10. Which best describes your professional activities?
- A. Patient care — emergency/urgent care department.
- B. Patient care — inpatient.
- C. Patient care — primary-care clinic or office.
- D. Laboratory/pharmacy.
- E. Public health.
- F. Other.

11. I plan to use these recommendations as the basis for . . . (*Indicate all that apply.*)
- A. health education materials.
- B. insurance reimbursement policies.
- C. local practice guidelines.
- D. public policy.
- E. other.

12. Each month, approximately how many patients do you examine?
- A. None.
- B. 1–5.
- C. 6–20.
- D. 21–50.
- E. 51–100.
- F. >100.

13. How much time did you spend reading this report and completing the exam?
- A. 1–1.5 hours.
- B. More than 1.5 hours but fewer than 2 hours.
- C. 2–2.5 hours.
- D. More than 2.5 hours.

14. After reading this report, I am confident I can describe the guidance for clinicians and other health-care practitioners regarding strategies to improve hand-hygiene practices and reduce transmission of microorganisms in health-care settings.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

15. After reading this report, I am confident I can describe the indications for hand hygiene in health-care settings.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

16. After reading this report, I am confident I can list the advantages of alcohol-based hand rubs.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

17. After reading this report, I am confident I can describe the barriers to hand hygiene in health-care settings.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

18. The objectives are relevant to the goal of this report.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

19. The tables and text boxes are useful.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

20. Overall, the presentation of the report enhanced my ability to understand the material.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

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October 25, 2002/Vol. 51/No. RR-16
Guideline for Hand Hygiene in Health-Care Settings
Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force

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1. [ ] A [ ] B [ ] C [ ] D
2. [ ] A [ ] B [ ] C [ ] D
3. [ ] A [ ] B [ ] C [ ] D [ ] E
4. [ ] A [ ] B [ ] C [ ] D
5. [ ] A [ ] B [ ] C [ ] D [ ] E
6. [ ] A [ ] B [ ] C [ ] D [ ] E
7. [ ] A [ ] B [ ] C [ ] D
8. [ ] A [ ] B [ ] C [ ] D
9. [ ] A [ ] B [ ] C [ ] D [ ] E [ ] F
10. [ ] A [ ] B [ ] C [ ] D [ ] E [ ] F
11. [ ] A [ ] B [ ] C [ ] D [ ] E
12. [ ] A [ ] B [ ] C [ ] D [ ] E [ ] F
13. [ ] A [ ] B [ ] C [ ] D
14. [ ] A [ ] B [ ] C [ ] D [ ] E
15. [ ] A [ ] B [ ] C [ ] D [ ] E
16. [ ] A [ ] B [ ] C [ ] D [ ] E
17. [ ] A [ ] B [ ] C [ ] D [ ] E
18. [ ] A [ ] B [ ] C [ ] D [ ] E
19. [ ] A [ ] B [ ] C [ ] D [ ] E
20. [ ] A [ ] B [ ] C [ ] D [ ] E
21. [ ] A [ ] B [ ] C [ ] D [ ] E
22. [ ] A [ ] B [ ] C [ ] D [ ] E
23. [ ] A [ ] B [ ] C [ ] D [ ] E [ ] F

Signature *Date I Completed Exam*

21. These recommendations will affect my practice.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

22. The availability of continuing education credit influenced my decision to read this report.

A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

23. How did you learn about this continuing education activity?

A. Internet.
B. Advertisement (e.g., fact sheet, *MMWR* cover, newsletter, or journal).
C. Coworker/supervisor.
D. Conference presentation.
E. *MMWR* subscription.
F. Other.

Correct answers for questions 1–8

1. D; 2. D; 3. D; 4. A; 5. E; 6. A; 7. A; 8. D.

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Ozone Data for CFP 2023 (2012)

This document includes excerpts from “Ozone in Food Processing, First Edition” book written by P. J. Cullen and Rip Rice, published in 2012. In addition, there is a list of references used in developing this book, published efficacy lab testing and other relevant information summarized for the council to support the submitted issue.

Ozone in Food Processing, First Edition. Edited by Colm O’Donnell, B.K. Tiwari, P.J. Cullen, and Rip G. Rice.

15.3.3 Safety history of ozone in commercial/industrial applications

Ozone has been in commercial use for the treatment of drinking water since 1906, when the city of Nice, France installed ozone to disinfect mountain spring water. This Mediterranean resort town has now used ozone continually for the treatment of its drinking water for over 100 years without incident, and today thousands of potable water plants throughout the world

are also using this technology. Many of the most recent new-construction industrial plants, and even many older upgraded plants, use high-purity oxygen to generate ozone, without experiencing hazards, either from the ozone or from the high-purity oxygen. In these many drinking water plants, ozone is generated routinely in quantities ranging from grams per hour (small plants) up to tons per day (large municipal plants). Many other commercial/industrial applications for ozone also exist throughout the world, including pulp bleaching, kaolin bleaching, wastewater treatment and reuse, bottled water treatment, swimming pools, cooling towers, synthesis of nylon intermediates, air treatment, marine aquaria, aquaculture, food storage and processing plants, wineries and so on.
In the century that has passed since ozone was first installed in Nice, there has never been a reported death due to ozone exposure. Why? Because engineers were quick to recognize the potential danger to humans of ozone exposure. Consequently, processes involving ozone are routinely designed with appropriate precautions to avoid exposure of workers to ozone.
The situation is analogous to that of chlorine, also a very strong disinfectant and oxidizing agent, and a chlorinating agent as well. This chemical was used as a poison gas during World War I, and many troops were killed on both sides of the trenches when exposed to it. But today, chlorine is an essential industrial chemical used safely in tons/day quantities for a variety of commercial/industrial processes, all as a result of attention to the safety of humans handling this strong disinfecting, oxidizing and chlorinating material.

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15.2 Points of application of ozone during food processing

Specific health and safety aspects of ozone in food processing are direct functions of the presence of ozone at specific points in the processing plant. Because of ozone's great versatility as an oxidant/disinfectant, there are a great number of places within any food processing plant where it can be and is being utilized. These applications can be considered in the two primary categories of aqueous ozone and gaseous ozone phases. Wherever ozone is applied in a food processing plant there is a resultant safety responsibility.

15.2.1 Aqueous phase ozone applications

Ozone in aqueous solution can be used to process plant influent water and product water (such as juice products), to provide ozone-containing water for spray washing of incoming food products prior to processing, for treatment of process water (sometimes for reuse, sometimes prior to discharge), for spray washing food products, for sanitizing plant equipment (clean-in-place, CIP) and for spray sanitation of floors and drains, as well as of food contact and non-food contact surfaces (surface sanitation). Food transportation trucks can also benefit from spray washing of empty food containers and the truck interiors, not only to reduce levels of microorganisms present, but also to destroy odors, colors and flavors and prevent odor transfers between foods during shipments. Ozone-containing water can be fed to an ice-making machine, where the small amount of ozone that off-gasses then gathers at the bottom of the ice storage chamber (the density of ozone gas is slightly higher than that of air) and its presence maintains the ice and chamber slime-free. When ozone is applied to treat a food processing plant's influent or effluent waters or to treat food processing waters for reuse, the water/ wastewater equipment is usually designed and operated as a mini-water/ wastewater treatment plant. Such subunits normally will be an adjunct to, but not an integral part of, the food storage and food processing lines. Consequently, system equipment will be designed with all of the necessary controls to ensure that no ozone will escape to come in contact with humans in those subunit areas.

Surface Sanitation. Another common application of ozone is for food contact surface sanitation. The inclusion of ozone-containing water within clean-in-place (CIP) cycles offers opportunities to food processors to treat manufacturing plant surfaces more efficiently and with greater efficacy. Aqueous ozone can also be used as a sanitizing rinse for food contact surfaces, such as cutting tables, as well as for nonfood contact surfaces, such as floors. Ozone can also be used to treat aseptic food packaging materials for surface disinfection.

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Opportunities for the Future

Interest in ozone is expected to continue to rise in response to consumer demands for environmentally friendly food processing technologies. A recent publication mapped trends in implementation or potential for implementation of ozone in the food industry. It found that ozone scored very high in terms of potential applications for fresh produce, seafood, and beverages. Another potential future application for ozone is its use to degrade pesticide residues, including organophosphates and organochlorinated compounds. As with many process technologies, ozone also has good potential for use as a hurdle technology to be combined with other sanitation and disinfection technologies to improve the safety of foods and beverages while extending their shelf life.

15.4.4 Third-party evaluation of aqueous ozone spray wash equipment

In 2002, the Toxicology Group, a wholly owned company of NSF International (Ann Arbor MI), conducted detailed third-party efficacy and hazard assessments and analyses for DEL Agricultural (a subsidiary of DEL Ozone, San Luis Obispo, CA) and Air Liquide America. Two devices (DEL AGW-0500 Mobile Ozone Surface Sanitation System, AL SSS 0500 Mobile Ozone Surface Sanitation System, and the DEL AGW-1500G Mobile Recirculating Ozone Sanitation System, AL SSS 1500 Mobile Recirculating Ozone Sanitation System) are manufactured by DEL Ozone and marketed by these two firms for spray washing applications in food processing plants. Both models are mobile. One provides a 10 gal/min water spray with a 3.0–3.5 ppm applied ozone dose, and is designed to sanitise equipment, walls, floors, drains, tables, conveyors, containers, tanks and barrels. The other, designed for CIP and COP (clean-out-of-place) processes, recirculates ozone-containing water at 35 gal/min with a 3.0 ppm applied ozone dose through tanks ranging in size from 50 to 2500 gallons. In any of these systems, the residual ozone dose that is applied as a spray is in the range of 1.5–2.0 ppm; and in the case of the recirculation system, the residual ozone dose is monitored and controlled at 2.0–2.5 ppm.

Third-party efficacy testing:

The methods used for the efficacy tests were AOAC Official Methods 960.09, Germicidal and Detergent Sanitizing Action of Disinfectants, and 961.02, Germicidal Spray Products as Disinfectants (Boisrobert 2002). Ozone spray washing was conducted on samples of individual microorganisms listed in Table 15.3, which also shows the number of log reductions obtained for each microorganism tested. Each microorganism received an ozone dosage of 1.85–2.25 ppm from the spray nozzle, except for *Escherichia coli*, which received an ozone dosage of 2.1 ppm.

Table 15.3 Efficacy testing of mobile ozone surface washing system (Boisrobert 2002; cited in Pascual et al. 2007).:

Microorganism	Log reduction
Trichophyton mentagrophytes (ATCC 9533)	6
Salmonella choleraesuis (ATCC 9533)	6
Staphylococcus aureus (ATCC 6358)	6
Pseudomonas aeruginosa (ATCC 15442)	6
Campylobacter jejuni (ATCC 33250)	4
Listeria monocytogenes (ATCC 7644)	4
Aspergillus flavus (ATCC 9296)	4
Brettanomyces bruxellensis (ATCC 10560)	4
Escherichia coli (ATCC 11229)	5

The results obtained (log reductions of 4–6 for the nine microorganisms tested) substantiate the efficacy of these two systems in sanitising previously cleaned nonporous surfaces, including processing equipment, which has come into contact with food (Pascual et al. 2007).

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Efficacy of Ozonated Water against Various Food-Related Microorganisms

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The antimicrobial effects of ozonated water in a recirculating concurrent reactor were evaluated against four gram-positive and four gram-negative bacteria, two yeasts, and spores of *Aspergillus niger*. More than 5 log units each of *Salmonella typhimurium* and *Escherichia coli* cells were killed instantaneously in ozonated water with or without addition of 20 ppm of soluble starch (SS). In ozonated water, death rates among the gram-negative bacteria—*S. typhimurium*, *E. coli*, *Pseudomonas aeruginosa*, and *Yersinia enterocolitica*—were not significantly different ($P > 0.05$). Among gram-positive bacteria, *Listeria monocytogenes* was significantly ($P < 0.05$) more sensitive than either *Staphylococcus aureus* or *Enterococcus faecalis*. In the presence of organic material, death rates of *S. aureus* compared with *L. monocytogenes* and *E. coli* compared with *S. typhimurium* in ozonated water were not significantly ($P > 0.05$) affected by SS addition but were significantly reduced ($P < 0.05$) by addition of 20 ppm of bovine serum albumin (BSA). More than 4.5 log units each of *Candida albicans* and *Zygosaccharomyces bailii* cells were killed instantaneously in ozonated water, whereas less than 1 log unit of *Aspergillus niger* spores was killed after a 5-min exposure. The average ozone output levels in the deionized water (0.188 mg/ml) or water with SS (0.198 mg/ml) did not differ significantly ($P < 0.05$) but were significantly lower in water containing BSA (0.149 mg/ml).

"The treatment of domestic water to provide a microbiologically safe, aesthetic, potable end product has been normal practice since before the turn of the twentieth century" (5). Chlorine at low concentrations has been the usual agent of choice in drinking-water purification. At the low concentrations of chlorine used, however, its limitations as a bactericide (3, 4) as well as limitations in its effectiveness against certain eukaryotic pathogens and viruses (18, 20, 21, 25, 27) have been recognized. Furthermore, chlorine at low concentrations may alter certain organic compounds in water producing off tastes and odors as well as forming chloro-organic compounds with carcinogenic potential (22).

As an alternative to chlorination in drinking-water disinfection, ozonation of water supplies, which was done first a century ago (29), has become an established means of disinfection and has been reviewed by Rice et al. (25). Bacteria, including *Escherichia coli*, *Staphylococcus aureus*, *Bacillus cereus*, *Bacillus megaterium*, *Salmonella typhimurium*, *Shigella flexneri*, and *Vibrio cholerae* are sensitive to ozonated water under various conditions (5, 6, 13, 17). Limited information on ozone's effectiveness against bacterial endospores (5, 17) and viruses (6, 20) as well as against eukaryotic pathogens including *Cryptosporidium parvum* (11, 21, 24) and *Giardia lamblia* and *Giardia muris* (12, 31, 32) also exists.

The use of ozone in the food industry has been investigated for food preservation, shelf life extension, equipment sterilization, and improvement of food plant effluents (9, 14, 19, 28).

The purpose of this investigation was to determine the antimicrobial efficacy of ozonated deionized water (with and without added organic material) generated by a recirculating ozone reactor (Lifex EV 2000R) against various heterotrophic bacteria and fungi important in the food industry as pathogens, spoilage organisms, and indicators of fecal contamination.

Pseudomonas aeruginosa ATCC 15442, *E. coli* ATCC 25922, *S. typhimurium* ATCC 6994, *S. aureus* ATCC 6538, *B. cereus* (food isolate), *Listeria monocytogenes* 4b (courtesy of Silliker Laboratories, Chicago Heights, Ill.), *Enterococcus faecalis* (food isolate), *Yersinia enterocolitica* ATCC 27729, *Candida albicans* ATCC 22572, *Zygosaccharomyces bailii* (purchased from Silliker Laboratories; isolated from mayonnaise), and *Aspergillus niger* (courtesy of James Grosklags, Northern Illinois University, DeKalb) were used in this investigation. The bacterial cultures were maintained on Difco (Detroit, Mich.) brain heart infusion agar slants except for *E. faecalis*, which was stored on Difco APT agar slants. All the bacterial cultures were stored at 4 to 6°C and transferred every 4 weeks. The two yeast cultures and *A. niger* were maintained on Difco potato dextrose agar slants, stored at 4 to 6°C, and transferred every 12 weeks. Loopfuls of cells from each of the bacterial strains except *E. faecalis* were aseptically transferred into 40 ml of brain heart infusion broth in 250-ml Erlenmeyer flasks and incubated at 35°C for 24 h, whereas *B. cereus* cells were incubated at 30°C for 24 h. *E. faecalis* cells were transferred to 40 ml of Difco APT broth in 250-ml Erlenmeyer flasks and incubated at 30°C for 24 h. For *C. albicans* and *Z. bailii*, loopfuls of cells were transferred to 40 ml of Difco potato dextrose broth in 250-ml Erlenmeyer flasks, placed in a gyratory water bath shaker model G76 (New Brunswick Scientific, Edison, N.J.) (100 to 125 rpm), and incubated at room temperature (18 to 22°C) for 48 h. After incubation, 30-ml volumes of each culture were centrifuged at 1,450 × *g* for 25 min at room temperature. The pellets were resuspended in 20 ml of sterile saline and centrifuged again at 1,450 × *g* for 25 min. After the second centrifugation, the pellets were resuspended in 10 ml of sterile saline. For the tests with soluble starch (SS; Fischer Chemical, Fairlawn, N.J.) and bovine serum albumin (BSA; Fraction V 96 to 99% albumin; Sigma, St. Louis, Mo.), the pellets were

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resuspended in 10 ml of sterile saline containing 20 ppm (20 mg/liter) of the corresponding organic material.

For *A. niger*, the spores from the stock culture were aseptically transferred to two potato dextrose agar slants and incubated at room temperature (18 to 22°C) for 8 days. After incubation, 15 ml of sterile 0.05% Triton X-100 (Sigma) was added to each tube and the spores were resuspended by using a vortex mixer (Baxter, McGaw Park, Ill.). The spore suspensions were centrifuged as described above, and the final pellet was resuspended in 15 ml of sterile saline. All washed cells and spores were chilled before use.

Ozone levels (in milligrams per liter) were measured by the indigo colorimetric method (1). Ozonated water was generated by a Lifex ozone apparatus (model EV 2000 R; Life Ozone Corp., Southfield, Mich.) using a 115 to 120 variable alternating current power source.

Duplicate ozone determinations of uninoculated solutions were performed directly at the generator outlet faucet and in the reservoir near the inlet tube before each organism was passed through the ozone apparatus. A concurrent system in which the ozone gas and water flowed in the same direction was used in this investigation. According to Lev and Regli (23), ozone concentrations (in milligrams per liter) can be conservatively measured in a "cocurrent" (sic) system in two ways: (i) outlet faucet concentration (C_{out}) and (ii) average concentration (C_{avg}), calculated as (C_{out} + inlet C_0)/2, where C_0 is the concentration near the inlet. Since C_0 was substantially lower in our system, C_{out} was a better measure for determining overall ozone concentration versus antimicrobial efficacy (23).

The antimicrobial effects of ozone were determined in deionized water with or without added organic material in the form of 20 ppm of SS or BSA, which may simulate organic levels in treated wastewater (30). BSA was dissolved directly in the deionized water, whereas SS was first dissolved by boiling a concentrated solution in deionized water before diluting. All solutions were ozonated at room temperature (19 to 21°C). The pH levels of nonozonated deionized water and ozonated deionized water were 5.7 and 6.1, respectively, whereas before and after ozonation in the presence of SS the pH remained at 6.0. In the presence of BSA, the pH was reduced from 6.4 to 6.0 after ozonation.

To a previously sanitized (70% ethanol followed by air drying) polyethylene container (capacity, 3.785 liters), 1.5 liters of deionized water with or without 20 ppm of SS or BSA was added. Four milliliters of washed cells or spores was pipetted into the polyethylene container, and the contents were stirred, yielding approximately 10^6 cells or spores per ml. Triplicate samples were extracted from the container to determine the initial cell or spore concentrations before ozonation. The ozone apparatus was equipped with a peristaltic pump producing a constant flow rate of 660 ml/30.0 s and an outlet faucet with an on-and-off lever. The hoses attached to and contained inside the ozone apparatus had a total volume of 150 ml. The hose attached to the peristaltic pump was primed and placed in uninoculated water while the faucet in the open position was placed over an empty container. The ozone apparatus was turned on, and the uninoculated water was pumped through the machine for 15 s, allowing approximately 330 ml to flush through the system. While still on, the inlet hose was momentarily blocked aseptically, removed from the uninoculated deionized water, and immediately immersed into the inoculated menstruum. After the uninoculated deionized water was allowed to purge the system for 25 s, a minimum of 400 ml of the inoculated suspension was flushed through the system and a sample designated "time zero" was taken. Immediately after the time zero sample, the faucet was placed in the inoculated container just over the water level, forming a recirculation loop. During inoculum recirculation, samples were taken after 1, 2, and 5 min. Final volumes in the container and ozone apparatus ranged from 1.0 to 1.1 liter with a recirculation rate of 47 s. A minimum of two separate evaluations were made for each organism.

After each run, the inlet hose was immersed in 1.0 liter of deionized water and the ozone apparatus was completely cleansed and rinsed. The apparatus was disassembled, and all hoses, the polyethylene container, beakers, and screens were sanitized with 70% ethanol and air dried. The apparatus was reassembled, and 1 liter of uninoculated deionized water was pumped through the system. Samples taken to check for residual contamination showed <10 cells or spores per ml.

Samples were collected from the ozone faucet into sterile test tubes (16 by 125 mm) and 1.1 ml was immediately pipetted into 10 ml of Difco D/E neutralizing broth and subjected to vortex mixing. Sterile deionized water was used for all subsequent dilutions. The pour plate technique was used to enumerate the surviving cells and spores. All platings were performed in duplicate. For all bacterial strains, except *E. faecalis*, Difco tryptic soy agar was used, whereas Difco APT agar was used to enumerate *E. faecalis*. All tryptic soy agar plates were incubated at 35°C for 48 h except for *B. cereus* plates, which were incubated at 30°C for 48 h. Potato dextrose agar plates incubated at room temperature (18 to 22°C) for 4 to 7 days were used to enumerate surviving yeast and mold spores.

Data were converted to $\log_{10}$ values, and the geometric means of duplicate plates per organism from at least two separate experiments were calculated. The log number of cells or spores killed per milliliter equaled the geometric mean before exposure to ozone minus the corresponding geometric mean after treatment for the various time periods. By using general linear-model procedures, the means and ranges for the C_{out} and C_{avg} ozone levels in the deionized water with 20 ppm of SS or BSA and deionized water without SS or BSA were calculated.

Statistical analysis programs PROC GLM (26) were used to test the significance of the data. Repeated-measures analysis of variance (univariate tests of the hypotheses) was used to compare survivorship of *E. coli*, *S. typhimurium*, *S. aureus*, and *L. monocytogenes* cells in ozonated deionized water containing SS or BSA with survivorship in ozonated deionized water without SS or BSA. The survival comparisons for each cell wall type were made in ozonated deionized water without SS and BSA. The conservative Greenhouse-Geisser adjustments were used to modify the F values. Bonferroni adjustments were used for multiple pairwise contrasts (0.017). Tukey's studentized range test (95% confidence level) was used to test the ozone concentrations for all possible comparisons of deionized water with and without added 20 ppm of SS or BSA. Ozone levels in deionized water, deionized water plus SS, and deionized water plus BSA were compared by a one-way analysis of variance.

The antimicrobial effects of ozone against two gram-positive bacteria, *S. aureus* and *L. monocytogenes*, are shown in Fig. 1. Statistical analyses of the curves indicated that neither organism showed a significant difference ($P > 0.05$) in a paired death rate comparison between the antimicrobial effect of ozonated deionized water with SS and the effect of that without SS or in the comparison between ozonated deionized water containing SS and that containing BSA. When the death rates in ozonated deionized water and ozonated water containing BSA were compared, however, the antimicrobial effects with no added organic material were significantly ($P < 0.05$) greater than in the presence of BSA. Overall, more than 4 log units of *L. monocytogenes* cells per ml was killed at time zero (instanta-

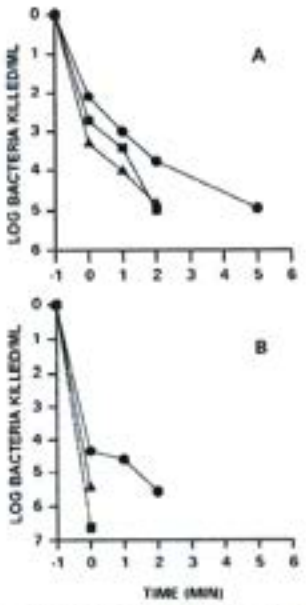

FIG. 1. Killing of viable cells of *S. aureus* (A) and *L. monocytogenes* (B) by ozone in deionized water containing no added organic material (▲) or 20 ppm of SS (■) or BSA (●). The data are means for at least two replicate experiments.

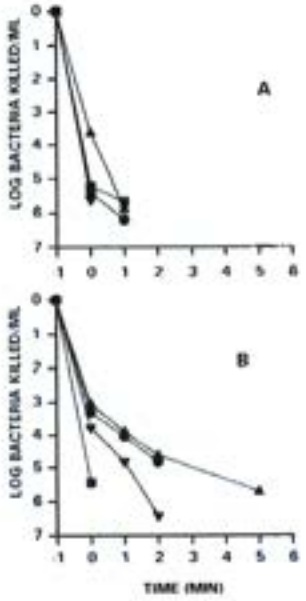

FIG. 3. Antimicrobial efficacy of ozone in deionized water against gram-negative bacteria *E. coli* (●), *S. typhimurium* (■), *P. aeruginosa* (▲), and *Y. enterocolitica* (▼) (A) and gram-positive bacteria *S. aureus* (●), *L. monocytogenes* (■), *B. cereus* (▲), and *E. faecalis* (▼) (B). The data are means for at least two replicate experiments.

neously) in the absence or presence of added organic material (Fig. 1A).

The death rate curves of ozonated deionized water with and without added organic material for *S. typhimurium* and *E. coli* are shown in Fig. 2. No significant difference ($P > 0.05$) between ozonated deionized water with SS and that without SS in the death rates or in the patterns of the curves for these two gram-negative bacteria was observed. For each bacterium, however, the death rates as well as the overall pattern of death obtained in ozonated water with or without SS were significantly greater ($P < 0.05$) than in ozonated water containing BSA. More than 5 log units each of *S. typhimurium* and *E. coli* cells per ml was killed instantaneously (time zero) after exposure to ozonated water or to ozonated water containing SS, whereas equivalent levels of death for *S. typhimurium* and *E. coli* in the presence of BSA occurred only after 2- and 5-min exposures, respectively (Fig. 2).

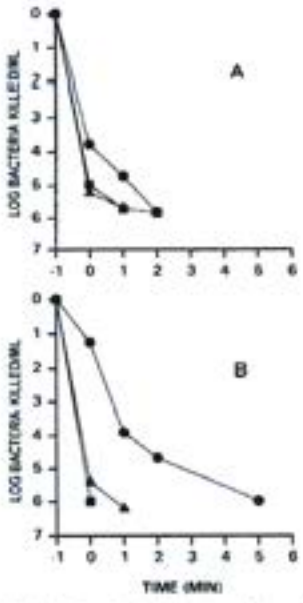

FIG. 2. Killing of viable cells of *S. typhimurium* (A) and *E. coli* (B) by ozone in deionized water containing no added organic material (▲) or 20 ppm of SS (■) or BSA (●). The data are means for at least two replicate experiments.

The antimicrobial effects of ozonated deionized water without added organic material against eight bacterial strains are presented in Fig. 3. With respect to the amount of death and the overall patterns of the death curves, no significant difference ($P > 0.05$) among the four gram-negative bacteria was observed (Fig. 3A). Among the gram-positive bacteria, the extent of death as well as the death rate curves for *S. aureus* and *E. faecalis* cells did not differ significantly ($P > 0.05$); however, *L. monocytogenes* displayed a significantly greater ($P < 0.05$) rate of death than *S. aureus* and *E. faecalis* (Fig. 3B). For *L. monocytogenes* cells, at time zero, more than 5 log units was killed by ozonated deionized water, whereas for *S. aureus*, *E. faecalis*, and *B. cereus*, 3 log units of bacteria or more was killed (Fig. 3B). Overall, except where instantaneous death occurred, most bacteria displayed biphasic death curves which were enhanced when effective ozone levels were reduced in the presence of BSA (Fig. 1 to 3).

The antimycotic effects of ozonated deionized water against yeasts of two genera and *S. niger* spores are shown in Fig. 4. Ozonated deionized water without added organic material caused more than 4.5 log units of killed cells per ml for the two yeasts, *C. albicans* and *Z. bailii*, at time zero. Less than 1 log unit of *A. niger* spores per ml was killed under the same conditions after 5 min of exposure.

Ozone concentrations in deionized water and deionized water containing 20 ppm of SS or BSA are presented in Table 1. Ozone concentrations were determined in two ways: at the outlet of the ozone apparatus (C_{out}) and over the whole system

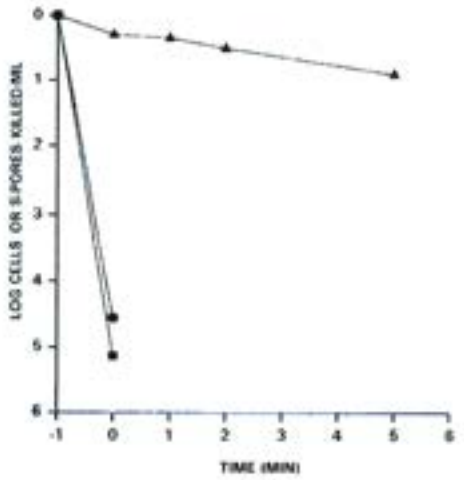

FIG. 4. Killing of fungal spores and viable yeast cells by ozone in deionized water with no added organic material. Symbols: ▲, *A. niger* spores; ●, *C. albicans*; ■, *Z. bailii*. The data are means for at least two replicate experiments.

(C_{avg}). No significant difference ($P > 0.05$) in the ozone levels (for C_{out} and C_{avg}) in deionized water and deionized water containing SS was observed. The ozone levels of C_{out} in deionized water and deionized water with SS added were 0.188 and 0.198 mg/liter, respectively, whereas C_{avg} levels were 0.064 and 0.068 mg/liter, respectively. The ozone levels for the deionized water containing BSA were significantly less ($P < 0.05$) than the ozone levels (C_{out} and C_{avg}) for deionized water and water containing SS. Average ozone concentrations in deionized water containing 20 ppm of BSA were 0.149 and 0.044 mg/liter for C_{out} and C_{avg}, respectively.

The results obtained in this study have shown that ozonated water is highly effective in killing both gram-positive and gram-negative food-associated bacteria. With the exception of *L. monocytogenes*, the gram-negative bacteria were substantially more sensitive to ozonated water than the gram-positive bacteria either in the absence or in the presence of added organic material. Yeast cells displayed sensitivity to ozonated water, whereas fungal spores were highly resistant.

Previous studies on the effects of ozone on microbes have involved the use of pure cultures and organisms naturally contaminating foods and water. Broadwater et al. (5), studying the effects of ozone on washed vegetative cells, reported that 0.12 mg/liter for *B. cereus* and 0.19 mg/liter for *E. coli* and *B. megaterium* were the minimal lethal threshold concentrations after 5 min of exposure. Fetner and Ingols (10) reported 0.4 to 0.5 mg/liter as the threshold concentration for *E. coli* after 1 min at 1°C. Both studies used varying ozone concentrations at a single time period and suggested that ozone killed microbes via an all-or-none phenomenon. Thus, in these studies either high ozone concentrations for a short period (1 min) or lower ozone concentrations for a single extended period (5 min) provided sufficient activity to reach the minimal threshold for complete killing. In the present study, however, ozone effectiveness determined by repeated sampling over a 5-min period at a single ozone concentration (0.15 to 0.20 mg/liter) indicated that an all-or-none killing phenomenon does not occur. Finch et al. (13) showed that *E. coli* in ozone demand-free phosphate water exhibited a disinfection rate consisting of an initial rapid stage followed by a slower inactivation stage. Several other studies using ozone have also shown that death rate kinetics for a variety of bacteria and viruses exhibit a biphasic process over an extended time period (6, 16, 20). In this study, biphasic death curves were observed for the majority of the gram-positive and gram-negative bacteria ozonated in the absence of added organic material (Fig. 3). This phenomenon was even more apparent wherever residual ozone levels were reduced by the presence of BSA (Fig. 1 and 2).

The sensitivity of microorganisms to ozone is profoundly affected by the organic nature of the medium, with protection caused both by physical factors, as in the case of agar, and by reduced ozone levels due to ozone demand of organic nutrients in the medium or in environmental waters (2, 8, 15, 16). This study shows that the type of organic material present during ozonation is more important than the amount present. Residual ozone levels in deionized water were significantly reduced only in the presence of 20 ppm of BSA, whereas 20 ppm of SS was without effect (Table 1). Consequently, death rates in the presence of BSA were reduced substantially but were not significantly affected in the presence of SS (Fig. 1 and 2).

The potential uses of ozone in the food industry include reduction of microorganisms on meat and poultry carcasses and in chilling water (19, 28), extension of shelf life of marine fish (14), reduction of atmospheric mold levels in meat and in small fruit storage rooms (9), and antimicrobial effects in bulk food items such as shelled eggs, bacon, beef, bananas, butter, mushrooms, cheese, and fruits (19). Additionally, ozone has been used synergistically with other antimicrobial agents (7, 14–16). The present study shows that ozonated water can effectively kill spoilage organisms (*P. aeruginosa* and *Z. bailii*), fecal contaminants (*E. faecalis* and *E. coli*), and food-borne pathogens (*L. monocytogenes*, *B. cereus*, *S. typhimurium*, *Y. enterocolitica*, and *S. aureus*). The sensitivity of the gram-negative pathogens and *L. monocytogenes* suggests that ozonated water might be especially applicable for killing these organisms on food surfaces such as fruits and vegetables where interference by organics may be minimal. Additionally, gaseous ozone might be effective in controlling *L. monocytogenes* in food environments. Although pure cultures of various food-borne pathogens and spoilage bacteria were used in this investigation, the ozone sensitivity data obtained on pure cultures used in this study should provide guidelines for further studies on ozone applications in the food and environmental industries.

TABLE 1. Mean concentrations and ranges of ozone in deionized water in the absence and presence of organic material

Additive (20 ppm)	Ozone (ppm) [mean (range)]	
	C_{out}	C_{avg}
None	0.188 (0.166–0.225)	0.064 (0.043–0.084)
SS	0.198 (0.166–0.246)	0.068 (0.052–0.092)
BSA	0.149[a] (0.131–0.168)	0.044[b] (0.036–0.053)

[a] Significantly less ($P < 0.05$) than the other C_{out} values.
[b] Significantly less ($P < 0.05$) than the other C_{avg} values.

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