Conference for Food Protection
2010 Issue Form

Internal Number: 057
Issue: 2010 III-001

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

All information above the line is for conference use only.

Title:

Report and Re-creation - Food Allergen Committee

Issue you would like the Conference to consider:

Acknowledgement of the Food Allergen Committee report and re-creation of the Committee to continue its work over the next two years.

Public Health Significance:

Nearly four percent of Americans (approximately 12 million) are affected by food allergies, including 3.7 percent of adults, and six percent of children younger than three years of age (Sicherer and Sampson 2006). Prevalence statistics vary according to methodology, including the assessment of food allergy via confirmed diagnosis, versus self-report (Rona, et al, 2007). Still, food allergy is a problem that pediatricians and scientists say is increasing among children (NIAID, 2006; Sicherer and Sampson, 2006). Additional research by FAAN (Food Allergy and Anaphylaxis Network) concludes that many food allergic reactions occur outside the home in restaurants and food service establishments.

Recommended Solution: The Conference recommends...:

acknowledgment of the Food Allergen Committee report and thanking the committee members for their work.

The Conference further recommends the re-creation of the Food Allergen Committee to extend the reach of food allergy education, training and awareness as follows:

- Identify appropriate strategies to develop an FDA "endorsed" Allergen Management Course, including the review of course curriculum.
- Review the pending publication of FDA materials and guidance document(s) related to allergen management.

- Utilize the strengths of groups like FAAN and IFIC Foundation (in cooperation with the CFP Food Allergen Committee) to define and lead a health professional outreach activity such as a "food allergy resource page" of educational materials suitable for state/local regulatory officials, food managers, and food employees.
- Add a CDC representative to serve on the CFP Food Allergen Committee to help enhance our current public health perspectives and assist in the development and dissemination of a health professional outreach activity.
- Report back to the 2012 Biennial Meeting with the outcome of these charges.

Submitter Information:

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Attachments:

- "Conference for Food Protection (CFP) Committee FINAL Report"
- "CFP Food Allergen Committee Roster"

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

Committee Name: Allergen Committee

Last Name	First Name	Position (Ch	Constituency	Employer	Address	City	State	Zip	Telephone
Flood	Anthony	co-chair	Other - Consumer	International Food Information Council	1100 Connecticut Ave. NW	Washington	DC	20036	202-296-6540
Prince	Gale	co-chair	Other - Consultant	Food Safety Consultant	7875 Woodstone Drive	Cincinnati	OH	45244	513-236-6264
Abel	Greg	member	Regulatory / Federal	USDA, FSIS, OPPD, LPDD	1400 Independence Ave, SW Room 2925 South Building	Washington	DC	20250-3700	(202) 205-0145
Canavan	Jeffrey W.	member	Regulatory / Federal						
Anderson	Bud	member	Regulatory / State	Virginia Department of Agriculture & Consumer Services	4677 Brookside Road	Roanoke	VA	24014	(540) 248-1579
Bombet	Carolyn	member	Regulatory / State	Louisiana Department of Health and Hospitals	628 N. 14th Street Box 10	Baton Rouge	LA	70802	(225) 342-7779
Miles	Pamela	member	Regulatory / State	Virginia Department of Agriculture & Consumer Services	102 Governor Street Room 349	Richmond	VA	23219	(804) 786-0412
Moris	Steven	member	Regulatory / State	Kansas Department of Agriculture	109 SW 9th Street	Topeka	KS	66612-1215	(785) 296-3511
Galindo	Teresa	member	Regulatory / Local	San Antonio Metro Health Department	332 W. Commerce	San Antonio	TX	78205	(210) 207-8853
Hirsch	Brian	member	Regulatory / Local	Summit County General Health District	1100 Graham Road Circle	Stow	OH	44224	(330) 926-5653
Jue	Robert	member	Regulatory / Local	Central District Health Department	707 N. Armstrong Place	Boise	ID	22202-4801	(208) 327-8523
Mitchell-Baker	Cassandra	member	Regulatory / Local	Fairfax County Health Department	10777 Main Street Suite 111	Fairfax	VA	22030	(703) 246-8438
Sommers	Maggie	member	Restaurants	National Restaurant Association	1200 17th Street NW	Washington	DC	20036-3097	202 331 5985
Foegle	Tom	member	Restaurants	Brinker International	6700 LBJ Freeway Suite 3105	Dallas	TX	75240	(972) 770-1745
Brooks	Scott	member	Restaurants	Yum! Brands	669 Long Meadow Spring	Branch	TX	78070	(502) 874-2501
Jackson	Keith	member	Restaurants	Potbelly Sandwich Works	222 Merchandise Mart, 24th Floor	Chicago	IL	60654	(312) 475-3854
Kohl	Larry	member	Retail	Food Marketing Institute	2345 Crystal Drive, Suite 800	Arlington	VA	22202-4801	(202) 220-0659
Tryba	Cas	member	Retail	Big Y Foods	2145 Roosevelt Ave	Springfield	MA	01102-7840	(413) 504-4450
Rossow	Todd	member	Retail	Publix Super Markets, Inc.	P.O. Box 32034	Lakeland	FL	33802	(863) 688-1188
McGuffey	Charles	member	Retail / Convenience	7-Eleven, Inc.	1626 S Greenstone Lane	Duncanville	TX	75137	(972) 828-6844
Grottenthaler	Robert	member	Industry / Manufacturing	Titteringtons Baking Company	48 Cummings Park	Woburn	MA	O1801	(781) 938-7600
Wallace	Susan	member	Academic	Johnson & Wales Univ	265 Harborside Avenue	Providence	RI	2905	(401) 598-1706
Swanson	Katherine	member	Expert / Advisory Members	Ecolab	655 Lone Oak Drive	Eagon	MN	55121	(651) 795-5943
Bardsher	Julia		Expert / Advisory Members	FAAN	11781 Lee Jackson Highway	Fairfax	VA	22033	703 563 3053

Committee Name: Allergen Committee

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Conference for Food Protection (CFP)
Committee FINAL Report

COMMITTEE NAME: 2008 – 2010 Food Allergen Committee

COUNCIL (I, II, III): Council III

DATE OF REPORT: January 2010

SUBMITTTED BY: Tony Flood and Gale Prince, co-chairs

COMMITTEE CHARGE(s):

1. Work directly with FDA pertaining to the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 (continuation charge of 2004 biennial meeting)

2. Work with industry and deliver food allergen information to state / local regulatory officials; food managers; health professionals; and food employees through appropriate marketing / outreach channels.

3. The Conference further recommends that the Food Allergen Committee work with the FDA to develop an appropriate educational component regarding food allergen awareness.

COMMITTEE ACTIVITIES (Progress Report)
SPECIFIC RECOMMENDATIONS

Progress Report – Charge #1
Work directly with FDA pertaining to the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 (continuation charge of 2004 biennial meeting)

- The CFP Food Allergen Committee is currently working with FDA to provide input and review of several resource and educational documents. These documents will help increase awareness about food allergy for the respective audiences as well as provide information and education for state / local regulatory officials; food managers; and food employees. The proposed projects for review include the following:
    - Provide input and review of the DRAFT allergen guidance document developed and written by FDA staff. The overall purpose of this “guide” is to serve as a resource for identifying and managing potential allergens that are present in foods at the food service level. It is also designed to complement the current food safety strategies that are already in place. We expect awareness will increase among users of this “guide”.
        - Timeline for completion – TBD

        - It has been reported by our FDA liaison, Becky Vigue, that the guidelines document is currently under internal review and that our Committee will have an opportunity to review the report and provide input. At this time we don't have a timeline for completion.

    - Provide review of the Allergen Management Course as recommended by the CFP Certification of Food Safety Regulatory Professionals (CFSRP) Workgroup. At the present time FDA's Division of Human Resource Development (DHRD), Office of Regulatory Affairs University (ORAU) is in the process of developing an allergen management course that will be available on its Web site. The work group agrees an allergen management course should be required training in the program standards but the review of the course should be completed by the Allergen Committee. The CFP CFSRP Work Group thinks that the appropriate expertise for reviewing the content of this course lies within the Allergen Committee rather than the CFSRP work group. Once the review of this course is complete, the CFP CFSRP work group is prepared to renew its deliberation as to how it fits in with the Program Standard 2 - Trained Regulatory Staff Curriculum.
        - Timeline for completion – ongoing

- The Allergen Management Course is still under development by FDA's DHRD. The CFP Allergen Committee will continue to seek out opportunities to provide review and input to the course. In the event the course will not continue as planned, we will work with FDA to identify appropriate strategies to develop a FDA "endorsed" training course. This proposed course would be developed by the CFP Allergen Committee, FDA and other appropriate stakeholders. It is critical that all future or proposed course developed by the CFP Allergen Committee be "endorsed" and "recognized" by FDA. This course would only be developed in the event the current course by FDA DHRD is not completed within a timely manner.

Progress Report – Charge #2

Work with industry and deliver food allergen information to state / local regulatory officials; food managers; health professionals; and food employees through appropriate marketing / outreach channels.

- The Committee discussed developing a food allergy resource page of education materials suitable for state / local regulatory officials, food managers and food employees.
    - Members of the Committee have provided input to different types of food allergy resource materials which have been developed for

their respective audiences. We will seek to better understand how we might be helpful in crafting new allergy resources or repackaging existing resource materials that are useful to the target audiences. By identifying what is currently available in regards to food allergy resources and educational materials, we understand and ultimately are able to identify specific gaps in food allergy resources. By participating in this exercise, we will be better equipped to develop or recommend the development of a tangible product that would address the very essence of the committee charge.

- This activity will also provide an opportunity for the Committee to better understand and identify possible marketing and outreach strategies for the project. The Committee also discussed ideas to extend the outreach of the project and to engage stakeholders such as National Environmental Health Association (NEHA), Food Marketing Institute (FMI), National Restaurant Association (NRA), International Food Information Council (IFIC), Institute of Food Technologists (IFT Extension, the Food Allergy and Anaphylaxis Network (FAAN) and others as identified by the committee as possible venues for marketing and outreach strategies.

- We recommend this outreach to be "spearheaded" by groups like FAAN or IFIC – these organizations have established relationships with several health professional organizations such as the American Academy of Allergy, Asthma and Immunology (AAAAI), the American Academy of Pediatrics (AAP) and the American Medical Association (AMA) to name a few. The Committee would continue to provide input and perspective on any future outreach activities.

- Along with the development of an allergen resource page, the International Food Information Council Foundation is collaborating with the NRA, FAAN and AAAAI to revise its current food allergy poster for restaurant staff. The poster will be available for a nominal fee or in some instances free to all food allergy stakeholders via various networks including web sites. The poster will be made available in English and Spanish and will be available for the 2010 CFP Biennial Meeting. Members of the CFP Allergen Committee will have an opportunity to provide input. An issue will be submitted to the 2010 Biennial Meeting seeking FDA and CFP "endorsement" of the poster.

Progress Report: Charge #3

The Conference further recommends that the Food Allergen Committee work with the FDA to develop an appropriate educational component regarding food allergen awareness.

- The Committee discussed options to address the charge. As discussed, the Committee identified "regulators and industry that is regulated" as the target audience in this charge. We feel it is important for this Committee to increase its awareness of the current FDA food allergen activities as outlined in the Food Allergen Labeling and Food Protection Act (FALCPA). We will continue to reach out to our FDA representatives and identify opportunities to broaden the FDA engagement to better align ourselves with the current thinking, communication and education strategies regarding food allergy overall.

- To address this particular charge, the CFP Food Allergen Committee will provide a brief update during the 2010 Biennial meeting.
    - The focus of this proposed session is hoped to increase awareness about food allergy control efforts for retail / food service industry and regulatory officials.

Additional discussions:

- The Committee felt it necessary to reach out to the Food Allergy and Anaphylaxis Network (FAAN) a resource organization in the event we have issues or questions or needed clarification regarding consumer-related / advocacy issues. The Committee co-chair Tony Flood met with the new leadership of FAAN in early 2009.
    - Julia Bradsher, President and CEO of FAAN is very interested in being engaged with the CFP Allergen Committee and in December, provided an update to the CFP committee via web cast.

SPECIFIC RECOMMENDATIONS

The CFP Food Allergen Committee recommends re-creation of the Allergen Committee. We also recommend the Committee be charged with the following:

- Identify appropriate strategies to develop an FDA "endorsed" Allergen Management Course, including the review of course curriculum.

- Review the pending publication of FDA materials guidance document(s) related to allergen management.

- Utilize the strengths of groups like FAAN and IFIC Foundation (in cooperation with the CFP Food Allergen Committee) to define and lead a health professional outreach activity such as a "food allergy resource page" of educational materials suitable for state/local regulatory officials, food managers, and food employees.

- Add a CDC representative to serve on the CFP Food Allergen Committee to help enhance our current public health perspectives and assist in the development and dissemination of a health professional outreach activity.

- Report back to the 2012 Biennial Meeting with the outcome of these charges.

COMMITTEE MEMBERSHIP

- Members of the CFP Food Allergen Committee were selected by categories. The categories include: regulatory / federal; regulatory / state; regulatory / local; restaurant; retail; retail / convenience; industry / manufacturing; academic; expert / advisory resource. A detailed list of committee members is attached along with contact information. We would like to thank the Committee members for their support and participation in the 2008 – 2010 CFP Food Allergen Committee.

This final report and the committee member roster is respectfully submitted by Tony Flood and Gale Prince, co-chairs of the 2008 – 2010 CFP Food Allergen Committee.

Conference for Food Protection
2010 Issue Form

Internal Number: 017
Issue: 2010 III-002

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

All information above the line is for conference use only.

Title:

Allergen Ingredients and Allergen Cross-contamination.

Issue you would like the Conference to consider:

Expand section 3-101.11 to provide greater guidance on food allergens. Also expand section 3-602.11 to reflect the existing labeling requirement to include the common name in plain English of all allergens in the ingredient section.

Public Health Significance:

Six to seven million people in the United States have food allergies. Food allergens cause an estimated 30,000 ER visits with 150-200 deaths yearly.

Recommended Solution: The Conference recommends...:

charging the Allergen Committee with the following:

- to develop recommended Food Code language changes to Section 3-101.11 and 3.602.11 to list possible cross-contamination sources (such as common hot-oil fryers, sanitized surfaces that have not been cleaned, dish machines with food debris, product thermometers, wiping cloth sanitizer solutions, airborne wheat flour, and ingredients such as barley, oats, and rye (which may be cross-contaminated with wheat during harvest and storage).

- to work with the FDA to finalize a definition for "gluten-free" and provide clarification for facilities that identify an allergen-free food and any necessary verification to their nutritional claims.

- to report back to the 2012 Biennial Meeting of the Conference for Food Protection.

Submitter Information:

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Conference for Food Protection
2010 Issue Form

Internal Number: 080
Issue: 2010 III-003

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

All information above the line is for conference use only.

Title:

Food Allergen Poster Endorsement

Issue you would like the Conference to consider:

The Food Allergen Committee seeks endorsement from the Conference for Food Protection and the FDA of the attached poster titled "What You Should Know About Food Allergies."

Public Health Significance:

It is well documented by physicians and food allergy advocacy organizations, that restaurants and other food establishments pose a number of dangers for food allergic individuals particularly with respect to cross-contamination and unexpected ingredients in certain foods. Approximately 13.7% of registrants in the United States Peanut and Tree Nut Allergy Registry have reported reactions associated with such establishments. (Furling TJ, DeSimone J, Sicherer SH "Peanut and tree nut allergic reactions in restaurants and other food establishments *J Allergy Clin Immunol*, 2001 Nov;108(5):867-70) Education and awareness about food allergies is paramount for restaurant staff as they are key communicators with patrons at any given food establishment. The poster "What you Should Know Food Allergies" servses to provide restaurant staff; managers and other foodservice personnel, with an additional educational tool to help increase awareness and provide basic undersanding about food allergy and what to do in an emergency.

Recommended Solution: The Conference recommends...:

that the Conference for Food Protection endorse the educational poster titled "What You Should Know About Food Allergies."

The Conference further recommends that a letter be sent to the FDA requesting their endorsement of this educational poster.

Note: poster is attached to this Issue as a PDF file.

Submitter Information:

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E-mail:	flood@ific.org

Attachments:

- "What you Should Know About Food Allergies"

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

WHAT YOU SHOULD KNOW ABOUT FOOD Allergies

Symptoms of a Food Allergic Reaction

▶ SYMPTOMS CAN RANGE FROM MILD TO LIFE THREATENING

Call 911 if a customer experiences any of the following symptoms

- Itching on or around the mouth, face, scalp, hands and/or feet
- Abdominal cramps
- Vomiting
- Diarrhea
- Hives (welts) or rash
- Swelling of the face, eyelids, lips, hands and/or feet
- Tightening of the throat (difficulty swallowing)
- Wheezing and hoarseness
- Shortness of breath
- Difficulty breathing
- Loss of consciousness

▶ WHAT TO DO:

If a guest informs you that he or she has a food allergy

- Inform the cook, manager and/or person in charge
- Check the ingredient lists for all components of the meal for potential allergens
- Review the meal preparation procedure to check for potential cross contact
- Share all information with the customer

To help avoid cross contact between allergen and non-allergen foods

- Use clean and sanitized equipment and work surfaces
- Never use the same utensil to serve different prepared dishes and sauces
- Remember that cooking oils, splatter and steam released from foods, can be sources of cross contact

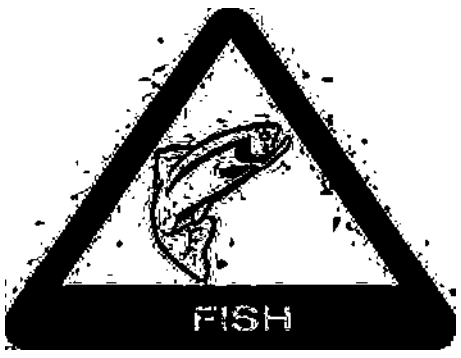
▶ STILL NOT SURE WHAT TO DO?

Ask a manager!

If you are not 100% sure about the ingredients in a menu item, say so. Don't guess. A life may depend on it!

MOST COMMON FOOD ALLERGIES

PEANUTS
Ground nuts, peanut butter



FISH
Tuna, salmon, anchovies

CRUSTACEAN SHELLFISH
Crab, lobster, shrimp

EGGS
Albumin, mayonnaise

SOY
Soy milk, soy bean, tempeh, tofu

NOTE:
Tony-there are several icons for tree nots on the http://www.foodprotection.org/resources/food-allergen-icons/icons.php website. Should I use all?

TREENUTS
Walnuts, pecans, almonds, cashews

WHEAT
Bread, cereal, grains, bran, flour, semolina

MILK
Also listed as casein

INTERNATIONAL FOOD INFORMATION COUNCIL FOUNDATION

AMERICAN ACADEMY OF ALLERGY ASTHMA & IMMUNOLOGY

NATIONAL RESTAURANT ASSOCIATION®

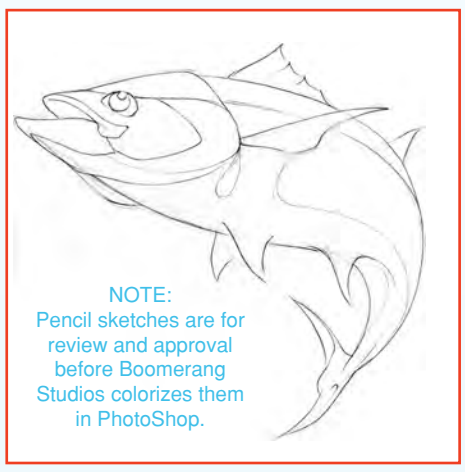
The Food Allergy & Anaphylaxis Network

CONTACT INFO HERE? WEBSITE?

WHAT YOU SHOULD KNOW ABOUT FOOD Allergies

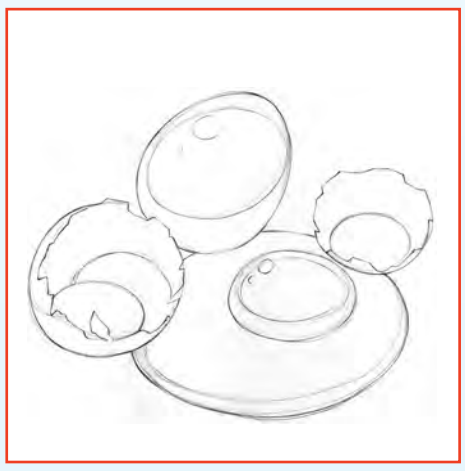
MOST COMMON FOOD ALLERGIES

PEANUTS
Ground nuts, peanut butter



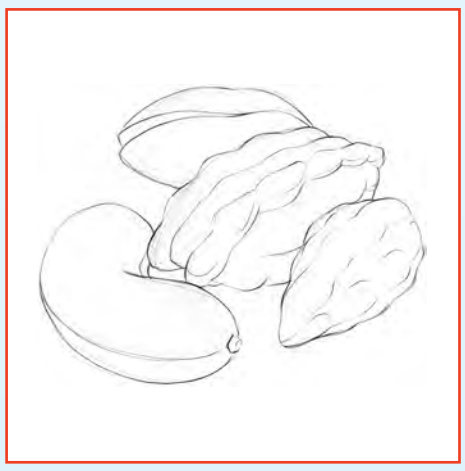
FISH
Tuna, salmon, anchovies

CRUSTACEAN SHELLFISH
Crab, lobster, shrimp



EGGS
Albumin, mayonnaise

SOY
Soy milk, soy bean, tempeh, tofu



TREENUTS
Walnuts, pecans, almonds, cashews

WHEAT
Bread, cereal, grains, bran, flour, semolina

MILK
Also listed as casein

Symptoms of a Food Allergic Reaction

SYMPTOMS CAN RANGE FROM MILD TO LIFE THREATENING

Call 911 if a customer experiences any of the following symptoms

- Itching on or around the mouth, face, scalp, hands and/or feet
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WHAT TO DO:

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STILL NOT SURE WHAT TO DO?

Ask a manager!

If you are not 100% sure about the ingredients in a menu item, say so. Don't guess. A life may depend on it!

Stay informed, visit:

INTERNATIONAL FOOD INFORMATION COUNCIL FOUNDATION

AMERICAN ACADEMY OF ALLERGY ASTHMA & IMMUNOLOGY

NATIONAL RESTAURANT ASSOCIATION®

The Food Allergy & Anaphylaxis Network

CONTACT INFO HERE? WEBSITE?

2ND PROOF 7/21/09 - LAYOUT DESIGN 2

Conference for Food Protection
2010 Issue Form

Internal Number: 004
Issue: 2010 III-004

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

All information above the line is for conference use only.

Title:

Report - Sanitizer Committee

Issue you would like the Conference to consider:

At the 2008 Conference for Food Protection, the FDA posed questions related to on-site generators of antimicrobial pesticides. The Sanitizer Committee was formed to address the following charge:

"to work with the FDA, EPA and other stakeholders to develop appropriate language for the Food Code addressing on-site generation of pesticides in food establishments and report back to the 2010 CFP Council III."

The 2008-10 Sanitizer Committee is submitting two issues to the 2010 Conference for Food Protection:

1. **Report - Sanitizer Committee**
2. **On-Site Generation of Antimicrobial Pesticides**

The following attachments are also submitted:

1. **'2008-10_Sanitizer_Committee_Final_Report'**
2. **'2008-10_Sanitizer_Committee_Roster'**
3. **'Food_Code_Recommendations_for_On-site_Generation_of_Antimicrobials'** (extracted from Committee Report)

Public Health Significance:

Proper use of sanitizers is an important step to prevent cross contamination and food safety failures. On-site generation of sanitizers and other antimicrobials is not addressed in the 2009 Food Code, and the regulatory process and requirements for sanitizers generated and used on-site varies considerably from the regulatory process for manufactured

products. Clarification of the Food Code requirements for on-site generated sanitizers is essential to ensure proper use of these materials and to avoid unproductive confusion for inspectors and operators.

Recommended Solution: The Conference recommends...:

acknowledgment of the 2008-10 Sanitizer Committee Report, with thanks to the members of the Sanitizer Committee for completing their task, and disbanding the committee.

Submitter Information:

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Attachments:

- "2008-10_Sanitizer_Committee_Final_Report"
- "2008-10_Sanitizer_Committee_Roster"

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

Conference for Food Protection
Committee FINAL Report

COMMITTEE NAME: 2008-10 Sanitizer Committee

COUNCIL (I, II, III): III

DATE OF REPORT: 22 December 2009

SUBMITTED BY: Katherine MJ Swanson & Tressa Madden, Co-Chairs

COMMITTEE CHARGE(S): to work with the FDA, EPA and other stakeholders to develop appropriate language for the Food Code addressing on-site generation of pesticides in food establishments and report back to the 2010 CFP Council III.

The term "pesticides" in the context of this charge was considered by the committee to mean sanitizers and potentially other antimicrobial solutions, but not rodenticides or agricultural pesticides. This is consistent with the name of the committee; i.e., the "Sanitizer" Committee.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

Specific Activities

Committee completed the charge through 12 conference calls, a few sub-committee conference calls, and email comments on working drafts. See Appendix 1 for dates and activity on conference calls. The work of the Committee focused on three (3) specific activities:

1. Describing the current federal regulatory requirements for on-site generators of antimicrobial pesticides
2. Addressing unresolved questions related to on-site generators of antimicrobial pesticides
3. Developing specific recommendations for language in the Food Code for on-site generation of antimicrobial solutions.

This report addresses each of these activities.

Requirements for On-site Generators of Antimicrobial Pesticides in Food Establishments

Background

- The *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA) of 1947 was enacted to regulate the marketing of pesticides and devices, and for other purposes.
- By law, the Environmental Protection Agency (EPA) is authorized to register a pesticide for sale and distribution in the United States only if it will not cause unreasonable adverse effects on human health or the environment when used according to its label.
- FIFRA provides EPA with the authority to oversee the registration, distribution, sale, and use of pesticides. FIFRA applies to all types of pesticides (unless exempt), including but not limited to antimicrobials. The antimicrobial class of pesticides includes disinfectants, sanitizers and other substances that are intended to control microorganisms in or on various surfaces or media. FIFRA requires sellers, distributors and users of registered pesticide products to follow the labeling directions on each product explicitly.
- Under FIFRA, no one may sell or distribute or use a pesticide or an article containing a pesticide, including but not limited to an antimicrobial pesticide, unless it is registered by EPA, or unless it is exempted by the regulations.

On-site Generator Status

- On-site generators of hard surface sanitizers/disinfectants, such as chlorine dioxide, ozone, hypochlorous acid (HOCl, generated by processes known as electrolyzed water, electro chemically activated water, electro activated water, etc.), are currently classified by EPA as devices.
- EPA does not currently require the registration of pesticidal devices; however, devices <u>are not</u> exempt from other pesticide requirements under FIFRA particularly with regards to labeling as defined in the Code of Federal Regulations (CFR) 40 CFR 156.10.

FIFRA Requirements

- All on-site generating devices are subject to a number of FIFRA's provisions, including labeling standards and production in registered establishments.
- On-site generators are subject to EPA device labeling requirements. No person may sell or distribute a pesticide device that is misbranded.
- The requirements for device labels are established by section 2(q)(1) and section 12 of FIFRA, as well as 40 CFR 152.500 and 156.10. No statement that is false or misleading can appear in a device's labeling. Statements that are subject to this standard include, but are not limited to, the following:
    - The name, brand, or trademark under which the product is sold
    - An ingredient statement
    - Statements concerning effectiveness of product
    - Hazard and precautionary statements for human and domestic animal hazards
    - Environmental and exposure hazards
    - The directions for use
- This provision of FIFRA is critical because it deals with statements of composition, antimicrobial effectiveness and safety of a pesticide or device.
    - Because there has been no requirement for device registration, what we see in the marketplace tends to be self certification of the performance, safety and efficacy of pesticide devices.
    - Third party data is presently acceptable to demonstrate due diligence in making pesticide claims on on-site generated and applied sanitizers. A certified lab is not required, and EPA fees are not assessed for each claim made.
    - EPA expects a device manufacturer to be able to substantiate claims. A device making a sanitizer claim is expected to meet the same performance standard using the same testing methodology as that of a registered pesticide product making a sanitizer claim.
- On-site generators may also be subject to state regulation. Each state can have its own statutes and regulations concerning pesticide and pest control device registration and regulation.

2009 Food Code Recommendations

- On-site generators of antimicrobial solutions are not specifically mentioned in the Food Code under Equipment or other provisions.
- Equipment must meet the recommendations of Food Code Parts 4-1 "Materials for Construction and Repair" and 4-2 "Design and Construction". According to § 4-205.10, equipment that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program are deemed to comply with Parts 4-1 and 4-2 of this chapter. As an example, an NSF Certification process includes:
        - Physical evaluations of design and construction, material evaluation and performance testing (when required).

  - Material requirements, including specifications that all materials that have contact, or potential contact, with food must not contribute contaminants of toxicological significance to the food.
  - Performance testing to verify that equipment conforms to all performance requirements of the standard. Note – Many products are certified to NSF Standard 169 for Special Purpose Food Equipment and Devices. This standard includes requirements for design, construction and materials but not efficacy of microbial claims.
- Equipment must meet the recommendations of § 4-402.11 "Fixed Equipment, Spacing or Sealing".

Resolution of 2008 Questions on On-site Generators of Antimicrobial Pesticides

At the 2008 Biennial Meeting of the Conference for Food Protection, the FDA posed questions related to on-site generators of antimicrobial pesticides. The Sanitizer Committee was formed, in part, to address these questions. The following questions (in ***bold and italics***) were posed to the committee. The Sanitizer Committee answered the questions in a general manner, rather than focusing on specific generators. This will hopefully allow for introduction of new antimicrobials in the future, as long as they meet the general requirements.

1. ***Does the chemical produced comply with §7-204.11 "Sanitizers, Criteria," which states that the sanitizer shall meet the requirements of 40 CFR §180.940?***

   - Of the on-site generated chemistries that the Committee considered (e.g., chlorine dioxide, hypochlorous acid, sodium hypochlorite, ozone), only chlorine dioxide, hypochlorous acid, hydrogen peroxide, and sodium hypochlorite are listed in 40 CFR 180.940 "Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions)." Ozone is not listed in 40 CFR 180.940, but it is approved under 21 CFR 173.368 as a secondary food additive. The 2009 Food Code also includes a new approved use of ozone in §7-204.12 as follows: "Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR 173.368 Ozone."

   - In the opinion of the majority of the Committee <u>based on science</u>, it seems reasonable that ozone and other secondary food additives should be allowed for sanitization of a food contact surface, <u>if</u> efficacy can be demonstrated and levels used are below those listed for secondary food additives.

   - EPA's position is that any chemical used on a food contact surface for sanitization purposes must be listed in 40 CFR 180.940 unless data are submitted showing there is no residue. If there is no residue, EPA would likely list the ingredient in 40 CFR 180.2020. Ozone is not listed in either reference. EPA procedures exist to add other sanitizers to the list if providers chose to do so, although this may not be a rapid process.

2. ***Does the unit comply with the requirements of FIFRA as implemented in 40 CFR §152.500?***

   - 40 CFR 152.500 addresses EPA requirements for pesticide devices, but no list of "approved" sanitizer generating devices currently exists. Further, the regulation does not specifically indicate whether an ozone, chlorine dioxide or electrolytic chlorine generator, as a class, falls under this regulation. Rather, the regulation specifies the requirements that a manufacturer must meet for an on-site generating device to comply with the regulation. The committee cannot determine if any or all on-site generators would meet this regulation. Compliance with the regulation falls to the specific pesticide device and the device manufacturer.

- The manufacturer of the generator should provide documentation that the device complies with 40 CFR 152.500 and the manufacturing establishment's registration number should be on the device. Compliance with 40 CFR 152.500 goes beyond labeling of the device with an EPA establishment number. The device must also comply in regard to how it is "labeled and marketed." Language regarding labeling and marketing for both pesticides and devices in 40 CFR 156.10 reads as follows:

  > "5) *False or misleading statements*. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to §152.500, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:
  >
  > > "(i) A false or misleading statement concerning the composition of the product;
  > >
  > > "(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;
  > >
  > > "(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;
  > >
  > > "(iv) A false or misleading comparison with other pesticides or devices;
  > >
  > > "(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;"

- Other provisions related to claims as to the safety of the pesticide or its ingredients are addressed in 40 CFR 156(a)(5)(ix). For example, "including statements such as 'safe', 'nonpoisonous,' 'noninjurious,' 'harmless' or 'nontoxic to humans and pets' with or without such a qualifying phrase as 'when used as directed' " may also be considered false or misleading.

- No regulatory body oversees testing that a device is in compliance with its labeling, therefore a user of an on-site generator or an inspector must rely on the manufacturer to self affirm that the device complies with the regulation when used according to the manufacturer's instructions. Compliance would involve validation that the output of a device is effective for its claimed uses and verification that the output of the device is within the required concentration, pH, oxidation reduction potential (ORP), or other parameters required to be effective at the point of use.

3. *Are there occupational exposure concerns that make the unit unsuitable for a retail/foodservice setting?*

Depending upon the on-site generator being considered, there may or may not be occupational exposure concerns for a unit. The Committee believes that addressing this question in detail is outside of the scope of the original charge; i.e., "to develop appropriate language for the Food Code addressing on-site generation of pesticides in food establishments." Historically, the Food Code has not been a vehicle to address <u>occupational safety</u> issues; rather it provides guidance to address food safety issues. For example, slicers have occupational safety issues, which are not reviewed in great depth in the Food Code. Should FDA wish to address occupational safety issues, OSHA limitations such as those in 29 CFR 1910.1000 could be referenced. Manufactures should include information based on

occupational issues and include appropriate sensors, timers, or shut off devices, as appropriate, to protect workers.

4. *Are there operational and user training issues, such as ability to adjust and maintain proper output concentrations that make it unsuitable for retail/foodservice?*

The Committee cannot answer this question for all potential devices available now or in the future, as the level of operational and training issues will vary. In general, the equipment must be installed properly, with sufficient capacity to produce the volume of sanitizer required. This will vary by location and use requirements. Food workers must know how to use the equipment properly, how to verify that the output is at the proper concentrations, and how to maintain the equipment. This is similar to other devices that may be used in a foodservice or retail establishment.

An example of information that is provided on certain devices is the following UL 979 disclaimer for "Water Treatment Appliances":

> "This category covers water treatment equipment employing ozone generation, investigated with respect to mechanical, electric shock, and fire hazards only. Maximum ozone threshold limit recommendations are set by the American Conference of Governmental Industrial Hygienists as found in 21 CFR 801.415 "Maximum Acceptable Level of Ozone." Compliance with the applicable regulations under conditions of normal and abnormal operation has not been investigated. The methods for controlling ozone release or the effectiveness of the water treatment have not been investigated."

- Visible onboard indicator of in-spec operation. Many ozone generators are adjustment free. When activated, they simply turn the supply of ozonated water on or off. Detailed installation and operating instructions should be concise and appropriate for the target audience.
- Emergency shut-off is recommended.

Both ozone and chlorine dioxide generators produce a gas dissolved in water, and the level present in the water is impacted by temperature of the water and mechanical agitation. Therefore, the concentration and potential efficacy of a solution of ozone or chlorine dioxide can change depending on how the solution is used. For example, a solution containing 5 ppm active ozone or chlorine dioxide in a spray bottle may have less than 1 ppm when that solution is sprayed onto a surface. A solution of ozone or chlorine dioxide made in 35°C water will have a lower active concentration than the same solution generated in 25°C water because of the potential for off-gassing. This phenomenon impacts both the safety and efficacy of the solution. Because of the potential for diffusion of the gas out of water, the concentration of the active ingredient is most accurately verified on the surface being sanitized, rather than in the stock solution prior to application (e.g., spraying the solution on a test strip rather than dipping the strip into the solution). This is unique to a gas dissolved in water because chemical solutions are not subject to the same type of activity loss through spraying. Users need to be trained on this to ensure proper operation.

The chemistries produced by an on-site generator can be tested for microbial efficacy under the same Association of Official Analytical Chemists (AOAC) standard used by the EPA for sanitizer registration. There is need for training of inspectors and users to understand how to determine if the solution generated has antimicrobial efficacy consistent with these standards. Unlike EPA-registered sanitizers, there is no list or registration number that the user or inspector can use to make this determination.

Because pesticidal devices are exempt from registration, EPA cannot require that efficacy data be submitted and will not approve a label for these devices for the same reason. The Committee suggests that data be developed under Good Laboratory Practices (GLP) using accepted AOAC methods specific to the active species produced by the given pesticide device.

Under proper concentration, contact time, temperature and pH, these chemistries can be effective sanitizers for food contact surfaces. There is need to validate and verify that the output of one of these systems can meet the definition of sanitization defined in §1.201 of the Food Code. No standard process exists to achieve this; however, it may be possible to require manufacturers to provide information on how they demonstrated effectiveness if they market the product for the purpose of generating a sanitizing solution.

Test strips as well as colorimetric and titrimetric methods exist for ozone, chlorine dioxide and HOCl/NaOCl, therefore the concentration can be verified on-site for any of these technologies. These should be used operationally to verify that the proper concentration is used and training is needed to ensure that the test methodology is used correctly.

Environmental monitors exist for ozone and chlorine dioxide that could provide background surveillance of the environment. Currently these devices may be prohibitively expensive and thus may not be practical in a food service or retail setting. Monitoring devices may not be necessary if it can be shown that the device cannot produce an output level considered by OSHA to be hazardous.

Other operational considerations include:

- Chlorine dioxide and ozone are minimally impacted by pH and hardness.
- The efficacy of HOCl/NaOCl is impacted by pH in a manner that is consistent with pH and temperature already identified in the Food Code, but it is minimally impacted by water hardness.
- In cases of water treatment, all of these oxidizers should be dosed at a concentration that overcomes the organic demand, leaving some residual active to provide kill. It is reasonable to think the same approach could be used for hard surface sanitization.
- An additional issue exists around controlling the concentration of ozone and chlorine dioxide in variable water conditions (temperature and agitation). This should be addressed by the manufacturer's instructions.

For the technologies considered, the potential for corrosion appears to be minimal under anticipated use conditions. For ozone and chlorine dioxide, the levels of active ingredient that would be required to achieve sanitization are in the single to tens of ppm levels. Further, ozone and chlorine dioxide disperse into the air as a water solution dries on a surface, making corrosion potential at typical use dilution levels minimal. However, in a closed space, chlorine dioxide has been known to cause corrosion on the top of a stainless steel container. With HOCl/NaOCl there is a breadth of historical experience of compatibility over the slightly alkaline pH ranges typically seen with commercial chlorine bleach (pH 8-10 in use dilution). An on-site generated solution with an equivalent pH and available chlorine content would likely have a similar performance profile. Acidic solutions of HOCl/NaOCl in the pH range of 2-4 could be more problematic over extended periods of time because of the high potential for chloride ion pitting on stainless steel under low pH high

chloride conditions. Any surface that is incompatible with bleach would also be incompatible with a generated solution of HOCl/NaOCl. The manufacturer's information should provide guidance on material compatibility for the product to assist with proper training and operation.

5. *Has the device been accepted for use in other non-retail applications? By whom?*

As previously mentioned, on-site generation of ozone, chlorine dioxide and HOCl/NaOCl are being used industrially for water treatment, bleaching, waste water recovery, and poultry washing. Ozone, chlorine dioxide and HOCl/NaOCl have also been used for laundry applications. Additionally, on-site generated HOCl/NaOCl and chlorine dioxide are used as high level disinfectants to decontaminate medical devices such as heat flexible endoscopes. On-site generators are used in dental applications to decontaminate dental unit waterlines, sanitize/disinfect dental office surfaces and as endodontic cleansers. HOCl/NaOCl on-site generators are used to treat acute and chronic wounds. On-site generators of chlorine dioxide and HOCl/NaOCl are used in agricultural applications to generate disinfecting agents. Furthermore, HOCl/NaOCl on-site generators have been approved by FDA as high level disinfectants, as a wound care irrigants and also as endodontic cleansers. There may be other applications.

6. *Does the manufacturer, the device and/or the sanitizer produced need to be EPA registered?*

There are FIFRA requirements that apply to the manufacturers of pesticidal devices. Also, the need for sanitizer registration depends on the nature of the sanitizer produced, by whom it is applied and whether there is intent to package/sell/distribute it.

Refer to the previous section on 'Requirements for On-site Generators of Antimicrobial Pesticides in Food Establishments.'

Recommended Food Code Language for On-site Generation of Antimicrobial Solutions

Based on the Committee's deliberations and the specific charge to identify language related to on-site generation of antimicrobial pesticides, the Committee identified several sections of the Food Code where on-site generators should be addressed. These are discussed in Table 1, which includes rationale for the change and specific language recommendations.

Specific Recommendations:

1. *Consider the recommended language in Table 1, including:*
    - *a.* Adding §4-204.124 to address equipment requirements for on-site generators
    - *b.* Adding ¶4-501.114 (F) to address the sanitizing solutions generated on-site
    - *c.* Updating Annex 3 for §4-501.114 to address FIFRA requirements for on-site generators
    - *d.* Adding ¶7-204.11 (B) to address pesticides that may not required a tolerance
    - *e.* Updating Annex 3 for §7-204.11 to address OSHA limits for gases dissolved in solution
    - *f.* Update §7-204.12 to address on-site generation of chemicals to wash vegetables.

2. *The Committee requests that the Sanitizer Committee be disbanded and note that the assigned charges are completed.*

REQUESTED ACTION:

The 2008-10 Sanitizer Committee is submitting two issues to the 2010 Biennial Meeting of the Conference for Food Protection:

1. Report – Sanitizer Committee
2. On-Site Generation of Antimicrobial Pesticides

The following attachments are also submitted:

1. '2008-10 Sanitizer Committee Final Report'
2. '2008-10 Sanitizer Committee Roster'
3. 'Food Code recommendations for on-site generation of antimicrobials' (extracted from Committee Report)

COMMITTEE MEMBER ROSTER

An abbreviated list of committee members follows, and a detailed list with contact information is attached. The Co-Chairs wish to thank these active committee members for their expertise and dedication to understanding this complex issue.

Name	Employer	City	State
Brania, Jonathan	Underwriters Laboratories, Inc.	Research Triangle Park	NC
Brickey, Matthew	National Restaurant Association	Washington	DC
Edwards, Dennis	Environmental Protection Agency	Washington	DC
Gordon, Christopher	Virginia Health Department	Richmond	VA
Grinstead, Dale	Johnson Diversey	Sturtevant	WI
Harris, Tanya	Tulsa Health Department	Tulsa	OK
Hepp, Mark	FDA Center for Food Safety & Applied Nutrition	College Park	MD
Herdt, Brandon	Ecolab	Eagan	MN
Hipp, Joel	Hobart Corp.	Troy	OH
Johnson, Thomas	Johnson Diversified Products, Inc.	Mendota Heights	MN
Kunduru, Mahipal	Safeway, Inc.	Pleasanton	CA
Lhotka, Lorinda	Alaska Dept. Environ. Conservation Food & Sanitation	Fairbanks	AK
Madden, Tressa (Co-Chair)	Oklahoma State Dept. of Health	Oklahoma City	OK
McMahan, Thomas	SuperValu, Inc.	Boise	ID
Moore, Veronica	FDA Center for Food Safety & Applied Nutrition	College Park	MD
Sampson, Mark	PuriCore	Malvern	PA
Schwarz, Thomas	International Flight Services Association	Burke	VA
Swanson, Katherine (Co-Chair)	Ecolab	Eagan	MN

The Sanitizer Committee thanks the Conference for Food Protection for the opportunity to explore this topic and hopes that the work of our Committee will benefit CFP and public health at large by harmonizing the language and clarifying jurisdictional authority for sanitizer use in retail and food service settings.

Respectfully submitted by,

Katherine MJ Swanson and Tressa Madden, Co-Chairs for the 2008-10 CFP Sanitizer Committee

Table 1 Recommended Food Code modification to address on-site generation of antimicrobial pesticides
[original 2009 Food Code text in plain font; underline is an insertion; ~~strikethrough is a deletion~~]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
4-204.124 On-Site Devices for Generation of Sanitizing Solutions new section	None	Chapter 4 of the Food Code addresses equipment for use in food establishments, and Part 4-2 specifically addresses the design and construction of such equipment. This section covers the equipment itself, NOT the solutions that the devices generate. It is important to address the equipment in the Food Code because FIFRA regulations require registration of the device manufacturer and not the resulting solution. The solutions are covered in subsequent sections.	4-204.124 On-Site Devices for Generation of Sanitizing Solutions Devices for generation of sanitizing solutions shall meet the characteristics specified under §4-202.11 and (A) Devices for generating pesticides must comply with regulations as established by section 2(q)(1) and section 12 of FIFRA, as well as 40 CFR 152.500 and 156.10. (B) Devices for generating pesticides shall display the manufacturing establishment's registration number.
4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization – Temperature, pH, Concentration, and Hardness (F) new paragraph	A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at contact times specified under ¶ 4-703.11(C) shall meet the criteria specified under § 7-204.11 SANITIZERS, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows [P]: … A-E unaltered	A sanitizer generated on-site should provide the same level of biocidal efficacy as a sanitizer manufactured in a different facility. A manufactured sanitizer must meet EPA testing and performance standards outlined in the Disinfectant – Technical Science Section DIS-TSS 4. Currently, no similar regulatory standard for solutions generated and used on-site exists. Pesticide devices and the sanitizers they produce for application on-site are exempt from registration requirements according to 40 CFR 152.500. At this point the EPA has not mandated registration of solutions produced by a pesticide device unless distributed or sold, but EPA does require that statements of performance, safety and efficacy related to the solution be true. ¶4-501.114 (D) refers to the use of chlorine, quats, or iodine based sanitizers at conditions and concentrations outside those specified in ¶¶ 4-501.114 (A)-(C). ¶4-501.114 (D) permits the use of those biocides if the permit holder demonstrates efficacy. ¶4-501.114 (E) allows the use of biocides other than chlorine, quats, or iodine, when used according to EPA-registered use instructions, which requires demonstration of efficacy by the supplier, which is accomplished by the EPA-registered label. This paragraph is not applicable to solutions generated on-site because there is no EPA-registered label, no efficacy standard and no regulatory oversight for such solutions that are generated and used on-site. New ¶4-501.114 (F) addresses the efficacy of solutions produced by pesticide generating devices and defines an efficacy standard that those solutions can be validated against. Guidance to the field regulatory personnel on how to verify that efficacy is proven is provided in Annex 3 for §4-501.114 (suggested language is below).	"A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at contact times specified under ¶ 4-703.11(C) shall meet the criteria specified under § 7-204.11 SANITIZERS, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows [P]: … (F) Any chemical substance produced and used on-site as a food contact surface SANITIZING solution shall have the concentration, temperature, pH and other conditions necessary to meet the definition of SANITIZATION in §1-201.10.

[original 2009 Food Code text in plain font; underline is an insertion; ~~strikethrough is a deletion~~]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
Annex 3 Public Health Reasons/ Administrative Guidelines Chemicals 4-501.114	New paragraphs within that section	The inclusion of ¶4-501.114 (F) addresses the efficacy of solutions produced by pesticide generating devices and provides an efficacy standard for those solutions. The field regulatory personnel may require guidance on how to verify that efficacy is met, which is addressed in the added paragraphs.	See below underlined section below.

Annex 3.
4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.

With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Correction Act of 1998, Federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation has moved from 21 CFR 178.1010 to 40 CFR 180.940. The Food Code contains provisions that were not captured in either 21 CFR 178.1010 or 40 CFR 180.940, such as pH, temperature, and water hardness. There is need to retain these provisions in the Code.

The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. Provisions for pH, temperature, and water hardness in section 4-501.114 have been validated to achieve sanitization; however, these parameters are not always included on EPA-registered labels. Therefore, it is critical to sanitization that the sanitizers are used consistently with the EPA-registered label, and if pH, temperature, and water hardness (for quats) are not included on the label, that the solutions meet the standards required in the Code.

With respect to chemical sanitization, section 4-501.114 addresses the proper use conditions for the sanitizing solution, i.e., chemical concentration range, pH, and temperature minimum levels and, with respect to quaternary ammonium compounds (quats), the maximum hardness level. If these parameters are not as specified in the Code or on the EPA-registered label, then this provision is violated.

By contrast, paragraph 4-703.11(C) addresses contact time in seconds. For chemical sanitization, this paragraph is only violated when the specified contact time is not met.

Section 7-204.11 addresses whether or not the chemical agent being applied as a sanitizer is approved and listed for that use under 40 CFR 180.940.

EPA sanitizer registration assesses compliance with 40 CFR 180.940; therefore if the product is used at the appropriate concentration for the application on the EPA-registered label, it is not necessary to consult 40 CFR 180.940 for further compliance verification. If a sanitarian determined that a solution exceeded the concentration for the application on the EPA-registered label or is used for an application that is not on the EPA-registered label, section 7-204.11 would be violated.

A variety of sanitizers can be generated on-site, including chlorine, hypochlorous acid (generated by processes known as electrolyzed water, electro chemically activated water, electro activated water, etc.), chlorine dioxide, ozone, and others. EPA does not require the registration of pesticidal devices; however, these devices must be produced in a registered establishment. The data plate should list the establishment number. Additionally, device label requirements are established by section 2(q)(1) and section 12 of FIFRA, as well as 40 CFR 152.500 and 156.10. No statement that is false or misleading can appear in a device's labeling. Statements that are subject to this standard include, but are not limited to:

- The name, brand, or trademark under which the product is sold
- An ingredient statement
- Statements concerning effectiveness of the product
- Hazard and precautionary statements for human and domestic animals
- Environmental and exposure hazards
- The directions for use

Because there is no EPA registration of solutions generated and used on-site, either the equipment manufacturer or the user of the equipment must generate data to validate the efficacy of the solution the device produces as well as the conditions for use of the solution (e.g., concentration, temperature, contact time, pH, and other applicable factors). These data should be available on-site. Section 4-703.11 requires that the conditions of use yields SANITIZATION as defined in paragraph 1-201.10(B), i.e., a 5 log (99.999%) reduction.

[original 2009 Food Code text in plain font; underline is an insertion; ~~strikethrough is a deletion~~]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
	EPA Disinfectant – Technical Science Section (DIS-TSS) 4 describes efficacy data requirements for sanitizing rinses for previously cleaned food-contact surfaces http://www.epa.gov/oppad001/dis_tss_docs/dis-04.htm. Chlorine equivalent testing is used for halide-based biocides (chlorine bearing chemicals, iodophors, and mixed halides) and a minimum of 99.999% reduction of *E. coli* and *S. aureus* for non-chlorine biocides. These procedures are required for EPA-registered sanitizers (e.g., bottled chlorine, iodine, quats, etc.), but modification is needed for on-site generated sanitizers. For example, the procedures specify that 3 different batches are to be tested, one of which must be 60 days old. A 60 day sample would not be relevant for on-site generated sanitizers because they should be used shortly after generation. Validation testing for on-site generated product should include a time element, because efficacy can reduce with time. Testing should include all factors that could impact the efficacy of the pesticide solution including water hardness, pH and temperature. The report should also clearly identify the minimum acceptable concentration of active ingredient required for that product to pass the test. This testing is best performed under Good Laboratory Practices. Some technologies generate chemicals that are addressed in the Code, such as chlorine or hypochlorous acid. Verifying performance of these chlorine-based solutions can be accomplished by confirming that the concentration, temperature, and pH of the sanitizing solutions comply with paragraph 4-501.114 (A) using test methods and equipment that is currently used. However, some on-site generators produce chemicals that are not listed as sanitizers in the Code (e.g. ozone, chlorine dioxide, hydrogen peroxide, etc.). The manufacturer should provide methods (e.g., test strips, kits, etc.) to verify that the equipment continues to generate the solution at the same concentration on-site. Some solutions, such as ozone, chlorine dioxide, and hypochlorous acid, may lose concentration more quickly than other solutions. Therefore, it is necessary to verify concentration on an on-going basis, and to comply with section 4-501.116. To summarize, a sanitizing solution that is too weak would be a violation of section 4-501.114. A solution that is too strong would be a violation of section 7-204.11. Section 7-202.12 would not be violated due to the existence of section 7-204.11 that specifically addresses the use chemical sanitizers.		
7-204.11 Sanitizer, Criteria	Chemical SANITIZERS and other chemical antimicrobials applied to FOOD-CONTACT SURFACEs shall meet the requirements specified in 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions). [P]	§7-204.11 addresses the toxicity of solutions used as sanitizers and requires them to comply with the EPA tolerance exemptions outlined in 40 CFR 180.940. Solutions generated on-site should comply with the same tolerance exemptions. The one exception to this is ozone, which is not addressed in 40 CFR 180.940. However, ozone is approved as a secondary food additive in 21 CFR 173.368 so ozone solutions generated on-site comply with the intent of that regulation. Several of the technologies used for on-site generation of pesticides produce gases dissolved in solution. Notable examples are ozone and chlorine dioxide. Dissolved gases can present some unique toxicology concerns. Verification of compliance with 40 CFR 180.940 also requires some clarification. Annex 3 §7-204.11 should address this (suggested language is below).	Chemical SANITIZERS, including those generated on-site, and other chemical antimicrobials applied to FOOD-CONTACT SURFACEs shall: (A) meet the requirements specified in 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions) [P]", or (B) be listed in 40 CFR 180.2020 Pesticide chemicals not requiring a tolerance or an exemption from a tolerance - Non-food determinations.

[original 2009 Food Code text in plain font; underline is an insertion; ~~strikethrough is a deletion~~]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
Annex 3 – Public Health Reasons/ Administrative Guidelines Chemicals 7-204.11 Sanitizers, Criteria.	7-204.11 Sanitizers, Criteria. See explanation in § 4-501.114 Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe.	Several of the technologies used for on-site generation of pesticides produce gases dissolved in solution. Notable examples of these technologies are ozone and chlorine dioxide. Dissolved gases can present some unique toxicology concerns and Annex 3 § 7-204.11 should address them.	7-204.11 Sanitizers, Criteria. See explanation in § 4-501.114 Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe. Some SANITIZERS produced by on-site generators are based on gases dissolved in solution. These may present toxicology issues if the gases can come out of solution and into the air at high concentrations. OSHA limits on gases like ozone and chlorine dioxide are outlined in 29 CFR 1910.1000. Although the amount of dissolved gas in solution may be very low when evenly distributed through out all the air in a site, the gas may not be evenly distributed. This may lead to localized concentrations, e.g., immediately over a three compartment sink, that exceed OSHA limits. It is the responsibility of the permit holder and equipment supplier to ensure that the equipment is used in a safe manner so that OSHA limits will not be exceeded anywhere in the permit holder's facility. The permit holder using a pesticide device is responsible for being in compliance with 40 CFR 180.940. Because no process for regulatory review of the output of a pesticide device exists, no standard method for checking compliance exists. As such, a potential user of a pesticide device needs to look elsewhere for evidence of compliance. This may include a statement from the device manufacturer, an analysis of the MSDS ingredient statement or a third party chemical analysis of the device output.

[original 2009 Food Code text in plain font; underline is an insertion; ~~strikethrough is a deletion~~]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria.	(A) Chemicals used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables. P (B) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR 173.368 Ozone.	§7-204.12 also addresses chemicals used for washing fruits and vegetables and requires them to comply with 21 CFR 173.315. Solutions generated on-site should comply with the same CFR.	(A) Chemicals including those generated on-site, used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables. P (B) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR 173.368 Ozone.

Appendix 1. Conference Call Dates and Accomplishments

1. December 8, 2008 – Reviewed FDA questions and identified electrolyzed water, ozone, and chlorine dioxide as the primary on-site generated antimicrobials to consider. Broke into sub-groups to address technologies.
2. January 28, 2009 – A draft of the "regulatory status" of on-site generators was introduced to provide the committee with background on the regulatory framework involved with these devices. This was the starting point for the "Requirements for On-site Generators of Antimicrobial Pesticides in Food Establishments" section of this report.
3. March 6, 2009 – Chlorine dioxide was removed from the list of antimicrobials because no one was aware of commercial applications for retail and food service. Examples of labeling for on-site generated sanitizers were provided.
4. April 17, 2009 – Continued to refine the "regulatory status" draft, limited work progressed on individual technologies; group formed to identify areas of the Food Code with language to be addressed.
5. June 1, 2009 – "Regulatory status" draft discussed, but lack of quorum prevented finalization.
6. June 27, 2009 – "Regulatory status" draft finalized after moving 6 former members to "inactive" status. This allowed the committee to achieve quorum.
7. July 31, 2009 – Began review of citations in the Food Code that could be addressed related to on-site generation of sanitizers. The complexity of the issue stimulated a request to review the initial questions of FDA. Co-chairs reviewed alternative to proceed. The charge specifically directed the committee to develop language for the Food Code, but the questions deal with general terms that may or may not be relevant to Food Code language.
8. September 25, 2009 – Draft answers to FDA's questions were provided to the committee for discussion and comment. A sub-committee was appointed to further refine the answers to FDA's questions.
9. October 19, 2009 – The sub-committee focused on potential language for recommended changes to Food Code language rather than addressing FDA's questions. This work addressed the specific charge to the committee, but did not address original questions posed at the 2008 CFP related to on-site generated sanitizers. A work group was formed to draft a final report that addressed:
    a. Requirements for On-site Generators of Antimicrobial Pesticides in Food Establishments (based on the "regulatory status" draft finalized June 27 by the committee),
    b. Resolution of 2008 Questions on On-site Generators of Antimicrobial Pesticides (to address FDA concerns) and
    c. Recommended Food Code Language for On-site Generation of Antimicrobial Solutions (to address the Committee charge).
10. November 12, 2009 – Draft final report discussed up to citation recommendations
11. November 17, 2009 – Draft final report discussed – Draft 3 of final report
12. November 23, 2009 – Draft final report discussed – Draft 4 of final report – consensus reached

Committee Name:

Council III
Sanitizer

30-Nov-09

Last Name	First Name	Position (Chair/ Member)	Constituency	Employer	Address	City	State	Zip	Telephone	Email
Hipp	Joel	member	Industry - equpment mfg.	Hobart Corp.	701 S. Ridge Avenue	Troy	OH	45374	937-332-2836	joel.hipp@hobartcorp.com
Brickey	Matthew	member	Industry - food service	National Restaurant Association	1200 17th Street, NW	Washington	DC	20036	202-331-5913	mbrickey@restaurant.org
Schwarz	Thomas	member	Industry - food service	International Flight Services Association	5700 Waters Edge Landing Court	Burke	VA	22015	703-250-5445	TLS4HACCP@aol.com
Kunduru	Mahipal	member	Industry - retail food stores	Safeway, Inc.	5918 Stoneridge Mall Roadc	Pleasanton	CA	94588	925-226-9393	mahipal.kunduru@safeway.com
McMahan	Thomas	member	Industry - retail food stores	SuperValu, Inc.	250 E. Parkcenter Blvd.	Boise	ID	83706	208-395-3265	Thomas.A.McMahan@supervalu.com
Grinstead	Dale	member	Other - sanitation services	Johnson Diversey	8310 16th Street	Sturtevant	WI	53177	262-631-4433	dale.grinstead@johnsondiversey.com
Herdt	Brandon	member	Other - sanitation services	Ecolab, Inc.	655 Lone Oak Drive	Eagan	MN	55121	651-795-5828	brandon.herdt@ecolab.com
Johnson	Thomas	member	Other - sanitation services	Johnson Diversified Products, Inc.	1408 Northland Drive, #407	Mendota Heights	MN	55120	651-587-0418	tomj@jdpinc.com
Sampson	Mark	member	Other - sanitation services	PuriCore	508 Lapp Road	Malvern	PA	19355	484-321-2719	msampson@puricore.com
Swanson	Katherine	Co chair	Other - sanitation services	Ecolab, Inc.	655 Lone Oak Drive	Eagan	MN	55121	651-975-5943	katie.swanson@ecolab.com
Brania	Jonathan	member	Other -services	Underwriters Laboratories, Inc.	12 Laboratory Drive	Research Triangle Park	NC	27709	919-549-1768	jonathan.brania@us.ul.com
Edwards	Dennis	member	Regulatory - federal	Environmental Protection Agency	7510C Ariel Rios Building, 1200 Pennsylvania Ave NW	Washington	DC	20460	703-308-8087	edwards.dennis@epamail.epa.gov
Hepp	Mark	member	Regulatory - federal	FDA/CFSAN	5100 Paint Branch Parkway	College Park	MD	20740	301-436-1203	mark.hepp@fda.hhs.gov
Moore	Veronica	member	Regulatory - federal	FDA/CFSAN	5100 Paint Branch Parkway	College Park	MD	20740	301-436-1409	Veronica.moore@fda.hhs.gov
Harris	Tanya	member	Regulatory - local	Tulsa Health Department	4616 E. 15th Street	Tulsa	OK	74112	918-595-4315	tharris@tulsa-health.org
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Lhotka	Lorinda	member	Regulatory - state	Alaska Dept. Environ. Conservation Food and	610 University Avenue	Fairbanks	AK	99709	907-451-2119	lorinda.lhotka@alaska.gov
Madden	Tressa	Co chair	Regulatory - state	Oklahoma State Dept. of Health	1000 NE 10th	Oklahoma City	OK	73117	405-271-5243	tressam@health.ok.gov

Conference for Food Protection
2010 Issue Form

Internal Number: 005
Issue: 2010 III-005

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

All information above the line is for conference use only.

Title:

On-Site Generation of Antimicrobial Pesticides

Issue you would like the Conference to consider:

To accomplish its charge, the 2008-10 Sanitizer Committee thoroughly reviewed three specific aspects related to on-site generation and use of sanitizers and other antimicrobials. These included 1) the current federal regulatory requirements for on-site generators of antimicrobial pesticides and 2) unresolved questions related to on-site generators of antimicrobial pesticides, and 3) specific recommendations for language in the Food Code for on-site generation of antimicrobial solutions. The Committee would like the Conference to consider its recommended language related to on-site generation and use of antimicrobials.

Public Health Significance:

Proper use of sanitizers is an important step to prevent cross contamination and food safety failures. On-site generation of sanitizers and other antimicrobials is not addressed in the 2009 Food Code, and the regulatory process for sanitizers generated and used on-site varies considerably from the regulatory process for manufactured products. Clarification of the Food Code requirements for on-site generated sanitizers is essential to ensure proper use of these materials and to avoid unproductive confusion for inspectors and operators.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending changes to the Food Code as detailed in the attached "Food_Code_Recommendations_for_On-site_Generation_of_Antimicrobials" (extracted from Table 1 of the CFP 2008-10 Sanitizer Committee Final Report). Detailed rationales for the recommended changes are included in the table.

The recommended new language is indicated below in underline format for additions and plain text for current 2009 Food Code language:

1. Adding §4-204.124 to address equipment requirements for on-site generators

"4-204.124 On-Site Devices for Generation of Sanitizing Solutions

"Devices for generation of sanitizing solutions shall meet the characteristics specified under §4-202.11 and

(A) Devices for generating pesticides must comply with regulations as established by section 2(q)(1) and section 12 of FIFRA, as well as 40 CFR 152.500 and 156.10.

(B) Devices for generating pesticides shall display the manufacturing establishment's registration number."

2. Adding §4-501.114 (F) to address the sanitizing solutions generated on-site

"A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at contact times specified under ¶ 4-703.11(C) shall meet the criteria specified under § 7-204.11 SANITIZERS, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows [P]:

...

"(F) Any chemical substance produced and used on-site as a food contact surface SANITIZING solution shall have the concentration, temperature, pH and other conditions necessary to meet the definition of SANITIZATION in §1-201.10."

3. Insert the following in Annex 3 for §4-501.114 to address FIFRA requirements for on-site generators, as indicated in the attachment.

"...section 7-204.11 would be violated.

"A variety of sanitizers can be generated on-site, including chlorine, hypochlorous acid (generated by processes known as electrolyzed water, electro chemically activated water, electro activated water, etc.), chlorine dioxide, ozone, and others. EPA does not require the registration of pesticidal devices; however, these devices must be produced in a registered establishment. The data plate should list the establishment number. Additionally, device label requirements are established by section 2(q)(1) and section 12 of FIFRA, as well as 40 CFR 152.500 and 156.10. No statement that is false or misleading can appear in a device's labeling. Statements that are subject to this standard include, but are not limited to:

- The name, brand, or trademark under which the product is sold
- An ingredient statement
- Statements concerning effectiveness of the product

- Hazard and precautionary statements for human and domestic animals
- Environmental and exposure hazards
- The directions for use

"Because there is no EPA registration of solutions generated and used on-site, either the equipment manufacturer or the user of the equipment must generate data to validate the efficacy of the solution the device produces as well as the conditions for use of the solution (e.g., concentration, temperature, contact time, pH, and other applicable factors). These data should be available on-site. Section 4-703.11 requires that the conditions of use yields SANITIZATION as defined in paragraph 1-201.10(B), i.e., a 5 log (99.999%) reduction.

"EPA Disinfectant - Technical Science Section (DIS-TSS) 4 describes efficacy data requirements for sanitizing rinses for previously cleaned food-contact surfaces http://www.epa.gov/oppad001/dis_tss_docs/dis-04.htm. Chlorine equivalent testing is used for halide-based biocides (chlorine bearing chemicals, iodophors, and mixed halides) and a minimum of 99.999% reduction of *E. coli* and *S. aureus* for non-chlorine biocides. These procedures are required for EPA-registered sanitizers (e.g., bottled chlorine, iodine, quats, etc.), but modification is needed for on-site generated sanitizers. For example, the procedures specify that 3 different batches are to be tested, one of which must be 60 days old. A 60 day sample would not be relevant for on-site generated sanitizers because they should be used shortly after generation. Validation testing for on-site generated product should include a time element, because efficacy can reduce with time. Testing should include all factors that could impact the efficacy of the pesticide solution including water hardness, pH and temperature. The report should also clearly identify the minimum acceptable concentration of active ingredient required for that product to pass the test. This testing is best performed under Good Laboratory Practices.

"Some technologies generate chemicals that are addressed in the Code, such as chlorine or hypochlorous acid. Verifying performance of these chlorine-based solutions can be accomplished by confirming that the concentration, temperature, and pH of the sanitizing solutions comply with paragraph 4-501.114 (A) using test methods and equipment that is currently used.

"However, some on-site generators produce chemicals that are not listed as sanitizers in the Code (e.g. ozone, chlorine dioxide, hydrogen peroxide, etc.). The manufacturer should provide methods (e.g., test strips, kits, etc.) to verify that the equipment continues to generate the solution at the same concentration on-site.

"Some solutions, such as ozone, chlorine dioxide, and hypochlorous acid, may lose concentration more quickly than other solutions. Therefore, it is necessary to verify concentration on an on-going basis, and to comply with section 4-501.116.

"...To summarize, a sanitizing solution that is too week would be a violation of section 4-501.114. A solution that is too strong would be a violation of section 7-204.11..."

4. Adding ¶7-204.11 (B) and inserting a reference to on-site generated antimicrobials to address pesticides that may not required a tolerance. The section to read as follows.

"Chemical SANITIZERS, including those generated on-site, and other chemical antimicrobials applied to FOOD-CONTACT SURFACEs shall:

(A) meet the requirements specified in 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions) [P]", or

(B) be listed in 40 CFR 180.2020 Pesticide Chemicals Not Requiring a Tolerance or an Exemption From Tolerance - Non-food determinations."

5. Adding the following at the end of existing Annex 3 for §7-204.11 to address OSHA limits for gases dissolved in solution.

"...The CFR reference that is provided lists concentrations of sanitizers that are considered safe.

"Some SANITIZERS produced by on-site generators are based on gases dissolved in solution. These may present toxicology issues if the gases can come out of solution and into the air at high concentrations. OSHA limits on gases like ozone and chlorine dioxide are outlined in 29 CFR 1910.1000. Although the amount of dissolved gas in solution may be very low when evenly distributed through out all the air in a site, the gas may not be evenly distributed. This may lead to localized concentrations, e.g., immediately over a three compartment sink, that exceed OSHA limits. It is the responsibility of the permit holder and equipment supplier to ensure that the equipment is used in a safe manner so that OSHA limits will not be exceeded anywhere in the permit holder's facility.

The permit holder using a pesticide device is responsible for being in compliance with 40 CFR 180.940. Because no process for regulatory review of the output of a pesticide device exists, no standard method for checking compliance exists. As such, a potential user of a pesticide device needs to look elsewhere for evidence of compliance. This may include a statement from the device manufacturer, an analysis of the MSDS ingredient statement or a third party chemical analysis of the device output."

6. Update ¶7-204.12 (A) to address on-site generation of chemicals to wash vegetables.

"(A) Chemicals including those generated on-site, used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables. [P]"

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Attachments:

- "Food_Code_Recommendations_for_On-site_Generation_of_Antimicrobials"

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

Food Code recommendations for on-site generation of antimicrobials
(Table 1 extracted from the 2008-2010 CFP Sanitizer Committee Final Report)

Table 1 Recommended Food Code modification to address on-site generation of antimicrobial pesticides
[original 2009 Food Code text in plain font; underline is an insertion; ~~strikethrough is a deletion~~]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
4-204.124 On-Site Devices for Generation of Sanitizing Solutions new section	None	Chapter 4 of the Food Code addresses equipment for use in food establishments, and Part 4-2 specifically addresses the design and construction of such equipment. This section covers the equipment itself, NOT the solutions that the devices generate. It is important to address the equipment in the Food Code because FIFRA regulations require registration of the device manufacturer and not the resulting solution. The solutions are covered in subsequent sections.	4-204.124 On-Site Devices for Generation of Sanitizing Solutions Devices for generation of sanitizing solutions shall meet the characteristics specified under §4-202.11 and (A) Devices for generating pesticides must comply with regulations as established by section 2(q)(1) and section 12 of FIFRA, as well as 40 CFR 152.500 and 156.10. (B) Devices for generating pesticides shall display the manufacturing establishment's registration number.
4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization – Temperature, pH, Concentration, and Hardness (F) new paragraph	A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at contact times specified under ¶ 4-703.11(C) shall meet the criteria specified under § 7-204.11 SANITIZERS, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows [P]: … A-E unaltered	A sanitizer generated on-site should provide the same level of biocidal efficacy as a sanitizer manufactured in a different facility. A manufactured sanitizer must meet EPA testing and performance standards outlined in the Disinfectant – Technical Science Section DIS-TSS 4. Currently, no similar regulatory standard for solutions generated and used on-site exists. Pesticide devices and the sanitizers they produce for application on-site are exempt from registration requirements according to 40 CFR 152.500. At this point the EPA has not mandated registration of solutions produced by a pesticide device unless distributed or sold, but EPA does require that statements of performance, safety and efficacy related to the solution be true. ¶4-501.114 (D) refers to the use of chlorine, quats, or iodine based sanitizers at conditions and concentrations outside those specified in ¶¶ 4-501.114 (A)-(C). ¶4-501.114 (D) permits the use of those biocides if the permit holder demonstrates efficacy. ¶4-501.114 (E) allows the use of biocides other than chlorine, quats, or iodine, when used according to EPA-registered use instructions, which requires demonstration of efficacy by the supplier, which is accomplished by the EPA-registered label. This paragraph is not applicable to solutions generated on-site because there is no EPA-registered label, no efficacy standard and no regulatory oversight for such solutions that are generated and used on-site. New ¶4-501.114 (F) addresses the efficacy of solutions produced by pesticide generating devices and defines an efficacy standard that those solutions can be validated against. Guidance to the field regulatory personnel on how to verify that efficacy is proven is provided in Annex 3 for §4-501.114 (suggested language is below).	"A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at contact times specified under ¶ 4-703.11(C) shall meet the criteria specified under § 7-204.11 SANITIZERS, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows [P]: … (F) Any chemical substance produced and used on-site as a food contact surface SANITIZING solution shall have the concentration, temperature, pH and other conditions necessary to meet the definition of SANITIZATION in §1-201.10.

[original 2009 Food Code text in plain font; underline is an insertion; ~~strikethrough is a deletion~~]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
Annex 3 Public Health Reasons/ Administrative Guidelines Chemicals 4-501.114	New paragraphs within that section	The inclusion of ¶4-501.114 (F) addresses the efficacy of solutions produced by pesticide generating devices and provides an efficacy standard for those solutions. The field regulatory personnel may require guidance on how to verify that efficacy is met, which is addressed in the added paragraphs.	See below underlined section below.

Annex 3.
4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.

With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Correction Act of 1998, Federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation has moved from 21 CFR 178.1010 to 40 CFR 180.940. The Food Code contains provisions that were not captured in either 21 CFR 178.1010 or 40 CFR 180.940, such as pH, temperature, and water hardness. There is need to retain these provisions in the Code.

The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. Provisions for pH, temperature, and water hardness in section 4-501.114 have been validated to achieve sanitization; however, these parameters are not always included on EPA-registered labels. Therefore, it is critical to sanitization that the sanitizers are used consistently with the EPA-registered label, and if pH, temperature, and water hardness (for quats) are not included on the label, that the solutions meet the standards required in the Code.

With respect to chemical sanitization, section 4-501.114 addresses the proper use conditions for the sanitizing solution, i.e., chemical concentration range, pH, and temperature minimum levels and, with respect to quaternary ammonium compounds (quats), the maximum hardness level. If these parameters are not as specified in the Code or on the EPA-registered label, then this provision is violated.

By contrast, paragraph 4-703.11(C) addresses contact time in seconds. For chemical sanitization, this paragraph is only violated when the specified contact time is not met.

Section 7-204.11 addresses whether or not the chemical agent being applied as a sanitizer is approved and listed for that use under 40 CFR 180.940.

EPA sanitizer registration assesses compliance with 40 CFR 180.940; therefore if the product is used at the appropriate concentration for the application on the EPA-registered label, it is not necessary to consult 40 CFR 180.940 for further compliance verification. If a sanitarian determined that a solution exceeded the concentration for the application on the EPA-registered label or is used for an application that is not on the EPA-registered label, section 7-204.11 would be violated.

A variety of sanitizers can be generated on-site, including chlorine, hypochlorous acid (generated by processes known as electrolyzed water, electro chemically activated water, electro activated water, etc.), chlorine dioxide, ozone, and others. EPA does not require the registration of pesticidal devices; however, these devices must be produced in a registered establishment. The data plate should list the establishment number. Additionally, device label requirements are established by section 2(q)(1) and section 12 of FIFRA, as well as 40 CFR 152.500 and 156.10. No statement that is false or misleading can appear in a device's labeling. Statements that are subject to this standard include, but are not limited to:

- The name, brand, or trademark under which the product is sold
- An ingredient statement
- Statements concerning effectiveness of the product
- Hazard and precautionary statements for human and domestic animals
- Environmental and exposure hazards
- The directions for use

Because there is no EPA registration of solutions generated and used on-site, either the equipment manufacturer or the user of the equipment must generate data to validate the efficacy of the solution the device produces as well as the conditions for use of the solution (e.g., concentration, temperature, contact time, pH, and other applicable factors). These data should be available on-site. Section 4-703.11 requires that the conditions of use yields SANITIZATION as defined in paragraph 1-201.10(B), i.e., a 5 log (99.999%) reduction.

[original 2009 Food Code text in plain font; underline is an insertion; ~~strikethrough is a deletion~~]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
	EPA Disinfectant – Technical Science Section (DIS-TSS) 4 describes efficacy data requirements for sanitizing rinses for previously cleaned food-contact surfaces http://www.epa.gov/oppad001/dis_tss_docs/dis-04.htm. Chlorine equivalent testing is used for halide-based biocides (chlorine bearing chemicals, iodophors, and mixed halides) and a minimum of 99.999% reduction of *E. coli* and *S. aureus* for non-chlorine biocides. These procedures are required for EPA-registered sanitizers (e.g., bottled chlorine, iodine, quats, etc.), but modification is needed for on-site generated sanitizers. For example, the procedures specify that 3 different batches are to be tested, one of which must be 60 days old. A 60 day sample would not be relevant for on-site generated sanitizers because they should be used shortly after generation. Validation testing for on-site generated product should include a time element, because efficacy can reduce with time. Testing should include all factors that could impact the efficacy of the pesticide solution including water hardness, pH and temperature. The report should also clearly identify the minimum acceptable concentration of active ingredient required for that product to pass the test. This testing is best performed under Good Laboratory Practices. Some technologies generate chemicals that are addressed in the Code, such as chlorine or hypochlorous acid. Verifying performance of these chlorine-based solutions can be accomplished by confirming that the concentration, temperature, and pH of the sanitizing solutions comply with paragraph 4-501.114 (A) using test methods and equipment that is currently used. However, some on-site generators produce chemicals that are not listed as sanitizers in the Code (e.g. ozone, chlorine dioxide, hydrogen peroxide, etc.). The manufacturer should provide methods (e.g., test strips, kits, etc.) to verify that the equipment continues to generate the solution at the same concentration on-site. Some solutions, such as ozone, chlorine dioxide, and hypochlorous acid, may lose concentration more quickly than other solutions. Therefore, it is necessary to verify concentration on an on-going basis, and to comply with section 4-501.116. To summarize, a sanitizing solution that is too weak would be a violation of section 4-501.114. A solution that is too strong would be a violation of section 7-204.11. Section 7-202.12 would not be violated due to the existence of section 7-204.11 that specifically addresses the use chemical sanitizers.		
7-204.11 Sanitizer, Criteria	Chemical SANITIZERS and other chemical antimicrobials applied to FOOD-CONTACT SURFACEs shall meet the requirements specified in 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions). [P]	§7-204.11 addresses the toxicity of solutions used as sanitizers and requires them to comply with the EPA tolerance exemptions outlined in 40 CFR 180.940. Solutions generated on-site should comply with the same tolerance exemptions. The one exception to this is ozone, which is not addressed in 40 CFR 180.940. However, ozone is approved as a secondary food additive in 21 CFR 173.368 so ozone solutions generated on-site comply with the intent of that regulation. Several of the technologies used for on-site generation of pesticides produce gases dissolved in solution. Notable examples are ozone and chlorine dioxide. Dissolved gases can present some unique toxicology concerns. Verification of compliance with 40 CFR 180.940 also requires some clarification. Annex 3 §7-204.11 should address this (suggested language is below).	Chemical SANITIZERS, including those generated on-site, and other chemical antimicrobials applied to FOOD-CONTACT SURFACEs shall: (A) meet the requirements specified in 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions) [P]", or (B) be listed in 40 CFR 180.2020 Pesticide chemicals not requiring a tolerance or an exemption from a tolerance - Non-food determinations.

Food Code recommendations for on-site generation of antimicrobials
(Table 1 extracted from the 2008-2010 CFP Sanitizer Committee Final Report)

[original 2009 Food Code text in plain font; underline is an insertion; ~~strikethrough is a deletion~~]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
Annex 3 – Public Health Reasons/ Administrative Guidelines Chemicals 7-204.11 Sanitizers, Criteria.	7-204.11 Sanitizers, Criteria. See explanation in § 4-501.114 Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe.	Several of the technologies used for on-site generation of pesticides produce gases dissolved in solution. Notable examples of these technologies are ozone and chlorine dioxide. Dissolved gases can present some unique toxicology concerns and Annex 3 § 7-204.11 should address them.	7-204.11 Sanitizers, Criteria. See explanation in § 4-501.114 Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe. Some SANITIZERS produced by on-site generators are based on gases dissolved in solution. These may present toxicology issues if the gases can come out of solution and into the air at high concentrations. OSHA limits on gases like ozone and chlorine dioxide are outlined in 29 CFR 1910.1000. Although the amount of dissolved gas in solution may be very low when evenly distributed through out all the air in a site, the gas may not be evenly distributed. This may lead to localized concentrations, e.g., immediately over a three compartment sink, that exceed OSHA limits. It is the responsibility of the permit holder and equipment supplier to ensure that the equipment is used in a safe manner so that OSHA limits will not be exceeded anywhere in the permit holder's facility. The permit holder using a pesticide device is responsible for being in compliance with 40 CFR 180.940. Because no process for regulatory review of the output of a pesticide device exists, no standard method for checking compliance exists. As such, a potential user of a pesticide device needs to look elsewhere for evidence of compliance. This may include a statement from the device manufacturer, an analysis of the MSDS ingredient statement or a third party chemical analysis of the device output.

Food Code recommendations for on-site generation of antimicrobials
(Table 1 extracted from the 2008-2010 CFP Sanitizer Committee Final Report)

[original 2009 Food Code text in plain font; underline is an insertion; ~~strikethrough is a deletion~~]

Food Code Reference	Food Code 2009 Citation Language (verbatim)	Rationale for Recommendation	Recommended Language
7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria.	(A) Chemicals used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables. P (B) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR 173.368 Ozone.	§7-204.12 also addresses chemicals used for washing fruits and vegetables and requires them to comply with 21 CFR 173.315. Solutions generated on-site should comply with the same CFR.	(A) Chemicals including those generated on-site, used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables. P (B) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR 173.368 Ozone.

Conference for Food Protection
2010 Issue Form

Internal Number: 036
Issue: 2010 III-006

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

All information above the line is for conference use only.

Title:

4-501.19 Manual & Mechanical Warewashing Equipment, Wash solution Temp.

Issue you would like the Conference to consider:

Manual warewashing in retail food establishments has been dependent on a number of variables to assure effective cleaning. Temperature is but one variable that is dependent on the cleaning agent used, the type of manual washing processes, the volume of wares being washed as well as the type and where they originate (i.e., hot or cold environments). Additionally, the temperature variable has been a challenge in warewashing in refrigerated environments such as meat markets. To overcome this variable, food retailers have worked with their chemical suppliers to provide cleaning agents (detergents) that work in a variety of environments as well as in warm versus hot water with consistent results. Force applied to the surface of wares via brush and/or spray devices have proven very effective in removing soil that can easily be rinsed prior to being sanitized. It is for this reason that 77% of the CFP 2006-2008 Criticality Committee recommended that this section be classified as a "Core [C] item." The 2009 Food Code classified this section as a "Priority Foundation [Pf] item." Due to the variables inherent in manual warewashing this section should be classified as "[C]" versus "[Pf]". In addition, water temperatures referenced within other areas of the 2009 Food Code allow for lower water temperatures used in conjunction with hand washing which suggests the water temperature can be lowered for all detergents, regardless of the cleaning task. The end result is not the temperature of wash water solution but the application of all the variables that apply to proper washing so that the items being cleaned are visually free of soil prior to the sanitization step.

Public Health Significance:

Retail food establishments have adjusted methodologies in manual warewashing processes to assure wares and utensils are properly cleaned prior to rinsing and sanitizing. Temperature is but one variable that can be compensated with proper scrubbing, water pressure spray devices, low temperature detergents among others. This is similar to FDA lowering the handwashing temperature requirements in the Food Code from 110°F to

100ºF without increasing risk. If one reviews the definitions of Core [C] items and Priority Foundation [Pf] items, this section would fall under the general sanitation, operational controls, or Sanitation Standard Operating Procedures (SSOP) rather than those defined under Priority Foundation [Pf]. By requiring the wares/equipment being cleaned are visually free of soil prior to sanitization makes the temperature but one variable that may need adjustment.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that section 4-501.19 be revised to remove the minimum wash solution temperature and be classified as a Core [C] item by removing the "[Pf]" and substituting "[C]" at the end of the section as indicated below AND requests that the Annex 3 entry for this section be amended as stated below.

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The temperature of the wash solution in manual warewashing equipment shall be maintained at ~~not less than 43°C (110°F)~~ a temperature to effectively remove visible soil. ~~or the temperature specified on the cleaning agent manufacturer's label instructions.~~ [C] ~~[Pf]~~

Further, the Annex 3 reference to Manual and Mechanical Warewashing Equipment, Wash solution Temperature be revised to address the importance of controlling the variables that help remove soils from the wares or utensils during washing and rinsing to assure effective sanitizing. An example change by replacement of the existing section is as follows:

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature is important for removing organic matter along with other variables. If the temperature is too low, the performance of the detergent may be adversely affected, e.g., animal fats that may be present on the dirty dishes would not be dissolved unless detergents are adjusted to work at lower water temperatures or other variables like power spraying, turbo washing, or heavy scrubbing are used. The manufacturer's label instruction should be consulted and followed for the correct application pertaining to cleaning agent. The items being washed should be visually cleaned by noting the absence of soil prior to sanitization.

~~The wash solution temperature in mechanical warewashing equipment is critical to proper operation. The chemicals used may not adequately perform their function if the temperature is too low. Therefore, the manufacturer's instructions must be followed. The temperatures vary according to the specific equipment being used.~~

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

Conference for Food Protection
2010 Issue Form

Internal Number: 085
Issue: 2010 III-007

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

All information above the line is for conference use only.

Title:

Reduced Minimum Temperatures for Mechanical Warewashing Equipment

Issue you would like the Conference to consider:

Standards and Codes have evolved over the years to be performance based rather than construction based which fosters innovation and progress while still maintaining the desired requirement. Toward the goal of enabling performance based design, sections 4-501.110 and 4-501.112 should be revised to eliminate the minimum temperature requirements and substitute wording that will allow equipment that has been verified as meeting the sanitization equivalent to 5 log reduction of microorganisms of public health importance. Section 4-703.11 must also be revised to allow a utensil surface temperature less than the current requirement of 160°F.

For far too long the minimum hot water sanitizing temperatures for commercial dishwashers have been wasting valuable energy. Approximately 18% of a typical restaurant's energy consumption is for water heating and sanitation[1]. It is time to reverse this trend and establish guidelines that can provide significant reductions in energy consumption and green-house gas emissions while still maintaining an approved level of sanitization.

The attached research data from the Ohio State University confirms that a 5 log reduction in pathogens of public health concern can be obtained in a conveyor dishwasher with reduced wash and final rinse temperatures. This same machine was also tested for the hot water sanitizing efficacy of 3600 heat unit equivalents (HUE) using NSF International Standard 3-2009 for Warewashing Equipment. These test results are also attached. If adopted in the Food Code, this revision has the potential to reduce the energy consumption for a single tank conveyor dishwasher by approximately 5,300 kW-hrs each year. The potential savings in one year for all conveyor dishwashers could approach 1.8 million kW-hrs. The North American Association of Food Equipment Manufacturers (NAFEM) and the Pacific Gas and Electric, Food Service Technology Center (FSTC) supports this proposal (see attached letters).

Section 4-703.11 of the Food Code must be revised to allow a reduced utensil surface temperature for machines with a reduced final rinse temperature. The 160°F utensil surface temperature was never intended to be a performance criterion, but was adapted as merely an inspection tool. The Food Code paragraphs 4-501.11, 4-501.14 (B), and 4-501.15 require the proper operation of a mechanical dishwasher. If the machine is operating in accordance with the nameplate times, temperatures, conveyor speed, etc. and if the wash and final rinse arms are spraying properly, adequate sanitization will take place. As an alternative to the 160°F utensil surface temperature, there are devices available that can record the time and temperature through the complete process to verify adequate sanitization on-site.

An additional benefit of reduced tank and final rinse temperatures is the potential to reduce cold water tempering of drain water required by section 701.7 and 803.1 of the 2009 International Plumbing Code. This code limits the temperature of water entering the sanitary drainage piping to 140°F to minimize expansion and contraction damage and softening of ABS and PVC pipes.

[1] Young, R., 2008, Greening Food Service Energy Efficiency: Issues and Resources, PG & E Food Service Technology Center

Public Health Significance:

This proposed change will maintain the current Code requirement of 5-log reduction in pathogens of public health concern. This can be confirmed by the NSF International Standard 3-2009 sanitizing efficacy performance requirement, or other means acceptable to the Authority Having Jurisdiction (AHJ). As long as the equipment is operated in accordance with the manufacturer's instructions, as required by 4-501.15 (A), adequate sanitization will be achieved. Research has shown that mechanical washing is more effective than manual warewashing and therefore is more flexible in operational parameters[2].

[2] Pascall, M., 2009, The number of warewashing cycles single batches of different chemical detergents can support in meeting the FDA Food Code mandates for commercial dishwashing machines in restaurants, Dept. of Food Science and Technology, The Ohio State University.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting the FDA Food Code be revised as follows:

4-501.110 Mechanical Warewashing Equipment, Wash Solution Temperature.

(A) The temperature of the wash solution in spray type warewashers that use hot water to SANITIZE may not be less than:

(1) For a stationary rack, single temperature machine, 74°C (165°F); Pf

(2) For a stationary rack, dual temperature machine, 66°C (150°F); Pf

(3) For a single tank, conveyor, dual temperature machine, 71°C (160°F); Pf or

(4) For a multitank, conveyor, multitemperature machine, 66°C (150°F). Pf

(B) The temperature of the wash solution in spray-type warewashers that use chemicals to SANITIZE may not be less than 49°C (120°F). Pf

(C) As an alternative to (A) above, the temperature of the wash solution in spray type warewashers that use hot water to SANITIZE may not be less than the marked minimum temperatures on the equipment data plate when the equipment has been evaluated and verified as meeting the sanitizing performance criteria of 5 log reduction of pathogens of public health concern. Pf

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

(A) Except as specified in ¶ (B) of this section, in a mechanical operation, the temperature of the fresh hot water SANITIZING rinse as it enters the manifold may not be more than 90°C

(194°F), or less than: Pf

(1) For a stationary rack, single temperature machine, 74°C (165°F); Pf or

(2) For all other machines, 82°C (180°F). Pf

(B) The maximum temperature specified under ¶ (A) of this section, does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying devices used for the in-place cleaning and SANITIZING of EQUIPMENT such as meat saws.

(C) As an alternative to (A) above, in a mechanical operation, the temperature of the fresh hot water SANITIZING rinse as it enters the manifold may not be more than 90°C (194°F), or less than the marked minimum temperature on the equipment data plate when the equipment has been evaluated and verified as meeting the sanitizing performance criteria of 5 log reduction in pathogens of public health concern. Pf

4-703.11 Hot Water and Chemical.

After being cleaned, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED in:

(A) Hot water manual operations by immersion for at least 30 seconds and as specified under § 4-501.111; [P]

(B) Hot water mechanical operations by being cycled through EQUIPMENT that is set up as specified under §§ 4-501.15, 4-501.112, and 4-501.113 and achieving a UTENSIL surface temperature of 71°C (160°F) as measured by an irreversible registering temperature indicator for machines with a marked minimum final rinse temperature of 180°F (82°C). For machines with a marked minimum final rinse temperature other than 180°F (82°C), the utensil surface temperature shall be as marked on the machine (typically 20°F (11°C) below the marked minimum final rinse temperature); [P] or...

{Note - this modification will require a new marking on the machine data plate for hot water sanitizing models with less than 180°F final rinse temperature. This will require a similar change to NSF 3.}

Submitter Information:

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Attachments:

- "OSU_Study_on_sanitizing_efficacy_with_reduced_temperatures.doc"
- "HUE_Test_Result.doc"
- "NAFEM_Support-Food_Code_Change.doc"
- "FSTC_Letter_of_Support_for_FDA_Code_Change-January_8_2010.pdf"
- "History_of_Dishwashing_Machine_Sanitation_12_14_09-JH.pdf"

The sanitization efficacy of a mechanical warewashing process with reduced wash and rinse temperatures

Final Report

Melvin Pascall, Jaesung Lee

Department of Food Science and Technology

The Ohio State University

Introduction:

Current FDA Food Code guidelines and NSF International Standard 3 requirements include minimum wash and final rinse temperatures for mechanical warewashing processes in the foodservice industry. These guidelines have been carried over since the early 1950's when studies were carried out to show the amount of heat, water volume, pump pressure and exposure time necessary for adequate sanitizing. These physical design constraints were included in the National Sanitation Foundation Standard 3 for Commercial Dishwashers. The Food Code also relied upon design criteria to assure adequate sanitization. In 1977, NSF 3 was updated to remove some of the design constraints and rely more on the performance criteria of 3600 Heat Unit Equivalents (HUE), based on the USDA milk pasteurization curve. This study showed that a further reduction in the design restriction but retaining the performance criteria will in fact maintain the same level of public health safety while substantially reducing energy consumption.

In the choice of a procedure to determine if washing and rinsing protocols meet the requirements of the Food Code, the choice of the test utensil, contaminating food type, challenge bacteria, reagent type and concentration/temperatures and exposure time should be carefully chosen so that a worst case scenario is created. Thus, less difficult to clean utensils, which include typical real world applications, would be properly sanitized by the chosen protocol. A milk-based product, soft cream cheese, was selected because an initial study performed by authors Lee and Pascall (2007), showed that milk products left on dirty dishes were found to harbor the highest bacterial load when compared with other types of food soils.

Objective:

The main goal of this study was to determine if reduced wash and rinse temperatures in a mechanical dishwashing process will have a negative impact on sanitizaton compared to existing minimum wash and rinse temperatures.

To meet the stated goal above, the objectives of this project were:

1. To evaluate the hot-water sanitization efficacies of a mechanical dishwashing processes on **ceramic plates cleaned at two different washing and rinsing temperatures (**160°F washing followed by 180°F rinsing, and 155°F washing followed by 170°F rinsing**).**
2. To demonstrate that reduced wash and rinse temperatures can maintain the sanitizing performance criteria of 5-log reduction in bacterial load, or 3600 heat unit equivalents**.**

Methods:

Bacterial Sample

Escherichia coli K12 (ATCC 29181) and *Listeria innocua* Seeliger (ATCC 33090) were used as surrogate organisms during this study. The cultures were stored frozen (-176°F) in 30% (v/v) sterile glycerol. When required for testing, a loopful of each organism was revived in 10 ml Trypticase soy broth supplemented with 0.3% (w/w) yeast extract (TSBYE) and incubated at 98.5°F for 24 h. A loopful of broth from this was inoculated on a Tryptic soy agar with a 0.3% (w/w) yeast extract (TSAYE) slant and incubated for 18 h at 98.5°F. The cells grown on the slant were stored at 37.5°F and used as a stock culture. At each experiment, a loopful of this stock culture was transferred to 20 ml TSBYE and incubated at 98.5°F until the final concentration of cells in the medium reached about 1.0 x 10^9 cfu ml^{-1}. Cells in the broth were harvested by centrifugation at 10,000 g for 10 min at 39°F. The supernatant was discarded and the pellets were resuspended in 20 ml sterile deionized potassium phosphate buffer (pH 7.2). Each cell suspension was separately mixed with each of the food samples to be tested in this study.

Preparation of the Food Samples

The contaminating organic matter (food items) used in this study was processed semi-solid cream cheese (15% fat). All food items were purchased from a local store the day before each experiment and kept at 39°F. There was no evidence of microbial growth on the TSAYE plated 10^{-1} diluted (w/w) food items. Cell suspensions of *E. coli* or *L. innocua* were inoculated into the cream cheese (1:10 w/w) and mixed to give an initial cell count of at least 1.0 x 10^8 cfu per food item. The cream cheese was pasted on to 8.5 inch ceramic plates (5 g for each plate). Contaminated plates were air-dried for 1 h at 75°F then exposed to varying washing cycles using a CL44e mechanical dishwasher manufactured by Hobart Corporation (Troy, OH). In order to determine the effect of air drying on the bacterial survival and to estimate the initial number of inoculated organisms on the food contaminated plates to be washed, each food type pasted on to a

set of the plates was sampled after air drying. After serial dilutions, bacteria survival numbers were determined by the plate count method.

Dishwashing Process on Test Plates

The inoculated plates were washed in the mechanical dishwasher. In each experiment, three different racks containing three plates were tested. The plates were placed in different positions in the rack. During the experiment, the plates in the racks were washed with 1,000 ppm of a Guardian Score (Ecolab, Inc., St. Paul, MN) detergent at 160ºF and rinsed at 180ºF. Prior to using the mechanical dishwasher, it was cleaned with hot water and filled with fresh detergent and water. The wash water was sprayed onto the plates at a flow rate of approximately 165 gallons per minute. Subsequently, the plates were rinsed with fresh water at a pressure of 20 psi. After washing and rinsing, all plates were placed on a sterile rack and air-dried for 15 min at 75°F prior to sampling. At the reduced temperature experiment, the test was performed at a wash temperature of 155ºF and rinsed at 170ºF.

Microbiological Sampling of the Utensil Surfaces

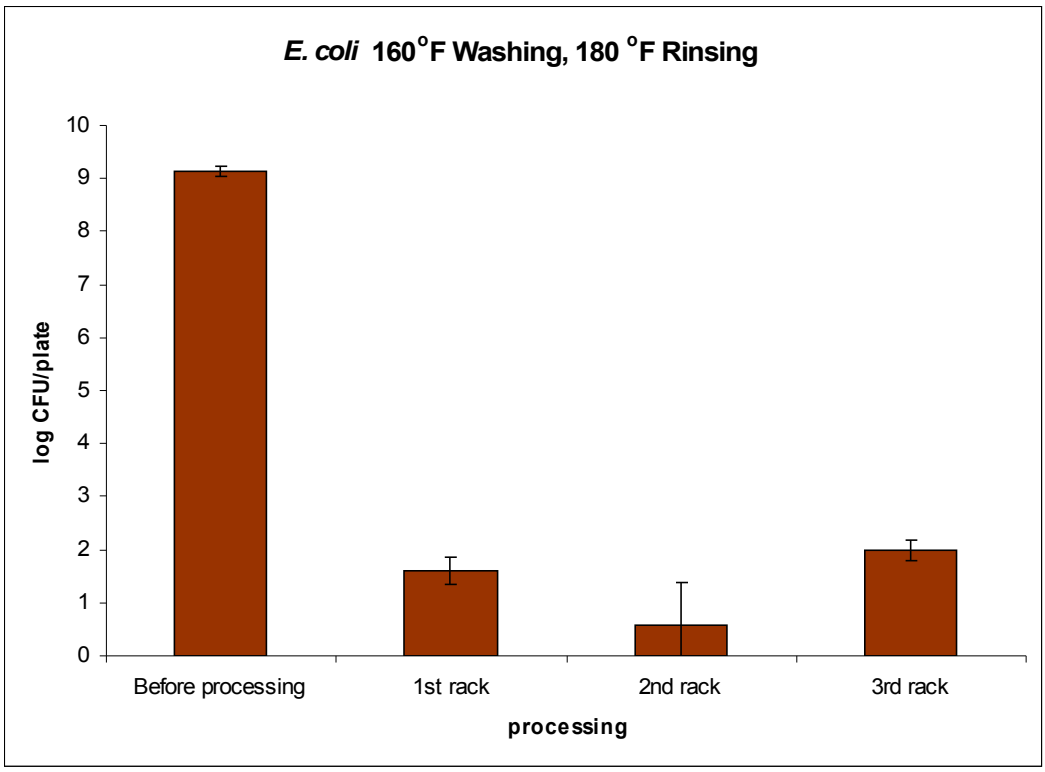
In the sampling for microbial enumeration, hygiene swabs were used to collect organisms from the surface of the plates that were previously washed. The swabs, made with sterile calcium alginate fiber tips on a wood applicators (Fisher Scientific, Pittsburgh, PA), were moistened before use with sterile peptone water. These swabs were transferred to test-tubes containing 2 ml of the peptone water. These tubes were then vigorously vortexed to release any bacterial cells from the fiber tip of the applicators.

Microbiological and Statistical Analysis

All cells were serially diluted and plated onto TSAYE to determine their viable counts after 24 h incubation at 98.5ºF. The detection limit for the test organisms was 2 CFU per the plate. In order to determine if the bacterial count on the washed samples resulted from organisms that were inoculated into the food, we simultaneously tested a comparable sample of food that was not inoculated with the bacterial species. The presence of any colonies in the comparable sample after washing would be evidence of contamination and in such cases, the entire batch of samples would be discarded. No less than two trials were used in each experiment. Variances of

microbial viability were analyzed by equal-variance *t*-test using a Microsoft Excel data analysis program (Ontario, Canada). The level of significance was set for $P<0.05$.

Figure 1. Enumeration of *E. coli* on plate before and after processing at different temperature using the mechanical dishwasher.



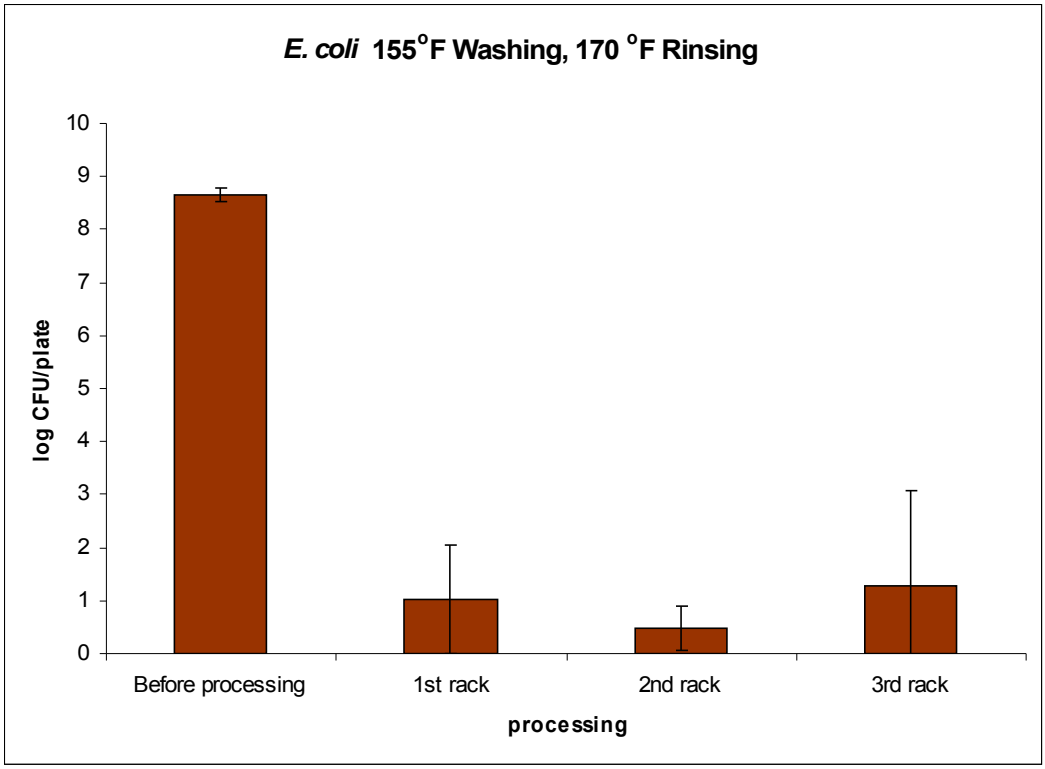
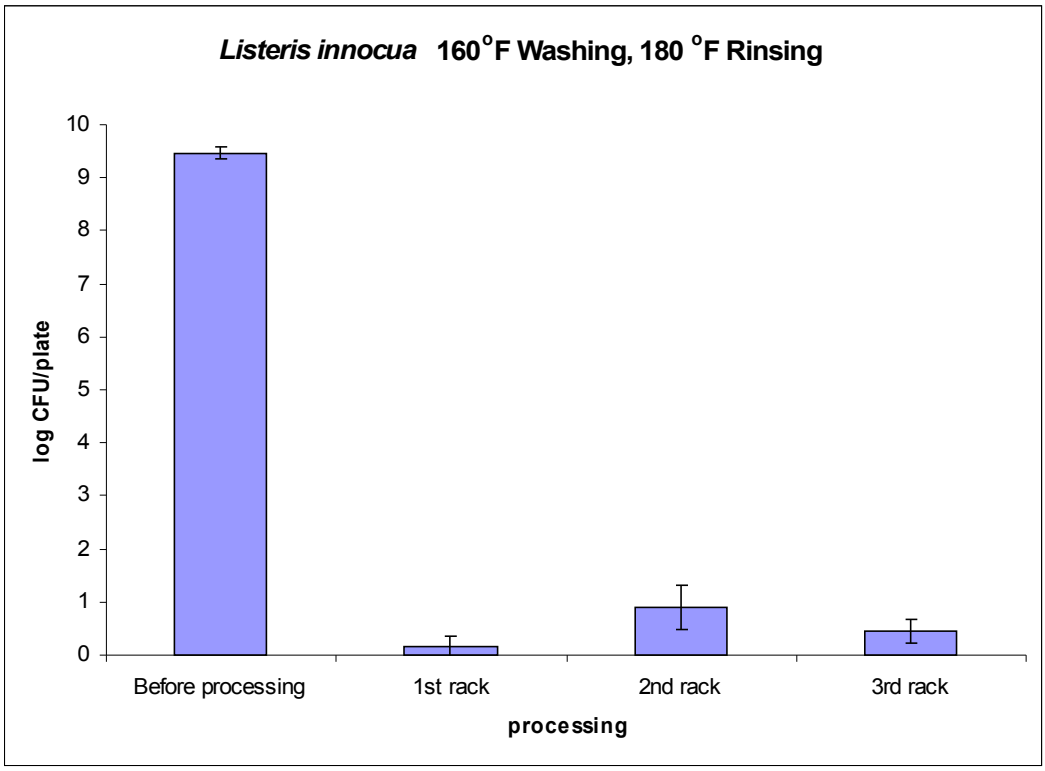
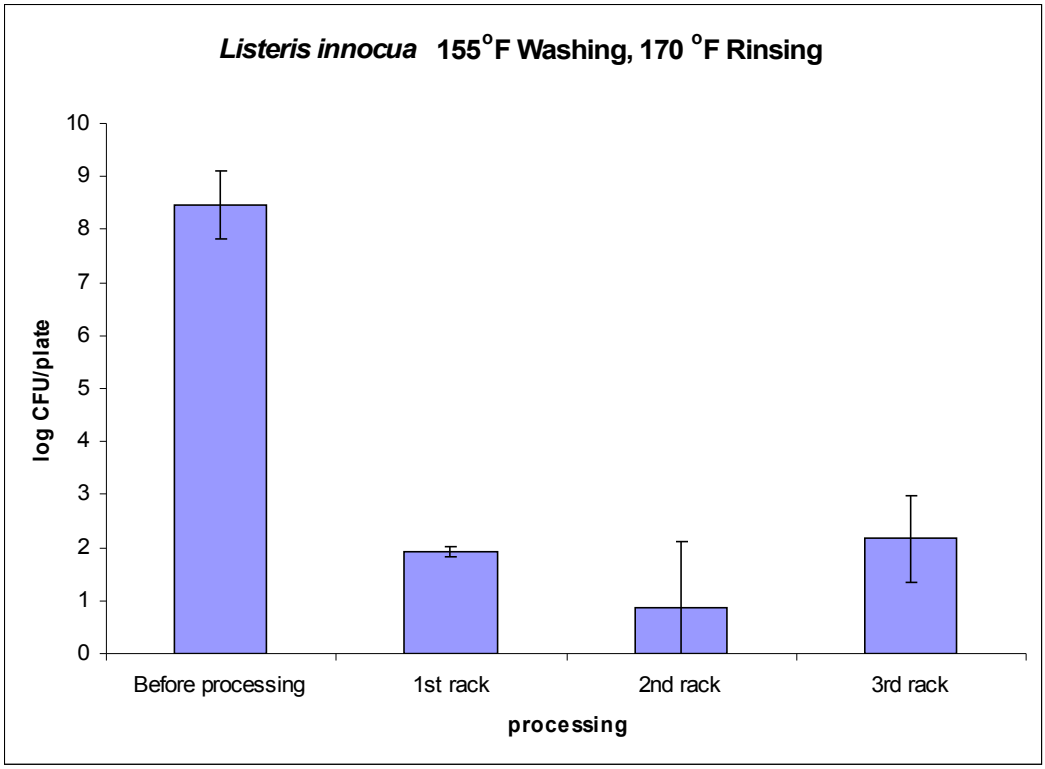


Figure 2. Enumeration of *L .innocua* on plate before and after processing at different temperature using the mechanical dishwasher.





Findings

- The application of lower washing and rinsing temperatures did not significantly (P>0.05) reduce the efficacy of the mechanical dishwashing process for bacterial numbers on the test plates compared with that on plates processed at standard temperatures (160ºF wash and 180ºF rinse).

- The results in Figures 1 and 2 show that all dishwashing processes had the ability to produce the 5-log bacterial load reduction.

Temperature Analysis Report

Machine Tested: CL44e
Test Info:
Test Notes: 157 wash 172 rinse dual upper rinse 2.1 gal 205 racks 9-22-09

Test Date: 09/22/2009
Test Time: 08:51 AM
Test File: 157wash172rinsedual
Duration of Test: 1m 10s

Channel Temperature Summary-

Channel:	1	2	3	4	5	6
Description:	wash	rinse	inlet	plate 1	plate 2	plate 3
Maximum Temp:	157.0°F	172.4°F	174.5°F	166.6°F	164.8°F	166.0°F
Minimum Temp:	156.0°F	170.1°F	173.9°F	86.6°F	86.1°F	85.3°F
Average Temp:	156.4°F	171.9°F	174.3°F	144.2°F	143.7°F	138.6°F
(based on)	All	All	All	All	All	All
Total HUEs:	n/a	n/a	n/a	3765.5	3910.9	4388.7

NAFEM®
North American Association of Food Equipment Manufacturers

January 4, 2010

Dear Conference for Food Protection Council Members

The North American Association of Food Equipment Manufacturers (NAFEM), supports changing the FDA Food Code to modify the temperature requirements for commercial dish machines.

The proposed change removes the temperature requirements for wash and rinse cycles and maintains the performance criteria currently required by the FDA (5-log pathogen reduction). Research has confirmed that sanitation requirements can be met while operating at lower temperatures – resulting in a machine that uses less energy which, in turn, reduces CO_2 emissions and lowers energy bills.

If the proposed changes are instituted, an operator of a rack conveyor machine, for example, could realize an estimated annual savings of 0.042 kW-hours per dish rack. This could save up to $539 *per machine* annually. With an estimated 6,000 new conveyor machines sold per year, the potential annual savings could be as high as $3,234,000 in energy costs and over 1.8 million kW-hours of energy – and this is representative for one type of dish machine only. These energy savings are the equivalent of:

- 1,314 metric tons of CO_2
- 280 acres of pine or fir forests (or preserving 12.5 acres of forest from deforestation)
- Enough energy to supply electricity to 171 homes for one year

We hope the council agrees with this proposal and approves this change. Thank you in advance for your consideration.

Sincerely,

Charlie Souhrada

Charlie Souhrada, CFSP
Director, Member Services
NAFEM

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Food Service Technology Center

January 8, 2010

Joel Hipp
Hobart, ITW Food Equipment Group
701 S. Ridge Ave
Troy/Ohio/45374

Joel,

The Food Service Technology Center (FSTC) supports the industry's effort to reexamine the minimum temperatures required to achieve sanitation in commercial dishmachines. If commercial dishmachines are able to expose the dishes to enough heat over time to effectively sanitize the dishes at a lower operating temperature, then the energy savings could be quite substantial.

It is estimated that foodservice operations in California consume an estimated 350 million therms of gas annually for hot water heating – representing 20% of the total gas consumed by commercial facilities. If this value were prorated for the Continental U.S., the commercial water heating load would approach 3.5 billion therms per year for commercial foodservice operations alone.

In most commercial foodservice operations, the operating temperature of the water heating system is driven by the needs of the commercial dishmachine. The rinse operation of the dishwasher requires inlet water temperatures typically in the 140° F range to the dishmachine (for low-temp applications) or to the booster heater (for high-temp applications) to ensure clean dishes. The water heater energy use required to heat and maintain proper operating temperatures could be reduced significantly if the standard operating temperatures were lower.

The FSTC estimates that 16 million therms of natural gas would be saved if all food service facilities in California that use gas water heating and have high-temp dishwashers where able to retrofit or purchase a new (Euro style) dishwasher that allowed the establishment to turn down the thermostat by 10°F. If these savings were projected to the continental U.S, the savings potential would be 160 million therms per year. This significant savings potential is possible if the FDA Food Code were modified to specify the minimum operating temperatures determined by NSF Standard 2 as meeting the sanitizing performance criteria of 5 log reduction of pathogens of public health concern.

Regards,

David Zabrowski
Food Service Technology Center

Sanitation is a way of life. It is the quality of living that is expressed in the clean home, the clean farm, the clean business and industry, the clean neighborhood, the clean community. Being a way of life it must come from within the people; it is nourished by knowledge and grows as an obligation and an ideal in human relations.

Where did 3600 HUE come from?

Early Days

- Ordinance and Code Regulating Eating and Drinking Establishments – U.S. Public Health Service, 1943
  - … irrespective of whether by hand or machine
    - Immersion at least 2 minutes at 170-180°F or ½ minute in boiling water (41,616 HUE's by today's standard)
- Mallmann, DeKoning, April 1947[1]
    - A rinse period of 10 sec. at 170°F for a single tank machine.
    - Test soil was designed so that it would *not* be removed during the entire process.
- Mallmann, Kahler, NSF 1949
    - Immersion at least 30 seconds at 170°F (10,404 HUE's today)

1 – Original study unavailable. Notes are from subsequent research report.

HUE is “invented” and milk pasteurization levels established

- Bactericidal Value of Dishwashing Machine Sprays, Fuchs, 1951
  - Curve defined by:
    - M. tuberculosis and milk pasteurization
      - 143°F for 1800 seconds, 161°F for 15 seconds ≡ 1800 HUE
      - At an arbitrary temperature:
        - » HUE/sec = H = $3.03438E\text{-}17 \times e^{0.265972 \times T}$
      - No *extra* credit for temperatures above 165°F

Pasteurization Defined

- High temperature/short time (HTST) Pasteurization
- The HTST pasteurization standard was designed to achieve a 5-log reduction (0.00001 times the original) in the number of viable microorganisms in milk. This is considered adequate for destroying almost all yeasts, mold, and common spoilage bacteria and also to ensure adequate destruction of common pathogenic heat-resistant organisms (including particularly *Mycobacterium tuberculosis*, which causes tuberculosis and *Coxiella burnetii*).

FDA Food Code “Definition” of Sanitization

- FDA Food Code in Chapter 1 Purpose and Definitions under the section on sanitization.
  - **"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, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

NSF

- NSF Summary Report: Study of Commercial Multiple-tank Spray-type Dishwashing Machines, March 1964
  - *M. phlei* (more heat resistant than *M. tuberculosis*)
  - Lower heat factors were required to destroy microorganisms in water than in milk
  - Organisms were suspended in capillary tubes at the dish surface (thus preventing dilution or wash off)
  - 1900 HUE required for “kill”
  - “Kill” not yet defined as 5-log
  - Concluded that the HUE method can be related to micro-biological results

NSF 1964

- For Mulitple Tank Conveyor Units
  - Wash water 150°F
  - Pumped rinse 160°F
  - Final rinse 180°F
  - Without reference to time exposures - However typical timing would yield 9900 HUE!

NSF 1977

- NSF Standard No.3, amended November, 1977
  - 3600 HUE recommended
    - Twice the recommended HUE for milk pasteurization
    - More than sufficient to kill *M. phlei*
- **Literature research suggests that 3600 was established as an "arbitrary" safety factor of 2 times the value established for milk pasteurization**

Evaluation of Household Dishwashing Machines for Use in Small Institutions – Bryan, DeHart - 1975

- Regard 3600 HUE as providing considerable margin
  - It is twice the heat exposure required for pasteurizing milk
  - Bacteria in water are killed by a lower cumulative heat factor than is required to kill bacteria in milk because water is less viscous than milk
  - The standard for pasteurizing milk, provides a considerable margin of safety
  - Pasteurization standards are based on the destruction of large numbers of *M. tuberculosis*.

The Sanitizing Efficiency Of Dishwashing Machines – Vaughan 1979

- …effective soil removal should be the primary feature of any dishwasher.
- 99.9% of the bacteria can be removed simultaneously with the removal of soil
  - Suggesting, mathematically, that only 2 log reduction would be needed by sanitization

Conclusions

- There is significant data and discussion indicating that 1800 heat equivalent units is a conservative requirement for the pasteurization of milk
- Doubling the HUE requirement for a warewashing machine adds an arbitrary additional factor of 2
- Dishes are an indirect food borne illness path to the human body, thus further reducing the risk factor

Conference for Food Protection
2010 Issue Form

Internal Number: 037
Issue: 2010 III-008

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

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Title:

Establishment of Criteria for Presence and Use of General Purpose Cleaners

Issue you would like the Conference to consider:

Currently there are no formulation or label requirements defined in the Food Code or 21 CFR for General Purpose Cleaners and related products, despite the fact that these products are widely used in proximity to food, as well as on food contact surfaces. Common types of chemical cleaners used within food service establishments include: general purpose cleaners, floor and wall cleaners, scouring agents, carbon removers and degreasers for cooking surfaces and utensils. The Food Code currently addresses several types of chemical compounds in Section 7-2, including chemicals, lubricants, pesticides, medicines and first aid supplies. However, one of the products most commonly found in retail food establishments are general purpose cleaners. USDA/FSIS previously addressed these products (Categories A1, C1) which provided criteria for presence and use, in its "White Book" program which was terminated in 1999. The recommended solution below reflects USDA/FSIS criteria for cleaners in its White Book program, and despite the program's termination as part of an overall transition to HACCP, remains the best available minimum criteria for general purpose cleaners.

Public Health Significance:

The Food Code does not have detailed criteria for the presence and use of general purpose cleaners. The proliferation of new "green" cleaners and other new cleaning formulations presents possible new contamination risks. The Food Code should provide more detailed guidance on formulations and use of general purpose cleaners.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA recommending the creation of a new section (7-204.15) to read as follows:

- *Chemical cleaner formulations shall not contain intentionally added heavy metals such as lead, mercury, arsenic, antimony, or known human carcinogens. Fragrance components such as pine oil or d-limonene are not acceptable at detectable levels. Boric acid and salts thereof may be used in products only at concentrations up to 90 percent in association with strong acids, strong alkalis, soaps, or synthetic detergents.Products shall be labeled for use within food establishments. Instructions specifying that use of chemical cleaners must be followed by a potable water rinse shall be included on the label, except for cleaners used in areas with subfreezing temperatures. Metal cleaners/polishes may only be used on non-food contact surfaces, and do not require a potable water rinse after use.*

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Conference for Food Protection
2010 Issue Form

Internal Number: 014
Issue: 2010 III-009

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

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Title:

Report - Blade Tenderization Committee

Issue you would like the Conference to consider:

Acknowledgement of the Blade Tenderization Committee final report.

Public Health Significance:

The Blade Tenderization Committee was charged with reviewing the guidance document "Guidelines on Injected and Mechanically Tenderized Beef Steak for Retail and Food Service Establishments" submitted to Council III at the 2008 CFP Biannual Meeting and making a revised document that would be reported back to CFP at the 2010 Biannual Meeting. The Committee:

a. Provided peer review of the "Guidelines on Blade Tenderized Beef for Restaurants and Retail Food Establishments" submitted at the 2006 and 2008 meetings,

b. Recommended changes to improve the document and possible changes to the Food Code, and

c. Considered recent scientific research and any new data of contamination by *Escherichia coli* O157:H7 and the impact on this by various processes including injected and mechanically tenderized beef steaks.

Recommended Solution: The Conference recommends...:

acknowledgement of the Final Committee Report from the Blade Tenderization Committee, with thanks to the committee for completing their work and disbanding the committee.

Submitter Information:

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Attachments:

- "Blade Tenderization Committee Report"

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

COMMITTEE NAME: Blade Tenderization Committee

COUNCIL: III

DATE OF REPORT: December 4, 2009

SUBMITTED BY: Robert G. Reinhard

COMMITTEE CHARGE:

1. The Blade Tenderization Committee guidance document "Guidelines on Injected and Mechanically Tenderized Beef Steak for Retail and Food Service Establishments" submitted to Council III at the 2008 CFP Biennial Meeting should be reviewed with comments and a revised document be reported back to CFP at the 2010 meeting. The Committee should:
    a. Provided peer review of the "Guidelines on Blade Tenderized Beef for Restaurants and Retail Food Establishments" submitted at the 2006 and 2008 Biennial Meetings,
    b. Recommend changes to improve the document and possible changes to the Code, and
    c. Considered recent scientific research and any new data of contamination by *Escherichia coli* O157:H7 and the impact on this by various processes including injected and mechanically tenderized beef steaks.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

The Committee is submitting two issues to the 2010 CFP Biennial Meeting: 1) modified peer-reviewed guidance document, "Guidelines for Injected and Mechanically Tenderized Beef Steak for Retail and Food Service Establishments" (re-titled "Guidelines for Producing or Cooking Mechanically Tenderized Beef for Retail and Food Service Establishments"), and 2) Final Report of the Blade Tenderization Committee. With the submission of the issues, the work of the committee is finished.

The committee met on nine separate occasions from April to November 2009 and attendance at each of the meetings ranged from five to fifteen members. In addition, on one occasion, seven members from the committee with two members from the Food and Drug Administration on a conference line met in person in Washington D.C. with the United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS). The purpose of this face-to-face meeting with FSIS was to discuss the committee's activities, numerous issues on the labeling of raw blade tenderized beef and the requirements for controlling the hazard and the most recent activities FSIS has initiated in federally inspected meat establishments that produce raw blade tenderized and injected beef.

In each of the meetings the committee discussed the Guidance document we were charged to review, recent scientific research and any new data of contamination by *Escherichia coli* O157:H7 and the impact on this by various processes including injected and mechanically tenderized beef steaks and/or made draft edits on the guidance

document. The committee recognized that other pathogens could have the same impact on the safety of non-intact beef but limited the discussion to *E. coli* O157:H7 since the outbreaks to date have been associated with *E. coli* O157:H7 and the controls for *E. coli* O157:H7 would also control other pathogens. The committee discussions and comments were generally focused on the various guidance document drafts; review and inclusion of the foodborne illness information in the guidance document as found in the original report; the type of tenderization, mechanically or injection, involved in each reported outbreak; the extent retail and food service establishments tenderize beef at their locations; the use of the consumer advisory in food service establishments; if the hazard is significant given recent research on translocation during blade tenderization and cooking/inactivation of the organism; and, whether the guidance document should address labeling, especially labeling that is not a regulatory requirement.

The committee reached a consensus that the guidelines would help retail and food service establishments limit and control contamination by *E. coli* O157:H7 in tenderized and injected beef. There was one committee member who suggested that the guidance document may no longer be needed since the recommendations have now been incorporated into the 2009 Food Code. However, the committee members agreed by consensus that the guidance document would provide useful information to retail and food service establishments that are specifically seeking information on producing and cooking mechanically tenderized or injected beef.

REQUESTED ACTION:

The Committee is submitting two Issues for consideration:

1. Requesting acknowledgement of the Committee report (see attachment titled: "Blade Tenderization Committee Report")

2. The Committee requests Council III acceptance of the new revised guidance document: "Guidelines for Producing or Cooking Mechanically Tenderized Beef for Retail and Food Service Establishments" with a request that the guidance document be made available to interested stakeholders on CFP's web site or as an addendum to the Food Code. (see attachment titled: "Guidelines for Producing or Cooking Mechanically Tenderized Beef…")

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Conference for Food Protection
2010 Issue Form

Internal Number: 015
Issue: 2010 III-010

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

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Title:

Guidelines for Producing or Cooking Mechanically Tenderized Beef for Retail

Issue you would like the Conference to consider:

The Blade Tenderization Committee submits up-dated "Guidelines for Producing or Cooking Mechanically Tenderized Beef for Retail and Food Service Establishments".

Public Health Significance:

The submitted guidelines are intended to control contamination by *Escherichia coli* (*E. coli*) O157:H7 and other pathogenic Shiga-toxin producing *E. coli* [STEC] *E. coli* and *Salmonella* species during the production, handling, or preparation of mechanically tenderized or injected beef at food service establishments and retail food stores. Since control procedures for *E. coli* O157:H7, and other pathogenic *E. coli* also control *Salmonella* and other microbiological pathogens, these recommended guidelines will refer specifically to the control of *E. coli* O157:H7 but will be inclusive of these additional foodborne pathogens.

E. coli O157:H7 is a significant public health concern in raw ground beef and the meat industry has implemented a variety of procedures to control this hazard. However, several recent *E. coli* O157:H7 outbreaks and resulting recalls linked to non-intact tenderized beef have raised concern about the safety of these products. The relatively recent recalls and outbreaks of non-intact tenderized beef products have also caused great interest in: 1) determining the potential risk these products pose to public health; and 2) the development of food safety preventive measures to control such risks during the production and preparation of non-intact beef products.

Recommended Solution: The Conference recommends...:

approval of the new revised guidance document titled "Guidelines for Producing or Cooking Mechanically Tenderized Beef for Retail and Food Service Establishments" and that it be made available to interested stakeholders on CFP's web site .

Additionally, the Conference recommends that a letter be sent to the FDA requesting that this guidance document be made available as an addendum to the Food Code.

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Attachments:

- "Guidelines for Producing or Cooking Mechanically Tenderized Beef..."

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

Guidelines for Producing or Cooking Mechanically Tenderized Beef for Retail and Food Service Establishments

The following guidelines are intended to control contamination by *Escherichia coli* (*E. coli*) O157:H7 and other pathogenic Shiga-toxin producing *E. coli* [STEC] *E. coli* and *Salmonella* species during the production, handling, or preparation of mechanically tenderized or injected beef at food service establishments and retail food stores. Since control procedures for *E. coli* O157:H7, and other pathogenic *E. coli* also control *Salmonella* and other microbiological pathogens, these recommended guidelines will refer specifically to the control of *E. coli* O157:H7 but will be inclusive of these additional foodborne pathogens.

E. coli O157:H7 is a significant public health concern in raw ground beef and the meat industry has implemented a variety of procedures to control this hazard. However, several recent *E. coli* O157:H7 outbreaks and resulting recalls linked to non-intact tenderized beef have raised concern about the safety of these products. The relatively recent recalls and outbreaks of non-intact tenderized beef products have also caused great interest in: 1) determining the potential risk these products pose to public health; and 2) the development of food safety preventive measures to control such risks during the production and preparation of non-intact beef products.

These guidelines have been developed for limiting contamination by *E. coli* O157:H7 during the production, handling, or preparation of mechanically tenderized beef (e.g., blade-tenderized beef, pinned beef) and in the production and preparation of injected mechanically tenderized beef. Tenderization is the process of treating whole muscle tissue by either a mechanical or chemical method to soften the beef tissues, primarily to enhance product quality. Mechanical tenderization uses blades, needles, or

25pounding devices (e.g., blade-tenderized beef, pinned beef) to soften the beef tissue.
26Other forms of tenderization use chemicals or enzymes and a mechanical processing step
27(e.g. scoring of the muscle and tumbling, needle tenderization).

28 Blade tenderized and other mechanically tenderized beef is a significant portion
29of the beef supplied to and used by the restaurant and food service industry. In 1975, it
30was estimated that over 90% of hotel, restaurant, and institutional (HRI) operations
31utilized blade tenderization (10) and in a 2003 survey conducted on behalf of the National
32Cattlemen's Beef Association, 94% of manufactures indicated they used mechanical
33tenderization to improve product quality (13).

34 Regardless of why blade tenderization is utilized, mechanically tenderized beef is
35not required to be labeled by either the USDA's Food Safety and Inspection Service or
36the Food and Drug Administration. While labeling may be seen as a value to inform a
37small proportion of consumers, labeling has never been documented as an effective way
38to appreciably affect consumer behavior broadly when it comes to cooking. All
39mechanically tenderized beef products, like all raw beef, must be labeled with "safe
40handling" instructions for consumers. Producers of beef injected with tenderizers or
41flavoring marinades are required to include the term "(solution or tenderizer) added (or
42injected)" on the principal display panel and to list the added ingredients on the
43ingredient statement of the label.

44 Scientific studies have shown a very low prevalence of *E. coli* O157:H7 on the
45surface of intact beef primals, ranging from 0.083 to 0.2% incidence (1). However,
46research has also demonstrated that when the product is mechanically tenderized, the
47blades or needles used in the mechanical process can transfer microorganisms from the

48surface of the beef to the interior (6, 7, 8, 10, 13). At high surface inoculation levels for
49*E. coli* O157:H7, after one-pass blade tenderization of beef only 3-4% of the initial
50inoculum was internalized into deeper parts/geometric center of the muscle (10, 13). In
51addition, in those studies that have quantified the surface inoculate (4 log CFU/g) versus
52those cells translocated after tenderization, very low levels of *E. coli* O157:H7 were
53transferred to the geometric center of the product; counts ranging from 0 to 0.83 CFU/g.
54This research indicates that adequate cooking temperatures targeted for the center of a
55product would effectively eliminate the levels of *E. coli* O157:H7 expected to be found in
56mechanically tenderized beef products. However, surface searing of a non-intact steak
57may not deliver enough lethality heat treatment to pathogens that may be present in the
58interior of the non-intact steak.

59 Guidelines for the production and handling of tenderized (mechanical or injected)
60meat at Federally Inspected meat processing facilities already exist. The meat processing
61guidelines are designed to prevent, eliminate or reduce contamination by *E. coli* O157:H7
62during the production, handling, and preparation of mechanically tenderized and injected
63beef. Recognizing that the guidelines for meat processors may not be applicable in retail
64and food service facilities, this document provides specific guidelines for the production
65and preparation of mechanically tenderized or injected beef that focus on measures to
66reduce the risk of contamination. A preventive control-based approach is reasonable
67given the expected low levels of contamination from *E. coli* O157:H7 in source materials
68and the current regulatory requirements on product labeling. Best practices should focus
69on controls that prevent the cross-contamination of source materials or product surfaces
70and minimize risks through application of an intervention prior to tenderization. In

71addition, the use of some of these guidelines on the receipt and holding of blade
72tenderized beef products from a manufacture assures the controls implemented in the
73production of that product are maintained at the retail or food service establishment.

74 **Guidance for Retail Establishments That Only Repackage Beef For Sale**

75 Since mechanically tenderized beef is not required to be labeled differently from
76intact beef, the retail establishment may not be able to distinguish mechanically
77tenderized beef from intact beef cuts. Therefore, retail establishments should use a
78preventive control approach in the repackaging process and set up purchase specifications
79with their suppliers.

80 Purchase specifications should require a continuing letter of guarantee from the
81supplier that:

82 1. Assures the beef product they purchase is inspected and passed according to the
83 Meat Inspection Act.
84 2. Includes a provision indicating that the product was produced following a food
85 safety preventive control program (e.g. HACCP) in which *E. coli* O157:H7 is
86 identified as a hazard likely to occur and that has a control step to eliminate the
87 hazard or reduce it to an acceptable level.

88 In addition to purchase requirements, the retail establishment should have in place
89control measures to reduce the risk of cross-contamination with *E. coli* O157:H7 and the
90proliferation of the organism in the packaging process. These controls include product
91temperature control, sanitation, and product control.

92

93

1. Product Temperature Control – To limit proliferation of *E. coli* O157:
    a. Verify temperature of refrigerated beef at delivery is 41ºF or less [Food Code 3- 202.11(A)]
    b. Control cold holding temperature of product from delivery to sale by refrigerating immediately at 41ºF or less [Food Code 3-501.16(A)(2)] Maintain frozen products prior to processing at a frozen state [Food Code 3-501.11]. Temper, thaw or slack frozen beef appropriately so product does not exceed the minimum growth temperatures for *E. coli* O157:H7 (less than 44.6 ºF). [Food Code 3-501.12]
    c. Maintain temperature control in the processing and storage areas such that the product being processed does not exceed the minimum growth temperature for E. coli O157:H7 (less than 44.6 ºF)
    d. Rotate product on first in-first out (FIFO) or first expired first out (FEFO) basis as a good retail practice.
    e. Verify temperature of beef in retail case/display is 41ºF or less [Food Code 3- 202.11(A)].
2. Sanitation Program – A system for monitoring the completeness and effectiveness of the sanitation procedures.
    a. Should be a written document that is designed to ensure sanitary conditions both before and during operations
    b. Should describe procedures for employee hygiene or these procedures should be described in a separate program [Food Code Chapter 2

116 Management and Personnel; FDA Employee Health and Personal Hygiene
117 Handbook]
118 c. Should include proper cleaning and sanitizing procedures that describe the
119 procedure for equipment breakdown to ensure effective and thorough
120 cleaning and sanitizing [Food Code Chapter 4, Parts 4-6 and 4-7].
121 d. Verify effectiveness of the sanitizing procedures
122 e. Prevent cross-contamination [Food Code Chapter 3, Part 3-3]
123 f. Make the sanitation program available to appropriate employees
124 responsible for managing or implementing these programs
125 g. Train all employees responsible for the sanitation procedures
126 3. Employee Health
127 a. A written employee health policy is recommended to be in place to
128 exclude ill food workers from the establishment. [Food Code Annex 3,
129 Part 2-2 Employee Health]
130 4. Product Traceability
131 a. Code the product and maintain sufficient documentation to allow trace
132 back for a time period to include any potential frozen storage that may
133 occur prior to consumption of the finished product.
134 5. Labeling
135 a. For beef products that are injected, identify any added marinade,
136 antimicrobial ingredient, flavoring or tenderizers in the ingredient
137 statement [Food Code 3-602.11]. Antimicrobial agents approved as

138 processing aides are exempted from labeling requirements (21 CFR §
139 101.100).
140 b. Provide required labeling for safe handling/cooking instructions [Food
141 Code 3-201.11(F)].
142
143 **Guidance for Retail and Food Service Establishments That Tenderize or Inject Beef**
144 Retail and Food Service establishments that mechanically tenderize or inject meat
145 products should apply measures to reduce the risk of contamination with *E. coli* O157:H7
146 and other pathogens during the processing of the product and particularly in the
147 mechanical tenderization or injection step of the process. These preventive controls
148 include, but are not limited to, product temperature control, sanitation, and product
149 traceability, labeling, and interventions. It is recommended that retail and food service
150 operations develop a specific written plan, such as a risk-based or HACCP plan to define
151 their preventive controls. Only employees trained to implement these procedures in
152 accordance with the written plan should be permitted to tenderize or inject beef products.
153 Procedures for tenderizing and injecting meat should include:
154 1. Product and Solution Temperature Controls to limit proliferation of *E. coli* O157:
155 a. Verify temperature of beef at delivery is 41ºF or less [Food Code 3-
156 202.11(A)]
157 b. Control cold holding temperature of product from delivery to sale by
158 refrigerating immediately at 41ºF or less [Food Code 3-501.16(A)(2)].
159 Maintain frozen products prior to processing at a frozen state. Temper,
160 thaw or slack frozen beef appropriately so product does not exceed the

minimum growth temperatures for *E. coli* O157:H7 (less than 44.6 ºF) [Food Code 3-501.12]

c. Maintain temperature control in the processing and storage areas such that the product being processed does not exceed the minimum growth temperature for E. coli O157:H7 (less than 44.6 ºF) [Food Code 3-501.12]

d. Maintain the time and temperature relationship on all re-used or re-circulated injected fluids or marinade so that they do not allow the outgrowth of *E. coli* O157:H7 [Food Code 3-501.16(A)(2)].

e. Rotate product on first in-first out (FIFO) or first expired first out (FEFO) basis as a good retail practice.

f. Verify temperature of beef at in retail case/display is 41ºF or less [Food Code 3- 501.16(A(2)]

2. Sanitation Program – A system for monitoring the completeness and effectiveness of the sanitation procedures.

a. Should be a written document that is designed to ensure sanitary conditions both before and during operations.

b. Should describe procedures for employee hygiene or these procedures should be described in a separate program [Food Code Chapter 2 Management and Personnel; FDA Employee Health and Personal Hygiene Handbook].

c. Should include specific procedures for proper cleaning and sanitizing that include the procedures for equipment breakdown to ensure effective and

183 thorough cleaning and sanitizing [Food Code Chapter 4, Parts 4-6 and 4-
184 7].
185 d. Should include specific procedures for the disassembly, cleaning and
186 sanitizing of the equipment used for the mechanical tenderization or
187 injection process. These procedures are outlined below:
188 i. Cleaning and sanitizing of equipment before operation and during
189 operation, especially reservoirs, and piping associated with
190 mechanical tenderizing/flavoring operations.
191 ii. Cleaning and sanitizing procedures for blades or needles that
192 include frequency of procedures, and methods and chemical
193 concentrations used.
194 e. Verify effectiveness of the sanitizing procedures
195 f. Prevent cross-contamination [Food Code Chapter 3, Part 3-3]
196 g. Make the sanitation program available to appropriate employees
197 responsible for managing or implementing these programs
198 h. Train all employees responsible for the sanitation procedures
199 3. Employee Health
200 a. A written employee health policy is recommended to be in place to
201 exclude ill food workers from the establishment [Food Code Annex 3, Part
202 2-2 Employee Health].
203 4. Product Control
204 a. Code the product and provide sufficient documentation to allow trace back
205 if necessary.

206 b. Develop purchase specifications for the suppliers to ensure that the beef to
207 be tenderized or injected has been tested negative for *E. coli* O157:H7
208 using N=60 sampling methodology.
209 c. Consider the use of approved antimicrobial agents as a surface treatment
210 prior to tenderization/injecting and/or an antimicrobial agent (e.g., lactic
211 acid) in the solution injected into the beef. A list of Safe and Suitable
212 Antimicrobial Agents Used in the Production of Meat and Poultry
213 Products is available from FSIS [FSIS Directive 7120.1;
214 http://www.fsis.usda.gov/Regulations_&_Policies/7000_Series-
215 Processed_Products/index.asp
216 5. Labeling
217 a. For beef products that are injected, identify any added marinade,
218 antimicrobial ingredient, flavoring or tenderizers in the ingredient
219 statement. Antimicrobial agents approved as processing aides are
220 exempted from labeling requirements (21 CFR § 101.100).
221 b. Provide required labeling for safe handling/cooking instructions.
222

223 **For Retail or Food Service Establishments That Cook or Thermally-Process**
224 **Mechanically Tenderized or Injected Beef Steaks**

225 Injected and other mechanically tenderized beef products are considered non-
226intact products. Time and temperatures for cooking non-intact products differ from those
227for cooking intact products [Food Code 3-401.11(A)(2), (C) and (D)]. Intact steaks may
228have contamination on the cut surfaces, and therefore cooking both the top and bottom to

229a surface temperature of 63ºC (145ºF) or above can inactivate pathogens on the surface.
230However, mechanically tenderized or injected steaks could have contamination below the
231surface, where the needles, blades or pins penetrate and therefore need more rigorous
232cooking.

233 The final internal temperature that must be achieved for blade-tenderized steaks,
234comminuted beef and injected beef, which are all considered non-intact, is 155°F (68°C)
235for 15 seconds or other times and temperatures combinations listed in Section 3-
236401.11(A)(2) of the Food Code. When a retail or food service establishment knows that
237meat is non-intact, they should follow these cooking procedures. Those establishments
238that cook these products at a lower internal temperature, e.g., as requested by the
239consumer, must provide a consumer advisory with a disclosure and reminder [Food Code
2403-603.11]. However, this alternative may not be used by food establishments that serve
241highly susceptible populations, such as nursing homes, hospitals, schools or daycare
242facilities [Food Code 3-801.11(C)]. Additionally, the Food Code [3-401.11(D)(2)] does
243not allow under-cooked comminuted meat to be served off a children's menu. A whole-
244muscle, intact steak as identified by labeling or letter of guarantee may be served or
245offered for sale in a ready-to-eat form by cooking to a surface temperature of 145°F
246(63°C) or above and a cooked color change is achieved on all external surfaces[Food
247Code 3-401.11(C)(3)]. It is best to always use a calibrated thermometer to ensure that
248correct temperature is achieved during cooking.
249 This guidance on cooking of mechanically tenderized beef is applicable to beef
250with ingredients added to induce tenderization, such as injected beef [as defined in Food

251Code 1-201.10(B)]. The guidelines provided above for cooking of mechanically

252tenderized beef also apply to injected/tenderized beef.

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Conference for Food Protection
2010 Issue Form

Internal Number: 054
Issue: 2010 III-011

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

All information above the line is for conference use only.

Title:

Report - Hot Holding Committee

Issue you would like the Conference to consider:

Acknowledgment of the Hot Holding Committee's report to the CFP 2010 Biennial Meeting.

Public Health Significance:

Sharing and applying the latest science and food safety knowledge allows stakeholders to have a share in the endeavor to promote a safe national food supply and thereby reduce the incidence of food borne illness.

Recommended Solution: The Conference recommends...:

acknowledgement of the Committee's Final report to the 2010 Biennial Meeting and thanking the committee members for their work.

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Attachments:

- "2008-10 Hot Holding Committee Final Report"
- "2008-10 Hot Holding Committee Roster"

- "2008-10 Hot Holding Committee Survey Summary"
- "2008-10 Hot Holding Committee Quantitative Microbial Risk Assessment Data"
- "2008-10 Hot Holding Committee Original Survey Document"

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

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III-Hot Holding	Zorn	David	Member	Regulatory - Federal	USFDA	5100 Paint Branch Pkwy	College Park	MD	20740	(301) 436-1825	david.zorn@fda.hhs.gov

Question 1: What type of product temperature monitoring devices do you use in your operations? (Check all that apply.)

21 Question 1: Bi-metallic
27 Question 1: Digital
12 Question 1: Infra-red
26 Question 1: Thermocouple
0 Question 1: Other, please specify

Question 2: Do you have written product temperature monitoring standard operating procedures for hot holding?

Yes 39 of 41

Question 2: • If yes, would you be willing to share? Please send attachments of your procedures to Co-Chair, Donna Garren at donna_garren@comcast.net.

Question 3: Do you calibrate your product temperature monitoring devices?

Yes 35 of 41

Question 4: How often do you calibrate the product temperature monitoring device?

0 Question 4: Every hour
2 Question 4: Every 4 hours or mid shift
21 Question 4: Once per day
13 Question 4: Once per week
4 Question 4: Not at all
7 Question 4: Other, please specify

Most electric are calibrated.
or when dropped
When replacing the battery
When temp is questioned, after it has been dropped
and if dropped
Before each shift
As needed, if there is a question as to the accuracy

Question 5: What method do you use to calibrate?

34 Question 5: Ice point method
1 Question 5: Boiling point method
2 Question 5: Both
2 Question 5: Other, please specify

hot water against a calibrated thermocouple done t
Auditor verify against mercury

Question 6: What is your corrective action when you find that your product temperature monitoring device is out of calibration? (Check all that apply)

25 Question 6: Manually calibrated
18 Question 6: Change battery
14 Question 6: Send to the manufacturer
17 Question 6: Discard and replace
3 Question 6: Other, please specify

Send for re-calibration internally
Record variance on the unit temporarily
Refer to mfr. calibration procedures

Question 7: Do you measure product temperature for hot holding continuously or periodically?

4 Question 7: Continuous
37 Question 7: Periodic

Question 8: If product temperature measurement is periodic, how often do you take temperature measurement?

3 Question 8: Hourly
13 Question 8: Every 2 hours
11 Question 8: Every 4 hours
14 Question 8: Other, please specify

4 times per day about every 3 hours
each shift in hot wells - check water temp
As required by our HACCP program
Every 3-hours
every 3 hours
Every 3 hours
2 times daily

Once Per Shift
Before shift and as product is replaced, every 3 h
1st cooked, then 3 periodic times througout the day
Once per shift 8 hour shift
temped as part of cooking process plus holding temp
3 hours
varies with product/procedures

Question 9: If product temperature measurement is continuous, how is the measurement recorded?

2 Question 9: Automatic system
8 Question 9: Manual system (hand written record)
2 Question 9: Other, please specify

Batch cooking recording method
N/A

Question 10: If product temperature measurement is continuous, how is the measurement captured?

8 Question 10: Internal
2 Question 10: Ambient
2 Question 10: Other, please specify

N/A
some roasts are probed too

Question 11: Do you stir the product before taking temperature?

Yes 26 of 41

Question 12: What is the location you take temperature in the product?

4 Question 12: On the surface
35 Question 12: In the center of the product
1 Question 12: Along the edge
5 Question 12: As far in as the probe reaches

Question 13: Is the location of the temperature measurement dependent on the food type?

Yes 25 of 41

Question 14: How far do you insert the product temperature device if you take temperature inside the product? Give approximate distance.

2 Question 14: < 1 inch
12 Question 14: 1 inch
17 Question 14: 2 inches
4 Question 14: 3 inches
10 Question 14: Other, please specify

it depends on the item. Typically in the middle
Into the center
depends upon the ingredient
Products thin. Will measure as far in as possible
center
geometric center
depends on the product (probe tip to the center)
Varies by food item
depends on product
depends on product

Question 15: If you insert the product temperature device <1 inch, what type of measuring device do you use?

5 Question 15: Bi-metallic
10 Question 15: Other, please specify

Question 16: Are there specific areas of hot holding equipment that you monitor product temperatures-i.e. corners of hot plates versus middle?

7 Question 16: Middle of warmer
7 Question 16: Perimeters of warmer
29 Question 16: Not applicable

Question 17: What corrective actions do you take when the temperature of the product is out of compliance with normal temperature limits?
26 Question 17: Discard

27 Question 17: Reheat
10 Question 17: Increase steam table temperature (increase thermostat and/or add sterno)
0 Question 17: No action
7 Question 17: Other, please specify

Follow HACCP procedures for that product
Evaluate warming unit, call service if necessary.
hardly ever find this. Always much hotter than 135
Discard if no time was documented
depends on time/temperature parameters
reheat 1X then discard if again
Depends on time & temp. of food

Question 18: If you choose to reheat the product, how many times do you reheat?

29 Question 18: One time
1 Question 18: Two times
0 Question 18: Three times
7 Question 18: Do not reheat
0 Question 18: Other, please specify

Question 19: What is your procedure for reheating?

16 Question 19: Microwave
16 Question 19: Convection oven
3 Question 19: Fryer
4 Question 19: Rotisserie oven
4 Question 19: Not applicable
10 Question 19: Other, please specify

boiling water bath
Steamer
original cooking method
boil over open flame
water bath
Combi-Oven
steamer or stove top
Steamer
Steamer or stove top
APW Cooker

Question 20: Are the product temperatures recorded?

Yes 35 of 40

Question 21: If temperatures are recorded, how is it recorded?

32 Question 21: Manually
5 Question 21: Electronically
1 Question 21: Other, please specify

N/A

Question 22: Is the product stirred periodically if on steam table?

Yes 36 of 38

Question 23: What is the maximum shelf life for each product during hot holding?

1 Question 23: 1 hour
4 Question 23: 2 hour
2 Question 23: 3 hour
19 Question 23: 4 hour
4 Question 23: 6 hour
6 Question 23: 8 hour
12 Question 23: Other, please specify

can be as much as a day (12 hours)
5 hrs
30 minutes, 12 hours, depending on product.
Any longer than that, becomes Quality Issue
average, time is product sp. (related to quality)
Varies from 10 mins to 4 hours depending on item
1 day
Note: 2 hours is for quality purposes
roasts can be held overnight used next day
varies with product, never exceeds 4 hours
Not to exceed the shift.
Products range from 10 minutes to 4 hours.

Question 24: What is done with the product when the maximum shelf life for hot holding has been reached at the end of service period or shift?

35 Question 24: Discarded
6 Question 24: Cooled and held for reheating
7 Question 24: Other, please specify

Cooled for packaging or conversion
cooled and re-worked later
One time reheat only.
Hardly ever see. use all the product
some items are cooled for reheating
Some product are blast chilled and packaged.
not applicable

Question 25: How are products held during hot holding?

4 Question 25: In packaged form
22 Question 25: In bulk hot display
15 Question 25: Both
4 Question 25: Other, please specify

Pre portioned
holding drawers on cook line
usually in serving pans (buffet concept)
wrapped in ovenable cook-in-bag

Question 26: If packaged, what type of container is used for hot holding?

15 Question 26: Plastic
8 Question 26: Metal
9 Question 26: Card board/paper
4 Question 26: Other, please specify

China
foil bottom, plastic tops or cardboard boxes
lexan
N/A

Question 27: What type(s) of equipment do you use for hot holding food? (Check all that apply)

9 Question 27: Hot plates
31 Question 27: Steam tables
14 Question 27: Heat lamps
18 Question 27: Soup kettles
11 Question 27: Combination, heat lamps and hot plates
12 Question 27: Other, please specify

Hot Box
Steam drawer
Warming cabinets and drawers
drawer style units
Electric Chafing Dishes
Warming cabinet.
Hot water bath on stove tops
alto shaam
APW Cook Units
alto shams and winston cabinets
compartmentalized product holding units
Dry heat display cases

Question 28: Do you address the effect of evaporative cooling? For example, do you cover or maintain in a hot case until it is served?

Yes 25 of 39

Question 29: What is the hot-holding temperature in your jurisdiction(s) with which you must comply? (check all that apply if multiple jurisdictions)

5 Question 29: 130 F
24 Question 29: 135 F
24 Question 29: 140 F
4 Question 29: 145 F
2 Question 29: Other, please specify

Not sure, internal policy is 165F
company standard for North America min.140F

Question 30: Do you hold product exceeding the temperature requirements in jurisdictions?

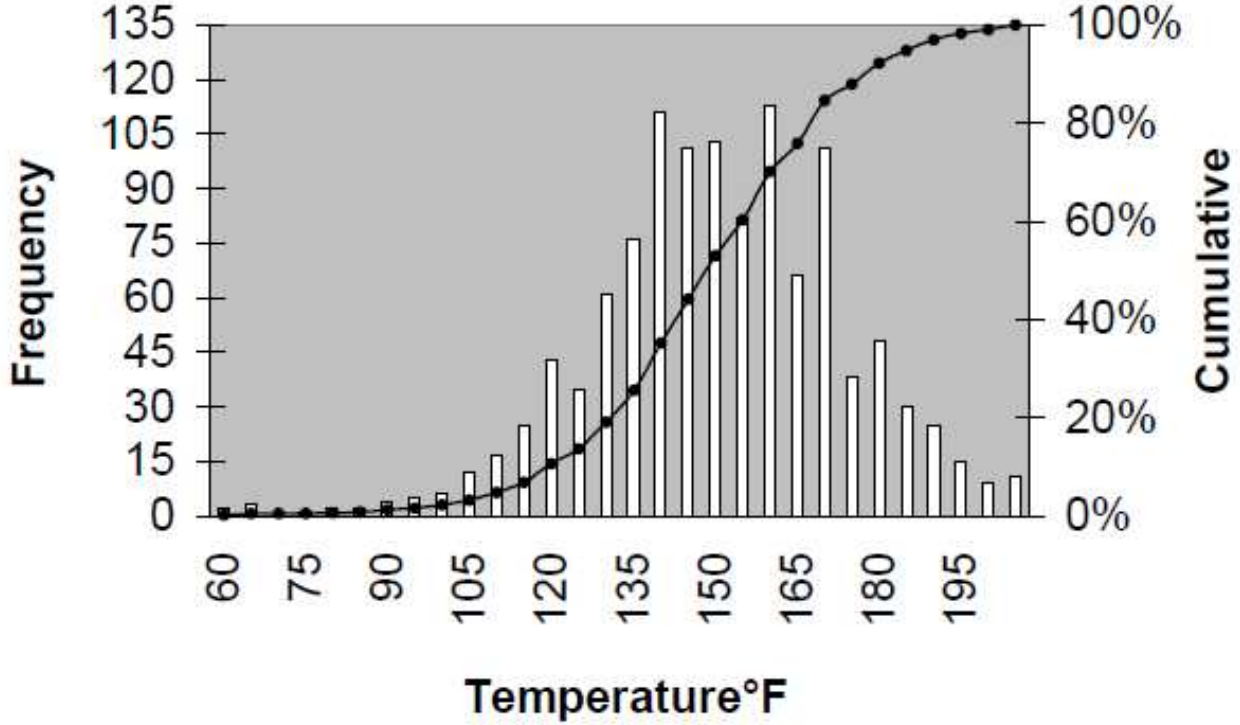
Yes 37 of 38

Simple preliminary QMRA for hot holding

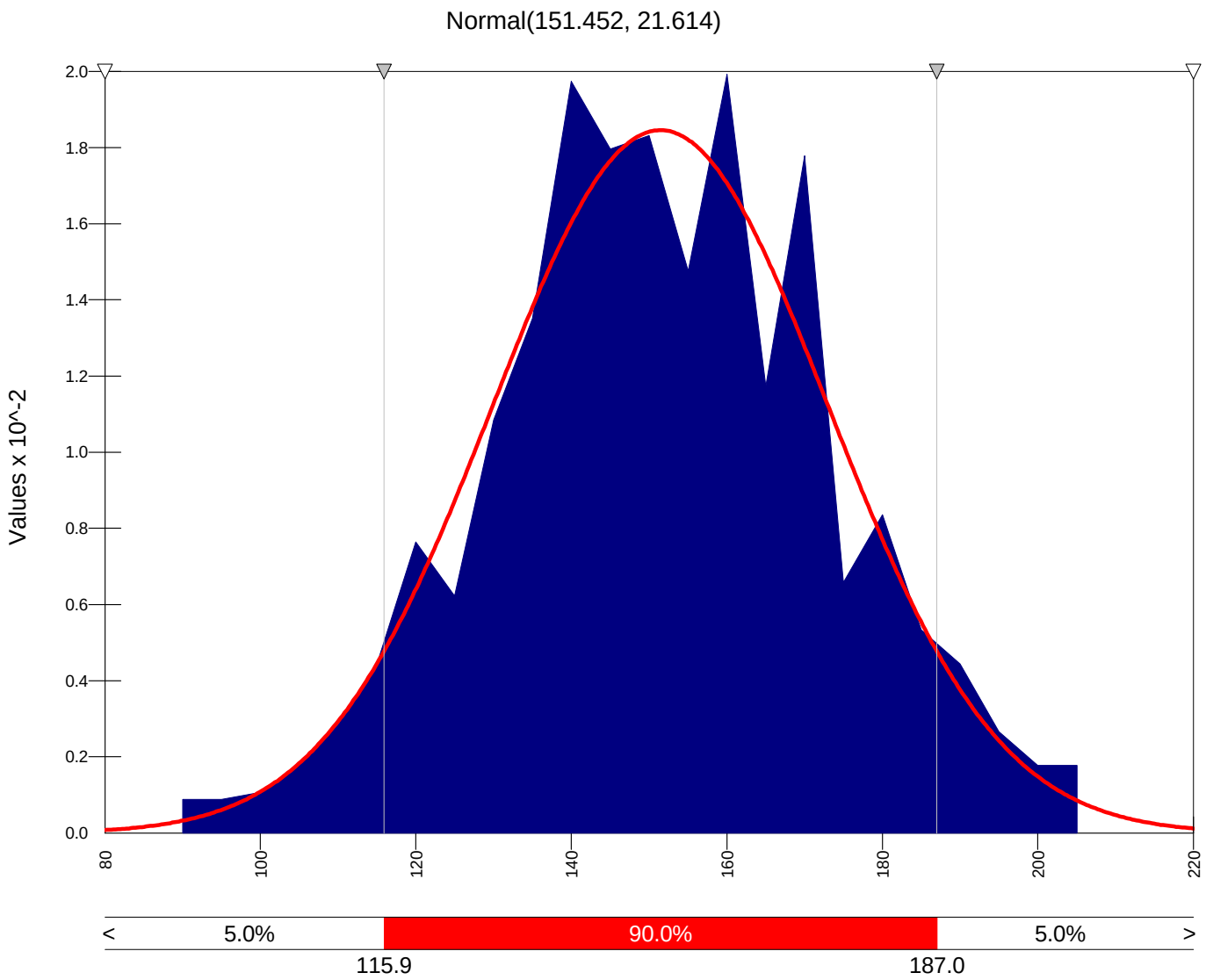
Don Schaffner

Temperature

Figure 1. Range and frequency distribution of hot holding temperatures in foods across food service and retail establishments in the U.S. (n=1147)



Normal distribution

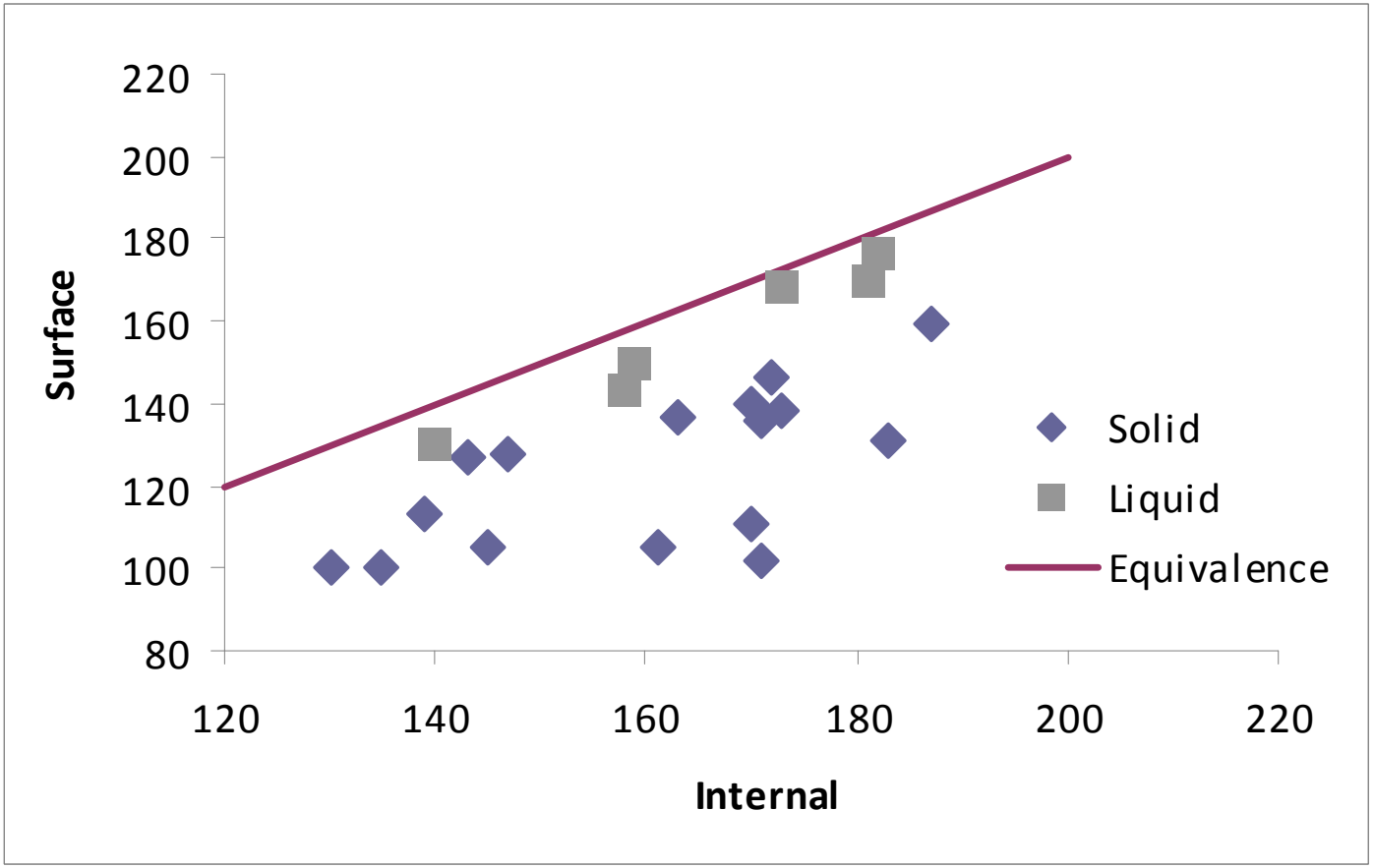


Evaporative cooling

Table 8. Temperature profiles (surface and interior) of hot held foods from four full service Maryland restaurants.

Product	Surface °F (std)	Interior °F (std)	Difference °F
Liquids:			
Gravy	150(3)	159(3)	9
Bean soup	170(4)	181(11)	11
Potato soup	168(7)	173(12)	5
Crab soup	176(5)	182(5)	6
White gravy	143(2)	158(2)	15
Clam chowder	130 (5)	140(6)	10
Solid or Semi-Solid			
Refried beans	105(7)	161(3)	56
Refried bean dip	105(6)	145(8)	40
Charro beans	136(7)	171(3)	35
Baked beans	131(4)	183(7)	52
Green beans	159(2)	187(4)	28
Mashed potatoes	127(5)	143(11)	16
Rice	137(3)	163(3)	16
Wild rice	146(14)	172(4)	26
Stuffing	138(5)	173(11)	35
Potatoes	140(8)	170(11)	30
Taco meat	111(12)	170(19)	59
Chicken	128(7)	147(15)	19
Beef	100(5)	130(4)	30
Turkey	113(5)	139(10)	26
Pork	98(4)	135(5)	37
Beef barbeque	102(6)	171(5)	69

Evaporative Cooling graph



Pathogens

Table 6. Effect of temperature on *Clostridium perfringens* growth parameters.

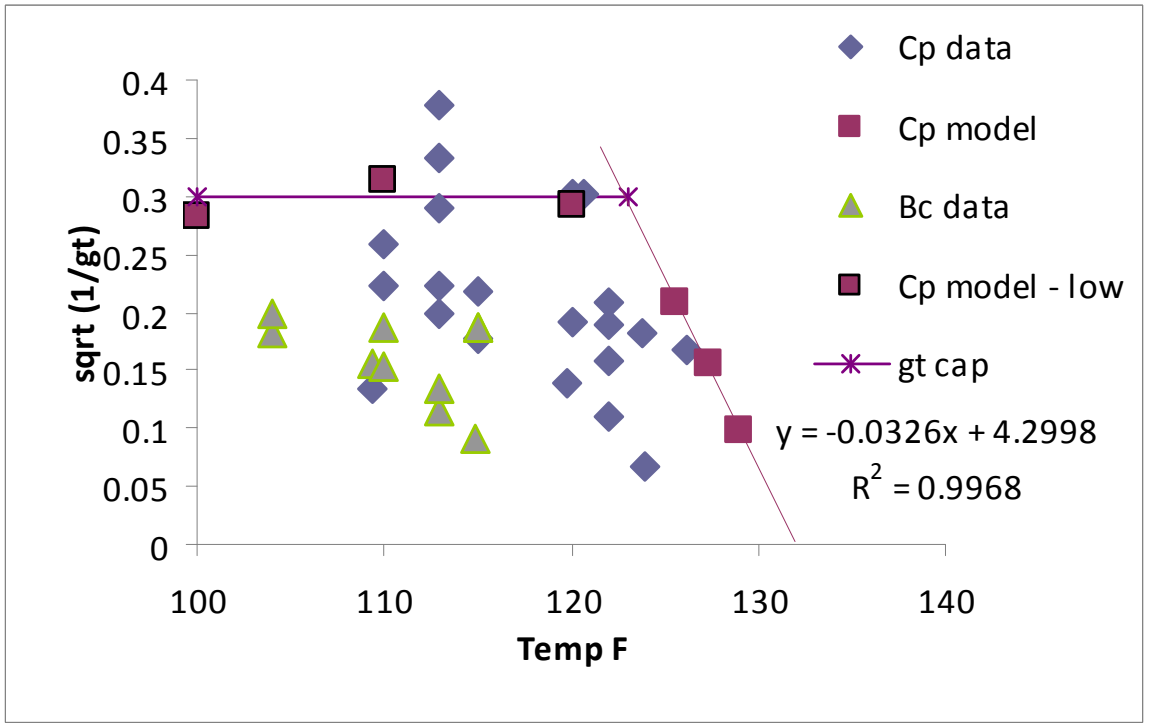
Temp °F	Temp °C	Food or substrate	Lag time (h)*	Generation time (min)*	pH	Bibliog.
109.4	43	Cooked meat broth	0	56	-	6
110	43.3	Chicken broth	1.08	20	6.4	7
110	43.3	Cooked meat medium	0.73	15	6.8	7
113	45	TG broth	0	20	-	17
113	45	Cooked chicken thigh	0	12	-	7
113	45	Autoclaved ground beef	1.5	7	6.1	21
113						
113						
115						
115						
119.8						
120						
120						
120.6	49.2	Autoclaved ground beef	ND	11	6.1	21
122	50	TG broth	0	23	7.2	17
122	50	Cooked roast beef	ND	84	-	4
122	50	Raw chicken breast	0	40	5.7	10
122	50	Raw chicken Leg	1	28	6.6	10
123.8	51	Autoclaved ground beef	ND	30	6.1	21
124	51.1	Cooked roast beef	ND	218	-	4
				36	7.0	25

Table 7. Effect of temperature parameters on *Bacillus cereus* growth.

Temp °F	Temp °C	Food or substrate	Lag time (h)*	Generation time (min)*	pH	Bibliog.
104	40	Skim milk	ND	30	6.6	18
104	40	TSB	ND	25	7	12
107.6	42	BHI	0	-	7.4	9
109.4	43	Rice	ND	41	-	19
110	43.3	Chicken broth	2.90	42	6.4	10
110	43.3	Cooked meat medium	2.10	29	6.8	10
113	45	TSB	ND	76	7.0	12
113	45	Rice + 10% beef extract	ND	55	7.0	12
114.8	46	BHI	ND	120	7.4	9
115	46.1	Chicken broth	4.50	29	6.4	10
115	46.1	Cooked meat medium	3.53	29	6.8	10
120	49.9	Chicken broth	NG	-	6.4	10
120	48.9	Cooked meat medium	NG	-	6.8	10
122	50	TSB	NG	-	7.0	12
122	50	BHI	NG	-	7.4	9
131	55	Rice + 10% beef extract	NG	-	7.0	12
131	55	TSB	NG	-	7.0	12
131	55	TSA	48	-	-	24

Generation times and lag phase duration reported in literature or estimated from graphs

Pathogens graphed



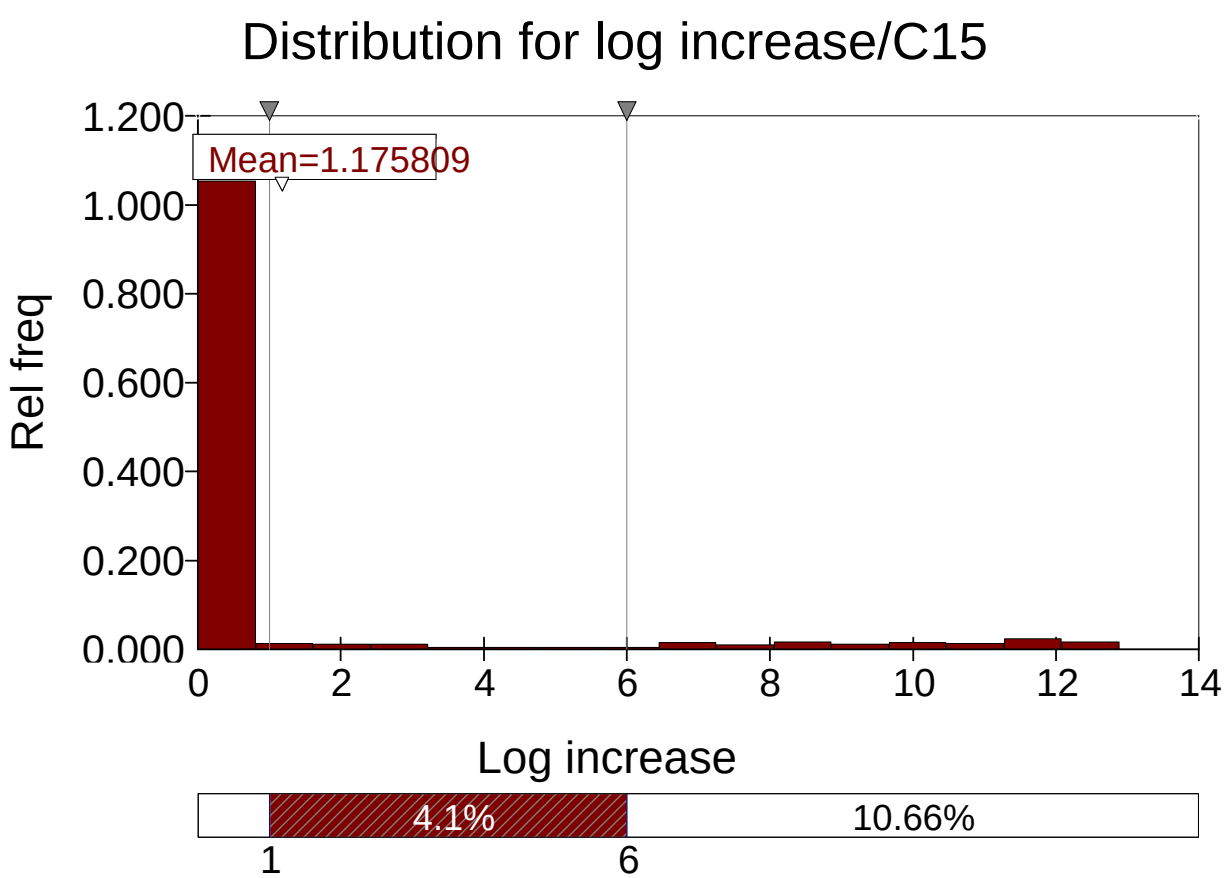
- Data from NACMCF
- Cp model from ComBase Perfringens Predictor
- Generation time capped
- Assumed lag time = 0

Model in @Risk, Excel

	A	B	C
1	**Description**	**Source**	**Math**
2	Temperature distribution	NACMCF – September 2001, pg 9	=RiskNormal(151.5, 21.6)
3	Magnitude of evaporative cooling	NACMCF – September 2001, pg 7	=RiskUniform(0,1)
4	Change due to EC	Assume varies uniformly from 100 F	=(C2-100)*C3
5	EC on or off, 1= on	Yes/no	0
6	Adjusted Temperature	Effect of EC	=C2-(C5*C4)
7	Error trap temp > 131.89	If temp > 131.89 no Cp growth	=IF(C6>131.89,131.89,C6)
8	sqrt 1/gt	NACMCF – September 2001, pg 4-5	=-0.0326*C7 + 4.2998
9	gen time (min)	calc from model	=1/(C8^2)
10	cap min gen time at 11 min	Cp can only grow so fast	=IF(C9<11,11,C9)
11	time (h)	assuming 4-8 hr	=RiskUniform(4,8)
12	time (min)	calc hr -> min	=C11*60
13	doublings Cp based on model	Calc	=C12/C10
14	CFU from 1	Calc	=2^C13
15	log increase	Calc	=RiskOutput("log increase") + LOG(C14)
16			
17			
18			

- Evaporative cooling effect is set on of off
- No good data on time, so time was assumed to vary from 4-8 hr

Simulation result, EC off

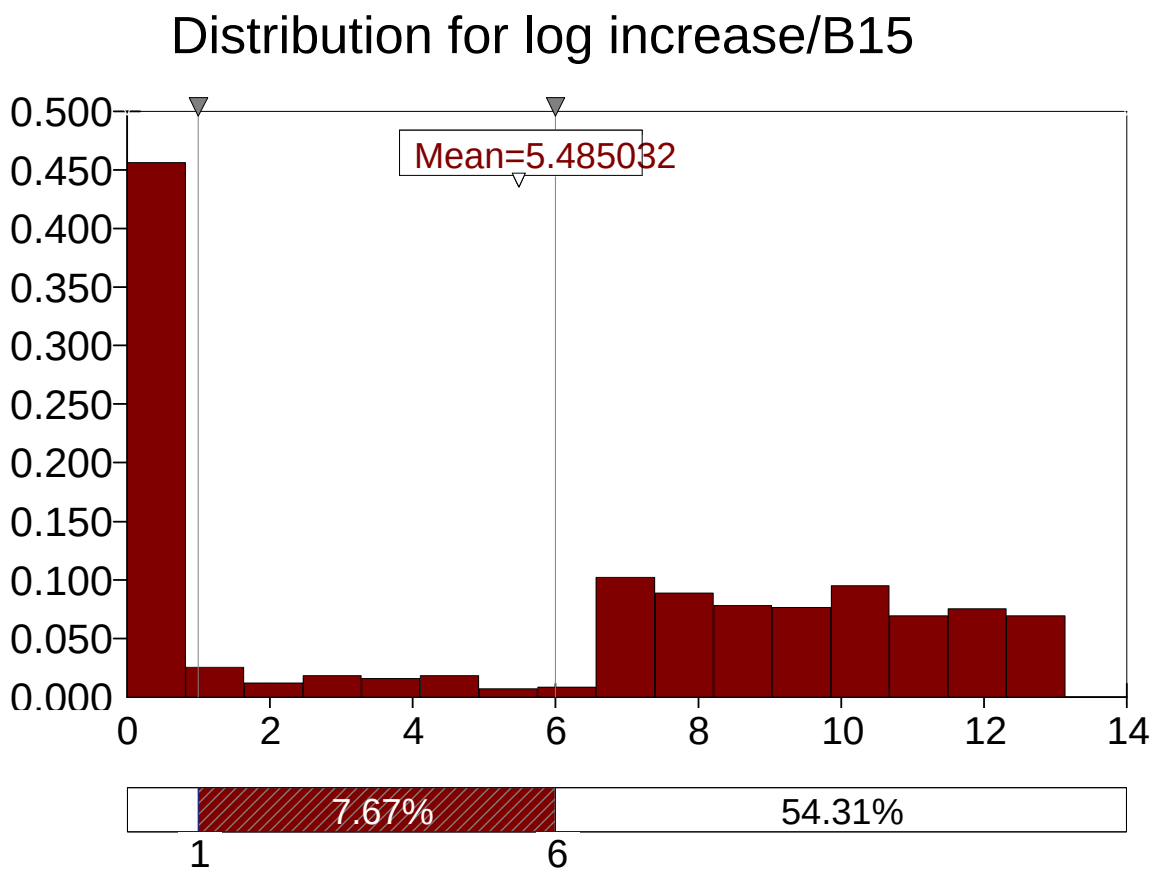


85% less than 1 log increase

10% very high log increases

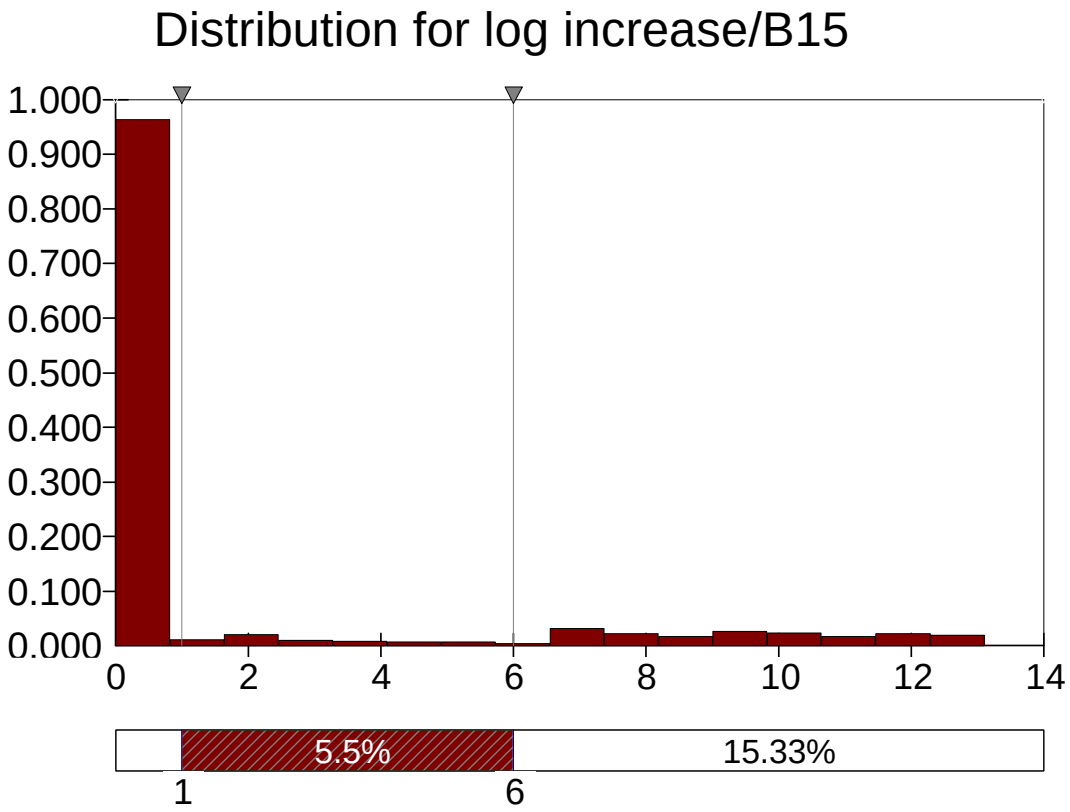
- Low temperatures, longer times

Simulation, EC on



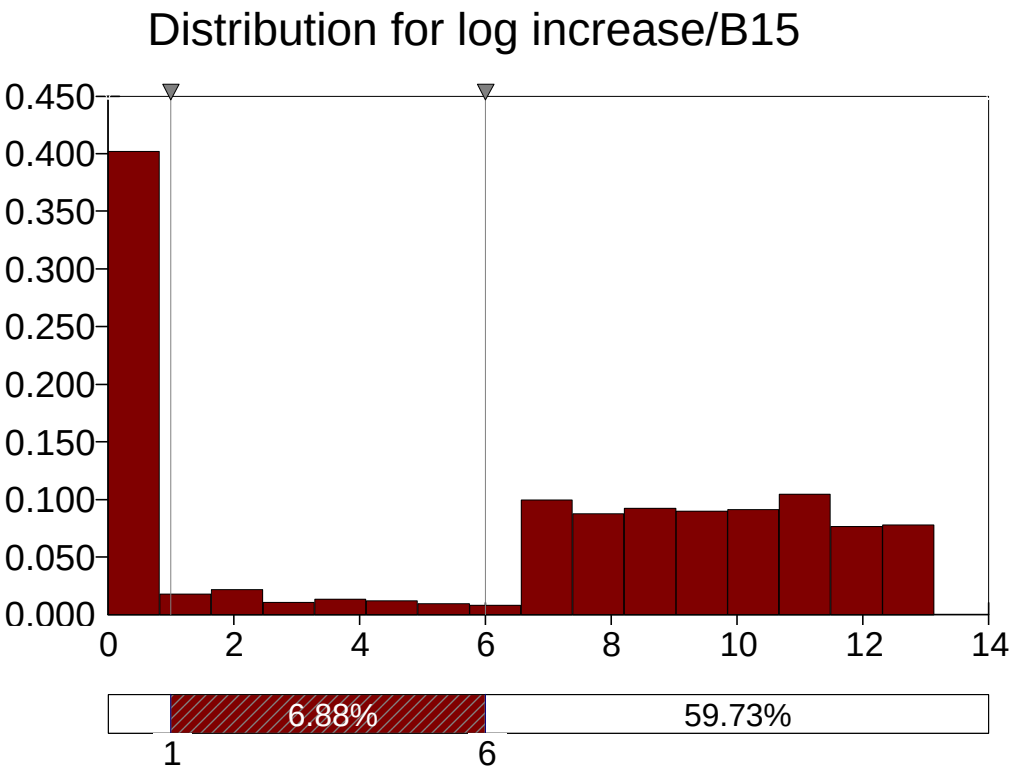
- ~38% less than 1 log increase
- 54% very high log increases

Simulation, EC off, Mean T⇩5 F



- ~80% less than 1 log increase
- 15% very high log increases
- About a 5% increase in predictions of > 1 log CFU increase

Simulation, EC on, Mean T ⇩5 F



- ~33% less than 1 log increase
- ~60% very high log increases

Simulation results

Fraction of the time the simulation predicts greater than a 1 log CFU increase during hot holding		
	Mean Temp 151.5	Mean Temp 146.5
No Evaporative Cooling	15%	21%
Evaporative Cooling assumed	62%	67%

More results, shorter times

- Mean 151.5, time = 0-4 hours, EC off
  - ~89% less than 1 log CFU
- Mean 146.5, time = 0-4 hours, EC off
  - ~85% less than 1 log CFU
- Mean 151.5, time = 0-4 hours, EC on
  - ~50% less than 1 log CFU
- Mean 146.5, time = 0-4 hours, EC on
  - ~45% less than 1 log CFU

Simplifications and assumptions

- Pathogens are always present
- Holding time varies uniformly, 0-4 or 4-8 h
- Lag time assumed to be zero
- All foods identical, all support growth
- Temperature constant throughout time period

Where to go from here?

- Remember a model is a like a map
  - It’s only an abstract version of reality
  - Useful, not completely trustworthy

- Modify assumptions?
- Try different scenarios?
- Enhance and expand model?

2008-10 CFP Hot Holding Committee Survey Original

Introduction: The Conference for Food Protection Hot Holding Committee is conducting a survey to gather data related to industry practices associated with hot holding food and product temperature measurements in retail and foodservice operations. All information collected in this survey is confidential. Any company information will be removed before a final report is shared with the Hot Holding Committee.

Directions: Please provide the response or responses that best describe your temperature monitoring and controls in your operations.

1. What type of product temperature monitoring devices do you use in your operations? (Check all that apply.)
    - Bi-metallic
    - Digital
    - Infra-red
    - Thermocouple
    - Other, please list:

2. Do you have written product temperature monitoring standard operating procedures for hot holding?
    - No
    - Yes.
    - If yes, would you be willing to share? Please attach your procedures to this survey.

3. Do you calibrate your product temperature monitoring devices?
    - No
    - Yes

4. How often do you calibrate the product temperature monitoring device?
    - Every hour
    - Every 4 hours or mid shift
    - Once per day
    - Once per week
    - Not at all
    - Other, please list:

5. What method do you use to calibrate?
    - Ice point method
    - Boiling point method
    - Both
    - Other method, please list:

6. What is your corrective action when you find that your product temperature monitoring device is out of calibration? (Check all that apply)
    - Manually calibrated
    - Change battery
    - Send to the manufacturer
    - Discard and replace
    - Other, please list:

7. Do you measure product temperature for hot holding continuously or periodically?
    - Continuous (go to question 9)
    - Periodic

8. If product temperature measurement is periodic, how often do you take temperature measurement?
    - Hourly
    - Every 2 hours
    - Every 4 hours
    - Other, please list:

9. If product temperature measurement is continuous, how is the measurement recorded?
    - Automatic system
    - Manual system (hand written record)
    - Other, please list:

10. If product temperature measurement is continuous, how is the measurement captured?
    - Internal
    - Ambient
    - Other, please list:

11. How and where do you measure product temperature? Answer following questions:

    11.1. Do you stir the product before taking temperature?

    - No
    - Yes

    11.2. What is the location you take temperature in the product?

    - On the surface
    - In the center of the product

- Along the edge
- As far in as the probe reaches

11.3. Is the location of the temperature measurement dependent on the food type?

- No
- Yes

11.4 How far do you insert the product temperature device if you take temperature inside the product? Give approximate distance.

- < 1 inch
- 1 inch
- 2 inches
- 3 inches
- Other, please list:

11.5 If you insert the product temperature device <1 inch, what type of measuring device do you use?

- Bi-metallic
- Other, please list:

11.6 Are there specific areas of hot holding equipment that you monitor product temperatures-i.e. corners of hot plates versus middle?

- Middle of warmer
- Perimeters of warmer
- Not applicable

11.7 What corrective actions do you take when the temperature of the product is out of compliance with normal temperature limits?

- Discard
- Reheat
- Increase steam table temperature (increase thermostat and/or add sterno)
- No action
- Other, please list:

11.8 If you choose to reheat the product, how many times do you reheat?

- One time
- Two times
- Three times
- Do not reheat
- Other, please list:

11.9 What is your procedure for reheating?

- Microwave
- Convection oven
- Fryer
- Rotisserie oven
- Not applicable
- Other, please list:

11.10 Are the product temperatures recorded?

- No
- Yes

11.11 If temperatures are recorded, how is it recorded?

- Manually
- Electronically
- Other, please list:

12. Is the product stirred periodically if on steam table?
    - No
    - Yes

13. What is the maximum shelf life for each product during hot holding?
    - 1 hour
    - 2 hour
    - 3 hour
    - 4 hour
    - 6 hour
    - 8 hour
    - Other, please list:

14. What is done with the product when the maximum shelf life for hot holding has been reached at the end of service period or shift?
    - Discarded
    - Cooled and held for reheating

- Other, please list:

15. How are products held during hot holding?
    - In packaged form
    - In bulk hot display
    - Both
    - Other, please list:

16. If packaged, what type of container is used for hot holding?
    - Plastic
    - Metal
    - Card board/paper
    - Other, please list:

17. What type(s) of equipment do you use for hot holding food? (Check all that apply)
    - Hot plates
    - Steam tables
    - Heat lamps
    - Soup kettles
    - Combination, heat lamps and hot plates
    - Other, please list:

18. Does your hot holding equipment have some type of certification, such as NSF or UL certification?
    - No
    - Yes

19. Do you address the effect of evaporative cooling? For example, do you cover or maintain in a hot case until it is served?
    - No
    - Yes

20. What is the hot-holding temperature in your jurisdiction(s) with which you must comply? (check all that apply if multiple jurisdictions)
    - 130 F
    - 135 F
    - 140 F
    - 145 F
    - Other, please list:

21. Do you hold product exceeding the temperature requirements in jurisdictions?
    - No
    - Yes

21. What are your hot holding requirements for products? (check all that apply)
    - 130 F
    - 135 F
    - 140 F
    - 145 F
    - Other, please list

22. Do you collect hot holding data in your operations?
    - No
    - Yes
    - If yes, would you be willing to share? Please attach your data to this survey.

23. Do you have 3rd party and/or internal audit reports on hot holding in your operations?
    - No
    - Yes
    - If yes, would you be willing to share? Please attach your data to this survey.

Conference for Food Protection
Committee FINAL Report

COMMITTEE NAME: **Hot Holding Committee**

COUNCIL (I, II, or III): **III**

DATE OF REPORT: **January 8, 2010**

SUBMITTED BY: **Donna M. Garren and Roger E. Coffman, Co-Chairs**

COMMITTEE CHARGE(s):

Study Change of Hot Holding Temperature from 135ºF to 130ºF. The 2008 Biennial Meeting recommended that a committee be formed under the direction of Council III to address the issues of hot holding temperatures and times, and any microbial risks that may be associated with different temperatures and times, as well as the accuracy and proper use of temperature measuring devices for this purpose and report back to Council III at the 2010 Biennial Meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

The analysis of TCS (temperature control for safety) food hot holding temperature data available to the Committee from academic, regulatory, and industry sources around the country, combined with the results of the Hot Holding Committee survey that was conducted via e-mail distribution to retail food companies in June, 2009 (see attachments titled: *Original Survey Document* and *Summary of Completed Survey*), resulted in these answers:

- Regardless of the regulated TCS hot holding temperature requirements in various United States jurisdictions (130ºF., 135ºF., 140ºF., 145ºF., or 150ºF.), the recorded TCS food temperature data assembled showed that a wide range of hot holding food temperatures are occurring (170ºF. to 105ºF.). TCS hot holding temperatures of 129ºF. and below can allow organisms, such as *Clostridium perfringens*, to multiply in an un-controlled environment, increasing the risk of foodborne illness.

- It is reasonable to interpolate that in the majority of cases, **the commercially manufactured hot holding units are set up, and have the ability to hold TCS food at the current regulatory/industry temperature standard of 130/135ºF. or above.**

- Food temperatures measured and reported at colder levels (from 130/135ºF. down to 105ºF.) indicate the food was affected by stratification in the hot holding unit. The colder temperatures for the top of food in hot holding units (steam tables) are due to many issues, including "evaporative cooling", lack of stirring, and to a lesser degree, equipment malfunction.

- Metal stem thermometers/metal stem thermocouples were the usual method of choice for temperature measurement. Some use of infrared thermometers for surface

temperature measurement was reported. Infrared thermometers would be less effective in gathering necessary information, due to the inability to measure the "internal" temperature of the TCS food items in steam tables (temperatures closer to the hot holding thermal heat source). A study of calibration methods for infrared units may also be necessary.

- Evaporative cooling is a major cause of the TCS hot holding food temperatures being below 130/135ºF. Data showing how much temperature loss is attributed to evaporative cooling, which foods are affected more by the temperature loss (thick, protein foods such as refried beans), the elapsed times that are involved (4 hours as an example), and corrective measures needed must be included in future analysis projects.

- One limiting factor to evaluating the occurrence of clostridium perfringens growth is that illnesses due to *Clostridium perfringens* are not a "reportable illness", so data collection on the public health affects of this organism is sporadic at best.

- The unknown value needed to calculate a safe TCS hot holding temperature is the evaporative cooling temperature loss that can be expected in hot holding units.

In conclusion, a scientifically reviewed value for what can be labeled as the **"evaporative cooling range"** must be determined. The "evaporative cooling range" would be the temperature loss that can occur in TCS food due to evaporative cooling in a hot holding unit over a set time period. The temperature that organisms begin to grow in TCS foods (129ºF. or below for *Clostridium perfringens*) must then be taken into account.

The scientifically based "evaporative cooling range" temperature could then be added to the 129ºF. growth limit to calculate a scientifically based higher "safe" TCS hot holding temperature.

Hot holding food data must continue to be assembled, processed, and analyzed for this study. Representatives from academia, industry and regulators can evaluate the collected information to reach an accurate recommendation for a hot holding temperature requirement, based on the risk to grow an organism such as *Clostridium perfringens* in TCS foods held in hot holding units. It is recommended that the charge issued to the Hot Holding Committee be re-issued, so that this study can be continued.

It is the recommendation of the Committee to re-create the Hot Holding Committee to continue the on-going studies of the science and data available on hot food holding, including:

- A study of calibration methods for infrared units.
- A study of evaporative cooling and temperature loss, elapsed time, and corrective action.
- A final recommendation for a hot holding temperature requirement based on risk.

REQUESTED ACTION

The Hot Holding Committee is submitting two Issues for Council III's consideration:
Issue 1 – Report - Hot Holding Committee
Issue 2 – Re-Create - Hot Holding Committee

The following attachments are submitted with this report:

- Original Survey Document
- Summary of Completed Survey
- Quantitative Microbial Risk Assessment (QMRA) for Hot Holding Survey Charts and Graphs
- 2008-10 Hot Holding Committee Roster

Conference for Food Protection
2010 Issue Form

Internal Number: 059
Issue: 2010 III-012

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

All information above the line is for conference use only.

Title:

Re-create - Hot Holding Committee

Issue you would like the Conference to consider:

The 2008-10 Hot Holding Committee has evaluated the information available on the TCS hot holding temperature requirement of 135ºF., has determined that more information is needed, and recommends that the committee be re-created to continue the work of the committee through 2012.

One specfic area of study would be the "evaporative cooling range" -- the temperature loss that can occur in TCS food due to evaporative cooling in a hot holding unit over a set time period. The purpose of the study would be to determine a scientifically based "evaporative cooling range" temperature that could then be added to the 129ºF. growth limit (for *Clostridium perfringens*) to calculate a scientifically based "safe" TCS hot holding temperature.

Public Health Significance:

The Public's health will continue to be served by further enhancing the latest science and food safety knowledge to promote a safe national food supply and thereby reduce the incidence of food borne illness.

Recommended Solution: The Conference recommends...:

that the Hot Holding Committee be re-created under the direction of Council III to address:

- a study of calibration methods for infrared units.
- the issues of evaporative cooling and its relationship to hot holding temperatures, including temperature loss, elapsed time, and corrective action.
- a final recommendation for a hot holding temperature requirement based on risk.

This scientifically based "evaporative cooling range" temperature could then be added to the 129°F. growth limit (for *Clostridium perfringens*) to calculate a scientifically based "safe" TCS hot holding temperature, and report back to Council III at the 2012 Biennial Meeting.

Submitter Information:

Name:	Roger E. Coffman, Co-Chair
Organization:	Hot Holding Committee
Address:	Lake County Health Dept. and Community Health Center118 S. Main St.
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Telephone:	847.984.5002 Fax: 847.526.7086
E-mail:	rcoffman@lakecountyil.gov

Attachments:

- "2008-10 Hot Holding Committee Final Report"

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

COMMITTEE NAME: **Hot Holding Committee**

COUNCIL (I, II, or III): **III**

DATE OF REPORT: **January 8, 2010**

SUBMITTED BY: **Donna M. Garren and Roger E. Coffman, Co-Chairs**

COMMITTEE CHARGE(s):
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COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

The analysis of TCS (temperature control for safety) food hot holding temperature data available to the Committee from academic, regulatory, and industry sources around the country, combined with the results of the Hot Holding Committee survey that was conducted via e-mail distribution to retail food companies in June, 2009 (see attachments titled: *Original Survey Document* and *Summary of Completed Survey*), resulted in these answers:

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- It is reasonable to interpolate that in the majority of cases, **the commercially manufactured hot holding units are set up, and have the ability to hold TCS food at the current regulatory/industry temperature standard of 130/135ºF. or above.**

- Food temperatures measured and reported at colder levels (from 130/135ºF. down to 105ºF.) indicate the food was affected by stratification in the hot holding unit. The colder temperatures for the top of food in hot holding units (steam tables) are due to many issues, including "evaporative cooling", lack of stirring, and to a lesser degree, equipment malfunction.

- Metal stem thermometers/metal stem thermocouples were the usual method of choice for temperature measurement. Some use of infrared thermometers for surface

temperature measurement was reported. Infrared thermometers would be less effective in gathering necessary information, due to the inability to measure the "internal" temperature of the TCS food items in steam tables (temperatures closer to the hot holding thermal heat source). A study of calibration methods for infrared units may also be necessary.

- Evaporative cooling is a major cause of the TCS hot holding food temperatures being below 130/135ºF. Data showing how much temperature loss is attributed to evaporative cooling, which foods are affected more by the temperature loss (thick, protein foods such as refried beans), the elapsed times that are involved (4 hours as an example), and corrective measures needed must be included in future analysis projects.

- One limiting factor to evaluating the occurrence of clostridium perfringens growth is that illnesses due to *Clostridium perfringens* are not a "reportable illness", so data collection on the public health affects of this organism is sporadic at best.

- The unknown value needed to calculate a safe TCS hot holding temperature is the evaporative cooling temperature loss that can be expected in hot holding units.

In conclusion, a scientifically reviewed value for what can be labeled as the **"evaporative cooling range"** must be determined. The "evaporative cooling range" would be the temperature loss that can occur in TCS food due to evaporative cooling in a hot holding unit over a set time period. The temperature that organisms begin to grow in TCS foods (129ºF. or below for *Clostridium perfringens*) must then be taken into account.

The scientifically based "evaporative cooling range" temperature could then be added to the 129ºF. growth limit to calculate a scientifically based higher "safe" TCS hot holding temperature.

Hot holding food data must continue to be assembled, processed, and analyzed for this study. Representatives from academia, industry and regulators can evaluate the collected information to reach an accurate recommendation for a hot holding temperature requirement, based on the risk to grow an organism such as *Clostridium perfringens* in TCS foods held in hot holding units. It is recommended that the charge issued to the Hot Holding Committee be re-issued, so that this study can be continued.

It is the recommendation of the Committee to re-create the Hot Holding Committee to continue the on-going studies of the science and data available on hot food holding, including:

- A study of calibration methods for infrared units.
- A study of evaporative cooling and temperature loss, elapsed time, and corrective action.
- A final recommendation for a hot holding temperature requirement based on risk.

REQUESTED ACTION

The Hot Holding Committee is submitting two Issues for Council III's consideration:
Issue 1 – Report - Hot Holding Committee
Issue 2 – Re-Create - Hot Holding Committee

The following attachments are submitted with this report:

- Original Survey Document
- Summary of Completed Survey
- Quantitative Microbial Risk Assessment (QMRA) for Hot Holding Survey Charts and Graphs
- 2008-10 Hot Holding Committee Roster

Conference for Food Protection
2010 Issue Form

Internal Number: 047
Issue: 2010 III-013

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

All information above the line is for conference use only.

Title:

Bare Hand Contact for RTE Ingredients that are Fully Cooked After Handling

Issue you would like the Conference to consider:

Foods that may be ready to eat (RTE) but are not treated as RTE in their application should not be regarded RTE. RTE foods that are further fully cooked should be treated as raw foods and bare hand contact should be permitted. An example of this case is pizza toppings for commercial pizza operations. These items, *e.g.*, cooked ground meat, cooked sausage and fresh uncooked vegetables, are RTE. However, they are ingredients placed on a pizza that is the baked in commercial ovens and served as a fully cooked pizza. Therefore, these items in this cooked pizza application are ingredients and should be able to be handled with properly cleaned bare hands.

Public Health Significance:

It is important that fully cooked foods meet the time and temperature requirements identified in the FDA Food Code. In this case, given that some of the RTE items on pizzas are animal products, the requirements for fully cooked status are Subparagraph 3-401.11 (A) (2) for comminuted, mechanically tenderized or injected meats, requiring 155 degrees F for 15 seconds; and Subparagraph 3-401.11 (A) (3) for poultry products, which requires cooking to internal temperature of 165 degrees F for 15 seconds. These temperatures and times, or their equivalents, are recognized as effective to destroy pathogenic bacteria in raw products that permit bare hand contact.

In order for ingredients to be handled with bare hands, they would not be considered RTE but instead as raw materials. The finished product for the consumer, in this case a pizza, is fully cooked to at least an internal temperature of 165 degrees F for 15 seconds. In addition, food establishments follow other Food Code requirements for personal hygiene and avoidance of cross-contamination to ensure that both ingredients and finished products are safe to consume and meet all FDA Food Code requirements.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that ¶ 3-301.11 (D) be amended by adding a new Subparagraph 3-301.11 (D) (1) with the following language:

3-301.11(D) (1) the ready-to-eat food is further fully cooked.

and renumbering ¶ (D) subparagraphs appropriately,

OR

that § 3-404.12 be added to the FDA Food Code to address RTE ingredients that are further fully cooked. The Section should include the following language:

Ingredients from containers that are used exclusively in food products which are subsequently fully cooked are not considered RTE and may be handled with bare hands.

Submitter Information:

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

Conference for Food Protection
2010 Issue Form

Internal Number: 045
Issue: 2010 III-014

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

All information above the line is for conference use only.

Title:

Hand Sanitizer Use between Glove Changes

Issue you would like the Conference to consider:

According to current FDA Food Code requirements, hands must be washed between glove changes. The use of a Food Code-compliant hand sanitizer should be permitted in lieu of a full hand wash between glove changes. Enabling the use of effective hand sanitizer between glove changes when there is not visible soil present may enhance compliance with personal hygiene requirements and therefore reduce the risk of food borne disease. Specific procedures for glove removal should be provided and the requirement for hand washing between glove changes should remain when gloves have been torn or hands have become soiled.

Public Health Significance:

CDC reports the number of food borne illness outbreaks associated with hand contact, with or without gloves, from 1998-2002 (Lynch et al, 2006) (Table 1) See Attachment for all Tables referenced. Norovirus is the dominant etiology for both bare-hand and gloved-hand contact. This is why hand washing before donning gloves the first time is essential. However, after hands have been washed, bacterial agents are the concern because they may be naturally present on some foods or on humans. Additionally, gloves may serve as "incubators" and allow bacteria to multiply inside the glove. This is not true for viruses; therefore use of hand antiseptics known to be effective against bacteria should be sufficient when changing gloves. Many hand antiseptics provide a 4 to 5 log reduction for vegetative bacteria through in vitro tests.

Hand antiseptic effectiveness

There are several test methods available to evaluate the efficacy of a hand antiseptic. Laboratory (*in-vitro*) tests are most frequently used for Food Code compliant hand antiseptics because they provide greater flexibility and the test can be conducted on a

number of pathogens to determine their relative susceptibility to the hand care product. Laboratory-based methods also reduce the variation that may be observed between individuals (*e.g.*, the amount of product used, the size of the hand, the thoroughness or rubbing, etc.).

Human subject tests (*in-vivo*) can be done to study the impact of additional factors such as the mechanical removal of the test organism on the hands. However, because human subjects are involved, generally a surrogate is used to represent pathogens and judgment is required to extrapolate the efficacy against a range of pathogens. The level of reduction observed through *in-vivo* testing is typically lower than that for *in-vitro* tests.

Table 2 provides an example of the variety of organisms that can be tested for a commercial Food Code compliant product, and lists the log reduction achieved using an *in vitro* test. Many of the organisms listed are not concerns for food borne illness. Results will vary by product, and potential by lab, strain, organism, and method used. For this study, 1 ml of culture was exposed to 10 ml of product for 15 sec then neutralized and plated for residual counts. (Swanson, 2009)

Alcohol is not the only active component that can provide an effective kill in a hand sanitizer. Table 3 provides an example of data for a hand antiseptic based on a quaternary ammonium compound. Because it is non-volatile, it may take longer for the product to evaporate than an alcohol based hand antiseptic, therefore the level of reduction for several periods of times is listed (Swanson, 2009).

References:

Lynch et al. 2006 Surveillance of food-borne disease outbreaks - United States, 1998-2002 MMWR 55(2210):1-34.

Swanson K 2009 Personal communication, December 17, 2009.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that § 2-301.16 be amended by adding ¶ (D) with the following language:

<u>2-301.16 (D) Hand antiseptics may be used in lieu of hand washing between glove changes that occur with no intervening contamination of food preparation by hands provided that:</u>

<u>(1) Hands are washed prior to donning gloves;</u>

<u>(2) Gloves are removed using a wrist-down motion, a hand antiseptic is applied to hands and thoroughly rubbed into the hands prior to regloving; and</u>

<u>(3) Hands must be washed if gloves are torn or hands become soiled</u>.

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Attachments:

- "Tables"

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Table 1. US reported hand-related outbreaks 1998-2002 (adapted from Lynch et al 2006)

Etiology		Bare-hand contact		Gloved-hand contact	
Bacterial	***Salmonella***	**37**	**40%***	**4**	**35%**
			94		**19**
	Staphylococcus aureus	**17**		**5**	
	Shigella	**12**		**3**	
	Escherichia coli	**12**		**1**	
	Clostridium perfringens	**8**		**2**	
	Campylobacter	**5**		**2**	
	Vibrio parahaemolyticus	**2**		**1**	
	Bacillus cereus	**1**		**1**	
Viral & Parasitic	**Norovirus**	**129**	**60%**	**30**	**65%**
			143		**34**
	Hepatitis A	**13**		**4**	
	Giardia intestinalis	**1**		**-**	
Multiple etiologies				**2**	**1**
Unknown etiology				**526**	**132**

Table 2. Log_{10} reduction of microorganisms in 15 seconds using a "time kill" protocol
(10 ml Food Code compliant, alcohol-based product, 1 ml culture)

Organism	**Log reduction**
Acinetobacter baumannii	>6.64
Bacillus megaterium	>5.78
Citrobacter freundii	>6.64
Clostridium difficile	5.03
Corynebacterium diphtheriae	>6.96
Enterobacter aerogenes	>6.59
Enterococcus faecalis MDR, VRE	>6.55
Enterococcus faecium MDR,VRE	>6.55
Escherichia coli	>5.97
Escherichia coli O157:H7	>5.70
Klebsiella pneumoniae subsp. *ozaenae*	>6.51
Klebsiella pneumoniae subsp. *pneumoniae*	>6.57
Lactobacillus plantarum	>5.80
Listeria monocytogenes	>6.74
Proteus mirabilis	>6.67
Proteus vulgaris	>6.70
Pseudomonas aeruginosa	>6.57
Salmonella Enteritidis	>6.92
Salmonella Typhimurium	>6.82
Serratia marcescens	>6.62
Shigella dysenteriae	>6.32
Shigella sonnei	>6.72
Staphylococcus aureus MRSA	>6.64
Staphylococcus epidermidis	>6.64

Table 3. Log_{10} reduction of microorganisms using a "time kill" protocol
(10 ml of Food Code compliant, quat-based product and 1 ml of culture)

Organism	**Log reduction**		
	15 sec	**30 sec**	**60 sec**
Enterobacter faecalis VRE	>4.60	>4.60	>4.60
Escherichia coli	>5.00	>5.00	>5.00
Escherichia coli O157:H7	3.48	>5.00	>5.00
Listeria monocytogenes	4.70	5.00	>5.00
Pseudomonas aeruginosa	>5.00	>5.00	>5.00
Salmonella choleraesuis	>5.00	>5.00	>5.00
Serratia marcescens	>5.00	>5.00	>5.00
Shigella flexneri	>4.30	>4.30	>4.30
Staphylococcus aureus	>5.00	>5.00	>5.00
Staphylococcus aureus MRSA	>5.00	>5.00	>5.00
Staphylococcus epidermidis	4.70	>5.00	>5.00
Streptococcus pyogenes	>4.30	>4.30	>4.30
Candida albicans	>3.77	>3.77	>3.77

Conference for Food Protection
2010 Issue Form

Internal Number: 060
Issue: 2010 III-015

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

All information above the line is for conference use only.

Title:

Temperature of Water for Handwashing Sinks

Issue you would like the Conference to consider:

To make the language in section 5-202.12 requiring handwashing sinks to be equipped to provide water at least at 38°C (100°F), consistent with that of 2-301.12 where "warm water" is required for handwashing.

Public Health Significance:

Handwashing is a vital step in providing food safety and successful handwashing requires several steps to be effective. The mechanical action of washing one's hands, use of soap, length of time hands are washed, rinsing, hand drying and proper handwash training, have all been noted as important factors in accomplishing proper hand washing. Sighting a specific threshold temperature of the water being supplied to the handwashing sink does not predicate successful handwashing, which can be accomplished at various water temperatures. Food Code 2-301.12 recommends to use "warm water" rather than water at a specific temperature. This is supported by work of Michaels et al (2002) which concluded that there was no statistical difference between log reductions in both resident or transient bacteria based on water temperature. This paper also suggested that use of higher water temperatures contributed to drying of skin, which may result in a disincentive for hand washing. Personal water temperature preferences may also encourage food handlers to wash their hands more frequent, for a longer time.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending changes to the Food Code section **5-202.12 Handwashing Sink, Installation** to read as follows:

5-202.12 Handwashing Sink, Installation.

(A) A handwashing sink shall be equipped to provide warm water ~~at a temperature of at least 38°C (100°F)~~ through a mixing valve or combination faucet. [Pf]

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Attachments:

- "Michaels et al 2002. Water temperature as a factor in handwashing efficacy"

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

Water temperature as a factor in handwashing efficacy

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Keywords:
antibacterial soap, handwashing, personal hygiene, skin damage, skin flora, water temperature

Abstract

For many years, sanitarians have specified that the hands of food service workers should be washed and rinsed in warm or hot water to reduce the risk of cross-contamination and disease transmission. In the food service environment, it has been suggested that handwashing with water at higher temperatures contributes to skin damage when frequent handwashing is necessitated, and that insistence on hot water usage is a deterrent to handwashing compliance. Separate handwashing studies involving different water temperatures and soap types (antibacterial versus non-antibacterial) were performed. The 'glove-juice' technique was employed for microbial recovery from hands in both studies. Initial work evaluated antimicrobial efficacy based on water temperature during normal handwashing with bland soap. Uninoculated, sterile menstrua (tryptic soy broth or hamburger meat) was used to study the effects of treatment temperatures (4.4°C, 12.8°C, 21.1°C, 35°C or 48.9°C) on the reduction of resident microflora, while Serratia marcescens-inoculated menstrua was used to evaluate treatment effects on the reduction of transient contamination. Results of this first study indicated that water temperature exhibits no effect on transient or resident bacterial reduction during normal handwashing with bland soap. The follow-up study examined the efficacy and skin irritation potential involving water temperatures with antimicrobial soaps. Hands of participants were contaminated with *Escherichia coli* inoculated ground beef, washed at one of two water temperatures (29°C or 43°C) using one of four highly active (USDA E2 equivalency) antibacterial soaps having different active ingredients (PCMX, Iodophor, Quat or Triclosan). Skin condition was recorded visually and with specialized instrumentation before and after repeated washing (12 times daily), measuring total moisture content, transepidermal water loss and erythema. Overall, the four soap products produced similar efficacy results. Although there were slight increases in Log_{10} reductions, visual skin irritation, loss of skin moisture content and transepidermal water loss at higher temperatures, results were not statistically significant for any parameter.

Introduction

A critical and thorough evaluation of simple handwashing procedures reveals numerous variables to be considered by food service managers in order to achieve maximum or appropriate de-germing of the hands and fingernail regions. Numerous studies have explored issues such as type of soap (i.e. antibacterial versus plain, liquid versus bar), amount of soap, nailbrush use, drying technique (i.e. cloth versus paper towels, paper towels versus air-drying), and application of instant hand sanitizers (postwash liquids). Previous studies indicate that these variables are crucial in achieving effective removal of transient bacteria from the hands under controlled testing conditions. Rarely mentioned in the scientific literature is testing to determine specific guidelines for water temperatures and flow rates. Many of the currently employed hand-

washing practices are based on untested traditions that could possibly result in compromised skin health. It is expected that warm or hot water would be beneficial in reducing bacterial counts from hands during handwashing, as heat provides energy for the increased solubility and melting of fats, oils and other soils which may serve as vehicles for bacterial transfer from hands. Warm/hot water, combined with the detergents present in soap, should theoretically provide greater emulsification of contaminating soils on the skin, resulting in a more efficient lifting of these soils for rinsing away.

Some food safety experts strongly recommend the use of antimicrobial soaps for food service workers, while others are now focusing on handwashing frequency. With the rise of antibiotic resistance, increased concern has been expressed with respect to antimicrobial soap usage. The reasoning has been that when warm/hot water is combined with antimicrobial soap, the temperature of activation is approached, accelerating chemical reactions and improving kill rates. Soil emulsification should allow for greater exposure of microorganisms in the contaminating soil to the antimicrobial active agents. Thus, bacterial population numbers may be reduced two ways: through soil emulsification and lifting/rinsing away, and inactivation provided by the antimicrobial agent(s) with higher temperatures doing a significantly better job. The infected food worker is the focus of improved hygiene measures, and food safety managers and regulators would be remiss to not try to optimize effectiveness. Asymptomatic food handlers have been identified as being responsible for approximately one-third of outbreaks traced back to the infected worker. Poor personal hygiene has been cited as a contributory factor in an average of 30% of foodborne illness outbreaks occurring in the U.S. between the years of 1973 and 1997 (Bean & Griffin 1990; Bean *et al*. 1996; Olsen *et al*. 2000). The vast majority of foodborne illness outbreak cases attributed to the infected food handler occurs in the food service environment (Michaels *et al*. 2002).

The main initiative in hand hygiene is the reduction of potentially pathogenic microorganisms from contaminated skin surfaces. Optimization of all variables involved in this task must not only provide sufficient removal and/or kill of potential pathogens, but must also refrain from damaging the skin, as this can affect handwashing compliance (Boyce and Pittet 2001) and seriously compromise food service safety. Skin damage associated with work from routine and frequent handwashing has also been seen to result in colonization of workers hands with potential pathogens.

With so many variables involved in such a 'simple procedure', it would make sense to explore and maximize all possible aspects of the process while minimizing negative collateral. This is especially important due to the many observations of food service workers revealing what is considered to be poor habits in handwashing techniques. Studies indicate that handwashing compliance drops considerably without supervision and monitoring, or in situations where skin damage occurs. This further amplifies the need to strengthen knowledge of all variables that might improve or weaken daily handwashing practices throughout the food processing and service industry.

As described by Price, two types of flora exist on the hands, transient and resident species (Price 1938). The transient flora is generally removed fairly easy. They do not have adhesion characteristics that hold them to the skins' surface and are somewhat suppressed by secretions and competitive exclusion by the resident flora (Dunsmore 1972). Resident flora is removed more slowly. Because of coevolution, resident flora have adapted to conditions on the skins' surface that cause rapid die-off of most transients. Invaginations such as the nail fold, hair follicles and sebum-producing sebaceous glands support a rich resident flora. Transient flora may consist of pathogens, spoilage bacteria or harmless environmental species. Under certain conditions, transient flora can change status and become permanent residents. Resident flora, as a rule, are not pathogenic types. Although colonization with coagulase-positive staphylococcus is fairly common (Noble & Pitcher 1978). Frequent or prolonged exposure of the skin to microbial contamination in soils, skin damage or fissures provide portals of entry to deeper tissue, and may result in many pathogenic bacteria found among the resident species (Price 1938; Kaul & Jewett 1981). Food workers in a number of different food industry segments (including catering and bakery) have been found colonized by varying numbers of potential pathogens (Seligman & Rosenbluth 1975).

The effective water temperature used for washing and rinsing hands was a topic of intense discussion at the U.S. Year 2000 Conference for Food Protection. This biannual conference assembles federal and state regulators, food safety academicians, food service industry scientists and safety managers to establish and recommend guidelines to the United States Food and Drug Administration (FDA) for inclusion into the FDA Model Food Code. This code, as adopted by individual US states, forms the basis for food safety regulation and enforcement activities to the food service industry. Several submitters of issues, brought before science and technology council (Council III), expressed their concern regarding the use of higher water temperatures as recommended of the food service/processing industry (Table 1). The United States Food and Drug

Table 1 Submitters and handwashing water temperature issues at the year 2000 Conference for Food Protection

Submitter	Issue	Reason
L. Wisniewski (Select Concepts – Consulting)	'Warm Water'	1. Hand Discomfort Decreases Frequency
M. Scarborough (Georgia Department of Human Resources, Division of Public Health)	37.7°C (100°F)	1. No Science (43°C vs. 37.8°C) 2. Plumbing Code @ 100°F Max. (Safety Concerns)
J. Budd (Healthminder/Sloan Valve Company)	35°C (95°F)	1. No Scientific Basis 2. Max Soap Efficacy at 35°C 3. Hand Comfort 4. Hot Water Discourages Hand Washing
E. Rabotoski (Wisconson ConferenceFood Protection)	'Tempered' 29.5°C (85°F) to 43°C (110°F)	1. Hand Discomfort 2. Possible Scalding
B. Adler (Minnesota Department of Health)	Impose Temp. Range 43°C 110°F To 54.4°C (130°F)	1. Need upper limit or subject to OSHA 2. Food workers Don't Wash 25 Sec. So Cannot Scald.
Reimers (H.E.B. Grocery Company)	'Tempered' To Warm	1. No Science . 2. Max Soap Efficacy 3. 43°C Risks Injury 4. Waste Water as Wait for Temp. at 43°C

Administration (FDA) Food Code provides recommendations for the food service industry to follow regarding food handling practices, application of HACCP principles and personal hygiene implementation (US Public Health Service 1999; US Public Health Service 2001). The main goal of the FDA has been the creation of uniform practices throughout all of the United States. The 1999 FDA Food Code requires sinks used for handwashing to be equipped so as to be 'capable of providing water of at least 43°C (110°F), accomplished through use of a mixing valve or a combination faucet' [tap] (US Public Health Service 1999).

All but one of the submitters requested temperature decreases with the intent of improving hand comfort, as the discomfort associated with higher temperatures results in decreases in hand washing frequency or compliance. Several submitters note a lack of scientific information on the subject. There is concern that a minimum handwashing temperature of 43°C (110°F), in addition to causing discomfort, will result in injury or scalding and may even be in conflict with local plumbing codes. Two submitters point out that soaps currently available target maximum effectiveness at around 35°C (95°F). Two submitters requested that the minimum temperature of 110°F (43°C) be changed to warm water or that it be tempered to a range of 85°F (29.5°C) to 110°F (43°C). and finally, one submission sought to place an upper temperature limit of 130°F (54.4°C), for fear that these regulations would be subject to Occupational Safety and Health Administration (OSHA) scrutiny and criticism without a limit. Interestingly, it was noted in this submission, through reference to the Consumer Product Safety Commission, that second or third-degree burns have been shown to occur in the elderly at temperatures not much over 43°C (110°F). Council I and the General assembly of voting delegates passed a recommendation to lower the regulatory water temperature minimum to 29.5°C (85°F). In recognition of concern expressed by a number of stakeholders with regards to the issue of handwashing water temperature, the initial results of the work described in this report and the will of state voting delegates, the 2001 Food Code lowered the required handwash water temperature to 37.8°C (100°F) (US Public Health Service 2001).

The universe of food handling situations requiring effective personal hygiene spans from temporary handwash stations set up in produce fields and county fairs to advanced state of the art clean room style kitchens used to produce extended shelf life ready-to-eat foods sold at retail. In quick service restaurants, workers frequently switch between food and money handling. Due to the potential for money to carry potential pathogens, as described by Michaels, hands may require washing from up to 40 times or more in an 8-h shift (Michaels 2002). In many of these situations, it is difficult to provide water meeting strict temperature ranges. With regard to international settings, it is doubtful that underdeveloped parts of the world will easily be able to tap into warm/hot water supplies, much less into clean water sources at all. Water temperature shortcomings have been a common point of criticism by

food safety experts when reviewing handwashing procedures in the developing world as part of HACCP activities. Further, no matter where the location, it is difficult to manage and monitor food handlers to insure that minimum temperature levels are maintained during all handwashing activities. When subject to regulatory inspections, in the U.S., violations are given to food industry entities based on Food Code specifications. In some cases, based on accumulation of violations with water temperature being one of them, mandatory 48 h closure can result. This appears to be both costly and unnecessary based on the results of the studies described here.

In an extensive literature review of the effect of water temperature on hygienic efficiency, only two existing experimental studies shed light on this issue. Both of these involved hand sampling studies, in which the objective was to remove, identify and enumerate as many bacteria on the hands as possible, either as normal or transient flora. In hand scrubbing experiments, Price found that at temperatures from 24°C (75.2°F) to 56°C (132.8°F) there was no difference in de-germing rate (Price 1938). Since he scrubbed hands with a brush for a specific period of time, each in turn in a series of sterile wash basins, he might have been capable of seeing differences upon counting the flora in each basin. After conducting over 80 experiments in a 9-year period, Price concluded that the largest variable in determining the rate of removal of bacteria from the hands was the vigorousness of scrubbing. Other factors such as soap used or water temperature were less important. In later hand sampling experiments by Larson and others (implementing the glove juice method for recovery of microorganisms), no differences in isolation rates were seen at either 6°C (42.8°F) or 23°C (73.4°F) (Larson *et al.* 1980). While this information is inconclusive and does not answer questions concerning bacterial loads suspended in a confounding soil, they tend to indicate that there may not be a noticeable difference in efficacy over a range of temperatures from 6°C (42.8°F) to 56°C (132.8°F).

Various menstrua have been used for handwashing efficacy studies. For studies involving transient flora, the most often used soil is tryptic soy broth (TSB). Microorganisms exhibit good survivability, with even distribution of contaminating microorganisms into skin cracks, creases and invaginations being possible. Ground beef probably represents the most appropriate menstrua because of concern for risks of *E. coli* O157:H7 infection, but is only occasionally used (Sheena & Stiles 1982; Stiles & Sheena 1985). Meade and others have shown numerous sporadic cases of foodborne illness have been tied to poor personal hygiene after ground beef preparation (Mead *et al.* 1997). In addition, due to it's viscosity, thixotrophic properties and level of organic soil, it would appear to be a good surrogate for fecal material.

A review of pertinent literature was also undertaken to determine if, independent of efficacy, facts on skin damage support a lowering of the temperature. The Consumer Product Safety Commission (CPSC) has noted that residential water heater thermostat settings should be set at 49°C (120°F) to reduce the risk of the majority of tap water scald injuries. Although the majority of scalding attributed to the home occur in children under the age of five and the elderly, third-degree burns are known to result in a two second exposure to 66°C (150°F), six-seconds at 60°C (140°F) and 30 s at 54.4°C (130°F) (US Consumer Product Safety Commission 2000). As we age, our skin becomes thinner, loosing suppleness. This fact is important as many seniors are now actively involved in the food service industry. Due particularly to the elder risk, some have recommended that water be delivered from the tap at even lower temperatures of less than 43°C (110°F) (Stone *et al.* 2000).

The activity of soaps, friction and rinsing become crucial since the temperatures recommended in handwashing water alone would not provide thermal destruction of pathogenic microorganisms. Relevant to the discomfort issue associated with hot water is a previously conducted study by Horn and Briedigkeit involving dishwashing soaps (Horn & Briedigkeit 1967). In that study, participants were only able to withstand water temperatures at 43°C, 45°C, and 49°C (110°F, 113°F and 120°F), with tolerance levels due to discomfort peaking at one-minute (Horn & Briedigkeit 1967). Even though considerably longer than the 10–25 second exposure period that would result from handwashing, it is indicative of the fact that temperatures from 43°C and upwards (110°F and upwards) are at or near the human discomfort threshold.

Friction has been described as a key element in removing microbial contaminants from hands (Price 1938; Kaul & Jewett 1981). Friction applied during hand drying is instrumental in finishing the process (Madeline & Tournade 1980; Knights *et al.* 1993; Michaels *et al.* 2002). Removal of transient flora appears to be even more friction dependent than removing resident flora. Surfactant and antimicrobial compounds in soap are responsible for lifting soil and killing microorganisms suspended in the soil. When using bland soap to wash hands, handwashing efficacy appears to be dependent on the effects of surfactant action of the soap along with friction applied during the washing and rinsing process. Rinsing also provides the necessary removal by dilution. To facilitate appro-

priate rinsing of the hands, some personal hygiene consultants have suggested the practice of using thicker, higher viscosity soaps in larger doses, which would require a longer, more vigorous rinsing routine.

Price, upon noticing that in his scrubbing experiments that water temperature had little effect at degerming of the skin, commented that water applied to the skin at a given temperature quickly reaches equilibrium with normal skin surface temperature unless hands are totally immersed (Price 1938).

Skin oils derived from sebum are liquid in the sebaceous gland and solidify on the skin surface. Beef tallow has a melting point range between 35°C and 40°C (95°F and 104°F), while lard or butterfat are liquefied at around 30°C (86°F) (Lide 1990). If handwashing efficacy for both resident and transient floras embedded in both natural and artificially applied fats depended on thermal melting, then log10 reduction figures should have been greatest at the highest temperature and least at temperatures causing fats and sebum to congeal.

Fats such as tallow or lard are distinguished from oils in that the latter are liquids at room temperature. Hand soap formulations are designed to lift soil through their foaming action, dispersing and solubilizing organic soils through action of detergent surfactants. Primary micelles are formed, having hydrophilic and hydrophobic groups attached to each end of the surfactant monomer. Soaps with multiple surfactants form mixed micelles, which increases efficiency with various soil mixtures. In water and organic soil mixtures, these form complex micelle structures around hydrocarbon moieties (encapsulation) resulting in microemulsions. Thus, the soap provides a 'bridge' between the oily droplet and water, permitting the soapy water to 'wash away' greasy material.

Materials and methods

The quantity of soap used for handwashing has the ability to effect handwashing efficacy, as shown by Larson (Larson *et al*. 1987). Various investigators (Michaud *et al*. 1972, 1976; Ojajarvi 1980; Stiles & Sheena 1987; Mahl 1989; Larson *et al*. 1990; Rotter & Koller 1992; Miller & James-Davis 1994; Paulson 1994) have used soap amounts in the range of 2.5–5.0 mL in their handwashing efficacy protocols. The higher levels are considered excessive, except in the area of hospital infection control. Many food service operations set soap dispensers at 1 mL per pump, and employees often times use multiple pumps. For this study, 3 mL of soap was chosen to represent an amount found to be significantly effective in an earlier study described (Larson *et al*. 1987).

Determination of appropriate handwashing duration for these studies (15 s) was arrived at through review of various governmental regulatory standards, test method guidelines and food safety specialist recommendations along with previous handwashing study observations. Suggested lathering times by specific entities are: The 1999 FDA Food Code (US Public Health Service 1999) (20 s), The American Society for Testing and Materials (American Society for Testing and Material 1995) (15 s), The Association for Professionals in Infection Control and Epidemiology (APIC) (Jennings & Manian 1999) (minimum of 10 s), and The American Society for Microbiology (American Society For Microbiology 1996) (a 10–15 second vigorous scrub). Several studies support a washing duration of at least 10 s, with sufficient transient removal efficiency achieved by 30 s. A study by Stiles and Sheena involving workers in a meat processing facility determined that a wash of 8–10 s was too short for adequate soil removal from the hands (Stiles & Sheena 1987). A study by Ojajarvi compared a 15 second and 2 minute wash, with the latter providing only an additional 3% transient bacterial reduction (Ojajarvi 1980). One observational study in food service indicates average duration times of 20 s in a silver service restaurant kitchen (Ayers 1998).

In our first study, the effects of water temperature on the reduction of both resident (normal) and transient bacteria during handwashing was performed at each of the following temperatures: 4.4°C (40°F), 12.8°C (55°F), 21.1°C (70°F), 35°C (95°F), or 48.9°C (120°F). Two separate laboratories participated in this work. Silliker Laboratories (South Holland, IL, USA) was responsible for transient flora experiments while Bio-Science Laboratories (Bozeman, MI, USA) performed normal flora studies. For transient flora studies, the experimental subjects' hands were artificially contaminated with Serratia marcescens in Tryptic Soy Broth (TSB) or irradiated ground hamburger. Sterile, uninoculated TSB and irradiated ground hamburger were used as confounding soils in testing for the reduction of the resident flora. Following hand contamination, baseline microbial counts were acquired using the 'glove-juice' method on one hand. Hands were moistened and washed/lathered for 15 seconds with 3 mL bland (nonantibacterial) soap, rinsed for 10 seconds (water flow rate of 7 L/minute) at the assigned water temperature (also used for the prelather moistening), and the opposing hand was then sampled using the same glove-juice technique. No drying of hands was performed, which would have had the effect of diminishing differences between experimental groups. Baseline and postwash readings were then compared to obtain bacterial reduction values. For this study, no skin condition assessments were performed.

The first study was performed using a non-antibacterial soap and examined temperature effects on bacterial reductions based on the solubility of greasy soils. It did not address the increased temperature effect on antimicrobial activation or possible skin damage. Therefore, the second study was undertaken, which not only involved a comparison of the microbial reduction effects of four antibacterial soaps at two different temperatures, but also evaluated skin conditions on the hands of participants throughout the study. The potential of each soap to cause negative skin changes at each water temperature combination was assessed by measuring the skin moisture content, rate of water loss from the skin, skin scaliness by computerized analysis of a digitized skin image, and by visual assessment of the dryness and erythema. This study was performed at BioScience Laboratories, employing eight subjects and using four different antimicrobial soaps, each having a different antimicrobial active ingredient. The soaps had antimicrobial activity equivalent to USDA E2 ratings (50-p.p.m. chlorine equivalency). The active ingredients in these products were Quaternary Ammonium (3% dual Quat formulation), Triclosan (1%), Parachlorometaxylenol (PCMX-3%), and Iodophor (7.5% PVP-I). Participants consisting of paid volunteers performed multiple handwashes during two five-day test periods (weeks one and two) seven days apart using *Escherichia coli* (ATCC #11229) contaminated gamma irradiated ground beef. On days one through five of weeks one and two, the skin condition was evaluated visually, for moisture content using the Corneometer® CM825, for total evaporative water loss using the TC350 Tewameter, and digitally using the Skin Visiometer® SV 500 with Visioscan® VC98. The visual skin dryness and erythema (redness) scoring was performed by a single blinded (unaware of subjects antimicrobial soap product/water temperature configuration) evaluator trained in assessment of skin damage or irritation using a 0–6 scoring system (see Table 2) as originally described by Griffith and others (Griffith *et al.* 1969). Log_{10} reduction data was determined with the first wash of days one, three and five under each water temperature condition. After handling the contaminated ground beef in a way to uniformly contaminate hands, one hand was sampled immediately (again, using the 'glove-juice' technique) for a baseline reading. The subjects' then washed both hands at the specific water temperature (85° ± 2°F for week one and 110° ± 2°F for week two) with their randomly assigned product with their opposing hand being sampled to establish microbial counts. Each subject then washed 11 consecutive times with their assigned test product each day drying hands between washes, then hands were evaluated visually and digitally 30 minutesfollowing the last wash. In all washing cases, lathering was performed for 15 seconds and rinsing for 10 seconds with three mL of the assigned test product.

Table 2 Grading scale for evaluating the skin of the hands*

Grade	Description
0	No visible damage, 'perfect' skin
1	Slight dryness, ashen appearance, usually involving dorsum only
2	Marked dryness, slight flaking involving dorsum only
3	Severe dryness dorsum, marked flaking, possibly fissures in webs
4	Severe flaking dorsum, surface fissures possibly with slight palmar dryness
5	Open fissures, slight erythema (>10% of dorsal and interdigital surface), with or without severe dryness, no bleeding
6	Bleeding cracks, deep open fissures, or generalized erythema (>25% of area)

*Griffith *et al.* 1969.

Results and discussion

After extensive statistical analysis of the results from the first set of experiments, it was determined that there was no significant difference in bacterial log_{10} reductions for either resident or transient bacteria at any of the test washing and rinsing temperatures. See Figs 1 and 2 for transient and resident flora data, respectively. Average log_{10} reduction results for each soap are presented in Fig. 3.

After extensive statistical analysis of the second experiment with antibacterial soaps involving the 2 sample *T*-test, Kruskal–Wallis test and Mann–Whitney test, no statistical difference in log_{10} reductions was detected between the two wash temperatures for any of the products or as a group. Overall, the four products produced similar handwashing efficacy results. Although most of the washes at the higher temperature did produce a slight increase in bacterial reductions, it was not enough to be considered statistically significant. Figure 4 shows Tewameter® readings measuring *trans* epidermal water loss, while Figs 5 and 6 show visual dryness and baseline adjusted Corneometer® values, respectively. Skin scaliness values using a Visiometer® are shown in Fig. 7. Along with the slight additional reduction of bacteria at the higher temperature was increased skin visual dryness, increased transepidermal water loss and decreased scaliness, also determined to be statistically insignificant. Skin scaliness is highest on day one and two at the higher temperature but for days three, four and five, this reverses.

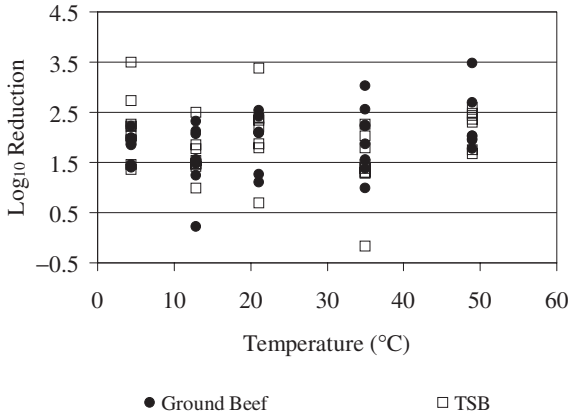

Figure 1 Handwashing efficacy (Log_{10} reduction) for transient flora (*S. marcescens*) in ground beef and TSB at selected water washing and rinsing temperatures.

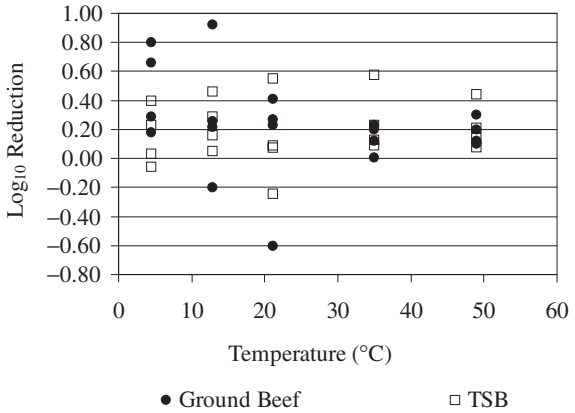

Figure 2 Handwashing efficacy (Log_{10} reduction) for resident flora in ground beef and TSB at selected water washing and rinsing temperatures.

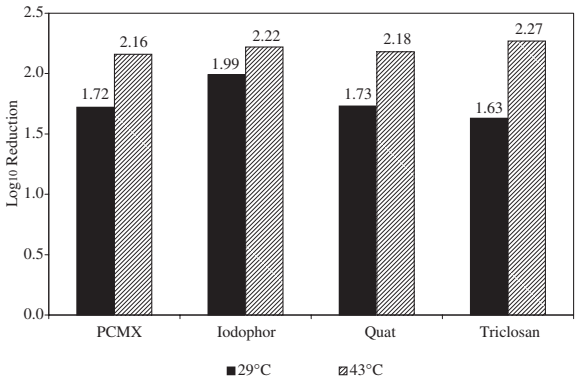

Figure 3 Average Log_{10} reduction of transient flora (*E. coli*) in ground beef using selected antimicrobial soaps.

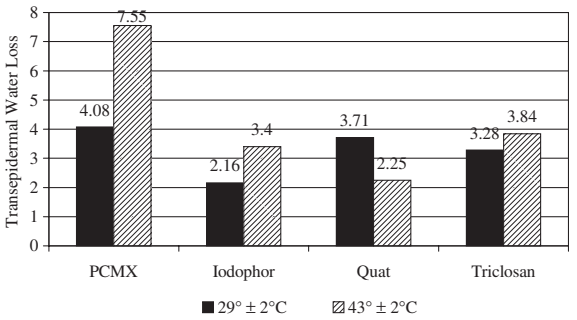

Figure 4 Average Tewameter® readings selected antimicrobial soaps at 2 different water temperatures.

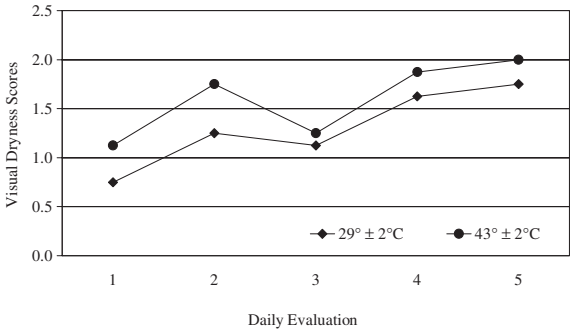

Figure 5 Average baseline-adjusted visual dryness scores (8 subjects) resulting from washing hands with 4 different E2 antimicrobial soaps for 5 days (12 ×/day).

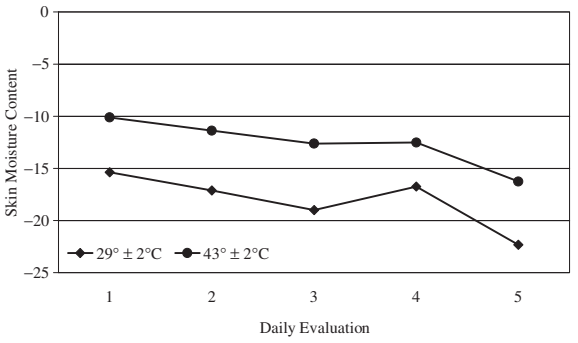

Figure 6 Baseline-adjusted Corneometer® readings (8 subjects) resulting from washing hands with 4 different antimicrobial soaps for 5 days (12 ×/day) at two different handwashing temperatures.

It is conceivable that the higher temperatures more rapidly removed loose layers of stratum corneum.

The results from both of these experiments are in agreement regarding the lack of hygienic benefits of washing hands at higher water temperatures and particularly at temperatures at the upper end of human tolerance, sometimes described as 'hot as you can stand'. From the first study, it is realized that higher water temperatures have no significant effect on the

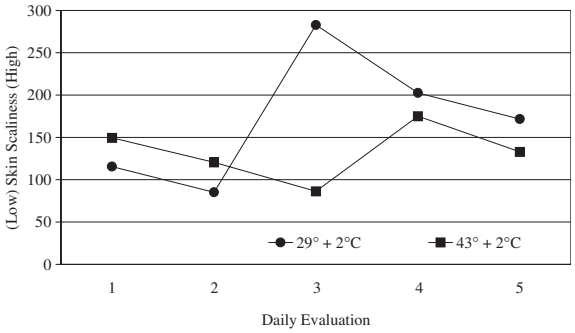

Figure 7 Average baseline-adjusted skin scaliness (8 subjects) resulting from washing hands with 4 different antimicrobial temperatures as measured using Visiometer®.

reduction of resident or transient bacteria in either easy to remove soil (TSB) or difficult to remove soil (ground beef) when using plain soap at a wide range of temperatures and using a standard hand wash. The second study provides additional support to the results of the first study by showing no statistically significant effect for the use of 110°F water (compared to 85°F water) to remove transient microorganisms embedded in ground beef from the hands when using any one of four different antibacterial based soaps or antibacterial soaps as a group. This experiment did show the trend toward higher kill as well as higher level of skin damage supporting propositions put forward by both camps. Log_{10} reductions do reflect slightly greater efficacy at higher temperatures but not at the level of significance expected, most probably due to the rapid equilibration to hand temperature described by Price (Price 1938).

Water has been identified as a skin irritant in its own rite, and part of this irritant potential can be exacerbated by temperature increase (Tsai & Maibach 1999). Repeated water exposure causes extraction or dilution of natural moisturizing factors in the stratum corneum. The water-holding property of the stratum corneum is provided in part by intercellular lipids and lipid rich sebaceous gland secretions (Noble & Pitcher 1978). The intercellular lipids, which when chromatographically fractionated, can be separated into cholesterol, cholesterol esters, phospholipids, free fatty acids, glycolipids and ceramide (Noble 1975; Imokawa *et al.* 1986). Loss of these lipid components results in a chapped and scaly skin appearance (Imokawa & Hattori 1985). Water induced irritation is known to exist in workers involved in continuous wet work, resulting in chapped and dry skin after wet work is completed (Halkier-Sorensen & Thestrup-Pedersen 1991).

Instances of primary irritant dermatitis to certain chemicals has been found to occur when hot water at 43°C (110°F) was used rather than lukewarm at 23°C–25°C (73°F–77°F) (Rothenborg *et al.* 1977). Detergent/surfactant formulations are known to cause changes to the stratum corneum such as disaggregation, swelling and morphological deterioration of corneocytes (Shukuwa *et al.* 1997). It has been found that heat plays a part in accelerating irritation of certain chemicals found in these detergent formulations. Berardesca and others found a significant difference between the temperatures of 20°C and 40°C (68°F and 104°F) in skin irritation to 5% sodium lauryl sulphate solution for a 4-day exposure period (Berardesca *et al.* 1995; Ohlenschlaeger *et al.* 1996). This irritation is documented using transepidermal water loss (TEWL) measurements, erythema (skin redness), skin reflectance, hydration (capacitance) and desquamation (stripping). Gross hand edema has been found to occur at temperatures between 35°C (95°F) and 45°C (113°F) when hands are completely immersed at those temperatures (King 1993). A significant increase in blood flow has also been shown in comparisons between 37°C and 43°C degrees (99°F and 110°F) (Nagasaka *et al.* 1987). Overall, these studies tend to show that food service workers derive no significant measurable benefit by using hot water (105°F +) to wash and rinse hands. Use of water at higher temperatures does seem to result in physiological changes collectively described as skin damage. There may be severe consequences of frequent use of hot water for handwashing at temperatures above 43°C (110°F), which can damage skin and heighten susceptibility to both allergens present in the food service environment and/or colonization (Larson *et al.* 1998). Rather, water temperature should be set at what is considered comfortable and generally conducive to handwashing.

The central components of effective handwashing thus consist of soap use in a way that promotes emulsification of soil (through vigorous friction/mechanical action) followed by thorough rinsing and drying, which again adds friction to the equation. Guidelines for handwashing in food service should probably not specify water temperature descriptors other than perhaps the word 'comfortable' when it comes to defining effective handwash standards. 'Warm' or 'tempered' would probably be acceptable, but more importantly as indicated by Jennings and Manian (1999), 'running water' should be to rinse away emulsified soils and associated transient contamination. Fingertips should be pointed down and hands rinsed and dried in a way to focus on parts of the hand that have shown to be missed during normal handwashing. This includes fingertips, thumbs and fingernail regions.

Conclusions

A review of the literature on the subject of handwashing water temperature requirements showed considerable variation with respect to expert opinion on optimal temperature for removal of microbial contaminants form hands. There in fact was a virtual absence of data to back up the various positions on the subject. Sanitarians and food safety experts have specified water temperatures varying from room temperature (running water) up to 'as hot as you can stand', the latter of which is probably in the range of from 49°C (120°F) to 55°C (131°F). Regulations in the US and elsewhere tend to focus on temperatures between 43°C (110°F) and 49°C (120°F). Concern that these temperatures could be detrimental to skin health without documented efficacy led to the experiments described here. Hands were contaminated with soils similar to those encountered in the food service environment. These soils contained marker bacteria allowing handwashing efficacy to be determined at specified water temperatures against both transient flora and resident flora simultaneously.

The initial experiment involved testing with bland non-antimicrobial soap at 5 temperatures from 4.4°C (40°F) to 49°C (120°F). Independent of soil or bacterial type (resident or transient) there was no significant difference in efficacy attributed to water temperature. In the second experiment antimicrobial soaps (4) were used having different antimicrobial active ingredients, at each of two water temperatures, 29.5°C (85°F) and 43°C (110°F). Skin condition was monitored with frequent handwashes (12 ×/day) for the second set of water washing temperature experiments. In this experiment, even though slightly higher efficacy with was seen with antimicrobial soaps at higher temperatures, overall, there was no statistical difference in efficacy as measured in Log_{10} reduction at the two water temperatures (regardless of soil or microflora types). Concomitant to the increase in efficacy at higher temperatures was a consistent trend for increases in measures of skin damage, such as skin moisture content, transepidermal water loss and erythema. This was also found not to be statistically significant.

Both the trend for higher efficacy of soaps with attendant skin damage at higher temperatures are grounded in theory. Under the conditions of these experiments neither was shown to be proven for practical application. Since efficacy is not markedly improved at higher temperatures but rather the real danger exists of skin damage, requirements for specific handwashing water temperature should be relaxed to improve acceptance of frequent handwashing by food workers at appropriate times to reduce foodborne illness potential. Water temperature should be in a comfortable range, perhaps tempered.

As has been shown by many previous researchers, overall handwashing effectiveness is more dependent on the vigorousness of execution than details such as the type of soap, the length of handwash or in this case water temperature. The results obtained in these experiments confirm the observations made by Price (Price 1938) and Larson (Larson *et al.* 1980) indicating water temperature had little or no effect on the removal of bacteria from hands. While their original reports dealt with optimizing skin sampling efficacy, for the types of experiments performed and described in the current report.

Unfortunately, food service regulatory authorities, health inspectors and environmental health officers in the US and elsewhere have fixated on handwashing water temperature because it is measurable and in the somewhat mistaken belief that higher temperatures would result in cleaner hands. Up until recently, the existence of adequate hygiene facilities (functioning toilet, toilet paper, functioning sink, soap and paper towels) and water temperature measurement were to some extent the only measurable qualities whereby food safety inspectors could cite food service facilities for violation. Poor personal hygiene is often used after the fact to describe as a contributing factor aiding to an outbreak. With handwash monitoring devices employees' handwashing can be monitored, documented and verified within the HACCP framework (Michaels 2002). With this new technology and information from this report indicating that water temperature for handwashing is relatively unimportant, perhaps regulatory authorities will be able to focus on other more important factors having a bigger impact on food safety.

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Conference for Food Protection
2010 Issue Form

Internal Number: 071
Issue: 2010 III-016

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

All information above the line is for conference use only.

Title:

Sequential Application of Hand Antiseptic for Use in No-Water Situations

Issue you would like the Conference to consider:

Effective hand hygiene for situations where soap and water are unavailable remains a challenge for food safety. Under the 2009 FDA Model Food Code, Section 2-301.16, employees may use a hand antiseptic to clean hands when food exposure is limited and handwashing sinks are not conveniently available. In addition, employees may use chemically treated disinfectant towelettes per Section 5-203.11(C).

It has now been found that an effective hand cleansing, equivalent to handwashing with soap and water as specified in Section 5-203.11, can be achieved by sequential use of alcohol-based hand antiseptics, wherein a first application is wiped off with a dry single-use towel, followed immediately by a second application that is allowed to dry as per normal use directions. The latest testing of this hand cleansing/degerming technique shows it to be effective in the presence of organic food soils. This adds an additional safety factor to support incorporation of the method into food safety practices for select situations.

This protocol is not a substitute for handwashing in stationary facilities where cleaning can be accomplished per 2-301.12.

[Note: After the near unanimous vote for adoption by Council III in 2008, this issue was extracted during the Assembly of Delegates, citing the need for additional testing which has now been concluded along with an additional two years of field testing under the guidance of the Southern Nevada Health District. SNHD has also cleared this intervention for school foodservice use during water outages.]

Public Health Significance:

Potential contamination of ready-to-eat foods is increased in situations where access to soap and water are limited or simply unavailable. The new proposed option increases the

odds of effective hand degerming in those situations, including its use between single-use glove changes.

Recommended Solution: The Conference recommends...:

a letter be sent to FDA requesting the following change to the Model Food Code:

5-203.11 Handwashing Sinks

(A)(B)(C)

(D) When food exposure is limited and handwashing sinks are not conveniently located, such as at outdoor events, mobile or temporary food service and some vending machine locations, employees may use a regimen of sequential application of hand antiseptic wherein the first application is treated as a handwash with full scrubbing action for 15 seconds and then, while wet, wiped off with a single-use paper towel, immediately followed by a second application which is allowed to dry per standard label instruction.

(i) Said hand antiseptic shall meet requirements of 2-301.16

(ii) Said hand antiseptic shall have supporting test data indicating statistical equivalence to a standard handwash in hand degerming.

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Attachments:

- "Determination of the Antimicrobial Efficacy of Three Test Articles (2008)"
- "Determination of the Antimicrobial Efficacy of Three Test Articles (2009)"
- "Sequential Application of Hand Antiseptic for Use in No-Water Situations"
- "SaniTwice: A Hand Hygiene Solution for Food Handlers"
- "Test Results For Heavy Soil Pilot SaniTwice Study"

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

January 17, 2008

FINAL REPORT #070723-150

DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF THREE (3) TEST ARTICLES USING A VARIATION OF THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE

Prepared for:

(SPONSOR)

Prepared by:

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This Study has been approved by the GIRB on _____

EXECUTIVE SUMMARY

The purpose of this study was to evaluate the antimicrobial efficacy of three (3) test articles using a modification of the Health Care Personnel Handwash evaluation. The indicator microorganism used for hand contaminations was *Escherichia coli* (ATCC #11229). Eleven (11) subjects used each of the three (3) test articles (reference Section 14.0 of this Final Report and a Protocol and/or SOP Deviation Recording Form [Form No. 99-QA-004] in Addendum I of this Final Report), one (1) at a time. Subjects performed two (2) consecutive hand contaminations with the challenge suspension in a beef broth medium, the first followed by a sample for baseline, and the second by a product application. Subjects then decontaminated their hands with a 70% Ethanol rinse and a nonmedicated soap wash, and then used a second Test Article. This procedure was repeated again with the remaining Test Article. The baseline and post-application samples were evaluated for the presence of *Escherichia coli* (ATCC #11229). The testing methods were based on the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash.* (FR59:116, 17 June 94) and ASTM E1174-06, *Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations.*

The critical index for this study was a two (2) $\log_{10}$ reduction in baseline populations after product application.

STATISTICAL ANALYSIS #1

For Test Article #1, Bland Foaming Handwash (Lot Number 275543), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean $\log_{10}$ reduction of 2.80 after product application and met the critical index of the study.

For Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2 produced a mean $\log_{10}$ reduction of 2.64 after product application and met the critical index of the study.

For Test Article #3, Sanitizing Hand Wipes (68.15% Ethanol; Lot Number 973-12), followed by Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), applied per Test Article #3 Application Procedure, the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 followed by Test Article #2, applied per Test Article #3 Application Procedure, produced a mean $\log_{10}$ reduction of 2.47 after product application and met the critical index of the study.

STATISTICAL ANALYSIS #2

Upon completion of the statistical analysis, Subject #12's data were determined to be outliers. Further investigation revealed that the subject appeared to have a learning disability and needed repeated instruction by the monitoring laboratory technician to be able to perform each of the steps required by the study protocol. The conclusions below results from a statistical analysis excluding data from testing of Subject #12.

For Test Article #1, Bland Foaming Handwash (Lot Number 275543), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean $\log_{10}$ reduction of 2.93 after product application and met the critical index of the study.

Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2 produced a mean $\log_{10}$ reduction of 2.83 after product application and met the critical index of the study.

Test Article #3, Sanitizing Hand Wipes (68.15% Ethanol; Lot Number 973-12), followed by Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), applied per Test Article #3 Application Procedure, the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 followed by Test Article #2, applied per Test Article #3 Application Procedure, produced a mean $\log_{10}$ reduction of 2.63 after product application and met the critical index of the study.

This Study has been approved by the GIRB on _____

January 17, 2008

FINAL REPORT # 070723-150

1.0 TITLE: **DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF THREE (3) TEST ARTICLES USING A VARIATION OF THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE**

2.0 TESTING FACILITY: **BIOSCIENCE LABORATORIES, INC.**
300 N. Willson Avenue
Bozeman, Montana 59715

3.0 STUDY DIRECTORS:

Robert R. McCormack - Principal Study Director
Kendra F. Drake - Associate Study Director

4.0 PURPOSE OF STUDY:

The purpose of this study was to evaluate the antimicrobial efficacy of three (3) test articles for use in the food service industry. Testing was performed per methodology based on the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450) and ASTM E1174-06, *Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations.*

5.0 SCOPE:

The purpose of this study was to evaluate the antimicrobial efficacy of three (3) test articles using a modification of the Health Care Personnel Handwash evaluation. The indicator microorganism used for hand contaminations was *Escherichia coli* (ATCC #11229). Eleven (11) subjects used each of the three (3) test articles, one (1) at a time. Subjects performed two (2) consecutive hand contaminations with the challenge suspension in a beef broth medium, the first followed by a sample for baseline, and the second by a product application. Subjects then decontaminated their hands with a 70% Ethanol rinse and a nonmedicated soap wash, and then used a second Test Article. This procedure was repeated again with the remaining Test Article. The baseline and post-application samples were evaluated for the presence of *Escherichia coli* (ATCC #11229). The testing methods were based on the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash.* (FR59:116, 17 June 94) and ASTM E1174-06, *Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations.* The Study Protocol was approved by the Gallatin Institutional Review Board (GIRB) on 12/04/07 (See Addendum I of this Final Report). One (1) deviation from the methodology described in the Study Protocol occurred (reference Section 14.0 of this Final Report), and as is detailed on a Protocol and/or SOP Deviation Recording Form (Form No. 99-QA-004) in Addendum I of this Final Report, it had no adverse effect upon the study outcome. No deviations from BioScience Laboratories, Inc., Standard Operating Procedures occurred during the course of this evaluation.

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6.0 STUDY DATES:

STUDY INITIATION DATE:	11/30/07
EXPERIMENTAL START DATE:	12/19/07
EXPERIMENTAL END DATE:	01/07/08
STUDY COMPLETION DATE:	01/17/08

7.0 TEST MATERIALS:

The test articles were provided to the Testing Facility by the Sponsor. Responsibility for determination of the identity, strength, purity, composition, stability, and solubility of the test articles, as well as responsibility for retention of the test articles, remained with the Sponsor. All documentation provided with the test articles is included in Addendum IX of this Final Report.

Test Article #1:	Bland Foaming Handwash
Lot Number:	275543
Expiration Date:	01/2010

Test Article #2:	Instant Hand Sanitizer Gel
Active Ingredient:	62% Ethanol
Lot Number:	240041 5179
Expiration Date:	06/2008

Test Article #3:	Sanitizing Hand Wipes
Active Ingredient:	68.15% Ethanol
Lot Number:	973-12
Expiration Date:	04/19/08

8.0 TEST ARTICLE APPLICATION PROCEDURES:

Test Period

8.1 Each subject was in testing for approximately four (4) hours on a single day and used each of the three (3) test articles. Prior to being admitted into testing, subjects were questioned regarding their adherence to the Protocol requirements. Subjects clipped their fingernails to a free edge of ≤ 1 mm, if they had not already done so. All jewelry was removed from the hands and arms prior to washing.

NOTE: Each subject used each of the three (3) test articles, one (1) at a time, per specified application procedures. After the Glove Juice Sampling Procedure was performed following test article application and prior to use of another test article, the subjects were required to decontaminate their hands by performing a one (1) minute rinse with 70% Ethanol and an air-dry, followed by a thirty (30) second handwash using a nonmedicated soap. The subjects waited a minimum of twenty (20) minutes following the use of the nonmedicated soap and prior to use of another test article.

8.2 A handwash was performed using a nonmedicated soap to remove dirt and oil from the hands. A technician instructed subjects in the appropriate technique and verified its proper execution by subjects. The temperature of the water used for all wash or rinse procedures was controlled at 40° ± 2°C (see Water Temperature Monitoring Sheets [Form No. 96-CT-017] in Addendum VII of this Final Report]).

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Inoculum Application Procedure

8.3 Four and one-half (4.5) mLs of the beef broth suspension containing at least 1 x 10^9 CFU/mL of *Escherichia coli* (ATCC #11229) were transferred into each subject's cupped hands in three (3) aliquant amounts of one and one-half (1.5) mLs.

8.4 The suspension was distributed over the entire surface of the hands (front and back), not reaching above the wrists, for twenty (20) ± five (5) seconds. Following distribution of the inoculum, the hands were held motionless, away from the body, and allowed to air-dry for thirty (30) ± five (5) seconds.

8.5 The procedure in Section 8.4 was repeated.

8.6 A final one and one-half (1.5) mL aliquant amount of the challenge suspension was dispensed into the subject's cupped hands and distributed over the entire surface of the hands (front and back), not reaching above the wrists, for twenty (20) ± five (5) seconds. The hands were allowed to air-dry for ninety (90) seconds.

8.7 After the timed ninety (90) second air-dry, the Glove Juice Sampling Procedure was performed. This first contamination cycle provided the baseline population level. It was followed with a thirty (30) second handwash using nonmedicated soap.

8.8 The challenge suspension was again dispensed into each subject's cupped hands and distributed as described above. After a timed ninety (90) second air-dry, the subjects applied their randomly assigned test article according to the directions below.

Test Article #1 Application Procedure

8.9 The subject wet hands within ten (10) seconds of completing the drying step.

8.10 Two (2) pumps (1.4 mL) of Test Article #1 were placed in the subject's cupped hands.

8.11 The subject lathered Test Article #1 for fifteen (15) seconds, followed by a ten (10) second rinse with water.

8.12 Following the water rinse, the subject used two (2) paper towels to pat-dry hands for ten (10) seconds.

Test Article #2 Application Procedure

8.13 Two (2) pumps (3.0 mL) of Test Article #2 were placed in the subject's cupped hands within ten (10) seconds of completing the drying step.

8.14 The subject rubbed Test Article #2 into the hands in a vigorous manner for fifteen (15) seconds.

8.15 Following Test Article #2 application, the subject used two (2) paper towels to pat-dry hands for ten (10) seconds.

8.16 An additional one (1) pump of Test Article #2 was placed in the subject's cupped hands (1.5 mL), and the hands were rubbed together until dry.

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Test Article #3 Application Procedure

8.17 Within ten (10) seconds of completing the drying step, the subject wiped both hands with Test Article #3 in a standardized fashion for twenty-five (25) seconds.

8.18 Following the wiping procedure, one (1) pump of Test Article #2 was placed in the subject's cupped hands, and hands were rubbed together until dry.

9.0 EQUIPMENT AND SUPPLIES:

The equipment and supplies used for this study are summarized in the Study Protocol, included in Addendum I of this Final Report, and are also detailed on Clinical Trials Equipment Tracking Forms (Form No. 01-L-009) and Clinical Trials Supplies Tracking Forms (Form 01-L-008) in Addendum VII of this Final Report.

10.0 MEDIA:

The growth media and diluting fluids used in this study are as described in the Study Protocol in Addendum I of this Final Report. Additional details are recorded on Media/Diluent Tracking Forms (Form No. 97-L-007) in Addendum VIII of this Final Report.

11.0 SUBJECT DEMOGRAPHICS:

Twenty-seven (27) overtly healthy subjects, at least eighteen (18) years of age were admitted into the study. Eleven (11) subjects completed the study (reference Protocol and/or SOP Deviation Recording Form [Form No. 99-QA-004] in Addendum I of this Final Report). Insofar as possible, the group of subjects selected was of mixed sex, age, and race. Hands and forearms were free from clinically evident dermatoses, other injuries to the area, and/or any other disorders that may have compromised the subject and the study. All subjects who participated in the Study signed the Study Description and Informed Consent Form, Subject Confidential Information and Acceptance Criteria, and Authorization to Use and Disclose Protected Health Information Form (Appendix I of Addendum I of this Final Report) and List of Restricted Products (Appendix II of Addendum I of this Final Report) prior to participating in the study. The demographics of the study are presented in the table below.

DEMOGRAPHIC SUMMARY	ALL SUBJECTS	
	Recruited	Received Product
AGE		
Minimum Age	19	19
Median Age	*35*	*45*
Maximum Age	69	69
SEX		
Males (M)	14	5
Females (F)	13	6
Total	*27*	*11*
RACE		
White/Caucasian (C)	26	10
Latino (L)	1	1
Total	*27*	*11*

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DID NOT PARTICIPATE IN TESTING	
SC = Schedule Conflict	1
QC = Qualification (Inclusion/Exclusion) Criteria Failure	10
NS = No Show	5

12.0 ADVERSE EVENTS:

No subject experienced an adverse event during or following completion of this study.

13.0 NEUTRALIZATION EVALUATION :

The results of a neutralization evaluation (BSLI SOP CT-1006) indicated that the neutralizer(s) used in the recovery medium successfully quenched the antimicrobial activity of the test articles. Study procedures followed guidelines set forth in ASTM E 1054-02, *Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents*, except that the microorganism was added to the neutralizer prior to the addition of the test articles. *Escherichia coli* (ATCC #11229) was used as the challenge species in the neutralizer validation study. All data resulting from the Neutralization Assay are included in Addendum VI of this Final Report.

14.0 DEVIATION FROM PROTOCOL:

Section 12.40 in Protocol 070723-150 states, "Within ten (10) seconds of completing the drying step (Section 12.31), the subject will wipe both hands with Test Article #3 in a standardized fashion for twenty-five (25) seconds." Subject 21 did not use Test Article #3 on both hands in a standardized fashion nor for the full twenty-five (25) seconds. Subject 21 dropped wipe with three (3) seconds left on the rub, continued without wipe, and one (1) pump of Test Article #2 was then placed in the subject's cupped hands. Subject 21 failed to follow applications instructions as directed by the monitoring laboratory technician. Subject 21's data for Test Article #3 were disregarded from the analysis, so there is no effect on the outcome of the study.

15.0 RESULTS - TABLES I THROUGH XII:

15.1 Table I presents the statistical summary of the $\log_{10}$ values following performance of Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]).

Table I: Statistical Summary of the $\log_{10}$ Recovery Values following Performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543])

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	22	8.18	0.24	8.08 to 8.29
Application 1	22	5.38	0.58	5.13 to 5.64
Application 1 Log_{10} Reduction	22	2.80	0.68	2.50 to 3.10

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15.2 Table II presents the log_{10} values and log_{10} reduction from baseline values, by subject, following performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]).

Table II: Log_{10} Values and Log_{10} Reduction from Baseline Values, by subject, following Performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543])

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	8.31	5.66	2.65
	Right	8.12	5.81	2.31
16	Left	8.34	4.33	4.01
	Right	8.34	5.27	3.07
3	Left	8.23	5.12	3.11
	Right	8.11	5.60	2.51
9	Left	8.43	4.97	3.46
	Right	8.19	5.11	3.07
20	Left	8.04	4.82	3.22
	Right	8.11	4.69	3.42
7	Left	8.19	4.14	4.05
	Right	8.14	4.69	3.45
18	Left	8.01	6.00	2.01
	Right	8.04	6.09	1.95
12	Left	7.66	5.87	1.79
	Right	7.58	6.22	1.36
21	Left	8.58	5.64	2.94
	Right	8.48	5.96	2.52
27	Left	8.21	5.55	2.67
	Right	8.21	5.76	2.44
26	Left	8.32	5.47	2.85
	Right	8.38	5.60	2.78

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15.3 Table III presents the statistical summary of the log_{10} values following performance of Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]).

Table III: Statistical Summary of the log_{10} Recovery Values following Performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179])

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	22	8.14	0.31	8.00 to 8.28
Application 1	22	5.50	0.79	5.15 to 5.85
Application 1 Log_{10} Reduction	22	2.64	0.89	2.24 to 3.03

15.4 Table IV presents the log_{10} values and log_{10} reduction from baseline values, by subject, following performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]).

Table IV: Log_{10} Values and Log_{10} Reduction from Baseline Values by subject following Performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179])

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	8.14	5.96	2.18
	Right	8.23	5.80	2.43
16	Left	8.28	5.99	2.29
	Right	8.25	6.45	1.80
3	Left	8.02	5.36	2.67
	Right	8.21	5.34	2.87
9	Left	8.43	4.96	3.47
	Right	8.39	5.56	2.84
20	Left	8.11	4.74	3.37
	Right	8.03	5.82	2.21
7	Left	8.29	4.19	4.10
	Right	8.20	4.85	3.35
18	Left	7.74	4.33	3.40
	Right	7.88	3.66	4.22
12	Left	7.25	6.47	0.78
	Right	7.45	6.90	0.55
21	Left	8.44	5.85	2.59
	Right	8.27	5.90	2.37
27	Left	8.27	6.21	2.06
	Right	8.31	5.61	2.69
26	Left	8.42	5.77	2.66
	Right	8.42	5.34	3.08

This Study has been approved by the GIRB on _____

15.5 Table V presents the statistical summary of the log_{10} values following performance of Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]).

Table V: Statistical Summary of the log_{10} Recovery Values following Performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Log Number 240041 5179])

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	20	8.07	0.34	7.92 to 8.23
Wash 1	20	5.60	0.64	5.30 to 5.90
Wash 1 Log_{10} Reduction	20	2.47	0.76	2.12 to 2.83

15.6 Table VI presents the log_{10} values and log_{10} reduction from baseline values, by subject, following performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]).

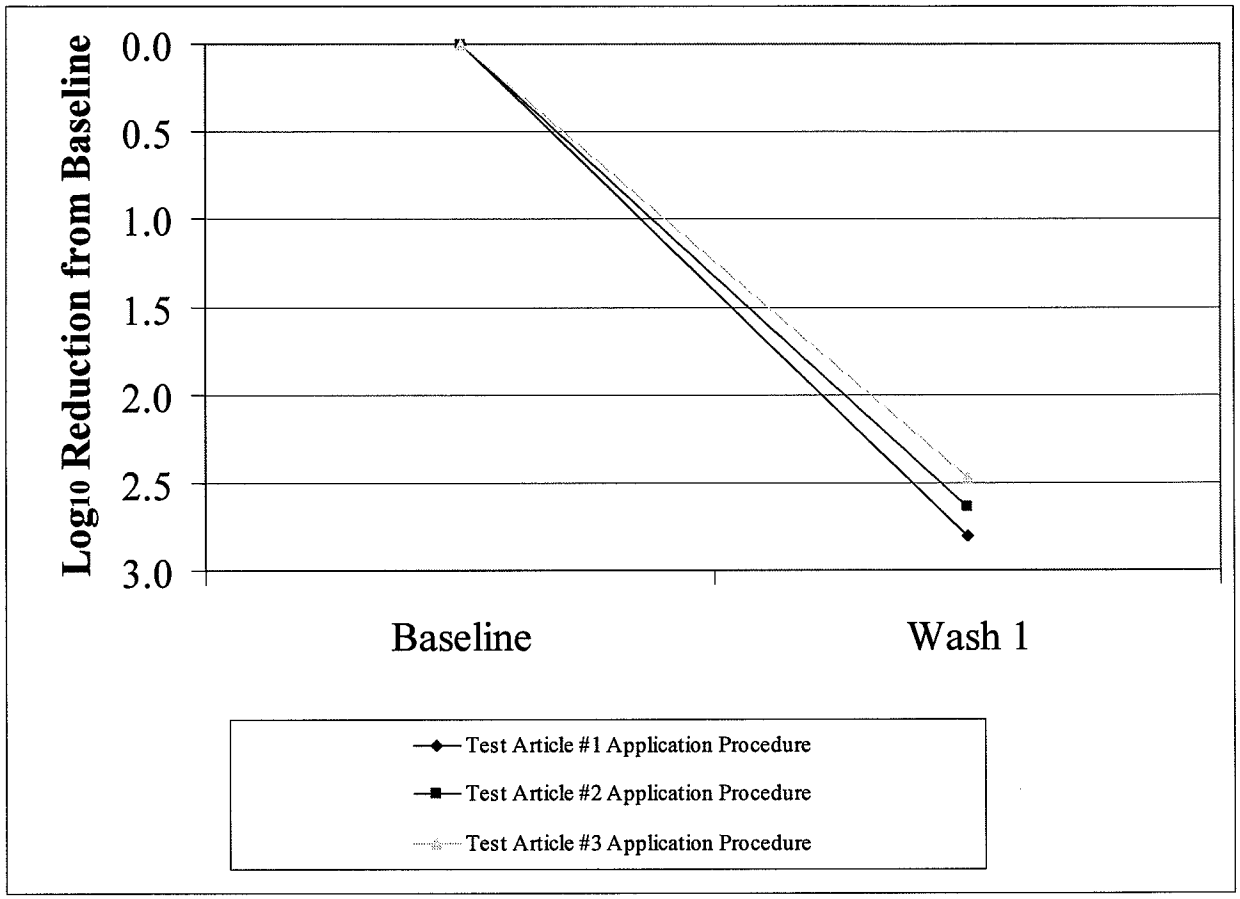
Table VI: Log_{10} Values and Log_{10} Reduction from Baseline Values by subject following Performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Log Number 240041 5179])

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	8.37	6.20	2.17
	Right	8.33	6.37	1.97
16	Left	8.13	5.31	2.82
	Right	8.29	5.81	2.48
3	Left	8.09	4.88	3.21
	Right	8.22	4.14	4.08
9	Left	8.41	5.18	3.23
	Right	8.35	5.33	3.02
20	Left	7.69	4.75	2.94
	Right	7.70	5.48	2.22
7	Left	8.16	5.07	3.09
	Right	8.23	6.32	1.91
18	Left	7.79	5.65	2.14
	Right	8.25	5.18	3.07
12	Left	7.23	6.21	1.03
	Right	7.35	6.30	1.05
21	Left	*	*	*
	Right	*	*	*
27	Left	8.16	5.33	2.83
	Right	8.23	5.86	2.38
26	Left	8.24	6.28	1.96
	Right	8.27	6.39	1.88

This Study has been approved by the GIRB on _____

15.7 Figure 1 presents the graphical presentation of the mean log10 reductions from baseline from each of the three (3) test article application procedures.

Figure 1: Graphical Presentation of the Mean log_{10} Reductions from Baseline From the Three (3) Test Article Application Procedures



15.8 Table VII presents the statistical summary of the log_{10} values following performance of Test Article #1 Application Procedure (Bland Foaming Handwash (Lot Number 275543)) excluding data from Subject 12.

Table VII: Statistical Summary of the log_{10} Recovery Values following Performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]) excluding Data from Subject #12

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	20	8.24	0.16	8.17 to 8.31
Application 1	20	5.32	0.56	5.05 to 5.58
Application 1 Log_{10} Reduction	20	2.93	0.58	2.66 to 3.19

This Study has been approved by the GIRB on _____

15.9 Table VIII presents the log_{10} values and log_{10} reduction from baseline values, by subject, following performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]) excluding data from Subject #12.

Table VIII: Log_{10} Values and Log_{10} Reduction from Baseline Values, by subject, following Performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]) excluding Data from Subject #12

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	8.31	5.66	2.65
	Right	8.12	5.81	2.31
16	Left	8.34	4.33	4.01
	Right	8.34	5.27	3.07
3	Left	8.23	5.12	3.11
	Right	8.11	5.60	2.51
9	Left	8.43	4.97	3.46
	Right	8.19	5.11	3.07
20	Left	8.04	4.82	3.22
	Right	8.11	4.69	3.42
7	Left	8.19	4.14	4.05
	Right	8.14	4.69	3.45
18	Left	8.01	6.00	2.01
	Right	8.04	6.09	1.95
12	Left	*	*	*
	Right	*	*	*
21	Left	8.58	5.64	2.94
	Right	8.48	5.96	2.52
27	Left	8.21	5.55	2.67
	Right	8.21	5.76	2.44
26	Left	8.32	5.47	2.85
	Right	8.38	5.60	2.78

This Study has been approved by the GIRB on _____

15.10 Table IX presents the statistical summary of the $\log_{10}$ values following performance of Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding data from Subject #12.

Table IX: Statistical Summary of the $\log_{10}$ Recovery Values following Performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding Data from Subject #12

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	20	8.22	0.19	8.13 to 8.30
Application 1	20	5.38	0.73	5.05 to 5.72
Application 1 Log_{10} Reduction	20	2.83	0.66	2.53 to 3.14

15.11 Table X presents the $\log_{10}$ values and $\log_{10}$ reduction from baseline values, by subject, following performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding data from Subject #12.

Table X: Log_{10} Values and Log_{10} Reduction from Baseline Values by subject following Performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding Data from Subject #12

Subject	Side	Baseline $\log_{10}$ Values	Application 1 $\log_{10}$ Values	Application 1 $\log_{10}$ Reduction from Baseline
1	Left	8.14	5.96	2.18
	Right	8.23	5.80	2.43
16	Left	8.28	5.99	2.29
	Right	8.25	6.45	1.80
3	Left	8.02	5.36	2.67
	Right	8.21	5.34	2.87
9	Left	8.43	4.96	3.47
	Right	8.39	5.56	2.84
20	Left	8.11	4.74	3.37
	Right	8.03	5.82	2.21
7	Left	8.29	4.19	4.10
	Right	8.20	4.85	3.35
18	Left	7.74	4.33	3.40
	Right	7.88	3.66	4.22
12	Left	*	*	*
	Right	*	*	*
21	Left	8.44	5.85	2.59
	Right	8.27	5.90	2.37
27	Left	8.27	6.21	2.06
	Right	8.31	5.61	2.69
26	Left	8.42	5.77	2.66
	Right	8.42	5.34	3.08

This Study has been approved by the GIRB on _____

15.12 Table V presents the statistical summary of the $\log_{10}$ values following performance of Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding data from Subject #12.

Table XI: Statistical Summary of the $\log_{10}$ Recovery Values following Performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Log Number 240041 5179]) excluding Data from Subject #12

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	18	8.16	0.22	8.05 to 8.27
Wash 1	18	5.53	0.63	5.21 to 5.85
Wash 1 $\log_{10}$ Reduction	18	2.63	0.61	2.33 to 2.93

15.13 Table XII presents the $\log_{10}$ values and $\log_{10}$ reduction from baseline values, by subject, following performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding data from Subject #12.

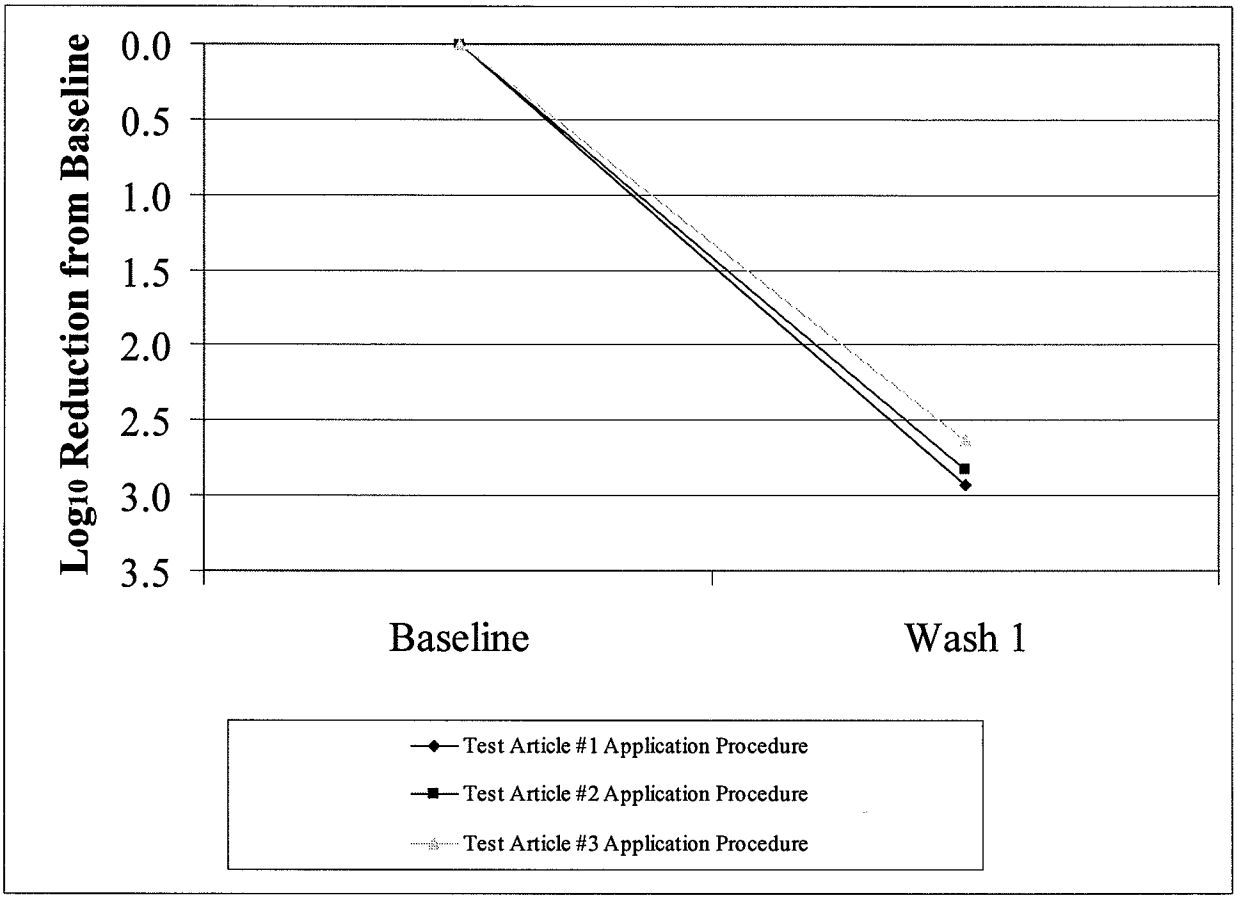
Table XII: $\log_{10}$ Values and $\log_{10}$ Reduction from Baseline Values by subject following Performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Log Number 240041 5179]) excluding Data from Subject #12

Subject	Side	Baseline $\log_{10}$ Values	Application 1 $\log_{10}$ Values	Application 1 $\log_{10}$ Reduction from Baseline
1	Left	8.37	6.20	2.17
	Right	8.33	6.37	1.97
16	Left	8.13	5.31	2.82
	Right	8.29	5.81	2.48
3	Left	8.09	4.88	3.21
	Right	8.22	4.14	4.08
9	Left	8.41	5.18	3.23
	Right	8.35	5.33	3.02
20	Left	7.69	4.75	2.94
	Right	7.70	5.48	2.22
7	Left	8.16	5.07	3.09
	Right	8.23	6.32	1.91
18	Left	7.79	5.65	2.14
	Right	8.25	5.18	3.07
12	Left	*	*	*
	Right	*	*	*
21	Left	*	*	*
	Right	*	*	*
27	Left	8.16	5.33	2.83
	Right	8.23	5.86	2.38
26	Left	8.24	6.28	1.96
	Right	8.27	6.39	1.88

This Study has been approved by the GIRB on _____

15.14 Figure 2 presents the graphical presentation of the mean log10 reductions from baseline from each of the three (3) test article application procedures excluding data from Subject #12.

Figure 2: Graphical Presentation of the Mean $\log_{10}$ Reductions from Baseline From the Three Test Article Application Procedures excluding Data from Subject #12



16.0 CONCLUSION:

The critical index for this study was a two (2) $\log_{10}$ reduction in baseline populations after product application.

STATISTICAL ANALYSIS #1

For Test Article #1, Bland Foaming Handwash (Lot Number 275543), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean $\log_{10}$ reduction of 2.80 after product application and met the critical index of the study.

For Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2 produced a mean $\log_{10}$ reduction of 2.64 after product application and met the critical index of the study.

This Study has been approved by the GIRB on _____

For Test Article #3, Sanitizing Hand Wipes (68.15% Ethanol; Lot Number 973-12), followed by Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), applied per Test Article #3 Application Procedure, the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 followed by Test Article #2, applied per Test Article #3 Application Procedure, produced a mean $\log_{10}$ reduction of 2.47 after product application and met the critical index of the study.

STATISTICAL ANALYSIS #2

Upon completion of the statistical analysis, Subject #12's data were determined to be outliers. Further investigation revealed that the subject appeared to have a learning disability and needed repeated instruction by the monitoring laboratory technician to be able to perform each of the steps required by the study protocol. The conclusions below results from a statistical analysis excluding data from testing of Subject #12.

For Test Article #1, Bland Foaming Handwash (Lot Number 275543), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean $\log_{10}$ reduction of 2.93 after product application and met the critical index of the study.

Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2 produced a mean $\log_{10}$ reduction of 2.83 after product application and met the critical index of the study.

Test Article #3, Sanitizing Hand Wipes (68.15% Ethanol; Lot Number 973-12), followed by Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), applied per Test Article #3 Application Procedure, the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 followed by Test Article #2, applied per Test Article #3 Application Procedure, produced a mean $\log_{10}$ reduction of 2.63 after product application and met the critical index of the study.

17.0 LABORATORY PERSONNEL:

The following employees of BioScience Laboratories, Inc., were involved in the testing or ancillary support of this Study. The laboratory personnel have been appropriately trained, and their training records are on-file in the Quality Assurance Unit at the Testing Facility.

STUDY DIRECTOR:	Robert R. McCormack Microbiologist
Sabrina Bakich Marketing Manager/Product Handling	Paul O' Brien Clinical Laboratory Technician
Amanda Berry Subject Recruitment	Alicia Pfile Microbiologist
Stephanie Cebulla Laboratory Support Technician	Christine Roath Microbiologist
Kendra F. Drake Associate Study Director, Microbiologist	Lori Schlotfeldt Supervisor of Laboratory Support

This Study has been approved by the GIRB on _____

LABORATORY PERSONNEL (Continued)

Collette Duley
Microbiologist

Erika Ecton
Subject Recruitment

Amanda Henry
Microbiologist

August Grace Johnson
Microbiologist

Jacqueline Joyner
Subject Recruitment

Lisa Lehman
Microbiologist

Ron Neibauer
Manager of Clinical Laboratories

Jessica Sheehy
Laboratory Support Technician

Carl Schmidt
Microbiologist

Brian Stancil
Clinical Laboratory Technician

Robert H. Stancil
Microbiologist

Clare Wilson
Microbiologist

Annette C. Woods
Microbiologist

Kristy Wuebber
Microbiologist

18.0 QUALITY ASSURANCE PERSONNEL:

Liv Graving
Quality Assurance Associate

Amy Juhnke
Manager of Quality Assurance/Document Control

Scott McCommon
Manager of Quality Control

John A. Mitchell, Ph.D.
Director of Quality Assurance

Janis Smoke
Quality Assurance Associate

19.0 DOCUMENTATION AND RECORD-KEEPING:

All documentation and records were compiled, analyzed, and will be retained by BioScience Laboratories, Inc., at its facility in Bozeman, Montana. All raw data for this study, as well as the Final Report, will be retained in safe storage by the Testing Facility for a period of at least three (3) years.

This Study has been approved by the GIRB on _____

20.0 ACCEPTANCE:

QUALITY ASSURANCE STATEMENT:

This study was inspected by the Quality Assurance Unit, and reports were submitted to the Study Director and Management in accordance with Standard Operating Procedures, as follows:

Phase	Date
Neutralization Assay	01/04/08
Product Testing	12/19/07 and 12/26/07
Data Audit	01/14/08
Final Report Review	01/17/08
Reports to Study Director and Management	12/19/07, 12/26/07, 01/04/08, and 01/17/08

This study was conducted in compliance with Good Laboratory Practices standards, as described by the FDA (reference CFR 21 Parts 50, 56, 312, and 314), with the following exception: test article preparations were not analyzed at BioScience Laboratories, Inc., to confirm concentration, stability, or homogeneity.

This Study has been approved by the GIRB on _____

INDEX OF ADDENDA

This Study has been approved by the GIRB on _____

BIOSCIENCE
LABORATORIES•INC

March 12, 2009

FINAL REPORT #081211-150

DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF THREE (3) TEST ARTICLES USED IN FOUR (4) APPLICATION CONFIGURATIONS USING A VARIATION OF THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE

Prepared for:

GOJO INDUSTRIES, INC. (SPONSOR)
One GOJO Plaza, Suite 500
Akron, Ohio 44311

Prepared by:

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EXECUTIVE SUMMARY

Twelve subjects used each of the four test article configurations over the course of two consecutive hand contaminations with *Escherichia coli* (ATCC #11229) in a beef broth medium as the indicator microorganism for each configuration. The four test configurations were assigned randomly according to an incomplete crossover design; that is, the order of use of each configuration was randomly determined. The first was followed by a sample for baseline, and the second by a product application. The subject then decontaminated their hands with a 70% ethanol rinse and a nonmedicated soap wash, and used a second test article configuration. This procedure was repeated twice more with the remaining test article configurations. The baseline and all post-application samples were evaluated for the presence of *Escherichia coli* (ATCC #11229). Testing was performed per a modification of the methodology in the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450).

The critical index for this study was a 2.0 $\log_{10}$ reduction in baseline populations after product application.

For Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), applied per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] of Test Article #1 into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean $\log_{10}$ reduction of 2.92 after product application and met the critical index of the study.

For Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), applied per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] of Test Article #2 rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2, applied per Test Article Configuration #2 Application Procedure, produced a mean $\log_{10}$ reduction of 4.44 after product application and met the critical index of the study.

For Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), applied per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL] of Test Article #2, pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2, applied per Test Article Configuration #3 Application Procedure, produced a mean $\log_{10}$ reduction of 4.61 after product application and met the critical index of the study.

For Test Article #3, PURELL® Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), applied per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL] of Test Article #3, pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 produced a mean $\log_{10}$ reduction of 3.64 after product application and met the critical index of the study.

March 12, 2009

FINAL REPORT #081211-150

1.0 TITLE: **DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF THREE (3) TEST ARTICLES USED IN FOUR (4) APPLICATION CONFIGURATIONS USING A VARIATION OF THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE**

2.0 SPONSOR: **GOJO INDUSTRIES, INC.**
One GOJO Plaza, Suite 500
Akron, Ohio 44311

3.0 TESTING FACILITY: **BIOSCIENCE LABORATORIES, INC.**
300 N. Willson Avenue
Bozeman, Montana 59715

4.0 STUDY DIRECTORS:

Robert R. McCormack - Principal Study Director
Kendra Drake - Associate Study Director

5.0 PURPOSE OF STUDY:

The purpose of this study was to evaluate the antimicrobial efficacy of three test articles used in four application configurations using a modification of the Health Care Personnel Handwash evaluation for use in the food service industry.

6.0 SCOPE:

A total of twelve subjects used each of the four test article configurations over the course of two consecutive hand contaminations with *Escherichia coli* (ATCC #11229) in a beef broth medium as the indicator microorganism for each configuration. The first was followed by a sample for baseline, and the second by a product application. The subject then decontaminated their hands with a 70% ethanol rinse and a nonmedicated soap wash, and used a second test article configuration. This procedure was repeated twice more with the remaining test article configurations. The baseline and all post-application samples were evaluated for the presence of *Escherichia coli* (ATCC #11229). The four test configurations were assigned randomly according to an incomplete crossover design; that is, the order of use of each configuration was randomly determined. Testing was performed per a modification of the methodology in the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450). The Study Protocol was approved by the Gallatin Institutional Review Board (GIRB) on 02/10/09. No deviations from the methodology described in the Study Protocol or from BioScience Laboratories, Inc., Standard Operating Procedures occurred during the course of this evaluation.

7.0 STUDY DATES:

STUDY INITIATION DATE:	02/06/09
EXPERIMENTAL START DATE:	02/13/09
EXPERIMENTAL END DATE:	02/23/09
STUDY COMPLETION DATE:	03/12/09

8.0 TEST MATERIALS:

The test articles were provided to the Testing Facility by the Sponsor. Responsibility for determination of the identity, strength, purity, composition, stability, and solubility of the test articles, as well as responsibility for retention of the test articles, remained with the Sponsor.

Test Article #1:	GOJO Luxury Foam Handwash (5400-520)
Active Ingredient:	N/A
Lot Number:	322503
Expiration Date:	11/2011

Test Article #2:	PURELL® Hand Sanitizing Gel VF481 (9900-501)
Active Ingredient:	70% ethanol
Lot Number:	306273
Expiration Date:	04/2010

Test Article #3:	PURELL® Instant Hand Sanitizer Foam (9800-502)
Active Ingredient:	62% ethanol
Lot Number:	320887
Expiration Date:	11/2010

9.0 EQUIPMENT AND SUPPLIES:

The equipment and supplies used for this study are summarized in the Study Protocol, included as Addendum I of this Final Report, and are also detailed on the Clinical Trials Equipment Tracking Forms (Form No. 01-L-009) and the Clinical Trials Supplies Tracking Forms (Form 01-L-008) in Addendum VII of this Final Report.

10.0 MEDIA:

The growth media and diluting fluids used in this study are as described in the Study Protocol in Addendum I of this Final Report. Additional details are recorded on the Media/Diluent Tracking Forms (Form No. 97-L-007) in Addendum VII of this Final Report.

11.0 SUBJECT DEMOGRAPHICS:

Twenty overtly healthy subjects at least 18 years of age were admitted into the study. Twelve subjects received product during testing. Insofar as possible, the group of subjects selected was of mixed sex, age, and race. Hands and forearms were free from clinically evident dermatoses, injuries, and/or any other disorders that may have compromised the subject and the study. All subjects who participated in the Study signed the Study Description and Informed Consent Form, Subject Confidential Information and Acceptance Criteria, and Authorization to Use and Disclose Protected Health Information Form (Appendix I of Addendum I of this Final Report) and List of Restricted Products (Appendix II of Addendum I of this Final Report) prior to participating in the study. The demographics of the study are presented in the table below.

DEMOGRAPHIC SUMMARY	ALL SUBJECTS	
	Recruited	Received Product
AGE		
Minimum Age	18	19
Median Age	42	49
Maximum Age	71	71
SEX		
Males (M)	8	3
Females (F)	12	9
Total	*20*	*12*
RACE		
White/Caucasian (C)	20	12
Total	*20*	*12*
DID NOT PARTICIPATE IN TESTING		
QC = Qualification (Inclusion/Exclusion) Criteria Failure	6	
NS = No Show	2	

12.0 ADVERSE EVENTS:

No subject experienced an adverse event during or following completion of this study.

13.0 NEUTRALIZATION:

A neutralization assay was performed to assure that the neutralizer(s) used in the recovery medium quenched the antibacterial properties of the test articles. Study procedures were based on guidelines set forth in ASTM E 1054-08, *Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents. Escherichia coli* (ATCC #11229) was used as the challenge species in the neutralizer validation study.

14.0 TEST METHODS:

14.1 Each subject was in testing for approximately five hours on a single day and used each of the four test article configurations. Prior to being admitted into testing, subjects were questioned regarding their adherence to protocol requirements. Subjects clipped their fingernails to a free edge of ≤ 1 mm, if they had not already done so. All jewelry was removed from the hands and arms prior to washing.

14.2 A handwash was performed using a nonmedicated soap to remove dirt and oil from the hands. A technician instructed subjects in the appropriate technique and verified its proper execution. The temperature of the water used for this and any subsequent wash or rinse procedures was controlled at 40° ± 2°C.

Inoculum Application Procedure

14.3 A total of 4.5 mL of the beef broth suspension containing at least 1×10^9 CFU/mL of *Escherichia coli* (ATCC #11229) was transferred into each subject's cupped hands in three aliquant amounts.

14.3.1 A 1.5 mL aliquot of the challenge suspension was dispensed into the subject's cupped hands. The suspension was distributed over the entire surface of the hands (front and back), not reaching above the wrists, for 20 ± 5 seconds. Following distribution of the inoculum, the hands were held motionless, away from the body, and allowed to air-dry for 30 ± 5 seconds.

14.3.2 The procedure in Section 14.3.1 was repeated.

14.3.3 A final 1.5 mL of the challenge suspension was dispensed into the subject's cupped hands and distributed over the entire surface of the hands (front and back), not reaching above the wrists, for 20 ± 5 seconds. The hands were allowed to air-dry for 90 seconds.

14.4 After the timed 90-second air-dry, the Glove Juice Sampling Procedure (Section 12.45 of the Study Protocol) was performed. This first contamination cycle provided the baseline population level. It was followed with a 30-second handwash using nonmedicated soap.

14.5 The challenge suspension was again dispensed into each subject's cupped hands and distributed. After a timed 90-second air-dry, the subjects applied their randomly assigned test article configuration according to the directions below.

14.6 Test Article Configuration #1 Application Procedure

14.6.1 Subject wet their hands within 10 seconds of completing the drying step (Section 14.5).

14.6.2 Two pumps (approximately 1.4 mL) of Test Article #1 were placed in the subject's cupped hands.

14.6.3 Subject lathered Test Article #1 for 15 seconds, followed by a 10-second rinse with water.

14.6.4 Following the water rinse, the subject used two paper towels to pat-dry hands for 10 seconds.

14.7 Test Article Configuration #2 Application Procedure

14.7.1 Within 10 seconds of completing the drying step (Section 14.5), one pump (approximately 1.5 mL) of Test Article #2 was placed in the subject's cupped hands, and the hands were rubbed together until dry.

14.8 Test Article Configuration #3 Application Procedure

14.8.1 Two pumps (approximately 3.0 mL) of Test Article #2 were placed in the subject's cupped hands within 10 seconds of completing the drying step (Section 14.5).

14.8.2 Subject rubbed Test Article #2 into the hands in a vigorous manner for 15 seconds.

14.8.3 Subject then used two paper towels to pat-dry hands for 10 seconds.

14.8.4 An additional one pump (approximately 1.5 mL) of Test Article #2 was placed in the subject's cupped hands, and the hands were rubbed together until dry.

14.9 Test Article Configuration #4 Application Procedure

14.9.1 Four pumps (approximately 2.8 mL) of Test Article #3 were placed in the subject's cupped hands within 10 seconds of completing the drying step (Section 14.5).

14.9.2 Subject rubbed Test Article #3 into the hands in a vigorous manner for 15 seconds.

14.9.3 Subject then used two paper towels to pat-dry hands for 10 seconds.

14.9.4 An additional two pumps (approximately 1.4 mL) of Test Article #3 were placed in the subject's cupped hands, and the hands were rubbed together until dry.

14.10 Each subject used each of the four test article configurations, one at a time, per specified application procedures. After the Glove Juice Sampling Procedure was performed following test article application, and prior to use of another test article configuration, subjects were required to perform a 1-minute rinse with 70% ethanol and an air-dry, followed by a 30-second handwash using a nonmedicated soap. Subjects waited a minimum of 20 minutes following the use of the nonmedicated soap before using another test article.

15.0 STATISTICAL ANALYSIS:

15.1 Minitab® Statistical Software package was used for all statistical calculations. All statistical tests were calculated using the 0.05 level of significance for Type I (α) error.

15.2 Descriptive statistics and confidence intervals were calculated using the 0.05 level of significance for Type I (α) error. Statistical calculations of means and standard deviations were generated on the $\log_{10}$ recovery data from baseline samples, post-product application samples, and the $\log_{10}$ differences between baseline and post-application samples.

15.3 The critical index for this study was a 2.0 $\log_{10}$ reduction after product application.

16.0 RESULTS - TABLES I THROUGH VIII AND FIGURE 1:

16.1 Table I presents a statistical summary of the $\log_{10}$ recovery values following application of Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels).

16.2 Table II presents the $\log_{10}$ values and $\log_{10}$ reduction from baseline values, by subject and hand, following application of Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels).

16.3 Table III presents a statistical summary of the $\log_{10}$ recovery values following application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] rubbed until dry).

16.4 Table IV presents the $\log_{10}$ values and $\log_{10}$ reduction from baseline values, by subject and hand, following application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] rubbed until dry).

16.5 Table V presents a statistical summary of the $\log_{10}$ recovery values following application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL], pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry).

16.6 Table VI presents the $\log_{10}$ values and $\log_{10}$ reduction from baseline values, by subject and hand, following application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL], pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry).

16.7 Table VII presents a statistical summary of the $\log_{10}$ recovery values following application of Test Article #3, PURELL® Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL], pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry).

16.8 Table VIII presents the $\log_{10}$ values and $\log_{10}$ reduction from baseline values, by subject and hand, following application of Test Article #3, PURELL® Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL], pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry).

16.9 Figure 1 presents a graphical presentation of the mean $\log_{10}$ reductions from baseline following application of each test article per the four test article application procedures.

Table I: Statistical Summary of the log_{10} Recovery Values Following Application of Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels)

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	24	7.77	0.31	7.64 to 7.90
Application 1	24	4.85	0.53	4.63 to 5.07
Application 1 Log_{10} Reduction	24	2.92	0.61	2.66 to 3.18

Table II: Log_{10} Values and Log_{10} Reduction from Baseline Values by Subject and Hand Following Application of Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels)

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	7.91	4.82	3.09
	Right	7.87	4.96	2.91
2	Left	7.55	5.11	2.43
	Right	7.72	5.17	2.56
3	Left	7.82	4.69	3.13
	Right	7.77	4.96	2.81
6	Left	8.01	3.49	4.52
	Right	7.99	3.18	4.82
7	Left	8.07	5.08	2.99
	Right	8.11	5.38	2.73
8	Left	7.99	4.90	3.09
	Right	7.96	5.25	2.72
10	Left	6.92	4.51	2.41
	Right	6.93	4.76	2.16
11	Left	7.64	5.28	2.36
	Right	7.71	5.44	2.28
13	Left	7.78	4.70	3.08
	Right	7.98	5.04	2.94
14	Left	7.47	4.75	2.72
	Right	7.56	4.96	2.60
15	Left	7.84	4.81	3.04
	Right	7.86	4.80	3.06
16	Left	8.00	5.02	2.98
	Right	7.99	5.29	2.70

Table III: Statistical Summary of the log_{10} Recovery Values Following Application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] rubbed until dry)

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	24	7.88	0.29	7.76 to 8.00
Application 1	24	3.44	0.47	3.24 to 3.64
Application 1 Log_{10} Reduction	24	4.44	0.47	4.24 to 4.64

Table IV: Log_{10} Values and Log_{10} Reduction from Baseline Values by Subject and Hand Following Application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] rubbed until dry)

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	7.99	3.18	4.81
	Right	7.99	3.18	4.81
2	Left	7.89	3.18	4.71
	Right	7.95	3.18	4.76
3	Left	7.86	3.18	4.69
	Right	7.95	3.18	4.78
6	Left	7.99	3.18	4.81
	Right	8.02	3.18	4.84
7	Left	8.13	4.36	3.77
	Right	8.19	4.72	3.48
8	Left	7.98	3.18	4.80
	Right	7.98	3.18	4.80
10	Left	6.99	3.18	3.82
	Right	7.05	3.18	3.88
11	Left	8.03	4.14	3.89
	Right	8.02	4.39	3.63
13	Left	7.87	3.49	4.39
	Right	8.05	3.49	4.57
14	Left	7.63	3.49	4.14
	Right	7.63	3.66	3.97
15	Left	7.87	3.18	4.69
	Right	8.05	3.18	4.87
16	Left	8.03	3.18	4.86
	Right	7.98	3.18	4.80

Table V: Statistical Summary of the log_{10} Recovery Values Following Application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL], pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry)

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	24	7.79	0.33	7.65 to 7.93
Wash 1	24	3.18	0.00	3.18 to 3.18
Wash 1 Log_{10} Reduction	24	4.61	0.33	4.47 to 4.75

Table VI: Log_{10} Values and Log_{10} Reduction from Baseline Values by Subject and Hand Following Application of Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL], pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry)

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	7.90	3.18	4.73
	Right	7.96	3.18	4.78
2	Left	7.58	3.18	4.40
	Right	7.71	3.18	4.53
3	Left	7.95	3.18	4.78
	Right	7.98	3.18	4.79
6	Left	7.99	3.18	4.82
	Right	7.95	3.18	4.77
7	Left	8.19	3.18	5.02
	Right	8.23	3.18	5.06
8	Left	7.89	3.18	4.71
	Right	7.90	3.18	4.73
10	Left	7.34	3.18	4.16
	Right	7.21	3.18	4.03
11	Left	7.95	3.18	4.77
	Right	7.89	3.18	4.71
13	Left	7.75	3.18	4.58
	Right	7.85	3.18	4.68
14	Left	7.07	3.18	3.89
	Right	6.98	3.18	3.81
15	Left	7.80	3.18	4.62
	Right	7.73	3.18	4.55
16	Left	8.01	3.18	4.83
	Right	8.16	3.18	4.98

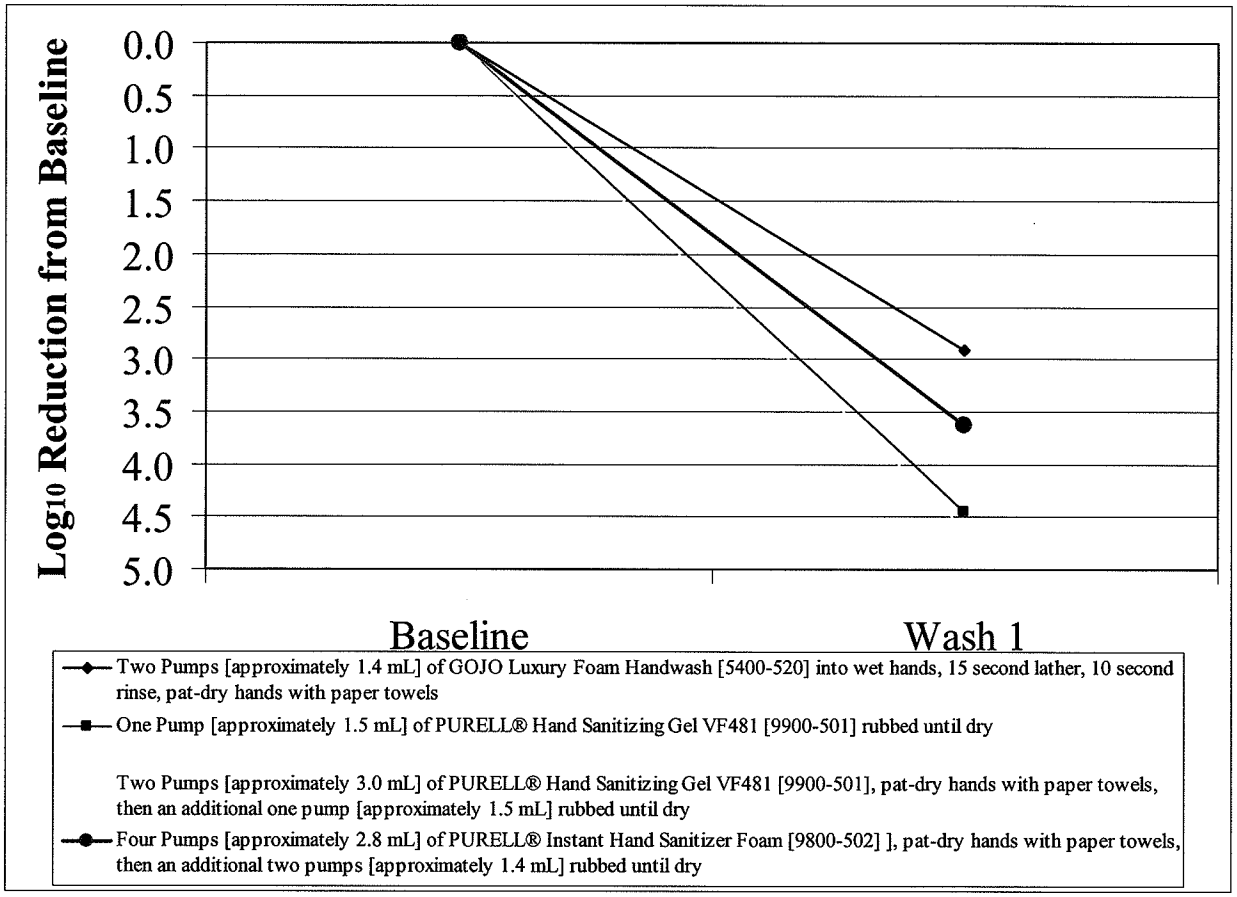
Table VII: Statistical Summary of the log_{10} Recovery Values Following Application of Test Article #3, PURELL® Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL], pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry)

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	24	7.80	0.34	7.66 to 7.94
Wash 1	24	4.16	0.56	3.93 to 4.40
Wash 1 Log_{10} Reduction	24	3.64	0.57	3.40 to 3.88

Table VIII: Log_{10} Values and Log_{10} Reduction from Baseline Values by Subject and Hand Following Application of Test Article #3, PURELL® Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL], pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry)

Subject	Side	Baseline log_{10} Values	Application 1 log_{10} Values	Application 1 log_{10} Reduction from Baseline
1	Left	7.98	4.19	3.79
	Right	8.03	4.55	3.48
2	Left	7.89	4.53	3.37
	Right	7.79	4.51	3.28
3	Left	7.64	3.79	3.85
	Right	7.73	4.23	3.51
6	Left	7.79	4.72	3.08
	Right	7.80	4.81	2.99
7	Left	8.08	3.18	4.90
	Right	8.10	4.03	4.07
8	Left	8.18	4.23	3.95
	Right	8.19	5.03	3.16
10	Left	7.32	3.18	4.14
	Right	7.02	3.18	3.84
11	Left	7.96	4.57	3.39
	Right	7.88	4.58	3.29
13	Left	7.91	4.27	3.64
	Right	7.80	4.58	3.22
14	Left	7.21	4.85	2.36
	Right	7.03	3.79	3.24
15	Left	7.84	3.96	3.87
	Right	7.94	3.18	4.75
16	Left	8.06	4.23	3.83
	Right	8.11	3.79	4.32

Figure 1: Graphical Presentation of the Mean log_{10} Reductions from Baseline Following Application of Each Test Article per the Four Test Article Application Procedures



17.0 CONCLUSION:

The critical index for this study was a 2.0 log_{10} reduction in baseline populations after product application.

For Test Article #1, GOJO Luxury Foam Handwash (5400-520; Lot Number 322503), applied per Test Article Configuration #1 Application Procedure (two pumps [approximately 1.4 mL] of Test Article #1 into wet hands, 15-second lather, 10-second rinse, pat-dry hands with paper towels), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean log_{10} reduction of 2.92 after product application and met the critical index of the study.

For Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), applied per Test Article Configuration #2 Application Procedure (one pump [approximately 1.5 mL] of Test Article #2 rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2, applied per Test Article Configuration #2 Application Procedure, produced a mean log_{10} reduction of 4.44 after product application and met the critical index of the study.

For Test Article #2, PURELL® Hand Sanitizing Gel VF481 (9900-501; Lot Number 306273), applied per Test Article Configuration #3 Application Procedure (two pumps [approximately 3.0 mL] of Test Article #2, pat-dry hands with paper towels, then an additional one pump [approximately 1.5 mL] rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2, applied per Test Article Configuration #3 Application Procedure, produced a mean $\log_{10}$ reduction of 4.61 after product application and met the critical index of the study.

For Test Article #3, PURELL® Instant Hand Sanitizer Foam (9800-502; Lot Number 320887), applied per Test Article Configuration #4 Application Procedure (four pumps [approximately 2.8 mL] of Test Article #3, pat-dry hands with paper towels, then an additional two pumps [approximately 1.4 mL] rubbed until dry), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 produced a mean $\log_{10}$ reduction of 3.64 after product application and met the critical index of the study.

18.0 LABORATORY PERSONNEL:

The following employees of BioScience Laboratories, Inc., were involved in the testing or ancillary support of this Study. The laboratory personnel have been appropriately trained, and their training records are on file in the Quality Assurance Unit at the Testing Facility.

STUDY DIRECTOR:	Robert R. McCormack Microbiologist
ASSOCIATE STUDY DIRECTOR:	Kendra Drake Microbiologist
Tammy Anderson IRB Coordinator	Nathan Nash Microbiologist
Jessica Baumgartner Microbiologist	Ron Neibauer Manager of Clinical Laboratories
Amanda Berry Supervisor of Subject Recruitment	Jeana Paulson Microbiologist
Stephanie Cebulla Laboratory Support Technician	Stephanie Scarff Laboratory Support Technician
Collette Duley Microbiologist	Amanda Shaffer Microbiologist
B. Cole Irvin Microbiologist	Jessica Sheehy Microbiologist
Patricia A. Mays Suko Supervisor of Laboratory Support	Clare Wilson Microbiologist

19.0 QUALITY ASSURANCE PERSONNEL:

Alicia Bogert
Quality Assurance Associate/Product Handling

Scott D. Ferraro
Manager of Quality Control

Amy L. Juhnke
Manager of Quality Assurance/Document Control

John A. Mitchell, Ph.D.
Director of Quality Assurance

Janis Smoke
Quality Assurance Associate

20.0 DOCUMENTATION AND RECORD-KEEPING:

All documentation and records were compiled, analyzed, and will be retained by BioScience Laboratories, Inc., at its facility in Bozeman, Montana. All raw data for this study, as well as the Final Report, will be retained in safe storage by the Testing Facility for a period of at least three years. BioScience Laboratories, Inc. will notify the Sponsor before any documents or records are destroyed.

21.0 ACCEPTANCE:

BIOSCIENCE LABORATORIES, INC. (TESTING FACILITY)
300 N. Willson Avenue
Bozeman, Montana 59715

President & CEO: _____ 03-12-09
Daryl S. Paulson, Ph.D. — Date

Principal Study Director: _____ 03/12/09
Robert McCormack — Study Completion Date

Associate Study Director: _____ 03/12/09
Kendra Drake — Date

Senior Clinical Director: _____ 03/12/09
Christopher M. Beausoleil, CCRP — Date

QUALITY ASSURANCE STATEMENT:

This study was inspected by the Quality Assurance Unit, and reports were submitted to the Study Director and Management in accordance with Standard Operating Procedures, as follows:

Phase	Date
Neutralization Assay	02/13/09
Product Testing	02/18/09
Data Audit	03/03/09 and 03/04/09
Final Report Review	03/11/09
Reports to Study Director and Management	02/13/09, 02/18/09, and 03/12/09

This study was conducted in compliance with Good Laboratory Practices standards, as described by the FDA (reference CFR 21 Parts 50, 56, 312, and 314), with the following exception: test article preparations were not analyzed at BioScience Laboratories, Inc., to confirm concentration, stability, or homogeneity.

Quality Assurance/ Associate: _____ 03/12/09
Janis Smoke — Date

INDEX OF ADDENDA

I GIRB-Approved Protocol #081211-150

II Qualification Criteria Questionnaire for Study 081211-150
Qualification Criteria of the Subject for Study 081211-150

III Sampling Data Sheets for Healthcare Personnel Handwash Study 081211-150
Irritation Evaluations for Study 081211-150

IV Neutralization Evaluation
- Neutralization Evaluation Results for Study 081211-150
- Project Notes (Form No. 95-G-001)
- Neutralization Evaluation Data Sheets for Protocol 081211-150
- Neutralization Statistics

V Q-Count™ Plate Counter Data Sheets (Form No. 00-L-009)
Q-Count™ Plate Count Data

VI Statistical Analysis

VII Study Notes and General Records
- Project Notes (Form No. 95-G-001)
- Age Calculation and Demographics Worksheet
- Study 081211-150 Randomization Scheme
- Clinical Trials Equipment Tracking Forms (Form No. 01-L-009)
- Clinical Trials Supplies Tracking Forms (Form No. 01-L-008)
- Water Temperature Monitoring Sheet (Form No. 96-CT-017)
- Incubator Log Forms (Form No. 96-L-008)
- Refrigerator Log Form (Form No. 96-L-015)
- Inoculum Preparation Tracking Form - Solid Media Preparation (Form No. 07-CT-002)
- Inoculum Preparation Tracking Form - Flask Preparation (Form No. 07-CT-001)
- Autoplate® 4000 Data Sheet for Healthcare Personnel Handwash Study 081211-150
- Media/Diluent Tracking Forms (Form No. 97-L-007)

VIII Product Information
- Product Receipt Log (Form No. 92-L-023)
- Sample Submission Form and Document Compliance Statement (Form No. 94-G-007)
- Material Safety Data Sheet (MSDS)
- Product-Tracking Forms (Form No. 93-L-029)

Sequential Application of Hand Antiseptic for Use in No-Water Situations (dubbed SaniTwice)

A New Hand Hygiene Option

Robert R. McCormack
BioScience Laboratories, Inc.
March 25, 2009

Background

- Current FDA Model Food Code requires food handlers to wash with soap and water to maintain clean hands.
- A reliable method of hand sanitization is needed for remote locations where water is not readily available. Among the many situations is the need to cleanse hands between changes of single-use gloves in no-water locations.

Background

- To meet this need, the “Sequential Application of Hand Antiseptic for Use in No-Water Situations” was developed:
  - A method of cleansing and sanitizing light to moderately soiled hands when soap and water are unavailable
  - Purpose is the removal and reduction of transient microorganisms from the hands

Study Objectives

- To demonstrate the antimicrobial effectiveness of this method as compared to standard handwashing with soap and water
- To evaluate the comparative effectiveness of various hand sanitizers for the reduction of bacteria when used in this methodology.

Modified Handwash Method

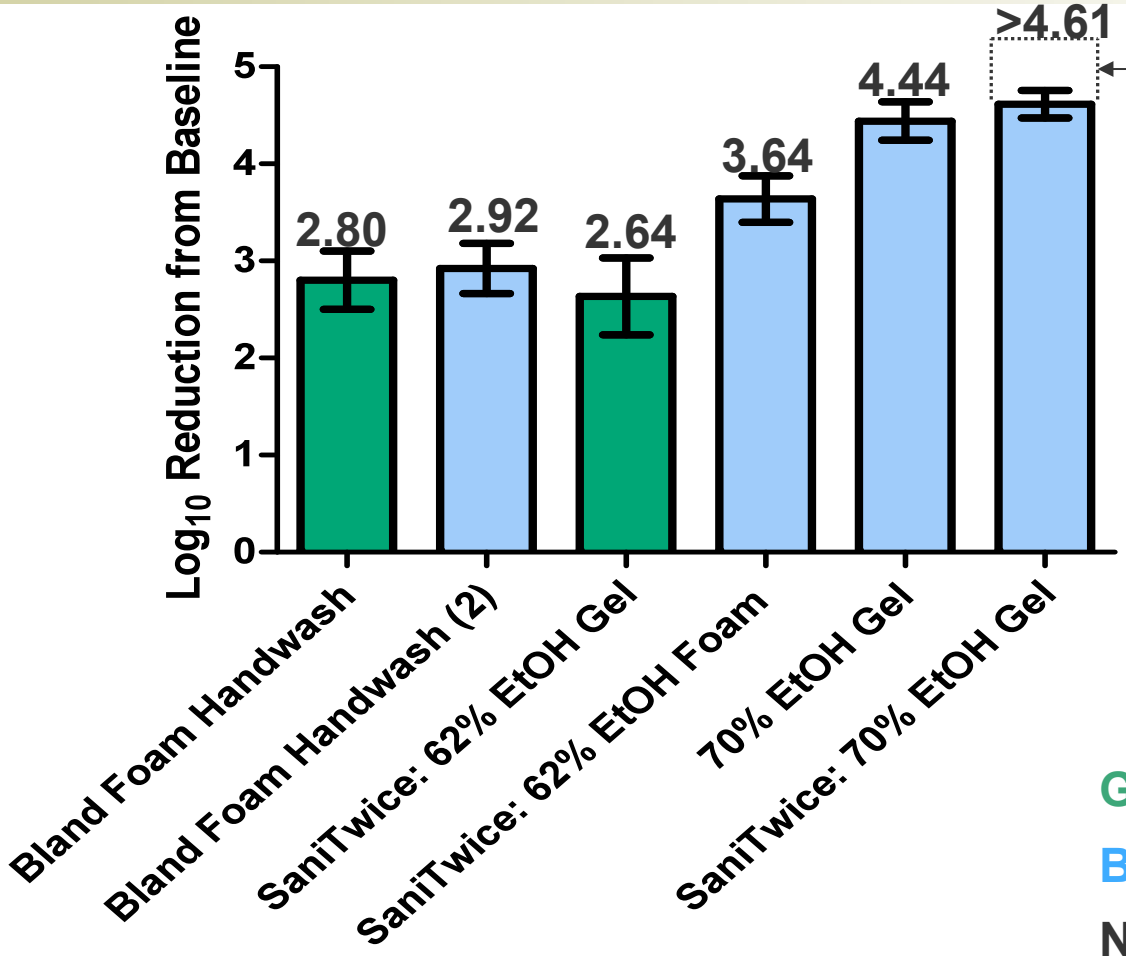
ASTM E1174

Step 1: Inoculate hands with about $1x10^9$ *Escherichia coli* (ATCC #11229) suspended in beef broth

(moderate soil conditions)

Step 2: Apply test product according to label application instructions

Results



Actual LR value is likely higher

(LR value reached detection limit of study)

Green: Study #1

Blue: Study #2

N ≥ 10

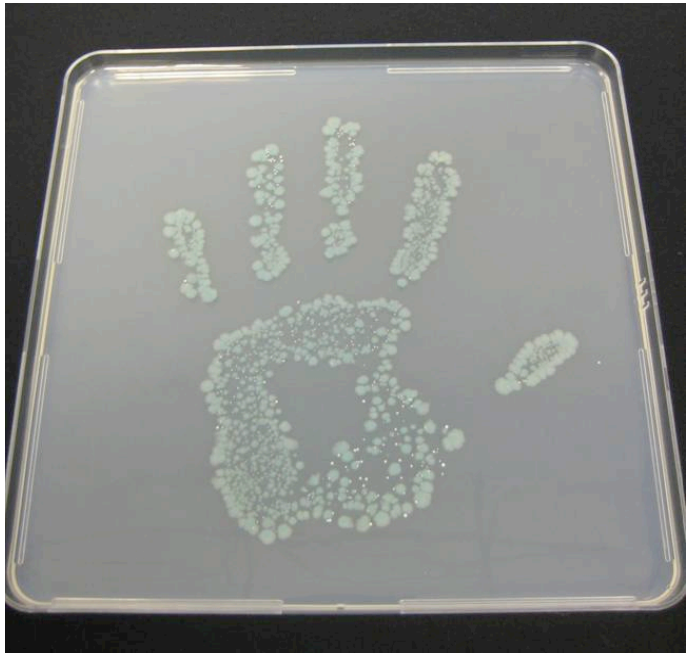
Statistical Analysis

- The antimicrobial efficacy of SaniTwice with 62% EtOH gel is equivalent to a typical bland handwash product

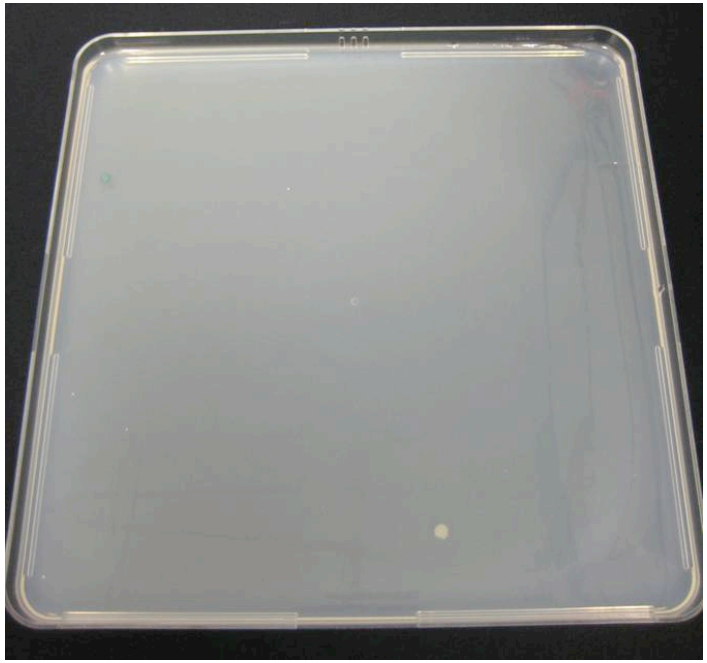
- SaniTwice with 62% EtOH foam is significantly better at reducing microorganisms on the hands than a typical bland handwash product

- SaniTwice with a high efficacy 70% EtOH gel is significantly better at reducing microorganisms on the hands than a typical bland handwash and the SaniTwice with 62% EtOH

What Does Your Hand Look Like After SaniTwice?



Hand contaminated with *E. coli*



Hand after performing SaniTwice with 70% EtOH gel

Conclusions

- Sequential Application of Hand Antiseptic for Use in No-Water Situations (SaniTwice) is an acceptable alternative to handwashing with soap and water
  - All SaniTwice regimens tested were equivalent or better at reducing the number of microorganisms on the hands than standard washing with soap and water

Conclusions

- There are statistically differentiated SaniTwice options based on antimicrobial efficacy requirements:
  - Good (62% EtOH gel)
  - Better (62% EtOH foam)
  - Best (High efficacy 70% EtOH gel)

Conclusions

- Use of a high efficacy product (70% EtOH gel) with the SaniTwice method results in superior reduction of bacteria on the hands
  - Complete kill of microorganisms (>4.61 LR)
  - SaniTwice is effective at cleansing and sanitizing the hands whereas using the product according to label instructions only sanitizes and does not clean the hands

Why Use SaniTwice?

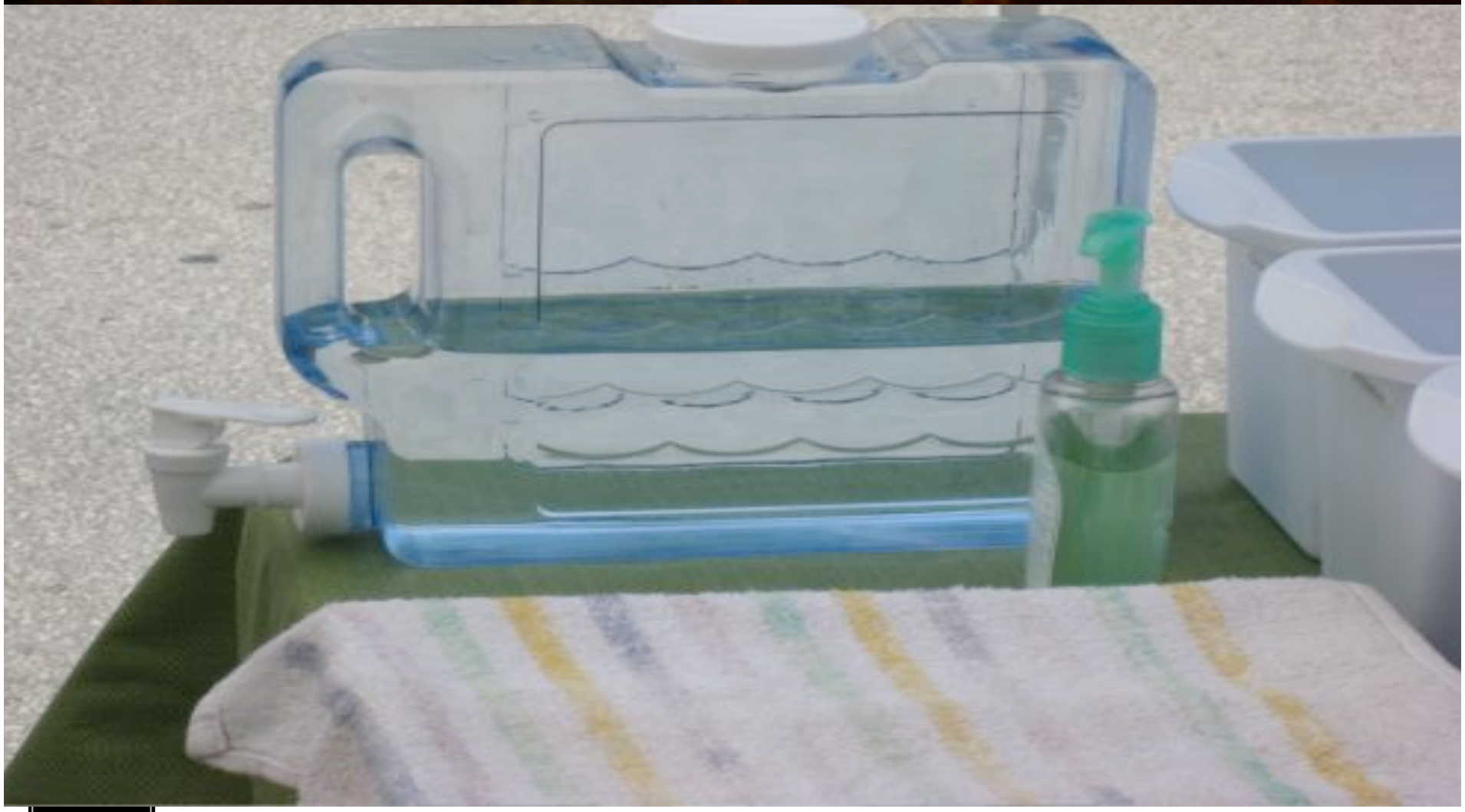
- SaniTwice is a simple method that requires only a supply of hand sanitizer and paper towels
- Use of the SaniTwice method in remote locations is an acceptable alternative to handwashing
- Use of the SaniTwice method with a high efficacy hand sanitizer will result in improved sanitization over soap and water alone

Why Use SaniTwice?

- It is actually used as confirmed by extended field testing under the guidance of the Southern Nevada Health District
- Superior to currently approved hand hygiene interventions for no-water situations as seen in the following two photos taken in Illinois
- (Other photos are available from the 2008 CFP venue in San Antonio Texas.)

Food Code Approved Intervention

Food Code Approved Intervention



Contact Information

Robert R. McCormack

Principal Study Director in Clinical Trial Laboratories

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SaniTwice®: A Hand Hygiene Solution for Food Handlers When Water is Unavailable

Sarah Edmonds[1], Cara Bondi[1], Robert McCormack[3], David Macinga[1], James Arbogast[1], James Mann[2], Michael Dolan[1]

1. GOJO Industries, Inc.
2. Handwashing for Life
3. BioScience Laboratories

IAFP 13July09
T2-08

Agenda

- Why “Sink-less” Hand Hygiene
- The SaniTwice® Solution
- FDA Model Food Code Considerations
- Conclusions

“Sink-less” Hand Hygiene

- Definition: hand hygiene (degerming) performed in settings where water is not available or is in limited supply
- Historically, a challenge without practical and effective solutions

Food Safety Challenge: Portable Bars

Food Safety Challenge: Military Buffet Line

Food Safety Challenge: Community Event

Food Safety Challenge: Cookoff

Food Safety Challenge: The Picnic

Food Safety Challenge: Symposium Serving Line

“Sink-less” Hand Hygiene

- Why not just have portable hand washing (i.e., the current paradigm)?

Food Safety Reality: Trickle Handwashing

Food Safety Reality: Trickle Handwashing

Is This Effective Hand Hygiene?

The SaniTwice® Solution

The SaniTwice Solution

- A reliable method of hand sanitization for (remote) locations where water is not available or in short supply
- A two stage method, “clean and kill”, for cleansing and sanitizing light to moderately soiled hands when soap and water are unavailable
- Purpose is the removal and reduction of transient microorganisms from the hands
- Benefit is reduction in risk of foodborne illness due to inadequate hand hygiene

SaniTwice Method

Step 1:

Apply excess of hand sanitizer (about 3 mL) and "wash" hands vigorously for 15 seconds

Step 2:

Remove remaining hand sanitizer and soil forcefully with paper towel while hands are still wet

Step 3:

Rub recommended amount (about 1.5 mL) of hand sanitizer on hands until dry

The SaniTwice Solution

Performance Study:

- *In vivo* microbiological efficacy

Study Objectives:

- Determine the effectiveness of the SaniTwice method as compared to standard handwashing with soap and water
- Compare effectiveness of various hand sanitizers when used in the SaniTwice methodology

Test Product Configurations

Test Product	Active	Application Method
Non-Antimicrobial Foam Handwash	N/A	Wash (Apply ~1.5ml, wash for 15s, rinse for 10s, towel dry)
Instant Hand Sanitizer Gel	62% ethanol	SaniTwice
Instant Hand Sanitizer Foam	62% ethanol	SaniTwice
Advanced Formula Instant Hand Sanitizer Gel	70% ethanol	Sanitize (Apply ~1.5ml, rub until dry)
Advanced Formula Instant Hand Sanitizer Gel	70% ethanol	SaniTwice

Two studies were conducted at BioScience Laboratories (2008-09)

Modified Handwash Method

ASTM E1174

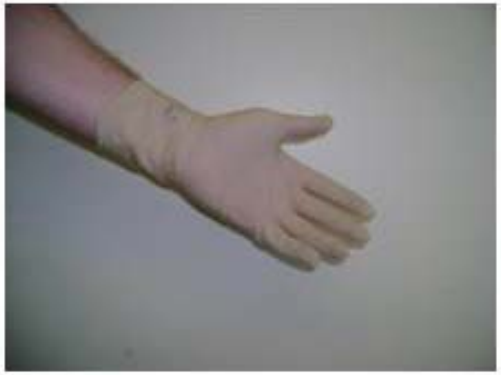
Step 1: Contaminate hands with about $1x10^9$ *Escherichia coli* (ATCC #11229) suspended in beef broth

(moderate soil conditions)

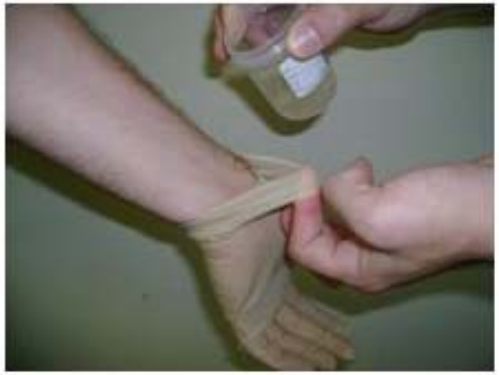
Step 2: Apply test product according to application instructions

Bacterial Measurement Steps

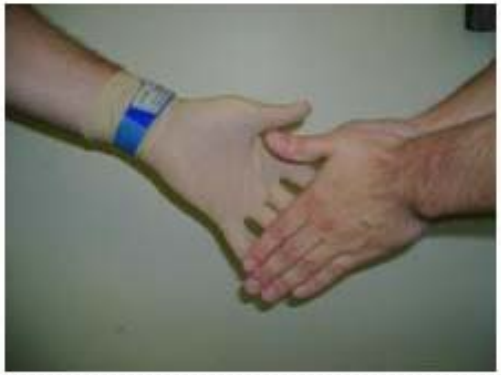
Step 3. Placement of sterile, latex glove



Step 4. Addition of sterile sampling fluid (GJ)



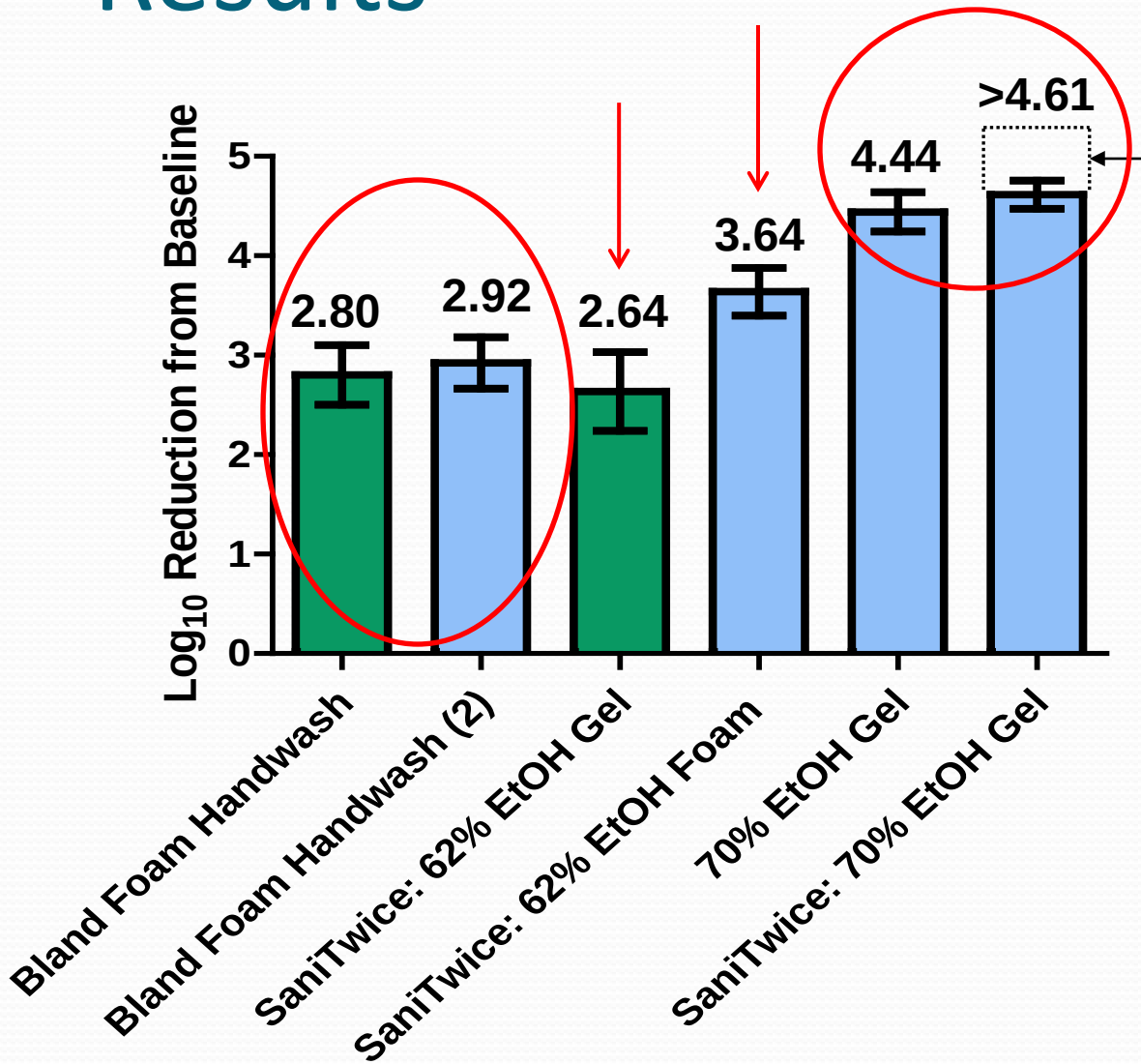
Step 5. Massage hand for 60 seconds



Step 6. Remove sample of glove-juice

Step 7: Serially dilute in neutralizing solution, plate on MacConkey Agar, grow overnight and compare to baseline values to calculate log reductions

Results



Actual LR value is likely higher

(LR value reached detection limit of study)

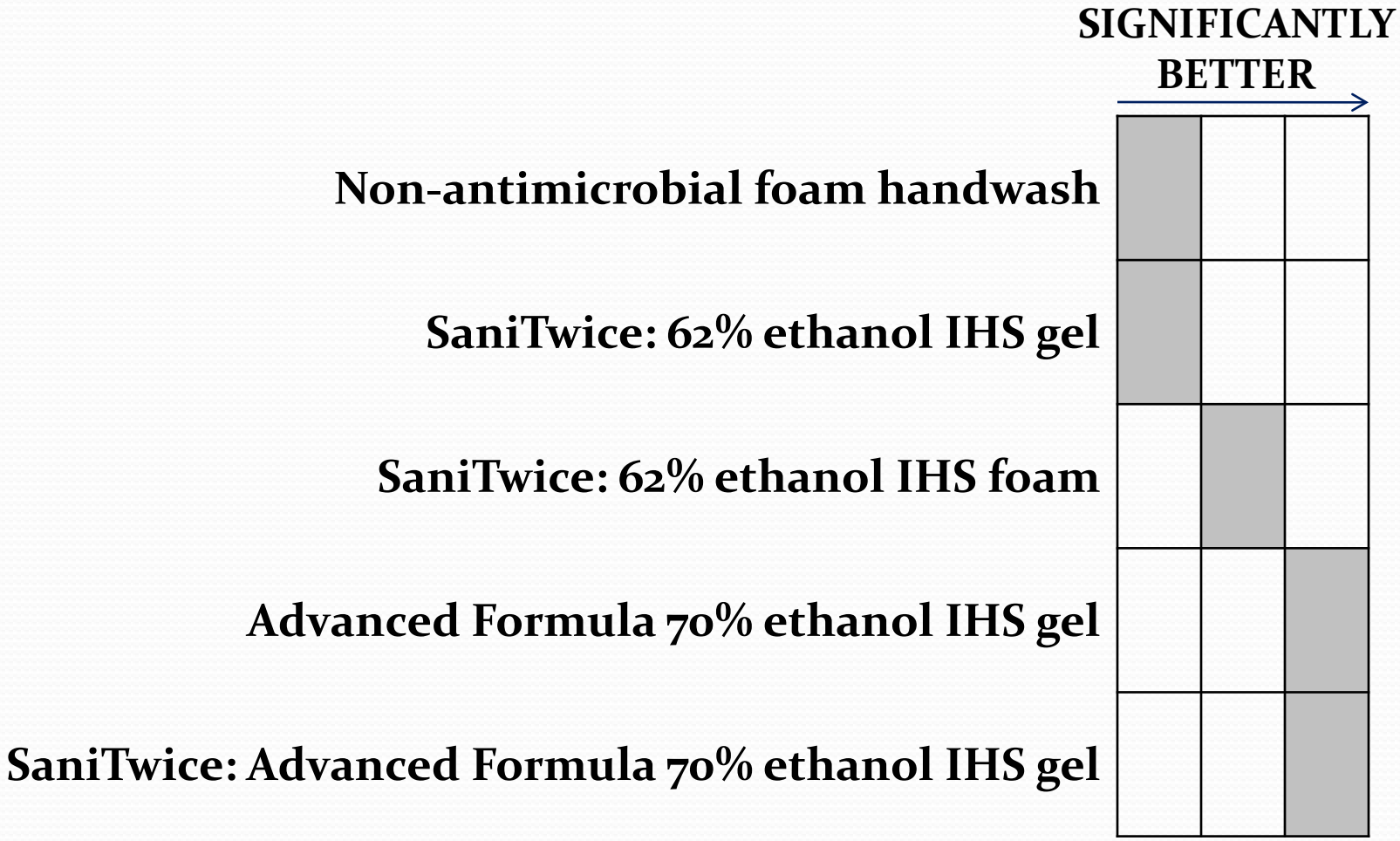
Green: Study #1

N=11

Blue: Study #2

N=12

Statistical Analysis



1 way ANOVA followed by post-hoc analysis ($p<0.05$)

What Does Your Hand Look Like After SaniTwice?

Hand contaminated with *E. coli*

Hand after performing SaniTwice with Advanced Formula 70% ethanol gel

Conclusions

- SaniTwice is an acceptable alternative to handwashing with soap and water
  - All SaniTwice regimens tested were equivalent or better than standard washing with soap and water
- SaniTwice is a good substitute to trickle handwashing for “sink-less” food handling situations

Conclusions

- There are statistically differentiated SaniTwice options based on efficacy results:
  - Good (62% ethanol IHS gel)
  - Better (62% ethanol IHS foam)
  - Best (Advanced Formula 70% ethanol IHS gel)

Conclusions

- Use of the Advanced Formula 70% ethanol gel with the SaniTwice method resulted in superior reduction of bacteria on the hands compared to washing with a non-antimicrobial handwash and water alone
  - Complete kill of microorganisms (>4.61 LR)

- The Advanced Formula 70% ethanol gel was highly effective at reducing bacteria on the hands when used alone; however, the SaniTwice method has the additional benefit of skin cleansing and soil removal

SaniTwice Field Research Study:
The Venetian Portable Bars

High User Acceptability and Compliance to the SaniTwice Regimen

FDA Model Food Code (2005)

- Section 2-301.16 outlines parameters for hand antiseptics:
  - "applied only to hands that are cleaned as specified under § 2-301.12."

There is now clear scientific and practical rationale for including the SaniTwice approach in the Food Code

- SaniTwice has been shown to be an effective hand hygiene regimen, equivalent in degerming to handwashing with soap and water as specified in Section 2-301.12(B)

In Conclusion…

Prayer is Good;

SaniTwice, Even Better!

GOJO INDUSTRIES

Internal Communication

CONFIDENTIAL

TO: Geo Money, Chris Fricker, Amy Stokes

FYI: Dave Macinga, Jim Arbogast, Mike Dolan, Jim Mann

FROM: Sarah Edmonds

SUBJECT: **TEST RESULTS FOR HEAVY SOIL PILOT SANITWICE STUDY**

DATE: December 2, 2009

STUDY OBJECTIVES:

- **Preliminary evaluation of whether SaniTwice is as effective as handwashing for reducing bacteria on heavily soiled hands**
- **Determine optimal soil type for full heavy soil SaniTwice study**

TEST PRODUCT CONFIGURATIONS:	ACTIVE:
GOJO Luxury Foam Handwash (5200-502) Wash for 15s with 2 pumps (~1.4 ml), rinse for 10s, towel dry	N/A
SaniTwice with PURELL Foam (9800-504) Apply 4 pumps (~2.8 ml), towel dry, apply 2 pumps (~1.4 ml) and rub until dry	62% ethanol

TEST METHOD: A modification of the USFDA Tentative Final Monograph for: *Effectiveness Testing of an Antiseptic Handwash or Health-Care Personnel Handwash* (FR59:116, 17 June 94, pp.31448-31450) using *Escherichia coli* (ATCC #11229) suspended in either chicken chunks or raw hamburger patties

TESTING LAB: Bioscience Laboratories, Bozeman, Montana, Study #091010-150

RESULTS:

Test Configuration	LR	SD	95% CI
Chicken Chunk Contamination			
GOJO Luxury Foam Handwash	2.96	0.48	2.62-3.30
SaniTwice with PURELL Foam	3.32	0.43	3.01-3.63
Raw Hamburger Contamination			
GOJO Luxury Foam Handwash	2.58	0.41	2.28-2.87
SaniTwice with PURELL Foam	2.69	0.34	2.45-2.93
Results Below from Previous SaniTwice Study # 081211-150 (beef broth as soil load)			
GOJO Luxury Foam Handwash	2.92	0.61	2.66-3.18
SaniTwice with PURELL Foam	3.64	0.57	3.40-3.88

LR=log reduction from baseline; SD=standard deviation; CI=confidence interval; N=10

CONCLUSIONS:

- **SaniTwice was as effective as handwashing for reducing bacteria on heavily soiled hands**
  - **Effective with chicken and raw beef soils**
- **As expected the raw beef appears to be a more difficult soil to penetrate**
  - **Both the handwash and PURELL Foam SaniTwice achieved about a 0.5 higher log reduction with the chicken than the beef**

NEXT STEPS:

- Design and conduct full SaniTwice study with raw hamburger to represent "worst-case" heavy soils found in foodservice (SE)

Conference for Food Protection
2010 Issue Form

Internal Number: 067
Issue: 2010 III-017

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

All information above the line is for conference use only.

Title:

Elimination of Open, Refillable Soap Dispensers

Issue you would like the Conference to consider:

The Food Code emphasizes the critical role of hygiene in prevention of foodborne illness. Numerous sections of the 2009 Food Code address specifications and requirements for water quality, air supply, surface and utility cleanliness, and cleaning materials. Similarly, various Code Sections, including 2-102.11(C)(8), 2-301.11-16, 5-202.12, 5-203.11, 5-204.11 and 5-205.11, delineate sink and faucet parameters, handwashing procedures, and other aspects for proper handwashing in food handling operations. However, the Code lacks specification for the types of soap dispensing systems suitable for handwashing products in food handling settings. This important gap creates the potential for increased microbiological contamination due to the use of open, refillable reservoir-type dispensing systems. It has been known for decades that contaminated soap can lead to disease transfer. Following a number of infectious disease outbreaks, the use of open, refillable soap systems in Healthcare facilities was essentially eliminated in the 1990's and codified in the 2002 CDC/HICPAC Guidelines for Hand Hygiene in Health-Care Settings. Very recent guidance from Health Canada (issued December 2009) requires professional food handler antiseptic products to be labeled "Do not refill container", essentially banning bulk dispensing systems for food environments in Canada.

Recent research by the University of Arizona demonstrates that high level bacterial contamination of open, refillable soap dispensing systems is widespread, including retail Foodservice settings. Additional studies at the University of Montana show that on-going recontamination of fresh soap in refillable dispensers is due to biofilm formation and nearly impossible to eliminate despite aggressive cleaning procedures. Further, these studies show that biofilm contamination of open, refillable dispensers occurs regardless of design or materials of construction. Even more recent studies by GOJO Industries demonstrate that soap contamination transfers from the dispensed soap to the hands during washing and subsequently to surfaces (fomites).

Solutions to this contamination problem are readily available. A plethora of sealed, non refillable dispensing systems are virtually universally available. While some of these systems are proprietary, many are essentially commodity products in the same way that open systems are today, providing a facility with a broad choice of products and suppliers.

Public Health Significance:

High level contamination (approaching pure bacterial cultures) of open, refillable and non hygienic soap dispensers with coliforms and other pathogenic organisms represents an unnecessary risk of infection to foodservice workers and patrons.

Recommended Solution: The Conference recommends...:

a letter be sent to FDA requesting the following change to the Model Food Code:

5-202.11

(C) A dispensing system for hand soap and/or hand antiseptic shall be of a sealed-refill design and not have a product reservoir susceptible to refilling from a secondary container, "topping off", or dilution with water or other materials. If used, individual bottles of hand soap or hand disinfectant shall be disposed of after use of the initial contents and not refilled.

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Attachments:

- "Bacterial Contamination of Soap from Open, Refillable Bulk Dispensers"
- "Evaluation of Contaminated Bulk Soap Dispensers for Biofilm Bacteria"
- "Handwashing with Contaminated Soap Results in Hand Contamination"
- "Opportunistic Pathogens From Contaminated Bilk Soap on the Hands"
- "Open Refillable Bulk Soap Dispensers in Public Restrooms"
- "Guidance Document: Human-Use Antiseptic Drugs"

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

How Safe is Your Soap?

Bacterial Contamination of Soap from Open Refillable Bulk Dispensers

Charles P. Gerba, PhD

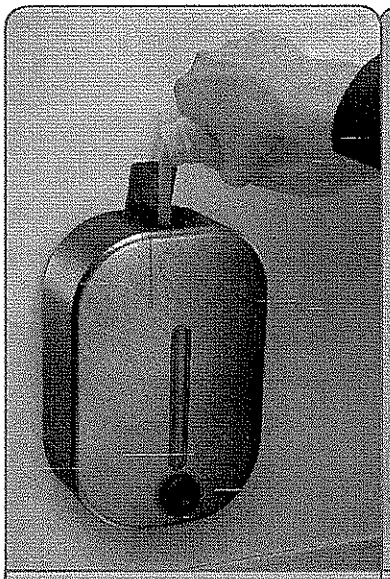
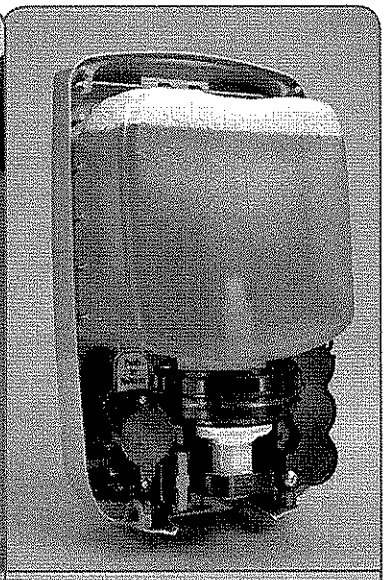
Marisa B. Chattman

Sheri L. Maxwell

An overview and summary of research studies conducted by The University of Arizona, Tucson, AZ, and presented to:

- The American Society for Microbiology 107th General Meeting
  Toronto, ON, Canada; May 21-25, 2007
- The National Environmental Health Association 71st Annual Educational Conference & Exhibition
  Atlantic City, NJ; June 18-21, 2007

Do you know the difference?

		
	Open Refillable Bulk Soap Dispenser	**Sealed Soap Dispensing System**
Design	• Open to the environment • Permanent nozzle is reused	• Factory sealed • New nozzle with each refill
Refilling Method	• Pour soap into dispenser from bottle	• Snap new cartridge into dispenser
Maintenance	• Labor intensive • Extensive cleaning and sanitizing required	• Labor-free • No need for cleaning and sanitizing
Contamination	• Prone to contamination	• Safe from contamination

Bacterial Contamination of Soap from Open Refillable Bulk Dispensers

Table of Contents

Bulk Soap Contamination Research Study Summary

Background

Several studies conducted during the last 25 years have demonstrated that liquid soaps can become contaminated with microorganisms and multiple instances of infections and nosocomial outbreaks associated with such contamination have been reported (1-4). Contamination often occurs after the product reaches the user (extrinsic contamination) (1;3;5) and has been observed in both nonmedicated (1) and antimicrobial products including those with the active ingredients Chloroxylenol (PCMX) (3), Benzalkonium chloride (5;6), Triclosan (4), and Chlorhexidine gluconate (2;5;7-10). All types of liquid soap, regardless of the active ingredient or preservative system, are susceptible to contamination when exposed to adverse circumstances. Soap dispensers with sealed disposable refills are an alternative to this contamination challenge. By contrast, open refillable ("bulk") soap dispensers continue to present significant risk of contamination during use. Because the addition of soap to a partially empty dispenser ("topping off") can lead to bacterial contamination in healthcare settings, the CDC recommends the use of soap dispensed from disposable containers or containers that are thoroughly washed and dried prior to refilling (11;12).

Recent studies conducted at the University of Arizona by prominent microbiologist, Dr. Charles P. Gerba, revealed that liquid hand soap collected from open refillable dispensers are a public health risk. Dr. Gerba determined the levels of bacteria in soap sampled from various types of dispensers. He found unsafe levels of bacterial contamination in soap from open refillable dispensers, whereas no bacterial contamination was found in soap from dispensers with sealed disposable refills. This research has been presented at two recent scientific conferences (13;14).

National Environmental Health Association 71st Annual Educational Conference & Exhibition
Atlantic City, NJ; June 18-21, 2007

Title: Bacterial Contamination of Liquid Hand Soaps Used in Public Restrooms

Authors: C. P. Gerba and S. Maxwell; University of Arizona, Tucson, AZ

Abstract

The objective of this study was to determine the occurrence of heterotrophic and coliform bacteria in liquid hand soaps collected from public restrooms across the United States. Sample locations included public restrooms in restaurants, health clubs, office buildings and retail stores. The liquid soap samples collected were from refillable dispensers (also referred to as "open systems" or "bulk soap" systems). Of 541 samples, 133 (25%) had bacterial numbers greater than 500 CFU/mL and 87 samples (16%) contained coliform bacteria. Approximately 65% of the bacteria isolated from the soap belonged to the coliform group. The average number of bacteria detected in the soap was 3.02 x 10^6 CFU/mL with a range of 590 to 5.3 x 10^7 CFU/mL. The average number of coliform bacteria was 3.94 x10^6 CFU/mL with a range of <10 to 6.5 x 10^7 CFU/mL. Opportunistic pathogens identified in the liquid soap samples included *Klebsiella oxytoca, Klebsiella pneumoniae, Enterobacter aerogenes, Serratia marcescens, Pseudomonas aeruginosa* and *Enterobacter sakazakii.* No bacteria were detected in dispensers that required sealed soap replacements. All of the organisms detected in the soap samples were Gram-negative bacteria. This is most likely because of the presence of sodium lauryl sulfate in the soap, which inhibits the growth of Gram- positive bacteria. The results suggest that some liquid soap dispensers become colonized by Gram-negative bacteria over time, possibly because of the degradation of preservatives in the liquid soap.

American Society for Microbiology 107th General Meeting
Toronto, ON, Canada; May 21-25, 2007

Title: Bacterial Contamination of Liquid Hand Soaps

Authors: M. Chattman, S. Maxwell and C. P. Gerba; University of Arizona, Tucson, AZ

Abstract

The occurrence of heterotrophic bacteria (HPC) and coliform bacteria in liquid hand soap from 130 refillable unsealed (a.k.a. open or bulk) dispensers collected from employee break rooms, airplane restrooms, kitchens and public restrooms was determined. The percentage of samples that contained HPC numbers above 500 CFU/mL was 23%, averaging 4.5 x 10^6 CFU/mL. Total coliform bacteria were detected in 22% of the samples, averaging 2.2 x 10^6 CFU/mL. Bacterial species most frequently identified included *Serratia marcescens, Enterobacter aerogenes,* and *Klebsiella pneumoniae.* One of the soap dispensers containing contaminated soap was monitored over a three month period. Various levels and types of bacterial contamination were observed. When bacteria were added to uncontaminated, factory-sealed, liquid hand soap the bacteria quickly died. Liquid hand soap from a public restroom, that contained large numbers of bacteria was pasteurized

and inoculated with *K. pneumoniae.* Growth was observed, indicating that degradation of preservatives must occur in the soap dispenser over time, allowing for the growth of bacteria. These results demonstrate that bacteria growing in soap dispensers are not resistant to the preservatives and that preservative degradation takes place, likely after introduction of the soap in the dispensers.

Contaminated Bulk Soap is a Public Health Risk

Dr. Gerba's studies demonstrate that soap from open refillable dispensers in public restrooms in the US are routinely contaminated with opportunistic pathogens. Soap users are exposed to an average of over 1,000,000 of these bacteria approximately 1 in 4 times they wash with soap from an open refillable soap dispenser. This level of contamination is 1000 times greater than upper limit recommended by cosmetic industry standards (15) and presents a potential health risk to the soap users as well as to others they may have contact with. Hands are known to be a common transmission vector and it has been shown that bacteria remain on the hands after using contaminated soap (1). The risk of acquiring an infection is greatest for anyone who has a defect in their body's normal defense mechanisms. Up to 20% of the US general public have impaired immune function and this percentage is growing due to advances in medicine which are prolonging life as well as the increase in the proportion of elderly in the population (16-18). The immunocompromised population includes a diverse group with a wide variety of conditions ranging from the severely immunocompromised (HIV/AIDS, cancer, organ or bone marrow transplant recipients) to pregnant women, young children and the elderly which exhibit non-specific general reduced immune function (19;20). The fetus, neonate and young children have reduced immune function for the first few years of life until their immune systems mature (19). Over 12% of the US population is over the age of 65 and are at a greater risk of acquiring infections due to their age-related diminished immunity (16;21). In addition, many common chronic conditions weaken the immune system including diabetes (which affects 10% of the population) (18), cirrhosis/alcoholism, chemical dependency, nutritional deficiencies, and any defects resulting in skin barrier function loss (burns, ulcers, or dermatitis) (17;20).

Illnesses Caused by the Contaminating Bacteria

In the recent study by Dr. Gerba, several of the bacterial species isolated from the contaminated soap (e.g. *Klebsiella, Enterobacter, Citrobacter, Serratia,* and *Pseudomonas*) are medically important opportunistic pathogens. These organisms cause a variety of illnesses including respiratory tract infections, pneumonia, urinary tract infections, bloodstream infections, surgical site infections, meningitis, skin ulcers, gastroenteritis as well as wound and soft tissue infections (22-24). *Klebsiella pneumoniae,* for example, is responsible for 1-5% of community-acquired pneumonia (25). *Enterobacter sakazakii* causes neonatal meningitis (26). *Citrobacter* causes sepsis, meningitis and central nervous system abscesses in neonates and young infants (27) and there has been one report of *Citrobacter koseri* causing a central nervous system infection in a healthy person with a fully functional immune system (28). *Citrobacter freundii* was also implicated as a potential cause of an outbreak of diarrheal disease (24). *Pseudomonas aeruginosa* is a common nosocomial pathogen causing urinary tract infections, sinusitis, wound infections, and pneumonia. Occasionally it has been known to cause a rare form of community-acquired pneumonia with a 33% mortality rate that can affect persons with healthy immune systems (29). *Serratia* has been implicated in multiple outbreaks due to contaminated soaps in healthcare facilities (1;3;4). *Pantoea* is a rare pathogen that was reported to be responsible for 7 infant deaths in a neonatal outbreak (30). The frequent presence of such high numbers of organisms known to be medically significant both in the community and in healthcare settings is quite alarming.

Reducing the Risks of Bulk Soap Contamination

Unsafe levels of contamination were found in 23% – 25% of soap samples collected from open refillable dispensers. In contrast, no contamination was found in soap samples collected from dispensers containing sealed disposable refills. It is recommended that all open refillable dispensers should be switched to dispensers with sealed disposable refills, which are a safer alternative and avoid unnecessary health risk.

Bacterial Contamination of Liquid Hand Soaps

Introduction

Liquid hand soap is used daily by millions of people worldwide. Hand washing, with soap and water, is a universally accepted method to reduce the microbial load on the hands. People encounter situations in which they are exposed to a variety of bacteria that have the ability to cause infection. In response to these situations, many people wash their hands with soap and water. Society recognizes that good hygiene can reduce the risk of bacterial infection. Some public facilities have soap dispensers that require sealed bags or cartridges while others have dispensers that are refillable by using stock soap solutions that are often diluted with tap water. Bulk open refillable liquid soap dispensers in many public restrooms and restaurants, offer a suitable environment for the growth of potentially disease causing microorganisms.

Materials and Methods

Soap was collected into sterile 50mL centrifuge tubes through the dispenser mechanism. One mL of Dey-Enger (DE) neutralizing broth (Remel, Lenexa, KS) was added to each sample tube and shaken for 30 seconds. Heterotrophic plate counts (HPC) were obtained by spread plating 0.1mL onto duplicate petri dishes containing R2A media (Difco, Sparks, MD) and incubated at 30°C for 5 days.

Coliform enumeration was performed by spread plating on mEndo agar plates (Difco, Sparks, MD) and incubating at 37°C for 24 hours. Representatives of each colony type were streaked for isolation on petri dishes containing Tryptic Soy Agar (TSA) (Difco, Sparks, MD). Identification of bacteria was performed by using API20E strips (BioMerieux, Marcy-l'Etoile, France).

Results

Table 1: Occurrence of Bacteria in Liquid Hand Soap from Refillable Dispensers

Type of soap dispenser	Total number of liquid soap samples tested	Number >500 CFU/mL	Coliform bacteria	Average number HPC CFU/mL	Average number coliform bacteria CFU/mL
Refillable	132	30	29	4.5×10^6	2.2×10^6
Disposable bag	20	0	0	0	0

Figure 1: Frequency of Detection of Various Bacteria in Soap Samples

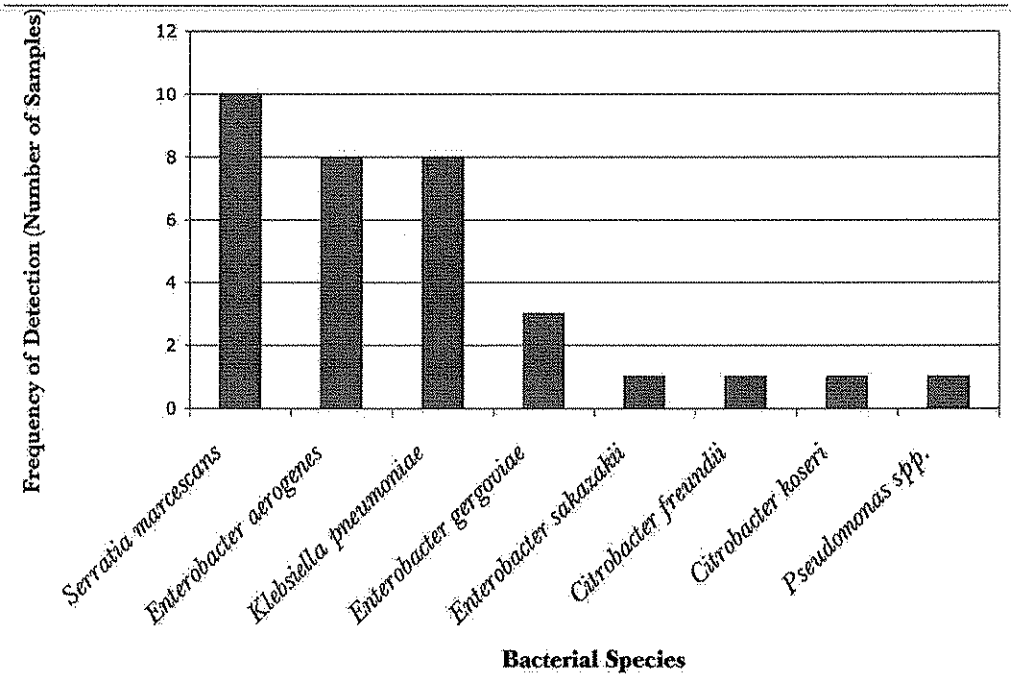


Table 2: Occurrence of HPC and Coliform Bacteria Over Time in a Restaurant Soap Dispenser

Date	HPC (CFU/mL)	Coliform bacteria (CFU/mL)
5/29	4.3×10^7	2.0×10^7
6/21	9.3×10^3	<1
7/17	1.9×10^7	8.2×10^6
7/31	9.5×10^6	7.3×10^6
8/14	1.2×10^7	9.0×10^6
8/28	<1	<1
9/12	3.2×10^7	2.6×10^7

Table 3: Growth of *Klebsiella pneumoniae* in Pasteurized Contaminated Soap (CFU/mL)

	Time (Days)			
Sample	**0**	**1**	**4**	**8**
9/12	6.3×10^2	3.4×10^4	5.9×10^5	2.5×10^6
Negative Control*	<1	<1	<1	<1

* Undiluted, pasteurized soap inoculated with same amount of bacteria as sample. Number of *Klebsiella pneumoniae* added to each soap sample was 5.6×10^3 (9.3×10^2 CFU/mL).

Table 4: Minimum Inhibitory Concentration of a Liquid Soap against *Klebsiella pneumoniae* (CFU/mL)

	Time (Days)				
Dilution	**0**	**60 min**	**1**	**5**	**10**
No Dilution	50	<1	<1	<1	<1
1:1	330	<1	<1	<1	<1
1:2	490	<1	<1	<1	<1
1:4	480	160	<1	<1	<1
1:10	410	320	<1	<1	<1
1:100	350	580	240	<1	<1
1:1000	410	550	240	1.5×10^4	1.5×10^5
Negative Control*	500	520	150	1.5×10^3	2.3×10^3

* No soap added.

Conclusions

- 22.7% of samples taken from refillable bulk dispensers contained >500 CFU/mL HPC, and 22% contained coliform bacteria, averaging 10^6 CFU/mL.
- Bacterial species identified were all opportunistic pathogens.
- No bacteria were found in sealed system soap dispensers.
- A soap dispenser monitored over a three-month period, demonstrated that bacterial contamination was prolonged although the levels and types of bacteria varied.
- Eight types of uncontaminated, factory-sealed, liquid hand soaps were inoculated with various species of bacteria. All of the bacteria quickly died in the soaps after addition, even when the soap was diluted.
- The minimum inhibitory concentration of a specific brand of soap used at a restaurant that had bacterial contamination in the soap indicated that it contained sufficient concentrations of preservatives to inhibit bacterial growth.
- Liquid soap from a public restroom, that contained large numbers of bacteria was pasteurized and inoculated with Klebsiella pneumoniae. Growth was observed, thus it appears that degradation of preservatives must occur in the soap dispenser, allowing for the growth of bacteria.
- Bacteria growing in the soap dispensers are not resistant to the preservatives and that preservative degradation takes place, likely after introduction of the soap into the dispensers.

Bacterial Contamination of Liquid Hand Soaps Used in Public Restrooms

Introduction

Washing hands with soap and water is a universally accepted method to reduce the microbial load on the hands and is used daily by millions of people worldwide. However, the majority of public facilities have soap dispensers that are refillable using a stock soap solution. The CDC recognized in 1975 that the use of these types of dispensers can result in a suitable environment for the growth of potentially disease causing microorganisms. Current health-care hand hygiene guidelines do not recommend the use of open refillable dispensers. The liquid soap used in these dispensers can become contaminated regardless of the preservative used when the microbial population exceeds the preservatives defenses. When product contamination has been reported, contamination was more likely to have occurred extrinsically (after product had been used) than intrinsically (during manufacturing). The likelihood of extrinsic contamination is greatest when the product is open to repeated exposure to bacteria from the user or the environment, hence, the packaging and the dispensing method plays a significant role in product safety.

Materials and Methods

Liquid soap samples were collected from public restrooms in five cities [Boston, MA (107), Atlanta, GA (120), Columbus, OH (109), Los Angeles, CA (94), and Dallas, TX (111)]. Samples were organized into 5 categories: office, health clubs, food service, retail locations and other (education, leisure, etc.). The total number of liquid soap samples analyzed in this report were 541, consisting of 428 soap samples from the sink area and 113 soap samples from the shower area at health clubs, 65 from men's showers and 48 from women's showers. A total of 428 liquid soap samples from the sink area, 226 from men's restroom sink areas and 202 from women's restroom sink areas, were analyzed for this report. Samples with <500 CFU/mL were not considered since industry standards allow for this amount of bacteria in liquid soap. All samples were confirmed to be from open refillable systems.

The samples were collected in sterile 50 mL conical tubes and shipped to the laboratory on ice. 1 mL of DE neutralizing broth (Remel, Lenexa, KS) was added to each sample tube and shaken vigorously for 60 seconds. Heterotrophic plate counts (HPC) were obtained by the spread plate method on R2A media (Difco, Sparks, MD). Plates were incubated at 30°C for 5 days. Any sample showing bacterial content was reexamined for Coliform bacteria.

Coliform analysis and enumeration was performed using the spread plate method on mEndo agar (Difco, Sparks, MD) and incubated at 35°C for 24 hours. Bacterial colonies were counted and recorded, representatives of all colony types were subcultured to TSA plates (Difco, Sparks, MD) for oxidase tests and identification. TSA plates were incubated at 35°C for 24 hours. Identification of bacteria was obtained using API20E strips (BioMerieux, Marcy-l'Etoile, France). *S. aureus* analysis was performed by using the spread plate method on TSA amended with 5% Sheep Blood (BA) (Hardy Diagnostics, Phoenix, AZ) to check for hemolysis. Plates were incubated for 24-48 hours at 35°C. Beta hemolytic isolates were enumerated and streaked onto a TSA plate and incubated for 24 hours at 35°C. Isolated colonies underwent further confirmation testing utilizing catalase production, microscopic morphology, coagulase production (tube and slide tests) and antibiotic (polymyxin) sensitivity.

Results

Figure 1: Locations Containing HCP and Percent of HCPs that were Coliforms

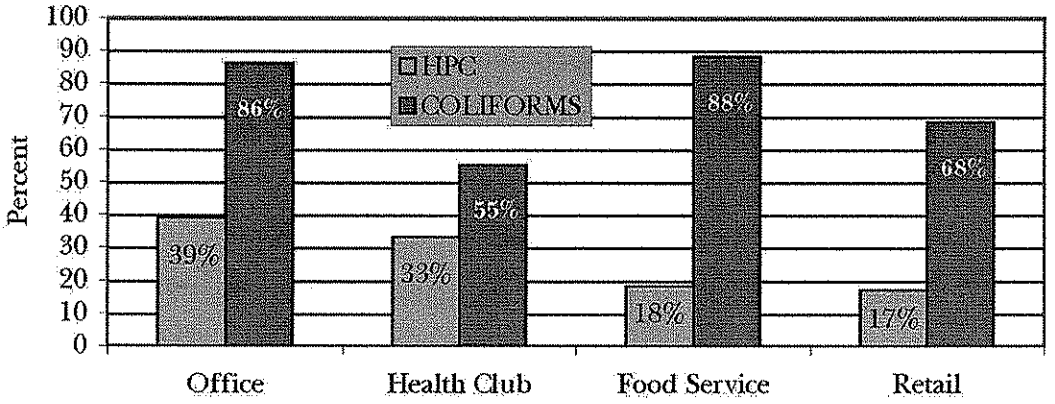


Figure 2: Frequency of Bacterial Species Isolated from Refillable Liquid Soap Dispensers

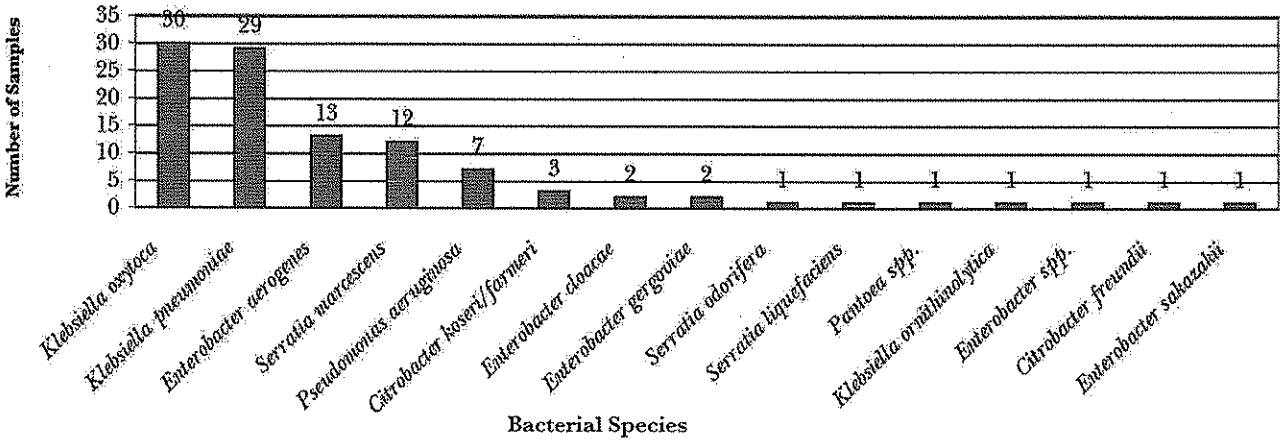
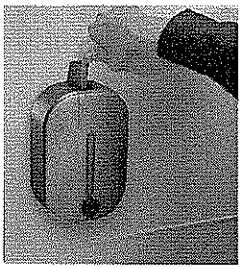


Figure 3:

Sealed System
0% Contaminated



Open Refillable Bulk Soap Dispenser Being Refilled
25% Contaminated

Table 1:

Total number of open refillable soap samples	Number of samples with bacteria	Number of samples with Coliforms
541	133 (25%)	87 (16%)

Summary

A total of 541 open refillable liquid soap samples were analyzed for bacteria, coliforms and Staphylococcus aureus. Of the 541 samples, 133 (25%) contained bacteria, 87 samples (16%) contained coliforms. The percent of bacteria isolated from open refillable liquid soap samples that were identified as coliforms was 65%. Heterotrophic bacterial numbers detected in the liquid soap samples ranged from 590 to 5.3 x 10^7 CFU/mL. The average number of bacteria found in one mL of soap was 3.02 x 10^6 CFU/mL. Coliform bacteria ranged from <10 to 6.5 x 10^7 CFU/mL, with an average of 3.94 x 10^6 per mL of soap. The frequency of contamination was similar for all cities tested, for both men and women's restrooms and for both wall mounted and counter-mounted dispensers. Klebsiella was the most frequently isolated genus of bacteria, followed by Enterobacter and Serratia. No Staphylococcus aureus were detected in any of the liquid soap samples analyzed.

Conclusions

High levels of bacterial contamination (average 3.02 x 10^6 CFU/mL) were found in 25% of the liquid soap samples in this study. Previous reports found no contamination in soap from sealed systems (figure 3). Since these samples represent a diverse cross section of geographical locales and individual sites, it is concluded that refillable open, or "bulk", liquid soap systems commonly found in the U.S. are routinely contaminated with bacteria. Many of the bacteria isolated are opportunistic pathogens which can cause a variety of health issues including respiratory infections, bloodstream infections, urinary tract infections and skin infections. The type and level of bacteria found in these systems represent a potential health risk to users, especially to any immunocompromised individuals.

Footnotes

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Evaluation of Contaminated Bulk Soap Dispensers for Biofilm Bacteria: Comparison of Two Methods of Analysis and Effectiveness of Dispenser Washing Procedures

MONTANA STATE UNIVERSITY

Center for Biofilm Engineering

#502
11/09

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a National Science Foundation Engineering Research Center in the MSU College of Engineering

INTRODUCTION

Bulk refillable soap dispensers are manually refilled with bulk soap through an opening in the top, Figure 1.

Previous research demonstrated that up to 25% of bulk hand soap dispensers are contaminated with approximately 6 LOG_{10}(CFU/mL) heterotrophic bacteria based upon samples collected from the bulk soap[1]. The contamination results from extrinsic sources and occurs when the preservative system in the soap is overcome.

This poster presents the results of a two-phase project. The goal of Phase 1 was to determine if biofilm growth within the dispensers contributed to bulk soap contamination, and Phase 2 investigated if washing the dispensers effectively reduced bacterial contamination .

Figure 1. Bulk refillable soap dispenser

PHASE 1 – BIOFILM TESTING

Viable plate counts paired with biochemical identification assays and molecular methods were used to determine the amount of biofilm present and the ecology of the biofilm communities found in three types of dispensers. The dispenser types tested were: plastic counter-mount (from a shopping center), plastic wall-mount (from an elementary school), and stainless steel wall-mount (from middle/high schools). All dispensers tested were previously determined to be contaminated in the field.

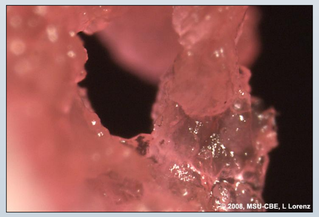


Figure 2. Stereoscope image of dried soap on the spigot opening of a plastic wall-mount dispenser. 5X

Viable Plate Count & Biochemical Identification Methods

Dispensers were received and visually inspected for any damage during shipment. Samples were collected and analyzed at three distinct steps:

- Sample A: the bulk soap (suspended bacteria)
- Sample B: the rinsed solution (loosely attached cells rinsed from the dispenser surfaces)
- Sample C: the scraped solution (surface associated cells scraped from the dispenser surfaces)

The three samples were then:

- Disaggregated and neutralized in D/E neutralizer (Disaggregation methods included sonicating and vortexing the sample with sterile 3mm glass beads, for 1 minute each, alternating with three repeats.)
- Diluted and plated for heterotrophic and coliform plate counts
- Filtered for total cell counts (Figure 3)

When possible, stereoscope images of the dispenser were taken between the rinse and scraping steps, with careful attention paid not to disrupt the biofilm within the dispenser (Figures 2 ,4 ,5 and 7).

Isolated colonies were picked from the heterotrophic and coliform plate counts and were sent in for biochemical organism ID.

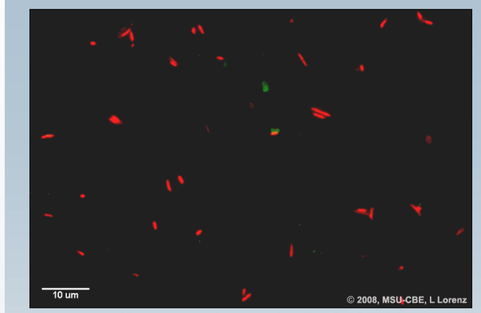


Figure 3. Epifluorescent image of cells obtained from a bulk refillable soap dispenser, filtered onto a polycarbonate membrane, and stained with Live/Dead for total cell counts. Total cell counts were an important way of determining the efficacy of the disaggregation methods. Disaggregation was determined to be efficient when single cells were seen, as shown above. 100X

Community Analysis Molecular Methods

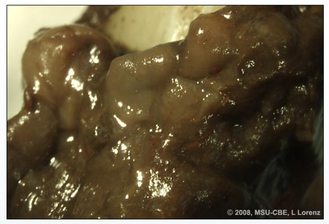
The community analysis approach was broken down into four steps:

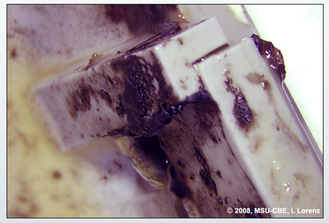
Biomass collection
- Collect pooled bulk and surface associated pellets

DNA preparation
- Cell lysis
- Removal of cell debris via centrifugation
- Precipitate proteins

Clone library construction
- Clone gene of interest (SSU rRNA gene via PCR)
- Ligation into plasmid & transformation into *E. coli*
- Screen/pick colonies

Organism identification
- Sequencing
- Bioinformatic analysis





Figures 4 and 5. Stereoscope images of unknown brown material found in all types of dispensers studied. Shown here: internal tubing from a counter-mounted dispenser (top) and lid of a plastic wall-mounted dispenser (bottom). 7.5X

BIOFILM TESTING RESULTS

Results indicated that (Figure 6) :

- The bulk soap, Sample A, was contaminated with 4-7 LOG_{10}(CFU/mL) bacteria.
- Samples B (loosely surface associated) and C (surface associated) contained 4-7 LOG_{10}(CFU/cm^2), (n=6).
- Total cell counts ranged from 4-8 LOG_{10}(CFU/cm^2) for all dispensers and sample types.

These results were Independent of dispenser type or construction material.

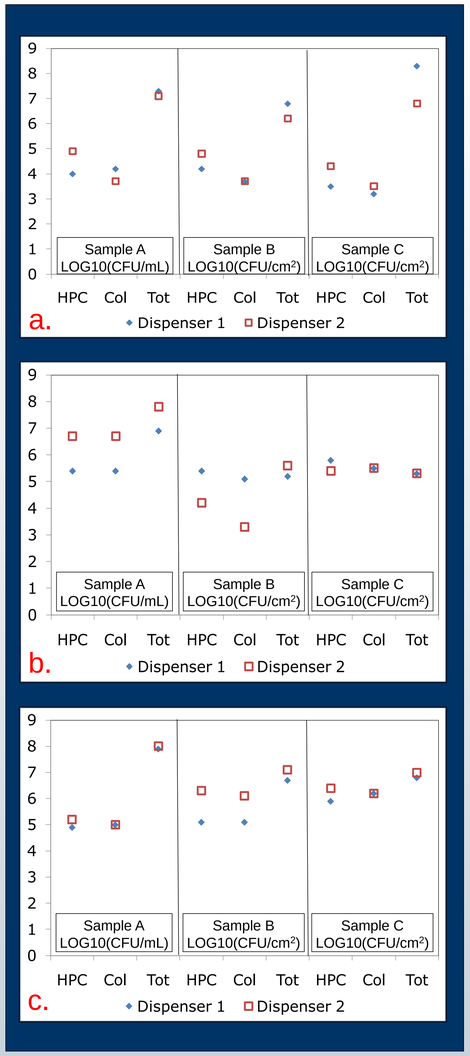


Figure 6. Panel a. is the counter-mounted dispenser results, b. the plastic wall-mounted dispenser results, and c. the stainless steel wall-mount dispenser results. For the viable plate count results, HPC refers to heterotrophic plate counts, Col refers to coliform counts and Tot refers to total cell counts. Samples A, B and C depict the bulk soap, loosely surface associate, and the surface associated biofilm counts, respectively.

METHODS COMPARISON

Overall, the results of the bacterial identification based upon biochemical assays versus molecular methods were comparable at the genus level, but some differences were observed (Table 1).

The biochemical profiling from all dispensers tested identified :
- 14 unique bacterial species
- 11 different genera

Whereas the molecular methods identified :
- 13 unique genera
- Possibly dozens of different species

All microorganisms observed are considered opportunistic pathogens and are mostly gram negative. The organisms identified were surprisingly consistent, and were independent of type and location of dispenser.

Table 1. Panel a. is an indirect comparison of field versus biochemically isolated microbes identified from the plastic wall-mounted dispensers. Panel b. is an indirect comparison of field identified microbes versus microbes identified using molecular methods from the plastic wall-mounted dispensers. Panel c. is a direct comparison of microbes identified using biochemical assays versus molecular based methods from stainless steel wall-mounted dispensers. Molecular ID isolates were based on DNA found in the dispensers, thus, viability of identified organisms could not be assessed.

Dispenser #	Field ID	Biochemical ID	Molecular ID
1	*Providencia rettgeri*	*Providencia rettgeri*	
	Pseudomonas aeruginosa	*Pseudomonas aeruginosa*	
	Citrobacter koseri	*Citrobacter freundii*	
	Serratia oderifera	*Serratia liquefaciens*	
		Klebsiella pneumoniae	
2	*Pseudomonas aeruginosa*	*Pseudomonas aeruginosa*	
	Stenotrophomonas maltophilia	*Burkholderia cepacia*	
	Aeromonas hydrophila	Yeast, not *C. albicans*	
		Gram positive bacillus (no further ID available)	

= same genus and species
= same genus

a.

Dispenser #	Field ID	Biochemical ID	Molecular ID
3	*Pseudomonas aeruginosa*		*Pseudomonas aeruginosa*
	Providencia rettgeri		*Providencia rettgeri*
	Serratia rubidae		*Serratia rubidaea*
			Achromobacter xylosoxidans
			Alcaligenes xylosoxidans
4	*Stenotrophomonas maltophilia*		*Stenotrophomonas sp.*
	Pseudomonas fluorescens		*Pseudomonas aeruginosa*
	Pseudomonas luteola		*Citrobacter sp.*
	Pseudomonas stuzeri		*Curvibacter sp.*
	Enterobacter cloacae		*Enterobacter sp.*
			Leptothrix sp.
			Pelomonas sp.
			Delftia acidovorans
			Rubrobacter xylanophilus

= same genus and species
= same genus

b.

Dispenser #	Molecular ID	Biochemical ID
22	*Pseudomonas sp. – probably P. aeruginosa*	*Pseudomonas aeruginosa*
	Providencia sp. – probably P. rettgeri	*Providencia/Proteus rettgeri*
	Serratia sp. – probably S. liquefaciens	*Serratia marcescens*
40	*Providencia sp.*	*Providencia/Proteus rettgeri*
	Stenotrophomonas sp.	*Stenotrophomonas maltophilia*
	Pseudomonas sp.	*Pseudomonas fluorescens/putida*
	Serratia sp.	*Serratia liquefaciens*
	Alcaligenes/Achromobacter sp.	*Acinetobacter lwoffii*

= same genus and species
= same genus

c.

PHASE 2 – DISPENSER WASHING STUDY

Washing studies were completed to determine if dispensers could be washed or sanitized to eliminate future contamination. The methods used were selected to mimic options that could be available during routine restroom maintenance by janitorial staff. Three washing procedures were analyzed for plastic wall mounted bulk refillable soap dispensers:

1) a simple hot water rinsing technique
2) a hot water rinsing and scrubbing technique
3) a hot water rinse, scrub, 5,000mg/L bleach treatment, hot water rinse combination

Positive and negative control dispensers were drained and refilled with sterile soap.

Samples were collected from the rinse steps and evaluated for heterotrophic and coliform plate counts. Bulk soap sampling was performed for up to two weeks to determine washing procedure efficacy.

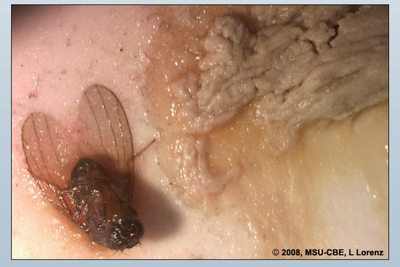


Figure 7. Stereoscope image of a fly found in the bottom dispenser assembly of a plastic wall-mounted dispenser. 7.5X

WASHING STUDY RESULTS

The washing study results (Figures 8-9) showed that bacterial counts in the bulk soap returned to pre-wash levels within two weeks of cleaning a dispenser and subsequently rinsing it with 5,000 mg/L bleach. The purple and blue X symbols represent the positive and negative control results, respectively.

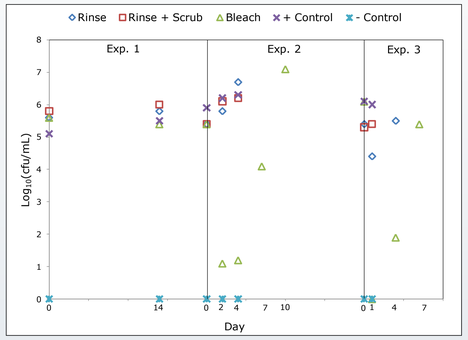


Figure 8. Dispenser washing study results: coliform counts

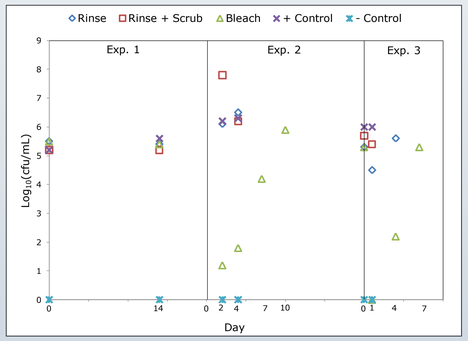


Figure 9. Dispenser washing study results: heterotrophic plate counts

CONCLUSIONS

- Dispensers contaminated with bacteria in the bulk soap also had high levels of biofilm bacteria.
- While the bacterial diversity was relatively low compared to other environments, detection of SSU rRNA gene sequences suggested the presence of organisms not detected via cultivation-based techniques (for some samples).
- The washing study results showed that bacterial counts in the bulk soap returned to pre-wash levels within two weeks regardless of the washing procedure used, although the bacterial counts in the dispensers rinsed with bleach did recover more slowly.

ACKNOWLEDGEMENTS

Funding was provided by GOJO Industries, Inc., Akron, OH.

[1]Gerba CP, and Maxwell SL, "Bacterial contamination of liquid hand soaps used in public restrooms," Poster Presentation at NEHA 71st Annual Educational Conference & Exhibition, Atlantic City, NJ, 2007.

Handwashing with Contaminated Soap Results in Hand Contamination and Transfer of Bacteria

Carrie Zapka[1], Cara Bondi[1], Sheri Maxwell[2], Esther Campbell[3], David Macinga[1], Michael Dolan[1], Charles Gerba[2]

[1]GOJO Industries, Inc., Akron, OH, [2]University of Arizona, Tucson, AZ , [3]Bioscience Laboratories, Inc., Bozeman, MT

Abstract

BACKGROUND/OBJECTIVE: Previous studies establish that open refillable bulk soap dispensers are often contaminated with species of *Klebsiella* and/or *Serratia* bacteria. In this study we evaluate whether these bacteria remain on the hands after handwashing and assess whether they can be transferred to other surfaces. **METHODS:** Hands were sampled using the glove juice method before and after handwashing with contaminated or uncontaminated soap. In addition, some participants touched an agar surface. **RESULTS:** No *Klebsiella* or *Serratia* were detected on the hands before using the test soaps or after using the uncontaminated control soap. Between 15 and over 190,000 of the marker bacteria remained on each hand exposed to the contaminated soaps and the transfer of the bacteria was visible on the agar touch plates. **CONCLUSIONS:** Use of contaminated soap may contribute to the transmission of opportunistic pathogens such as *Klebsiella pneumoniae* and *Serratia marcescens*.

Background

Bulk

Sealed

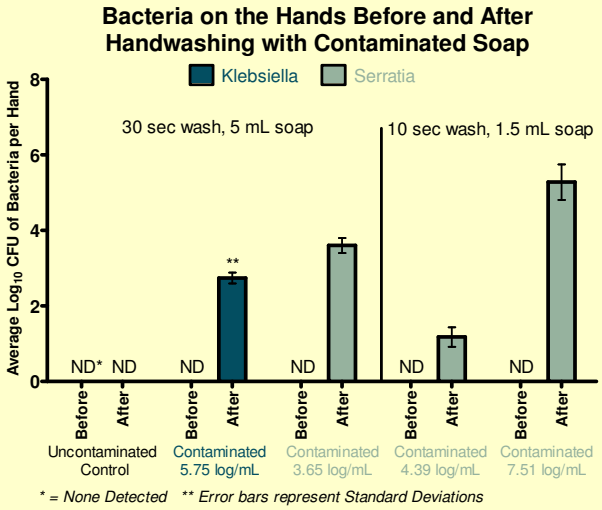
Permanently mounted soap dispensers provided in public restrooms can be refilled either with sealed cartridges/bags or by pouring soap from a larger bulk container such as a gallon jug. Since soap contaminated with bacteria has been linked to outbreaks, the CDC recommends against the use of bulk soap dispensers in healthcare settings. However, in non-healthcare settings, bulk dispensers are still quite common and are often contaminated. Recent reports have found that 23-25% of open refillable bulk soap dispensers found in public restrooms are contaminated with unsafe levels of potentially pathogenic organisms. Sealed dispensing systems were free from contamination. With a growing immunocompromised population, it is prudent to investigate how remediation of this unnecessary health risk could reduce the risk of community-acquired infections. The objective of this study was to evaluate whether bacteria from contaminated soap remains on the hands after handwashing and to assess whether they can be transferred to other surfaces.

Methods

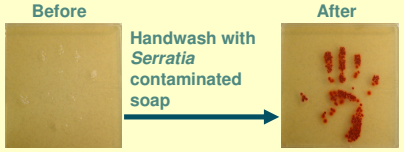
A laboratory simulation of handwashing with contaminated bulk soap was conducted. The testing methods were based on a modification of the FDA Tentative Final Monograph (TFM) for Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash (FR59:116, 17 June 1994, pp. 31448-31450). Soap formulation chemistry, bacteria used, and levels of soap contamination tested simulated contaminated bulk soap found in public rest rooms. Two different handwash methods were tested. In the first study the handwash was designed to mimic an ideal procedure, e.g. one conducted by a healthcare worker (5 mL of soap, 30 sec wash, 30 sec rinse). In the second study the handwash was modeled after the typical washing behavior observed in the general public (1.5 mL of soap, 10 sec wash, 10 sec rinse). A total of 5 soap samples were tested; one uncontaminated control, one sample contaminated with *Klebsiella pneumoniae*, and three samples contaminated with *Serratia marcescens*. *Klebsiella* and *Serratia* were used since they were two of the most common types of bacteria found in contaminated bulk soap, accounting for over 2/3 of all contaminants. Contaminated samples were prepared by repeatedly inoculating unpreserved soap formulations with bacteria until the soap became contaminated. A range of levels of contamination were tested from relatively low (<10,000 CFU/mL, <4 Log_{10}CFU/mL) to high (>10,000,000 CFU/mL, >7 Log_{10}CFU/mL) bacterial contamination. The number of contaminating bacteria on both hands of 6 participants were measured before and after handwashing with each test soap (N=12) using the glove juice method. In addition, after washing with each soap 1 or 2 participants touched an agar surface with one or both of their hands (N=2 or N=4).

Results

- ✓None of the participants had detectable amounts of *Klebsiella* or *Serratia* on their hands before washing
- ✓No *Klebsiella* or *Serratia* were detected on hands after washing with an uncontaminated control soap
- ✓After handwashing with contaminated soap between 15 to over 190,000 bacteria from the soap remained on each hand (averaging from 1.18 to 5.28 Log_{10} CFU).
- ✓Use of soap with the highest contamination level resulted in the greatest contamination level on the hands.



✓Both *Klebsiella* and *Serratia* from the contaminated hands of participants were transferred to agar surfaces following handwashing with contaminated soap.



Conclusions

- ✓**Washing hands with contaminated soap results in contamination of the hands and transfer of the bacteria to surfaces.**
- ✓**Contaminated bulk soap may contribute to the transmission of opportunistic pathogens such as *Klebsiella* and *Serratia.***
- ✓**Further research is needed to evaluate the public health risk of using contaminated bulk soap by patrons of public restrooms.**

NASN 2009 NASN 41st Annual Conference
Boston Seaport World Trade Center
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Transforming School Communities: Partners for Student Success

Opportunistic Pathogens From Contaminated Bulk Soap on the Hands of Students and Staff in an Elementary School

Carrie A Zapka[1], Sheri L Maxwell[2], David R Macinga[1], Michael J Dolan[1], Charles P Gerba[2], James W Arbogast[1]

[1]GOJO Industries, Inc., Akron, OH, [2]University of Arizona, Tucson, AZ

Abstract

Previous research revealed that approximately 23% of open refillable bulk soap dispensers in public restrooms are contaminated with an average of 3,000,000 bacteria/ml soap. This study was performed to evaluate hand contamination and bacterial transmission by hands after washing with bulk soap. Gram-negative bacteria on the hands of 10 students and 10 staff were quantified before and after using either contaminated bulk soap or uncontaminated control soap. In addition, the transfer of gram-negative bacteria from the hands to an agar surface was evaluated. Hands were found to harbor over 10-fold more opportunistic pathogens after washing with contaminated bulk soap than before washing (2047 vs 179). An average of 1 gram-negative bacterium was transferred to surfaces touched by students or staff either before the hand wash or after washing with uncontaminated control soap. After washing with the contaminated soap, the average number of gram-negative bacteria transferred to surfaces increased to 38 for children and 9 for adults. These results suggest that contaminated bulk soap may play a role in the transmission of bacteria in schools, particularly among children.

Background

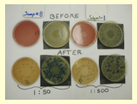
Hand soap dispensers used in school restrooms can be refilled with soap that is either bulk or sealed. Bulk dispensers are refilled by pouring soap from a large container into the open reservoir and typically the nozzle that the soap is ejected through is not replaced. In contrast, sealed dispensers are refilled by replacing bags or cartridges that contain soap sealed inside with a new nozzle. Soap in bulk dispensers is prone to contamination because it is constantly exposed to bacteria from the environment, such as from the hands of the person refilling the soap, the spray of toilet water after flushing, or from dust in the air. Since contaminated bulk soap dispensers have caused outbreaks in hospitals, the CDC recommends against their use in healthcare settings. However, no such guidelines exist to protect patrons of public restrooms in the community or our students in schools. In our previous studies, we tested soap from over 500 dispensers across the United States to evaluate the prevalence of contaminated soap in public restrooms. We were surprised to learn that 1 in 4 bulk dispensers are contaminated with an average of over 3 million bacteria, most of which are known to be opportunistic pathogens. Exposure to such high levels of these organisms can be a significant health risk to individuals with compromised immune systems which, is estimated to be at least 20% of the population. In contrast, soap from sealed dispensing systems was free from contamination. We identified an elementary school in which the antibacterial soap in all of their plastic wall mounted bulk soap dispensers were highly contaminated with 19 different species of *Pseudomonas, Providencia, Citrobacter, Stenotrophomonas, Aeromonas, Enterobacter, Pasteurella,* and *Serratia* bacteria. The objective of this study was to evaluate bacterial hand contamination and hand transmission among children and adults in an elementary school with a contaminated bulk soap problem.

Methods

10 staff and 10 students each participated in up to 4 handwashes each using one of 14 contaminated bulk soap dispensers. 11 staff participated in up to 2 handwashes each during the follow up study which was conducted 4 months after the contaminated bulk soap dispensers were replaced with sealed soap dispensing systems. Participants were instructed to wash and dry their hands as they normally would after using the restroom. All hands were tested both before and after handwashing using one of two methods.



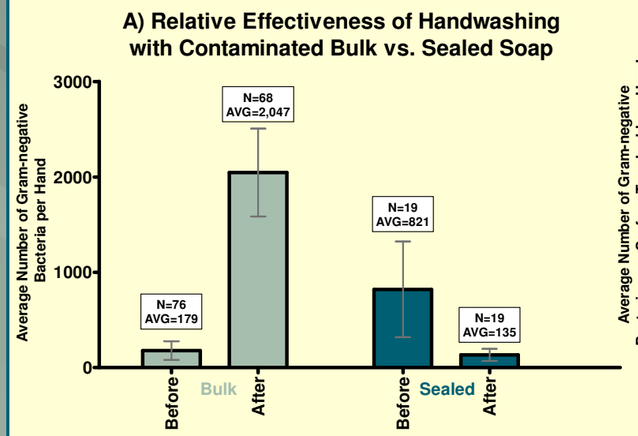
Method A: The number of bacteria on one hand of each participant was measured using the glove juice procedure.

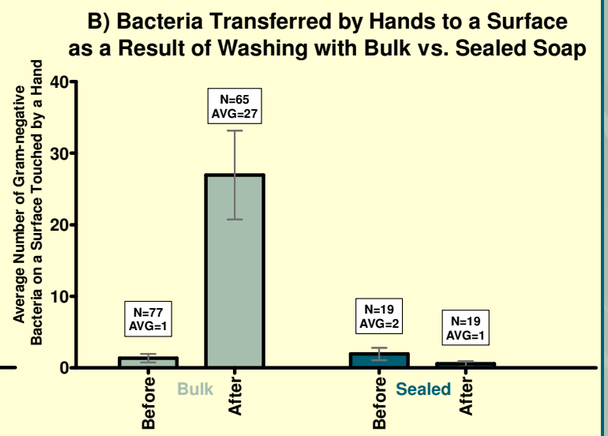



Method B: Bacterial transfer to a surface was measured with the opposite hand using the hand stamp procedure.


Results were obtained from counting bacteria that grew on MacConkey's agar. Statistical comparisons were performed using the Student's t-test on the Log_{10} transformed bacterial colony counts.

Results





✓Washing with contaminated bulk soap significantly increased the number of gram-negative bacteria per hand from 179 to 2047 on average for all students and staff ($P < 0.0001$). Students' hands retained significantly more bacteria than the staff, 3148 vs. 474 ($P < 0.01$).

✓Washing with sealed soap significantly reduced the number of bacteria from 821 to 135 ($P < 0.05$).

✓Hands had significantly less gram-negative bacteria after washing with sealed soap compared to after washing with contaminated bulk soap, 135 vs. 2047 ($P < 0.0001$).

✓Washing with contaminated bulk soap significantly increased the number of gram-negative bacteria transferred to a surface from 1 before washing to 27 after on average for all students and staff ($P < 0.0001$). Students transferred significantly more bacteria to the surface they touched after washing with contaminated bulk soap than the staff did, 38 vs. 9 ($P < 0.01$).

Conclusions

✓Hand soap dispensers which are refilled by pouring bulk soap into an open reservoir are often contaminated with opportunistic pathogens.

✓Washing with contaminated bulk soap resulted in a 10-fold increase in the number of pathogenic bacteria that were found on the hands of students and staff in an elementary school.

✓Hands washed with contaminated bulk soap transferred a significantly higher number of opportunistic pathogens to touched surfaces compared to hands washed with soap from a sealed refill.

✓Contaminated bulk soap may play a role in the transmission of bacteria in schools, particularly among children.

✓Schools using bulk soap dispensers could reduce the potential risk of infections by upgrading to dispensers which utilize only sealed soap refills.

Open Refillable Bulk Soap Dispensers in Public Restrooms: A Public Health Risk?

Carrie A. Zapka, MS [1], Sheri L. Maxwell, BS [2], Jennifer L. Cadnum, BS [3], David R. Macinga, PhD [1], Curtis J. Donskey, MD [3], Michael J. Dolan, BS [1], **Charles P. Gerba, PhD*** [2].

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Presenter Disclosures
Dr. Charles P. Gerba

The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months:

GOJO Industries, Inc.
Sponsored Research

Learning Objectives

1. Describe how to identify open refillable bulk soap dispensers
2. Explain why open refillable soap dispensers are susceptible to bacterial contamination
3. Discuss why contaminated bulk soap in community settings could be a public health risk, particularly for susceptible populations

Soap Microbial Quality

- Handwash products are regulated by the FDA. Excessive contamination is a violation.[1]
- Soap is not expected to be sterile.
  - "It is the responsibility of the manufacturer to assure that… the species and quantity of microbes do not present a hazard to the consumer when using the product as directed…"[2]
- Guidelines recommend <1000 total bacteria/mL & the absence of pathogens.[2]

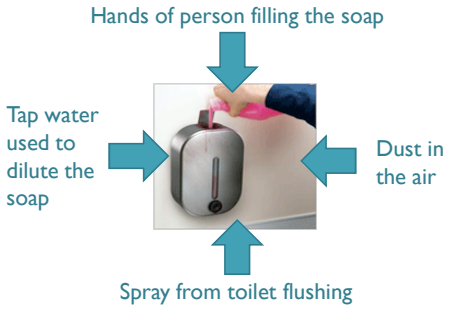
1) http://www.cfsan.fda.gov/~dms/cos-218.html
2) The Cosmetic, Toiletry, and Fragrance Association. Technical Guidelines. Microbial Limits for Cosmetics and Toiletries. 2001

Soap Dispensers

- Open Refillable Bulk
  - Refilled by pouring soap from a larger volume container
  - Open to environment
  - Same nozzle used indefinitely

- Closed Sealed Systems
  - Soap provided in a disposable sealed bag or cartridge refill
  - New nozzle with each refill

How Does the Soap Become Contaminated?



Contaminated Soap Causes Infection in Health-Care Settings

- Many reported infections and outbreaks[1]
  - Fatal *Pseudomonas aeruginosa* infection from use of contaminated shampoo[2]
  - *Serratia marcescens* infections linked to contaminated soap. Hands 54 times more likely to be contaminated after washing[3]
- Susceptible populations are at greatest risk
  - >20% of US population is immune-compromised[4]

1) Weber D, Rutala W, and Sickbert-Bennett E. Antimicrobial Agents and Chemotherapy 2007 Dec;51(12):4217–4224.
2) Fainstein V, Andres N, Umphrey J, and Hopfer R. J. Infect. Dis., 158, 655, 1988.
3) Sartor C, Jacomo V, Duvivier C et al. Infect Control Hosp Epidemiol 2000 March;21(3):196-9.
4) Gerba, D, Rose, J., Haas C. International Journal of Food Microbiology 30 (1996) 113-123.

CDC Health-Care Recommendation

- "Do not add soap to a partially empty soap dispenser. This practice of "topping off" dispensers can lead to bacterial contamination of soap[1]."
- Since the risk is well-documented bulk dispensers are rare in Health-Care

1) 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. Morbidity and Mortality Weekly Report. October 25, 2002 / Vol. 51 / No. RR-16.

Is it Safe to Use Bulk Soap Dispensers in Community Settings?

- Prior to our research, no studies had been conducted in the US to assess this potential risk.
- Our studies indicate that patrons of public restrooms are routinely exposed to unsafe levels of bacterial contamination.
- This represents an unnecessary health risk, particularly for the immunocompromised susceptible population.

Bulk Soap Contamination is Widespread

- Soap from over 500 bulk dispensers in public restrooms were tested from across the US
- Unsafe levels of bacteria occur in 23 - 25% of bulk soap dispensers[1,2]
  - Fecal-based organisms found in over 16% of the soap samples
  - Average user exposed to >one million bacteria per handwash
  - Soap from sealed systems showed no contamination

1 M. Chattman, S. Maxwell and C. P. Gerba; Bacterial Contamination of Liquid Hand Soaps. University of Arizona, Tucson, AZ; American Society for Microbiology 107th General Meeting; Toronto, ON, Canada; May 21-25, 2007.
2 C. P. Gerba and S. Maxwell; University of Arizona, Tucson, AZ; National Environmental Health Association 71st Annual Educational Conference & Exhibition; Atlantic City, NJ; June 18-21, 2007.

Bacteria Remain on Hands After Washing with Contaminated Soap

- Bacterial contaminants remain on hands after handwashing and are transferred to touched surfaces[1,2]

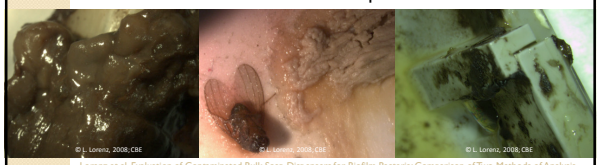
After washing with liquid soap that was not contaminated

After washing with contaminated liquid soap

1 BioScience Laboratories, Inc; Bozeman, MT; Study #071209-150; Feb 22, 2008.
2 BioScience Laboratories, Inc; Bozeman, MT; Study #080307-150; May 22, 2008.

Contaminated Dispensers Should Be Replaced, Cleaning Is Ineffective

- New soap is re-contaminated by biofilm bacteria adhering to inside of dispenser
- Even dispensers scrubbed with hot water and sanitized with 5000 mg/L bleach were contaminated 7-10 days after new uncontaminated soap was added



Lorenz et al. Evaluation of Contaminated Bulk Soap Dispensers for Biofilm Bacteria: Comparison of Two Methods of Analysis and Effectiveness of Dispenser Washing Procedures. Montana State University Center for Biofilm Engineering. Poster to be presented at the 5th ASM Conference on Biofilms Nov 2009.

Study Objectives

- Assess the factors contributing to contamination
  - Are some types of soap more likely to become contaminated?
  - Are certain types/models of bulk dispensers more susceptible to contamination?
  - How do contamination rates compare between different types of facilities?
- Test for the presence of specific organisms of public health concern
  - Food-borne pathogen *E. coli*
  - Antibiotic-resistant organisms

Method- Soap Sampling

- ~ 10 mL of soap collected into sterile collection containers and tested <1 week
- 155 bulk samples collected from Ohio
  - restaurants, bars, gas stations, schools, office buildings, retail stores, health clubs, grocery stores, theaters, etc.

Method- Soap Analysis

- Microbial load
  - Dilute into buffer with neutralizers and plate onto R2A
  - >1000 CFU/mL threshold for contamination
  - Dominant colony types identified
- Active ingredient
  - HPLC used to determine % PCMX or Triclosan
- Food-borne pathogen screen
  - Enrichment based water quality test used to determine if *Escherichia coli* bacteria were present
- Antibiotic resistance
  - Contaminants were tested for their ability to grow on media containing antibiotics, two classes were tested

Results- High levels of Contamination Observed

- 21% (32/155) of bulk soap samples were contaminated with >1000 CFU/mL bacteria
- Average level 6.3 x 10^6 CFU/mL
- 13 different gram negative species isolated including *Pseudomonas, Providencia, Achromobacter, Citrobacter* and *Serratia*
  - These opportunistic pathogens can cause respiratory tract infections, pneumonia, urinary tract infections, pink eye, skin ulcers, gastroenteritis, soft tissue infections, etc.

Results- All Types of Bulk Dispensers from All Types of Facilities Were Contaminated

Type of Facility	Total	Contaminated	%
Shopping	22	4	18%
Recreation	15	3	20%
Dining	28	6	21%
Other/Unknown	90	19	21%
Dispenser Type	**Total**	**Contaminated**	**%**
Counter	21	3	14%
Wall plastic	48	8	17%
Wall metal	16	4	25%
Other/Unknown	70	17	24%

Results- All Types of Soap Were Contaminated

Type of Soap	Total	Contaminated	%
Bland	110	23	21%
Antimicrobial- Triclosan	26	8	31%
Antimicrobial- PCMX	14	1	7%
Other/Unknown	5	0	0%
Color of Soap	**Total**	**Contaminated**	**%**
Blue	6	1	17%
clear/white	33	2	6%
green	13	4	31%
orange	31	12	39%
pink	55	11	20%
peach	9	0	0%
yellow	6	2	33%
Other/Unknown	2	0	0%

Results- *E. coli* and Antibiotic Resistant Bacteria Were Found

- E. coli was detectable in 28% (7/25) of the contaminated soaps tested
- Resistance to quinolones or ceftazidime was observed in 28% (22/78) of the isolates, most frequently in species of *Pseudomonas*, 68% (15/22), but also in *Klebsiella*, *Serratia*, *Burkholderia* and *Enterobacter* species.
  - 5% (4/78) of the isolates were resistant to both antibiotics.

Conclusions

- Bulk hand soap is prone to bacterial contamination.
- Contamination is associated with the open design of the dispenser.
  - it is not limited to any particular type of soap or type of bulk dispenser
- Contaminated soap can harbor food-borne pathogens and antibiotic resistant organisms.

Conclusions

- The species typically found in contaminated soap can cause infections.
- Immune-compromised handwashers with poor skin integrity are at greatest risk of acquiring an infection.
- Further research is warranted to determine the extent to which contaminated bulk soap in public restrooms poses an unnecessary public health risk.

What Can You Do?

- Notice what type of soap dispensers are used in the areas you service
- Educate facilities about the potential risk
- If reoccurring infections due to gram negative pathogens occur, consider testing the soap as a possible reservoir
- Particularly in settings with high proportions of susceptible patrons, recommend the use of sealed systems

Acknowledgements

In addition to the authors, the following persons have also contributed to the research presented here

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  - Esther Campbell
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  - Dr. Darla Goeres
  - Lindsey Lorenz
  - Dr. Matthew Fields
  - Brad Ramsay

Thank You

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Issue Attachment:

Elimination of Open, Refillable Soap Dispensers

Health Canada

"Guidance Document: Human-Use Antiseptic Drugs" Effective 11/27/2009

Page 33/34 Section 7.4 Labelling
"Do not refill container."

http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/antiseptic_guide_ld-eng.pdf

Conference for Food Protection
2010 Issue Form

Internal Number: 019
Issue: 2010 III-018

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

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Title:

Updating ROP Criteria with regard to Cook Chill and Sous Vide

Issue you would like the Conference to consider:

Section 3-502.12 Reduced Oxygen Packaging without a Variance, Criteria.

Section 3.502.12 (B)(2) currently specifies four food intrinsic properties that permit ROP without a variance: (a) Has an a_w of 0.91 or less, (b) Has a pH of 4.6 or less, (c) Is a cured meat or poultry product, and (d) Is a food with a high level of competing organisms. These criteria were meant to be barriers or hurdles to the growth of psychrotrophic *Clostridium botulinum* and *Listeria monocytogenes.* As currently written the first two criteria represent the Aw growth minima for *L. monocytogenes* and the pH minima for *Clostridium botulinum* (non-psychrotrophs). For example a food product fully cooked in its bag to proper Food Code temperatures with a pH of 4.9 would not qualify despite destruction of *Listeria monocytogenes* via cooking and inhibition of psychrotrophic *C. botulinum* with a pH under 5.0. This issue seeks to clarify this section with regard to ensuring operations have at least one science-based barrier to growth (in addition to refrigeration) individually, of both psychrotrophic *Clostridium botulinum* and *Listeria monocytogenes.*

Public Health Significance:

When properly performed cook-chill and sous vide processing minimizes many risks of foodborne illness. When performed improperly, these processes may lead to growth of the foodborne pathogens *Clostridium botulinum* (psychrotrophic strains) or *Listeria monocytogenes*.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending that changes be made to the Food Code Section 3-502.12 Reduced Oxygen Packaging without a Variance, Criteria

To:

3.502.12 (B)(2) Except as specified under ¶¶ (C) - (E) of this section, requires that the packaged food shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria for each pathogen: psychrotrophic *Clostridium botulinum* and *Listeria monocytogenes*: [Pf]

(a) Has an a_w of 0.91 or less for *Listeria monocytogenes* or 0.97 or less for psychrotrophic *C. botulinum*,[Pf]

(b) Has a pH of 4.6 or less for *Listeria monocytogenes* or 5.0 or less for psychrotrophic *C. botulinum*,[Pf]

(c) Is a meat or poultry product cured at a food processing plant regulated by the USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact package, [Pf] ~~or~~

(d) Is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables; [Pf]

(e) Is a food that has received a cooking step of 90°C for 10 minutes to destroy psychrotrophic *C. botulinum*

(f) Is a food that has been ROP packaged and subsequently cooked in the package as specified in FC 3-401 or FC 3-403.11 for *Listeria monocytogenes*.

(An alternative Table format of the above suggested change is included in the attachment).

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Attachments:

- "Table format and references"

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

Attachment 1 - Updating ROP Criteria with regard to Cook Chill and Sous Vide

Suggested change to Food Code using a Table Format

3.502.12 (B)

(2) Except as specified under ¶¶ (C) - (E) of this section, requires that the packaged food shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria each for psychrotrophic *Clostridium botulinum* and *Listeria monocytogenes*: [Pf]

Barriers to Growth or Thermal Destruction	*ROP pathogens of Concern*	
	psychrotrophic *Clostridium botulinum*	*Listeria monocytogenes*
Aw	≤ 0.97	≤ 0.91
pH	≤ 5.0	≤ 4.6
Cured Meat product	Is a MEAT or POULTRY product cured at a FOOD PROCESSING PLANT regulated by the USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact PACKAGE	
Competing Microflora	Is a FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables	
Thermal Destruction	90°C for 10 minutes (or equivalent as specified in the US FDA 2001 Appendix 4 - Bacterial Pathogen Growth and Inactivation. In: Fish and Fisheries Products Hazards and Controls Guidance).	*Cooking in a sealed bag as specified in 3-401 or reheating as specified in 3-403.11*

Science-based references summary

Psychrotrophic *C. botulinum* cook 90°C for 10 minutes.

1. Michael W. Peck. *Clostridium botulinum* and the safety of refrigerated processed foods of extended durability. See Box 2. Line 4.

Quote Box 2: It is recommended that the heat treatments or combination processes reduce the number of viable spores of non-proteolytic C. botulinum by a factor of 10^6 (a 6-decimal process). The Advisory Committee on the Microbiological Safety of Food (ACMSF) concluded that the safety of REPFEDs with respect to non-proteolytic C. botulinum could be ensured by one of the following:

…(4) storage at chill temperature combined with a heat treatment of 90°C for 10min or equivalent lethality [e.g. 70°C for 675 min, 75°C for 464 min, 80°C for 129min, 85°C for 36min] (the European Chilled Food Federation recommended alternative equivalent heat treatments, e.g. 80°C for 270min, 85°C for 52 min.)"

2. Betts. 1995. Growth and heat resistance of psychrotrophic Clostridium botulinum in relation to sous vide products.

Quote Page 61, "It can be seen from table 5. That the highest D90 value obtained in the CFDRA studies was 1.1 min: a process of 6.6 min at 90°C should therefore be sufficient to achieve a 6 log reduction for these strains of psychrotrophic C. botulinum. Based on these data, it is recommended that building in a safety margin to allow for variation in heat resistance between strains and in different food products a process of 10 min at 90°C could be given to all sous vide products with a shelf life of greater than 10 days".

3. 2008. Food Standards Agency guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*.

Quote Page 9: "The ACMSF recommended that, in addition to chill temperatures which should be maintained throughout the food chain, the following controlling factors should be used singly or in combination to prevent growth and toxin production by non-proteolytic C. botulinum in chilled foods with a shelf-life of more than 10 days: a heat treatment of 90°C for 10 minutes or equivalent lethality".

4. 2001. FDA Appendix 4 - Bacterial Pathogen Growth and Inactivation. Fish and Fisheries Products Hazards and Controls Guidance. Third Edition.

Follows…

Appendix 4 - Bacterial Pathogen Growth and Inactivation

June 2001

Fish and Fisheries Products Hazards and Controls Guidance
Third Edition

Return to table of contents

Bacterial Pathogen Growth and Inactivation

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/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/temperature guidance is not appropriate.

In summary, the table indicates that:

- If the product is held at internal temperatures above 70°F (21°C) during processing, exposure time should ordinarily be limited to two hours (three hours if *Staphylococcus aureus* is the only pathogen of concern);
- If the product is held at internal temperatures above 50°F (10°C), but not above 70°F (21°C), exposure time should ordinarily be limited to six hours (twelve hours if *Staphylococcus aureus* is the only pathogen of concern);
- If the product is held at internal temperatures both above and below 70°F (21.1°C), exposure times above 50°F (10°C) should ordinarily be limited to 4 hours, as long as no more than 2 of those hours are above 70°F (21.1°C).

It is not possible to furnish recommendations for each pathogen, process, type of seafood, 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 ("Pathogen Modeling Program" [PMP]) and the United Kingdom ("Food MicroModel" [FMM]). 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, generation time). FDA does not endorse or require the use of such modelling 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-temperature limits derived from such predictive models.

Table #A-3 contains information on the destruction of *Listeria monocytogenes*. Lethal rate, as used in this table, is the relative lethality of one minute at the designated internal product temperature as compared to the lethality of one minute at the reference internal product temperature of 158°F (70°C) (i.e. z = 13.5°F [7.5°C]). For example, one minute at 145°F (63°C) is 0.117 times as lethal as one 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 innoculum in the food.

Table #A-4 contains information on the destruction of *Clostridium botulinum* type B (the most heat resistant form of nonproteolytic *Clostridium botulinum*). Lethal rate, as used in this table, is the relative lethality of one minute at the designated internal product temperature as compared to the lethality of one 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, they may not be sufficient for the destruction of nonproteolytic *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	.92	4.3	9.3	10	39.2°F 4°C	131°F**** 55°C	aerobe
Campylobacter jejuni	.987	4.9	9.5	1.5	86°F 30°C	113°F 45°C	micro-aerophilic*
Clostridium botulinum, type A, and proteolytic B and F	.935	4.6	9	10	50°F 10°C	118.4°F 48°C	anaerobe**
Clostridium botulinum, type E, and nonproteolytic B and F	.97	5	9	5	37.9°F 3.3°C	113°F 45°C	anaerobe**
Clostridium perfringens	.93	5	9	7	50°F 10°C	125.6°F 52°C	anaerobe**
pathogenic strains of *Escherichia coli*	.95	4	9	6.5	43.7°F 6.5°C	120.9°F 49.4°C	facultative anaerobe***
Listeria monocytogenes	.92	4.4	9.4	10	31.3°F -0.4°C	113°F 45°C	facultative anaerobe***
Salmonella spp.	.94	3.7	9.5	8	41.4°F 5.2°C	115.2°F 46.2°C	facultative anaerobe***
Shigella spp.	.96	4.8	9.3	5.2	43°F 6.1°C	116.8°F 47.1°C	facultative anaerobe***
Staphylococcus aureus- growth	.83	4	10	20	44.6°F 7°C	122°F 50°C	facultative anaerobe***
Staphylococcus aureus- toxin	.85	4	9.8	10	50°F 10°C	118°F 48°C	
Vibrio cholerae	.97	5	10	6	50°F 10°C	109.4°F 43°C	facultative anaerobe***
Vibrio parahaemolyticus	.94	4.8	11	10	41°F 5°C	113.5°F 45.3°C	facultative anaerobe***
Vibrio vulnificus	.96	5	10	5	46.4°F 8°C	109.4°F 43°C	facultative anaerobe***
Yersinia enterocolitica	.945	4.2	10	7	29.7°F -1.3°C	107.6°F 42°C	facultative anaerobe***

* requires limited levels of oxygen ** requires the absence of oxygen *** grows either with or without oxygen. **** growth significantly delayed (>24 hr.) at 131°F (55°C)

Table A-2
Time/Temperature Guidance for Controlling Pathogen Growth and Toxin Formation in Seafoods

Potentially Hazardous Condition	***Product Temperature***	***Maximum Cumulative Exposure Time***
Growth and toxin formation by ***Bacillus cereus***	39.2-43°F (4-6°C) 44-50°F (7-10°C)	5 days 17 hours*

	51-70°F (11-21°C) Above 70°F (above 21°C)	6 hours* 3 hours
Growth of ***Campylobacter jejuni***	86-93°F (30-34°C) Above 93°F (above 34°C)	48 hours 12 hours
Germination, growth, and toxin formation by ***Clostridium botulinum*** type A, and proteolytic B and F	50-70°F (10-21°C) Above 70°F (above 21°C)	11 hours 2 hours
Germination, growth, and toxin formation by ***Clostridium botulinum*** type E, and nonproteolytic 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 (above 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 (above 21°C)	21 days 1 day 6 hours* 2 hours*
Growth of pathogenic strains of ***Escherichia coli***	44.6-50°F (7-10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	14 days 6 hours 3 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) Above 70°F (above 21°C)	7 days 2 days 12 hours* 3 hours*
Growth of ***Salmonella*** species	41.4-50°F (5.2-10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	14 days 6 hours 3 hours
Growth of ***Shigella*** species	43-50°F (6.1-10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	14 days* 12 hours* 3 hours*
Growth and toxin formation by ***Staphylococcus aureus***	44.6-50°F (7-10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	14 days 12 hours* 3 hours
Growth of ***Vibrio cholerae***	50°F (10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	21 days 6 hours* 2 hours*
Growth of ***Vibrio parahaemolyticus***	41-50°F (5-10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	21 days 6 hours* 2 hours*
Growth of ***Vibrio vulnificus***	46.4-50°F (8-10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	21 days 6 hours 2 hours
Growth of ***Yersinia enterocolitica***	29.7-50°F (-1.3-10°C) 51-70°F (11-21°C) Above 70°F (above 21°C)	1 days 6 hours 2.5 hours
* Additional data needed.		

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 nonproteoteolytic *Clostridinum 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 nonproteolytic *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.

Page Last Updated: 11/10/2009
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Conference for Food Protection
2010 Issue Form

Internal Number: 021
Issue: 2010 III-019

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

All information above the line is for conference use only.

Title:

Reduce confusion in ROP Criteria with regard to Cook Chill and Sous Vide

Issue you would like the Conference to consider:

The currrent section on ROP criteria with regard to cook-chill or sous vide without a variance (3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria) has two items that may be misinterpreted by regulators and operators. One section, 3-502.12 (B)(2) specifies conditions that permit storage of ROP at 41°F for up to 14 days. Another section, 3.502.12 (D)(2)(e) specifies holding temperature options of 38°F and 34°F. This section does not provide for a 41°F option at 14 days, yet does not exclude instructions provided in 3-502.12 (B)(2). Clarity is needed in the intent and wording of this section of the food code.

Public Health Significance:

When properly performed cook-chill and sous vide processing minimizes many risks of foodborne illness. When performed improperly, these processes may lead to growth of the foodborne pathogens *Clostridium botulinum* (psychrotrophic strains) or *Listeria monocytogenes*.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the FDA make changes to the Food Code Parts 3-502.12 Reduced Oxygen Packaging without a Variance, to clarify original storage temperature and shelf life intent to users by adding a new subsection (v) to Section 3-502.12. (D)(2)(e) as follows:

<u>(v) maintained at 41°F for foods that meet criteria specified in 3-502.12 (B)(2).</u>

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Attachments:

- "Food Code Section 3.502.12"

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

(C) If time without temperature control is used as the public health control up to a maximum of 6 hours:

Time – maximum up to 6 hours

(1) The FOOD shall have an initial temperature of 5ºC (41ºF) or less when removed from temperature control and the FOOD temperature may not exceed 21ºC (70ºF) within a maximum time period of 6 hours; P

(2) The FOOD shall be monitored to ensure the warmest portion of the FOOD does not exceed 21ºC (70ºF) during the 6-hour period, *unless an ambient air temperature is maintained that ensures the FOOD does not exceed 21ºC (70ºF) during the 6-hour holding period*; Pf

(3) The FOOD shall be marked or otherwise identified to indicate: Pf

(a) The time when the FOOD is removed from 5ºC (41ºF) or less cold holding temperature control, Pf and

(b) The time that is 6 hours past the point in time when the FOOD is removed from cold holding temperature control; Pf

(4) The FOOD shall be:

(a) Discarded if the temperature of the FOOD exceeds 21°C (70°F), P or

(b) Cooked and served, served at any temperature if READY-TO-EAT, or discarded within a maximum of 6 hours from the point in time when the FOOD is removed from 5ºC (41ºF) or less cold holding temperature control; P and

(5) The FOOD in unmarked containers or PACKAGES, or marked with a time that exceeds the 6-hour limit shall be discarded. P

(D) A FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION may not use time as specified under ¶¶ (A), (B) or (C) of this section as the public health control for raw EGGS.

Specialized Processing Methods

3-502.11 Variance Requirement.

A FOOD ESTABLISHMENT shall obtain a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 and under § 8-103.11 before: Pf

(A) Smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement; Pf

(B) Curing FOOD; Pf

(C) Using FOOD ADDITIVES or adding components such as vinegar: Pf

(1) As a method of FOOD preservation rather than as a method of flavor enhancement, Pf or

(2) To render a FOOD so that it is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL OF SAFETY FOOD); Pf

(D) Packaging FOOD using a REDUCED OXYGEN PACKAGING method *except where the growth of and toxin formation by* ***Clostridium botulinum*** *and the growth of* ***Listeria monocytogenes*** *are controlled as specified under § 3-502.12*; Pf

(E) Operating a MOLLUSCAN SHELLFISH life-support system display tank used to store or display shellfish that are offered for human consumption;Pf

(F) Custom processing animals that are for personal use as FOOD and not for sale or service in a FOOD ESTABLISHMENT; Pf

(G) Preparing FOOD by another method that is determined by the REGULATORY AUTHORITY to require a VARIANCE; Pf or

(H) Sprouting seeds or beans. Pf

Clostridium botulinum and Listeria monocytogenes Controls

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

(A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11, a FOOD ESTABLISHMENT that PACKAGES POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) using a REDUCED OXYGEN PACKAGING method shall control the growth and toxin formation of ***Clostridium botulinum*** and the growth of ***Listeria monocytogenes***. P

(B) A FOOD ESTABLISHMENT that PACKAGES POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) using a REDUCED OXYGEN PACKAGING method shall have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and that: Pf

(1) Identifies the FOOD to be PACKAGED; Pf

(2) Except as specified under ¶¶ (C) - (E) of this section, requires that the PACKAGED FOOD shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria: Pf

(a) Has an A_W of 0.91 or less, Pf

(b) Has a pH of 4.6 or less, Pf

(c) Is a MEAT or POULTRY product cured at a FOOD PROCESSING PLANT regulated by the USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact PACKAGE, Pf or

(d) Is a FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables; Pf

(3) Describes how the PACKAGE shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to: Pf

(a) Maintain the FOOD at 5°C (41°F) or below, Pf and

(b) Discard the FOOD if within 14 calendar days of its PACKAGING it is not served for on-PREMISES consumption, or consumed if served or sold for off-PREMISES consumption; Pf

(4) Limits the refrigerated shelf life to no more than 14 calendar days from PACKAGING to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first; P

(5) Includes operational procedures that:

(a) Prohibit contacting READY-TO-EAT FOOD with bare hands as specified under ¶ 3-301.11(B), Pf

(b) Identify a designated work area and the method by which: Pf

(i) Physical barriers or methods of separation of raw FOODS and READY-TO-EAT FOODS minimize cross contamination, Pf and

(ii) Access to the processing EQUIPMENT is limited to responsible trained personnel familiar with the potential HAZARDS of the operation, Pf and

(c) Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES; Pf and

(6) Describes the training program that ensures that the individual responsible for the REDUCED OXYGEN PACKAGING operation understands the: Pf

(a) Concepts required for a safe operation, Pf

(b) EQUIPMENT and facilities, Pf and

(c) Procedures specified under Subparagraph (B)(5) of this section and ¶ 8-201.14(D). Pf

Fish

(C) *Except for FISH that is frozen before, during, and after PACKAGING*, a FOOD ESTABLISHMENT may not PACKAGE FISH using a REDUCED OXYGEN PACKAGING method. P

Cook-Chill or Sous Vide

(D) Except as specified under ¶ (C) of this section, a FOOD ESTABLISHMENT that PACKAGES FOOD using a cook-chill or sous vide process shall:

(1) Implement a HACCP PLAN that contains the information as specified under ¶ 8-201.14(D); Pf

(2) Ensure the FOOD is:

(a) Prepared and consumed on the PREMISES, or prepared and consumed off the PREMISES but within the same business entity with no distribution or sale of the PACKAGED product to another business entity or the CONSUMER, Pf

(b) Cooked to heat all parts of the FOOD to a temperature and for a time as specified under § 3-401.11, P

(c) Protected from contamination before and after cooking as specified under Parts 3-3 and 3-4, P

(d) Placed in a PACKAGE with an oxygen barrier and sealed before cooking, or placed in a PACKAGE and sealed immediately after cooking and before reaching a temperature below 57°C (135°F), P

(e) Cooled to 5°C (41°F) in the sealed PACKAGE or bag as specified under § 3-501.14 and subsequently: P

(i) *Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held*

at that temperature until consumed or discarded within 30 days after the date of PACKAGING;[P]

(ii) *Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), removed from refrigeration equipment that maintains a 1°C (34°F) food temperature and then held at 5°C (41°F) or less for no more than 72 hours, at which time the* FOOD *must be consumed or discarded*; [P]

(iii) *Cooled to 3°C (38°F) or less within 24 hours of reaching 5°C (41°F) and held there for no more than 72 hours from* PACKAGING*, at which time the food must be consumed or discarded*; [P] or

(iv) Held frozen with no shelf life restriction while frozen until consumed or used. [P]

(f) Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily, [Pf]

(g) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, [Pf] and

(h) Labeled with the product name and the date PACKAGED;[Pf] and

(3) Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP PLAN and:

(a) Make such records available to the REGULATORY AUTHORITY upon request, [Pf] and

(b) Hold such records for at least 6 months; [Pf] and

(4) Implement written operational procedures as specified under Subparagraph (B)(5) of this section and a training program as specified under Subparagraph (B)(6) of this section.[Pf]

(E) A FOOD ESTABLISHMENT that PACKAGES cheese using a REDUCED OXYGEN PACKAGING method shall:

Cheese

(1) Limit the cheeses PACKAGED to those that are commercially manufactured in a FOOD PROCESSING PLANT with no ingredients added in the FOOD ESTABLISHMENT and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses; [P]

(2) Have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and as specified under ¶¶ (B)(1), (B)(3)(a), (B)(5) and (B)(6) of this section; [Pf]

(3) Labels the PACKAGE on the principal display panel with a "use by" date that does not exceed 30 days from its packaging or the original manufacturer's "sell by" or "use by" date, whichever occurs first; [Pf] and

(4) Discards the REDUCED OXYGEN PACKAGED cheese if it is not sold for off-PREMISES consumption or consumed within 30 calendar days of its PACKAGING. [Pf]

3-6 Food Identity, Presentation, and On-premises Labeling

Subparts

Accurate Representation

3-601.11 Standards of Identity.

PACKAGED FOOD shall comply with standard of identity requirements in 21 CFR 131-169 and 9 CFR 319 Definitions and standards of identity or composition, and the general requirements in 21 CFR 130 – Food Standards: General and 9 CFR 319 Subpart A – General.

3-601.12 Honestly Presented.

(A) FOOD shall be offered for human consumption in a way that does not mislead or misinform the CONSUMER.

(B) FOOD or COLOR ADDITIVES, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a FOOD.

Labeling

3-602.11 Food Labels.

(A) FOOD PACKAGED in a FOOD ESTABLISHMENT, shall be labeled as specified in LAW, including 21 CFR 101 - Food labeling, and 9 CFR 317 Labeling, marking devices, and containers.

(B) Label information shall include:

(1) The common name of the FOOD, or absent a common name, an adequately descriptive identity statement;

(2) If made from two or more ingredients, a list of ingredients in descending order of predominance by weight, including a declaration of artificial color or flavor and chemical preservatives, if contained in the FOOD;

(3) An accurate declaration of the quantity of contents;

(4) The name and place of business of the manufacturer, packer, or distributor; and

(5) The name of the FOOD source for each MAJOR FOOD ALLERGEN contained in the FOOD unless the FOOD source is already part of the common or usual name of the respective ingredient (Effective January 1, 2006). Pf

(6) Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(Q)(3) - (5), nutrition labeling as specified in 21 CFR 101 - Food Labeling and 9 CFR 317 Subpart B Nutrition Labeling.

(7) For any salmonid FISH containing canthaxanthin as a COLOR ADDITIVE, the labeling of the bulk FISH container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin.

(C) Bulk FOOD that is available for CONSUMER self-dispensing shall be prominently labeled with the following information in plain view of the CONSUMER:

(1) The manufacturer's or processor's label that was provided with the FOOD; or

(2) A card, sign, or other method of notification that includes the information specified under Subparagraphs (B)(1), (2), and (5) of this section.

(D) *Bulk, unPACKAGED FOODS such as bakery products and unPACKAGED FOODS that are portioned to CONSUMER specification need not be labeled if:*

(1) *A health, nutrient content, or other claim is not made;*

(2) *There are no state or local LAWS requiring labeling; and*

(3) *The FOOD is manufactured or prepared on the PREMISES of the FOOD ESTABLISHMENT or at another FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT that is owned by the same PERSON and is regulated by the FOOD regulatory agency that has jurisdiction.*

3-602.12 Other Forms of Information.

(A) If required by LAW, CONSUMER warnings shall be provided.

(B) FOOD ESTABLISHMENT or manufacturers' dating information on FOODS may not be concealed or altered.

Consumer Advisory

3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.

(A) Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(4) and under ¶ 3-801.11(C), if an animal FOOD such as beef, EGGS, FISH, lamb, milk, pork, POULTRY, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in READY-TO-EAT form or as an ingredient in another READY-TO-EAT FOOD, the PERMIT HOLDER shall inform CONSUMERS of the significantly increased RISK of consuming such FOODS by way of a DISCLOSURE and REMINDER, as specified in ¶¶ (B) and (C) of this section using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means. Pf

(B) DISCLOSURE shall include:

(1) A description of the animal-derived FOODS, such as "oysters on the half shell (raw oysters)," "raw-EGG Caesar salad," and "hamburgers (can be cooked to order)"; Pf or

(2) Identification of the animal-derived FOODS by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients. Pf

(C) REMINDER shall include asterisking the animal-derived FOODS requiring DISCLOSURE to a footnote that states:

(1) Regarding the safety of these items, written information is available upon request; Pf

(2) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness; Pf or

(3) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness, especially if you have certain medical

conditions. Pf

3-7 Contaminated Food

Subparts

3-701 Disposition

Disposition

3-701.11 Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.

(A) A FOOD that is unsafe, ADULTERATED, or not honestly presented as specified under § 3-101.11 shall be discarded or reconditioned according to an APPROVED procedure. P

(B) FOOD that is not from an APPROVED source as specified under §§ 3-201.11 - .17 shall be discarded. P

(C) READY-TO-EAT FOOD that may have been contaminated by an EMPLOYEE who has been RESTRICTED or EXCLUDED as specified under § 2-201.12 shall be discarded. P

(D) FOOD that is contaminated by FOOD EMPLOYEES, CONSUMERS, or other PERSONS through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be discarded. P

3-8 Special Requirements For Highly Susceptible Populations

Subparts

3-801 Additional Safeguards

Additional Safeguards

3-801.11 Pasteurized Foods, Prohibited Re-Service, and Prohibited Food.

In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION:

(A) The following criteria apply to JUICE:

(1) For the purposes of this paragraph only, children who are age 9 or less and receive FOOD in a school, day care setting, or similar facility that provides custodial care are included as HIGHLY SUSCEPTIBLE POPULATIONS;

(2) PREPACKAGED JUICE or a PREPACKAGED BEVERAGE containing JUICE, that bears a warning label as specified in 21 CFR, 101.17(g) Food labeling, warning, notice, and safe handling statements, Juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens, or a PACKAGED JUICE or BEVERAGE containing JUICE, that bears a warning label as specified under ¶ 3-404.11(B) may not be served or offered for sale; P and

(3) UNPACKAGED JUICE that is prepared on the premises for service or sale in a READY-TO-EAT form shall be processed under a HACCP PLAN that contains the information specified under ¶¶ 8-201.14(B) - (E) and as specified in 21 CFR Part 120 – Hazard Analysis and Critical Control Point (HACCP) Systems, Subpart B Pathogen Reduction, 120.24 Process controls. P

(B) Pasteurized EGGS or EGG PRODUCTS shall be substituted for raw EGGS in the preparation of: P

(1) FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, EGGNOG, ice cream, and EGG-fortified BEVERAGES, P and

(2) Except as specified in ¶ (F) of this section, recipes in which more than one EGG is broken and the EGGS are combined; P

(C) The following FOODS may not be served or offered for sale in a READY-TO-EAT form: P

(1) Raw animal FOODS such as raw FISH, raw-marinated FISH, raw MOLLUSCAN SHELLFISH, and steak tartare, P

(2) A partially cooked animal FOOD such as lightly cooked FISH, rare MEAT, soft-cooked EGGS that are made from raw EGGS, and meringue; P and

(3) Raw seed sprouts. P

(D) FOOD EMPLOYEES may not contact READY-TO-EAT FOOD as specified under ¶¶ 3-301.11(B) and (D). P

(E) Time only, as the public health control as specified under ¶ 3-501.19(D), may not be used for raw EGGS. P

(F) *Subparagraph (B)(2) of this section does not apply if:*

(1) *The raw EGGS are combined immediately before cooking for one CONSUMER'S serving*

at a single meal, cooked as specified under Subparagraph 3-401.11(A)(1), and served immediately, such as an omelet, soufflé, or scrambled EGGS*;*

(2) *The raw* EGGS *are combined as an ingredient immediately before baking and the* EGGS *are thoroughly cooked to a* READY-TO-EAT *form, such as a cake, muffin, or bread; or*

(3) *The preparation of the food is conducted under a HACCP* PLAN *that:*

(a) *Identifies the* FOOD *to be prepared,*

(b) *Prohibits contacting* READY-TO-EAT FOOD *with bare hands,*

(c) *Includes specifications and practices that ensure*:

(i) ***Salmonella* Enteritidis** *growth is controlled before and after cooking, and*

(ii) ***Salmonella* Enteritidis** *is destroyed by cooking the* EGGS *according to the temperature and time specified in Subparagraph 3-401.11(A)(2),*

(d) *Contains the information specified under ¶ 8-201.14(D) including procedures that:*

(i) *Control cross contamination of* READY-TO-EAT FOOD *with raw* EGGS*, and*

(ii) *Delineate cleaning and* SANITIZATION *procedures for* FOOD-CONTACT SURFACES*,* and

(e) *Describes the training program that ensures that the* FOOD EMPLOYEE *responsible for the preparation of the* FOOD *understands the procedures to be used.*

Re-service of Food

(G) Except as specified in paragraph (H) of this section, FOOD may be re-served as specified under Subparagraph 3-306.14(B)(1) and (2).

Prohibited Re-service of Food

(H) *Food may not be re-served under the following conditions:*

(1) *Any* FOOD *served to patients or clients who are under contact precautions in medical isolation or quarantine, or protective environment isolation may not be re-served to others outside.*

(2) *Packages of* FOOD *from any patients, clients, or other* CONSUMERS *should not be re-served to* PERSONS *in protective environment isolation.*

Page Last Updated: 11/05/2009
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Conference for Food Protection
2010 Issue Form

Internal Number: 020
Issue: 2010 III-020

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

All information above the line is for conference use only.

Title:

3-302.11 Packaged and Unpackaged Food - Separation

Issue you would like the Conference to consider:

Currently Annex 3 gives guidance on separating raw animal foods during storage, preparation, holding, and display that is "...based on a succession of cooking temperatures since cooking temperatures as specified under § 3-401.11 are based on thermal destruction data and anticipated microbial load." Because of this guidance, many jurisdictions prohibit packaged ground beef (cook to 155°F) from being stored, held, or displayed above whole muscle beef products (cook to 145 °F) even though 3-302.11(A)(4) recognizes that storing the FOOD in packages or wrappings is an exception to separating raw animal FOODS. Ground beef is cooked to a higher temperature to kill potential internal contamination. Whole muscle beef can be cooked to kill surface contamination only. If the packaged whole muscle beef were to be cross-contaminated from the packaged ground beef, it would still only be a surface contaminant and normal cooking temperature of 145 °F would render the product safe. This fact is supported by 3-302.11(A)(2) which allows combining certain types of raw animal FOODS as ingredients. Request the Conference to consider amending Section 3-302.11 of the Food Code along with Annex 3 (Public Health Reasons/Administrative Guidelines) to recognize that packaged ground meat displayed for sale over packaged whole muscle cuts is an acceptable practice that has minimal risk.

Public Health Significance:

In the unlikely event the juice or pieces of ground beef products from a packaged product were to get onto a piece of packaged whole muscle beef, the normal cooking requirements for the whole muscle product would be adequate to render the food safe based in part on similar information applicable to seared steak found in the 2009 Food Code Annex which states:

Seared Steak

The provision for allowing seared steaks was reviewed by the National Advisory Committee for Microbiological Criteria on Foods (NACMCF) and USDA. Paragraph 3-401.11(C) includes their recommendations.

USDA comments included, "For the purposes of this discussion, steak is a whole beef muscle. It does not include whole beef muscle that has been pinned, injected, or chopped and formed. It may be cut cross grain, such as sirloin, chuck, or porterhouse; or it may be cut with the grain, such as flank, skirt, or Chateaubriand. Other species, such as poultry, pork, and lamb are not included."

NACMCF comments included, "Due to the low probability of pathogenic organisms being present in or migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be safe if the external surfaces are exposed to temperatures sufficient to effect a cooked color change. In addition, the cut (exposed) surfaces must receive additional heat to effect a complete sear across the cut surfaces. Grill or char marks may be applied to the complete surface searing. The meat should be seared on both top and bottom surfaces utilizing a heating environment (e.g., grill or broiling oven) that imparts a temperature at the surface of the intact steak of at least 145°F to achieve a cooked color change on all external surfaces. The searing of all surfaces should be continuous until the desired degree of doneness and appearance are attained. This is considered a ready-to-eat food."

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that Section 3-302.11 have (A)(1)(d) added as follows:

3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.

(d) *Packaged raw Ground beef may be stored or displayed with or above packaged whole muscle beef*

and Annex 3 (Public Health Reasons/Administrative Guidelines) be amended by adding the following at the end of the paragraph.

Annex 3 - 3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.

"...from these products packaged in-house. Another exception is permitted for *packaged raw ground beef to be stored or displayed adjacent to or above packaged whole muscle beef since the packaging is an acceptable barrier for separating and if there were leakage in both packages, the surface of the whole muscle cuts would receive sufficient heat treatment similar to searing a steak and make the whole muscle cut safe when standard cooking instructions are followed. "*

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Conference for Food Protection
2010 Issue Form

Internal Number: 058
Issue: 2010 III-021

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

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Title:

Packaged Ice Manufacturing at Retail

Issue you would like the Conference to consider:

Currently, the Food Code references Ice in Section 3-202.16. It is defined as a food or a cooling medium made from drinking water. However, the Food Code does not appear to reference the manufacture and distribution of packaged ice at the retail level. The International Packaged Ice Association recommends that CFP support recognition in the Food Code of packaged ice manufacturing sold for human consumption.

The International Packaged Ice Association (IPIA) represents more than 400 packaged ice manufacturers and distributors. The IPIA mandates as a prerequisite to association membership that member producers demonstrate compliance with PIQCS (Packaged Ice Quality Control Standards). PIQCS was developed over ten years ago and is based on Good Manufacturing Practices specific to packaged ice and HACCP (Hazard Analysis Critical Control Point). The PIQCS standards are available at:

http://www.packagedice.com/downloads/PIQCSManualFINAL.pdf.

However, an estimated 40% of the packaged ice sold at retail for human consumption is produced at the retail level without specific guidance or inspection.

Public Health Significance:

Ice is widely used in retail food establishments, and is sold as packaged ice from a large number of retail food establishments. Ice receives little attention as a possible source of food borne illness. Packaged Ice is a manufactured food and as such is subject to the Good Manufacturing Practices Regulations for Foods contained in the Code of Federal Regulations, Title 21, Chapter 1, Part 110 [21CFR; Part 110]. Both Congress and the FDA acknowledged this in the "Fiscal Year 2010 Department of Agriculture Appropriations Bill" (the annual legislation that has the authority to fund the Food and Drug Administration). It

contained the following language on packaged ice: *"Packaged Ice Manufacturing: The Committee recognizes that ice is a food product produced in the United States for both interstate and intrastate commerce, and has been made aware of concerns regarding individual retail outlets that manufacture and bag ice. The Committee directs FDA to work to educate manufacturers regarding safe production of ice, including the issuance of a Food Facts sheet informing the public about existing FDA regulations that apply to ice manufacturers. Further, the Committee directs FDA to consider whether or not formal regulations regarding the safe handling, processing, and packaging of packaged ice sold for human consumption would be an appropriate measure."*

The processing of bottled water is subject to the product specific Code of Federal Regulations, Title 21, Chapter 1, Part 165 [21CFR; Part 165]. Many states have adopted and currently enforce these regulations which contain provisions pertinent to ice. However, there are no specific packaged ice processing regulations at the Federal level, and only two states, Florida and Montana, implement such requirements for packaged ice production at the retail and wholesale level, similar to those they enforce for bottled water. The Florida and Montana regulations are attached. Packaged ice plants range in size from the smaller retail packaged ice manufacturing operation to the large commercial wholesale manufacturer. They also include the self service mobile ice vending units.

The list of possible contaminants that could be present in packaged ice by not following proper GMP's is comprised of well known microorganisms and enteric viruses. Source water contamination, contaminated food contact surfaces, with the most common being mold, mildew and slime in the ice machine and unsanitized ice scoops, and cross contamination in the handling process can occur. The manual nature of the bagging process by smaller retail packaged ice manufacturers (an estimated 40% of packaged ice manufactured and sold to the public) speaks to this last possibility of ice contamination from improper personnel hygienic practices, including pathogen transmission by sneezing, coughing, and open sores with bare hand contact. Potential contaminants include chemical, viral, bacteriological and parasitic pathogens.

The number of documented cases of contaminated ice when GMP's were not followed is small in comparison to higher profile foods. The number may be small for two reasons. First, there is a popular misconception that ice is a preservative for other foods and the freezing process kills microorganisms. Second, ice is not one of the first food products looked at if at all when a food borne illness incident occurs. The CDC indicates that over 50,000 cases per year of reported food borne illness are of unknown origin and ice is widely used in retail food establishments.

Annex 2 of the Food Code references two reports on ice contamination:

1. Cliver, D.O., 1988. Virus transmission via foods; A scientific status summary by the

Institute of Food Technologists' Expert Panel on Food Safety and Nutrition. Food

Technol. 42(10):241-248.

2. Jackson, G.L., 1990. Parasitic protozoa and worms relevant to the U.S. Food

Technol. 44(5):106-112.

Other supporting reports:

1. 2002 article from NACS (National Association of Convenience Stores): *" In the past 25 years, over 475,000 cases of waterborne disease outbreaks have been recorded. To bring this closer to home: "A survey of convenience store, on-premise ice machines indicated that 36 percent of packaged ice produced came from water that did not meet EPA drinking water standards," according to Dr. Debra Huffman of the University of South Florida. She continues to say, "Regardless of the type of microorganism such as E.coli, hepatitis, or protozoa, the results are the same, lack -- of water treatment and/or poor ice processing conditions result in people becoming ill."*

2. Example from January, 2007, Houlihans restaurant in Indiana

Health officials are particularly concerned with those patrons who consumed drinks with ice. "*Restaurant patrons may have been exposed to hepatitis A "*

3. Example attached Anderson Cooper 360, 2008

4. Example attached ABC News Science Fair project

5. AFDO guidelines attached for handling and manufacturing packaged ice

In conclusion, the public is at increased risk of being exposed to contaminated or adulterated ice because there are currently no specific government health and safety standards for the manufacturing of Packaged Ice at the wholesale or retail levels.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting modification of the Food Code,

- **Add to Section 1-201.10 Statement of Application and Listing of Terms:**

"Packaged Ice" means food intended for human consumption that is formed from drinking water, spring water or purified water by freezing to a solid state that is sealed in packages and offered for sale for human consumption.

- **Modify Section 3-202.16, to read**:

3-202.16 Ice, including packaged ice.

Ice, including packaged ice, for use as a food or a cooling medium shall be made from drinking water

- **Modify Annex 3, Public Health Reasons/Administrative Guidelines to read:**

3-202.16 Ice, <u>including packaged ice</u>.

Freezing does not invariably kill microorganisms; on the contrary, it may preserve them.

Therefore, ice that comes into contact with food to cool it or that is used directly for

consumption must be as safe as drinking water that is periodically tested and approved

for consumption.

- **Modify Guide 3-B Instructions for Marking the Food Establishment Report- page 19 to read:**

29. Water and ice, <u>including packaged ice</u> from approved source. <u>Packaged ice meets 21 CFR (Code of Federal Regulations) 101 labeling requirements.</u>

Submitter Information:

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Attachments:

- "State of Florida regulations for packaged ice"
- "State of Montana Ice Regulations"
- "ABC News Science Fair Project"
- "Anderson Cooper 360"
- "AFDO Guidelines for Handling and Manufacturing Packaged Ice"

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

5K-4.023 Packaged Ice.

(1) In addition to the requirements in the general food products statute, Chapter 500, F.S., and all applicable rules in Chapter 5K-4, F.A.C., packaged ice plant operators and packaged ice dealers shall comply with the following rules.

(2) DEFINITIONS:

(a) ICE means food intended for human consumption that is formed from drinking water by freezing to a solid state.

(b) IMPORTED means manufactured, processed, packaged, stored or distributed from a point outside of the state of Florida.

(c) MAXIMUM CONTAMINANT LEVEL (MCL) means the maximum permissible level of a contaminant as set forth in Chapter 403, F.S., and Chapter 64E-8, F.A.C. (1/93), titled "Drinking Water Systems", and Chapter 62-550, F.A.C. (5/94), titled "Drinking Water Standards, Monitoring and Reporting".

(3) REQUIREMENTS:

(a) Each person or public body that establishes, maintains, or operates a packaged ice plant must obtain a Packaged Ice Plant Operating/Food Permit from the department each year. Each packaged ice plant location must have a permit.

(b) Each packaged ice dealer must obtain a Packaged Ice Dealer/Food Permit from the department each year. Ice transported into the state and packaged either before or after importation into the state must meet all of the requirements of this section and must be packaged, labeled, handled, and otherwise processed and sold according to the provisions of this section.

(c) Any packaged ice plant operator who is also a packaged ice dealer shall be issued a combined Packaged Ice Plant Operating-Dealer/Food Permit by the department. Such permit shall be issued each year upon compliance with all statutory and rule requirements for the issuance of a Packaged Ice Plant Operating Permit and a Packaged Ice Dealer Permit. Each location must have a permit.

(d) Each packaged ice plant operator or packaged ice dealer who is engaged in the sale or distribution of any other food product and whose operation qualifies as a food establishment under Chapter 500, F.S., shall be issued a combined Food/Packaged Ice Permit by the department. Such permit shall be issued each year upon compliance with all statutory and rule requirements for the issuance of a Food Permit, a Packaged Ice Plant Operating Permit, a Packaged Ice Dealer Permit, or a combination thereof. Each location must have a permit as per Section 500.12(1)(a), F.S. and subsection 5K-4.020(2), F.A.C.

(e) All permits shall expire on December 31 of each year.

(f) Application for permits must be made in writing to the department on form IN-63, an Annual Food Permit Application, (Revised 10/94).

(4) PERMIT FEES:

(a) Each packaged ice plant operator must pay the department an annual non-refundable fee of $250.00 for each permit.

(b) Each packaged ice dealer must pay the department an annual non-refundable fee of $100.00 for each permit.

(c) Each packaged ice plant operator who is also a packaged ice dealer must pay the department an annual, non-refundable fee for each permit. Such fee shall be the greater of the Packaged Ice Plant Operating or the Packaged Ice Dealer permit fee required in this subsection.

(d) Each packaged ice plant operator or packaged ice dealer who is engaged in the sale or distribution of any other food product and whose operation qualifies as a food establishment under Chapter 500, F.S., must pay the department an annual, non-refundable fee for each permit. Such fee shall be the greater of the Food Permit fee required by Rule 5K-4.020, F.A.C., or the applicable permit fee required by this subsection.

(e) Fees charged to applicants for new permits shall be prorated with the applicant paying 1/12th of the applicable fee for each month remaining in the calendar year, including the month of application.

(5) SOURCE WATER AND FINISHED PRODUCT QUALITY:

(a) All water used for the manufacture of ice intended for human consumption and in preparation of brine solutions must be from an approved drinking water supply as described in Chapter 64E-8 or 62-550, F.A.C.

(b) Imported packaged ice product must be manufactured from source water that has been approved as a drinking water supply by the agency with jurisdiction in the state where the ice is manufactured and packaged.

(c) Packaged ice dealers importing product must submit to the department a copy of the current source certification or a letter from the agency with jurisdiction for approval of drinking water supplies. This information must be submitted to the department with each annual permit application.

(d) Packaged ice must be in conformance with maximum contaminant levels that have been established for drinking water supplies in Chapters 64E-8 and 62-550, F.A.C.

(e) All packaged ice plants shall submit to an approved laboratory, once every three months, a sample of each type of finished product for microbiological analysis. A copy of the quarterly analytical results shall be forwarded to the department by out-of-state packaged ice dealers. In-state packaged ice plants shall maintain these records as required by Section 500.509, F.S., and make them available to the department upon request.

(f) The quarterly laboratory analysis must include testing for fecal and total coliform organisms and Heterotrophic Plate Count (HPC). Total coliforms shall not be greater than 2.2 organisms/100 ml. using the Most Probable Number (MPN) method or not greater than 1 organism/100 ml. using the Membrane Filtration (MF) method. The HPC shall not exceed 500 colonies/ml. Packaged ice shall have no fecal coliform-positive samples.

(g) Should finished product samples exceed the standards outlined in paragraph (f) of this subsection, the plant shall submit samples to an approved laboratory, on a weekly basis, until two (2) consecutive acceptable samples are obtained. Copies of weekly sample analyses shall be submitted to the department upon receipt by the packaged ice plant or packaged ice dealer.

(h) The department shall collect and analyze samples of source water and finished product when necessary to determine if the source water and/or finished product meet quality standards established in this rule. When indicated by reason of complaint or illness, the department may obtain and analyze or require the ice plant to obtain and have analyzed, by an approved laboratory, samples of source water and/or finished product.

(i) All records of sampling and analyses of source water and finished product shall be maintained by the plant for a period of not less than 2 years and shall be made available to the department upon request.

(6) PROCESSING AND PACKAGING:

(a) Ice shall be processed and packaged using methods that preclude contamination of the product.

(b) Air used for water agitation shall be filtered or otherwise treated to render it free of oil, dust, dirt, insects and extraneous material.

(c) Manual packaging of product shall be performed in a manner that will preclude contamination of the packaging material and the product.

(d) Any spillage created during manufacture, packaging, transportation or storage shall be disposed of and shall not be packaged or re-packaged for sale for human consumption.

(e) Ice packaging material shall be of foodgrade quality and closures shall be designed to adequately protect its contents. Only pin holes or a butterfly vent that does not exceed 1/4 inch in diameter shall be used in ice packaging material. Pin holes or butterfly vents must be located in the upper 1/3 portion of the bag.

(f) Packaging material shall be protected from contamination during storage and handling.

(7) STORAGE AND TRANSPORTATION:

(a) Packaged ice plants producing product that is not to be used for human consumption shall store this product in a designated area that is clearly identified and separated from other packaged ice products.

(b) Packaged ice shall be stored above the floor protected from splash and shall not be located in areas susceptible to overhead dripping.

(c) Wooden platforms or pallets shall not be used for the purpose of transporting ice or storing ice above the floor unless platforms or pallets have been designed or covered with surfaces that protect the product from splintering. Such surfaces shall be easily cleaned and sanitized or shall be replaced between uses.

(d) Product shall be transported in an enclosed facility designed and equipped to protect the product from contamination and shall be maintained in a clean condition.

(e) Packaged ice shall be handled in such a manner to preclude contamination during transportation and delivery. At no time during transport or delivery shall the packaged ice product come into contact with the floor or ground.

(8) LABELING: Packaged ice plants producing product that is not to be sold for human consumption shall designate “NOT FOR HUMAN CONSUMPTION” on the package. This designation shall be clearly visible to the consumer.

(9) NOTIFICATION TO THE DEPARTMENT: The operator or manager of a packaged ice plant or dealer who knows or should know that a primary maximum contaminant level has been exceeded or believes or has reason to believe that circumstances exist such as source contamination, spills, accidents, natural disasters, breakdowns in the sanitary processing of ice or other similar problems that may adversely affect the safety of the packaged ice, shall immediately notify the department of the incident.

(10) PRODUCT RECALL PROCEDURES:

(a) If the department determines, based upon results of representative sample tests and risk analysis that an immediate hazard to

the health, safety and welfare of the public is present in any packaged ice product, the department shall order the packaged ice plant or dealer to initiate a product recall to effectively avoid or significantly minimize the threat to the public's health and if appropriate, issue a notification to customers. The plant or dealer shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.

(b) When a laboratory report reveals a maximum contaminant level (MCL) has been exceeded, but when investigation indicates that the condition causing the MCL to be exceeded was promptly corrected and that previously distributed product will not cause illness nor present any significant health hazard, a company recall and media notification shall not be necessary. In circumstances where a recall or media notification is not necessary but consumer complaints indicate problems regarding product taste or odor, the department shall order the plant to communicate the exceedence of the MCL and the implementation of corrective measures by direct mailings to affected customers.

(11) DEPARTMENT RESPONSIBILITIES AND DUTIES: Packaged ice plant operators and packaged ice dealers shall allow the department to examine records pertaining to the operation and maintenance of the plant or source water.

(12) FORMS: Form IN-63, an Annual Food Permit Application (Revised 10/94), is hereby incorporated by reference. Copies may be obtained from the Florida Department of Agriculture and Consumer Services, 3125 Conner Boulevard, Room 294, Tallahassee, Florida 32399-1650.

Specific Authority 500.509, 500.12(1)(d), 570.07(23) FS. Law Implemented 500.453, 500.509 FS. History–New 1-19-95, Formerly 5E-6.023, Amended 8-8-95.

DEPARTMENT OF PUBLIC HEALTH
AND HUMAN SERVICES

CHAPTER 110

FOOD AND DRUG STANDARDS

Subchapter 8

Drinking Water and Ice

37.110.801 DRINKING WATER (1) Any person engaged in the production, packaging, manufacturing or processing of drinking water, culinary bottled water, or water otherwise processed and packaged for human consumption, is subject to the licensing requirements of 50-50-201, MCA, for food manufacturing establishments. Any manufacturing or bottling plant located in a state, territory, or nation other than Montana that prepares water in bottles or other containers for drinking or culinary purposes for sale in Montana must also be licensed by the department.

(2) Each food manufacturing establishment in Montana where water is prepared for sale in bottles or other containers for human consumption and the sources of all such water must be inspected at least once each year by the local health officer, sanitarian or sanitarian-in-training employed by or contracted with the local board of health having jurisdiction. A copy of each inspection must be submitted to the department within 30 days after the inspection occurs.

(3) Each food manufacturing establishment in Montana where water is prepared for sale in bottles or other containers for human consumption must:

(a) obtain its water from a community public water system approved by the water quality division of the department of environmental quality, or, if water is obtained from a separate or independent system, that system must comply with the statutes governing public water supplies, 75-6-101 et seq., MCA, the rules governing public water supplies, ARM 17.38.201 et seq., and the rule governing plans for public water supplies or wastewater systems, ARM 17.38.101.

(b) maintain sampling records demonstrating compliance with the bacteriologic, chemical and radiologic sampling requirements specified in (6)(b) of this rule for at least 12 months after the date of sampling.

(4) The operation of all food manufacturing establishments involved in producing, packaging, manufacturing, or processing drinking or bottled water and the products marketed must comply with these rules and with the Montana Food, Drug and Cosmetic Act, 50-31-101 et seq., MCA; the food manufacturing establishment rules, ARM 37.110.301 et seq.; the federal standards regarding food labeling, 21 CFR 101; the federal quality standards for foods with no identity standards, 21 CFR 103; the federal standards for processing and bottling of bottled drinking water, 21 CFR 129; and the Fair Packaging and Labeling Act, 15 USC 1451 et seq.

(5) Every food manufacturing establishment desiring to sell, market or distribute bottled water in Montana, whether located in Montana or not, must apply for a license on a form provided by the department, which must be signed by the owner or the owner's legal representative, and must submit the fee required by 50-50-206, MCA. Such fee must be payable to the department and the application must be postmarked no later than midnight on December 31 of each year. Submission of a renewal application and fee after this time will require the food manufacturing establishment to submit the late fee required by 50-50-206, MCA. The license year is January 1 through December 31.

(6) In addition to the fee, the late fee, if applicable, and the application form identified in (5) above, the food manufacturing establishment must submit the following to the department for review:

(a) A certification affidavit from the state or local health officer, sanitarian or sanitarian-in-training employed by or contracted with the local board of health having jurisdiction, affirming that the establishment meets the requirements of 21 CFR 103 and 129;

(b) If the source water is not mineral water, copies of the most recent inorganic, volatile organic, organic chemical and radiological analyses of the establishments water showing compliance of the source water with the maximum contaminant levels for regulated water systems as required by 40 CFR 141; or a certification affidavit from the state or local health officer, sanitarian, or sanitarian-in-training employed by or contracted with the local board of health having jurisdiction, affirming that the water source complies with these standards;

(c) Test results for pesticides and synthetic organic chemicals, if the department determines such tests are necessary or if random testing has shown there is or may be contaminants present at levels which may adversely affect public health;

(d) A copy, photocopy, or printer's proof of each label for each product to be marketed and for each size to be marketed;

(e) A description of the source of the water, water treatment used, all substances added to the water, and any other documentation required by the department to verify that labels and terminology used on the labeling conform with applicable law; and

(f) For products labeled "mineral water" or for a label containing the term "mineral water", copies of the results of laboratory testing of mineral content and total dissolved solids (TDS) of the product, obtained during the 12 months preceding the license year from an agency approved to test drinking water by the department or another public health agency.

(7)(a) The department hereby adopts by reference:

(i) ARM 37.110.301 et seq., setting standards for food manufacturing establishments;

(ii) ARM 37.110.201 et seq., setting standards for public water supplies;

(iii) ARM 17.38.101, governing plans for public water supplies;

(iv) 21 CFR 101, setting food labeling standards;

(v) 21 CFR 103, setting quality standards for foods with no identity standards;

(vi) 21 CFR 129, setting standards for processing and bottling bottled drinking water;

(vii) 40 CFR 141, containing maximum contaminant levels for drinking water, and

(viii) 15 USC 1451 et seq., containing federal law on packaging and labeling.

(b) Copies of these statutes and rules may be obtained, upon payment of copying costs, from the Department of Public Health and Human Services, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, Montana 59620-2951. (History: Sec. 50-31-104, 50-31-201 and 50-50-103, MCA; IMP, Sec. 50-31-104, 50-31-201 and 50-50-103, MCA; NEW, 1994 MAR p. 2832, Eff. 10/28/94; AMD, 1995 MAR p. 368, Eff. 3/17/95; TRANS, from DHES, 2001 MAR p. 2423.)

37.110.802 ICE (1) This rule applies only to ice that is intended for human consumption and is sold in packaged form or in bulk form for food, drink or culinary purposes. This rule does not apply to persons, hotels, restaurants, inns, caterers, food service contractors, or theaters that manufacture or furnish ice solely to or for their customers in a manner that is incidental to the production, sale or dispensing of other goods and services.

(2) Natural ice that is cut from water on a stream, creek, river, lake, pond, or other body of surface water may not be used as ice for human consumption.

(3) Except as provided in (1) above, any person who manufactures, transports, distributes, sells or provides ice, with or without charge, to the public must obtain a food manufacturing license and must comply with these rules and with the statutes governing food manufacturing establishments, 50-50-101 et seq., MCA; the rules governing food manufacturing establishments, ARM 37.110.301, et seq.; and the rules governing public water systems, ARM 17.38.201 et seq.

(4) Ice plants must be operated in a clean and sanitary manner. The room in which ice production occurs may not be used for any purposes other than ice or food production and the storage and refrigeration of ice or food.

(5) Ice production facilities shall meet the provisions of 21 CFR 110, which provides standards for current good manufacturing practice in manufacturing, packing, or holding human food.

(6) Ice produced and packaged for sale to the public must be labeled in accordance with the Montana Food, Drug and Cosmetic Act, Title 50, chapter 31, MCA, and in accordance with 21 CFR 101, which establishes federal food labeling standards, and must display legible labeling including, but not limited to, the identity of the product, the net weight or contents of the package, and the name and place of business of the manufacturer, packer, distributor, seller, or provider.

(7) Packaged ice transportation, hauling vehicles, and bulk containers, including display or storage freezers, are regarded as a part of the licensed premises and are subject to review or inspection by the department or the local health officer, sanitarian, or sanitarian-in-training employed by or contracted with the local board of health having jurisdiction, prior to issuance or renewal of its license or on a regular annual inspection.

(8) The food manufacturing establishment must sample and have analyzed its manufactured ice products, and the waters from which the ice is made, at least once a month for compliance with the maximum microbiological contaminant levels contained in ARM 17.38.207, and send the results to the department. The food manufacturing establishment is also required to comply with the bacteriological quality sampling provisions of ARM 17.38.215 (3) through (7) for transient non-community water systems. The department may increase the required sampling frequency based upon sampling results or other conditions which indicate an increased risk to the health of the users of the product. The department may decrease the required sampling frequency to quarterly or biannually based on a showing that the source consistently does not contain the contaminant, is either a community water system or a groundwater source not under direct influence of surface water, and that the samples consistently meet the required sanitary standards, rendering the source and operation generally not vulnerable to microbiological contamination.

(9) The delivery of ice to the customer must be done under sanitary conditions. Ice must be packaged in durable freezable containers labeled in conformance with the labeling requirements as described in (6) above. Boxes or containers intended for non-food use or for use in packaging another food are not acceptable transport containers. All boxes, containers, cases or contact surfaces within bins or transport vehicles must be constructed of food grade materials.

(10) Natural or manufactured ice that does not conform to standards set forth in this rule must be conspicuously identified or labeled as unsafe or inedible and may not be sold or distributed for human consumption. Such ice may be used for cooling or refrigeration purposes only if such use does not permit it to come in direct contact with food or drink meant for human consumption. If such ice is sold or distributed for refrigeration purposes, the seller or distributor must notify the buyer or consumer that it is not safe for human consumption.

(11) The department hereby adopts by reference ARM 37.110.301 et seq., setting standards for food manufacturing establishments; ARM 17.38.201, et seq., setting standards for public water supply systems; 21 CFR 110, setting standards for packing, manufacturing, or holding human food; and 21 CFR 101, setting food labeling standards. Copies of these rules may be obtained, upon payment of copying costs, from the Department of Public Health and Human Services, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, Montana 59620-2951. (History: Sec. 50-31-104, 50-31-201 and 50-50-103, MCA; IMP, Sec. 50-31-104, 50-31-201 and 50-50-103, MCA; NEW, 1994 MAR p. 2832, Eff. 10/28/94; TRANS, from DHES, 2001 MAR p. 2423.)

Rules 03 and 04 reserved

37.110.805 COMMON CARRIERS (1) Water and ice provided by common carriers for drinking or culinary purposes in railway trains, buses, or other public transportation conveyances and in all railway stations in Montana must be taken from supplies which conform to standards for drinking water contained in 40 CFR 141 and 40 CFR 142.

(2) The department hereby adopts by reference 40 CFR 141, setting maximum contaminant levels and other standards for drinking water, and 40 CFR 142, establishing procedures for implementing and enforcing drinking water standards. Copies of these rules may be obtained, upon payment of copying costs, from the Department of Public Health and Human Services, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, Montana 59620-2951. (History: Sec. 50-50-103, MCA; IMP, Sec. 50-50-103, MCA; NEW, 1994 MAR p. 2832, Eff. 10/28/94; TRANS, from DHES, 2001 MAR p. 2423.)

Rules 06 through 09 reserved

37.110.810 MINIMUM PERFORMANCE REQUIREMENTS FOR LOCAL HEALTH AUTHORITIES (1) To qualify for reimbursement under 50-50-305, MCA, for regulation of sources of drinking water and ice, a local board of health must either enter into a written, signed cooperative agreement with the department that establishes the duties and responsibilities of the local board of health and the department consistent with this subchapter, or ensure that the following are done by the local health officer, sanitarian, or sanitarian-in-training:

(a) Ensure that, at least once per year, each plant or establishment within the jurisdiction of the local board of health where water is prepared for sale in bottles or other containers or artificial ice is manufactured, and the sources of all such water, are inspected, either by the foregoing individuals or by another government agency and, at the same time, that a sample of the water is submitted to a DEQ-approved laboratory for analysis for contaminants.

(b) Submit quarterly inspection reports to the department within 10 days following the close of each quarter of the fiscal year (1st quarter--September 30; 2nd quarter--December 31; 3rd quarter--March 31; 4th quarter--June 30) on forms approved by the department.

(c) Retain for 5 years all documentation of enforcement of this subchapter, including but not limited to inspection reports, consumer complaints, illness investigations, plans of correction, and enforcement actions, and, upon request, submit copies of the documentation to the department or otherwise make it available to the department.

(2) A failure by the local board of health to meet all of its responsibilities under the cooperative agreement or under (1)(a) through (d) above shall result in the withholding of funds from the local board reimbursement fund in an amount to be determined by the department. (History: Sec. 50-50-305, MCA; IMP, Sec. 50-50-305, MCA; NEW, 1994 MAR p. 2941, Eff. 11/11/94; AMD, 1995 MAR p. 26, Eff. 11/11/94; TRANS, from DHES, 2001 MAR p. 2423.)

Fast-Food Ice Dirtier Than Toilet Water

Seventh-Grader's Science Project Turns Up Some Disturbing Results

Feb. 20, 2006

Jasmine Roberts never expected her award-winning middle school science project to get so much attention. But the project produced some disturbing results: 70 percent of the time, ice from fast food restaurants was dirtier than toilet water.

The 12-year-old collected ice samples from five restaurants in South Florida -- from both self-serve machines inside the restaurant and from drive-thru windows. She then collected toilet water samples from the same restaurants and tested all of them for bacteria at the University of South Florida.

In several cases, the ice tested positive for E. coli bacteria, which comes from human waste and has been linked to several illness outbreaks across the country.

"These [bacteria] don't belong there," said Dr. David Katz, medical contributor to "Good Morning America." "It's not cause for panic, although it is alarming because what she found is nothing new. You're not more likely to get sick now. But she's done us a favor by sounding the alarm."

Both Roberts and Katz said that the ice is likely dirtier because machines aren't cleaned and people use unwashed hands to scoop ice. Toilet water is also surprisingly bacteria-free, because it comes from sanitized city water supplies.

Support from Big Brother

Roberts got interested in the project after reading a newspaper article about bacteria in airplane water and decided to do something similar. Plus, she said, all of her friends chew on ice, and it drives her crazy.

"I just picked the not-obvious choice," the seventh-grader said of her project. Her 18-year-old brother, Justus, is also an award-winning science fair veteran who said he has encouraged his little sister's interest in science.

Anderson Cooper 360
Tuesday, June 21, 2005
7:00 – 8:00 p.m.
Transcript

HEIDI COLLINS, CNN CORRESPONDENT: It's cold, refreshing and oh- so-good on a hot summer day, but did you ever think about what's in your ice?

JENNIFER BERG, NEW YORK UNIVERSITY: Fecal matter in ice is a serious problem.

COLLINS: Jennifer Berg is the head of the graduate department at the Food Science and Nutrition program at New York University. She says ice can hold bacteria that makes you just as sick as anything else you eat.

BERG: Tainted ice is usually a result of having e.coli, fecal matter inside the ice.

COLLINS (on camera): How worried should people be about something like this?

BERG: You know, we don't want to make the American public completely neurotic and so cared of our food supply, when in reality we have a safer food supply than most countries, but we do need to be careful.

COLLINS (voice-over): Ice can become contaminated in many ways, like microorganisms in the water supply. But according to the experts CNN consulted, the most common causes of ice contamination are poor handling and storage.

Take Denton, Texas, 1999. Fifty-eight members of a high school drill team were infected with various levels of gastrointestinal illnesses at a camp. The ice got contaminated with e.coli after campers used their bare hands to scoop ice out of the machine. And recently, a British government study surveyed clubs, bars and pubs in London, and found half the ice they used was full of bugs and bacteria that can make people sick.

(on camera): So that got us thinking, what would we find if we bought ice just like you would on any given day at any given restaurant across the country?

(voice-over): We took our ice samples in Chicago, Dallas, Atlanta, New York and Los Angeles, at a combination of fast food chains and local establishments in each town, a total of 23 samples. In each location, we walked in and ordered our drinks with our ice on the side, and then carefully, without touching the ice, poured it into sterile bags, and then set the samples off to a certified food laboratory, Microbac Laboratories in Warrendale, Pennsylvania.

(on camera): Now, our study didn't follow all EPA protocol. That would mean we would have had to have gone to each restaurant four or five times, tested the city water, and then made sure that our sample ice touched nothing before it went into our sample bags. But

our results were tested against the most basic EPA standards, and what we found was disturbing.

(voice-over): In every city but one, there was a restaurant that failed those EPA standards.

This McDonalds in Atlanta failed. This Dunkin Donuts in Chicago failed. This 7-Eleven in Dallas failed, and so did this Burger King in Los Angeles.

On the day we tested, according to Microbac Laboratories, each ice sample from these four establishments was contaminated with fecal matter.

(on camera): That's disgusting.

BERG: It's so easy to spread. It's very easy to prevent, very easy to prevent. It's a matter of washing in very warm water, really washing not just the hands but up until, you know, through the forearm, with soap, very hot water, drying it off, training employees to all do that.

COLLINS (voice-over): And the one city that got a clean bill of ice? Well, that surprised even us.

(on camera): When you think of New York, you think horribly dirty city, but yet when we did our little ice samples, not a single place failed. Why?

BERG: New York City has much more stringent laws and regulations in place inspecting food. The other thing is, in a city like New York, and if you're talking about the fast food places that you've looked at, they have very high volume. By the end of the evening, that ice machine has emptied out. They've completely depleted their supply.

COLLINS (voice-over): We then contacted the establishments that failed our single tests. In every case, after hearing the results of our test, the owner/operator said they shut down their ice machines and cleaned them thoroughly, and also retrained their employees.

All four restaurants said they retested their ice after cleaning the machines and found no trace of bacteria.

7-Eleven sent us this: "The safety of 7-11 customers is of the utmost importance to us." And from Dunkin Donuts: "Dunkin Donuts strives to endure adherence to food safety standards." McDonald's issued this statement from the franchise owner: "My restaurant has an excellent track record with our local health department. My last inspection score was 99 out of 100." Burger King responded by telling us: "The particular restaurant has consistently achieved high health and safety results from both our internal and external audits, as well as those of the local health department."

However, health departments in Atlanta and in Los Angeles told us they do not test water

in ice machines during health inspections.

To be fair, none of the other locations of these establishments failed our tests in other cities, and we only tested the failed establishments once. But clearly, there is contaminated ice out there. So, will it make you sick?

BERG: You personally, Heidi, probably not, but chances are people did. Young children, older people, anybody who was sick to begin with.

COLLINS: Most common complaints: Nausea, vomiting and diarrhea.

So what can you do to protect yourself? If you are lucky enough to live in one of the handful of states that have food safety officers, look for the sign telling you that one is on duty. Otherwise, if you see the server filling your cup, make sure they are wearing gloves, and they don't touch the ice.

Or you could do what Jennifer Berg does.

(on camera): Do you get ice in any of your drinks when you're out to eat?

BERG: I just decided it's OK to just have beverages room temperature.

(END VIDEOTAPE)

COLLINS: So whether you drink your drink with or without ice, you should know dirty hands in the ice bin is only half the problem. The other culprit for the contaminated ice is the ice machine itself. These dispensers need to be cleaned on a daily basis to prevent that buildup of water and bacteria in the very bottom of the bin and in the water lines.

COOPER: So are there any actual numbers on how many people get sick from ice?

COLLINS: Not really. There are not exact numbers. In fact, the CDC has been tracking the outbreaks of illnesses since about 1968 caused by contaminated ice, but they don't have precise figures, because people usually think they're getting sick from the food they eat, and hardly anybody really thinks of ice as a food.

COOPER: All right. Heidi Collins, thanks.

AFDO* GUIDELINES
FOR THE INSPECTION AND ENFORCEMENT
OF GMP REGULATIONS
FOR HANDLING AND MANUFACTURING PACKAGED ICE

INTRODUCTION

This nation has established very comprehensive standards governing the sanitary processing of food and the safety of food. Ice is a food and is subject to these same standards. It makes sense to prepare beverages under strict sanitary and safety standards and to pour these beverages over ice subjected to the same standards.

Ice is a manufactured food and as such is subject to the Good Manufacturing Practices Regulations for Foods contained in the Code of Federal Regulations, Title 21, Chapter 1, Part 110. Additionally, many states have passed the model Food and Drug Act which contains the same language as the federal statute. Therefore, ice is also defined as a food under most state laws and regulations.

PURPOSE

These guidelines provide information to uniformly apply the Good Manufacturing Regulations to packaged ice manufacturing and handling operations. This information should be used as guidance during inspections of packaged ice manufacturing and handling operations and should be taken into consideration when violations of Good Manufacturing Practices are evaluated for regulatory follow-up.

These guidelines have been prepared as an adjunct to the GMP Regulations and do not replace or supersede them. In addition, the Packaged Ice Association has developed specific guidance for ice manufacturing and handling operations which, if followed, will result in general compliance with the GMP regulations and these guidelines.

Many inspections are being conducted by state and local governments which cover convenience stores and other types of establishments that also house a small ice manufacturing operation. These inspections should evaluate the packaged ice manufacturing and handling processes for compliance with the GMP Regulations and these guidelines.

Inspections of large ice manufacturing plants must be inspected using these same standards to evaluate compliance.

PERSONNEL-MANAGEMENT

Evaluate the cleanliness of employee's clothing. If it is heavily soiled, immediate correction is required. Clothing that contains grease, oil, dirt, or other material must not be permitted for an employee who handles ice or food contact surfaces.

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Employees must wash and sanitize hands after handling objects that are not clean or sanitized. Frequent handling of unsanitized objects and returning to handling ice or food contact surfaces represents a serious violation of GMP Regulations.

PACKAGED ICE GUIDELINES

Where ice is manufactured in facilities housing more than one operation and employees are engaged in both operations assessments must be made about the potential for cross-contamination of the ice. Therefore, it may be necessary for health officials to prohibit the housing of two operations in the same area. For example, housing ice manufacturing operations in garages and gas stations is unacceptable unless very carefully controlled conditions are met.

Employees must not be allowed to consume food, drink beverages, smoke, etc. in the ice manufacturing area. Also, employees must wear hair restraints.

Management is responsible for a sanitation training program that promotes continual awareness and adherence to high sanitary standards. This can be evaluated through and observation of employee's personal cleanliness and practices. When good sanitary practices are violated, management must take appropriate action to correct them.

When good sanitary practices are violated, discuss them with the owner and recommend changes that will solve the problems. Serious deficiencies in good sanitary practices cannot be solved without management's commitment.

ICE PLANT ENVIRONMENT

The area surrounding the ice manufacturing area must be free of debris that will harbor rodents, insects, and other pests. Thus, the inspection should evaluate the environment. Old equipment must be removed, tall grass and weeds must be cut frequently, and pools of water in the yard area must be eliminated.

The sewer system must function properly and never constitute a problem with back-ups or overflows that have the potential of contaminating equipment or ice.

Generally, plant environments can be easily controlled, and there should be no reason for harborages to exist. These violations may become more significant when the ice plant is infested with rodents, insects, or other pests. When this occurs, health officials must insist that the plant environment be improved as part of the plant clean up process. Live infestations by pests require that the plant be closed until the animals and insects are removed.

PLANT CONSTRUCTION AND DESIGN

There are several ice manufacturing systems sandwiched into other operations which are not compatible with food manufacturing processes. When this situation occurs, health officials have a responsibility to require that the ice processing area be separated by an enclosure within these buildings or other suitable separation to prevent the potential for contamination.

The enclosed area must be large enough to permit employees to work within the enclosure and to perform all the manufacturing and packaging steps within the enclosure. The enclosure must be well constructed, clean, and prevent potential for contamination.

Health officials must insist that holes in walls be repaired, that ill fitting doors, windows, and screens be repaired, and that the construction itself permit easy cleaning of the walls, floors, and equipment.

SANITARY OPERATION AND CONTROLS

Equipment must be cleaned on a schedule of frequency that prevents accumulation of mold, fungus, and bacteria. A formal cleaning program and schedule which includes the use of sanitizers to eliminate micro-organisms must be developed and used. Inspections must include an evaluation of the cleaning schedules and an evaluation of the status of all equipment and the plant environment.

Health officials must insist that cleaning of the plant and equipment be frequent enough to prevent contamination. At the least, equipment must be cleaned and sanitized before the beginning of operations when the operation or plant has been shut down. Other cleaning schedules will be based on the needs of individual plants and must cover cleaning following processing interruptions.

Ice cannot be packaged on platforms open to the environment; nor can it be processed in a truck, unless the truck is specifically dedicated to the packaging of ice and meets the same standards set forth in these guidelines.

Live animals and birds must not be permitted in the plant. Infestations by live animals and bird require immediate correction. Therefore, the facility must be closed until these pests are eliminated.

Single service supplies, such as bags and other containers, must not be reused. Single service containers must be stored in an area free from potential contamination with non food items such as toxic substances, and dirt. These containers must be free from potential contamination from pests such as insects, rodents, and animals.

WATER
Water used in the entire plant must be potable water unless the health authority authorizes the use of non-potable water for certain operations. Water from an approved city water supply is considered potable water and needs no testing for quality.

A plant may use a private water supply provided the following conditions are met:
--The water must be tested under worst case environmental conditions to establish a water quality profile. This research should demonstrate that worst case environmental conditions have no adverse impact on water quality or reveal those conditions which do impact on quality.

--Plans must be established to suspend use of private water supplies under those conditions which have been shown to adversely affect the quality of the water without regard to further testing before suspension of use. Water tests must be conducted before the private supply is again used.

For example, private well water must be assessed following periods of heavy rainfall producing heavy rainfall run off. These assessments will produce a profile that establishes the impact of such events. This data provides guidance to control the quality of water without conducting laboratory analysis to establish water quality following these events.
It is not enough to simply test water from private wells randomly according to an arbitrary schedule. Rather, evaluations must be performed in relationship to events that may adversely affect water quality as mentioned above.

Water quality is one of the highest priorities in an ice plant. Health officials must carefully evaluate water quality control programs during every inspection.

Private well water must be tested monthly in addition to the tests specified above. This will detect changes in water quality which are not triggered by environmental events. Pesticide and chemical contamination should be part of any periodic test program.

ENFORCEMENT GUIDELINES
Public health officials must insist on high standards and compliance with the Good Manufacturing Practices for Food Regulations.

1. When employees are dressed in clothing that is heavily soiled with grease, dirt, or other debris, immediate correction must be made. This can be corrected by the pant owner providing clean outerwear when these employees handle ice, or other suitable alternatives. It is a serious violation of GMPs when employees clad in filthy garments handle ice or food contact surfaces. Failure to correct these conditions should result in suspension of operating permits or closure until corrections are made.

2. It is a serious violation of GMPs to manufacture or process ice in a building infested with rodents, insects, or wild or domestic animals. Plants so infested must be closed until a permanent correction has been made.

3. Water from private wells must be tested under worst case environmental conditions. Failure to develop appropriate profiles for private wells represents a serious public health problem. Public health officials should help develop a plan to test private wells and to develop an acceptable overall water control program. Once a plan is developed, it must be implemented immediately. Failure to implement and adhere to this plan should result in closure until correction is made.

4. Ice must be tested periodically for the presence of bacteria. This should be done each 90 to 120 days. These tests must be more frequent when internal conditions do not conform to Good Manufacturing Practices Guidelines. Failure to perform this key step should result in immediate sampling by the health authority. Also, licenses should be suspended until an appropriate product testing program is implemented or other action appropriate to local standards may be taken. Under no circumstances should the public be expected to consume ice that has not been subjected to an effective quality control program, and periodic testing is a cornerstone of all public health and Good Manufacturing Practices programs.

5. The ice manufacturing area must be in a facility housing a food plant providing barriers to a potential contamination of the ice, be in a facility dedicated to the manufacture of ice, or be within an enclosure in another facility. Failure to follow these guidelines should result in closure and license suspension until permanent correction is made.

6. Cross connections between potable water and non-potable water lines are cause for immediate closure until the plumbing has been corrected. This requires permanent correction before ice can be manufactured.

# # #

Conference for Food Protection
2010 Issue Form

Internal Number: 035
Issue: 2010 III-022

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

All information above the line is for conference use only.

Title:

Antimicrobial Treatments for Washing Fruits & Vegetables

Issue you would like the Conference to consider:

Approved antimicrobial treatments for washing fruits and vegetables can be useful to reduce the risk of cross contamination, particularly for produce that will be served without cooking. Language in Annex 3 §3-302.15 Washing Fruits and Vegetables may cause confusion regarding when antimicrobial treatments can be used for washing fruits and vegetables in retail and food service establishments, and do not clearly convey the potential benefit of these treatments. Additionally, some antimicrobial treatments that are approved for washing fruits and vegetables contain surfactants and statements in Annex 3 §3-302.15 could be misinterpreted to exclude these as acceptable solutions.

Public Health Significance:

Antimicrobial treatments used for washing fruits and vegetables must be used at the correct concentration to assure that no harmful residues are transferred to foods. When used at appropriate concentrations, antimicrobial treatments can reduce the risk of cross contamination through wash water. Recent, peer reviewed research (e.g. Zhang et. al 2009) demonstrates the potential benefit of using several antimicrobials to reduce transfer of a pathogen from contaminated produce to uncontaminated produce, as compared to using water alone.

FDA Guidance to the Industry (February 2008), which is included as a reference in Annex 3, includes the following statement, which clearly recognizes that sometimes temperature differentials may not be practical and alternative methods to reduce risk do exist.

"When it is not practical to reduce the temperature differential between the wash/cooling water and the produce, it is especially important that processors follow practices to minimize pathogens in the water or on the surface of produce. Such practices may include

using antimicrobial chemicals in the wash water or using spray type wash treatments instead of submerging produce."

Providing practical alternative approaches for washing produce is important to protect public health at the retail level as well.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending the following changes to the Food Code:

Annex 3 §3-302.15 Washing Fruits and Vegetables.

"... All fresh produce, except commercially washed, pre-cut, and bagged produce, must be thoroughly washed using ~~under running,~~ potable water, with or without antimicrobial treatments, before eating, cutting or cooking. ..."

"... To reduce the likelihood of infiltration, wash water temperature should be maintained at 10°F warmer than the pulp temperature of any produce being washed. Because certain fruits and vegetables are susceptible to infiltration of microorganisms during soaking or submersion, it is recommended that soaking or submerging produce during cleaning be avoided. When it is not practical to reduce the temperature differential between the wash/cooling water and the produce, it is especially important to follow practices to minimize pathogens in the water or on the surface of produce. Such practices may include using antimicrobial chemicals in the wash water or using spray type wash treatments. It is important that proper handwashing procedures are followed, in accordance with ¶ ~~Section~~ 2-301.12 (F) Cleaning Procedure, before and after handling fresh produce."

"... Washing fresh fruits and vegetables with unapproved soap, detergent or other surfactants that do not have antimicrobial properties should be avoided as they facilitate infiltration ~~and may not be approved for use on food~~. ... "

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Attachments:

- "Zhang, et al. 2009 antimicrobial transfer reference"
- "FDA 2008 Guidance to Industry on fresh cut Fruits and Vegetables."

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Efficacy of Antimicrobial Agents in Lettuce Leaf Processing Water for Control of *Escherichia coli* O157:H7

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ABSTRACT

The objectives of this research were to study transfer and control of *Escherichia coli* O157:H7 during simultaneous washing of inoculated and uninoculated lettuce pieces and to determine the efficacy of antimicrobial agents (peroxyacetic acid, mixed peracid, and sodium hypochlorite) on reducing the transfer of *E. coli* O157:H7 through processing water with or without organic load. Lettuce leaf pieces (5 by 5 cm) were inoculated with a five-strain mixture of green fluorescent protein–labeled *E. coli* O157:H7 at 5.6 log CFU per piece. One inoculated lettuce piece was added to five uninoculated leaves during washing. Peroxyacetic acid and mixed peracid were tested at 10, 20, and 30 ppm, and chlorine was tested at 30 and 50 ppm. No organic load (liquefied lettuce leaves) and 10% organic load in processing water were compared. Without organic load, peroxyacetic acid at 30 ppm, mixed peracid at 10, 20, and 30 ppm, and chlorine at 30 and 50 ppm all significantly reduced *E. coli* O157:H7 in processing water by 1.83, 1.73, 1.50, 1.83, 1.34, and 1.83 log CFU/ml, respectively, compared with washing with water alone. These antimicrobials at all concentrations tested also significantly reduced transfer of the bacteria from an inoculated leaf to uninoculated leaves in the processing water by 0.96 to 2.57 log CFU per piece. A 10% organic load in the processing water reduced efficacy of antimicrobial agents. In this contaminated water, peroxyacetic acid at 10 and 20 ppm and chlorine at 30 ppm produced effects not significantly different from those of water alone. Therefore, it is important to understand the impact of organic load when validating the effectiveness of antimicrobial treatments.

Lettuce is one of the most commonly consumed leafy greens, with a farm value of over $1.5 billion in 2005 in the United States *(10)*. Lettuce is perceived by consumers as healthful and nutritious. Contamination of vegetables by human pathogens can occur at many locations in the farm-to-fork continuum, including contamination of seeds and of product during production, harvesting, postharvest handling, transport distribution, storage, processing, and preparation *(13)*. Survival and growth of foodborne human pathogens on fresh and fresh-cut produce has been widely reported *(3–5, 12, 14, 15, 21)*. The efficacy of different antimicrobials used to kill foodborne pathogens on fresh and fresh-cut produce has been studied extensively, and most antimicrobials are minimally effective, reducing pathogen contamination by only 1 to 2 log CFU/g *(3, 5, 9, 21)*.

Antimicrobial agents often are added to water in flumes that convey or wash fresh fruits and vegetables. The addition of these agents reduces the number of microorganisms in fruit and vegetable processing water. Reducing the number of microorganisms in recycled processing water helps prevent the water from becoming a vehicle of cross-contamination *(7, 8, 11, 16, 18, 19)*. Antimicrobial chemicals in processing water also can reduce microorganisms on the surfaces of fruits and vegetables. However, processing water antimicrobials are more effective for reducing microorganisms in water suspensions than on fruit and vegetable surfaces *(1, 2, 6, 11, 18–20)*.

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This study was conducted (i) to investigate transfer of *Escherichia coli* O157:H7 from an inoculated lettuce leaf piece to uninoculated lettuce leaf pieces during washing, (ii) to determine the efficacy of peroxyacetic acid, mixed peracid, and chlorine for reducing the transfer of *E. coli* O157:H7 under conditions of high organic load, and (iii) to determine the efficacy of peroxyacetic acid, mixed peracid, and chlorine for reducing *E. coli* O157:H7 in lettuce processing water.

MATERIALS AND METHODS

Bacterial strains and culture conditions. Five strains of *E. coli* O157:H7 were used: ATCC 43888 (human feces), EO122 (cattle isolate), K3995 (spinach isolate), K4492 (lettuce, clinical isolate), and F4546 (alfalfa sprout outbreak isolate). A plasmid (pGFPuv) containing a *gfp* gene was introduced into each strain using a $CaCl_2$ heat shock method *(17)*. Expression of green fluorescent protein (GFP) in labeled cells was evaluated by epifluorescence microscopic examination of colonies. The five strains were cross-streaked onto tryptic soy agar (Difco, Becton Dickinson, Sparks, MD) to confirm lack of cross-inhibitory activity. All strains were grown at 37°C for 24 h on brain heart infusion agar (BHIA; Difco, Becton Dickinson) or in brain heart infusion broth (BHIB; Difco, Becton Dickinson) supplemented with ampicillin (Roche Diagnostics, Indianapolis, IN) at a concentration of 100 μg/ml (BHIA-amp and BHIB-amp, respectively). Colonies of these GFP-labeled strains were viewed under a 396-nm wavelength UV lamp for enumeration.

All *E. coli* O157:H7 strains were transferred to BHIB-amp three times at 24-h intervals before they were used as inocula. Cells from overnight culture (10 ml) were sedimented by centri-

fugation at 5,000 × *g* for 10 min and resuspended in 10 ml of 0.1% sterile peptone water (Difco, Becton Dickinson). Approximately equal populations of each of the five strains were combined. Dilutions were made in 0.1% sterile peptone water to create a culture suspension for inoculation of approximately 10^6 CFU/ml.

Antimicrobial agents. Peroxyacetic acid (Tsunami 100), mixed peracid (Tsunami 200), and sodium hypochlorite (XY-12) were provided by Ecolab, Inc. (St. Paul, MN).

Preparation of lettuce for inoculation. Iceberg lettuce (*Lactuca sativa* L.) was purchased from a grocery store (Griffin, GA). Two or three layers of outer leaves were removed from each head of lettuce, and inner leaves were aseptically cut into pieces (ca. 5 by 5 cm), using as much of the leaf portion as possible and avoiding stem areas.

Inoculation of lettuce leaves. Lettuce leaf pieces were placed on a sterile surface in a laminar flow biosafety cabinet, and 100 μl of the five-strain mixture of culture suspension was spot inoculated with a micropipettor onto the adaxial side of each leaf piece to achieve an initial *E. coli* O157:H7 population of 5.6 log CFU per inoculated lettuce piece. The inoculated leaf pieces were placed in a sterile plastic container with a lid and held at 4°C for approximately 2 h to allow bacterial attachment before treatment. A minor cut (ca. 2 mm) on one side was made on all inoculated leaf pieces to differentiate these pieces from uninoculated leaf pieces during treatment.

Organic load preparation. Two outer layers of iceberg lettuce leaves were discarded. Green leaves (100 g) were placed in a sterile blender jar with 100 g of sterile water tempered to 4°C. Leaves were blended on high speed until they were liquefied and particulates were small enough to be suctioned through a pipette. This organic load preparation was blended immediately before use.

Antimicrobial use solution: chemistry without organic load. The appropriate amount of test antimicrobial was pipetted into 250 ml of sterile deionized water in a 500-ml volumetric flask, and additional sterile deionized water was added to the 500-ml mark.

Antimicrobial use solution: chemistry with 10% organic load. The appropriate amount of test antimicrobial was pipetted into 250 ml of sterile deionized water as above, 50 ml of the organic load preparation was added, and additional sterile deionized water was added to the 500-ml mark.

Antimicrobial use solution: concentration of antimicrobial agent. Concentrations of free chlorine and total peracid in use solutions were determined by an iodine–sodium thiosulfate redox titration (Oxidizer Kit 322, Ecolab). The following antimicrobial agents were evaluated: water; peroxyacetic acid at 10, 20, and 30 ppm; mixed peracid at 10, 20, and 30 ppm; and sodium hypochlorite at 30 and 50 ppm at pH 6.8. All antimicrobials were evaluated without organic load and with a 10% organic load preparation.

Treatment of lettuce leaves with antimicrobial agents. All testing was conducted in a refrigerated room (4 to 5°C). The use solutions (with or without organic load) were poured into the mixing vessel (modified version of the CDC Biofilm Reactor, BioSurface Technologies Corp., Bozeman, MT) and stirred at 125 rpm with a magnetic stir bar on a stir plate. Five uninoculated lettuce pieces and one inoculated lettuce piece were placed in the mixing vessel and agitated for 1.5 min treatment. Lettuce pieces were then removed aseptically and separately placed into Whirl-Pak bags (Nasco, Fort Atkinson, WI) containing 10 ml of 0.5% sodium thiosulfate neutralizing agent (Fisher Scientific, Fair Lawn, NJ). Lettuce pieces were then individually macerated at 230 rpm for 30 s, and serial dilutions were plated in duplicate on BHIA-amp and incubated at 35 ± 2°C for 48 h.

One milliliter of each treated use solution from the mixing vessel was pipetted into 9 ml of 0.5% sodium thiosulfate. Serial dilutions were plated in duplicate and incubated under the conditions described above.

Control: test substance neutralization. Triplicate neutralization checks were performed on each type of chemistry. If more than one use solution concentration was used, the most concentrated solution was tested. For control A, an uninoculated lettuce piece was dipped into the test substance use solution for 1.5 min and then removed and placed into a small Whirl-Pak bag containing 10 ml of the neutralizing agent (0.5% sodium thiosulfate). Subsequently, 0.1 ml of *E. coli* O157:H7 test system suspension (10^5 CFU/ml) was added and mixed. For control B, an uninoculated lettuce piece was dipped into the test substance diluent (sterile deionized water) for 1.5 min and then removed and placed into a small Whirl-Pak bag containing 10 ml of the neutralizing agent. Subsequently, 0.1 ml of *E. coli* O157:H7 test system suspension (10^5 CFU/ml) was added and mixed. For control C, 0.1 ml of *E. coli* O157:H7 test system suspension (10^5 CFU/ml) was added to 10 ml of sterile peptone water and mixed. Leaf pieces from controls A, B, and C were held at room temperature for 30 min before the microbiological assay. Portions (0.25 ml in quadruplicate and 0.1 ml in duplicate) of each control were plated on BHIA-amp and incubated at 35 ± 2°C for 48 h.

The neutralizing agent was considered to have effectively neutralized the test substance when the average plate count from control C equaled that of control A ± 10%. The neutralizing agent was not detrimental to the culture suspension when the average plate count from control C equaled that of control B ± 10%.

Control: test substance diluent (sterile deionized water) sterility. Portions (0.25 ml in quadruplicate and 0.1 ml in duplicate) of sterile deionized water were plated on BHIA-amp and incubated at 35 ± 2°C for 48 h.

Control: *E. coli* O157:H7–free lettuce pieces. An uninoculated lettuce piece was aseptically placed into a Whirl-Pak bag, 10 ml of neutralizing agent was added, and the bag contents were homogenized in a laboratory blender (Stomacher 400, Seward, Worthington, UK) at 230 rpm for 30 s. Portions (0.25 ml in quadruplicate and 0.1 ml in duplicate) of homogenate were plated on BHIA-amp and incubated at 35 ± 2°C for 48 h.

Control: *E. coli* O157:H7–free organic load. Portions (0.25 ml in quadruplicate and 0.1 ml in duplicate) of organic load were plated on BHIA-amp and incubated at 35 ± 2°C for 48 h.

All chemical solutions were stored at 4°C 1 day before the experiment. The entire experiment was conducted in a room with temperature set at 4°C.

Statistical analysis. Data were analyzed using the general linear models procedure of SAS (SAS 9.1.3; SAS Institute, Inc., Cary, NC at $\alpha = 0.05$. Duncan's multiple range tests were used to determine significant differences ($\alpha = 0.05$) between mean values. The entire study was repeated three times.

TABLE 1. E. coli *O157:H7 on lettuce leaves and in processing water with and without antimicrobials and without organic load*[a]

Antimicrobial agent	Concn (ppm)	Mean (±SD) *E. coli* O157:H7 population[b]		
		Inoculated leaves after treatment (log CFU/piece)	Posttreatment processing water (log CFU/ml)	Uninoculated leaves after treatment (log CFU/piece)
Peroxyacetic acid	10	3.31 ± 0.11 AB	0.88 ± 0.84 AB	0.20 ± 0.34 BC
	20	3.21 ± 0.36 ABC	0.76 ± 1.32 AB	0.44 ± 0.27 B
	30	2.38 ± 0.18 BC	ND B	ND C
Mixed peracid	10	2.27 ± 0.55 BC	0.10 ± 0.17 B	0.07 ± 0.12 BC
	20	2.10 ± 1.84 C	0.33 ± 0.58 B	0.18 ± 0.18 BC
	30	ND D	ND B	ND C
Chlorine	30	3.42 ± 0.35 AB	0.49 ± 0.84 B	0.19 ± 0.32 BC
	50	2.60 ± 0.44 ABC	ND B	0.07 ± 0.11 BC
Water		3.68 ± 0.23 A	1.83 ± 0.24 A	2.54 ± 0.19 A

[a] *E. coli* O157:H7 population on inoculated untreated leaves was at 5.6 log CFU per piece.
[b] Within a column, means with the same letter are not significantly different at $\alpha = 0.05$. ND, not detected. Detection limits were 1 CFU/ml of processing solution and 10 CFU per leaf piece.

RESULTS

E. coli O157:H7 populations for control A were 2.97, 2.92, and 2.98 log CFU/ml for 30 ppm of peracetic acid, 30 ppm of mixed peracid, and 50 ppm of chlorine, respectively, and 2.98 and 2.96 log CFU/ml for controls B and C, respectively. These values were approximately the same, indicating that the neutralizing agent effectively neutralized the test substance and was not detrimental to *E. coli* O157:H7. The sterile deionized water used for all solutions, the lettuce leaves, and the prepared organic load were all negative for *E. coli* O157:H7.

A single lettuce leaf piece inoculated with *E. coli* O157:H7 at 5.6 log CFU transferred contamination in 500 ml of water at approximately 2 log CFU/ml with or without the presence of organic material. Although the contamination levels were not significantly different, peroxyacetic acid at 10 and 20 ppm held the level of contamination in the solution to 1 log CFU/ml less than that of water when no additional organic material was present. All other antimicrobial solutions had significantly less *E. coli* O157:H7 than did water when no additional organic material was present. In posttreatment solutions without organic load containing mixed peracid at 10 and 20 ppm, *E. coli* O157:H7 levels were 1.5 log CFU/ml less than those in water. *E. coli* O157:H7 was not detected (detection limit of 1 CFU/ml) in posttreatment solutions when mixed peracid and peroxyacetic acid were at 30 ppm or chlorine was at 50 ppm. The average *E. coli* O157:H7 population detected was 0.5 log CFU/ml after chlorine treatment at 30 ppm, which was more than 1 log CFU/ml less than that for water alone (Table 1).

The presence of 10% organic material reduced the effectiveness of several antimicrobial treatments for control of *E. coli* O157:H7 transfer to the washing solutions. There were no significant differences between *E. coli* O157:H7 levels in water and in chlorine at 30 ppm, mixed peracid at 10 ppm, and peroxyacetic acid at 10 and 20 ppm. In posttreatment solutions with 10% organic load, *E. coli* O157:H7 was not detected in mixed peracid at 20 and 30 ppm. Peroxyacetic acid at 30 ppm had *E. coli* O157:H7 levels that were significantly less than those in water ($\alpha = 0.05$) by 1.7 log CFU/ml. Chlorine at 30 ppm and 50 ppm had *E. coli* O157:H7 levels that were 0.8 and 1.3 log CFU/ml, respectively, less than those in water only (Table 2).

In contrast to the results for the posttreatment solutions, the *E. coli* O157:H7 populations transferred to uninoculated leaves were significantly smaller for all antimicrobial treatments than for water only with or without added organic material. When one leaf piece inoculated with *E. coli* O157:H7 at 5.6 log CFU was mixed with five uninoculated leaf pieces in 500 ml of untreated water, the mean population on the uninoculated leaves after treatment was greater than 2.5 log CFU per leaf piece. When no added organic material was present, the mean population on uninoculated leaves in antimicrobial solutions was at least 2 log units less than that for water only, and no *E. coli* O157:H7 was detected on uninoculated leaves treated with peroxyacetic acid or mixed peracid at 30 ppm. There was no significant difference between the results for those treatments and the leaf results for mixed peracid at 10 and 20 ppm and chlorine at 30 or 50 ppm (Table 1).

The presence of 10% organic material added to the antimicrobial solutions reduced the effectiveness of limiting transfer of *E. coli* O157:H7 to uninoculated leaves; however, all antimicrobial treatments resulted in significantly lower cell numbers on uninoculated leaves compared with the numbers on leaves in untreated water. Chlorine at 30 and 50 ppm and peroxyacetic acid at 10 ppm had mean cell numbers 1 log or more lower than those for untreated water. Peroxyacetic acid at 20 and 30 ppm and mixed peracid at 10, 20, and 30 ppm had mean cell numbers >2 log less than those in untreated water (Table 2).

For *E. coli* O157:H7 on inoculated lettuce leaves after treatment without organic load, a significant reduction ($\alpha = 0.05$) of 1.9 log CFU per leaf piece was achieved by washing with water alone. A reduction of 3.2, 3.5, and >4.6 log CFU per leaf piece was achieved by peroxyacetic acid at 30 ppm, mixed peracid at 20 ppm, and mixed peracid at 30 ppm, respectively, and this reduction was significantly different from that achieved with water alone.

TABLE 2. E. coli *O157:H7 on lettuce leaves and in processing water with and without antimicrobials and in the presence of 10% organic load*[a]

Antimicrobial agent	Concn (ppm)	Mean (±SD) *E. coli* O157:H7 population[b]		
		Inoculated leaves after treatment (log CFU/piece)	Posttreatment processing water (log CFU/ml)	Uninoculated leaves after treatment (log CFU/piece)
Peroxyacetic acid	10	3.99 ± 0.45 A	1.61 ± 0.09 AB	1.26 ± 0.70 BC
	20	3.25 ± 0.69 A	1.27 ± 0.63 AB	0.68 ± 0.79 CD
	30	1.66 ± 1.47 BC	0.10 ± 0.17 CD	0.07 ± 0.12 D
Mixed peracid	10	3.42 ± 0.43 A	1.24 ± 0.81 AB	0.57 ± 0.39 CD
	20	2.57 ± 0.46 AB	ND D	0.27 ± 0.31 D
	30	0.90 ± 0.85 C	ND D	0.13 ± 0.12 D
Chlorine	30	2.86 ± 0.41 AB	1.15 ± 1.00 ABC	1.68 ± 1.00 B
	50	2.88 ± 0.29 AB	0.59 ± 1.02 BCD	0.80 ± 1.39 BCD
Water		3.93 ± 0.56 A	1.96 ± 0.26 A	2.64 ± 0.15 A

[a] *E. coli* O157:H7 population on inoculated untreated leaves was at 5.6 log CFU per piece.
[b] Within a column, means with the same letter are not significantly different at $\alpha = 0.05$. ND, not detected. Detection limit was 1 CFU/ml of processing water.

The 2.18-log reduction achieved by washing with chlorine at 30 ppm and the 3.0-log reduction with 50 ppm of chlorine was not significantly different than that achieved with water alone. The reduction of *E. coli* O157:H7 on inoculated leaves was significantly greater for the mixed peracid solution at 30 ppm than for any other treatment. When no added organic material was present, *E. coli* O157:H7 was not detected, representing a >5-log reduction from the initial level of 5.56 log CFU per leaf piece. A similar trend was observed for treatments with 10% organic load, with slightly lower efficacy of all antimicrobial agents (Table 2).

DISCUSSION

Compared with water without antimicrobial agents, peroxyacetic acid and mixed peracid at 30 ppm were more effective for reducing the numbers of *E. coli* O157:H7 cells in processing water, with or without 10% organic load, and on inoculated lettuce leaves. However, peracid agents at 10 and 20 ppm (which are below the specified label use concentration) were much less effective than 30 ppm for reducing *E. coli* O157:H7 in processing water and on inoculated lettuce leaves (Tables 1 and 2). According to the Federal Insecticide, Fungicide and Rodenticide Act (http://www.epa.gov/oecaagct/lfra.html), it is a violation of Federal Law to use an Environmental Protection Agency–registered product in a manner that is inconsistent with its labeling. The results of this study demonstrate that improper use of antimicrobial agents (e.g., reduced concentration) under produce processing conditions will not achieve the intended purpose of controlling pathogenic microorganisms in processing water.

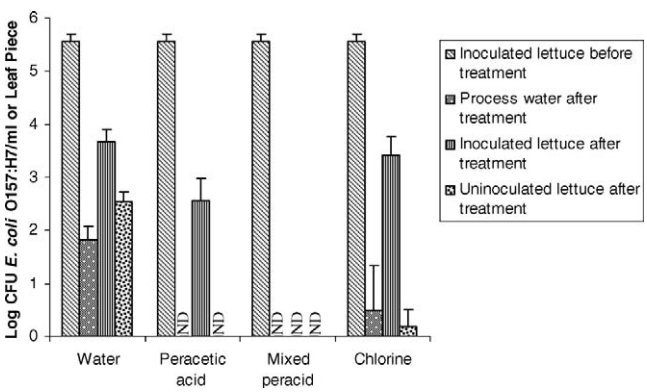

FIGURE 1. *Comparison of antimicrobial agents at 30 ppm in processing water without organic load for their effect on* E. coli *O157:H7 in processing water and on inoculated and uninoculated lettuce leaves. ND, not detected. The experiment was repeated three times. One sample was evaluated for inoculated lettuce before treatment, processing water after treatment, and inoculated lettuce after treatment in each replicate. Five samples were evaluated for uninoculated lettuce after treatment in each replicate. Error bars represent the standard deviation.*

E. coli O157:H7 on inoculated leaves contaminated processing water and was transferred to uninoculated leaves in the processing water for all treatments except 30 ppm of mixed peracid and 30 ppm of peroxyacetic acid. *E. coli* O157:H7 contamination reached 2.5 and 2.6 log CFU per leaf piece on uninoculated leaf pieces when they were washed with leaf pieces inoculated at 5.6 log CFU per leaf piece in water without and with 10% organic load, respectively (Tables 1 and 2). In comparison with washing with water only, peroxyacetic acid, mixed peracid, and chlorine treatments at all concentrations resulted in significantly lower numbers of *E. coli* O157:H7 cells on uninoculated leaves (Tables 1 and 2). Proper levels of antimicrobials in processing water are necessary to prevent transfer of pathogens from contaminated leaves to uncontaminated leaves during washing.

Treatments with 30 ppm of peroxyacetic acid and mixed peracid reduced the population of *E. coli* O157:H7 on inoculated leaves by ≥1 log CFU per leaf piece more than did treatment with chlorine at 30 ppm with or without 10% organic load; however, only the 30-ppm mixed peracid treatment result was significantly different from that of chlorine (Figs. 1 and 2). In the postwash water containing 10% organic load, only peroxyacetic acid at 30 ppm, mixed peracid at 20 and 30 ppm, and chlorine at 50 ppm were

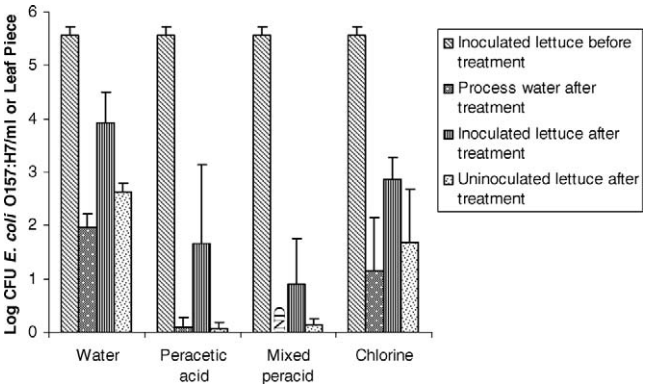

FIGURE 2. *Comparison of antimicrobial agents at 30 ppm in processing water in the presence of 10% organic load for their effect on* E. coli *O157:H7 in processing water and on inoculated and uninoculated lettuce leaves. ND, not detected. The experiment was repeated three times. One sample was evaluated for inoculated lettuce before treatment, processing water after treatment, and inoculated lettuce after treatment in each replicate. Five samples were evaluated uninoculated lettuce after treatment in each replicate. Error bars represent the standard deviation.*

significantly more effective than water for reducing *E. coli* O157:H7. In the presence of 10% organic load in processing water, peroxyacetic acid and mixed peracid at 30 ppm significantly reduced the contamination of uninoculated leaves by *E. coli* O157:H7 (ca. 0.1 log CFU per leaf piece), whereas chlorine at 30 ppm left 1.68 log CFU per leaf piece on uninoculated leaves (Tables 1 and 2). Results of this study revealed that mixed peracid at 30 ppm in the presence of organic load was more effective for inactivating *E. coli* O157:H7 in processing water and preventing contamination of uninoculated leaves than was chlorine at 30 ppm.

The organic load had a greater effect on the efficacy of chlorine than on that of peroxyacetic acid and mixed peracid. The 10% organic load in the processing water reduced the efficacy of chlorine at 30 ppm but had only minor effects on the mixed peracid and peroxyacetic acid treatments at 30 ppm. For example, *E. coli* O157:H7 counts in posttreatment water with 30 ppm of chlorine, peroxyacetic acid, or mixed peracid but without organic load were 0.49 log CFU/ml, not detected, and not detected, respectively, but with 10% organic load were 1.15 and 0.1 log CFU/ml and not detected, respectively (Tables 1 and 2). The organic load also negatively impacted the effectiveness of chlorine at 30 ppm but not the effectiveness of mixed peracid or peroxyacetic acid for preventing the transfer of *E. coli* O157:H7 to the uninoculated leaves. *E. coli* O157:H7 was not detected on uninoculated leaves after treatment with 30 ppm of peroxyacetic acid or mixed peracid without organic load, but the pathogen counts increased by approximately 0.1 log CFU per leaf piece in the presence of 10% organic load. In contrast, treatment with 30 ppm of chlorine resulted in an increase of *E. coli* O157:H7 on uninoculated leaves from 0.19 log CFU per leaf piece without organic load to 1.68 log CFU per leaf piece with 10% organic load (Tables 1 and 2). Thus, the reuse of processing water and subsequent buildup of organic matter both influence the effectiveness of antimicrobial treatments.

The results of this work revealed the potential impact of organic load on the effectiveness of antimicrobial treatment used to reduce the transfer of *E. coli* O157:H7 from contaminated leaves to the processing water and to uncontaminated leaves. Although this study did not replicate conditions that exist during processing, it illustrates the need to evaluate more than just the antimicrobial concentration when validating the effectiveness of produce processing controls. Factors such as organic load, fluid/produce ratio, antimicrobial type and concentration, and other variables during processing can have a profound effect on the potential for spreading contamination throughout a production lot. Additional research on the critical factors beyond antimicrobial type and concentration is needed to enhance pathogen control during produce processing.

ACKNOWLEDGMENTS

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Web reference in support of 2010 CFP conference for issue:

Title: Antimicrobial Treatments for Washing Fruits and Vegetables

- FDA 2008 Guidance for Industry, Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables
  http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064458.htm (Sections VIII.C.2.a and VIII.2.C.b)

Conference for Food Protection
2010 Issue Form

Internal Number: 068
Issue: 2010 III-023

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

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Title:

Food Establishment Response Procedure to Vomiting & Diarrheal Contamination

Issue you would like the Conference to consider:

Many food establishments, including several institutional facilities that serve large populations have targeted the reduction of transmission of viruses and other pathogens by instituting procedures for cleaning and disinfection in the wake of a vomiting and diarrheal event in the facility. However, the 2009 Food Code is silent on what should be required of food establishments in terms of responding to such contamination events within a food establishment. Prompt and proper response is important to reduce the risk of transmission of norovirus and other pathogens that may be present in vomitus or fecal matter and that may become widely dispersed throughout a facility in the event of an uncontrolled discharge.

Public Health Significance:

Studies have shown that norovirus can survive on fomite surfaces for up to 12 days and that routine cleaning, without a disinfectant specifically to address norovirus, may be ineffective in eliminating its presence on fomite surfaces and can even serve as a means of spreading the virus to other fomites.(7, See Attached References) Noroviruses are the most common cause of sporadic cases and outbreaks of acute gastroenteritis (AGE) and transmission occurs via foodborne and person-to-person routes, airborne inhalation of vomitus droplets, and also through contact with contaminated environmental surfaces.(3) Food employees exposed to vomitus are at risk of contracting norovirus illness and can subsequently transfer the virus to ready-to-eat food items served to consumers.

Clean up of norovirus is different from routine cleaning and sanitizing and involves a more stringent cleaning and disinfecting process. For example, quaternary ammonium compounds are often used for routinely sanitizing food preparation surfaces or disinfecting large surfaces (e.g. countertops and floors), however, such compounds (which act by disrupting viral envelopes) do not have significant activity against certain pathogens,

including norovirus. (4) It is therefore important that food establishments have procedures for the cleaning and disinfection of vomitus or diarrheal contamination events that address, among other items, the use of proper disinfectants.

Noroviruses (genus *Norovirus*, family *Caliciviridae*) are a group of related, single-stranded RNA, nonenveloped viruses that cause acute gastroenteritis in humans. (3) Noroviruses are transmitted primarily through the fecal-oral route, either by consumption of fecally contaminated food or water or by direct person-to-person spread. Good evidence exists for transmission due to aerosolization of vomitus that presumably results in droplets contaminating surfaces or entering the oral mucosa and being swallowed.(3)

CDC estimates that 23 million cases of acute gastroenteritis are due to norovirus infection annually. (8) In 2006, the most recent year for which surveillance for Foodborne Disease Outbreak data have been analyzed, norovirus was the most common cause, accounting for 54% of outbreaks and 11,879 cases. Calicivirus caused 337 (98%) of the confirmed foodborne disease outbreaks attributed to viruses; all calicivirus outbreaks reported were attributed to norovirus. (1)

Norovirus is highly contagious, and it is thought that an inoculum of as few as 10 viral particles may be sufficient to infect an individual. (2) In addition, the potential transmission level of norovirus shed in the feces at levels up to 1 trillion viral particles per gram of feces and one projectile vomiting incident can contaminate the environment with 300,000 viral particles. (6, 9) One study found that employees who reported having cleaned up vomitus were more likely to contract illness than those who did not. (5)

Norovirus is the most common cause of gastroenteritis in people of all ages and it is responsible for greater than 50% of all foodborne gastroenteritis outbreaks. Norovirus causes acute onset of vomiting (often explosive) and diarrhea (also often explosive) which can contaminate surfaces and become airborne increasing the chances of additional infections.

When the food employee has been diagnosed, has a recent history or exposure to, or is the suspect source of a confirmed disease outbreak of norovirus, it must be reported to the person in charge per the FDA Food Code in subparagraphs 2-201.11(A)(2)(a), 2-201.11(A)(4)(a), 2-201.11(A)(5)(a), and 2-201.11.(B). If a food employee has been diagnosed with norovirus it must also be reported to the regulatory authority. (10)

The Food Code also instructs the Person in Charge to exclude or restrict a food employee who exhibits, or reports a symptom, or who reports a diagnosed illness or a history of exposure to norovirus, but it is silent on instruction to the Person in Charge on how to address a situation where the food employee or other individual becomes physically ill in areas where food may be prepared, stored or served. Once such an episode has occurred, timely effective clean-up is imperative.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting modification of the 2009 Food Code to require that food establishments:

1) Develop and have access to a plan for responding to unexpected events that result in the discharge of vomitus or feces in any area other than a toilet; and

2) That such a plan address:

· the procedures for containment and removal of any discharges, including airborne particulates;

· the procedure for cleaning, sanitizing, and, as necessary, the disinfection of any surfaces that may have become contaminated;

· the procedures for the evaluation and disposal of any food that may have been exposed to discharges;

· the availability of effective disinfectants, personal protective equipment, and other cleaning and disinfecting equipment and appurtenances intended for response and the proper use and disposal of such;

· the circumstances under which a food employee is to wear personal protective equipment for cleaning and disinfecting of a contaminated area;

· notification to food employees on the proper use of personal protective equipment and procedures to follow in containing, cleaning, and disinfecting a contaminated area;

· the availability of effective disinfectants, personal protective equipment, and other cleaning and disinfecting equipment and appurtenances intended for response and the proper use and disposal of such;

· the segregation of areas that may have been contaminated so as to minimize the unnecessary exposure of employees, customers and others in the facility to the discharges or to surfaces or food that may have become contaminated;

· minimizing risk of disease transmission through the exclusion and restriction of ill employees as specified in 2-201.12 of the Food Code;

· minimizing risk of disease transmission through the prompt removal of ill customers and others from areas of food preparation, service and storage; and

· the conditions under which the plan will be implemented.

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Attachments:

- "Attachment A-References:Procedure to Vomiting & Diarrheal Contamination"

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Conference for Food Protection
2010 Issue Form

Internal Number: 018
Issue: 2010 III-024

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

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Title:

Drying Agents

Issue you would like the Conference to consider:

Clarification to the 2009 US Food Code section 7-204.14 Drying Agents, Criteria, and the associated section in Annex 3 is needed to account for other regulatory procedures that can be used to clear food additives for their use in drying agents. Due to the absence of specific regulations in FDA's 21 Code of Federal Regulations (CFR) for drying agents, the FDA Food Code serves as the sole guidance for the use of drying agents in food facilities. The Food Code does not include use of Generally Recognized as Safe (GRAS) self-determinations by a panel of experts as specified in 21 CFR 170.30 or using the Food Contact Notification (FCN) process, which is included in the Federal Food Drug and Cosmetic Act (FFDCA) Section 409, and 21 CFR Parts 174.5 (d) (5). Both of these processes are appropriately used to qualify suitable components for drying agents and other chemicals associated with production and preparation of food.

Public Health Significance:

Some chemicals may be poisonous or toxic if not used properly and in accordance with FDA regulations. The lack of clear and explicit guidance surrounding drying agents not only creates confusion and allows for misinterpretation. Lack of clear and explicit guidance can also lead to the improper use of chemicals and may subsequently cause public health issues such as the adulteration of food, or potentially acute and chronic health effects to both the consumer and the employees of the food facilities.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA recommending the following changes to the Food Code,

7-204.14 Drying Agents, Criteria

Drying agents used in conjunction with sanitization shall:

(A) Contain only components that are listed as one of the following:

(1) Generally recognized as safe for use in food as specified in 21 CFR 182 - Substances Generally Recognized as Safe, or 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, P

(2) Generally recognized as safe for the intended use as specified in 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe, P

(3) Generally recognized as safe (GRAS) as determined by independent GRAS self-determinations by a panel of experts as specified in 21 CFR 170.30, P

(4) Subject of a Food Contact Notification (FCN) that is effective in accordance with the Federal Food Drug and Cosmetic Act (FFDCA) Section 409, P

FDA publishes the effective FCN's on their website at: http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm

(5~~3~~) Approved for use as a drying agent under a prior sanction specified in 21 CFR 181 - Prior-Sanctioned Food Ingredients, P

(6~~4~~) Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR Parts 174~~175~~-178, P or

(7~~5~~) Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles; P and

(B) When sanitization is with chemicals, the approval required under Subparagraph (A)(3) or (A)(5) of this section or the regulation as an indirect food additive required under Subparagraph (A)(4) of this section, shall be specifically for use with chemical sanitizing solutions. P

2) Annex 3. Chapter 7- Part 204.14 Sanitizers, Criteria.

"If the chemical wash, boiler water additive, or drying agent used is not made up of components that are approved as food additives or generally recognized as safe, illness may result. This could be due to residues that may remain from the use of compounds such as unrecognized drying agents. This is why only those chemicals that are listed in the CFR or are appropriately cleared as food additives can be used.

"Chemicals that are not listed for these uses may be submitted for review by filing a Food Additive Petition, a Food Contact Notification (FCN), have GRAS clearance, or meet the Threshold of Regulation (TOR) requirements. Wash chemicals, boiler water additives, and

drying agents are classified as food additives because of the possibility that they may end up in food. Therefore, they are subject to review before being used or listed in the CFR.

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Conference for Food Protection
2010 Issue Form

Internal Number: 016
Issue: 2010 III-025

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

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Title:

Specialized Processing Methods

Issue you would like the Conference to consider:

Removing section 3-502.11 (variance requirements) from the Retail / Restaurant License. The special processing methods should require a Food Processor License.

Public Health Significance:

The special processing methods require additional initial training as well as continual training for the inspector to maintain the technical proficiency required for these facilities. Many jurisdictions have only a few facilities requiring a variance (1-2 per inspector). The inspector may miss critical violations and spend extra time reviewing the requirements.

Recommended Solution: The Conference recommends...:

that a Committee be established to investigate and recommend specific requirements for specialized processing methods such as brewing beer, wine production, smoking and curing, acidifying foods, and sprouts, and removing these processes from variance requirements as stated in Food Code Section 3-502.11.

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