

# Conference for Food Protection - Committee FINAL Report

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**Committee Final Reports are considered *DRAFT until deliberated and acknowledged by the assigned Council at the Biennial Meeting***

**COMMITTEE NAME:** 2014-2016 Hand Hygiene Committee (HHC)

**COUNCIL or EXECUTIVE BOARD ASSIGNMENT:** Council III

**DATE OF REPORT:** December 10, 2015

**SUBMITTED BY:** Lori LeMaster and Christina Bongo-Box, Co-Chairs

## **COMMITTEE CHARGE(s):**

Issue: 2014 III-011

The committee is charged to:

1. Recreate the Hand Hygiene Committee, working in collaboration with FDA, CDC, and FSIS, to be charged with the following:
  - a. Ascertain if additional definitions are necessary to clarify the hand hygiene procedures listed in the Food Code.
  - b. Use current research including the documents created by the Committee's 2012- 2014 work (Hand Contamination Event Hazard Chart; Questions to Consider when Evaluating Studies of Alternative Handwashing Approaches; and Scientific, Regulatory and Behavioral Consideration of Hand Hygiene Regimes) to determine if alternatives to hand hygiene procedures equivalent to those described in the Food Code are available.
  - c. Identify situations where procedures exist to prevent hand soil and contamination.
  - d. Review available research on the efficacy and public health significance of antibacterial soaps, and their impact on hand hygiene procedures in the food industry.
2. Report back the Committee's findings, outcomes, and recommendations to the 2016 Biennial Meeting of the Conference for Food Protection.

## **COMMITTEE ACTIVITIES AND RECOMMENDATIONS:**

1. Progress on Overall Committee Activities:
  - a. During the first call of the HHC, the committee discussed the options for how to approach work on the assigned charges; specifically whether to work in subgroups or consider each charge together as the whole committee. The committee agreed that in order to obtain consensus on the charges, the work would be done by the entire HHC, rather than by sub-committees.

The committee agreed on a biweekly call schedule and calls were held on 9/25/14, 10/9/14, 10/23/14, 12/4/14, 1/29/15, 2/5/15, 2/12/15, 2/26/15, 3/26/15, 4/9/15, 5/21/15, 6/18/15, 7/16/15,

7/30/15, 8/13/15, 8/27/15, 9/10/15, 10/8/15, and 10/22/15. Calls were recorded through Pragmatic and call recordings and call notes/minutes were shared with the group.

As a part of the March, 2015 HHC Progress Report, the HHC requested that the Executive Board provide clarification of the following sections of the charge:  
Original Charge sections:

Section a - Ascertain if additional definitions are necessary to clarify the hand hygiene procedures listed in the Food Code.

. The HHC requested clarification whether the committee is also asked to provide recommendations for additional definitions if they are needed. The HHC provided the following recommended language: (Ascertain if additional definitions are necessary and proposed recommendations to clarify the hand hygiene procedures listed in the Food Code.

Section c - Identify situations where procedures exist to prevent hand soil and contamination. The HHC provided the following recommended language:

Identify methods and available research that describe where procedures exist to prevent hand soil and contamination.

Section d. Review available research on the efficacy and public health significance of antibacterial soaps, and their impact on hand hygiene procedures in the food industry. The committee voted unanimously to request that this charge be removed:

FDA published a proposed rule regarding the available data and FDA's criteria for establishing the safety and effectiveness of antiseptic washes for consumer use in December 2013. Although CDER has not yet defined antiseptic criteria for food handler use, we plan to address these products in the future.

The Executive Board denied the request to revise any of the charges and provided this guidance:

"The Committee can choose to explain how they fulfilled charges by the recommendations as stated in their report. However, charges cannot be changed or removed."

- i. Regarding the first section of the Charge;1.a: Ascertain if additional definitions are necessary to clarify the hand hygiene procedures listed in the Food Code.

The committee considered this charge first and initially could not come to consensus that additional definitions were necessary to clarify the hand hygiene procedures in the Food Code. The group agreed to "table" this charge and work on the other charges and reconsider this item if gaps in definitions were identified through work on other charges.

After the HHC worked charge 1.b, the committee identified two potential definitions that would clarify the current hand hygiene procedures listed in the Food Code: HAND CLEANING COMPOUND and ANTISEPTIC HAND RUB The committee formed a small work group to research and recommend language to the whole committee. The entire HHC was able to achieve consensus to recommend the following be added as defined terms to the Food Code:

- a) HAND CLEANING COMPOUND- A formulated hand hygiene product used to remove soils and transient microorganisms on hands, being submitted as Issue HHC-2

b) ANTISEPTIC HAND RUB- An antiseptic hand hygiene product applied to the hands and rubbed until dry, used to reduce the transient microorganisms, being submitted as Issue HHC-3

- ii. Regarding the second section of the Charge; 1.b. Use current research including the documents created by the Committee's 2012-2014 work (Hand Contamination Event Hazard Chart; Questions to Consider when Evaluating Studies of Alternative Handwashing Approaches; and Scientific, Regulatory and Behavioral Consideration of Hand Hygiene Regimes) to determine if alternatives to hand hygiene procedures equivalent to those described in the Food Code are available.

The committee was charged with reviewing current research to determine if alternatives hand hygiene procedures exist that are equivalent to the hand hygiene procedures described in the Food Code.

The HHC began work on this charge on 12/4/14.

There was extensive discussion about how to approach this charge. The voting members voted unanimously on the following points:

- a) There is no standard by which to determine "equivalent hand hygiene procedures"
- b) To move forward by reviewing the submitted studies to look for trends in the literature.

The group divided into six small groups and each small work group was assigned a few of the studies listed below to review and report back to the whole group on the 1/29/15 call. The sub-committees met between 12/4/14 and 1/29/15.

The HHC reviewed the following studies:

- 2010-2012 Hand Hygiene Committee / Swanson Et. Al.,2012
- M. A. Davis, H. Sheng, J. Newman, D. D. Hancock and C. J. Hovde. "Comparison of waterless hand-hygiene preparation and soap-and-water hand washing to reduce coliforms on hands in animal exhibit settings". *Epidemiol Infect* 2006;134: 1024-1028..
- Sarah L. Edmonds,\* James Mann, Robert R. McCormack, David R. Macinga, Christopher M. Fricker, James W. Arbogast, And Michael J. Dolan. "SaniTwice: A Novel Approach to Hand Hygiene for Reducing Bacterial Contamination on Hands When Soap and Water are Unavailable". *J Food Prot.* 2010;73(12):2296-2300.
- Sarah L. Edmonds,\* Robert R. McCormack, Sifang Steve Zhou, David R. Macinga, and Christopher M. Fricker. "Hand Hygiene Regimens for Reduction of Risk on Food Service Environments" *J Food Protect* 2012;75(7):1303-1309.
- Sarah L. Edmonds, Ms; Carrie Zapka, Ms; Douglas Kasper, Md; Robert Gerber, Md;Robert McCormack, Bs; David Macinga, Phd; Stuart Johnson, Md; Susan Sambol, Bs,Mt (Ascp); Christopher Fricker, Phd; James Arbogast, Phd; Dale N. Gerding, Md. "Effectiveness of Hand Hygiene for Removal of Clostridium difficile Spores from Hands". *Infect Control Hosp Epidemiol* 2013;34(3):302-305.
- Angela Fraser, James W. Arbogast, Lee-Ann Jaykus, Richard Linton, and Didier Pittet. "Rethinking Hand Hygiene in the Retail and Foodservice Industries: Are Recommended Procedures Based on the Best Science and Practical Under Real-world Conditions?" *Food Protection Tends.* December 2012.
- Akrum H. Tamimi • Sheri Carlino •Sarah Edmonds • Charles P. Gerba. "Impact of Alcohol-Based Hand Sanitizer Intervention on the Spread of Viruses in Homes". *Food Environ. Virol* 2014.
- Pengbo Liu • David R. Macinga • Marina L. Fernandez •Carrie Zapka • Hui-Mien Hsiao • Brynn Berger, "Comparison of the Activity of Alcohol-Based Handrubs Against Human

Noroviruses Using the Fingerpad Method and Quantitative Real-Time PCR". *Food Environ. Virol* 2011;3:35-42.

- Liu, Macinga, Fernandez, Zapka, Hsiao, Berger, Arbogast, Moe. "Comparison of the Activity of Alcohol-Based Handrubs against Human Noroviruses Using the Fingerpad Method and Quantitative Real-Time PCR." *Food and Environmental Virology*, December 2010.
- Macinga, Sattar, Jaykus And Arbogast. "Improved Inactivation of Noneveloped Viruses and Their Surrogates by a Novel Alcohol-Based Hand Sanitizer". *Appl. Environ. Microbiol* 2008;74(16):5047-5052.
- Amy J. Pickering , Alexandria B. Boehm , Mathew Mwanjali , And Jennifer Davis. Efficacy of Waterless Hand Hygiene Compared with Handwashing Soap: A Field Study in Dar es Salaam , Tanzania. *Am. J. Trop. Med. Hyg* 2010;82(2):270-278.
- Amy J. Pickering, Jennifer Davis And Alexandria B. Boehm "Efficacy of alcohol-based hand sanitizer on hands soiled with dirty and cooking oil" *Journal of Water and Health* 2011.
- Racicot, Kocher, Beauchamp, Letellier and Vaillancourt Assessing most practical and effective protocols to sanitize hands of poultry catching crew members. *Preventive Veterinary Medicine* 2013;111:92-99.
- Donald W. Schaffner\* and Kristin M. Schaffner Management of Risk of Microbial Cross-Contamination from Uncooked Frozen Hamburgers by Alcohol-Based Hand Sanitizer. *J. Food Protect* 2007;70(1):109-113.
- Josie L. Traub-Dargatz, J. Scott Weese, Joyce D. Rousseau, Magdalena Dunowska, Paul S. Morley, David A. Dargatz. "Pilot study to evaluate 3 hygienic protocols on the reduction of bacterial load on the hands of veterinary staff performing routine equine physical examinations". *Can Vet J* 2006;47:671-676.

Each of the small work groups reported to the full committee on the results of their review of their assigned studies during the 1/29/15 HHC call. Overall, the majority of the studies reviewed by the group were not applicable directly to food service, or they were limited in scope and application. The primary conclusion reiterated by every small group during their review of the literature is that a standard to determine an alternative method for hand hygiene procedures "equivalency" does not exist but is necessary. The HHC members agreed that there is a real need for food service-focused research to understand the different levels of risk associated with different food handling activities in food establishments.

Since the literature review could not establish alternatives that are equivalent to the handwashing procedures, the group formed a sub-group to review and report back to the entire HHC their findings regarding the following published standard handwashing methods:

- ASTM E2011-13 (" Standard Test Method for Evaluation of Hygienic Handwash and Handrub Formulations for Virus-Eliminating Activity Using the Entire Hand")
- ASTM E2946-13 ("Standard Test Method for Determining the Bacteria-Reducing Effectiveness of Food-Handler Handwash Formulations Using Hands of Adults")
- ASTM E2783 ("Standard Test Method for Assessment of Antimicrobial Activity for Water Miscible Compounds Using a Time-Kill Procedure")
- ASTM 1174 ("Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations")
- ASTM E2755 ("Standard Test Method for Determining the Bacteria-Eliminating Effectiveness of Healthcare Personnel Hand Rub Formulations Using Hands of Adults")
- EN 1276 ("Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)")

- EN 1499 (“Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2/step 2)”)
- EN 1500 (“Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2)”)

The subcommittee developed a Comparison of Selected Hand Hygiene Efficacy Test Methods table (attached) to review and evaluate all of the standard methods listed above to assess their strengths, limitations, reproducibility, and relevance in food settings. The subcommittee recommended to the full committee that ASTM E2783 and ASTM 2946 could be included in the Food Code in a meaningful and logical way; by creating science based performance standards for hand hygiene products used in the food industry.

No recommendations of equivalent alternate procedures could be made by the full committee based on the subcommittee’s findings of no agreed-upon performance measure comparable to the Food Code procedures exist.

It was shared with the committee that FDA is working to develop performance standards that will allow for the evaluation of different methods for soil removal from hands of food service workers or food production situations. No clear timeframe for these performance standards was available at this time.

The HHC recommends that a letter be sent to the FDA encouraging the development of handwashing performance standards.

iii. Regarding the third section of the Charge 1.c. Identify situations where procedures exist to prevent hand soil and contamination. The committee identified the following procedures that potentially prevent hand soil and contamination:

1. Properly using utensils. For example, filling a glass with ice using a scoop.
2. Handling raw animal foods with tongs instead of bare hands.
3. Properly using gloves.
4. Using other barriers when handling food, such as deli paper.
5. Segregating job duties so that the food handlers assigned to work with raw animal foods are not required to also handle ready to eat foods or other clean utensils.
6. Double-gloving.

iv. Regarding the fourth section of the Charge 1.d. Review available research on the efficacy and public health significance of antibacterial soaps, and their impact on hand hygiene procedures in the food industry.

FDA published a proposed rule regarding the available data and FDA’s criteria for establishing the safety and effectiveness of antiseptic washes for consumer use in December, 2013: <https://www.federalregister.gov/articles/2013/12/17/2013-29814/safety-and-effectiveness-of-consumer-antiseptics-topical-antimicrobial-drug-products-for>

The FDA Center for Drug Evaluation and Research (CDER) has not yet defined antiseptic criteria for food handler use.

The Hand Hygiene Committee membership agreed that it was unable to complete this charge because any recommendations resulting from the charge would include FDA policy matters that are outside the scope of the CFP. Resolution of the charges requires the active

engagement of FDA CDER, a regulatory body for drugs, with FDA Center for Food Safety and Applied Nutrition (CFSAN) and interagency engagement is beyond the scope of CFP.

The HHC Recommends that a letter be sent to the FDA encouraging the FDA to work in conjunction with CDER to define antiseptic criteria for food handler use.

2. Recommendations for consideration by Council:  
Based on the committee's work, the Committee Co-Chairs are submitting 3 issues on behalf of the Committee. Recommendations of this Committee through these issues are:
  - a. Thank the Committee for its work, acknowledge the Committee's report, and disband the Committee.
  - b. Add the following definition to the Food Code:  
**Hand Cleaning Compound** - A formulated hand hygiene product used to remove soils and transient microorganisms on hands.
  - c. Add the following definition to the Food Code:  
**Antiseptic Hand Rub** - An antiseptic hand hygiene product applied to the hands and rubbed until dry, used to reduce the transient microorganisms.
  - d. Recommend that a letter be sent to the FDA encouraging the development of handwashing performance standards.
  - e. Recommend that a letter be sent to the FDA encouraging the FDA to work in conjunction with CDER to define antiseptic criteria for food handler use.

#### **CFP ISSUES TO BE SUBMITTED BY COMMITTEE:**

1. Issue 1- Report- 2014-2016 Hand Hygiene Committee (HHC)
  2. Issue 2- HHC Recommended Food Code Definitions for "Hand Cleaning Compound" and
  3. Issue 3 - HHC Recommended Food Code Definitions for - "Antiseptic Hand Rub"
  4. Issue 4 - HHC recommended letters to FDA
- 1) Recommend that a letter be sent to the FDA encouraging the development of handwashing performance standards.
  - 2) Recommend that a letter be sent to the FDA encouraging the FDA to work in conjunction with CDER to define antiseptic criteria for food handler use.

#### **COMMITTEE MEMBER ROSTER (attached):**