

# 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 Trends*. 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):**

**Committee Name: 2014 - 2016 Hand Hygiene Committee - Council III**

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	Telephone	Email
Bongo-Box	Christina	Co-Chair	Food Service Industry	Popeyes Louisiana Kitchen Inc	Atlanta	(404) 459-4718	<a href="mailto:christinabongo@gmail.com">christinabongo@gmail.com</a>
LeMaster	Lori	Co-Chair	State Regulator	TN Department of Health	Nashville	(615) 741-7206	lori.lemaster@tn.gov
Adams Hutt	Dr. Catherine	Member	Food Service Industry	National Restaurant Association	Aubrey	(630) 605-3022	cadams@rdrsol.com
Buffer	Janet	Member	Retail Food Industry	The Kroger Company	Cincinnati	(513) 387-7332	<a href="mailto:janet.buffer@kroger.com">janet.buffer@kroger.com</a>
Carotenuto	Tony	Member	Federal Regulator	Navy and Marine Corps Public Health Center	Portsmouth	(757) 953-0712	anthony.carotenuto@med.navy.mil
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Gaither	Marlene	Member	Local Regulator	Coconino County (AZ) Health Department	Flagstaff	(928) 679-8761	mgaiter@coconino.az.gov
Huffman	Troy	Member	State Regulator	Nebraska Department of Health and Human Services	Lincoln	(402) 471-0387	troy.huffman@nebraska.gov
Johnson	Anna	Member	State Regulator	FL Dept of Agriculture	Deltona	(407)335-3497	<a href="mailto:anna.johnson@freshfromflorida.com">anna.johnson@freshfromflorida.com</a>
Oswald	Steve	Member	Retail Food Industry	Wakefern Food Corporation	Elizabeth	(908) 527-3624	steve.oswald@wakefern.com
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**Table 1. Comparison of selected hand hygiene efficacy test methods by key step or variable**

Key Step or Variable	ASTM E2783 (Time Kill)	EN 1276	Chlorine Equivalency former USDA E2/E3 rating)	ASTM E1174	ASTM E2755	ASTM E2946	ASTM E2011	EN 1499	EN 1500
<b>Vitro/vivo</b>	In Vitro	In Vitro	In Vitro	In Vivo	In Vivo	In Vivo	In Vivo	In Vivo	In Vivo
<b>Purpose / Target Application in Design</b>	"In vitro" hand hygiene product evaluation	"In vitro" antimicrobial activity of disinfectants and hand hygiene products	<ul style="list-style-type: none"> <li>"In vitro" designed to test efficacy of halogen based disinfectants and sanitizers</li> </ul>	"In vivo" product evaluation ("healthcare personnel hand wash")	"In vivo" activity of hand hygiene personnel hand rubs	"In vivo" activity of food handler hand hygiene formulations	"In vivo" antiviral activity of hand hygiene formulations	"In vivo" hand washes – ensure a minimum performance standard	"In vivo" hand rubs – ensure a minimum performance standard
<b>Test Organism(s)</b>	Any BSL 1 or 2 organisms; we could recommend a specific list that are highly food relevant (e.g. e. Coli, listeria, salmonella, etc.)	<i>Ps. aeruginosa</i> ATCC 15442, <i>E. coli</i> ATCC 10536, <i>S. aureus</i> ATCC 6538, <i>Enterococcus hirae</i> ATCC 10541	<i>S. aureus</i> ATCC 6538, <i>S. typhi</i> ATCC 6539	<i>Serratia marcescens</i> and <i>E. coli</i>	<i>Serratia marcescens</i> ATCC 14756, <i>S. aureus</i> ATCC 6538, or 33591	<i>E. coli</i> ATCC 11229	Human Rotavirus, Human Rhinovirus Type 37, Feline calicivirus, Human Adenovirus Type 5	<i>E. coli</i> K12 NCTC 10538	<i>E. coli</i> K12 NCTC 10538

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Key Step or Variable	ASTM E2783 (Time Kill)	EN 1276	Chlorine Equivalency former USDA E2/E3 rating)	ASTM E1174	ASTM E2755	ASTM E2946	ASTM E2011	EN 1499	EN 1500
<b>Soil Type(s):</b>	None	Flexible: Can be chosen based on the condition of use	Inoculated broth	4.5 mL of inoculums in nutrient broth	0.2 mL of inoculum in nutrient broth	Beef broth is “moderate” soil, Hamburger is “heavy” soil	Bovine serum	Inoculated broth	Inoculated broth
<b>Soil Load (Quantity):</b>	Volume of the inoculum in Nutrient broth used	0.3g/L clean conditions; 3 g/L dirty conditions	10 µl of inoculated broth for tube 1 and total 100 µl for tube 10	4.5 mL of inoculums in Nutrient broth	0.2 mL of inoculum in nutrient broth	4.5 mL of Beef broth for moderate soil  Handling contaminated hamburger for 2 min	5% in the virus inoculum	Amount of inoculated broth which ends up on the hands during immersion of the hands	None specifically added. Just dried TSB from inoculating broth
<b>Method of Contamination:</b>	Inoculation of the product	Inoculation of the product	Inoculation of the product	3-1.5 mL of an overnight broth culture of the test organism	200µl of a concentrated broth suspension of the test organism	4.5 mL of Beef broth for moderate soil  Handling contaminated hamburger for 2 min	1.5 mL of the suspension, 90 sec spread, 90 sec dry  Or 20µL of virus suspension on each finger tip	Immersion into seeded broth	Immersion into seeded broth
<b>Baseline Recovery (Pre-Test Value):</b>	Not specified	1.5x10 <sup>8</sup> -5x10 <sup>8</sup>	N/A	5x10 <sup>8</sup> -1x10 <sup>9</sup>  Liquid suspension used for contamination. Recovery is not specified	≥10 <sup>8</sup> cfu/hand (Usually 8.5-9.0 log <sub>10</sub> cfu/hand)	Suspension 1x10 <sup>8</sup>	The virus “pull” shall contain ≥10 <sup>7</sup> infective unit/mL	Inoculum 2x10 <sup>8</sup> -2x10 <sup>9</sup>  Log pre-values at least 5	Inoculum 2x10 <sup>8</sup> -2x10 <sup>9</sup>  Log pre-values at least 5 per mL

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Key Step or Variable	ASTM E2783 (Time Kill)	EN 1276	Chlorine Equivalency former USDA E2/E3 rating)	ASTM E1174	ASTM E2755	ASTM E2946	ASTM E2011	EN 1499	EN 1500
<b>Test Article Application Details:</b>	N/A	N/A	N/A	5 mL of the test product during handwashing using 40°C water for 1 min handwashing	1.5 ml of a test material (calculations for foaming materials provided)	5 mL of the test material Wash for 30±5 sec, rinse for 30±5 sec	Volume specified by manufacturer	3 ml applied and washed for 30 or 60 sec +15 sec rinse or following manufacturer instructions	3 ml applied and rubbed for 30 seconds, then sampled
<b>Number of Subjects / Replicates (Minimum, Recommended)</b>	N/A	N/A	N/A	Not specified FDA CDER asks for at least 12 subjects	At least 8 subjects Total depends on number of test materials, study purpose, and regulatory requirements governing the study.	At least 8 subjects	At least 6 subjects	At least 12 subjects	18-22 subjects
<b>Internal Reference:</b>	None	None	Referenced Chlorine solution	None	None	None	None	Soft soap (British Pharmacopoeia 1993) 200g/L	2x3ml of 60% isopropanol rubbed for 60 seconds total
<b>Acceptance Criteria:</b>	None	5 log reduction	Test article is at least equivalent to 50 ppm chlorine	None in the test method. Per 2015 FDA HC TFM: 2 Logs after the 1 <sup>st</sup> application, 3 Logs after 10 <sup>th</sup> application	None in the test method.	None in the test method.	None in the test method	Statistically non-inferior to the reference product	Statistically non-inferior to the reference product

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Key Step or Variable	ASTM E2783 (Time Kill)	EN 1276	Chlorine Equivalency former USDA E2/E3 rating)	ASTM E1174	ASTM E2755	ASTM E2946	ASTM E2011	EN 1499	EN 1500
<b>Can bland Handwash be a benchmark?</b>	Yes, not in the test method	N/A	N/A	Yes, not in the test method	N/A	Yes, not in the test method	Yes, not in the test method	N/A	N/A
<b>Product dilution</b>	Undiluted	Undiluted	Undiluted	Undiluted	Undiluted	Undiluted	Undiluted	Undiluted	Undiluted
<b>Contact time</b>	Flexible; most typical is 15 sec, 30 sec and 60 sec.	5 min	1, 2.5 and 5 min	30 sec lather + 30 sec rinse	1.5 mL application volume, Rub until hands are dry.  Or manufacturer's recommendations	30±5 sec	10-20 sec for handwash, 20-30 sec for hand rub, or other times representative use condition time	30 or 60 sec +15 sec rinse or following manufacturer instructions	30 sec

**Table 2. Comparison of selected hand hygiene test methods by strengths and limitations and suitability for inclusion in Model Food Code**

Method	Strengths	Limitations	Expected variability and reproducibility	Relevance and Fit for Food Code (H/M/L)	Recommended for CFP & Food Code
<b>ASTM E2783 (Time Kill)</b>	<p>“In vitro” test, relatively inexpensive, can be run with many organisms and by many labs with good reproducibility.</p> <p>Large amount of data and experience using this method</p>	<p>“In vitro” test (i.e. results will not necessarily predict real world hand hygiene results or the <i>in-vivo</i> methods)</p>	<p>Results more variable when the product has high foam; results are highly dependent of the mixing technique</p>	<p>High: Good screening test, should be required as a means to ensure broad spectrum antimicrobial effectiveness before “in vivo” testing.</p>	<b>Yes</b>
<b>Chlorine Equivalency</b>	<p>“In vitro” test. Long history of use</p>	<p>Risks posed by working with <i>S. typhi</i> (typhoid fever)</p> <p>Data is not relevant for hand antiseptics in general, especially those that do not contain halogen based active ingredients</p>	<p>Products with border line efficacy have high variability in results</p>	<p>Low</p>	No
<b>EN 1276</b>	<p>“In vitro” test</p> <p>Includes options of soils to be added, based on the industry. Could be tested for clean and dirty conditions</p>	<p>Some of microorganisms are not relevant for food retail use</p> <p>The test method is not designed for chemistries affected by soil</p>	<p>No</p>	<p>Low</p>	No
<b>ASTM 1174</b>	<p>“In vivo” test</p>	<p>Designed for healthcare</p>	<p>Fair reproducibility</p>	<p>Medium</p>	No

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Method	Strengths	Limitations	Expected variability and reproducibility	Relevance and Fit for Food Code (H/M/L)	Recommended for CFP & Food Code
	A lot of data available for this test	applications No soil used besides the inoculum broth <i>E. coli</i> (not <i>Serratia</i> ) should be required for food retail application	Cannot compare across tests		
<b>ASTM E2755</b>	"In vivo"	Price of the test (relatively expensive) Some of microorganisms are not relevant for food retail use	Fair reproducibility Cannot compare across tests	Medium	No
<b>ASTM E2946</b>	"In vivo" test Designed for food handler applications (bacteria) Two different food relevant soils (moderate and heavy)	Recently released, so limited experience with the method	Fair reproducibility Cannot compare across tests	High	<b>Yes</b>
<b>ASTM E2011</b>	"In vivo" test	No soil used besides the inoculum broth Viruses only Viruses are not included in FDA CDER Monograph for hand antiseptics.	Fair reproducibility Cannot compare across tests	Medium (viruses only)	No

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Method	Strengths	Limitations	Expected variability and reproducibility	Relevance and Fit for Food Code (H/M/L)	Recommended for CFP & Food Code
EN 1499	"In vivo" test	Designed for healthcare applications  Limited history of use in US	No	Low	No
EN 1500	"In vivo" test	Designed for healthcare applications  Limited history of use in US	No	Low	No