

**Conference for Food Protection  
2012 Issue Form**

**Internal Number: 072  
Issue: 2012 III-001**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

---

**Title:**

Report - Hand Hygiene Committee

**Issue you would like the Conference to consider:**

At the 2010 Conference for Food Protection Biennial Meeting, the Hand Hygiene Committee was formed and charged "to address:

1. the efficacy/risk reduction strategies of alternative hand hygiene regimes compared to handwashing with respect to foodborne pathogens including viruses,
2. identify settings where alternatives to handwashing are appropriate,
3. recommend studies that should be completed to get research questions answered for when scientific literature is not available, and
4. report back to the 2012 Conference."

The 2010-2012 Hand Hygiene Committee is submitting four issues to the 2012 Conference for Food Protection:

1. Report - Hand Hygiene Committee
2. Disseminate the 2010-2012 Hand Hygiene Committee Report
3. Re-Create - Hand Hygiene Committee
4. Limit Hand Hygiene Committee Size

**Public Health Significance:**

The main purpose of washing hands is to cleanse the hands of soil, pathogens and chemicals that can potentially cause disease. Transmission of pathogenic bacteria, viruses and parasites to food from contaminated surfaces, raw food or ill workers by way of improperly washed hands continues to be a major factor in the spread of foodborne illnesses.

**Recommended Solution: The Conference recommends...:**

- acknowledgement of the 2010-12 Hand Hygiene Committee report, and
- thanking the 2010-2012 Hand Hygiene Committee for its work addressing scientific, regulatory and behavioral considerations related to efficacy and risk reduction strategies of alternative hand hygiene regimes compared to handwashing.

The future of the Hand Hygiene Committee is submitted as a separate Issue.

**Submitter Information:**

Name: Katherine M.J. Swanson, Co-Chair  
Organization: 2010-2012 Hand Hygiene Committee  
Address: Ecolab Inc., 655 Lone Oak Drive  
City/State/Zip: Eagan, MN 55121  
Telephone: 651-795-5943 Fax: 651-204-7520  
E-mail: katie.swanson@ecolab.com

**Attachments:**

- "2010-12 Hand Hygiene Committee Final Report"
- "Scientific Regulatory and Behavioral Considerations of Hand Hygiene Regimes"
- "2010-12 Hand Hygiene 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:** 2010-2012 Hand Hygiene Committee

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

**DATE OF REPORT:** January 23, 2012

**SUBMITTED BY:** Committee Co-Chairs Katherine MJ Swanson and Mark Sampson

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

The Conference recommends that a committee be formed to include appropriate stakeholders including Center for Food Safety and Applied Nutrition (CFSAN), CDC and Center for Drug Evaluation and Research (CDER) to address:

1. the efficacy/risk reduction strategies of alternative hand hygiene regimes compared to handwashing with respect to foodborne pathogens including viruses,
2. identify settings where alternatives to handwashing are appropriate,
3. recommend studies that should be completed to get research questions answered for when scientific literature is not available [added by the CFP Board] and report back to the 2012 Conference.

## **COMMITTEE ACTIVITIES AND RECOMMENDATIONS:**

### **Sub-committee Structure and Approach**

Interest in participating in the 2010-2012 Hand Hygiene Committee was very high, with 50+ people volunteering to serve. The Committee, therefore divided into three sub-committees to address the charge. The complexities of the science, behavioral and regulatory considerations involved with hand hygiene products suggested that an educational report for CFP membership could be beneficial to clarify the multiple elements of the subject. The committee, therefore focused its work on creating such a report and each sub-committee addressed specific topics related to the charge.

- Science of hand hygiene – Co-chairs Don Schaffner and Dale Grinsted
  - Identify the hazards associated with hand hygiene-related food safety issues including bacteria, viruses, allergens and others if appropriate
  - Briefly review the pros and cons of methods used to evaluate effectiveness of hand hygiene solutions (*in vivo* versus *in vitro*)
  - Summarize the available science on the efficacy of hand hygiene approaches at removing hazards and reducing risk, including handwashing and other approaches
- Regulatory status of hand hygiene products for food handlers – Co-chairs Mark Sampson and Catherine Adams Hutt
  - Provide a fact-based summary of current regulatory requirements for hand hygiene products, the regulatory jurisdiction and antimicrobial claims that are allowed by the regulatory authority to form a common understanding for the committee and CFP members.
  - Attempts to change existing federal regulatory requirements outside of the Food Code were out of scope.
- Behavioral aspects of hand hygiene – Chair Michele Samarya-Timm
  - Identify compliance issues and behavioral aspects of hand hygiene
  - Identify potential public health benefit of improved hand hygiene compliance using different approaches
  - Address Charge #2 related to settings where alternatives to handwashing may apply

All sub-committees were asked to recommend research to answer unresolved questions. The work products of these groups were combined and reviewed with the full committee to build consensus on this final report to address the charges.

CDER and CFSAN FDA committee consultants requested that the following statement be used to clarify the FDA's involvement with the Committee:

"FDA supports the Conference for Food Protection (CFP) process; however, there are some instances within this committee (and subcommittees) that discussion on certain topics can lead to a conflict of interest for FDA. When the CFP Hand Hygiene Committee (and its subcommittees) addresses issues relating to efficacy, uses and corresponding efficacy data, methods, standards, effectiveness and what constitutes an acceptable drug applied to human skin (hand antiseptic), FDA CDER and CFSAN can not engage fully in all committee discussions due to a conflict of interest with the regulatory process already in place through FDA CDER."

### **Executive Summary**

Addressing the effectiveness of hand hygiene strategies is a complex issue involving scientific, regulatory and behavioral considerations. In the United States, several vegetative bacterial pathogens or their toxins are associated with foodborne illness outbreaks where inappropriate application of hand hygiene regimens were noted; however, norovirus is by far the pathogen reported most frequently in these outbreaks (CDC 2006). A majority of these reported norovirus-associated foodborne outbreaks also involve food that was handled by ill individuals (CDC 2006). Many of these outbreaks may not have occurred if ill food handlers were effectively excluded from the establishment. Because of the low median infectious dose for norovirus and certain other agents (e.g., Shigella, Hepatitis A), it is questionable whether even effective hand hygiene regimens would be capable of preventing transfer of highly infectious pathogens when food is handled by symptomatic people.

Effectiveness of any hand hygiene regimen involves many factors, including the hand hygiene product type (e.g., soap, hand antiseptic), amount applied, method of application, duration of application and pathogen of concern. Norovirus is more resistant to chemical agents used in hand hygiene products than vegetative bacteria. While bacterial spores are also more resistant than vegetative bacteria, sporeformers of foodborne illness concern must be in their vegetative state and grow in the food to a high level to present a food safety risk. Thus inactivation of spores is not a major concern for hand hygiene in a food handler setting.

Handcare products that make antimicrobial claims are regulated as drugs in the US. Currently there are no antimicrobial hand hygiene products for food handler applications in the US with FDA-approved claims for antiviral effectiveness, thus there is no ready mechanism for an establishment to choose a hand antiseptic product that may be effective against foodborne viral pathogens when used according to label instructions. The antiviral profile of several commercially available products has been assessed in peer-reviewed literature (e.g., Park et al., 2010; Liu et al., 2011), demonstrating that some products can achieve significant reductions.

Behavioral issues related to hand hygiene involve both use of proper procedure and commitment to perform the task, thus there is a need to understand human factors in order to remove barriers and enhance hand hygiene compliance. Some laboratory studies suggest that application of some form of hand hygiene is better than doing nothing at all; however, this has not been evaluated in the context of a risk assessment that evaluated human variation in application of hand hygiene regimes. At least one regulatory jurisdiction allows the use of alternatives to handwashing, such as a two step hand cleanser-sanitizer protocol, in certain settings where water is limited. Behavioral and risk assessment research that evaluates the magnitude of risk reduction achieved by varying forms of hand hygiene actions (i.e., nothing, rinsing, hand sanitizing, washing, or washing and brushing) would be useful to move from an all-or-nothing approach in every situation, to one recognizing that different procedures may be suitable for different situations.

In conclusion, the Committee was unable to identify specific situations where application of alternatives to handwashing is appropriate. However, the Committee believes that its approach of considering scientific, regulatory and behavioral factors creates the ground work necessary that such recommendations would be

possible in the future. Thus the Committee recommends continuation of this work and is submitting an issue to re-create the Hand Hygiene Committee.

## **Charge 1 – Address the efficacy/risk reduction strategies of alternative hand hygiene regimes compared to handwashing with respect to foodborne pathogens including viruses**

### ***Introduction***

The main purpose of washing hands is to cleanse the hands of soil, pathogens and chemicals that can potentially cause disease. Transmission of pathogenic bacteria, viruses and parasites to food from contaminated surfaces, raw food or ill workers by way of improperly washed hands continues to be a major factor in the spread of foodborne illnesses. In this report, hand hygiene products available to reduce the risk of spreading infectious agents are categorized as:

- handwashing agents (plain soaps or antimicrobial soaps)
- hand wipes (plain and antiseptic) and
- hand antiseptics (antiseptic waterless agents)

*Handwashing* with plain soap suspends microorganisms and mechanically removes them by rinsing with water. Plain bar soap, foam and liquid preparations are comprised of detergents with surfactant (surface-active agents), which increase the cleaning properties of water and gives the product the ability to remove soil from surfaces, such as human skin. Microbial reduction using plain soap is due to the physical removal of foreign material or microorganisms, not a biocidal effect.

An *antimicrobial soap* combines the cleaning action of plain soap (i.e., physical removal of foreign material) with antiseptic agents that kill microorganisms. The antimicrobial agents used in antimicrobial soaps (e.g., chloroxylenol, quaternary ammonium compounds, chlorhexidine gluconate, iodine/iodophors and triclosan) have an immediate effect that reduces the number of microflora on skin and in certain cases may exhibit residual or sustained activity that continues to reduce the number of microbial flora after the handwash is complete. The effectiveness of these agents is primarily directed toward vegetative bacteria.

*Antimicrobial wipes* are towelettes or paper towels that are saturated with an antimicrobial solution that has been shown to reduce the numbers of microorganisms on skin. The antimicrobial ingredient is typically isopropyl or ethyl alcohol and/or a quaternary ammonium compound. There are also some specialized products with other antimicrobial ingredients.

*Hand antiseptics* (also called hand sanitizers) are waterless agents with antiseptic properties that decrease the number of microorganisms present. For the purposes of this paper, hand antiseptics do not require the use of water. Alcohol-based hand antiseptics are the most common type and typically contain ethanol or isopropanol and may contain n-propanol or a combination of these agents. Hand antiseptics are typically not designed as hand cleansers and thus are usually intended to be used on visibly clean hands as a single application. However, most hand antiseptics contain emollients, emulsifiers and water, all of which can act as cleaning agents when assisted by hand-to-hand rubbing and physical removal with a paper towel, in a manner similar to a hand wipe.

### ***Foodborne pathogens associated with hand hygiene-related outbreaks***

To address the charge, the committee first identified the foodborne pathogens relevant to hand hygiene interventions. The CDC (2009) provides a list of infectious diseases that are transmitted through handling the food supply, which is summarized in Table 1 below and in Annex 3 Section 2-201.11 of the 2009 Food Code. Two categories are identified – 1) those pathogens that are *often* transmitted by food when handled by an infected person and 2) those pathogens that are *occasionally* transmitted thorough handling by an infected worker but usually transmitted by contamination at the source or in food processing or by non-foodborne routes. Those “often” involving infected workers include pathogens with low infective dose (e.g., the viruses, *Salmonella* Typhi and *Shigella*) and those that are shed in high numbers when an active infection exists (e.g., the viruses, *Staphylococcus aureus* and *Streptococcus pyogenes*). The 2009 Food Code Sections 2-201.12 and 2-201.13 specify exclusion or restriction of food workers from a food establishment when certain diagnoses or symptoms listed in Table 1 exist. Annex 3 of the Food Code (2009, page 337) specifically notes that “exclusion of food employees exhibiting or reporting diarrhea symptoms is an essential

intervention in controlling the transmission of norovirus from infected food employees' hands to RTE food items." This recognizes that even thorough hand hygiene may not be sufficient to prevent transmission of disease when food is handled by symptomatic food handlers.

**Table 1** CDC listing of infectious and communicable diseases transmitted through handling the food supply

Category	Agent	Modes of transmission	Symptoms that indicate infection that could be transmitted to others through food
Pathogens <i>often</i> transmitted by food contaminated by infected persons who handle food	Viruses - Norovirus - Hepatitis A virus - Sapovirus Bacteria - <i>Salmonella</i> Typhi - <i>Shigella</i> species - <i>Staphylococcus aureus</i> - <i>Streptococcus pyogenes</i>	<ul style="list-style-type: none"> <li>• Failure of food handlers to:               <ul style="list-style-type: none"> <li>- wash hands,</li> <li>- wear clean gloves, or</li> <li>- use clean utensils</li> </ul> </li> <li>• Also transmitted person to person</li> </ul>	<ul style="list-style-type: none"> <li>• Diarrhea</li> <li>• Vomiting</li> <li>• Open skin sores, boils</li> <li>• Fever</li> <li>• Dark urine</li> <li>• Jaundice</li> </ul>
Pathogens <i>occasionally</i> transmitted by food contaminated by infected persons who handle food, but <i>usually</i> transmitted by contamination at the source or in food processing or by non-foodborne routes	Bacteria - <i>Campylobacter jejuni</i> - Enterohemorrhagic <i>E. coli</i> - Enterotoxigenic <i>E. coli</i> - Non-typhoidal <i>Salmonella</i> - <i>Vibrio cholera</i> - <i>Yersinia enterocolitica</i> Parasites - <i>Cryptosporidium</i> species - <i>Entamoeba histolytica</i> - <i>Giardia intestinalis</i> - <i>Taenia solium</i>	<ul style="list-style-type: none"> <li>• Usually intrinsically contaminated or cross-contaminated during processing or preparation</li> <li>• Occasionally transmitted by infected food handler with acute diarrhea</li> <li>• Bacterial pathogens often require multiplication in the food before they will cause disease</li> </ul>	<ul style="list-style-type: none"> <li>• Acute diarrheal illness</li> </ul>

Adapted from: CDC 2009. Federal Register November 23, 2009, 74(224):61151

CDC (2006) also published foodborne illness contributing factors that were reported for outbreaks occurring from 1998-2002. In that time period, of the 3072 outbreaks for which contributing factors were reported, 25% identified bare-hand contact, 20% identified infected persons and 6% identified gloved-hand contact as factors contributing to these outbreaks. Table 2 summarizes the CDC (2006) data by etiology for foodborne illness outbreaks reported as being associated with hand contact (with or without gloves) or handling by an infected person as a contributing factor. Norovirus was the dominant etiology for outbreaks involving these contributing factors, and bacterial etiologies were reported for 40% of the bare-hand contact outbreaks, 35% of gloved-hand outbreaks and 35% of infected person outbreaks involved bacterial agents. Only one parasite (*Giardia intestinalis*) and no chemicals were reported to be associated with hand hygiene related outbreaks in this time period.

It cannot be determined from these data how many outbreaks "involving infected persons or carrier" included symptomatic food handlers, for which handwashing may not be adequate to prevent spread of illness as previously discussed. It is interesting to note that for each of the pathogens listed by CDC as "*often* transmitted through food contaminated by infected persons" (see Table 1), the number of outbreaks reported to be handled by an infected person was frequently much greater than the number involving bare-hand contact. Conversely, for "pathogens *occasionally* transmitted by food contaminated by an infected handler," the number of outbreaks associated with bare-hand contact was higher than the number associated with infected persons handling food.

Vegetative bacterial pathogens are generally more easily inactivated by chemical agents used in antimicrobial hand care products than the viruses and parasites of foodborne illness concern. While bacterial spores are also more resistant than vegetative bacteria, sporeformers of foodborne illness concern must be in their vegetative state and grow in the food to a high level to present a food safety risk. Thus inactivation of spores is not a major concern for hand hygiene in a food handler setting.

This analysis suggests that norovirus is the most common pathogen associated with hand hygiene-related foodborne illness outbreaks. Thus, when addressing “the efficacy/risk reduction strategies of alternative hand hygiene regimes compared to handwashing,” norovirus should be considered.

**Table 2** Hand contact contributing factors reported for foodborne illness outbreaks 1998-2002 in the United States

Etiology		Bare-hand contact	Gloved-hand contact	Infected person or carrier
		n (% of confirmed)	n (% of confirmed)	n (% of confirmed)
Bacterial	Non-typhoidal <i>Salmonella</i>	37 (15)	4 (7)	64 (18)
	<i>Staphylococcus aureus</i>	17 (7)	5 (9)	30 (9)
	<i>Shigella</i>	12 (5)	3 (5)	16 (5)
	<i>Escherichia coli</i>	12 (5)	1 (2)	6 (2)
	<i>Clostridium perfringens</i>	8 (3)	2 (4)	2 (1)
	<i>Campylobacter</i>	5 (2)	2 (4)	1 (<1)
	<i>Vibrio parahaemolyticus</i>	2 (1)	1 (2)	1 (<1)
	<i>Bacillus cereus</i>	1 (<1)	1 (2)	1 (<1)
	<i>Streptococcus</i>	0 (0)	0 (0)	1 (<1)
	<b>Total Bacterial</b>	<b>94 (40)</b>	<b>19 (35)</b>	<b>122 (35)</b>
Viral	Norovirus	129 (54)	30 (55)	202 (58)
	Hepatitis A	13 (5)	4 (7)	16 (5)
	<b>Total Viral</b>	<b>142 (59)</b>	<b>34 (62)</b>	<b>218 (62)</b>
Parasitic	<i>Giardia intestinalis</i>	1 (<1)	0 (0)	2 (1)
Multiple etiologies		2 (1)	1 (2)	7 (2)
<b>Total confirmed etiology</b>		<b>239 -</b>	<b>55 -</b>	<b>349 -</b>
<b>Unknown etiology</b>		<b>526 -</b>	<b>132 -</b>	<b>251 -</b>

Adapted from: CDC 2006. MMWR 55(SS10):1-34.

**Methods used to evaluate effectiveness of hand hygiene solutions (in vivo versus in vitro)**  
(per previous discussion, FDA was not able to comment on this section)

Ideally, well-controlled and statistically valid epidemiological outcome studies would be available to determine the relative effectiveness of hand hygiene products and regimens. Unfortunately, these types of studies are very rare and pose fundamental design and execution challenges. As a result, the primary methods used to evaluate effectiveness of hand hygiene products are laboratory-based, including *in vivo* (using living subjects) and *in vitro* (not using living subjects) testing, and to a limited extent risk modeling.

The type of test used to evaluate the effectiveness of hand hygiene solutions can have a significant impact on the results generated. Because of this, it is important to understand how a test was conducted when attempting to compare the effectiveness of hand hygiene solutions and it is difficult to compare the results from one study to another. It is important to note that, the most common pathogen associated with transmission of foodborne illness via hands, human norovirus, cannot be cultured in the laboratory. Murine norovirus and feline calicivirus have been used as surrogates to estimate reductions in infectivity, but the scientific debate on the “best” surrogate continues because the mode of inactivation for different antimicrobial agents varies (e.g., Cannon et al. 2006; Park et al. 2010). Currently, human norovirus results can be studied using polymerase chain reaction (PCR) technology, which reflects destruction of ribonucleic acid (RNA) as an indirect measure of loss of infectivity. However, it is possible for a virus to lose infectivity without destruction of RNA.

While standardized methods (e.g., ASTM, EN standards) exist for both *in vivo* and *in vitro* tests, methods used in the literature vary widely in their procedures and approach. This section provides a brief overview of the different types of tests used and the variation that can occur. It is not the intent of this report to recommend any specific type of test.

### *In vivo* tests

*In vivo* tests evaluate performance of hand hygiene measures using the hands of human test subjects. Many different *in vivo* tests using a wide variety of methodologies have been used to evaluate the performance of hand hygiene measures. Key differences include use of an inoculum, handwash technique and sampling method.

Use of an inoculum: In some cases the area being washed is inoculated with a marker organism (e.g., *E. coli*, *Staphylococcus aureus* or *Serratia marcescens*). Although *Serratia* is not commonly found on hands, its red pigment makes it easy to distinguish from background flora when conducting tests. *Serratia* is referred to as a “transient” hand microbe because it is only present for a short time on the hands, typically on the surface of skin. This is in contrast to “resident” hand microbes that are almost always present on hands, sometimes deep in the skin tissue. The use of a marker organism like *Serratia* can help to evaluate the performance of the handwash process on transient rather than resident flora, and to standardize the starting concentration of microorganisms on the skin of the test subjects.

In some *in vivo* tests, no inoculum is used. The level and nature of microorganisms present on human skin varies from person to person and over time for a given individual. These factors must be taken into account when interpreting these test results. Montville and Schaffner (2011) found that choice of the specific marker organism makes little difference, but that the choice between marker organisms and resident flora has a substantial impact on the results. According to their analysis, this appears to be primarily due to a difference in starting concentration. Quantifying differences is easier when starting with a uniformly high concentration because it helps to keep endpoint numbers above the level of detection.

Handwash technique: Standardized *in vivo* tests use a prescribed handwash method, but not all studies in the literature use standardized test methods. Some allow the test subject to wash their own hands and others have a technician conduct the wash. This can influence the variation observed in procedures practiced by human subjects. More variation is typically observed when each subject performs the hand hygiene procedure.

Sampling method: There are many ways to enumerate the organisms remaining on the skin after washing. For example, in the *glove juice test*, the test subject dons disposable gloves, a sampling fluid is added to the gloves, the subject’s hands are massaged and the microbes in the sampling fluid in the glove are enumerated. Other sampling techniques include collecting wash fluid into basins and enumerating organisms in the collected fluid, rubbing fingertips in Petri dishes containing a sampling fluid, placing a cylinder on the skin, adding a sampling fluid to cylinder and scrubbing the skin using a sterile swab, or simply pressing the finger tips to an agar plate.

The large inherent variability with any *in vivo* test coupled with differences in enumeration methodology leads to one of the major disadvantages of *in vivo* testing – conflicting, inconsistent and often non-comparable results. The variability also contributes to another disadvantage – cost. Multiple subjects are needed to estimate variability and it is not uncommon for a single test on a single subject to cost in excess of a thousand dollars. The variability of *in vivo* testing often requires high numbers of test subjects to statistically demonstrate differences, thus studies can be quite expensive. Use of pathogens for *in vivo* testing presents ethical issues that must be carefully considered.

Despite the disadvantages associated with *in vivo* hand hygiene efficacy testing, an advantage is that *in vivo* testing may provide information on how effectively a hand hygiene procedure will reduce microbial levels on hands in actual use. However, *in vivo* tests described do not prove that a tested hand hygiene procedure will actually prevent or reduce illness in the real world. At best, it provides a surrogate endpoint for the hand hygiene procedure’s ability to prevent or reduce the risk of disease. Clinical trials to evaluate prevention of disease are rarely, if ever, performed.



### *In vitro* tests

*In vitro* studies do not involve human or animal test subjects. The most common type of *in vitro* test for hand hygiene studies is the suspension or *time-kill test*. In these studies, the test microorganism is suspended in a solution containing the test product. After a specified exposure time, an aliquot of solution is removed, the antimicrobial activity is typically neutralized and any surviving microorganisms are determined. As with *in vivo* tests, many variables must be considered for *in vitro* testing, including product and test organism concentrations, types of organisms, the presence and concentration of interfering substances such as soil or hard water, the use of different temperatures, different neutralizer systems and various exposure times. Typically, greater reductions are observed for *in vitro* tests than for *in vivo* tests because of the direct exposure of the microorganism to the antimicrobial agent. Even seemingly trivial variations in test procedures, such as growing the inoculum on solid versus liquid media or the number of times the test cultures have been transferred, can affect the results. As with *in vivo* testing, this can make comparison of results between different studies difficult.

An advantage of *in vitro* tests is that they are relatively easy and inexpensive to do. This makes it easier to study more organisms and to collect sufficient replicates in a reproducible manner to demonstrate statistical significance even when the data are variable. The largest drawback of *in vitro* testing is that they are further removed from the clinical endpoint than *in vivo* tests. Just as an *in vivo* test is not a perfect predictor of a clinical endpoint, so an *in vitro* test is not a perfect predictor for an *in vivo* result.

The Hand Hygiene Committee summarized advantages and disadvantages of *in vivo* and *in vitro* efficacy testing in Table 3. Both types rely on enumeration of viable microbial targets to measure the extent of reduction after a treatment, which is possible for many pathogens involved in foodborne illness transmitted via hands, but currently not human norovirus.

**Table 3** Advantages and disadvantages of *in vivo* and *in vitro* tests to demonstrate efficacy of hand hygiene solutions.

Test method	Advantages	Disadvantages
<i>In vivo</i> (uses human subjects)	<ul style="list-style-type: none"><li>• Closer to clinical endpoints</li><li>• May demonstrate impact of full hand hygiene procedure (i.e., rinsing, friction, duration)</li></ul>	<ul style="list-style-type: none"><li>• Significant person-to-person variation</li><li>• Expensive and difficult to conduct</li><li>• Concerns with human exposure to certain pathogens</li></ul>
<i>In vitro</i> (does not use human subjects)	<ul style="list-style-type: none"><li>• Typically less variable than <i>in vivo</i> methods</li><li>• Can study more organisms in a controlled manner</li><li>• Less expensive</li></ul>	<ul style="list-style-type: none"><li>• Further removed from clinical endpoints</li></ul>

### ***Summarize the available science on the efficacy of hand hygiene approaches at removing hazards and reducing risk, including handwashing and other approaches***

(per previous discussion, FDA was not able to comment on this section)

As discussed above, the wide variety of test methods used to study hand hygiene procedures makes it very difficult to compare the efficacy of handwashing to alternative hand hygiene regimes. Recent peer-reviewed papers summarize much of the available science on this topic. Todd et al. (2010a) provide an extensive review of nearly 250 publications addressing the impact of washing and drying of hands to reduce microbial contamination. Montville and Schaffner (2011) looked more specifically at a quantitative comparison of antimicrobial versus non-antimicrobial hand soaps and evaluated the impact of methodological differences in the extent of reduction achieved. Both of these reviews reported that many factors influence the efficacy of handwashing, including the type and volume of soap used, friction, and duration of washing. Some of the findings of these reviews include:

- Using <1mL portion of hand soap appeared to be less effective than using 1ml or more.
- Vigorous washing is an important factor in that it removes or loosens microorganisms with mechanical action.
- On average, use of antimicrobial soaps results in fewer microorganisms on hands.
- Todd et al. (2010a) found that duration of handwashing is an important factor and duration of at least 15 seconds is needed. They concluded that while washing up to 30 seconds may provide somewhat greater

microbial removal from hands, this further reduction may not be meaningful as it involves removing resident microorganisms that are not generally associated with transmission of foodborne illness. Various studies have indicated that the average wash duration by the general public and food handlers is about 10 seconds, in spite of the 15 second recommendations.

- Frequency of handwashing is also an important factor. Several studies suggest that while most individuals (>85%-95%) self-report washing hands after using the bathroom, observational studies indicated that the frequency (particularly among men) was considerably lower (ca. 70%). In food settings the frequency of handwashing at appropriate times may be as low as 30% during peak business hours. However, training and specific interventions could increase that to over 50%.
- Temperature has relatively little impact on the efficacy of handwashing. Temperatures that are too high (over 110°F) increase the risk of skin damage and reduce handwashing compliance.
- Drying, particularly using towels, removes ca. 90% of the organisms that remain after washing. Removal of microorganisms by air dryers is more questionable. Moreover, the time needed to dry hands with many air drying systems is often longer than towel drying, so hands often remain wet for people who do not wait. Wet hands have been shown to harbor and transfer organisms more easily than dry hands. There is also some concern that the airflow from certain air driers may be a source of contamination.

Todd et al. (2010b) provides a recent comprehensive, peer review of waterless hand antiseptics relevant to food handlers, including 150 references. They found that product type, concentration, volume and contact time influenced results. They concluded that “alcohol-based antiseptics should be combined with regular handwashing schedules and should not replace handwashing and drying or the use of fingernail brushes.” In regard to wiping methods, they indicated that food handlers may ignore some of the steps in two or three stage procedures, thus they did not recommend such procedures in general. However, they also stated that “because [two or three stage] wipe methods tested have been more effective than soap and water, they should be considered feasible, practical hand hygiene interventions for remote food service situations or where water availability is limited.”

The effectiveness of hand antiseptics against human norovirus was questioned by Todd et al. (2010b) based on the available literature at the time of their review. However, Park et al. (2010) compared the effectiveness of seven hand antiseptics against murine norovirus (MNV) and feline calicivirus (FCV) as potential surrogates for human norovirus. One ethanol-based and one triclosan-based hand antiseptic reduced both MNV and FCV by >2.6 and ≥ 3.4 logs, respectively, using *in vitro* infectivity test methods. Four products demonstrated effectiveness against either MNV or FCV. The chlorhexidine product was not effective against either virus. Thus effectiveness varied among the different hand antiseptics. Liu et al. (2011) studied inactivation of human norovirus using the *in vivo* finger pad test, reporting log reductions of RNA from 0.10 to 3.74 for six commercially available hand antiseptic products. This study also illustrated the large variation that can be observed among hand antiseptic products. These two studies did not include a measure of the reduction that could be achieved with handwashing treatments. Further, some of the products studied may not have “Food Code” compliant ingredients.

A number of *in vivo* studies have included handwashing and hand antiseptics in the same investigation. Some of these studies concluded that hand antiseptics were ineffective at reducing microbial levels on hands while others suggested that they are effective in either reducing numbers or reducing transfer of infection. Two examples of studies that concluded hand antiseptics were ineffective include the following.

- Courtenay et al. (2005) compared washing with soap and water, rinsing with either warm or cool water, and ethanol-based hand antiseptics for reducing *E. coli* on hands. The soap and water washing demonstrated >2.6 log reduction, which was significantly greater than solely rinsing with warm water (2.2 log reduction), rinsing with cool water (1.5 log reduction) or ethanol-based hand antiseptic (0.2-0.7 log reduction).
- Lin et al. (2003) studied the effect of six handwashing techniques on *E. coli* and FCV levels inoculated under natural and artificial fingernails. Washing techniques included use of tap water alone, soap and water, antimicrobial soap, hand antiseptic, soap plus hand antiseptic, and soap plus nailbrush. Only reductions in counts under the fingernails were reported. For *E. coli*, no significant difference was noted between any of the washing techniques except washing with soap using a nailbrush. The nailbrush technique reduced the *E. coli* population approximately 2.5 – 3 logs while other techniques reduced the population 1 – 2 logs. For FCV, soap with nailbrush washing also significantly reduced the population greater than 2 logs for both nail

types. The hand antiseptic treatment resulted in a significantly lower reduction of FCV for both nail types (<1 log) than other treatments. Interestingly, there was no significant difference between log reductions of either *E. coli* or FCV from finger nails when tap water alone was compared to any of the handwashing methods using soap without a nail brush.

Conversely, a number of studies concluded that the use of hand antiseptics reduced organisms on hands the same or better than washing alone. For example:

- Brown et al. (2007) evaluated reductions of microbial counts on uninoculated hands following washing with plain soap, antimicrobial soap or use of an alcohol-based hand antiseptic. Fingers were touched to agar plates before and after treatment, and qualitative assessment of the number of bacteria present was determined. The alcohol-based hand antiseptic reduced the relative counts significantly more than the plain or antimicrobial soap treatments.
- Schaffner and Schaffner (2007) determined the effectiveness of an alcohol-based hand antiseptic on hands contaminated with a nonpathogenic surrogate for *E. coli* O157:H7, where the source of the contamination was frozen hamburger patties. The effectiveness of the hand antiseptic was similar to that for handwashing and glove use previously reported. The person-to-person microbial reduction variability from hand antiseptic use is similar to published data for glove use and was less variable than published data on handwashing effectiveness.
- Paulson (1999) studied the reduction of *Serratia marcescens* for hand hygiene regimens including plain lotion soap, antimicrobial lotion soap, alcohol-based hand antiseptic, and combinations of these using the glove juice method. The alcohol treatment alone or in combination with handwashing, reduced the population almost 4 logs. The soap treatments alone provided a 2 – 3 log reduction in *Serratia* counts and there was no statistically significant difference between antimicrobial and plain soap treatments, although the antimicrobial treatment was consistently higher. A combined treatment was recommended.
- Michaels et al. (2003) studied the impact of varying volumes of alcohol-based hand antiseptic on reducing inoculated transient microflora from previously washed hands, as well as the impact of the hand antiseptics on reducing levels of transient flora from under finger nails. Levels of hand antiseptic at 3mL or 6mL resulted in a significant reduction of transient flora over washing alone, while lower levels did not. Consistent with the results reported by Lin et al. (2003), washing hands with a nail brush was required for significant reductions under fingernails.
- Restaino and Wind (1990) reviewed literature available at the time and reported that appropriate alcohol preparations were more effective in reducing microbial counts than handwashing alone. They also commented on the need to use products that are non-irritating to the skin.

It is clear from the studies summarized that there is a large amount of variability between and within studies with behavioral aspects frequently compounding interpretations of data. Montville and Schaffner (2011) concluded that “The inherent variability in handwashing seen in the published literature underscores the importance of using a sufficiently large sample size to detect difference when they occur.”

Few studies have attempted to assess the effect of hand antiseptics from a risk reduction perspective. Bidawid et al. (2004) studied the transfer of feline calicivirus (FCV) from fingertips to a variety of surfaces. Finger pads were contaminated with FCV, allowed to dry, and then touched to various surfaces to evaluate the percent of transfer. Results (see Figure 1) demonstrated that treating hands with water, soap and water, or alcohol significantly reduced the percentage transferred, with less than 1% transferred following handwashing or a water rinse, ca. 1-3% transferred after treatment with alcohol, and 13-48% transfer if no hand hygiene intervention was used. While alcohol treatments were not as effective as soap and water or water alone, all of these hand hygiene interventions were significantly more effective than no hand hygiene treatment at all.

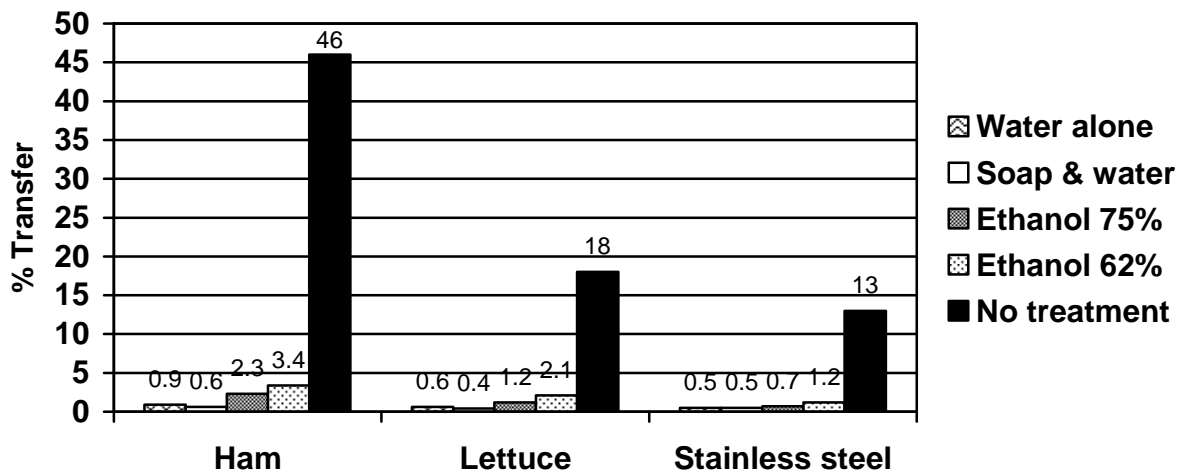


Figure 1 Feline calicivirus transfer from inoculated finger pads to ham, lettuce and stainless steel surfaces after treatment with various hand hygiene regimens. Adapted from Bidawid et al. (2004)

### ***Regulatory requirements related to efficacy of hand hygiene products***

This section is intended to provide a brief overview of the regulatory requirements related to the efficacy of hand hygiene products. It is not intended to be a comprehensive, complete discussion of the regulatory approval process. It represents the Hand Hygiene Committee's best understanding of the process, and FDA was not able to comment on this section. Those seeking additional information about FDA's position on the appropriate uses of hand antiseptics in food establishments are directed to Annex 3 of the FDA Food Code.

#### ***Approval process***

Hand antiseptics that meet specific criteria described in Section 2-301.16 of the 2009 Food Code may be applied "only to hands that are cleaned as specified under Section 2-301.12" in retail and foodservice establishments. Annex 3 – Section 2-301.16 of the 2009 Food Code explains that hand antiseptics are drug products that must comply with FDA CDER regulations, and provides more information on where approved products are listed as well as other requirements not related to the effectiveness of the products against foodborne pathogens.

As drugs, hand antiseptics must be demonstrated to be safe and effective. This can be accomplished by one of two means:

1. The hand antiseptic may be approved by FDA under a new drug application (NDA). Drugs approved through this route are listed in Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book" (FDA 2011).
2. The hand antiseptic may have an active ingredient identified by FDA (1994) in the Tentative Final Monograph (TFM) for Health-Care Antiseptic Drug Products for OTC Human Use in the handwash category, be listed with FDA as a drug, and comply with other relevant drug requirements.

The TFM specifies the active ingredients that can be contained within handwash products, as well as labeling, product testing and other general requirements. The *in vitro* and *in vivo* testing provisions in the TFM are well detailed and list specific organisms that products can make claims against. There is also a clinical study requirement depending on the final claim. The TFM antimicrobial spectrum tests determine the efficacy of products using Minimum Inhibitory Concentration (MIC) and time kill tests against 25 laboratory strains and 25 fresh clinical isolates included in a specific list of vegetative bacteria and the yeast *Candida*. Time-kill tests are also required using "standard ATCC strains identified for the MIC tests. The TFM also requires an *in vivo* handwash assay using *Serratia* as the test organism. There are currently no virus tests listed on the TFM and therefore antiviral hand hygiene claims are not available through the TFM, despite the fact that as noted above, norovirus is by far the pathogen reported most frequently in outbreaks where inappropriate application of hand hygiene regimens were noted.

For hand antiseptics, the TFM classifies alcohol 60–95% and povidone iodine 5–10% as Category 1 – Generally Recognized as Safe and Effective. Many potential active ingredients for hand antiseptics including triclosan, triclocarban, benzalkonium chloride, benzethonium chloride and parachlorometaxyleneol, are classified in Category III, requiring more data for final determination on safety and efficacy. Pending a Final Monograph, products based upon ingredients classified as Category III can be marketed provided they meet the performance testing requirements of the TFM. Premarket approval through the New Drug Application (NDA) process is required for products that contain active ingredients not listed in the TFM.

### FDA Guidance on Hand Antiseptics

While the CDC recommends alcohol-based hand gels as a suitable alternative to handwashing for health care personnel *“if hands are not visibly soiled”* (CDC 2002), FDA (2003) clarified that this recommendation is not applicable to food establishments. This exclusion is based on the differences in controlling common nosocomial pathogens in health care settings and common foodborne pathogens in retail and foodservice settings. FDA (2003) also highlights that the pathogens most commonly transmitted by hands in health care settings differ from those in retail and food service settings, and the types and levels of soil on the hands of health care workers differ from foodservice/retail workers.

The FDA (2003) factsheet concluded:

“Proper handwashing, as described in the Food Code continues to serve as a vital and necessary public health practice in retail and food service. Using alcohol gel in place of handwashing in retail and food service does not adequately reduce important foodborne pathogens on foodworkers’ hands. Concern about the practice of using alcohol-based hand gels in place of handwashing with soap and water in a retail or food service setting can be summarized into the following points:

- “Alcohols have very poor activity against bacterial spores, protozoan oocysts, and certain nonenveloped (nonlipophilic) viruses; and
- “Ingredients used in alcohol-based hand gels for retail or food service must be approved food additives, and approved under the FDA monograph or as a New Drug Application (NDA); and
- “Retail food and food service work involves high potential for wet hands and hands contaminated with proteinaceous material. Scientific research questions the efficacy of alcohol on moist hands and hands contaminated with proteinaceous material.”

It is important to note that even in health care settings, alcohol-based hand gels are to be used as an alternative to handwashing *“only if hands are not visibly soiled”* (CDC 2002).

### State and Local Jurisdictions

At least one regulatory jurisdiction allows the use of alternatives to Food Code compliant handwashing in specific situations where water is limited. For example, hand sanitizers are required after handwashing with non-potable water on Colorado River rafting trips (National Park Service 2011), and a two step hand cleanser-sanitizer protocol was approved by the Southern Nevada Health District when water is not available and only pre-packaged foods are used (Jim Mann, personal communication). Research on the impact of adoption of alternative procedures on hand hygiene compliance or public health outcomes would be useful to further inform the discussion on alternatives to handwashing. Such studies have been conducted in health care and home settings by academic, medical, public health and industry researchers (e.g., Hilburn et al. 2003, Sandora et al. 2005), but not in food handling settings.

### Regulatory Status Summary

In summary, hand care products with antimicrobial claims are considered to be drugs, thus approval and registration are under the regulatory jurisdiction of FDA’s Center for Drug Evaluation and Research. Antiviral hand hygiene claims are not available through the Tentative Final Monograph and to date no US antimicrobial hand care product with virucidal claims for food handler application has been approved through the New Drug Application (NDA) process. As a drug, antimicrobial hand care products should be used following label instructions. FDA’s Center for Food Safety and Applied Nutrition provides guidance through the *Food Code* on when and where hand hygiene practices should be applied.

### ***Identify compliance issues and behavioral aspects of hand hygiene***

As previously discussed, many factors such as time, temperature, friction, product volume, product type, etc., influence the effectiveness of hand hygiene regimes. At the same time, motivating food workers to apply proper hand hygiene procedures at the right time is an important food safety need. Thus, procedures are important for effective hand hygiene. Operators make their final choice of protocols based on the requirements in the Food Code guidance and their risks, based on their customer mix, menu, facilities and system control. There is no one-size-fits-all protocol for the wide range of food service and retail establishment practices that exist. Procedures should be selected to assure their minimum cleanliness levels are maintained.

The Committee identified barriers to proper handwashing behaviors by discussing the question "*If hand hygiene (hand antiseptic) was allowed in place of handwashing, would there be a significant increase in desired behaviors, either for use: 1) in place of handwashing or 2) in addition to handwashing?*"

For this exercise, the Committee considered only behaviors and *not* necessarily effectiveness. The Committee discussed which factors encourage or discourage desired handwashing behaviors for both traditional soap and water wash, and use of approved hand antiseptic. Information reported in Tables 4-6 is based on expertise of the Behavior Sub-committee of the CFP Hand Hygiene Committee, with review by the full committee. No quantitative or qualitative data were reviewed during the sub-committee's discussion.

**Table 4** What encourages / discourages desired behaviors regarding *how* to perform hand hygiene?  
(Note: effectiveness of the application is not considered in this comparison)

Potential barriers	Handwashing	Hand antiseptic or alternative
Water temperature	Too hot or cold discourages Just right encourages	Not applicable
Type of product (Like or dislike scent, feel, etc.)	How well does it lather? Does it cause dry hands or maintain skin health? Does it sting?	Does it make hands sticky? Does it cause dry skin or maintain skin health? Does it sting?
Towel vs. hand dryer	Slow drier discourages Empty or malfunctioning towel dispensing discourages	Drier not applicable. Towel may be needed (wipes or two-step procedure), thus availability or malfunctioning situations are similar.
Urgency / pressure / motivation	Must go to sink to perform	Can be applied "on the go" for a one step process
Proximity of product and equipment, ease of reaching	Need sink (plumbing), soap, drying equipment	Portable or easy installation in multiple locations. Potentially closer to work station.
Training (need to know how, when and why)	Applies equally. Potentially more material available on procedure.	Applies equally
Supplies available and working	Applies equally	Applies equally
Laziness	Applies equally	Applies equally
Ease – automated vs. manual. Method of dispensing	Automatic options may encourage or discourage. Must be functioning	Automated dispensing quicker when functioning. Must be functioning.
Time	Takes too long (perception)	Fewer steps for single application
Double handwashing	Takes too long	Applicable to two-step process
Policy – management commitment and enforcement	Applies equally	Applies equally
Job aids – detailed instructions	Applies equally	Applies equally
Hand hygiene signs	Applies equally	Applies equally
Behavior modeled by co-workers and management	Can motivate or de-motivate	Can motivate or de-motivate
Requirement for employment	Applies to both	Applies to both
Existence of regulations	Encourages policy, not employees	Currently hinders adoption
Visible / type of soil	Adjust to soil type	Appropriate for visibly clean hands only. May be unpleasant on heavily soiled hands
Pleasant experience	Applies equally	Applies equally

Factors that may either encourage or discourage *how* handwashing or hand antiseptic behaviors performed are listed in Table 4. Many of the barriers apply equally to how hand hygiene is performed for either handwashing or hand antiseptic use. Perceived speed of application for use of single step hand antiseptic applications may remove a potential barrier that exists for handwashing. Hand antiseptics may also remove barriers associated with proximity to the supplies need to perform the task. While the issue of training applies equally to both types of hand hygiene, it was noted that much emphasis has been placed on the proper handwashing technique. This may vary for different hand antiseptic applications and may be less obvious (e.g., single application versus two-step process; need to fully cover fingers, finger tips and nail area).

Factors that may either encourage or discourage *when* desired handwashing or hand antiseptic behaviors are appropriate are listed in Table 5. Again, many potential barriers apply equally to both hand hygiene regimens. The perceived need is an area where differences exist. Some workers wash their hands when they are heavily soiled from a self-protection standpoint. Conversely, single step hand antiseptics are typically designed to be used on visibly clean hands; therefore the visual cue of hands looking dirty does not apply. The sub-committee thought that there were opportunities to reduce confusion on when to wash hands or use hand antiseptics, for example when used with gloves (see the section on when alternatives may be appropriate).

**Table 5** What encourages / discourages desired behaviors regarding *when* to perform hand hygiene?  
(Note: effectiveness of the application is not considered in this comparison)

Potential barriers	Handwashing	Hand antiseptic or alternative
Perceived need	Wash when hands look or feel dirty. Workers wash to protect themselves (e.g., after clearing a messy table)	Perceived need for single step may change because this should be done on clean hands. Likely the same for a two step process
Touch points / requirements (too many)	Applies equally	Applies equally
Policy– management commitment and enforcement	Applies equally	Applies equally
Training – urgency	Applies equally	Applies equally
Focus on the why	Applies equally	Applies equally
Clarifying specifics in Food Code / misinterpretations	Potentially reduce confusion on requirements	Potentially reduce confusion on requirements and interpretation of regulations
In concert with glove use / confusion with glove use	Potentially reduce confusion on requirements	Potentially reduce confusion on requirements
Clarifying examples	Potentially reduce confusion on requirements	Potentially reduce confusion on requirements
Motivation	Applies equally	Applies equally
Proximity / ease	Need sink (plumbing), soap, drying equipment	Portable or easy installation in multiple locations. Potentially closer to work.
When need to wash – settings / relevance	When they look or feel dirty	Apply to visibly clean hands
Requirement to stay employed	Applies equally	Applies equally
Visibility of kitchen	Depends on customers – are they more interested in the food / techniques or hygiene?	Less time away from food prep
Pleasant experience (some products make hands feel and/or smell good)	Applies equally	Applies equally
Hand antiseptic is a second barrier	May be tempted to skip washing	May do it more often if it is quicker

Factors that may either encourage or discourage regarding why to perform hand hygiene are listed in Table 6. Communication of the reasons why hand hygiene should be performed is very important for employee acceptance

and increases the likelihood that proper hand hygiene will be performed. Most of the factors that can encourage hand hygiene behaviors apply equally to both washing and antiseptic use. However, explaining why there are different considerations for when hand antiseptics are appropriate, may cause confusion and thus create a barrier to compliance. This type of communication must be planned carefully.

**Table 6** What encourages / discourages desired behaviors regarding *why* to perform hand hygiene?

(Note: effectiveness of the application is not considered in this comparison)

Potential barriers	Handwashing	Hand antiseptic or alternative
Buy-in / encouragement	Handwashing is a recognized foundation for food safety and healthy living.	Explaining the differences of when handwashing is appropriate versus when alternatives are appropriate may complicate the message and confuse the "Why"
Expected practice / culture of hand hygiene	Applies equally	Applies equally
Not a lot of training tools; print training vs. activity based	Applies equally	Applies equally
Trainer effectiveness	Applies equally	Applies equally
Oral vs. written	Applies equally	Applies equally
Proximity	Getting staff to the sink	Getting to the product
Lack of motivation	Applies equally	Applies equally
Expectation of customers	Visibility of kitchen	Visibility of kitchen
Pleasant experience	Applies equally	Applies equally
Location / availability of supplies	Applies equally	Applies equally, but may be easier to have sanitizer available in some locations
Equipment working correctly	Applies equally	Applies equally

***Identify potential public health benefit of improved hand hygiene compliance using different approaches***

Several studies have evaluated the use of alcohol-based hand sanitizers in reducing infection rates in a variety of settings, including schools, day care settings, hospitals and long term care facilities. Two examples described below to illustrate the type of information that can be gained.

- o Hilburn et al. (2003) studied use of alcohol-based hand sanitizers in acute care facilities and reported a 36.1% decrease in infection rates when alcohol-based products were used. Key factors cited to contribute to this improvement included enhanced effectiveness against causative agents and increased hand care compliance because products were easy to use and gentle to the skin, which removes a barrier for hand hygiene application. The CFP Hand Hygiene Committee notes that these results may not be immediately transferable to food handling settings because the agents, and likely the hand sanitizer products, differ. However, research on compliance in foodservice settings may be beneficial to determine if a similar improvement is noted.
- o Sandora et al (2005) studied use of alcohol-based hand sanitizer coupled with hand hygiene education with children enrolled in 26 child care centers. They monitored transfer of secondary illness to people in the home. The CFP Hand Hygiene Committee recognizes that the primary mode of transmission in this study is person-to-person and that the pathogens involved may not necessarily be foodborne pathogens. However, the secondary illnesses were significantly lower for families with alcohol-based hand sanitizers in the home compared to control families.

While the Hilburn et al. (2003) "clinical end point" data demonstrate a benefit from hand sanitizers in clinical settings, the study was confounded with many other factors such as training, other interventions and increased handwashing. Therefore it is difficult to determine the effect of the hand sanitizers alone. Respiratory illness and gastroenteritis are seasonal events that occur with some frequency in institutional type settings. Foodborne illness outbreaks are less frequent thus conducting these types of studies specifically for food handling considerations will be problematic.



## **Charge 2 – Identify settings where alternatives to handwashing are appropriate**

The Committee considered the information above and practical aspects of preparing, holding and serving food in its consideration of identifying settings where alternatives to handwashing are appropriate. From a practical and behavioral matter, the Committee thought it useful to clarify situations when and where alternatives to handwashing, such as hand antiseptics are not the best option. These include:

- Anywhere there is a properly functioning hand sink
- After toilet use
- At the start of a shift
- After lunch break
- Between handling raw and RTE foods
- After sneezing into hands
- If person has cuts, skin infections
- When hands look or feel soiled

The Committee also recognized that there are situations where alternatives to handwashing may be appropriate as a risk reduction strategy. For example, when hands are not visibly soiled hand antiseptics may *potentially* be an option:

- Between glove use
- After touching hair
- After coughing / sneezing / drinking
- In areas where there is environmentally no water
- In water outages / boil water situations
- During temporary events
- In farm stands
- For mobile vendors

The Committee recognized that there are water-short situations where the specific **dual step hand cleanser-sanitizer protocol** (Edmonds 2010) may be a potential alternative to water/soap handwashing as a risk reduction strategy. Some may question if providing an alternative may drive operators to use hand-antiseptics in place of traditional handwashing. The product costs of alcohol washing versus water washing will strongly favor traditional handwashing where running potable water is conveniently available.

The committee was unable to make specific recommendations. However, given time and integration of scientific and behavioral considerations, specific recommendations may be possible using a risk management approach.

## **Charge #3 – Recommend studies that should be completed to get research questions answered for when scientific literature is not available**

Much of the research conducted on hand hygiene is done in areas other than food-related settings. There is a need for such studies to be conducted to inform decision making. Potential questions that could be addressed through research include:

- If hand antiseptic use was allowed in lieu of soap and water handwashing, would there be a significant increase in desired behaviors and would this reduce foodborne illness?
- Does providing options (soap and water vs. alternative hand hygiene methods) in foodservice or retail settings increase real-world compliance? If so, what is the public health benefit?
- Can studies on hand hygiene behaviors in hospitals be extrapolated to foodservice environments?
- What handwashing / hand hygiene options increase frequency of use?
- Why are food handlers not washing their hands?
- What is the range of temperatures that are considered to be comfortable for handwashing?
- Can new risk assessment and risk management models be applied to hand hygiene in food services settings to quantify the changes in risk when different interventions are applied?
- Can case-control epidemiological studies be conducted to compare hand hygiene related foodborne illness outbreaks in regulatory jurisdictions that allow the use of alternatives to handwashing, to those that do not?
- What is the clinical endpoint effect of various hand hygiene practices in a food setting?

Data supported answers to the above questions would help inform decision making on proposing alternatives to handwashing in certain situations to protect public health.

## References

1. Bidawid, S., N. Malik, O. Adegbonrin, S.A. Sattar, and J.M. Farber. 2004. Norovirus cross-contamination during food handling and with feline calicivirus as a surrogate. *J. Food Prot.* 67:103-109.
2. Brown, J.M., J.S. Avens, P.A. Kendall, D.R. Hyatt, and M.B. Stone. 2007. Survey of consumer attitudes and the effectiveness of hand cleansers in the home. *Food Prot. Trends* 27(8): p. 603-611
3. Cannon, J.L., E. Papafragkou, G.W. Park, J. Osborne, L. Jaykus, J. Vinjé. 2006. Surrogates for the study of norovirus stability and inactivation in the environment: a comparison of murine norovirus and feline calicivirus. *J. Food Prot.* 69(11):2761-5.
4. CDC (Centers for Disease Control and Prevention). 2002. 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. *Morb. Mort. Wkl. Rep.* 51(RR-16):32. Available at <http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>. Accessed 26 October 2011.
5. CDC. 2006. Surveillance for foodborne-disease outbreaks – United States, 1998-2002. *Surveillance Summaries: Morb. Mort. Wkl. Rep.* 55(SS10):1-34.
6. CDC. 2009. Diseases transmitted through the food supply. *Federal Register* 74(224):61151-61152.
7. Courtenay, M., L. Ramirez, B. Cox, I. Han, X. Jiang, and P. Dawson. 2005. Effects of various hand hygiene regimes on removal and/or destruction of *Escherichia coli* on hands. *Food Service Technol.* 5(2-4):77-84.
8. Edmonds, S.L., J. Mann, R.R. McCormack, D.R. Macinga, C.M. Fricker, J.W. Arbogast and M.J. Dolan. 2010. SaniTwice: a novel approach to hand hygiene for reducing bacterial contamination on hands when soap and water are unavailable. *J. Food Prot.* 73(12):2296–2300.
9. FDA (Food and Drug Administration). 1994. The tentative final monograph (TFM) for health-care antiseptic drug products for OTC human use. *Federal Register* 59(116):31402-31452. Available at <http://www.fda.gov/OHRMS/DOCKETS/98fr/94-14503.pdf>. Accessed 16 November 2011.
10. FDA. 2003. FDA fact sheet on hand hygiene in retail and food service establishments. Available at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm135577.htm>. Accessed 16 November 2011.
11. FDA. 2011. Orange book: approved drug products with therapeutic equivalence evaluations. Available at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>. Accessed 16 November 2011.
12. Hilburn, J., B.S. Hammond, E.J. Fendler and P.A. Groziak. 2003. Use of alcohol hand sanitizer as an infection control strategy in an acute care facility. *Am. J. Infect. Control.* 31:109-116.
13. Lin, C.-M., F.-M. Wu, H.-K. Kim, M.P. Doyle, B.S. Michaels, and L.K. Williams. 2003. Comparison of hand washing techniques to remove *E. coli* and calicivirus under natural or artificial nails. *J. Food. Prot.* 66(12):2296-2301.
14. Liu, P., D.R. Macinga, M.L. Fernandez, C. Zapka, H.-M. Hsiao, B. Berger, J.W. Arbogast, and C.L. Moe 2011. Comparison of the activity of alcohol-based handrubs against human noroviruses using the fingerpad method and quantitative real-time PCR. *Food Environ. Virol.* 3:35-42.
15. Michaels, B., V. Gangar, C-M Lin and M. Doyle. 2003. Use limitations of alcoholic instant hand sanitizer as part of a food service hand hygiene program. *Food Service Technol.* 3:71-80.
16. Montville, R. and D.W. Schaffner. 2011. A meta-analysis of the published literature on the effectiveness of antimicrobial soaps. *J. Food Prot.* 74(11):1875-1882.
17. National Park Service. 2011. Colorado River management Plan, 2011 Commercial Operating Requirements, page 16.
18. Park, G.W., L. Barclay, D. Macinga, D. Charbonneau, C.A. Pettigrew and J. Vinje. 2010. Comparative efficacy of seven hand sanitizers against murine norovirus, feline calicivirus, and GII.4 norovirus. *J. Food Prot.* 73(12):2232-2238.
19. Paulson, D.S., E.J. Fendler, M.J. Dolan and R.A. Williams. 1999. Close look at alcohol gel as an antimicrobial sanitizing agent. *Am. J. Infect Control.* 27(4):332-338.
20. Restaino, L. and C.E. Wind. 1990. Antimicrobial effectiveness of hand washing for food establishments. *Dairy, Food Environ Sanitation.* 10(3):136-141.
21. Sandora, T.J., E.M. Taveras, M-C. Shih, E.A. Resnick, G.M. Lee, D. Ros-Degnan, and D.A. Goldmann. 2005. A randomized, controlled trial of a multifaceted intervention including alcohol-based hand sanitizer and hand-hygiene education to reduce illness transmission in the home. *Pediatrics* 116(3):587-594.
22. Schaffner, D.W. and K.M. Schaffner (2007) Management of risk of microbial cross-contamination from uncooked frozen hamburgers by alcohol-based hand sanitizer. *J. Food Prot.* 70(1):109-113.
23. Todd, E.C., B.S. Michaels, D. Smith, J.D. Greig, and C.A. Bartleson. 2010a. Outbreaks where food workers have been implicated in the spread of foodborne disease. Part 9. washing and drying of hands to reduce microbial contamination. *J.*

*Food Prot.* 73(10):1937-1955. Available at <http://www.ingentaconnect.com/content/iafp/jfp/2010/00000073/00000010/art00020>. Accessed 9 November 2011.

24. Todd, E.C., B.S. Michaels, J. Holah, D. Smith, J.D. Greig, and C.A. Bartleson. 2010b. Outbreaks where food workers have been implicated in the spread of foodborne disease. Part 10. alcohol-based antiseptics for hand disinfection and a comparison of their effectiveness with soap. *J. Food Prot.* 73(11):2128-2140. Available at <http://www.ingentaconnect.com/content/iafp/jfp/2010/00000073/00000011/art00026>. Accessed 9 November 2011.

### **Recommendation(s) for future charge:**

The CFP Hand Hygiene Committee recommends the following:

1. Acknowledgement of the 2010-12 Hand Hygiene Committee report.
2. Thanking the 2010-2012 Hand Hygiene Committee for its work addressing scientific, regulatory and behavioral considerations related to efficacy and risk reduction strategies of alternative hand hygiene regimes compared to handwashing.
3. Submission of *Scientific, Regulatory and Behavioral Considerations of Hand Hygiene Regimes* to a peer reviewed journal, with the 2010-2012 Hand Hygiene Committee listed as a co-author.
4. Posting *Scientific, Regulatory and Behavioral Considerations of Hand Hygiene Regimes*, if published, on the CFP website as an educational tool that illustrates the interaction of scientific, regulatory and behavioral considerations related to alternative hand hygiene regimes compared to handwashing with respect to foodborne pathogens including viruses.
5. Re-creation of the Hand Hygiene Committee to more closely examine the current Food Code requirements for when employees are required to wash their hands using soap and running water. If credible information suggests that one or more of the situations under which food employees are currently required to wash their hands does not result in meaningful risk reduction, work with FDA to explore whether those mandates could be modified, either in the Code itself or by recognizing when it is appropriate to waive the requirement (e.g., other approaches to hand hygiene are available and practiced).
6. The re-created Committee uses the report of the 2010-2012 Committee as a reference, illustrating the interactions of scientific, regulatory and behavioral considerations related to alternative hand hygiene regimes compared to handwashing. The committee should characterize what recent research tells us about:
  - the extent to which the current minimum requirements for how and when employees are to wash their hands are effective in rendering food employees hands free of various soils, as well as, any pathogens of concern;
  - what other regimens for cleansing employees hands, if any, may deliver outcomes that are similar to or better than handwashing so as to suggest that they could be included as acceptable methods for rendering hands free of soil and pathogens.
7. The size of the Hand Hygiene Committee to be limited to less than 20 members (including advisors and chairs), to facilitate participation of the full committee on conference calls while maintaining adequate representation from relevant stakeholders. This will lead to a more coordinated work product since there would be continuity of thought. While the CFP conference call system can accommodate up to 25, scheduling a conference call for this number of people is problematic.
8. The committee report back its findings to the 2014 Biennial Meeting.

### **REQUESTED ACTION:**

The Hand Hygiene committee will submit four (4) issues at the 2012 Conference based on the recommendations of the committee. The issues are:

- Report – 2010-2012 Hand Hygiene Committee
- Disseminate the 2010-2012 Hand Hygiene Committee Report
- Re-create – Hand Hygiene Committee
- Limit Hand Hygiene Committee Size

### **Attachments**

1. *2010-12 Hand Hygiene Committee Final Report*
2. *Scientific Regulatory and Behavioral Considerations of Hand Hygiene Regimes*
3. *2010-2012 Hand Hygiene Committee Roster*

**COMMITTEE MEMBER ROSTER:**

The committee roster is attached. The Co-chairs wish to thank these active committee members for their expertise and dedication to addressing this complex issue.

Respectfully submitted by,

Katherine MJ Swanson and Mark Sampson, Co-chairs for the 2010-2012 Hand Hygiene Committee

1           **Scientific, Regulatory and Behavioral Considerations of Hand Hygiene**

2  
3 Katherine M.J. Swanson\*<sup>1</sup>, Mark Sampson<sup>2</sup>, Donald W. Schaffner<sup>3</sup>, Dale Grinstead<sup>4</sup>, Michéle Samarya-  
4 Timm<sup>5</sup>, Catherine Adams-Hutt<sup>6</sup>, and the Conference for Food Protection 2010-2012 Hand Hygiene  
5 Committee<sup>†</sup>

6  
7 <sup>1</sup>Ecolab Inc., 655 Lone Oak Drive, Eagan, MN 55121; <sup>2</sup>Sterilox Food Safety, 162 Ash Way, Doylestown,  
8 PA 18901; <sup>3</sup>Rutgers University, 65 Dudley Road, New Brunswick, NJ 08901; <sup>4</sup>Diversey, Inc., 8310 16<sup>th</sup>  
9 Street, Sturtevant, WI 53177; <sup>5</sup>Somerset County Department of Health, PO Box 3000, 27 Warren Street,  
10 Somerville, NJ 08876; <sup>6</sup>National Restaurant Association, 601 Pennsylvania Avenue, NW # 1505,  
11 Washington DC 20004

---

\* Author for correspondence: Phone: +1 651.795.5943; Email: [katie.swanson@ecolab.com](mailto:katie.swanson@ecolab.com) ,

12 **ABSTRACT**

13           Addressing the effectiveness of hand hygiene strategies involves scientific, regulatory and  
14 behavioral considerations. In the United States, norovirus is the pathogen reported most frequently in  
15 outbreaks associated with lapses in hand hygiene; however several bacterial pathogens have also been  
16 implicated. Effectiveness of any hand hygiene regimen involves many factors, including the product type  
17 (e.g., soap, hand antiseptic), amount applied, application method, duration and pathogen of concern.  
18 Handcare products making antimicrobial claims are regulated as drugs in the United States. Through  
19 2011, no antimicrobial hand hygiene products for food handler applications have FDA-approved claims  
20 for antiviral effectiveness. However, the antiviral profile of several commercially available products has  
21 been assessed in peer-reviewed literature, demonstrating that some products can achieve significant  
22 reductions. Hand hygiene behavioral issues involve use of proper procedure and a commitment to  
23 perform the task, thus understanding human factors is important to enhance hand hygiene compliance.  
24 Behavioral and risk assessment research that evaluates the magnitude of risk reduction achieved by  
25 varying forms of hand hygiene actions (i.e., nothing, rinsing, hand sanitizing, washing, or washing and  
26 brushing) would be useful to move from an all-or-nothing approach in every situation, to one recognizing  
27 that different procedures may be suitable for different situations.

28 **INTRODUCTION**

29           The main purpose of washing hands is to cleanse the hands of soil, pathogens and chemicals  
30 that can potentially cause disease. Transmission of pathogenic bacteria, viruses and parasites to food  
31 from contaminated surfaces, raw food or ill workers by way of improperly washed hands continues to be a  
32 major factor in the spread of foodborne illnesses. In this report, hand hygiene products available to  
33 reduce the risk of spreading infectious agents are categorized as:

- 34       • handwashing agents (plain soaps or antimicrobial soaps)
- 35       • hand wipes (plain and antiseptic) and
- 36       • hand antiseptics (antiseptic waterless agents)

37           *Handwashing* with plain soap suspends microorganisms and mechanically removes them by  
38 rinsing with water. Plain bar soap, foam and liquid preparations are comprised of detergents with  
39 surfactant (surface-active agents), which increase the cleaning properties of water and gives the product  
40 the ability to remove soil from surfaces, such as human skin. Microbial reduction using plain soap is due  
41 to the physical removal of foreign material or microorganisms, not a biocidal effect.

42           An *antimicrobial soap* combines the cleaning action of plain soap (i.e., physical removal of foreign  
43 material) with antiseptic agents that kill microorganisms. The antimicrobial agents used in antimicrobial  
44 soaps (e.g., chloroxylenol, quaternary ammonium compounds, chlorhexidine gluconate, iodine/iodophors  
45 and triclosan) have an immediate effect that reduces the number of microflora on skin and in certain  
46 cases may exhibit residual or sustained activity that continues to reduce the number of microbial flora  
47 after the handwash is complete. The effectiveness of these agents is primarily directed toward vegetative  
48 bacteria.

49           *Antimicrobial wipes* are towelettes or paper towels that are saturated with an antimicrobial  
50 solution that has been shown to reduce the numbers of microorganisms on skin. The antimicrobial  
51 ingredient is typically isopropyl or ethyl alcohol and/or a quaternary ammonium compound. There are also  
52 some specialized products with other antimicrobial ingredients.

53           *Hand antiseptics* (also called hand sanitizers) are waterless agents with antiseptic properties that  
54 decrease the number of microorganisms present. For the purposes of this paper, hand antiseptics do not  
55 require the use of water. Alcohol-based hand antiseptics are the most common type and typically contain

56 ethanol or isopropanol and may contain n-propanol or a combination of these agents. Hand antiseptics  
57 are typically not designed as hand cleansers and thus are usually intended to be used on visibly clean  
58 hands as a single application. However, most hand antiseptics contain emollients, emulsifiers and water,  
59 all of which can act as cleaning agents when assisted by hand-to-hand rubbing and physical removal with  
60 a paper towel, in a manner similar to a hand wipe.

61

## 62 **FOODBORNE PATHOGENS ASSOCIATED WITH HAND HYGIENE-RELATED OUTBREAKS**

63 The CDC (6) provides a list of infectious diseases that are transmitted through handling the food  
64 supply, which is summarized in Table 1 and in Annex 3 Section 2-201.11 of the 2009 Food Code. Two  
65 categories are identified – 1) those pathogens that are *often* transmitted by food when handled by an  
66 infected person and 2) those pathogens that are *occasionally* transmitted thorough handling by an  
67 infected worker but usually transmitted by contamination at the source or in food processing or by non-  
68 foodborne routes. Those “often” involving infected workers include pathogens with low infective dose  
69 (e.g., the viruses, *Salmonella* Typhi and *Shigella*) and those that are shed in high numbers when an  
70 active infection exists (e.g., the viruses, *Staphylococcus aureus* and *Streptococcus pyogenes*). The 2009  
71 Food Code Sections 2-201.12 and 2-201.13 specify exclusion or restriction of food workers from a food  
72 establishment when certain diagnoses or symptoms listed in Table 1 exist. Annex 3 of the 2009 Food  
73 Code (page 337) specifically notes that “exclusion of food employees exhibiting or reporting diarrhea  
74 symptoms is an essential intervention in controlling the transmission of norovirus from infected food  
75 employees’ hands to RTE food items.” This recognizes that even thorough hand hygiene may not be  
76 sufficient to prevent transmission of disease when food is handled by symptomatic food handlers.

77 CDC (5) also published foodborne illness contributing factors that were reported for outbreaks  
78 occurring from 1998-2002. In that time period, of the 3072 outbreaks for which contributing factors were  
79 reported, 25% identified bare-hand contact, 20% identified infected persons and 6% identified gloved-  
80 hand contact as factors contributing to these outbreaks. Table 2 summarizes the CDC (5) data by etiology  
81 for foodborne illness outbreaks reported as being associated with hand contact (with or without gloves) or  
82 handling by an infected person as a contributing factor. Norovirus was the dominant etiology for  
83 outbreaks involving these contributing factors, and bacterial etiologies were reported for 40% of the bare-



84 hand contact outbreaks, 35% of gloved-hand outbreaks and 35% of infected person outbreaks involved  
85 bacterial agents. Only one parasite (*Giardia intestinalis*) and no chemicals were reported to be associated  
86 with hand hygiene related outbreaks in this time period.

87 It cannot be determined from these data how many outbreaks “involving infected persons or  
88 carrier” included symptomatic food handlers, for which handwashing may not be adequate to prevent  
89 spread of illness as previously discussed. It is interesting to note that for each of the pathogens listed by  
90 CDC as “often transmitted through food contaminated by infected persons” (see Table 1), the number of  
91 outbreaks reported to be handled by an infected person was frequently much greater than the number  
92 involving bare-hand contact. Conversely, for “pathogens *occasionally* transmitted by food contaminated  
93 by an infected handler,” the number of outbreaks associated with bare-hand contact was higher than the  
94 number associated with infected persons handling food.

95 Vegetative bacterial pathogens are generally more easily inactivated by chemical agents used in  
96 antimicrobial hand care products than the viruses and parasites of foodborne illness concern. While  
97 bacterial spores are also more resistant than vegetative bacteria, sporeformers of foodborne illness  
98 concern must be in their vegetative state and grow in the food to a high level to present a food safety risk.  
99 Thus inactivation of spores is not a major concern for hand hygiene in a food handler setting.

100 This analysis suggests that norovirus is the most common pathogen associated with hand  
101 hygiene-related foodborne illness outbreaks. Thus when addressing “the efficacy/risk reduction strategies  
102 of alternative hand hygiene regimes compared to handwashing,” norovirus should be considered.

103

#### 104 **METHODS TO EVALUATE EFFECTIVENESS OF HAND HYGIENE SOLUTIONS**

105 Ideally, well-controlled and statistically valid epidemiological outcome studies would be available  
106 to determine the relative effectiveness of hand hygiene products and regimens. Unfortunately, these  
107 types of studies are very rare and pose fundamental design and execution challenges. As a result, the  
108 primary methods used to evaluate effectiveness of hand hygiene products are laboratory-based, including  
109 *in vivo* (using living subjects) and *in vitro* (not using living subjects) testing, and to a limited extent risk  
110 modeling.

111 The type of test used to evaluate the effectiveness of hand hygiene solutions can have a  
112 significant impact on the results generated. Because of this, it is important to understand how a test was  
113 conducted when attempting to compare the effectiveness of hand hygiene solutions and it is difficult to  
114 compare the results from one study to another. It is important to note that, the most common pathogen  
115 associated with transmission of foodborne illness via hands, human norovirus, cannot be cultured in the  
116 laboratory. Murine norovirus and feline calicivirus have been used as surrogates to estimate reductions in  
117 infectivity, but the scientific debate on the “best” surrogate continues because the mode of inactivation for  
118 different antimicrobial agents varies (e.g., 3, 18). Currently, human norovirus results can be studied using  
119 polymerase chain reaction (PCR) technology, which reflects destruction of ribonucleic acid (RNA) as an  
120 indirect measure of loss of infectivity. However, it is possible for a virus to lose infectivity without  
121 destruction of RNA.

122 While standardized methods (e.g., ASTM, EN standards) exist for both *in vivo* and *in vitro* tests,  
123 methods used in the literature vary widely in their procedures and approach. This section provides a brief  
124 overview of the different types of tests used and the variation that can occur. It is not the intent of this  
125 report to recommend any specific type of test.

#### 126 ***In vivo* tests**

127 *In vivo* tests evaluate performance of hand hygiene measures using the hands of human test  
128 subjects. Many different *in vivo* tests, using a wide variety of methodologies, have been used to evaluate  
129 the performance of hand hygiene measures. Key differences include use of an inoculum, handwash  
130 technique and sampling method.

131 *Use of an inoculum.* In some cases the area being washed is inoculated with a marker organism  
132 (e.g., *E. coli*, *Staphylococcus aureus* or *Serratia marcescens*). Although *Serratia* is not commonly found  
133 on hands, its red pigment makes it easy to distinguish from background flora when conducting tests.  
134 *Serratia* is referred to as a “transient” hand microbe because it is only present for a short time on the  
135 hands, typically on the surface of skin. This is in contrast to “resident” hand microbes that are almost  
136 always present on hands, sometimes deep in the skin tissue. The use of a marker organism like *Serratia*  
137 can help to evaluate the performance of the handwash process on transient rather than resident flora,  
138 and to standardize the starting concentration of microorganisms on the skin of the test subjects.

139 In some *in vivo* tests, no inoculum is used. The level and nature of microorganisms present on  
140 human skin varies from person to person and over time for a given individual. These factors must be  
141 taken into account when interpreting these test results. Montville and Schaffner (16) found that choice of  
142 the specific marker organism makes little difference, but that the choice between marker organisms and  
143 resident flora has a substantial impact on the results. According to their analysis, this appears to be  
144 primarily due to a difference in starting concentration. Quantifying differences is easier when starting with  
145 a uniformly high concentration because it helps to keep endpoint numbers above the level of detection.

146 *Handwash technique.* Standardized *in vivo* tests use a prescribed handwash method, but not all  
147 studies in the literature use standardized test methods. Some allow the test subject to wash their own  
148 hands and others have a technician conduct the wash. This can influence the variation observed in  
149 procedures practiced by human subjects. More variation is typically observed when each subject  
150 performs the hand hygiene procedure.

151 *Sampling method.* There are many ways to enumerate the organisms remaining on the skin after  
152 washing. For example, in the *glove juice test*, the test subject dons disposable gloves, a sampling fluid is  
153 added to the gloves, the subject's hands are massaged and the microbes in the sampling fluid in the  
154 glove are enumerated. Other sampling techniques include collecting wash fluid into basins and  
155 enumerating organisms in the collected fluid, rubbing fingertips in Petri dishes containing a sampling fluid,  
156 placing a cylinder on the skin, adding a sampling fluid to cylinder and scrubbing the skin using a sterile  
157 swab, or simply pressing the finger tips to an agar plate.

158 The large inherent variability with any *in vivo* test coupled with differences in enumeration  
159 methodology leads to one of the major disadvantages of *in vivo* testing – conflicting, inconsistent and  
160 often non-comparable results. The variability also contributes to another disadvantage – cost. Multiple  
161 subjects are needed to estimate variability and it is not uncommon for a single test on a single subject to  
162 cost in excess of a thousand dollars. The variability of *in vivo* testing often requires high numbers of test  
163 subjects to statistically demonstrate differences, thus studies can be quite expensive. Use of pathogens  
164 for *in vivo* testing presents ethical issues that must be carefully considered.

165 Despite the disadvantages associated with *in vivo* hand hygiene efficacy testing, an advantage is  
166 that *in vivo* testing may provide information on how effectively a hand hygiene procedure will reduce

167 microbial levels on hands in actual use. However, *in vivo* tests described do not prove that a tested hand  
168 hygiene procedure will actually prevent or reduce illness in the real world. At best, it provides a surrogate  
169 endpoint for the hand hygiene procedure's ability to prevent or reduce the risk of disease. Clinical trials to  
170 evaluate prevention of disease are rarely, if ever, performed.

### 171 ***In vitro* tests**

172 *In vitro* studies do not involve human or animal test subjects. The most common type of *in vitro*  
173 test for hand hygiene products is the suspension or "time-kill" test. In these studies, the test  
174 microorganism is suspended in a solution containing the test product. After a specified exposure time, an  
175 aliquot of solution is removed, the antimicrobial activity is typically neutralized and any surviving  
176 microorganisms are determined. As with *in vivo* tests, many variables must be considered for *in vitro*  
177 testing, including product and test organism concentrations, types of organisms, the presence and  
178 concentration of interfering substances such as soil or hard water, the use of different temperatures,  
179 different neutralizer systems and various exposure times. Typically, greater reductions are observed for *in*  
180 *vitro* tests than for *in vivo* tests because of the direct exposure of the microorganism to the antimicrobial  
181 agent. Even seemingly trivial variations in test procedures, such as growing the inoculum on solid versus  
182 liquid media or the number of times the test cultures have been transferred, can affect the results. As with  
183 *in vivo* testing, this can make comparison of results between different studies difficult.

184 An advantage of *in vitro* tests is that they are relatively easy and inexpensive to do. This makes it  
185 easier to study more organisms and to collect sufficient replicates in a reproducible manner to  
186 demonstrate statistical significance even when the data are variable. The largest drawback of *in vitro*  
187 testing is that they are further removed from the clinical endpoint than *in vivo* tests. Just as an *in vivo* test  
188 is not a perfect predictor of a clinical endpoint, so an *in vitro* test is not a perfect predictor for an *in vivo*  
189 result.

190 The CFP 2010-2012 Hand Hygiene Committee summarized advantages and disadvantages of *in*  
191 *vivo* and *in vitro* efficacy testing in Table 3. Both types rely on enumeration of viable microbial targets to  
192 measure the extent of reduction after a treatment, which is possible for many pathogens involved in  
193 foodborne illness transmitted via hands, but currently not human norovirus.

194

195 **EFFICACY OF HAND HYGIENE APPROACHES AT REMOVING PATHOGENS AND REDUCING RISK**

196 As discussed above, the wide variety of test methods used to study hand hygiene procedures  
197 makes it very difficult to compare the efficacy of handwashing to alternative hand hygiene regimes.  
198 Recent peer-reviewed papers summarize much of the available science on this topic. Todd et al. (23)  
199 provide an extensive review of nearly 250 publications addressing the impact of washing and drying of  
200 hands to reduce microbial contamination. Montville and Schaffner (15) looked more specifically at a  
201 quantitative comparison of antimicrobial versus non-antimicrobial hand soaps and evaluated the impact of  
202 methodological differences in the extent of reduction achieved. Both of these reviews reported that many  
203 factors influence the efficacy of handwashing, including the type and volume of soap used, friction, and  
204 duration of washing. Some of the findings of these reviews include:

- 205 • Using <1mL portion of hand soap appeared to be less effective than using 1ml or more.
- 206 • Vigorous washing is an important factor in that it removes or loosens microorganisms with  
207 mechanical action.
- 208 • On average, use of antimicrobial soaps results in fewer microorganisms on hands.
- 209 • Todd et al. (23) found that duration of handwashing is an important factor and duration of at least 15  
210 seconds is needed. They concluded that while washing up to 30 seconds may provide somewhat  
211 greater microbial removal from hands, this further reduction may not be meaningful as it involves  
212 removing resident microorganisms that are not generally associated with transmission of foodborne  
213 illness. Various studies have indicated that the average wash duration by the general public and food  
214 handlers is about 10 seconds, in spite of the 15 second recommendations.
- 215 • Frequency of handwashing is also an important factor. Several studies suggest that while most  
216 individuals (>85%-95%) self-report washing hands after using the bathroom, observational studies  
217 indicated that the frequency (particularly among men) was considerably lower (ca. 70%). In food  
218 settings the frequency of handwashing at appropriate times may be as low as 30% during peak  
219 business hours. However, training and specific interventions could increase that to over 50%.
- 220 • Temperature has relatively little impact on the efficacy of handwashing. Temperatures that are too  
221 high (over 110°F) increase the risk of skin damage and reduce handwashing compliance.

222 • Drying, particularly using towels, removes ca. 90% of the organisms that remain after washing.  
223 Removal of microorganisms by air dryers is more questionable. Moreover, the time needed to dry  
224 hands with many air drying systems is often longer than towel drying, so hands often remain wet for  
225 people who do not wait. Wet hands have been shown to harbor and transfer organisms more easily  
226 than dry hands. There is also some concern that the airflow from certain air driers may be a source  
227 of contamination.

228 Todd et al. (24) provides a recent comprehensive, peer review of waterless hand antiseptics  
229 relevant to food handlers, including 150 references. They found that product type, concentration, volume  
230 and contact time influenced results. They concluded that “alcohol-based antiseptics should be combined  
231 with regular handwashing schedules and should not replace handwashing and drying or the use of  
232 fingernail brushes.” In regard to wiping methods, they indicated that food handlers may ignore some of  
233 the steps in two or three stage procedures, thus they did not recommend such procedures in general.  
234 However, they also stated that “because [two or three stage] wipe methods tested have been more  
235 effective than soap and water, they should be considered feasible, practical hand hygiene interventions  
236 for remote food service situations or where water availability is limited.”

237 The effectiveness of hand antiseptics against human norovirus was questioned by Todd et al.  
238 (24) based on the available literature at the time of their review. However, Park et al. (18) compared the  
239 effectiveness of seven hand antiseptics against murine norovirus (MNV) and feline calicivirus (FCV) as  
240 potential surrogates for human norovirus. One ethanol-based and one triclosan-based hand antiseptic  
241 reduced both MNV and FCV by  $>2.6$  and  $\geq 3.4$  logs, respectively, using *in vitro* infectivity test methods.  
242 Four products demonstrated effectiveness against either MNV or FCV. The chlorhexidine product was not  
243 effective against either virus. Thus effectiveness varied among the different hand antiseptics. Liu et al.  
244 (14) studied inactivation of human norovirus using the *in vivo* finger pad test, reporting log reductions of  
245 RNA from 0.10 to 3.74 for six commercially available hand antiseptic products. This study also illustrated  
246 the large variation that can be observed among hand antiseptic products. These two studies did not  
247 include a measure of the reduction that could be achieved with handwashing treatments. Further, some of  
248 the products studied may not have “Food Code” compliant ingredients.

249 A number of *in vivo* studies have included handwashing and hand antiseptics in the same  
250 investigation. Some of these studies concluded that hand antiseptics were ineffective at reducing  
251 microbial levels on hands while others suggested that they are effective in either reducing numbers or  
252 reducing transfer of infection. Two examples of studies that concluded hand antiseptics were ineffective  
253 include the following.

- 254 • Courtenay et al. (7) compared washing with soap and water, rinsing with either warm or cool water,  
255 and ethanol-based hand antiseptics for reducing *E. coli* on hands. The soap and water washing  
256 demonstrated >2.6 log reduction, which was significantly greater than solely rinsing with warm  
257 water (2.2 log reduction), rinsing with cool water (1.5 log reduction) or ethanol-based hand  
258 antiseptic (0.2-0.7 log reduction).
- 259 • Lin et al. (13) studied the effect of six handwashing techniques on *E. coli* and FCV levels inoculated  
260 under natural and artificial fingernails. Washing techniques included use of tap water alone, soap  
261 and water, antimicrobial soap, hand antiseptic, soap plus hand antiseptic, and soap plus nailbrush.  
262 Only reductions in counts under the fingernails were reported. For *E. coli*, no significant difference  
263 was noted between any of the washing techniques except washing with soap using a nailbrush.  
264 The nailbrush technique reduced the *E. coli* population approximately 2.5 – 3 logs while other  
265 techniques reduced the population 1 – 2 logs. For FCV, soap with nailbrush washing also  
266 significantly reduced the population greater than 2 logs for both nail types. The hand antiseptic  
267 treatment resulted in a significantly lower reduction of FCV for both nail types (<1 log) than other  
268 treatments. Interestingly, there was no significant difference between log reductions of either *E.*  
269 *coli* or FCV from finger nails when tap water alone was compared to any of the handwashing  
270 methods using soap without a nail brush.

271 Conversely, a number of studies concluded that the use of hand antiseptics reduced organisms  
272 on hands the same or better than washing alone. For example:

- 273 • Brown et al. (2) evaluated reductions of microbial counts on uninoculated hands following washing  
274 with plain soap, antimicrobial soap or use of an alcohol-based hand antiseptic. Fingers were  
275 touched to agar plates before and after treatment, and qualitative assessment of the number of

276 bacteria present was determined. The alcohol-based hand antiseptic reduced the relative counts  
277 significantly more than the plain or antimicrobial soap treatments.

278 • Schaffner and Schaffner (22) determined the effectiveness of an alcohol-based hand antiseptic on  
279 hands contaminated with a nonpathogenic surrogate for *E. coli* O157:H7, where the source of the  
280 contamination was frozen hamburger patties. The effectiveness of the hand antiseptic was similar  
281 to that for handwashing and glove use previously reported. The person-to-person microbial  
282 reduction variability from hand antiseptic use is similar to published data for glove use and was less  
283 variable than published data on handwashing effectiveness.

284 • Paulson (19) studied the reduction of *Serratia marcescens* for hand hygiene regimens including  
285 plain lotion soap, antimicrobial lotion soap, alcohol-based hand antiseptic, and combinations of  
286 these using the glove juice method. The alcohol treatment alone or in combination with  
287 handwashing, reduced the population almost 4 logs. The soap treatments alone provided a 2 – 3  
288 log reduction in *Serratia* counts and there was no statistically significant difference between  
289 antimicrobial and plain soap treatments, although the antimicrobial treatment was consistently  
290 higher. A combined treatment was recommended.

291 • Michaels et al. (15) studied the impact of varying volumes of alcohol-based hand antiseptic on  
292 reducing inoculated transient microflora from previously washed hands, as well as the impact of the  
293 hand antiseptics on reducing levels of transient flora from under finger nails. Levels of hand  
294 antiseptic at 3mL or 6mL resulted in a significant reduction of transient flora over washing alone,  
295 while lower levels did not. Consistent with the results reported by Lin et al. (13), washing hands  
296 with a nail brush was required for significant reductions under fingernails.

297 • Restaino and Wind (20) reviewed literature available at the time and reported that appropriate  
298 alcohol preparations were more effective in reducing microbial counts than handwashing alone.  
299 They also commented on the need to use products that are non-irritating to the skin.

300 It is clear from the studies summarized that there is a large amount of variability between and  
301 within studies with behavioral aspects frequently compounding interpretations of data. Montville and  
302 Schaffner (16) concluded that “The inherent variability in handwashing seen in the published literature



303 underscores the importance of using a sufficiently large sample size to detect difference when they  
304 occur.”

305         Few studies have attempted to assess the effect of hand antiseptics from a risk reduction  
306 perspective. Bidawid et al. ( 1) studied the transfer of feline calicivirus (FCV) from fingertips to a variety of  
307 surfaces. Finger pads were contaminated with FCV, allowed to dry, and then touched to various surfaces  
308 to evaluate the percent of transfer. Results (see Figure 1) demonstrated that treating hands with water,  
309 soap and water, or alcohol significantly reduced the percentage transferred, with less than 1% transferred  
310 following handwashing or a water rinse, ca. 1-3% transferred after treatment with alcohol, and 13-48%  
311 transfer if no hand hygiene intervention was used. While alcohol treatments were not as effective as  
312 soap and water or water alone, all of these hand hygiene interventions were significantly more effective  
313 than no hand hygiene treatment at all.

314

## 315 **REGULATORY REQUIREMENTS RELATED TO EFFICACY OF HAND HYGIENE PRODUCTS**

### 316 **Approval process**

317         Hand antiseptics that meet specific criteria described in Section 2-301.16 of the 2009 Food Code  
318 may be applied “only to hands that are cleaned as specified under Section 2-301.12” in retail and  
319 foodservice establishments. Annex 3 – Section 2-301.16 of the 2009 Food Code explains that hand  
320 antiseptics are drug products that must comply with FDA Center for Drug Evaluation and Research  
321 (CDER) regulations, and provides more information on where approved products are listed as well as  
322 other requirements not related to the effectiveness of the products against foodborne pathogens.

323         As drugs, hand antiseptics must be demonstrated to be safe and effective. This can be  
324 accomplished by one of two means:

- 325         1. The hand antiseptic may be approval by FDA under a new drug application (NDA). Drugs  
326         approved through this route are listed in Approved Drug Products with Therapeutic Equivalence  
327         Evaluations, also known as the “Orange Book” ( 11).
- 328         2. The hand antiseptic may have an active ingredient identified by FDA (9) in the Tentative Final  
329         Monograph (TFM) for Health-Care Antiseptic Drug Products for OTC Human Use in the

330 handwash category, be listed with FDA as a drug, and comply with other relevant drug  
331 requirements.

332 The TFM specifies the active ingredients that can be contained within handwash products, as well  
333 as labeling, product testing and other general requirements. The *in vitro* and *in vivo* testing provisions in  
334 the TFM are well detailed and list specific organisms that products can make claims against. There is  
335 also a clinical study requirement depending on the final claim. The TFM antimicrobial spectrum tests  
336 determine the efficacy of products using Minimum Inhibitory Concentration (MIC) against 25 laboratory  
337 strains and 25 fresh clinical isolates included in a specific list of vegetative bacteria and the yeast  
338 *Candida*. Time kill tests are also required using “standard ATCC strains identified for the MIC tests. The  
339 TFM also requires an *in vivo* handwash assay using *Serratia* as the test organism. There are currently no  
340 virus tests listed on the TFM and therefore antiviral hand hygiene claims are not available through the  
341 TFM, despite the fact that as noted above, norovirus is by far the pathogen reported most frequently in  
342 outbreaks where inappropriate application of hand hygiene regimens were noted.

343 For hand antiseptics, the TFM classifies alcohol 60–95% and povidone iodine 5–10% as  
344 Category 1 – Generally Recognized as Safe and Effective. Many potential active ingredients for hand  
345 antiseptics including triclosan, triclocarban, benzalkonium chloride, benzethonium chloride and  
346 parachlorometaxyleneol, are classified in Category III, requiring more data for final determination on safety  
347 and efficacy. Pending a Final Monograph, products based upon ingredients classified as Category III can  
348 be marketed provided they meet the performance testing requirements of the TFM. Premarket approval  
349 through the New Drug Application (NDA) process is required for products that contain active ingredients  
350 not listed in the TFM.

#### 351 **FDA guidance on hand antiseptics**

352 While the CDC recommends alcohol-based hand gels as a suitable alternative to handwashing  
353 for health care personnel “*if hands are not visibly soiled*” (4), FDA (10) clarified that this recommendation  
354 is not applicable to food establishments. This exclusion is based on the differences in controlling common  
355 nosocomial pathogens in health care settings and common foodborne pathogens in retail and foodservice  
356 settings. FDA (10) also highlights that the pathogens most commonly transmitted by hands in health care

357 settings differ from those in retail and food service settings, and the types and levels of soil on the hands  
358 of health care workers differ from foodservice/retail workers. The FDA (10) factsheet concluded:

359 “Proper handwashing, as described in the Food Code continues to serve as a vital and necessary  
360 public health practice in retail and food service. Using alcohol gel in place of handwashing in retail  
361 and food service does not adequately reduce important foodborne pathogens on foodworkers’  
362 hands. Concern about the practice of using alcohol-based hand gels in place of handwashing  
363 with soap and water in a retail or food service setting can be summarized into the following  
364 points:

- 365 • “Alcohols have very poor activity against bacterial spores, protozoan oocysts, and certain  
366 nonenveloped (nonlipophilic) viruses; and
- 367 • “Ingredients used in alcohol-based hand gels for retail or food service must be approved food  
368 additives, and approved under the FDA monograph or as a New Drug Application (NDA); and
- 369 • “Retail food and food service work involves high potential for wet hands and hands  
370 contaminated with proteinaceous material. Scientific research questions the efficacy of alcohol  
371 on moist hands and hands contaminated with proteinaceous material.”

372 It is important to note that even in health care settings, alcohol-based hand gels are to be used as  
373 an alternative to handwashing “only if hands are not visibly soiled” according to CDC (4).

#### 374 **State and local jurisdictions**

375 At least one regulatory jurisdiction allows the use of alternatives to Food Code compliant  
376 handwashing in certain settings where water is limited (17). It is important to understand the specific  
377 situations where such alternatives are allowed. Research on the impact of adoption of alternative  
378 procedures on hand hygiene compliance and potentially case control studies to investigate public health  
379 outcomes of such programs would be useful to further inform the discussion on alternatives to  
380 handwashing.

#### 381 **Regulatory status summary**

382 Hand care products with antimicrobial claims are considered to be drugs, thus approval and  
383 registration are under the regulatory jurisdiction of FDA’s Center for Drug Evaluation and Research.  
384 Antiviral hand hygiene claims are not available through the Tentative Final Monograph and to date no US

385 antimicrobial hand care product with virucidal claims for food handler application has been approved  
386 through the New Drug Application (NDA) process. As a drug, antimicrobial hand care products should be  
387 used following label instructions. FDA's Center for Food Safety and Applied Nutrition provides guidance  
388 through the *Food Code* on when and where hand hygiene practices should be applied.

389

## 390 **COMPLIANCE ISSUES AND BEHAVIORAL ASPECTS OF HAND HYGIENE**

391 As previously discussed, many factors such as time, temperature, friction, product volume,  
392 product type, etc., influence the effectiveness of hand hygiene regimes. At the same time, motivating food  
393 workers to apply proper hand hygiene procedures at the right time is an important food safety need. Thus,  
394 procedures are important for effective hand hygiene. Operators make their final choice of protocols based  
395 on the requirements in the Food Code guidance and their risks, based on their customer mix, menu,  
396 facilities and system control. There is no one-size-fits-all protocol for the wide range of food service and  
397 retail establishment practices that exist. Procedures should be selected to assure their minimum  
398 cleanliness levels are maintained.

399 The Committee identified barriers to proper handwashing behaviors by discussing the question "If  
400 hand hygiene (hand antiseptic) was allowed in place of handwashing, would there be a significant  
401 increase in desired behaviors, either for use: 1) in place of handwashing or 2) in addition to  
402 handwashing?"

403 For this exercise, the Committee considered only behaviors and *not* necessarily effectiveness.  
404 The Committee discussed which factors encourage or discourage desired handwashing behaviors for  
405 both traditional soap and water wash, and use of approved hand antiseptic. Information reported in  
406 Tables 4-6 is based on expertise of the Behavior Sub-committee of the CFP Hand Hygiene Committee,  
407 with review by the full committee. No quantitative or qualitative data were reviewed during the Sub-  
408 committee's discussion.

409 Factors that may either encourage or discourage *how* handwashing or hand antiseptic behaviors  
410 performed are listed in Table 4. Many of the barriers apply equally to how hand hygiene is performed for  
411 either handwashing or hand antiseptic use. Perceived speed of application for use of single step hand  
412 antiseptic applications may remove a potential barrier that exists for handwashing. Hand antiseptics may

413 also remove barriers associated with proximity to the supplies need to perform the task. While the issue of  
414 training applies equally to both types of hand hygiene, it was noted that much emphasis has been placed  
415 on the proper handwashing technique. This may vary for different hand antiseptic applications and may  
416 be less obvious (e.g., single application versus two-step process; need to fully cover fingers, finger tips  
417 and nail area).

418 Factors that may either encourage or discourage *when* desired handwashing or hand antiseptic  
419 behaviors are appropriate are listed in Table 5. Again, many potential barriers apply equally to both hand  
420 hygiene regimens. The perceived need is an area where differences exist. Some workers wash their  
421 hands when they are heavily soiled from a self-protection standpoint. Conversely, single step hand  
422 antiseptics are typically designed to be used on visibly clean hands; therefore the visual cue of hands  
423 looking dirty does not apply. The sub-committee thought that there were opportunities to reduce  
424 confusion on when to wash hands or use hand antiseptics, for example when used with gloves (see the  
425 section on when alternatives may be appropriate).

426 Factors that may either encourage or discourage regarding *why* to perform hand hygiene are  
427 listed in Table 6. Communication of the reasons why hand hygiene should be performed is very important  
428 for employee acceptance and increases the likelihood that proper hand hygiene will be performed. Most  
429 of the factors that can encourage hand hygiene behaviors apply equally to both washing and antiseptic  
430 use. However, explaining why there are different considerations for when hand antiseptics are  
431 appropriate, may cause confusion and thus create a barrier to compliance. This type of communication  
432 must be planned carefully.

433

#### 434 **PUBLIC HEALTH BENEFIT OF IMPROVED HAND HYGIENE COMPLIANCE**

435 Several studies have evaluated the use of alcohol-based hand sanitizers in reducing infection  
436 rates in a variety of settings, including schools, day care settings, hospitals and long term care facilities.  
437 Two examples described below to illustrate the type of information that can be gained.

- 438 • Hilburn et al. ( 12) studied use of alcohol-based hand sanitizers in acute care facilities and reported  
439 a 36.1% decrease in infection rates when alcohol-based products were used. Key factors cited to  
440 contribute to this improvement included enhanced effectiveness against causative agents and

441 increased hand care compliance because products were easy to use and gentle to the skin, which  
442 removes a barrier for hand hygiene application. The CFP Hand Hygiene Committee notes that  
443 these results may not be immediately transferable to food handling settings because the agents,  
444 and likely the hand sanitizer products, differ. However, research on compliance in foodservice  
445 settings may be beneficial to determine if a similar improvement is noted.

446 • Sandora et al. (21) studied use of alcohol-based hand sanitizer coupled with hand hygiene  
447 education with children enrolled in 26 child care centers. They monitored transfer of secondary  
448 illness to people in the home. The CFP Hand Hygiene Committee recognizes that the primary  
449 mode of transmission in this study is person-to-person and that the pathogens involved may not  
450 necessarily be foodborne pathogens. However, the secondary illnesses were significantly lower for  
451 families with alcohol-based hand sanitizers in the home compared to control families.

452 While the Hilburn et al. (12) “clinical end point” data demonstrate a benefit from hand sanitizers in  
453 clinical settings, the study was confounded with many other factors such as training, other interventions  
454 and increased handwashing. Therefore it is difficult to determine the effect of the hand sanitizers alone.  
455 Respiratory illness and gastroenteritis are seasonal events that occur with some frequency in institutional  
456 type settings. Foodborne illness outbreaks are less frequent thus conducting these types of studies  
457 specifically for food handling considerations will be problematic.

#### 458 **Settings where alternatives to handwashing may be appropriate**

459 The Committee considered the information above and practical aspects of preparing, holding and  
460 serving food in its consideration of identifying settings where alternatives to handwashing are appropriate.  
461 From a practical and behavioral matter, the Committee thought it useful to clarify situations when and  
462 where alternatives to handwashing, such as hand antiseptics are not the best option. These include:

- 463 • Anywhere there is a properly functioning hand sink
- 464 • After toilet use
- 465 • At the start of a shift
- 466 • After lunch break
- 467 • Between handling raw and RTE foods
- 468 • After sneezing into hands

469 • If person has cuts, skin infections

470 • When hands look or feel soiled

471 The Committee also recognized that there are situations where alternatives to handwashing may  
472 be appropriate as a risk reduction strategy. For example, when hands are not visibly soiled hand  
473 antiseptics may *potentially* be an option:

474 • Between glove use

475 • After touching hair

476 • After coughing / sneezing / drinking

477 • In areas where there is environmentally no water

478 • In water outages / boil water situations

479 • During temporary events

480 • In farm stands

481 • For mobile vendors

482 The Committee recognized that there are water-short situations where the specific **dual step hand**  
483 **cleanser-sanitizer protocol (8)** may be a potential alternative to water/soap handwashing as a risk  
484 reduction strategy. Some may question if providing an alternative may drive operators to use hand-  
485 antiseptics in place of traditional handwashing. The product costs of alcohol washing versus water  
486 washing will strongly favor traditional handwashing where running potable water is conveniently available.  
487 The committee was unable to make specific recommendations. However, given time and integration of  
488 scientific and behavioral considerations, specific recommendations may be possible using a risk  
489 management approach.

490

## 491 **RESEARCH NEEDS**

492 Much of the research conducted on hand hygiene is done in areas other than food-related  
493 settings. There is a need for such studies to be conducted to inform decision making. Potential questions  
494 that could be addressed through research include:

495 • If hand antiseptic use was allowed in lieu of soap and water handwashing, would there be a  
496 significant increase in desired behaviors and would this reduce foodborne illness?

- 497 • Does providing options (soap and water vs. alternative hand hygiene methods) in foodservice or  
498 retail settings increase real-world compliance? If so, what is the public health benefit?
- 499 • Can studies on hand hygiene behaviors in hospitals be extrapolated to foodservice environments?
- 500 • What handwashing / hand hygiene options increase frequency of use?
- 501 • Why are food handlers not washing their hands?
- 502 • What is the range of temperatures that are considered to be comfortable for handwashing?
- 503 • Can new risk assessment and risk management models be applied to hand hygiene in food services  
504 settings to quantify the changes in risk when different interventions are applied?
- 505 • Can case-control epidemiological studies be conducted to study hand hygiene related foodborne  
506 illness outbreaks comparing regulatory jurisdictions allow the use of alternatives to handwashing, to  
507 those that do not?
- 508 • What is the clinical endpoint effect of various hand hygiene practices in a food setting?

509 Data supported answers to the above questions would help inform decision making on proposing  
510 alternatives to handwashing in certain situations to protect public health.

511

## 512 **ACKNOWLEDGEMENTS**

513 This report was extracted from the report of the Conference for Food Protection 2010-2012 Hand Hygiene  
514 Committee. Authors were Chairs or Co-chairs of Sub-committees that addressed scientific, behavioral  
515 and regulatory issues. Individuals from the Hand Hygiene Committee that voted for publication of this  
516 report included the following:

517 Katherine M.J. Swanson, Hand Hygiene Committee Co-chair and Ecolab Inc.; Mark Sampson, Hand  
518 Hygiene Committee Co-chair, Regulatory Sub-committee Co-chair, and Sterilox Food Safety; Donald  
519 Schaffner, Science Sub-committee Co-chair and Rutgers University; Dale Grinstead, Science Sub-  
520 committee Co-chair and Diversey Inc.; Michele Samarya-Timm, Behavior Sub-committee and Somerset  
521 County (NJ) Department of Health; Catherine Adams-Hutt, Regulatory Sub-committee Co-chair and  
522 National Restaurant Association representative; Thomas Bell, Procter and Gamble; Margaret Binkley, The  
523 Ohio State University; Patrick J. Brown, Great Atlantic and Pacific Tea Company; John C. Chrisman,  
524 Darden Restaurants Inc.; Michael J. Dolan, GOJO Industries, Inc.; Marlene Gaither, Coconino County



525 (AZ) Health Department; Courtney Halbrook, Yum! Brands, Inc.; Christina Johnson, Publix Supermarkets;  
526 Thomas Johnson, Johnson Diversified Products, Inc.; Terrence Kennedy, Starbucks Coffee Company;  
527 James Mann, Handwashing for Life Institute; Eric Moore, Aramark; Erin Palumbo, Supervalu-Shaw's  
528 Supermarkets; Andrew Plante, Brinker International; Angela Sanchez, CKE Restaurants Inc.; Aaron  
529 Smith, Stop and Shop Supermarkets; Daniel Tew, Yum! Brands, Inc.; Linda Zaziski, independent.

530

## 531 REFERENCES

- 532 1. Bidawid, S., N. Malik, O. Adegbunrin, S.A. Sattar, and J.M. Farber. 2004. Norovirus cross-  
533 contamination during food handling and with feline calicivirus as a surrogate. *J. Food Prot.* 67:103-9.
- 534 2. Brown, J.M., J.S. Avens, P.A. Kendall, D.R. Hyatt, and M.B. Stone. 2007. Survey of consumer  
535 attitudes and the effectiveness of hand cleansers in the home. *Food Prot. Trends* 27(8): p. 603-11.
- 536 3. Cannon, J.L., E. Papafragkou, G.W. Park, J. Osborne, L. Jaykus, J. Vinjé. 2006. Surrogates for the  
537 study of norovirus stability and inactivation in the environment: a comparison of murine norovirus and  
538 feline calicivirus. *J. Food Prot.* 69(11):2761-5.
- 539 4. CDC (Centers for Disease Control and Prevention). 2002. Guideline for hand hygiene in health-care  
540 settings: recommendations of the healthcare infection control practices advisory committee and the  
541 HICPAC/SHEA/APIC/IDSA hand hygiene task force. *Morb. Mort. Wkl. Rep.* 51(RR-16):32. Available  
542 at: <http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>. Accessed 26 October 2011.
- 543 5. CDC. 2006. Surveillance for foodborne-disease outbreaks – United States, 1998-2002. *Surveillance*  
544 *Summaries: Morb. Mort. Wkl. Rep.* 55 (SS10):1-34.
- 545 6. CDC. 2009. Diseases transmitted through the food supply. *Federal Register* 74 (224):61151-2.
- 546 7. Courtenay, M., L. Ramirez, B. Cox, I. Han, X. Jiang, and P. Dawson. 2005. Effects of various hand  
547 hygiene regimes on removal and/or destruction of *Escherichia coli* on hands. *Food Service Technol.* 5  
548 (2-4):77-84.
- 549 8. Edmonds, S.L., J. Mann, R.R. McCormack, D.R. Macinga, C.M. Fricker, J.W. Arbogast and M.J.  
550 Dolan. 2010. SaniTwice: a novel approach to hand hygiene for reducing bacterial contamination on  
551 hands when soap and water are unavailable. *J. Food Prot.* 73 (12):2296–300.

- 552 9. FDA (US Food and Drug Administration). 1994. The tentative final monograph (TFM) for health-care  
553 antiseptic drug products for OTC human use. *Federal Register* 59 (116):31402-52. Available at:  
554 <http://www.fda.gov/OHRMS/DOCKETS/98fr/94-14503.pdf>. Accessed 16 November 2011.
- 555 10. FDA. 2003. FDA fact sheet on hand hygiene in retail and food service establishments. Available at:  
556 [http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrain  
557 ingResources/ucm135577.htm](http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm135577.htm). Accessed 16 November 2011.
- 558 11. FDA. 2011. Orange book: approved drug products with therapeutic equivalence evaluations.  
559 Available at: <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>. Accessed 16 November  
560 2011.
- 561 12. Hilburn, J., B.S. Hammond, E.J. Fendler and P.A. Groziak. 2003. Use of alcohol hand sanitizer as an  
562 infection control strategy in an acute care facility. *Am. J. Infect. Control.* 31:109-16.
- 563 13. Lin, C.-M., F.-M. Wu, H.-K. Kim, M.P. Doyle, B.S. Michaels, and L.K. Williams. 2003. Comparison of  
564 hand washing techniques to remove *E. coli* and calicivirus under natural or artificial nails. *J. Food.*  
565 *Prot.* 66 (12):2296-301.
- 566 14. Liu, P., D.R. Macinga, M.L. Fernandez, C. Zapka, H.-M. Hsiao, B. Berger, J.W. Arbogast, and C.L.  
567 Moe 2011. Comparison of the activity of alcohol-based handrubs against human noroviruses using  
568 the fingerpad method and quantitative real-time PCR. *Food Environ. Virol.* 3:35-42.
- 569 15. Michaels, B., V. Gangar, C-M Lin and M. Doyle. 2003. Use limitations of alcoholic instant hand  
570 sanitizer as part of a food service hand hygiene program. *Food Service Technol.* 3:71-80.
- 571 16. Montville, R. and D.W. Schaffner. 2011. A meta-analysis of the published literature on the  
572 effectiveness of antimicrobial soaps. *J. Food Prot.* 74 (11):1875-82.
- 573 17. National Park Service. 2011. Colorado River Management Plan, 2011 Commercial Operating  
574 Requirements, page 16.
- 575 18. Park, G.W., L. Barclay, D. Macinga, D. Charbonneau, C.A. Pettigrew and J. Vinje. 2010. Comparative  
576 efficacy of seven hand sanitizers against murine norovirus, feline calicivirus, and GII.4 norovirus. *J.*  
577 *Food Prot.* 73 (12):2232-8.
- 578 19. Paulson, D.S., E.J. Fendler, M.J. Dolan and R.A. Williams. 1999. Close look at alcohol gel as an  
579 antimicrobial sanitizing agent. *Am. J. Infect Control.* 27 (4):332-8.

- 580 20. Restaino, L. and C.E. Wind. 1990. Antimicrobial effectiveness of hand washing for food  
581 establishments. *Dairy, Food Environ Sanitation*. 10 (3):136-41.
- 582 21. Sandora, T.J., E.M. Taveras, M-C. Shih, E.A. Resnick, G.M. Lee, D. Ros-Degnan, and D.A.  
583 Goldmann. 2005. A randomized, controlled trial of a multifaceted intervention including alcohol-based  
584 hand sanitizer and hand-hygiene education to reduce illness transmission in the home. *Pediatrics* 116  
585 (3):587-94.
- 586 22. Schaffner, D.W. and K.M. Schaffner (2007) Management of risk of microbial cross-contamination  
587 from uncooked frozen hamburgers by alcohol-based hand sanitizer. *J. Food Prot.* 70 (1):109-13.
- 588 23. Todd, E.C., B.S. Michaels, D. Smith, J.D. Greig, and C.A. Bartleson. 2010a. Outbreaks where food  
589 workers have been implicated in the spread of foodborne disease. Part 9.washing and drying of  
590 hands to reduce microbial contamination. *J. Food Prot.* 73 (10):1937-1955. Available at:  
591 <http://www.ingentaconnect.com/content/iafp/jfp/2010/00000073/00000010/art00020>. Accessed 9  
592 November 2011.
- 593 24. Todd, E.C., B.S. Michaels, J. Holah, D. Smith, J.D. Greig, and C.A. Bartleson. 2010b. Outbreaks  
594 where food workers have been implicated in the spread of foodborne disease. Part 10. alcohol-based  
595 antiseptics for hand disinfection and a comparison of their effectiveness with soap. *J. Food Prot.* 73  
596 (11):2128-2140. Available at:  
597 <http://www.ingentaconnect.com/content/iafp/jfp/2010/00000073/00000011/art00026>. Accessed 9  
598 November 2011.

599 **Table 1** CDC\* listing of infectious and communicable diseases transmitted through handling the food  
 600 supply

<b>Category</b>	<b>Agent</b>	<b>Modes of transmission</b>	<b>Symptoms that indicate infection that could be transmitted to others through food</b>
Pathogens <i>often</i> transmitted by food contaminated by infected persons who handle food	Viruses - Norovirus - Hepatitis A virus - Sapovirus Bacteria - <i>Salmonella</i> Typhi - <i>Shigella</i> species - <i>Staphylococcus aureus</i> - <i>Streptococcus pyogenes</i>	<ul style="list-style-type: none"> <li>• Failure of food handlers to:               <ul style="list-style-type: none"> <li>- wash hands,</li> <li>- wear clean gloves, or</li> <li>- use clean utensils</li> </ul> </li> <li>• Also transmitted person to person</li> </ul>	<ul style="list-style-type: none"> <li>• Diarrhea</li> <li>• Vomiting</li> <li>• Open skin sores, boils</li> <li>• Fever</li> <li>• Dark urine</li> <li>• Jaundice</li> </ul>
Pathogens <i>occasionally</i> transmitted by food contaminated by infected persons who handle food, but <i>usually</i> transmitted by contamination at the source or in food processing or by non-foodborne routes	Bacteria - <i>Campylobacter jejuni</i> - Enterohemorrhagic <i>E. coli</i> - Enterotoxigenic <i>E. coli</i> - Non-typhoidal <i>Salmonella</i> - <i>Vibrio cholera</i> - <i>Yersinia enterocolitica</i> Parasites - <i>Cryptosporidium</i> species - <i>Entamoeba histolytica</i> - <i>Giardia intestinalis</i> - <i>Taenia solium</i>	<ul style="list-style-type: none"> <li>• Usually intrinsically contaminated or cross-contaminated during processing or preparation</li> <li>• Occasionally transmitted by infected food handler with acute diarrhea</li> <li>• Bacterial pathogens often require multiplication in the food before they will cause disease</li> </ul>	<ul style="list-style-type: none"> <li>• Acute diarrheal illness</li> </ul>

601 \*Adapted from: CDC (5)

602 **Table 2** Hand contact contributing factors reported for foodborne illness outbreaks 1998-2002 in the  
 603 United States\*

		<b>Bare-hand</b>		<b>Gloved-hand</b>		<b>Infected person</b>	
		<b>contact</b>		<b>contact</b>		<b>or carrier</b>	
<b>Etiology</b>		n (% of confirmed)		n (% of confirmed)		n (% of confirmed)	
Bacterial	Non-typhoidal <i>Salmonella</i>	37	(15)	4	(7)	64	(18)
	<i>Staphylococcus aureus</i>	17	(7)	5	(9)	30	(9)
	<i>Shigella</i>	12	(5)	3	(5)	16	(5)
	<i>Escherichia coli</i>	12	(5)	1	(2)	6	(2)
	<i>Clostridium perfringens</i>	8	(3)	2	(4)	2	(1)
	<i>Campylobacter</i>	5	(2)	2	(4)	1	(<1)
	<i>Vibrio parahaemolyticus</i>	2	(1)	1	(2)	1	(<1)
	<i>Bacillus cereus</i>	1	(<1)	1	(2)	1	(<1)
	<i>Streptococcus</i>	0	(0)	0	(0)	1	(<1)
	<b>Total Bacterial</b>	<b>94</b>	<b>(40)</b>	<b>19</b>	<b>(35)</b>	<b>122</b>	<b>(35)</b>
Viral	Norovirus	129	(54)	30	(55)	202	(58)
	Hepatitis A	13	(5)	4	(7)	16	(5)
	<b>Total Viral</b>	<b>142</b>	<b>(59)</b>	<b>34</b>	<b>(62)</b>	<b>218</b>	<b>(62)</b>
Parasitic	<i>Giardia intestinalis</i>	1	(<1)	0	(0)	2	(1)
	Multiple etiologies	2	(1)	1	(2)	7	(2)
<b>Total confirmed etiology</b>		<b>239</b>	<b>-</b>	<b>55</b>	<b>-</b>	<b>349</b>	<b>-</b>
<b>Unknown etiology</b>		<b>526</b>	<b>-</b>	<b>132</b>	<b>-</b>	<b>251</b>	<b>-</b>

\*Adapted from: CDC (4)

604

605 **Table 3** Advantages and disadvantages of *in vivo* and *in vitro* tests to demonstrate efficacy of hand  
 606 hygiene solutions.

Test method	Advantages	Disadvantages
<i>In vivo</i> (uses human subjects)	<ul style="list-style-type: none"> <li>• Closer to clinical endpoints</li> <li>• May demonstrate impact of full hand hygiene procedure (i.e., rinsing, friction, duration)</li> </ul>	<ul style="list-style-type: none"> <li>• Significant person-to-person variation</li> <li>• Expensive and difficult to conduct</li> <li>• Concerns with human exposure to certain pathogens</li> </ul>
<i>In vitro</i> (does not use human subjects)	<ul style="list-style-type: none"> <li>• Typically less variable than <i>in vivo</i> methods</li> <li>• Can study more organisms in a controlled manner</li> <li>• Less expensive</li> </ul>	<ul style="list-style-type: none"> <li>• Further removed from clinical endpoints</li> </ul>

607

608 **Table 4** What encourages / discourages desired behaviors regarding **how** to perform hand hygiene?  
 609 (Note: effectiveness of the application is not considered in this comparison)

<b>Potential barriers</b>	<b>Handwashing</b>	<b>Hand antiseptic or alternative</b>
Water temperature	Too hot or cold discourages Just right encourages	Not applicable
Type of product (Like or dislike scent, feel etc.)	How well does it lather? Does it cause dry hands or maintain skin health? Does it sting?	Does it make hands sticky? Does it cause dry skin or maintain skin health? Does it sting?
Towel vs. hand dryer	Slow drier discourages Empty or malfunctioning towel dispensing discourages	Drier not applicable. Towel may be needed (wipes or two-step procedure), thus availability or malfunctioning situations are similar.
Urgency / pressure / motivation	Must go to sink to perform	Can be applied "on the go" for a one step process
Proximity of product and equipment, ease of reaching	Need sink (plumbing), soap, drying equipment	Portable or easy installation in multiple locations. Potentially closer to work station.
Training (need to know how, when and why)	Applies equally. Potentially more material available on procedure.	Applies equally
Supplies available and working	Applies equally	Applies equally
Laziness	Applies equally	Applies equally
Ease – automated vs. manual. Method of dispensing	Automatic options may encourage or discourage. Must be functioning	Automated dispensing quicker when functioning. Must be functioning.
Time	Takes too long (perception)	Fewer steps for single application
Double handwashing	Takes too long	Applicable to two-step process
Policy – management commitment and enforcement	Applies equally	Applies equally
Job aids – detailed instructions	Applies equally	Applies equally
Hand hygiene signs	Applies equally	Applies equally
Behavior modeled by co-workers and management	Can motivate or de-motivate	Can motivate or de-motivate
Requirement for employment	Applies to both	Applies to both
Existence of regulations	Encourages policy, not employees	Currently hinders adoption
Visible / type of soil	Adjust to soil type	Appropriate for visibly clean hands only. May be unpleasant on heavily soiled hands
Pleasant experience	Applies equally	Applies equally

610

611 **Table 5** What encourages / discourages desired behaviors regarding **when** to perform hand hygiene?

612 (Note: effectiveness of the application is not considered in this comparison)

<b>Potential barriers</b>	<b>Handwashing</b>	<b>Hand antiseptic or alternative</b>
Perceived need	Wash when hands look or feel dirty. Workers wash to protect themselves (e.g., after clearing a messy table)	Perceived need for single step may change because this should be done on clean hands. Likely the same for a two step process
Touch points / requirements (too many)	Applies equally	Applies equally
Policy– management commitment and enforcement	Applies equally	Applies equally
Training – urgency	Applies equally	Applies equally
Focus on the why	Applies equally	Applies equally
Clarifying specifics in Food Code / misinterpretations	Potentially reduce confusion on requirements	Potentially reduce confusion on requirements and interpretation of regulations
In concert with glove use / confusion with glove use	Potentially reduce confusion on requirements	Potentially reduce confusion on requirements
Clarifying examples	Potentially reduce confusion on requirements	Potentially reduce confusion on requirements
Motivation	Applies equally	Applies equally
Proximity / ease	Need sink (plumbing), soap, drying equipment	Portable or easy installation in multiple locations. Potentially closer to work.
When need to wash – settings / relevance	When they look or feel dirty	Apply to visibly clean hands
Requirement to stay employed	Applies equally	Applies equally
Visibility of kitchen	Depends on customers – are they more interested in the food techniques or hygiene?	Less time away from food prep
Pleasant experience (some products make hands feel and / or smell good)	Applies equally	Applies equally
Hand antiseptic is a second barrier	May be tempted to skip washing	May do it more often if it is quicker

613



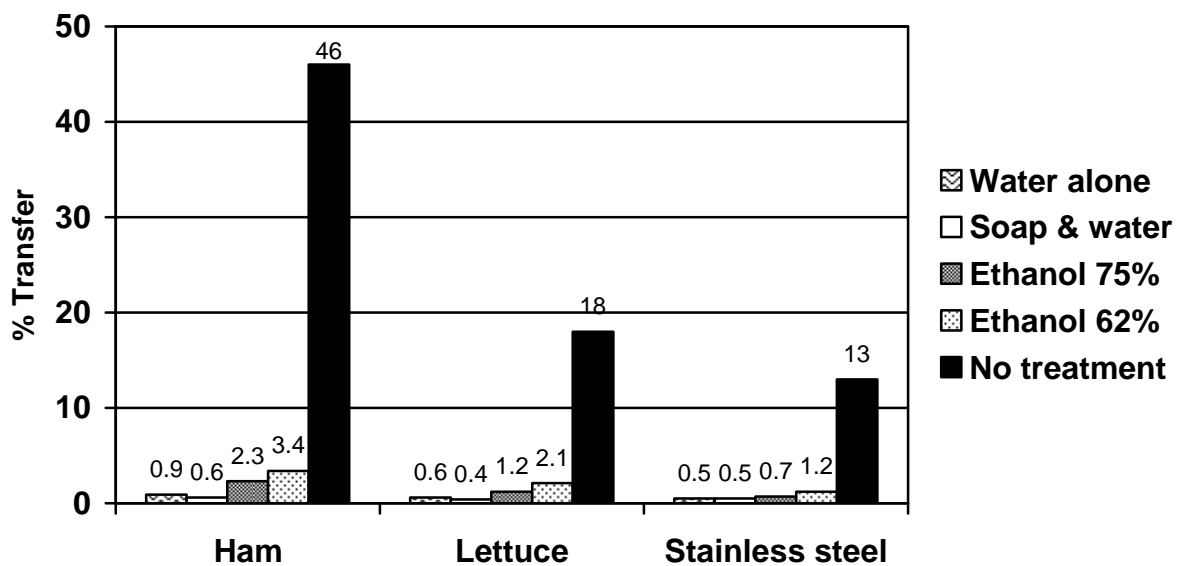
614 **Table 6** What encourages / discourages desired behaviors regarding *why* to perform hand hygiene?

615 (Note: effectiveness of the application is not considered in this comparison)

Potential barriers	Handwashing	Hand antiseptic or alternative
Buy-in / encouragement	Handwashing is a recognized foundation for food safety and healthy living.	Explaining the differences of when handwashing is appropriate versus when alternatives are appropriate may complicate the message and confuse the “Why”
Expected practice / culture of hand hygiene	Applies equally	Applies equally
Not a lot of training tools; print training vs. activity based	Applies equally	Applies equally
Trainer effectiveness	Applies equally	Applies equally
Oral vs. written	Applies equally	Applies equally
Proximity	Getting staff to the sink	Getting to the product
Lack of motivation	Applies equally	Applies equally
Expectation of customers	Visibility of kitchen	Visibility of kitchen
Pleasant experience	Applies equally	Applies equally
Location / availability of supplies	Applies equally	Applies equally, but may be easier to have sanitizer available in some locations
Equipment working correctly	Applies equally	Applies equally

616

617 **Figure 1** Feline calicivirus transfer from inoculated finger pads to ham, lettuce and stainless steel  
618 surfaces after treatment with various hand hygiene regimens. Adapted from Bidawid et al. (1)



619

Committee Name:

2010-12 CFP Hand Hygiene Committee

1-Dec-11

Last Name	First Name	Position	Constituency	Employer	Address	City	State	Zip	Telephone	Email
Swanson	Katie	Co-Chair	Other - Sanitation Serv	Ecolab Inc	655 Lone Oak Drive	Eagan	MN	55121-1560	(651) 795-5943	katie.swanson@ecolab.com
Sampson	Mark	Co-Chair	Other - Sanitation Serv	Sterilox Food Safety	162 Ash Way	Doylestown	PA	18901	484 321 2709	msampson@puricore.com
Adams Hutt	Catherine	Member	Other - Association	National Restaurant Association	601 Pennsylvania Ave, NW #1505	Washington	DC	20004	(630) 605-3022	cadams@rdrsol.com
Bell	Thomas	Member	Other - Sanitation Serv	Procter & Gamble	5299 Spring Grove Avenue	Cincinnati	OH	45217	(613) 627-5579	bell.ct@pg.com
Binkley	Margaret	Member	Academia	The Ohio State University	1787 Neil Ave.	Columbus	OH	43210	(614) 292-4529	binkley.62@osu.edu
Brown	Patrick J.	Member	Industry - Retail	Great Atlantic & Pacific Tea Company	2 Paragon Drive	Montvale	NJ	07645	(201) 571-8039	brownp@aptea.com
Chrisman	John C.	Member	Industry - Food Service	Darden Restaurants Inc.	1000 Darden Center Drive	Orlando	FL	32837	(407) 245-4785	jchrisman@darden.com
Dolan	Michael J.	Member	Other - Sanitation Serv	GOJO Industries, Inc.	P.O. Box 991	Akron	OH	44309-0991	(330) 255-6294	dolanm@gojo.com
Gaither	Marlene	Member	Regulatory - Local	Coconino County (AZ) Health Dept	2500 N. Fort Valley Road	Flagstaff	AZ	86001	(928) 527-8520	mgaither@coconino.az.gov
Grinstead	Dale	Member	Other - Sanitation Serv	Diversey	8310 16th Street	Sturtevant	WI	53177	(262) 631-4433	<a href="mailto:dale.grinstead@diversev.com">dale.grinstead@diversev.com</a>
Halbrook	Courtney	Member	Industry - Food Service	Yum! Brands, Inc.	7100 Corporate Drive	Plano	TX	75208	972-338-6824	<a href="mailto:courtney.halbrook@yum.com">courtney.halbrook@yum.com</a>
Johnson	Christina	Member	Industry - Retail	Publix Supermarkets	5500 Park Ridge Boulevard	Boynton Beach	FL	32436	561 214 3591	<a href="mailto:christina.johnson@publix.com">christina.johnson@publix.com</a>
Johnson	Jennifer	Member	Industry - Food Service	Walt Disney Parks and Resorts US	PO Box 10000	Lake Buena Vista	FL	32830-1000		jennifer.johnson@disney.com
Johnson	Thomas	Member	Other - Sanitation Serv	JDP, Inc.	1408 Northland Drive, #407	Mendota Heights	MIN	55120	(651) 686-8499	tomj@jdpinc.com
Kennedy	Terrence	Member	Industry - Food Service	Starbucks Coffee Company	50 Beach Street	Manchester	MA	01944	(617) 784-2884	tkennedy@starbucks.com
Mann	James	Member	Other - Consulting Serv	Handwashing for Life Institute	1216 Flamingo Parkway	Libertyville	IL	60048	(847) 918-0254	jmann@handwashingforlife.com
Moore	Eric	Member	Industry - Food Service	Aramark	1717 Arch St.	Philadelphia	PA	19103	(215) 409-7343	moore-eric2@aramark.com
Moris	Steve	Member	Regulatory - State	Kansas Dept of Agriculture	109 SW 9 <sup>th</sup> St. 3 <sup>rd</sup> Floor	Topeka	KS	66612	785-296-5600	Steve.Moris@KDA.KS.GOV
Morris	Sheri L.	Member	Regulatory - State	PA Dept of Ag/ Fd Safety & Lab Serv	2301 North Cameron Street	Harrisburg	PA	17110-9408	(717) 787-4315	shmorris@state.pa.us
Palumbo	Erin	Member	Industry - Retail	Supervalu-Shaw's Supermarkets	750 West Center Street	W. Bridgewater	MA	02919	(505) 313-3387	erin.palumbo@shaws.com
Plante	Andrew	Member	Industry - Food Service	Brinker International	6700 LBJ Freeway Suite 3105	Dallas	TX	75240	(972) 770-1778	andrew.plante@brinker.com
Samarya-Timm	Michele	Member	Regulatory - Local	Somerset County Dept of Health	PO Box 3000, 27 Warren Street	Somerville	NJ	08876	(908) 541 5749	SamaryaTimm@co.somerset.nj.us
Sanchez	Angela	Member	Industry - Food Service	CKE Restaurants Inc.	1051 N. Wineville Ave.	Ontario	CA	91764-5360	(909) 912-3814	asanchez@ckr.com
Schaffner	Donald	Member	Academia	Rutgers University	65 Dudley Road	New Brunswick	NJ	08901	(732) 932-9611	schaffner@aesop.rutgers.edu
Smith	Aaron	Member	Industry - Retail	Stop & Shop Supermarkets	1385 Hancock Street	Quincy	MA	02169	(617) 549-8318	aaron.smith@stopandshop.com
Tew	Daniel	Member	Industry - Food Service	Yum! Brands, Inc.	1900 Colonel Sanders Lane, MD 1529	Louisville	KY	40213	(502) 874-2422	daniel.tew@yum.com
Zaziski	Linda	Member	Other	Free agent	316 Maizie Land	Sparta	MI	49345	(586) 243-6932	<a href="mailto:Linda.Zaziski@charter.net">Linda.Zaziski@charter.net</a>
Williams	Laurie	Advisor	Regulatory - Federal	FDA CFSAN	5100 Paint Branch Parkway	College Park	MD	20740	240-402-2938	<a href="mailto:Laurie.Williams@fda.hhs.gov">Laurie.Williams@fda.hhs.gov</a>
Lewis	Glenda	Alternate	Regulatory - Federal	FDA CFSAN	5100 Paint Branch Parkway	College Park	MD	20740	240-402-2150	<a href="mailto:Glenda.Lewis@fda.hhs.gov">Glenda.Lewis@fda.hhs.gov</a>
Silverman	Meryl	Advisor	Regulatory - Federal	USDA-FSIS	5601 Sunnyside Ave., Rm 2-2108A	Beltsville	MD	20705	301-504-0844	<a href="mailto:meryl.lubran.fsis.usda.gov">meryl.lubran.fsis.usda.gov</a>
Hicks	John C.	Advisor	Regulatory - Federal	USDA-FSIS	5601 Sunnyside Ave.	Beltsville	MD	20705	301-504-0840	<a href="mailto:john.hicks@fsis.usda.gov">john.hicks@fsis.usda.gov</a>
Sharp	Donald	Advisor	Regulatory - Federal	US CDC	1600 Clifton Road NE, MS G24	Atlanta	GA	30333	(404) 639-2213	das8@cdc.gov