Conference for Food Protection
2010 Issue Form

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

All information above the line is for conference use only.

Title:
Hand Sanitizer Use between Glove Changes

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

Public Health Significance:
CDC reports the number of food borne illness outbreaks associated with hand contact, with or without gloves, from 1998-2002 (Lynch et al, 2006) (Table 1) See Attachment for all Tables referenced. Norovirus is the dominant etiology for both bare-hand and gloved-hand contact. This is why hand washing before donning gloves the first time is essential. However, after hands have been washed, bacterial agents are the concern because they may be naturally present on some foods or on humans. Additionally, gloves may serve as "incubators" and allow bacteria to multiply inside the glove. This is not true for viruses; therefore use of hand antiseptics known to be effective against bacteria should be sufficient when changing gloves. Many hand antiseptics provide a 4 to 5 log reduction for vegetative bacteria through in vitro tests.
Hand antiseptic effectiveness
There are several test methods available to evaluate the efficacy of a hand antiseptic. Laboratory (*in-vitro*) tests are most frequently used for Food Code compliant hand antiseptics because they provide greater flexibility and the test can be conducted on a number of pathogens to determine their relative susceptibility to the hand care product. Laboratory-based methods also reduce the variation that may be observed between individuals (*e.g.*, the amount of product used, the size of the hand, the thoroughness or rubbing, etc.).
Human subject tests (*in-vivo*) can be done to study the impact of additional factors such as the mechanical removal of the test organism on the hands. However, because human

subjects are involved, generally a surrogate is used to represent pathogens and judgment is required to extrapolate the efficacy against a range of pathogens. The level of reduction observed through *in-vivo* testing is typically lower than that for *in-vitro* tests.

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

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

References:

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

Swanson K 2009 Personal communication, December 17, 2009.

Recommended Solution: The Conference recommends...:

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

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

(1) Hands are washed prior to donning gloves;

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

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

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Attachments:

- "Tables"

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

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

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

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

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

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