

Conference for Food Protection – Committee FINAL Report

Template approved: 08/14/2013

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COMMITTEE NAME: 2012-2014 Hand Hygiene Committee (HHC)

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council III

DATE OF REPORT: December 06, 2013 Revised 2/17/2014

SUBMITTED BY: Co-Chairs Angela Sanchez (Industry) and Michéle Samarya-Timm (Regulatory)

COMMITTEE CHARGE(s):

Issue 2012 Council III-006

This committee is charged to:

Charge 1: 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 research 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).
- Determine if/when double gloving procedures would be acceptable without hand washing. If so, what would those acceptable procedures be?
- Determine what glove criteria or standards would need to be met for a glove to be considered a utensil and not require hand washing.

Charge 2: 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;

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- 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.

Charge 3: The committee report back its findings to the 2014 Biennial Meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. Progress on Overall Committee Activities:

- a) The Hand Hygiene Committee (HHC) was charged with some significant issues to be completed by the 2014 CFP Biennial Meeting. In recognition of this, the committee discussed if it would be advantageous to create sub-groups for the charges. After consideration, the committee acknowledged the value of diverse perspectives in working towards all the deliverables, and decided to best utilize the cross-discipline expertise of the members by discussing and addressing all charges as a group, therefore no sub-groups were created.

Monthly committee calls were held on the 3rd Tuesday of every month at 4:00pm ET. Call dates: September 10, 2012; October 16, 2012; November 20, 2012; January 15, 2013; February 19, 2013; March 19, 2013; April 16, 2013; May 21, 2013.

By May 2013, the committee doubled the frequency and duration of calls (moved to 2x/month, 1 ½ hours/call) to delve deeper into discussions towards anticipated deliverables. The remaining call dates were: August 06, 2013; August 20, 2013; September 03, 2013; October 01, 2013; October 15, 2013; October 29, 2013; and November 19, 2013.

All calls were recorded through Pragmatic, and the recording information provided to the entire committee. Minutes and recordings from this committee were also shared with the CFP Emergency Action Plan for Retail Food Establishments Committee (EAP), at their request.

- i. Charge 1: Charge: More closely examine the current Food Code requirements for when employees are required to wash their hands using soap and running water.

Charge 1. Findings:

- (a) In order to assist in examining the current Food Code requirements on employee handwashing, the HHC created a chart "Hand

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Contamination Event Hazard Chart” attached to Issue # 1 Report – Hand Hygiene Committee (HHC).

The HHC considered several charts to determine which would be most useful in documenting aspects of the committee charge, finally settling on a hand contamination event hazard analysis rubric chart. The chart was designed to allow discussion on areas where handwashing would reduce a food safety related risk and skip over situations where handwashing might not make a significant difference.

1. Outcome: The committee consensus is that any instance where the hazard (pathogenic, biological, chemical or physical) is not significant to cause illness or harm, it could be extrapolated that handwashing would not significantly reduce the food safety hazard. The Hand Contamination Event Hazard Chart may be a useful resource since it mirrors the process of determining priority risk designations. The committee noted that the Hand Contamination Event Hazard Chart is based on the opinion of subject matter experts, and should be used in addition to, not as a replacement for, peer reviewed scientific study.
- (b) “When to Wash” hierarchy
Based on the Hand Contamination Event Hazard Chart, the committee contemplated recommending that the “When to Wash” section of the Food Code be rearranged according to a hierarchy of relative risk. After careful consideration, consensus indicated a hierarchy of handwashing moments is not necessary, as order does not matter from a regulatory perspective.
- (c) Risk from touching face / hair
Based on the Hand Contamination Event Hazard Chart, the committee reached consensus that touching face and/or hair is not a significant food safety hazard. Although *Staphylococcus aureus* (*S. aureus*) could be transferred to food after touching face or hair, PHF/TCS food would need to be subsequently temperature abused and the toxin produced in order to be a potential cause of the disease.

The HHC could not reach consensus to recommend that touching face/hair be removed from the “when to wash” list in the Food Code. However, the committee expressed the value of recommending further research that substantiates touching these areas poses minimal risk to food.

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(d) Definitions: Defining handwashing, hand sanitizing and hand cleansing. A committee member proposed a need for definitions of handwashing, hand sanitizing and hand cleansing. The HHC consensus is that the definitions are inclusive in the text of the Food Code: Section 2-301.12 Cleaning Procedure; and Section 2-301.16 Hand Antiseptics. Further, the HHC felt that time constraints and CFP deliverables prevented further discussion.

1. Defining contamination: A committee member proposed that the term "contamination", as used in the Food Code needs to be defined, as it is difficult to assess reduction if there is not a set threshold. Here, too, the HHC felt that time constraints prevented further discussion.

2. Foodservice Glove

Before engaging in discussions of if/when double gloving procedures would be acceptable without soap and water handwashing, the HHC defining what constitutes a foodservice glove, and recommends that modified language to the 2013 FDA Food Code requesting that the following definition be included in Paragraph 1-201.10 (B) of the 2013 FDA Food Code in underline format as follows: Foodservice Glove – a non-porous, SINGLE-USE covering worn over the front and back of the hand during FOOD preparation or service, with the intention of preventing cross-contamination. (See attached Issue # HHC 2–recommended Foodservice Glove Language Changes to the Food Code.)

3. Double Gloving

In exploring the practice of double-gloving, committee members identified that a double gloving or similar procedure is approved in Washington State, however this committee did not obtain or review the written protocols or rationale. Based on observed practices in the field and considering the prevention of cross contamination, the HHC discerned best practices for double-gloving and developed a double-glove procedure/definition to be included in the Food Code as new language, (See Issue # HHC 2–Recommended Foodservice Glove Language Changes to the Food Code.):

a. The use of a loose-fit FOODSERVICE GLOVE – used over or in addition to a FOODSERVICE GLOVE for the purposes of allowing a FOOD EMPLOYEE to switch tasks without a necessary FOODSERVICE GLOVE change or handwashing. The loose-fit FOODSERVICE GLOVE must be capable of being removed or disposed of without contamination to the primary FOODSERVICE GLOVE, hands or forearms. In developing a

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procedure for double-gloving, the HHC found the Food Code language of “changing tasks” too vague and feels it may need to be clarified to drive home the intent that the change in task leads to a contamination event and to establish the extent of cross contamination potential between raw and RTE foods being handled. The HHC recognizes there may be situations where a double-glove procedure would not be appropriate.

- (e) The HHC recognizes that single use utensils such as gloves used by food establishments must meet certain materials requirements (no migration of deleterious substances, etc.), and that gloves used should not impart any unapproved additives to the food.
 - (f) Recommended clarification: (1) wash hands when switching from raw to RTE foods, (2) remove term “soiled equipment” in lieu of “contaminated equipment.”
 - (g) In November 2013, FDA announced 2013 Food Code Edition, which addresses handwashing. Paragraph 2-301.14(H) of the 2013 Food Code was amended to clarify that the requirement to wash hands before donning gloves is specific to the beginning of a task involving food handling and not during the task.
 - (h) Determine what glove criteria or standards would need to be met for a glove to be considered a utensil and not require hand washing. In reviewing the Food Code, the HHC discerned that the current FDA Food Code does consider a glove as a utensil. Applicability and Terms Defined Section, 1-201.10:
“Utensil” means a FOOD-CONTACT implement or container used in the storage, preparation, transportation, dispensing, sale, or service of FOOD, such as KITCHENWARE or TABLEWARE that is multiuse, SINGLE-SERVICE, or SINGLE-USE; gloves used in contact with FOOD; temperature sensing probes of FOOD TEMPERATURE MEASURING DEVICES; and probe-type price or identification tags used in contact with FOOD.
- ii. Charge 2:
- (a) Charge: Use the report of the 2010-2012 Committee as a reference, alternative hand hygiene regimes compared to handwashing. The committee should characterize what recent research tells us about:
 - 1. the extent to which the current minimum requirements for how and when employees are to wash their hands are

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effective in rendering food employees hands free of various soils, as well as, any pathogens of concern; and

2. what other regimens for cleansing employees hands, if any, may deliver outcomes that are similar to or better than hand washing so as to suggest that they could be included as acceptable methods for rendering hands free of soil and pathogens.

(b) Charge 2 Findings:

1. Existing Studies

Assessing the effectiveness of current handwashing requirements necessitates a scientific approach. The HHC agreed that literature reviews were necessary to appropriately evaluate this aspect of the charge. All HHC members were regularly requested to provide any related science literature to the committee for consideration. No new studies were identified that address situations under which food employees are currently required to wash their hands does not result in meaningful risk reduction/extent to which proposed regimen was as effective or better as handwashing.

2. Alternatives to Soap and Water Handwashing

The HHC reviewed the charge of considering other regimens for cleansing employee hands, but it was noted that this topic could not be appropriately discussed before establishing a complete list of possible alternatives.

To address this, the HHC used content from the 2010-2012 HHC Final Report as a baseline, and identified the following list of alternatives:

- 1) No handwash (i.e., do nothing)
- 2) Gloves alone (with no handwashing interventions)
- 3) Soap and water handwash (all variations, including with or without nailbrush, various timing, etc.)
- 4) Soap and water handwash followed by hand antiseptic
- 5) Hand antiseptic alone (gels, dips, wipes, sprays)
- 6) Double application of hand antiseptic
- 7) Stricter personal hygiene standards in lieu of more frequent handwashing
- 8) Handwashing machines

iii. Questions to consider when evaluating studies of alternative approaches:

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The HHC sought scientific literature on alternative approaches to soap and water handwashing, but found there was limited literature available. Before evaluating available studies, there was some question of how to assess credibility of literature. Accordingly, the HHC created a document titled "Questions to Consider When Evaluating Studies of Alternative Handwashing Approaches." (See attached to report).

iv. Dual Cleanse Sanitize Protocol

The HHC looked at one of the alternative approaches – the Dual Cleanse Sanitize Protocol. In evaluating this approach, the committee reviewed the sole study identified by the HHC -- Edmonds, 2010 – Journal of Food Protection Volume 73, Number 12, December 2010, pp 2296-2300 (5). The HHC considered, "What information (if any) is lacking for this committee to recommend a dual step hand sanitizer process in lieu of soap and water handwashing?" Applying the HHC's list of "Questions to Consider When Evaluating Studies of Alternative Handwashing Approaches" the committee found the Dual Cleanse Sanitize Protocol needs further studies, as the following information was considered missing or incomplete:

Methodology questions on submitted study

- What were the objectives, control measures, outcomes, etc. of the referenced study?
- What are the limitations of the study referenced (For example, can the results be broadly applied to all sanitizers or are there limitations? Have studies also tested other formulations or brands?)
- What "dose" of sanitizer is necessary for step 1 and step 2?
- What is the efficacy of the dual step method vs. a single step method?
- Has this process been studied with additional foodborne pathogens and the ability to reduce these pathogens on hands?
- Has this process been evaluated against Norovirus vs. regular hand washing procedures? Is there a clinical study? Virucidal claims are subject to NDA (New Drug Application), as FDA does not accept the claim for virucidal activity without a population clinical study to determine that it makes a difference in the numbers of sickened people.

Behavioral questions on submitted study

- Has this process been researched for ease / frequency of use (e.g., will employees use the method?), and undesirable side effects (e.g., rashes/dry, cracked skin)
- Are there any behavioral studies to ascertain if this process is appropriately and consistently used by foodservice personnel in the field? Are there any differences in compliance rates in a variety of settings (major food company vs. "mom and pop")?

Other questions on the submitted study

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- Who funded the referenced study?
- Has this study been replicated by academia or additional independent third parties without a fiscal or commercial interest?
- Has this study been replicated in actual foodservice settings?
- Are there any legal issues surrounding acceptance of the study/terminology that would affect acceptance by CFP (e.g., copyright, trademark, etc.)?
- What was the discernment process / criteria used by any agencies that have accepted this process?
- Is there sufficient scientific evidence to support a recommendation to the Food Code?

Discussions identified other concerns. The Dual Cleanse Sanitize Protocol proposes using a hand antiseptic as a hand cleanser. FDA Center for Drug Evaluation and Research (CDER) regulates over-the-counter and prescription drugs, including hand antiseptics. There is no known CDER approval for this use of a hand antiseptic. Further guidance or statements from CDER regarding this issue may be helpful. However, the scope of recommending a *process* using a *product* not approved by CDER for that purpose may be beyond the HHC.

On the basis of the listed information gaps, numerous unanswered questions, and need for further studies, the committee consensus is to *not* recommend this protocol.

2. Recommendations for Consideration by Council:

a) RESEARCH NEEDS

The 2010-2012 HHC identified that further research is needed to see if the use of an alternative handwashing regimen actually leads to meaningful risk reduction. The 2012-2014 HHC agrees with this assessment. FDA is in the process of pursuing the development of a standard method that allows for evaluating or comparing the effectiveness of hand hygiene procedures for soil removal in the retail food setting.

However, 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:

1. If hand antiseptic use were allowed in lieu of soap and water handwashing, would there be a significant increase in desired behaviors?

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2. Does providing options (soap and water vs. alternative hand compliance? If so, what is the public health benefit?
 3. Can studies on hand hygiene behaviors in hospitals be
 4. What handwashing / hand hygiene options increase frequency of use?
 5. Why are food handlers not washing their hands?
 6. What is the range of temperatures that are considered to be comfortable for handwashing?
 7. 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?
 8. Can case-control epidemiological studies be conducted to study hand hygiene related foodborne illness outbreaks comparing regulatory jurisdictions allow the use of alternatives to handwashing, to those that do not?
 9. What is the clinical endpoint effect of various hand hygiene practices in a food setting?
 10. Does touching face/hair pose minimal risk to food?
 11. Data supported answers to the above questions would help inform decision making on proposing alternatives to handwashing in certain situations to protect public health.
- c). The Committee has formally requested the CFP Executive Board approve submission of the document, "Scientific, Regulatory and Behavioral Considerations of Hand Hygiene Regimes" to a peer reviewed journal for publication, with the 2010-2012 Hand Hygiene Committee listed as a co-author. After the document "Scientific, Regulatory and Behavioral Considerations of Hand Hygiene Regimes" is published, the Committee requests that it be POSTED 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. The Committee requests this document be posted in PDF format.

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- d). recommend that a letter be sent to the FDA requesting the following definition be included in Paragraph 1-201.10 (B) of the 2013 FDA Food Code in underline format as follows: Foodservice Glove – a non-porous, SINGLE-USE covering worn over the front and back of the hand during FOOD preparation or service, with the intention of preventing cross-contamination.
- e). Add provision and public health rationale for double-glove procedure to the 2013 FDA Food Code
- f). Amend Section 2-301.14(G) of the 2013 FDA Food Code to allow for a handwashing exception during the double gloving procedure.
- g). Recommend modifying language for clarification of the Food Code of “changing tasks” as written in Paragraph 2-301.14 (F) of the Food Code to (1) wash hands when switching from raw to RTE foods, and (2) remove term in Paragraph 2-301.14 (E) of the 2013 Food Code, “soiled equipment” to “contaminated equipment”.

References:

CDC Contributing factors: <http://www.cdc.gov/outbreaknet/pdf/table4-combined-2009-10.pdf>

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

The Committee submits the following Issues and attachments to the 2014 CFP Biennial Meeting:

Issue #1: Report –Hand Hygiene Committee Final Report - Acknowledgement of the CFP Hand Hygiene Committee Final Report.

Attachments to Issue # 1 include:

- # 1 - Hand Hygiene Committee Final Report
- # 2 - Hand Hygiene Committee Roster
- # 3 - Hand Contamination Event Hazard Chart
- # 4 - Questions to Consider when Evaluating Studies of Alternative Handwashing Approaches

Issue #2: Recommended Foodservice Glove Language Changes to the Food Code

Issue #3: Re-create - Hand Hygiene Committee

Charges for a Re-created committee:

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Use the Hand Contamination Event Hazard Chart, and current research, to work with the FDA to explore if the mandate to wash hands after touching face/hair can be modified.