

**Conference for Food Protection
2008 Issue Form**

**Internal Number: 002
Issue: 2008 III-001**

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

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Title:

Report: Blade Tenderization Committee

Issue you would like the Conference to consider:

The Final Report of the Blade Tenderization Committee.

Public Health Significance:

E. coli O157:H7 foodborne illnesses associated with mechanically-tenderized or injected steaks have been reported in 2000, 2003, and 2004. In 2007, there were 3 reported foodborne illness outbreaks due to mechanically tenderized and injected beef. Although the level of surface contamination of steaks is expected to be very low, the number of *E. coli* O157:H7 necessary to cause illness also is very small - estimated to be approximately 4 CFU/gm. The National Advisory Council on Microbiological Criteria for Foods (NACMCF), in evaluating the risk of *E. coli* O157:H7 in blade tenderized steaks concluded that: 1) non-intact blade-tenderized steaks served very rare with cold spots (less than 120° F internal temperature) present a concern/risk, particularly to immunocompromised individuals; 2) there was insufficient data to address the need for labeling of blade tenderized steaks at this time. In the absence of labeling requirements, a guidance document was developed by this Committee to prevent contamination by *E. coli* O157:H7 or other pathogens during the production, handling, or preparation of blade tenderized beef, and other mechanically tenderized beef in retail establishments and restaurants. (Note: guidance document titled "*Guidelines on Injected and Mechanically Tenderized and Injected Beef Steak for Retail and Food Service Establishments*" is presented as an attachment to another Committee submitted Issue titled *Guidelines on Tenderized Beef for Retail and Food Service Establishments*.)

The guidelines include measures that retail establishments and restaurants can adopt to prevent contamination by *Escherichia coli* (*E. coli*) O157:H7 or other pathogens during the production, handling, or preparation of blade tenderized beef, and other mechanically tenderized beef. Restaurants and retail establishments receive steaks or similar cuts of meat that have been mechanically tenderized but typically are not labeled to signify that the

products have been so treated. Section 3-401.11(C)(3) of the *FDA Food Code* states that a raw or undercooked whole-muscle, intact beef steak may be served or offered for sale provided that it is cooked to a surface temperature of 63°C (145°F) or above and a cooked color change is observed on all exterior surfaces. These cooking recommendations should not be applicable to blade tenderized beef steaks or other mechanically tenderized and non-intact beef steaks because pathogens may contaminate below the surface during the tenderization process. In addition, generally, it is not possible to visually discern a blade tenderized beef steak from an intact beef steak. Consequently, neither the food service preparer nor the consumer would know that the cooking requirements of Section 3-401.11(C)(3) may not be sufficient to result in a safe product nor be able to use the appropriate cooking time and temperature to destroy any pathogens in the product.

Recommended Solution: The Conference recommends...:

that the Final Report of the Blade Tenderization Committee be acknowledged and that the Committee members be thanked for their efforts.

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Attachments:

- "Final Report Blade Tenderization Committee"

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.

Final Report of the Blade Tenderization Committee – January 10, 2008

Prepared by Paul M. Uhler

The committee was formed following the 2006 CFP and was given the following Charges and Guidelines:

1. Definition changes for the Food Code

- a. Section 1-201-10 (B) – change definition of “injected”

From: **“Injected”** means manipulating a MEAT so that infectious or toxigenic microorganisms may be introduced from its surface to its interior through tenderizing with deep penetration or injecting the MEAT such as by processes which may be referred to as “injecting,” “pinning,” or “stitch pumping.”

To: **“Injected”** meat means meat to which liquid substances have been introduced by processes that are referred to as “injecting,” “pump marinating,” or “stitch pumping.”

- b. Section 1-201-10 (B) – add definition for “mechanically tenderized”

“Mechanically tenderized” means manipulating meat with deep penetration by processes which may be referred to as “blade tenderizing,” “jaccarding,” “pinning,” “needling,” or using blades, pins, needles or any mechanical device; but does not include injecting solutions into meat.

2. Guidelines

The Committee should:

- a. Provide peer review of the “Guidelines on Blade Tenderized Beef for Restaurants and Retail Food Establishments” submitted at the 2006 meeting,
- b. Recommend changes to improve the document and possible changes to the Code, and
- c. Consider recent data of contamination by *Salmonella* and *Escherichia coli* O157:H7 and the impact on this by various processes including injected and mechanically tenderized beef steaks.

Committee Activities:

The Committee is submitting three issues to the 2008 CFP: 1) Change in Sections of the FDA Model Food Code to Better Define Tenderization; 2) The modified peer-reviewed guidance document, “Guidelines on Tenderized Beef Steak for Retail and Food Service Establishments” (retitled “Guidelines for Injected and Mechanically Tenderized Beef Steak for Retail and Food Service Establishments”), and 3) Final Report of the Blade Tenderization Committee.

With the submission of the issues, the work of the committee is finished.

The committee met on five separate occasions. At least eight members attended each of the meetings. One member from state government resigned and two others from the federal government joined the meetings

The committee discussed the current definition in the FDA Food Code for “Injected,” the addition of a definition for mechanically tenderized, and what change would have to be made to Section 3-401.11(A)(2) if the current definition were changed and a new definition added. Since most of the early meetings were consumed discussing the definitions and implications for the FDA Food Code, it was decided that this matter would be resolved more effectively through voting by email. The voting would allow more time to be used discussing the guidelines. The balloting had to be revised and resent due to a disagreement on wording that would be acceptable to FDA. The third ballot was unanimously approved 12-0 (2 votes not cast).

Most of the discussion and comments on the various drafts centered on the introductory material – the number of foodborne illness reports; the type of tenderization, mechanically or injection, involved in each reported outbreak; whether to include other pathogens or limit the discussion to *Escherichia coli* O157:H7, and whether the guidelines are intended to prevent or limit contamination by *E. coli* O157:H7. The sections of the guidelines addressing actions at retail and food service establishments did not have as much discussion during the meetings or in the comments as did the introductory material.

The outbreaks were listed in a table as this provided a better overview than a narrative discussion. The table also allowed the process involved, mechanical tenderization or injection, to be more easily identified with each outbreak. The committee recognized that other pathogens could be involved in the tenderization process but limited the discussion to *E. coli* O157:H7 since the outbreaks to date have been associated with *E. coli* O157:H7 and the control for *E. coli* O157:H7 would also control for the other pathogens, such as *Salmonella*. The committee reaches a consensus that the guidelines would help establishments limit contamination by *E. coli* O157:H7 but there was much discussion on the terms limit, minimize and prevent.

The majority of comments and discussion on the specific controls were that the controls be applicable to retail and food service establishments and should not include controls that are applicable only at federally or state-inspected establishments.

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**Conference for Food Protection
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Title:

Change FDA Food Code to Better Define Tenderization

Issue you would like the Conference to consider:

The 2006 Biennial Meeting of the Conference for Food Protection recommended that a committee be created to make the following changes to definition in the *FDA Food Code*:

Section 1-201-10 (B) change "Injected " definition to:

"Injected" means MEAT to which liquid substances have been introduced by processes that are referred to as "injecting", "pump marinating" or "stitch pumping".

Section 1-201-10 (B) add "Mechanically tenderized" definition:

"Mechanically tenderized" means manipulating meat with deep penetration by processes which may be referred to as "blade tenderizing", "jaccarding", "pinning", or "needling", but does not include injecting solutions into meat.

Modification of Section 1-201.10 (B) of the *FDA Food Code* provides more specificity in the differences between forms of tenderization such as mechanical tenderization (e.g., pinning or blade tenderizing) and injecting marinade or tenderizing solution.

As a result of removing the process of mechanical tenderizing from the definition of injected, Committee members discussed and agreed that Food Code section 3-401.11(A)(2) needed to be modified to add the words "mechanically tenderized" into the requirement for cooking raw animal foods at 68°C (155°F) for 15 seconds.

Public Health Significance:

Section 3-401.11(C)(3) of the Food Code reads that a raw or undercooked whole muscle, intact beef steak may be served or offered for sale provided that it is cooked to a surface temperature of 63°C(145°F) or above and a cooked color change is achieved on all

external surfaces. Injected is defined in the Food Code as a means of manipulating a MEAT so that infectious or toxigenic microorganisms may be introduced from its surface to its interior through tenderizing with deep penetration or injecting the MEAT such as by processes which may be referred to as "injecting," "pinning," or "stitch pumping." The definition as written is too broad and actually incorporates multiple processes. Although both mechanical tenderization and injection of meat render the meat non-intact, creating separate definitions will show the difference in the process. Both injected and mechanically tenderized meat are to be cooked according to section 3-401.11 (A)(2) of the Food Code at 68 °C (155 °F) for 15 seconds. Food establishments may cook injected or mechanically tenderized steaks at a time/temperature less than 68°C(155°F) for 15 seconds but a disclosure and reminder of a consumer advisory must be posted (Section 3-603.11).

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending the following changes to the Food Code:

1. That separate definitions be created in 1-201.10(B) for "mechanically tenderized" and "injected" using the following wording:

"Injected" meat means ~~manipulating a meat so that infectious or toxigenic microorganisms may be introduced from its surface to its interior through tenderizing with deep penetration or injecting the meat such as by processes which may be~~ to which liquid substances have been introduced by processes that are referred to as "injecting," "pinning," "pump marinating," or "stitch pumping."

"Mechanically tenderized" means manipulating meat with deep penetration by processes which may be referred to as "blade tenderizing", "jaccarding", "pinning", "needling", or using blades, pins, needles or any mechanical device; but does not include injecting solutions into meat.

2. That subparagraph 3-401.11(A)(2) Raw Animal Foods be revised to read:

(A)(2) 68°C (155°F) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites, mechanically tenderized, and injected meats:

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**Conference for Food Protection
2008 Issue Form**

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Delegate Action:	Accepted _____	Rejected _____	

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Title:

Guidelines on Tenderized Beef for Retail and Food Service Establishments

Issue you would like the Conference to consider:

The 2006 Conference recommended that a CFP committee should be created to provide peer review of the "Guidelines on Blade Tenderized Beef for Restaurants and Retail Food Establishments" and report back to the 2008 CFP on recommended changes to improve the document and possible changes to the code. In addition, the CFP recommended that the committee should consider recent data of contamination by *Salmonella* and *E. coli* O157:H7 and the impact on this by various processes including injected and mechanically tenderized beef steaks.

At the 2004 Biennial Meeting, Issue # 2004 III-032 "Provide guidance to retail establishments and restaurants on the handling of steaks that have been blade tenderized" was submitted and discussed. Council III members recommended and the delegates voted as follows: "The Conference recommends that the FDA and USDA work together and submit guidance for blade tenderized products at the 2006 Conference for Food Protection". The USDA, in consultation with FDA, developed the document "Guidelines for Tenderized Beef for Restaurants and Retail Food Establishments". The guidance material was based on recommendations from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and the Beef Industry Food Safety Council (BIFSCO) Best Practices document. These guidelines will help these establishments in establishing controls in the purchase, preparation, cooking or sale of these non-intact products. The charge was continued to the 2008 Biennial Meeting.

The CFP Committee tasked with reviewing this guidance document discussed and made changes to the guidance document. The guidance includes recommendations for the purchase of tenderized beef by restaurants or retail establishments, sanitation procedures, and the proper cooking of these products.

Public Health Significance:

E. coli O157:H7 foodborne illnesses associated with mechanically-tenderized or injected steaks have been reported in 2000, 2003, and 2004. In 2007, there were 3 reported foodborne illness outbreaks due to mechanically tenderized and injected beef. Although the level of surface contamination of steaks is expected to be very low, the number of *E. coli* O157:H7 necessary to cause illness also is very small - estimated to be approximately 4 CFU/gm. NACMCF, in evaluating the risk of *E. coli* O157:H7 in blade tenderized steaks concluded that: 1) non-intact blade-tenderized steaks served very rare with cold spots (less than 120° F internal temperature) present a concern/risk, particularly to immunocompromised individuals; 2) there was insufficient data to address the need for labeling of blade tenderized steaks at this time. In the absence of labeling requirements, this guidance document was developed to prevent contamination by *E. coli* O157:H7 or other pathogens during the production, handling, or preparation of blade tenderized beef, and other mechanically tenderized beef in retail establishments and restaurants.

The guidelines include measures that the retail establishments and restaurants can adopt to prevent contamination by *Escherichia coli* (*E. coli*) O157:H7 or other pathogens during the production, handling, or preparation of blade tenderized beef, and other mechanically tenderized beef. Restaurants and retail establishments receive steaks or similar cuts of meat that have been mechanically tenderized but typically are not labeled to signify that the products have been so treated. Section 3-401.11(C)(3) of the Food Code states that a raw or undercooked whole-muscle, intact beef steak may be served or offered for sale provided that it is cooked to a surface temperature of 63°C (145°F) or above and a cooked color change is observed on all exterior surfaces. These cooking recommendations should not be applicable to blade tenderized beef steaks or other mechanically tenderized and non-intact beef steaks because pathogens may contaminate below the surface during the tenderization process. In addition, generally, it is not possible to visually discern a blade tenderized beef steak from an intact beef steak. Consequently, neither the food service preparer nor the consumer would know that the cooking requirements of 3-401.11(C) (3) may not be sufficient to result in a safe product nor be able to use the appropriate cooking time and temperature to destroy any pathogens in the product.

Recommended Solution: The Conference recommends...:

That FDA add the CFP Committee peer-reviewed guidance document "Guidelines on Injected and Mechanically Tenderized Beef Steak for Retail and Food Service Establishments" (see attached) to Annex 2, Supporting Documents in the FDA Food Code.

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Attachments:

- "Guidelines on Injected and Mechanically Tenderized and Injected Beef Steak "

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.

Guidelines on Injected and Mechanically Tenderized and Injected Beef Steak for Retail and Food Service Establishments

The following guidelines are intended to control contamination by *Escherichia coli* (*E. coli*) O157:H7 and other pathogenic *E. coli* and *Salmonella* spp. during the production, handling, or preparation of mechanically tenderized or injected beef in food service establishments and retail food stores. Because control of *E. coli* O157:H7 and other pathogenic *E. coli* (e.g., other Shiga-toxin producing *E. coli* [STEC]) also controls for *Salmonella* and other vegetative pathogens, the recommendations will refer to *E. coli* O157:H7 control but will be inclusive of these foodborne pathogens.

The following guidelines for limiting contamination by *E. coli* O157:H7 during the production, handling, or preparation of blade tenderized beef can also be applied to other injected and mechanically tenderized beef in retail establishments. Tenderization is the process of treating whole muscle tissue by either a mechanical or chemical method to soften the meat tissues. Mechanical tenderization uses blades, needles, or pounding devices, etc. (e.g., blade-tenderized meat, pinned meat) to soften the meat tissue. Other forms of tenderization use chemicals or enzymes in marinating or needle injection processing steps. During mechanical tenderization, the blades or needles can transfer microorganisms from the surface of the meat to the interior (Johnston et al., 1978; Gill and McGinnis, 2004; Gill et al., 2005; Spring, 1999). Spring (1999) reported that overall the blade tenderization process transferred 3 – 4 % of the surface microorganisms

to the center of the muscle. Since cattle are considered a carrier of *E. coli* O157:H7, the primary consideration for either mechanical/chemical tenderization or marinade injection of beef is whether the establishment has controls to minimize the transfer of microorganisms to the interior, in particular *E. coli* O157:H7, from surface of the muscle tissue to the product interior.

Since 2000, several outbreaks of foodborne illness from *E. coli* O157:H7 have been attributed to mechanically tenderized beef or injected beef products (Table 1).

In 2000, two cases were linked to consumption of mechanically tenderized sirloin steaks at a national steakhouse restaurant chain. In 2003, the cases of foodborne illness were linked to mechanically tenderized and injected steaks produced at a federally inspected processing plant and sold door-to-door (Laine et al., 2005). The steaks in the 2003 outbreak were injected with a 12% solution that included water and flavorings. The steaks then underwent multiple passes through the blade tenderizing apparatus. A general cleaning and sanitizing of the blades was performed daily but a complete disassembly of the equipment for cleaning and sanitizing was performed only weekly. The vendor's recommendations to cook directly after removal from the freezer contradicted the safe handling instructions on the package to thaw before cooking. The cases in the 2004 outbreak were linked to consumption of tenderized, marinated beef steak at four separate restaurants of a national chain. In response to these outbreaks, FSIS published a Notice in the Federal Register (FSIS, 2005) indicating that as part of their annual reassessment of their HACCP plan, establishments producing mechanically

tenderized beef must take into account these outbreaks to determine if their HACCP plans adequately address biological hazards, particularly *E. coli* O157:H7. In 2007, eight cases of *E. coli* O157:H7 illness were associated with a small regional chain of restaurants that tenderized and injected a flavoring into steaks with illness occurring from consumption of steaks from five separate restaurants.

Table 1. Outbreaks of foodborne disease associated with injected and mechanically tenderized beef products			
Year	State	Treatment	Reference
2000	Michigan	Mechanically tenderized	FSIS (2005)
2003	Multistate	Mechanically tenderized and injected	Laine <i>et al.</i> (2005)
2004	Colorado	Mechanically tenderized and injected	FSIS (2005)
2007	Pennsylvania	Mechanically tenderized and injected	http://www.fsis.usda.gov/PDF/Recall_019_2007_Release.pdf Personal communication (2007)
2007	California	Needle injected	Personal communication (2007)
2007	Michigan	Mechanically tenderized	www.fsis.usda.gov/FSIS_Recalls/index.asp —

Blade tenderized and other mechanically tenderized meat, which is a significant portion of the meat supplied to and used by the restaurant and food store industry (in 1975, it was estimated that over 90% of hotel, restaurant, and institutional (HRI) operations utilized blade tenderization estimated (Sporing, 1999)), are not required to label the products as ‘blade tenderized’, ‘pinned’, or ‘mechanically tenderized’. Producers of meat injected with chemical tenderizers or flavoring marinades are required to include the term “(solution or tenderizer) added (or injected)” on the principal display panel, and the added ingredients in the ingredient statement of the label. In many instances, there is no difference in appearance between mechanically tenderized or injected and not mechanically tenderized or injected. Therefore, retailers and consumers may not be able to distinguish mechanically tenderized or injected beef from those that are intact.

Mechanically tenderized meat products are considered non-intact products.

Recommended time and temperatures for cooking intact products differ from those for cooking non-intact products. For example, surface searing of an intact steak may be adequate because of the absence of pathogens in its interior. However, identical searing of a non-intact steak may not deliver a lethal heat treatment to pathogens that may be present in the interior of the non-intact steak.

In order to assist retailers and consumers in distinguishing mechanically tenderized beef from beef that is not, the retailer should request that the supplier provide documentation from the processor/packer to disclose if the product is mechanically tenderized. Because mechanical tenderization will affect the recommended time and temperature necessary to

destroy pathogens like *E. coli* O157:H7, disclosing this information would help retailers and consumers in determining the proper time and temperature for cooking.

The retail establishment can prevent or control the potential hazard from *E. coli* O157:H7 at one or more of the following points in the process by applying some or all of the following guidelines at those points. The recommendations for retail establishments that do not tenderize or inject beef products before sale differ from those for establishments that do tenderize or inject beef products.

For Retail Establishments That Only Repackage Beef For Sale

Because mechanically tenderized beef is not labeled, the retail establishment may not be able to distinguish mechanically tenderized beef from intact beef cuts. Therefore, retail establishments should set up purchase specifications with the supplier to:

- Disclose on the package or accompanying document whether the beef product has been tenderized with a blade or needle.
- Send a letter of guaranty indicating whether the beef product has been mechanically tenderized with a blade or needle. Letters of guaranty from intermediate distributors who may not be aware whether meat has been mechanically tenderized are not adequate.
- Include all ingredients of the marinade, flavoring or tenderizing solution that has been injected into the meat.

The information can be detailed in the purchase specifications that the retail establishment sets up with its suppliers. The purchase specifications should be routinely reviewed and periodically updated. The information in the purchase specifications helps determine if the retailer that the product is tenderized or not. If such information is not provided, it should be assumed that the product has been tenderized for all future use, resale, repackaging and labeling of the products.

The retailer that repackages beef for sale may voluntarily disclose if the package contains tenderized or non-tenderized beef.

For Retail Establishments That Tenderize or Inject Beef

Retail establishments that mechanically tenderize or inject their products should apply measures to reduce the risk of contamination with *E. coli* O157:H7 and other pathogens during mechanical tenderization or injection. These controls include, but are not limited to, product temperature control, sanitation, product control, and labeling. (Much of the information for this section, except for labeling, was adapted from the Best Practices document (BIFSCO, 2005) that was developed for industry.)

- Product Temperature Control – To prevent the growth of any pathogens, particularly *E. coli* O157:H7 which has a minimum growth temperature of 46°F:

- Verify temperature of meat at delivery is 41°F or less [Food Code 3-202.11(A)].
 - Control cold holding temperature of product from delivery to sale by refrigerating immediately at 41°F or less [Food Code 3-501.16(A)(2)].
 - Maintain temperature control in the processing and storage areas.
 - Rotate product on first in-first out (FIFO) basis or on the basis of product shelf life.
 - Store and display raw meat at 41°F (5°C) or less according to the FDA Food Code [Food Code 3-501.16(A)(2)]. Since *E. coli* O157:H7 can grow at 46°F (8°C), it is important to refrigerate any mechanically tenderized or injected product well below this temperature to prevent multiplication in the meat interior which takes longer to reach lethality.
- Sanitation Program – A system for monitoring the completeness and effectiveness of the sanitation procedures.
 - Should be a written document that is designed to ensure sanitary conditions both before and during operations.
 - Should describe procedures for employee hygiene.
 - Should include proper cleaning and sanitizing procedures that describe the procedure for equipment breakdown to ensure effective and thorough cleaning and sanitizing.

- Must have as a primary focus the disassembly, cleaning and sanitizing of the equipment used for the mechanical tenderization or injection process.

These procedures are outlined below:

- Cleaning and sanitizing of equipment and floors before operation and during operation, especially reservoirs, and piping associated with mechanical tenderizing/flavoring operations.
 - Cleaning and sanitizing procedures for blades or needles that include frequency of procedures, and methods and chemical concentrations used.
 - Fully dismantling the needle or blade assembly for a thorough cleaning on a daily basis. Ideally, have 2 sets of blades or injector needles for dismantling and soaking in a sanitizing solution.
 - Use an antimicrobial agent (e.g., lactic acid) in the solution injected into the meat.
- Verify effectiveness of the sanitizing procedures.
 - Prevent cross-contamination of raw or ready-to-eat products.
 - Make the sanitation program available to all employees.
 - Train all employees responsible for the sanitation procedures.
- Employee Health
 - A written employee health policy must be in place to exclude ill food workers from the establishment.

- Product Control (Recommended procedures)
 - Code the product and provide sufficient documentation to allow trace back if necessary. Trace back procedures allow for effective recall on contaminated product.
 - Assigned lot codes may be based on product packaging dating.
 - Develop purchase specifications for the suppliers to ensure that the meat has been tested for *E. coli* O157:H7 using N=60 sampling methodology and that the supplier is using adequate sanitation procedures.

Alternatively, the product should be considered as untested, and thus, potentially harboring *E. coli* O157:H7.

- Labeling (Recommended procedures)
 - Identify any added marinade, flavoring or chemical tenderizers in the ingredient statement.
 - Disclose on consumer packages whether the product is mechanically-tenderized
 - Provide proper product handling and cooking instructions for mechanically-tenderized or injected beef products.

For Retail Establishments That Cook or Thermally-Process Mechanically Tenderized or

Injected Beef Steaks

Injected and other mechanically tenderized beef products are considered non-intact products. Time and temperatures for cooking non-intact products differ from those for cooking intact products. Intact steaks would have contamination on the cut surfaces, and therefore cooking by searing can inactivate pathogens on the surface. However, mechanically tenderized or injected steaks would have contamination below the surface, where the needles, blades or pins penetrate and would need more rigorous cooking that penetrates the muscle.

Therefore, the retail establishment or the consumer cooking the beef product should read the label for validated cooking instructions. If the retail establishment cooks or otherwise thermally processes mechanically-tenderized raw beef for sale, it should be aware that some methods of preparation deliver a greater lethality than other methods. Spring (1999) investigated three methods of preparation for blade-tenderized steaks – oven broiler, electric skillet, and commercial gas grilling. Cooking in an electric skillet was found the least effective in reducing the level of pathogens, not consistently achieving a 5- \log_{10} reduction of *E. coli* O157:H7 even at 170°F (76.7°C). With the skillet method, there was considerable variability in the temperature delivered to the product.

Commercial gas grilling was found to provide a greater reduction of *E. coli* O157:H7 than the skillet at the same temperature but less than the broiler oven. A 5- \log_{10} reduction of *E. coli* O157:H7 was achieved with commercial gas grilling only when an internal temperature of 150°F (65.6°C) was reached. Cooking in an oven broiler to 140°F (60°C) was found to provide the most consistent results, achieving a 5- \log_{10} reduction of *E. coli* O157:H7. However, a risk assessment conducted by FSIS (2002) indicated that there was

no difference in the reduction of *E. coli* O157:H7 in intact (non-tenderized) compared to non-intact (tenderized) beef steaks that were broiled, regardless of temperature of cooking used.

The final internal temperature that must be achieved for blade-tenderized steaks, comminuted and injected meats, which are all considered non-intact, is 155°F (68°C) for 15 seconds or these times and temperatures listed in the chart for Section 3-401.11(A)(2) of the Food Code. Those establishments that cook these products at a lower internal temperature, e.g., as requested by the consumer, must provide a consumer advisory with a disclosure and reminder [Food Code 3-603.11]. However, this alternative may not be used by food establishments that serve highly susceptible populations, such as nursing homes or hospitals [Food Code 3-801.11(C)]. A whole-muscle, intact steak as identified by the processor by disclosure or letter of guaranty may be served or offered for sale in a ready-to-eat form by cooking to a surface temperature of 145°F (63°C) or above and a cooked color change is achieved on all external surfaces [Food Code 3-401.11(C)(3). It is best to always use a thermometer to ensure that correct temperature is achieved during cooking.

This guidance on cooking of mechanically tenderized beef is also applicable to beef with ingredients added to induce tenderization, such as marinated meat or injected beef.

Producers of injected beef are required to declare on the label that a solution was added (by injection or marination), and the added solution is declared in the ingredient section of the label. If a retail establishment or restaurant receives these tenderized beef products,

it should use the same guidance for cooking them as delineated for mechanically-tenderized steaks on these products.

Food service establishments have the option of serving a mechanically tenderized or injected beef steak that is surface seared, undercooked (rare), if a disclosure and reminder of a consumer advisory is posted.. This would give the consumer information regarding the product purchased. Alternatively, the retail establishment could treat all raw beef that are not labeled as if they have been tenderized, and cook these to at least 155°F (68°C) for 15 seconds. Similarly, if an establishment knows that the beef is mechanically tenderized, it could refuse to cook those products to a temperature less than 155°F (68°C) for 15 seconds.

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**Conference for Food Protection
2008 Issue Form**

**Internal Number: 010
Issue: 2008 III-004**

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:

Report: Food Allergen Committee

Issue you would like the Conference to consider:

The Food Allergen Committee seeks Council III acknowledgement of the Committee Report and recommends the re-creation of the Food Allergen Committee.

Public Health Significance:

Food allergy is now considered a public health and food safety concern which affects one in 25 Americans. It is estimated to affect 1 in 17 children under age 3. Eight foods account for 90 percent of the reactions: milk, eggs, peanuts, tree nuts, fish, shellfish, wheat, and soy. Scientists believe food allergies are increasing; the cause is unknown. The only way for affected individuals to prevent an allergic reaction is to avoid the food allergen. To do so requires education and awareness of the food industry and regulators to provide accurate and reliable ingredient information to consumers.

Recommended Solution: The Conference recommends...:

acknowledgement of the Food Allergen Committee Report with thanks to the Committee Members for their work during the past two years, and re-creation of the Food Allergen Committee with the charge to:

- continue working on current and emerging food allergy issues affecting consumers, industry and government;
- work directly with the FDA pertaining to The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 (*continuation charge from the 2004 Biennial meeting*);

and

- report back to the 2010 CFP Biennial Meeting.

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Attachments:

- "Food Allergen Committee Report"

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 2006-2008
Executive Board Meeting Committee Update**

Council III – Food Allergen Committee

Date of Committee Report: January 10, 2008

Submitted By: Anne Munoz-Furlong, Co-Chair

Committee Charge(s):

1. Work directly with the FDA pertaining to The Food Allergen Labeling and Consumer Protection Act of 2004, which may include the review of guidelines for the foodservice and retail industries, to include: assisting in developing a list (albeit not exhaustive) of ingredients and sub-ingredients that are, in fact, major food allergens (as defined by FALCPA), along with their common or usual name to assist industry and regulators in identifying when a recipe contains a major food allergen;
2. Work to identify and deliver food allergen information to state/local regulatory officials, food managers, health professionals, and food employees through appropriate marketing/outreach channels.
3. Report any additional recommendations to the Executive Board prior to the 2008 CFP meeting.

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CONSUMER

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Progress Report/Committee Activities

Following is an update on the three charges of our committee.

Charge #1: Work directly with the FDA pertaining to The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004, which may include the review of guidelines for the foodservice and retail industries, to include: assisting in developing a list (albeit not exhaustive) of ingredients and sub-ingredients that are, in fact, major food allergens (as defined by FALCPA), along with their common or usual name to assist industry and regulators in identifying when a recipe contains a major food allergen;

Status: We are waiting to receive the report from FDA regarding FALCPA and how we can be of assistance to fulfill the first charge of our committee. No progress has been made. Charge to be continued.

Charge #2: Work to identify and deliver food allergen information to state/local regulatory officials, food managers, health professionals, and food employees through appropriate marketing/outreach channels.

Status: The committee has reviewed and developed materials to fulfill this charge.

See Issues titled:

“Food allergy info for restaurant & food service managers & employees”

“Advice to Food-Allergic Individuals from Prof. Medical Societies”

“Food Allergy information for state/local regulatory officials”

The Food Allergen committee was divided into three subcommittees—1) food managers and food employee, 2) state/local regulatory, and 3) health professional/consumer.

The committee believes that awareness and education for each stakeholder is necessary. All three subcommittees have developed recommendations, including examples of materials, to be submitted to CFP as issues, to fulfill the second charge of our committee. The materials include a power point presentation to be used as a training aid for regulators, a sample letter to medical professional societies, sample awareness poster information, and a sample allergen check list for food suppliers and manufacturers.

Charge #3: Report any additional recommendations to the Executive Board prior to the 2008 CFP meeting.

We submitted a request and received approval to include celiac in the health professionals food allergen information.

Requested Actions

We believe there is an ongoing need for the Food Allergen Committee. With emerging allergens, new legislation, consumer concerns, and so many other areas of interest as related to food allergens, there would be no shortage of issues to review. Therefore, our committee respectfully requests re-creating the Food Allergen Committee of the CFP.

**Conference for Food Protection
2008 Issue Form**

**Internal Number: 012
Issue: 2008 III-005**

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:

Advice to Food-Allergic Individuals from Professional Medical Societies

Issue you would like the Conference to consider:

The Food Allergen Committee respectfully requests that the Conference for Food Protection (CFP) send a letter to leading professional medical societies suggesting that they provide educational materials to patients with strategies for how to dine in restaurants safely. Food-allergic individuals (FAI) need advice/guidance concerning the inherent risks involved with eating food served in or provided by a restaurant or food service establishment. Unfortunately, lack of this advice/guidance contributes to food-allergy reactions and fatalities.

Public Health Significance:

A) Food allergy is an increasing food safety and public health issue, affecting approximately 4% of the U.S. population, or twelve million Americans. An Estimated 6.8 million Americans are allergic to seafood; three million are allergic to peanuts/tree nuts. Severe allergic reactions to foods (anaphylaxis) account for 30,000 emergency room visits, 2,000 hospitalizations, and 150 deaths each year in the U.S.

B) A review of 63 cases of fatal food-allergic reactions, showed *almost half* of the reactions involved food provided by restaurants or food service establishments.[i],[ii]

C) Restaurant and retail food service employees generally receive little or no training on crucial issues such as: the serious nature of food allergies; understanding ingredient labels; the importance of avoiding accurate, complete and reliable ingredient information; and avoiding cross contact during food preparation.

To illustrate, in a recently published survey of restaurant personnel, 24% of the respondents indicated that consuming a small amount of a food allergen would be safe; 35% believed that fryer heat would destroy an allergen; 54% considered a buffet safe if

kept "clean"; and 25% thought that removing an allergen from a finished meal (e.g., removing nuts from a dish) was safe.[iii] None of these statements are true.

D) Unfortunately, the fatality studies cited above, and other studies of food allergy-induced reactions in restaurants and retail food service have shown that the FAI did not take the proper precautionary steps to minimize risks such as avoiding high-risk foods including desserts, sauces or fried foods. Food-allergic individuals should be advised to clearly identify themselves to food service employees as having a food allergy. *However, the advice to do so is often NOT conveyed directly to the food allergic individual by their health care provider.*

E) Celiac disease (also known as celiac sprue and gluten sensitive enteropathy) is not a true food allergy, but an immune response to dietary glutens predominately found in wheat, barley, and rye. Celiac disease is a lifelong condition with no cure affecting an estimated 3 million Americans. Strict avoidance of gluten in the diet is the only known means of preventing the complications of celiac disease.

[i] Bock SA, Muñoz-Furlong A, Sampson HA. Fatalities due to anaphylactic reactions to foods. Journal of Allergy and Clinical Immunology 2001;107:101-3.

[ii] Bock SA, Muñoz-Furlong A, Sampson HA. Further fatalities caused by anaphylactic reactions to food, 2001-2006. Journal of Allergy and Clinical Immunology 2007 Apr; 119(4)1016-8.

[iii] Ryan Ahuja and Scott H. Sicherer. Food-allergy management from the perspective of restaurant and food establishment personnel. Annals of Allergy, Asthma & Immunology 2007;98:344-348.

Recommended Solution: The Conference recommends...:

that the Conference Chair send a letter on behalf of the Conference for Food Protection to leading professional medical societies such as the American Medical Association, the American Academy of Pediatrics, the American Academy of Allergy, Asthma & Immunology, and the American College of Allergy, Asthma & Immunology, the American Dietetic Association, and the American College of Family Physicians, urging them to distribute information to food-allergic patients concerning safe dining strategies at restaurants and other food service establishments, including:

- Selecting restaurants wisely - for example, avoiding seafood houses if fish or shellfish allergic.
- Speaking to the manager or other person in charge regarding food allergy questions.
- Avoiding high risk foods such as fried foods unless cooked in a designated fryer, desserts and sauces.
- Being prepared to quickly handle an allergic reaction.

See attached sample letter titled: *Proposed Draft of Letter to Professional Medical Societies*.

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Attachments:

- "Proposed Draft of Letter to Professional Medical Societies"

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.

Proposed Draft of Letter to Professional Medical Societies

As the leading professional medical societies in the United States, the Conference for Food Protection (CFP) urges you to distribute information to patients with food allergy or celiac disease concerning dining at restaurants and other food service establishments.

Food allergy is an increasing food safety and public health issue, affecting approximately 4% of the U.S. population, or twelve million Americans. An estimated 6.8 million Americans are allergic to seafood; three million are allergic to peanuts/tree nuts.

Severe reactions, or anaphylaxis, to foods account for 30,000 emergency room visits, 2,000 hospitalizations, and 150 deaths each year in the U.S.

There is no cure for food allergy; strict avoidance of the allergen is the only way to prevent a reaction. Avoidance is difficult because even a trace amount of an allergen is enough to trigger a severe, life-threatening reaction.

Food allergy reactions are often the result of food served in or provided by restaurants and other food service establishments (school cafeterias, catered events, food vendors, etc.). Unfortunately, many of these reactions are fatal. In a review of 63 cases of food-induced fatalities, *almost half* involved food provided by restaurants or food service establishments.

The fatality research cited above, along with other studies of food allergy-induced reactions in restaurants, have shown that the individual did not take the proper precautionary steps to minimize risks such as avoiding high-risk foods such as desserts, sauces or fried foods. Food-allergic individuals should be advised to clearly identify themselves to restaurant staff.

Celiac disease (also known as celiac sprue and gluten sensitive enteropathy) is not a true food allergy, but an immune response to dietary glutens predominately found in wheat, barley, and rye. Celiac disease is a lifelong condition with no cure affecting an estimated 3 million Americans. Strict avoidance of gluten is the only known means of preventing symptoms of celiac disease.

The CFP urges you to distribute information to food-allergic patients and/or celiac patients concerning the inherent risks involved with eating at restaurants and other food service establishments. Safe dining strategies include:

- Selecting restaurants wisely – for example, avoiding seafood houses if allergic to fish or shellfish.
- Speaking to the manager or other person in charge regarding food allergy questions.
- Avoiding high risk foods such as fried foods unless cooked in a designated fryer, desserts, and sauces.
- Being prepared to quickly handle an allergic reaction.

Providing food-allergic individuals with this information will prevent reactions and fatalities.

The Conference for Food Protection (CFP), which meets at least biennially, is a powerful organization that identifies emerging problems of food safety and formulates recommendations. The CFP is managed by an Executive Board representing local, state, and federal food regulatory agencies, the food industry, academia, and consumer organizations. The first Conference for Food Protection was sponsored in 1971 by the U.S. Food and Drug Administration and the American Public Health Association.

**Conference for Food Protection
2008 Issue Form**

**Internal Number: 011
Issue: 2008 III-006**

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:

Food allergy info for restaurant & food service managers & employees

Issue you would like the Conference to consider:

The Food Allergen Committee requests that the Conference for Food Protection (CFP) provide a venue for educational materials regarding the eight major allergens to restaurant and food service managers and employees.

The FALCPA (Food Allergen Labeling and Consumer Protection Act) was effective January 1, 2006 and requires labels to disclose the eight most common allergens in a manner clearly identifiable to the consumer: crustacean (e.g., crab, shrimp), egg, fish (e.g., bass, cod), milk, peanut, soy, tree nuts (e.g., almonds, pecans, walnuts), and wheat. These eight allergens account for over 90% of all food allergies. Allergen awareness is important not only for good consumer service and safety but also as a requirement of the Section 2-102.11(C)(9) of the 2005 Food Code. The person in charge must have an understanding of allergens and the foods within his establishment that may contain them.

The attached "*Sample Retail Allergen Awareness*" educational information includes an example of what is required and includes both corporate and store level requirements to make information readily available to customers via websites, hotlines, etc.

Public Health Significance:

A) Food allergy is an increasing food safety and public health issue, affecting approximately 4% of the U.S. population, or twelve million Americans. An Estimated 6.8 million Americans are allergic to seafood; three million are allergic to peanuts/tree nuts. Severe allergic reactions, or anaphylaxis, to foods account for 30,000 emergency room visits, 2,000 hospitalizations, and 150 deaths each year in the U.S.

B) A review of 63 cases of fatal food-allergic reactions, showed *almost half* of the reactions involved food provided by restaurants or food service establishments.[i],[ii]

C) Restaurant and retail food service employees generally receive little or no training on crucial issues such as: the serious nature of food allergies; understanding ingredient labels; the importance of avoiding accurate, complete and reliable ingredient information; and avoiding cross-contact during food preparation.

To illustrate, in a recently published survey of restaurant personnel, 24% of the respondents indicated that consuming a small amount of a food allergen would be safe; 35% believed that fryer heat would destroy an allergen; 54% considered a buffet safe if kept "clean"; and 25% thought that removing an allergen from a finished meal (e.g., removing nuts from a dish) was safe.[iii] None of these statements are true.

D) Unfortunately, the fatality studies cited above, and other studies of food allergy induced reactions in restaurants and retail food service have shown that the individual did not take the proper precautionary steps to minimize risks such as avoiding high-risk foods including desserts, sauces or fried foods. Food-allergic individuals should be advised to clearly identify themselves as having a food allergy. *However, this advice is often not conveyed directly to the food allergic individual.*

[i] Bock SA, Muñoz-Furlong A, Sampson HA. Fatalities due to anaphylactic reactions to foods. *Journal of Allergy and Clinical Immunology* 2001;107:101-3.

[ii] Bock SA, Muñoz-Furlong A, Sampson HA. Further fatalities caused by anaphylactic reactions to food, 2001-2006. *Journal of Allergy and Clinical Immunology* 2007 Apr; 119(4)1016-8.

[iii] Ryan Ahuja and Scott H. Sicherer. Food-allergy management from the perspective of restaurant and food establishment personnel. *Annals of Allergy, Asthma & Immunology* 2007;98:344-348.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending a modification to the Food Code to require that educational food allergen awareness materials be posted in all food establishments in a location visible to all employees, and that an example of the required information be available in the Food Code Annex; including:

- what the Person in Charge needs to know to answer questions from an inspector;
- store level actions for informing consumers and disclosing ingredient information; and
- strategies for avoiding cross contact.

A sample of this information is attached to this Issue as "*Sample Retail Allergen Awareness.*"

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Attachments:

- "Sample Retail Allergen Awareness Materials"

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.

Sample Retail Allergen Awareness

POST THIS ALLERGEN AWARENESS POSTER IN A VISIBLE LOCATION FOR ALL EMPLOYEES

Requirements for Owners/Managers:

You must be able to answer the following questions from an inspector.

Describe foods identified as major food allergens. See list below:

Milk	Soybeans
Eggs	Fish (such as bass, flounder, cod, trout)
Wheat	Crustacean shell fish (such as crab, lobster, shrimp)
Peanuts	Tree Nuts (such as almonds, pecans, walnuts, coconut)

Describe symptoms that a major food allergen could cause in a sensitive individual who has an allergic reaction:

Gastrointestinal - Nausea, vomiting, diarrhea, abdominal pain

Systemic - Anaphylactic shock, Hives, rash, welts, itchy, skin inflammation

Respiratory - Sneezing, congestion, itchy throat, eyes, ears, and nose, airway constriction

Store Level Actions:

Advise Customers to read the ingredient statements on packaged foods

Familiarize yourself with allergens found in unpackaged food

Direct customer to 1-800 ____ ____ line if unsure or to a web link if available

If a Customer asks a question about an ingredient and you don't know the answer-don't guess!
Tell the customer you don't know and refer them to website or hotline.

Keep your equipment and display cases clean

- Follow your good retailing practices for keeping equipment clean
- Be prepared to provide ingredient labels.
- If sampling an item, clearly identify to the customer allergen content if any

**Conference for Food Protection
2008 Issue Form**

**Internal Number: 013
Issue: 2008 III-007**

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:

Food Allergy information for state/local regulatory officials

Issue you would like the Conference to consider:

The CFP Food Allergen Committee requests that the Conference for Food Protection (CFP) provide food allergen resource information for state/local regulatory officials to improve their knowledge of allergen issues. The information could be posted on the CFP website.

The information would include allergen ingredient listing, allergen guide for retail food establishments, food allergen labeling requirements, allergen checklist for food suppliers and manufacturers, and a power point presentation, for state/local regulatory officials to use as presented or to adapt to their needs for training and education.

Public Health Significance:

Food allergies affect 1 in 25 Americans and 1 in 17 children under age 3 and the incidence is rising. There is no cure; strict avoidance of the allergen is the only way to avoid a reaction. Food allergy reactions are estimated to cause 30,000 emergency room visits and 150 to 200 deaths each year. Teenagers are the highest risk group for fatal reactions. Close to 50% of fatal reactions are caused by food from restaurants or retail food service establishments, according to several studies. Tens of thousands of other reactions occur, which do not require emergency medical attention.

Studies indicate that reactions are caused from undeclared allergens on packaged food products and from food served in restaurants or retail food establishments. Increased information and knowledge of allergen issues by retail food regulatory inspectors and retail food industry workers will reduce the potential for allergic reactions due to cross contact and labeling omissions.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending that food allergen resource information be included as part of the recommended curriculum in the *FDA Voluntary National Retail Food Regulatory Program Standards, Standard #2, Trained Regulatory Staff* and that a compendium of educational materials be made available to state/local regulators. Examples of educational materials currently available are attached to this Issue:

- *"Sample Allergen Check List for Food Suppliers and Manufacturers"*
- *"MN Allergen Labeling Document"*
- *"MN Allergen Awareness PowerPoint Presentation"*

The Conference further recommends that the Food Allergen Awareness Committee work with the FDA Office of Regulatory Affairs University (ORA U) to develop an appropriate educational component regarding food allergen awareness.

Submitter Information:

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Attachments:

- *"Sample Allergen Check List for Food Suppliers and Manufacturers"*
- *"MN Allergen Labeling Document"*
- *"MN Allergen Awareness Power Point Presentation"*

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.

SAMPLE ALLERGEN CHECK LIST FOR FOOD SUPPLIERS AND MANUFACTURERS

Product Name: _____ UPC Code: _____

For each product complete the table below:

Column I indicates the allergens that may be found in the product, from addition or cross-contact.

Column II indicates the allergens present in other products that are run on the **same** equipment but at a different time.

Column III indicates whether any allergens are present in your plant.

Please fill in each cell of the table with a **YES** or **NO** and, when applicable, include the name of the ingredient. **DO NOT LEAVE EMPTY CELLS.**

	Column I	Column II	Column III
Food Ingredients that may cause allergies (Check back of this page for additional derivatives)	Present in the Product	Present in other products manufactured on the same line	Present in the same manufacturing plant
Peanut or its derivatives , e.g., Peanut pieces, protein, oil, butter, flour, and mandelona nuts (an almond flavored peanut product) etc. Peanut may also be known as ground nut.			
Tree Nuts [almonds, Brazil nuts, cashews, hazelnuts (filberts), macadamia nuts, pecans, pine nuts, (pinyon, pinon) pistachios and walnuts] or their derivatives , e.g., nut butters and oils, protein, pieces, etc.			
Milk or its derivatives , e.g., milk caseinate, whey, isolates, milk protein concentrates, yogurt, powdered products, etc.			
Eggs or its derivatives , e.g., frozen yolk, egg white, powder, and egg protein isolates, etc.			
Fish or its derivatives , e.g., fresh water or saltwater, octopus, squid, fish protein and extracts, oils, etc.			
Crustaceans (including crab, crayfish, lobster, prawn, and shrimp) and Shellfish (including snails, clams, mussels, oysters, cockle and scallops) or their derivatives , e.g., extracts, etc.			
Soy or its derivatives , e.g., lecithin, oil, tofu, and protein isolates, etc.			
Wheat or its derivatives , e.g., flour, starches, and brans, etc.			
Others: Sulfites - sulfur dioxide and sodium metabisulfite, FD&C #5 , etc.			

Do you have procedures to avoid cross-contact of the product with the allergens not present in the product but noted in Columns II and III? **YES** or **NO**

Please attach a finished product label to this form for each product. If, for any reason, there are any modifications in this product, you are responsible for updating your records including labels and specifications.

Facility Name: _____

Facility Address: _____

Facility Contact: _____ Signature: _____ Date: _____

Inspectors Name: _____ Signature: _____ Date: _____



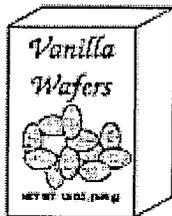
Food Allergen Labeling Requirements

All packaged foods regulated under the Federal Food, Drug, and Cosmetic Act (FFD&C Act) that are labeled on or after January 1, 2006, must comply with food allergen labeling requirements found in the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004. FALCPA's labeling requirements extend to retail and food-service establishments that package, label, and offer products for human consumption. FALCPA's labeling requirements do not apply to foods that are placed in a wrapper or container in response to a consumer's order - such as the paper or box used to provide a sandwich ordered by a consumer. However, FDA advises consumers who are allergic to particular foods to ask questions about ingredients and preparation when eating at restaurants or any place outside the consumer's home.

The Act identifies eight foods or food groups as the major food allergens. They are milk, eggs, fish (e.g., bass, flounder, cod), Crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, walnuts, pecans), peanuts, wheat, and soybeans.

It requires that food manufacturers and retailers label food products that contain ingredients, including a flavoring, coloring, or incidental additive that are, or contain protein from a major food allergen using plain English to identify the allergens. This can be accomplished in one of two ways.

1. Include the name of the food source in parenthesis following the common or usual name of the major food allergen in the list of ingredients in instances when the name of the food source of the major allergen does not appear elsewhere in the ingredient statement. For example:



Ingredients: Enriched flour (wheat flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, partially hydrogenated soybean oil, and/or cottonseed oil, high fructose corn syrup, whey (milk), eggs, vanilla, natural and artificial flavoring) salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin (soy), mono-and diglycerides (emulsifier)

2. Place the word "Contains" followed by the name of the food source from which the major food allergen is derived, immediately after or adjacent to the list of ingredients, in type size that is no smaller than the type size used for the list of ingredients. For example:

Contains Wheat, Milk, Eggs, and Soy

If a "Contains" statement is used on a food label, the statement must include the names of the food sources of all major food allergens used as ingredients in the packaged food. For example, if "sodium caseinate," "whey," "egg yolks," and "natural peanut flavor" are declared in a product's ingredients list, any "Contains" statement appearing on the label immediately after or adjacent to that statement is required to identify all three sources of the major food allergens present (e.g., "Contains milk, egg, peanuts") in the same type (i.e., print or font) size as that used for the ingredient list.

Specific requirements:

- In the case of tree nuts, the specific type of nut must be declared (e.g., almonds, pecans, or walnuts).
- The species must be declared for fish (e.g., bass, flounder, or cod) and Crustacean shellfish (crab, lobster, or shrimp).
- "Soybean," "soy," and "soya" are reasonable synonyms for the common or usual name "soybeans," and any one of these terms may be used to identify the food source of the major food allergen "soybeans." Packaged foods that are made using soybeans as an ingredient or as a component of a multi-component ingredient (e.g., soy sauce or tofu) should continue to use the word "soybeans" as the appropriate common or usual name for this ingredient to identify properly the ingredient (e.g., "soy sauce (water, wheat, soybeans, salt)").
- Exempted products:
 - raw agricultural commodities (generally fresh fruits and vegetables) are exempt as are
 - highly refined oils derived from one of the eight major food allergens and any ingredient derived from such highly refined oil.

References:

- Guidance for Industry Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004
<http://www.cfsan.fda.gov/~dms/alrguid2.html>
- Advice to Consumers: Food Allergen Labeling And Consumer Protection Act of 2004 Questions and Answers <http://www.cfsan.fda.gov/~dms/alrgqa.html>
- Food Allergen Labeling and Consumer Protection Act of 2004
<http://www.cfsan.fda.gov/~dms/alrgact.html>

**MN Dept of Agriculture
Dairy, Food, Feed and Meat Inspection Division
625 Robert St N St Paul MN 55155
651-201-6027**

Allergen Awareness

Minnesota Dept of Agriculture
Dairy and Food Inspection
Division

Why the concern?

- It is estimated that **2 percent of adults** and about **5 percent of infants** and young children in the United States suffer from food allergies.
- Approximately **30,000 consumers** require emergency room treatment and **150 Americans die each year** because of allergic reactions to food.

Eight major food allergens

Account for 90 percent of all documented food allergic reactions:

- Milk and Milk products
- Eggs
- Legumes (peanuts and soy)
- Tree Nuts
- Wheat
- Crustaceans
- Fish
- Shellfish

Is there a problem?

- Allergen survey in Minnesota and Wisconsin in 1999, FDA found that **25 percent of sampled foods failed to list peanuts or eggs as ingredients** on the food labels although the foods contained these allergens.
- Consumers are unable to recognize *derivatives* of the big 8 allergens.

Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004

- **Effective January 1, 2006**, the Food and Drug Administration (FDA) is requiring food labels to clearly state if food products contain any ingredients that contain protein derived from the eight major allergen food types.

How will food labels change as a result of FALCPA?

- FALCPA requires the labeling on food products that contains an ingredient that is, or contains, a protein from a major food allergen to be declared in **one of two ways**.

The first option:

- To include the **name of the food source in parenthesis** following the common or usual name of the major food allergen in the list of ingredients (in instances when the name of the food source of the major allergen does not appear elsewhere in the ingredient statement).

Example: Option 1

Ingredients: Enriched flour (wheat flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, partially hydrogenated soybean oil, and/or cottonseed oil, high fructose corn syrup, whey (milk), eggs, vanilla, natural and artificial flavoring) salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin (soy), mono-and diglycerides (emulsifier)

The second option:

Is to place the word "**Contains**" followed by the name of the food source from which the major food allergen is derived, **immediately after or adjacent to the list of ingredients**, in type size that is no smaller than the type size used for the list of ingredients.

Example: *Contains Wheat, Milk, and Soy*

Example: Option 2

Ingredients: Enriched flour (wheat flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, partially hydrogenated soybean oil, and/or cottonseed oil, high fructose corn syrup, whey, eggs, vanilla, natural and artificial flavoring) salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin, mono-and diglycerides (emulsifier)

Contains Wheat, Milk, and Soy

Type or species:

- FALCPA requires the **type of tree nut** (e.g., almonds, pecans, walnuts); the **type of fish** (e.g., bass, flounder, cod); and the **type of Crustacean shellfish** (e.g., crab, lobster, shrimp) to be declared.

Both domestic and imported foods.

- FALCPA's requirements apply to **all packaged foods** sold in the U.S. **that are regulated under** the Federal Food, Drug, & Cosmetic Act, including **both domestic and imported foods**.
- FDA regulates all foods except meat products, poultry products, and egg products.

Are flavors, colors, and food additives subject to the allergen labeling requirements?

- **Yes.** FALCPA requires that the label of food products that contain ingredients, **including a flavoring, coloring, or incidental additive that are (or contain) a major food allergen** use plain English to identify the allergens.

Are there any foods exempt from the new labeling requirements?

- **Yes.** Under FALCPA, raw agricultural commodities (generally **fresh fruits and vegetables**) are exempt as are **highly refined oils** derived from one of the eight major food allergens and any ingredient derived from such highly refined oil.

Incidental additives

- Processing aids that contain allergenic ingredients are not exempt from ingredient declaration under the incidental additives regulation (21 CFR 101.100(a)(3)), and therefore, must be declared.

Is a major food allergen that has been unintentionally added, as the result of cross-contact, subject to labeling requirements?

- **No.** FALCPA's labeling requirements do not apply to major food allergens that are **unintentionally added** to a food as the result of cross-contact.
- Cross-contact may result from methods of growing and harvesting crops, as well as, from the use of shared storage, transportation, or production equipment.

Advisory Labeling

- FALCPA does not address the use of advisory labeling for **unintentional ingredients** resulting from the manufacturing process.
- FDA advises that advisory labeling such as "may contain [allergen]" **should not be used as a substitute for adherence to current Good Manufacturing Practices.**
- In addition, any advisory statement such as "may contain [allergen]" must be truthful and not misleading.

Must products with labels that do not comply with FALCPA be removed from sale once the new labeling law is effective?

- **FALCPA does not require any action with respect to products labeled before January 1, 2006.**
- **Products that are labeled after 1/1/06 that do not comply are considered misbranded.**

What to look for during an inspection for allergens.



Ingredient Purchasing & Storage

- Obtain a fully disclosed ingredient list.
- Protect raw ingredients in storage to prevent cross contact.
- Label raw material to indicate allergen content.
- Take care when you substitute raw materials.

Production

- **Production scheduling for allergen vs. non-allergen**
- **Do not allow reuse of single service articles.**
- **Dedicate separate utensils or equipment to allergenic products.**
- **Protect work-in-progress from cross-contact with allergenic ingredients.**
- **Limit use of rework.**
- **Proper sanitation (follow SSOP's)**

Display/Service

- For bulk food displays, use dedicated trays and utensils or display areas.
- If foods with allergenic ingredients can not be adequately separated, offer only as a packaged food.
- In-store demos should prominently display product ingredients.
- Do not provide product to unaccompanied children.

Questions/comments?

Minnesota Department of Agriculture



**Conference for Food Protection
2008 Issue Form**

**Internal Number: 039
Issue: 2008 III-008**

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:

Report: Barrier Hazards Committee

Issue you would like the Conference to consider:

There have been anecdotal reports of severe allergic reaction to proteins found in latex gloves in food service. These reactions are primarily from wearing gloves while preparing food, but there has also been an instance of an extremely sensitized individual reacting to the proteins on a sandwich prepared by a glove-wearing individual.

Therefore the Barrier Hazards Committee was charged to work with the FDA to investigate the unintended allergenic and toxicological consequences of the use of barriers when handling ready-to-eat (RTE) foods. In addition to exploring issues with latex, the Committee also sought reports of reaction to the petrol-chemical compounds found in non-latex gloves.

The 2008 Barrier Hazards Committee Report is attached.

Public Health Significance:

The establishment of a barrier between hands and RTE food is an important element of food safety methodologies advocated by the FDA in the Food Code. It is imperative that such barriers do not cause unintended consequences which may lead operators or individuals to disregard the use of such barriers.

Recommended Solution: The Conference recommends...:

acknowledgement of the Conference for Food Protection Barrier Hazard Committee report and thanks the Committee members for their work during the past two years.

Additionally, the Conference recommends that a letter be sent to the FDA, USDA, and CDC recommending that further research be conducted into the hazards of using latex

gloves in food service, and making any necessary changes to the Food Code and other regulations to prevent unintended adverse reactions to food workers and consumers.

Submitter Information:

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Attachments:

- "Final Barrier Hazard Committee Report"

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 2006-2008
Executive Board Meeting Committee Update – Council III- Barrier Hazards Committee Report**

Date of Committee Report: January 9, 2008

Submitted By: Gregory A. Pallaske, Chair

Committee Charge(s): Work with the FDA to investigate the unintended allergenic and toxicological consequences of the use of barriers when handling ready-to-eat (RTE) foods.

Committee:

Name	Constituency (Fed, State, Local, Industry, Consumer, Academia, Other)	Employer	Email
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Roger Coffman	Local Regulatory	Lake Co (IL) Dept of Health	rcoffman@co.lake.il.us
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Greg Pallaske (Chair)	Industry	US Foodservice	Greg.pallaske@usfood.com

Progress Report/Committee Activities:

The committee first tried to search the literature for non-medical examples of latex allergy issues- specifically, describing (with documentation) incidents where a food service worker, or a customer, had a serious reaction to latex. Nearly all of the information available discusses latex reactions in healthcare employees. The committee felt that latex allergies must be related to the Food Code in order to seek change via the National Conference for Food Protection (NCFP) or the U.S. Food and Drug (FDA) Administration.

Result: we were unable to find medically documented incidents in sufficient numbers to warrant an issue submission. Even the anecdotal incidences seem to be less frequent than they were 5 years ago.

Unfortunately, there is no central clearinghouse for latex reaction reports. The FDA/CFSAN Adverse Event Reporting System (CAERS) reported they would not have any Adverse Event reports as (latex)

gloves aren't a CFSAN product. Other web sites on allergic reactions, anaphylactic shock, and food allergens do not maintain records of medically documented food service-related reactions to latex.

The committee also sought reports of reaction to the petrol-chemical compounds found in non-latex gloves. Again, the results were negative.

Finally, the committee reviewed available glove technologies:

Summary of Current, Most Commonly Utilized Disposable Food Service Glove Materials

Sources and Notes:

- NSF Protocol P155 for Food Contact Disposable Gloves / latest version is October 2005.
- The NSF document covers polyethylene, vinyl, natural rubber latex, synthetic blends, and nitrile.
- ASTM had no standard for polyethylene gloves of any kind, so NSF created that portion of P155.
- ASTM currently does not have a published food gloves document, but will have later in 2008 & it will cover the glove types mentioned above. The NSF P155 document contains 10 ASTM medical glove standards & some other testing standards. Here are the 10 ASTM standards in P155:
 - ASTM D412, "Test Method for Vulcanized Rubbers and Thermoplastic Rubbers and Thermoplastic Elastomers – Tension" (latest revision), American Society for Testing and Materials.
 - ASTM D573 "Test Method for Rubber – Deterioration in an Air Oven" (latest revision), American Society for Testing and Materials (ASTM).
 - ASTM D882 "Standard Test Method for Tensile Properties of Thin Plastic Sheeting" (latest revision), American Society for Testing and Materials (ASTM).
 - ASTM D3578 "Standard Specification for Rubber Examination Gloves" (latest revision), American Society for Testing and Materials (ASTM).
 - ASTM D3767 "Standard Practice for Rubber – Measurement of Dimensions" (latest revision), American Society for Testing and Materials (ASTM).
 - ASTM D5151 "Test Method for Detection of Holes in Medical Gloves" (latest revision), American Society for Testing and Materials (ASTM).
 - ASTM D5250 "Standard Specification for Poly(vinyl chloride) Gloves for Medical Application" (latest revision), American Society for Testing and Materials (ASTM).
 - ASTM D5712 "Standard Test Method for Analysis of Protein in Natural Rubber and Its Products" (latest revision), American Society for Testing and Materials (ASTM).
 - ASTM D6124 "Standard Test Method for Residual Powder on Medical Gloves" (latest revision), American Society for Testing and Materials (ASTM).
 - ASTM D6319 "Standard Specification for Nitrile Examination Gloves for Medical Application" (latest revision), American Society for Testing and Materials (ASTM).

Polyethylene

Polyethylene gloves are made of plastic resins extruded into lightweight sheet films. Two sheets of polyethylene film are seamed and heat sealed to form gloves; these gloves are non-powdered. Different resins and extrusion processes are utilized to manufacture three grades of Polyethylene gloves:

- Low Density Polyethylene (LDPE)
- Cast Polyethylene (CPE)
- High Density Polyethylene (HDPE)

Benefits

- Least costly
- Appropriate for single-use, light tasks
- Easy donning – loose fit, flexibility

Disadvantages

- Decreased dexterity and durability compared to other glove materials

Vinyl

Vinyl gloves are made by dipping hand molds into the synthetic material polyvinyl chloride (PVC). Other synthetic glove materials are made from different formulations of PVC to improve flexibility and durability. Vinyl gloves are available in powdered and powder-free.

Benefits

- Low cost
- Appropriate for single-use, light and medium tasks
- Closer fit for tasks requiring dexterity
- Alternative for those concerned with Hevea NRL latex allergy

Disadvantages

- Decreased dexterity and durability compared to other glove materials
- Can cause allergic contact dermatitis from residual processing chemicals

Nitrile

Nitrile gloves are made by dipping hand molds into the petroleum-based synthetic material - carboxylated butadiene acrylonitrile copolymer (butyl rubber / BR). Nitrile gloves have excellent puncture and abrasion resistance and are resistant to breakdown from exposure to animal fats. Nitrile gloves are available in powdered and powder-free.

Benefits

- Appropriate for single-use, medium to heavy tasks
- Form-fitting for good tactile sensitivity and dexterity
- Alternative for those concerned with Hevea natural rubber latex (NRL) allergy

Disadvantages

- More costly
 - * Due to escalating crude oil prices, nitrile prices have steadily increased
 - In 2004 butyl rubber prices rose by 40%
- Can cause allergic contact dermatitis from residual processing chemicals

Natural Rubber Latex

Natural rubber latex (NRL) gloves are made by dipping hand molds into processed natural latex, a sap-like plant byproduct harvested from the rubber tree *Hevea brasiliensis*. NRL gloves are available in powdered and powder-free.

Benefits

- Appropriate for single-use, light to moderate tasks
- Form-fitting for good tactile sensitivity and dexterity

Disadvantages

- Cost has dramatically increased
 - * (ROSWELL, Ga. – JUNE 28, 2006) – A national health care corporation announced today that it will be shifting the production of exam gloves from latex to synthetic alternatives over the next four to 18 months. The decision was based on growing customer demand for synthetic solutions and in response to unprecedented increases in the cost of latex raw materials.
- NRL gloves can cause Immunoglobulin E-mediated allergic reactions in sensitized individuals and can cause sensitization, especially in atopic individuals

- Can cause allergic contact dermatitis from residual processing chemicals

New Disposable Glove Materials on the Horizon

North American latex

A new type of latex gloves are made by dipping hand molds into processed guayule latex (NRG), extracted from the desert shrub indigenous to the southwest United States and northern Mexico. The species (*Parthenium argentatum* (Gray)) is a new industrial crop.

- Clinical trials indicate NRG is safe for use in individuals who have developed an allergy to Hevea NRL.
- Suitable for commercial applications, single or multiple use

ASTM D 1076: Standard Specification for Rubber - Concentrated, Ammonia Preserved, Creamed, and Centrifuged Natural Latex

Publication Date: Jun 1, 2006

Category 4—Centrifuged, or centrifuged and creamed, guayule latex, or other natural rubber latex, containing less than 200 µg total protein per gram dry weight of latex, with ammonia or other hydroxide, with other necessary preservatives and stabilizers.

This specification is not necessarily applicable to latices prepared or preserved by other methods, and shall not be construed as limiting the desirability or usefulness of other categories of latices. It does apply to natural latex sources other than *Hevea brasiliensis* but does not apply to compounded latex concentrates.

Additional source of natural rubber

Alternative sources of natural rubber in development include:

- Sunflower
- Russian dandelion
- Goldenrod

Existing FDA position on natural latex (from Food Code Annex 3):

Natural Rubber Latex (NRL) Gloves

Natural rubber latex gloves have been reported to cause allergic reactions in some individuals who wear latex gloves during food preparation, and even in individuals eating food prepared by food employees wearing latex gloves (refer to Annex 2, 3-304.15). This information should be taken into consideration when deciding whether single-use gloves made of latex will be used during food preparation.

Although many allergic reactions occur as a result of occupational exposure, CFSAN is actively reviewing its current policy on the use of disposable NRL gloves in food operations in light of the possible transmission of the latex protein via food. To gain additional information regarding allergic reactions allegedly due to the ingestion of food contaminated by NRL in retail settings, CFSAN has been collecting reports of such reactions from consumers who have contacted the Agency. Several offices within CFSAN will continue to collaborate in reviewing incoming data. The results of these activities and other related efforts will be used to determine if policy changes regarding the use of latex in food operations, based on food safety considerations, are warranted.

The FDA, Office of Food Additive Safety, Division of Food Contact Notification, reviews gloves submitted for food-contact use in the food industry on the basis of the glove's formulation or components. FDA regulates NRL gloves used for medical purposes only.

FDA is aware of the following information related to occupational hazards (not food safety hazards) associated with the use of NRL gloves:

- The National Institute for Occupational Safety and Health (NIOSH) published a 1997 Alert titled "Preventing Allergic Reactions to Natural Rubber Latex in the Workplace" (NIOSH publication number 97-135) which is found at <http://www.cdc.gov/niosh/latexalt.html>.

- The American College of Allergy, Asthma and Immunology (ACAAI) and the American Academy of Allergy Asthma and Immunology (AAAAI) issued a joint statement discouraging the routine use of NRL gloves by food handlers. (1997) <http://www.acaal.org/public/physicians/joint.htm>.

The AAAAI provides information on latex allergies on the web at http://www.aaaai.org/patients/resources/fastfacts/latex_allergy.stm.

The ACAAI provides information on latex allergies on the web at <http://www.acaai.org/public/facts/latex.htm>.

- An OSHA Technical Information Bulletin recommends reducing allergy potential by reducing unnecessary exposure to NRL. Stating "Food service workers ... do not need to use NRL gloves for food handling..." (1999) http://www.osha.gov/dts/tib/tib_data/tib19990412.html.

Conclusion:

A severe allergic reaction to latex is life-threatening, frightening, and incredibly meaningful to the victim and her family. The committee felt that the opportunity to reduce such events was important enough to conduct research and possibly recommend changes in the Food Code to the FDA. As noted above, however, not enough documented data exist to form a science-based conclusion and recommendation.

Recommendation to the Council:

The committee recommends the council accept this report and disband the Barrier Hazards Committee.

**Conference for Food Protection
2008 Issue Form**

**Internal Number: 050
Issue: 2008 III-009**

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:

Report: Sanitizer Committee

Issue you would like the Conference to consider:

There are inconsistencies between the 2005 Food Code requirements for sanitizers and the use directions on EPA-registered products. This has lead to confusion on the part of state and local regulators as well as business operators. A Sanitizer Committee was formed by CFP Council III in 2006 with the following charge:

"A sanitizer subcommittee be created with USDA, FDA, EPA and other stakeholders to review and recommend changes to Food Code and EPA regulations with regards to sanitizer concentrations, exposure time, temperature and pH, with the goal of harmonizing the language and clarifying the responsibilities."

The 2006-08 Sanitizer Committee's Final Report is attached to this Issue.

Public Health Significance:

Proper use of sanitizers is an important step to prevent cross contamination and food safety failures. Clarification of the Food Code requirements for sanitizers is essential to ensure proper use of these materials and to avoid unproductive confusion for inspectors and operators. EPA, FDA, state, sanitizer users, and sanitizer manufacturers must engage in healthy discussion to identify harmonized language to clarify responsibility.

Recommended Solution: The Conference recommends...:

acknowledgment of the 2006-08 Sanitizer Committee Report, with thanks to the members of the Sanitizer Committee for completing their task.

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Attachments:

- "2006-08 Sanitizer Committee Final Report"

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 2006-2008
Executive Board Meeting Committee Update –
Sanitizer Committee Final Report

Date of Committee Report: January 11, 2007

Submitted By: Katherine M.J. Swanson and Dale Grinstead, Co-chairs

Committee Charge(s):

A sanitizer subcommittee be created with USDA, FDA, EPA and other stakeholders to review and recommend changes to Food Code and EPA regulations with regards to sanitizer concentrations, exposure time, temperature and pH, with the goal of harmonizing the language and clarifying the responsibilities.

Committee Membership (Name, Constituency, Employer and email):

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Progress Report/Committee Activities:

The Sanitizer Committee completed deliberations related to the charge during eleven (11) conference calls. We were successful in engaging active participation of EPA, which helped tremendously in developing recommended language to harmonize the Food Code with EPA regulations and practices, which has jurisdiction over sanitizers in the US.

Our process involved creation of a detailed table containing current sanitizer-related provisions of the Food Code along with text identifying potential inconsistencies with EPA regulations. This table was used to guide discussion, and was modified to provide rationale and recommended changes to the Food Code as conference calls progressed. Environmental Protection Agency representative Tajah Blackburn reviewed this table within that agency to ensure agreement between Food Code provisions and EPA regulations and practices. Table 1 of this report captures the final consensus of the Sanitizer Committee deliberations. It also contains detailed rationale for the proposed changes to the Food Code. The Committee firmly believes that incorporating the recommended changes into the Food Code will fulfill the Committee's charge of harmonizing the language and clarifying the responsibilities of EPA and FDA.

Two points generated substantial discussion during conference calls.

1. *The Chlorine table in 4-501.114 (A)*

The table in section 4-501.114 (A) identifies temperature requirements for different chlorine concentrations based on pH of the solution. As currently written, this table may be interpreted to suggest that a sanitizer could be used at a concentration other than that specified on the EPA-registered label.

Sanitizer Committee Consensus: The EPA-registered label must be followed. Changes in the wording of the Food Code are recommended to emphasize the need to follow the EPA-registered label and to reduce the potential for misinterpretation. The Committee also reviewed the references cited in the Food Code related to the information in the table. Consensus was reached that this information has been validated to be effective and should be retained in the Food Code because EPA-registered labels may not include details on pH and temperature of use. Local jurisdictions and equipment manufactures (for example, warewashing machines) may refer to this information to assure effectiveness of their application. The Committee recommends adding concentration ranges and a reference to EPA-registered labels in the table to provide further clarity on implementation. Please refer to Table 1 for additional information and the specific recommendation.

2. *Annex 3 for 4-501.114 as related to the Quaternary Ammonium Compound example*

The example provided in Annex 3 for 4-501.114 related to a maximum level of 200 ppm for quaternary ammonium compounds (quats) is no longer consistent with EPA regulations. In September 2007, EPA amended 40 CFR 180.940 to allow levels of certain quats at levels up to 400 ppm for food service and other applications. This amendment resolved the inconsistency between an EPA-registered product that was in the market and 40 CFR 180.940; however, it created inconsistency between the example in Annex 3 and 40 CFR 180.940.

Consensus: Removal of prescriptive examples that cite other regulations will prevent inconsistency if those regulations are amended. Focusing on EPA-registered label use directions provides a readily available source of information for inspectors and users, and should be used to assess compliance. Citing EPA-registered label use instructions in the Food Code will also reduce confusion and considerable effort on the part of inspectors to resolve potential regulatory conflict that has limited, if any, public health benefit.

The Committee also identified several inconsistencies between EPA practices and the Food Code, and provided recommendations that will harmonize the language in regard to sanitizers. These are discussed in Table 1 and are summarized as follows:

A. *Emphasize compliance with EPA-registered labels*

All sanitizer formulations must be "registered" with EPA for regulatory compliance. The registration process involves registration of each specific label, not just the manufacturer or the active ingredient. Technically, the manufacturer is not "approved" by EPA, but rather the label is "registered" with EPA.

Consensus: Change "EPA-approved manufacturer's label use instructions" or similar wording, to "EPA-registered label use instructions" throughout the sanitizer-related provisions of the Code to be technically accurate, emphasize adherence to label instructions, reduce confusion, and harmonize language. This would apply to sections 4-501.114 introduction; 4-501.114 (A), (C), and (E); and 4-703.11(C).

B. *Change the minimum temperature for iodine for consistency with EPA protocol*

EPA registration tests for iodine sanitizers are conducted at 20°C (68°F). This is lower than the minimum temperature prescribed in the Food Code, which is 24°C (75°F). Since efficacy is part of the EPA evaluation process, EPA-registered products have been demonstrated to be effective at 20°C.

Consensus: The Committee recommends lowering the Food Code minimum temperature for iodine to 20°C (68°F) in section 4-501.114 (B). This is consistent with science and harmonizes the Food Code with EPA registration.

C. Change “exposure time” to “contact time” for consistency with EPA terminology

EPA uses the term “contact time” in a consistent manner with the Food Code term “exposure time.” Both refer to the time that the surface is submerged, sprayed, wiped, etc. with the sanitizing solution.

Consensus: This Committee recommends changing the term “exposure time” to “contact time” in 4-501.114 introduction, 4-703.11 (C)(1-4), and Annex 3 for 4-501.114 to harmonize with EPA-registration practice.

D. On-site generation of sanitizers

New technology is driving introduction of units that generate sanitizer solutions on site. These products do not have EPA-registered labels because the solution is generated on-site. However, for public health reasons, chemicals generated must be used at appropriate levels to provide effective sanitization while not exceeding levels that would present a chemical safety issue. The Committee worked with EPA to develop language that would cover use of these sanitizing solutions.

Consensus: The Committee recommends adding a new 4-501.114 (F) to address on-site generated sanitizing solutions. The specific wording recommended, as listed in Table 1, is “any chemical substance produced and used on-site as a food contact sanitizing solution must be in compliance with 40 CFR 180.940.”

E. Duplication in Annex 3 for 4-501.14 and 4-501.114

The Committee observed that several paragraphs in Annex 3 for section 4-501.14 repeat those in Annex 3 for section 4-501.114. This appears to be a clerical error since many of the paragraphs are related to sanitizer concentration (the subject of 4-501.114) and not cleaning frequency (the subject of 4-501.14).

Consensus: The Committee recommends deletion of the non-applicable paragraphs in 4-501.14 as indicated in Table 1.

F. Clarify EPA, FDA, and Food Code Sanitizer jurisdiction

Annex 3 for section 4-501.114 is important to explain the shift of jurisdiction for sanitizers from FDA to EPA and to explain the background for provisions discussed in 1 and 2, as well as A – C above.

Consensus: In addition to removing the example on quaternary ammonium compounds as explained #2 above, the Committee suggests additional changes for Annex 3 section 4-501.114 in Table 1 of this report to clarify the jurisdictional shift from FDA to EPA.

In conclusion, the 2006-08 Sanitizer Committee will submit three issues to the 2008 Conference for Food Protection:

1. **2006-08 Sanitizer Committee Report**
2. **Harmonizing the Food Code with EPA Sanitizer Provisions**
3. **Quaternary Ammonium Compounds & Harmonization with EPA Practice**

The Sanitizer Committee thanks the Conference for Food Protection for the opportunity to explore these issues and hopes that the work of our Committee will benefit CFP and public health at large by harmonizing the language and clarifying jurisdiction for sanitizer use in retail and food service settings.

Respectfully submitted by

Katherine MJ Swanson, Co-Chair for the 2006-08 CFP Sanitizer Committee

Table 1. Recommended Food Code modification for consistency with EPA requirements

Food Code Reference	Specific Food Code 2005 Citation Language (verbatim)	Rationale for Recommendation	Recommended solution																														
4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitation – Temperature, pH, Concentration, and Hardness 4-501.114 (A)	<p>A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at exposure times specified under 4-703.11(C) shall meet the criteria specified under 7-204.11 Sanitizers, Criteria, shall be used in accordance with the EPA-approved manufacturer’s label use instructions, and shall be used as follows:</p> <table border="1" data-bbox="401 609 884 1073"> <thead> <tr> <th data-bbox="401 609 569 743">Minimum Conc.</th> <th colspan="2" data-bbox="569 609 884 743">Minimum Temperature</th> </tr> </thead> <tbody> <tr> <td data-bbox="401 743 569 829">MG/L</td> <td data-bbox="569 743 716 829">pH 10 or less °C (°F)</td> <td data-bbox="716 743 884 829">pH 8 or less °C (°F)</td> </tr> <tr> <td data-bbox="401 829 569 862">25</td> <td data-bbox="569 829 716 862">49 (120)</td> <td data-bbox="716 829 884 862">49 (120)</td> </tr> <tr> <td data-bbox="401 862 569 894">50</td> <td data-bbox="569 862 716 894">38 (100)</td> <td data-bbox="716 862 884 894">24 (75)</td> </tr> <tr> <td data-bbox="401 894 569 1073">100</td> <td data-bbox="569 894 716 1073">13 (55)</td> <td data-bbox="716 894 884 1073">13 (55)</td> </tr> </tbody> </table>	Minimum Conc.	Minimum Temperature		MG/L	pH 10 or less °C (°F)	pH 8 or less °C (°F)	25	49 (120)	49 (120)	50	38 (100)	24 (75)	100	13 (55)	13 (55)	<p>All sanitizer formulations must be “registered” with EPA for regulatory compliance; technically they are not “approved”. Each specific label is registered, not just the manufacturer or the active ingredient. Clarification of wording is needed.</p> <p>As currently presented, the table may be interpreted to suggest that a sanitizer could be used at a concentration other than that specified on the EPA-registered label. This is not the case. Changing the column heading from “Minimum conc,” to “EPA-registered label conc.” is recommended to prevent misinterpretation.</p> <p>Manufacturers may or may not include temperature of use on the EPA label and sometimes refer the user to “local sanitation regulations” for contact times or temperatures. Because of this, information on temperature (included in this section) and contact time (included in section 4-703.11 (C)) is needed to provide guidance.</p> <p>Certification of chlorine sanitizing warewashing equipment under NSF Standard 3, section 6.1 specifies minimum temperature (120°F in general, 75°F for glassware), minimum sanitizer concentration (50 ppm), and other factors under which validation studies are conducted. This information is included on the warewashing machine data plate.</p>	<p>“A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at <u>exposure contact</u> times specified under 4-703.11(C) shall meet the criteria specified under 7-204.11 Sanitizers, Criteria, shall be used in accordance with the EPA-approved <u>manufacturer’s EPA-registered</u> label use instructions, and shall be used as follows: “</p> <p>“A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart:</p> <table border="1" data-bbox="1549 609 2053 1073"> <thead> <tr> <th data-bbox="1549 609 1717 743">Minimum <u>EPA-registered</u> label Conc.</th> <th colspan="2" data-bbox="1717 609 2053 743">Minimum Temperature</th> </tr> </thead> <tbody> <tr> <td data-bbox="1549 743 1717 829">MG/L</td> <td data-bbox="1717 743 1885 829">pH 10 or less °C (°F)</td> <td data-bbox="1885 743 2053 829">pH 8 or less °C (°F)</td> </tr> <tr> <td data-bbox="1549 829 1717 862">25 – 49</td> <td data-bbox="1717 829 1885 862">49 (120)</td> <td data-bbox="1885 829 2053 862">49 (120)</td> </tr> <tr> <td data-bbox="1549 862 1717 894">50 – 99</td> <td data-bbox="1717 862 1885 894">38 (100)</td> <td data-bbox="1885 862 2053 894">24 (75)</td> </tr> <tr> <td data-bbox="1549 894 1717 1073">≤100</td> <td data-bbox="1717 894 1885 1073">13 (55)</td> <td data-bbox="1885 894 2053 1073">13 (55)</td> </tr> </tbody> </table>	Minimum <u>EPA-registered</u> label Conc.	Minimum Temperature		MG/L	pH 10 or less °C (°F)	pH 8 or less °C (°F)	25 – 49	49 (120)	49 (120)	50 – 99	38 (100)	24 (75)	≤100	13 (55)	13 (55)
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4-501.114 (B)	<p>An iodine solution shall have a:</p> <ol style="list-style-type: none"> (1) Minimum temperature of 24°C (75°F), (2) pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective, and (3) Concentration between 12.5 mg/L and 25 mg/L 	<p>NSF iodine sanitizing warewashing machine certification is conducted at 24°C (75°F). Iodophor EPA registration tests are run at 20°C (68°F). Since an assessment of efficacy is part of the EPA evaluation process, and not all applications are for warewashing; the minimum temperature stated in the Food Code should be lowered for consistency with EPA practice. This would not prevent NSF from using the higher temperature for equipment validation tests.</p>	<p>“An iodine solution shall have a:</p> <ol style="list-style-type: none"> (1) Minimum temperature of 24°C (75°F) 20°C (68°F),”... 																														

Table 1 (continued) Recommended Food Code modification for consistency with EPA requirements

Food Code Reference	Specific Food Code 2005 Citation Language (verbatim)	Rationale for Recommendation	Recommended solution
4-501.114 (C)	A quaternary ammonium compound solution shall: (1) Have a minimum temperature of 24°C (75°F), (2) Have a concentration as specified under 7-204.11 and as indicated by the manufacturer's use directions included in the labeling, and (3) Be used only in water with 500mg/L hardness or less or in water having a hardness no greater than specified by the manufacturer's label;	No inconsistencies are noted between Food Code and EPA requirements; however, clause (2) is redundant with the initial paragraph. Deletion is recommended remove redundancy. Also modify wording regarding the manufacturer's label to reflect the standard EPA-registered label wording. There will be an inconsistency between the minimum temperature for quat and iodine; however, EPA registration temperatures for quat and iodine are 24°C and 20°C, respectively.	A quaternary ammonium compound solution shall: (1) Have a minimum temperature of 24°C (75°F), <u>and</u> (2) Have a concentration as specified under 7-204.11 and as indicated by the manufacturer's use directions included in the labeling, and (3) Be used only in water with 500mg/L hardness or less or in water having a hardness no greater than specified by the <u>manufacturer's EPA-registered label use instructions</u> ;
4-501.114 (D)	If another solution of a chemical specified under (A)-(C) of this section is used, the PERMIT HOLDER shall demonstrate to the REGULATORY AUTHORITY that the solution achieves SANITATION and the use of the solution shall be APPROVED; or	Sanitizers must be registered with EPA for their specific use following specific protocols recognized by EPA and they must be used per label instructions. This section of the Food Code should not provide flexibility to use other concentrations, potentially in conjunction with other treatments, as long as it is validated to be effective by the "permit holder," i.e. the legal entity operating the establishment. As long as the use is consistent with the EPA registered label, it should be allowed.	If another solution use condition (e.g. <u>temperature, pH, water hardness, etc.</u>) of a chemical specified under (A)-(C) of this section is used, the PERMIT HOLDER shall demonstrate to the REGULATORY AUTHORITY that the solution achieves SANITATION, and the use of the solution shall be APPROVED; or
4-501.114 (E)	If a chemical SANITIZER other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the manufacturer's use directions included in the labeling.	Sanitizers must be registered with EPA for compliance.	"If a chemical SANITIZER other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the <u>EPA-registered label</u> manufacturer's use directions included in the labeling.
4-501.114 (F)	New	The Food Code currently does not address on-site generation of sanitizing solutions. There is need to clarify what is allowed for this purpose for safety and efficacy.	<u>Any chemical substance produced and used on-site as a food contact sanitizing solution must be in compliance with 40 CFR 180.940.</u>

Reference for 4-501.114

- Miller, M.P. Principle Investigator, 1984. Relationship of factors affecting bactericidal effectiveness of chlorine sanitizing solutions. Final report. National Sanitation Foundation, Ann Arbor, MI. Subcontract No. 9013-092-108-H0620-101; Booz, Allen & Hamilton, Inc. Contract No. 223-80-2295.
- Miller, M.P. Principle Investigator, 1985. Relationship of factors affecting bactericidal effectiveness of chlorine sanitizing solutions. Addendum to Final report. National Sanitation Foundation, Ann Arbor, MI Subcontract No. 9013-092-108-H0620-101; Booz, Allen & Hamilton, Inc. Contract No. 223-80-2295.
- National Sanitation Foundation, Ann Arbor, MI November 1990. Report on the bacterial effectiveness of a chlorine sanitizing solution at contact times of less than 10 seconds. Purchase Order #FDA 665531-00-90-RB.

Table 1 (continued) Recommended Food Code modification for consistency with EPA requirements

Food Code Reference	Specific Food Code 2005 Citation Language (verbatim)	Rationale for Recommendation	Recommended solution
4-703.11 Sanitation of Equipment and Utensils - Hot Water and Chemical	After being cleaned, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED in:		
4-703.11(A)	Hot water manual...	Not relevant	
4-703.11(B)	Hot water mechanical...	Not relevant	
4-703.11(C)	<p>Chemical manual or mechanical operations, including the application of SANITIZING chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under 4-501.114 by providing:</p> <ol style="list-style-type: none"> (1) Except as specified under Subparagraph (C)(2) of this section, an exposure time of at least 10 seconds for a chlorine solution specified under 4-501.114(A) (2) An exposure time of at least 7 seconds for a chlorine solution of 50 mg/L that has a pH of 10 or less and a temperature of at least 38°C (100°F) or a pH of 8 or less and a temperature of at least 24°C (75°F), (3) An exposure time of at least 30 seconds for other chemical SANITIZING solutions, or (4) An exposure time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields SANITIZATION as defined in Subparagraph 1-201.10(B). 	<p>EPA uses the term “contact time” in a consistent manner with the term “exposure time”, meaning the time that the surface is submerged, sprayed, wiped, etc. with the solution. The committee recommends using “contact time” in place of “exposure time” throughout the Food Code for consistency.</p> <p>Sanitizer products must be used consistent with EPA registered labels; which frequently, but not always, specify a <u>contact</u> time. EPA registration tests use a 30 second contact time followed by immediate neutralization. As currently written, this section may be misinterpreted to allow shorter contact times than those specified on EPA-registered labels. Additional wording is proposed to avoid misinterpretation.</p> <p>Data to validate efficacy of the times in Subparagraphs (1) and (2) exist (Miller 1984, Miller 1985, NSF, 1990) and included contact times shorter than 30 seconds. A 7 second <u>application</u> time is used by NSF Standard 3 for low temperature commercial warewash machine certification based on these reports. While the sanitizer is “applied” for a minimum of 7 seconds, the sanitizer remains on the surface for a longer period of time because it is not rinsed off. These provisions were in the Food Code prior to transfer of jurisdiction to EPA. They have a long history of effective use and are in multiple state regulations. Therefore, retaining these provisions in the Food Code is important to ensure continued use of appropriate conditions for low temperature warewashing machine certification. At the same time, they do not conflict with EPA labels that have no time requirement specified for warewashing.</p> <p>The committee therefore recommends adding wording to clarify that times specified on EPA registered labels must be followed, while retaining the provision for shorter times.</p>	<p>Chemical manual or mechanical operations, including the application of SANITIZING chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under 4-501.114. <u>Contact times shall be consistent with those on EPA-registered label use instructions, or if time is not specified</u> by providing:</p> <ol style="list-style-type: none"> (1) Except as specified under Subparagraph (C)(2) of this section, an exposure <u>a contact</u> time of at least 10 seconds for a chlorine solution specified under 4-501.114(A) (2) An exposure <u>A contact</u> time of at least 7 seconds for a chlorine solution of 50 mg/L that has a pH of 10 or less and a temperature of at least 38°C (100°F) or a pH of 8 or less and a temperature of at least 24°C (75°F), (3) An exposure <u>A contact</u> time of at least 30 seconds for other chemical SANITIZING solutions, or (4) An exposure <u>A contact</u> time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields SANITIZATION as defined in Subparagraph 1-201.10(B).

Table 1 (continued) Recommended Food Code modification for consistency with EPA requirements

Food Code Reference	Specific Food Code 2005 Citation Language (verbatim)	Rationale for Recommendation	Recommended solution
7-204.11 Sanitizers, Criteria	Chemical SANITIZERS and other chemical antimicrobials applied to FOOD-CONTACT SURFACES shall meet the requirements specified in 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions).	This provision (7-204.11) is included to address chemical safety issues related to use of hazardous chemicals or hazardous levels of chemicals on food contact surfaces. When EPA registers a sanitizer under FIFRA, a review of 40 CFR 180.940 is done to ensure that the proposed chemical meets chemical safety issues for its intended use. Therefore, the inclusion of this provision is not intended to direct inspectors or operators to 40 CFR 180.940 to ascertain compliance of a product that is being used in a manner consistent with its EPA registered label. Instead, it is more appropriately used by EPA to check for tolerance levels allowed, and by manufacturers to understand what may be used as sanitizers.	No changes recommended.

Table 1 (continued) Recommended Food Code modification for consistency with EPA requirements

Food Code Reference	Specific Food Code 2005 Citation Language (verbatim)	Rationale for Recommendation	Recommended solution
<p>Annex 3 - Public Health Reasons/ Administrative Guidelines 4-501.14 Warewashing Equipment, Cleaning Frequency</p>	<p>With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Coordination Act of 1998, federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation has moved from 21 CFR 178.1010 to 40 CFR 180.940.</p> <p>During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day.</p> <p>With respect to chemical sanitization, section 4-501.114 addresses the proper make-up for the sanitizing <u>solution</u>, i.e., chemical concentration, pH, and temperature at the required <u>minimum</u> levels specified when considered together and, with respect to quaternary ammonium compounds (quats), the <u>maximum</u> hardness level. If these minimums (maximum hardness) are not as specified, then this provision is violated.</p> <p>By contrast, paragraph 4-703.11(C) addresses exposure time in seconds. For chemical sanitization, this paragraph is only violated when the specified exposure time is not met.</p> <p>Section 7-204.11 addresses two additional considerations. The first is whether or not the chemical agent being applied as a sanitizer is <u>approved</u> and listed for that use under 40 CFR 180.940. If the chemical used is not thus listed, this section is violated.</p> <p>The second consideration under this section is whether the product, if approved and listed, is being used in accordance with the "Limits" provided for that product under its 40 CFR 180.940 listing. The concern here is an indirect food additives concern, since chemical sanitizing solutions are not rinsed off in this country. For example, 40 CFR 180.940(a) lists several quaternary ammonium compounds as approved for "food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils," each listing adding a Limit that states, "When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound." If a sanitarian determined that a solution of any of these quats was 600 ppm, section 7-204.11 would be violated.</p> <p>To summarize, a too weak sanitizing solution would be a violation of section 4-501.114. A too strong solution would be a violation of section 7-204.11. Section 7-202.12 would not be violated due to the existence of section 7-204.11 that specifically addresses the use of chemical sanitizers.</p>	<p>With the exception of the second paragraph of Annex 3 section 4-501.14, all of the other wording repeats wording from Annex 3 section 4-501.114. This seems to be an error because 4-501.14 addresses frequency of cleaning, with no specific mention of sanitizers, whereas 4-501.114 specifically addresses sanitizers.</p> <p>Inclusion of the discussion of EPA in this section therefore creates redundancy and confusion, and should be deleted.</p>	<p>Delete all paragraphs except paragraph two, which follows.</p> <p>"During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day."</p>

Table 1 (continued) Recommended Food Code modification for consistency with EPA requirements

Food Code Reference	Specific Food Code 2005 Citation Language (verbatim)	Rationale for Recommendation	Recommended solution
<p>Annex 3 Public Health Reasons/ Administrative Guidelines 4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitation – Temperature, pH, Concentration, and Hardness</p>	<p>With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Coordination Act of 1998, federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation has moved from 21 CFR 178.1010 to 40 CFR 180.940.</p> <p>The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. All sanitizers approved for use under 40 CFR 180.940 must be used under water conditions stated on the label to ensure efficacy. Therefore, it is critical to sanitization that the sanitizers are used properly and the solutions meet the minimum standards required in the Code.</p> <p>With respect to chemical sanitization, section 4-501.114 addresses the proper make-up for the sanitizing <u>solution</u>, i.e., chemical concentration, pH, and temperature at the required <u>maximum</u> [should state “minimum”] levels specified when considered together and, with respect to quaternary ammonium compounds (quats), the <u>maximum</u> hardness level. If these minimums (maximum hardness) are not as specified, then this provision is violated.</p> <p>By contrast, paragraph 4-703.11(C) addresses exposure time in seconds. For chemical sanitization, this paragraph is only violated when the specified exposure time is not met.</p> <p>Section 7-204.11 addresses two additional considerations. The first is whether or not the chemical agent being applied as a sanitizer is <u>approved</u> and listed for that use under 40 CFR 180.940. If the chemical used is not thus listed, this section is violated.</p> <p>The second consideration under this section is</p>	<p>With the shift in regulatory responsibility, transfer of certain sanitizer provisions in the Food Code did not occur and has led to confusion. The Food Code covers information relevant to application of sanitizers in food service operations that were not included in 21 CFR 178.1010. Specifically, the tables cited in 4-501.114 of the Food Code, and contact times cited in 4-703.11(C).</p> <p>Some products (e.g. low temperature dish machine sanitizers) comply with NSF certification criteria, and no EPA protocol exists for registration of such products in combination with factors such as temperature, pH, hardness, etc. Additionally, not all EPA-registered labels include a statement of water conditions for use. Therefore, this Annex needs to explain why provisions are retained in the Food Code.</p> <p>The example provided for quaternary ammonium compounds is no longer consistent with 40 CFR 180.940, which has been amended to allow use of certain quats not to exceed 400 ppm. (Federal Register Volume 72, Number 172, September 6, 2007, page 51180-7). Inclusion of a specific example such as this provides an opportunity for inconsistency as regulations are amended. Removal of specific examples and citing consistency with the EPA-registered label would reduce the potential for inconsistency,</p>	<p>With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Coordination Act of 1998, federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation has moved from 21 CFR 178.1010 to 40 CFR 180.940. <u>The Food Code contains provisions that were not captured in either 21 CFR 178.1010 or 40 CFR 180.940, such as pH, temperature, and water hardness. There is need to retain these provisions in the Code.</u></p> <p>The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. All sanitizers approved for use under 40 CFR 180.940 must be used under water conditions stated on the label to ensure efficacy. <u>Provisions for pH, temperature, and water harness in 4-501.114 have been validated to achieve sanitization; however, these parameters are not always included on EPA-registered labels.</u> Therefore, it is critical to sanitization that the sanitizers are used <u>consistently with the EPA-label, and, if pH, temperature, and water hardness (for quat) are not included on the label, that properly and</u> the solutions meet the minimum standards required in the Code.</p> <p>With respect to chemical sanitization, section 4-501.114 addresses the proper make-up for use <u>conditions for the sanitizing solution</u>, i.e., chemical concentration <u>range</u>, pH and temperature at the <u>required maximum</u> minimum levels specified when considered together and, with respect to quaternary ammonium compounds (quats), the maximum hardness level. If these minimums (maximum hardness) <u>parameters are not as specified in the Code or on the EPA-registered label</u>, then this provision is violated.”</p>

Table 1 (continued) Recommended Food Code modification for consistency with EPA requirements

	<p>whether the product, if approved and listed, is being used in accordance with the “Limits” provided for that product under its 40 CFR 180.940 listing. The concern here is an indirect food additives concern, since chemical sanitizing solutions are not rinsed off in this country. For example, 40 CFR 180.940(a) lists several quaternary ammonium compounds as approved for “food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils,” each listing adding a Limit that states, “When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound.” If a sanitarian determined that a solution of any of these quats was 600 ppm, section 7-204.11 would be violated.</p> <p>To summarize, a too weak sanitizing solution would be a violation of section 4-501.114. A too strong solution would be a violation of section 7-204.11. Section 7-202.12 would not be violated due to the existence of section 7-204.11 that specifically addresses the use of chemical sanitizers.</p>	<p>confusion, and effort to understand what is allowed.</p>	<p>By contrast, paragraph 4-703.11(C) addresses exposure <u>contact</u> time in seconds. For chemical sanitization, this paragraph is only violated when the specified exposure <u>contact</u> time is not met.</p> <p>Section 7-204.11 addresses two additional considerations. <u>The first is whether or not the chemical agent being applied as a sanitizer is approved, and listed, and used in accordance with the “Limits” for that use under 40 CFR 180.940. If the chemical used is not thus listed, this section is violated.</u></p> <p>“The second consideration under this section is whether the product, if approved and listed, is being used in accordance with the “Limits” provided for that product under its 40 CFR 180.940 listing. The concern here <u>This is an indirect food additives concern, since chemical sanitizing solutions are not rinsed off in this country the United States. EPA sanitizer registration assesses compliance with 40 CFR 180.940, therefore if the product is used at the appropriate concentration for the application on the EPA-registered label, it is not necessary to consult 40 CFR 180.940 for further compliance verification. For example, 40 CFR 180.940(a) lists several quaternary ammonium compounds as approved for “food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils,” each listing adding a Limit that states, “When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound. If a sanitarian determined that a solution of any of these quats was 600 ppm exceeded the concentration for the application on the EPA-registered label or is used for an application that is not on the EPA-registered label, section 7-204.11 would be violated.”</u></p> <p>To summarize, a too weak <u>too weak</u> sanitizing solution <u>that is</u> would be a violation of section 4-501.114. A too strong <u>too strong</u> solution would be a violation of section 7-204.11. Section 7-202.12 would not be violated due to the existence of section 7-204.11 that specifically addresses the use of</p>
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Table 1 (continued) Recommended Food Code modification for consistency with EPA requirements

			chemical sanitizers.
Annex 3 – Public Health Reasons/Administrative Guidelines Chemicals 7-204.11 Sanitizers, Criteria.*	See explanation in § 4-501.114 Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe.	No inconsistencies noted	No change needed

**Conference for Food Protection
2008 Issue Form**

**Internal Number: 052
Issue: 2008 III-010**

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:

Harmonizing the Food Code with EPA Sanitizer Provisions

Issue you would like the Conference to consider:

The 2006-08 Sanitizer Committee thoroughly reviewed inconsistencies between the 2005 Food Code and EPA regulations and practices, and reached consensus on specific Food Code changes that would harmonize the language between the Food Code and EPA. The Sanitizer Committee would like the Conference to consider approval of these changes.

Public Health Significance:

Use of effective concentrations of sanitizers is an important step to prevent cross contamination and food safety failures. It is also important that the concentration of sanitizer used is below the levels set by EPA to prevent use of potentially hazardous levels. Clarification of the Food Code requirements for sanitizers is essential to ensure proper use of these materials and to avoid unproductive confusion for inspectors and operators.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending changes to the Food Code as detailed in the attached '*Recommended changes to harmonize Food Code and EPA sanitizer provisions*' (extracted from Table 1 of the CFP 2006-08 Sanitizer Committee Final Report). Detailed rationales for the recommended changes are included in the table. These recommendations include:

1. Changing "EPA-approved manufacturer's label use instructions" or similar wording, to "EPA-registered label use instructions" in sections 4-501.114 introduction, 4-501.114 (C)(3) and (E); and 4-703.11(C) to be technically accurate, emphasize adherence to label instructions, and harmonize language.

2. Adding concentration ranges and a reference to EPA-registered labels in the table in section 4-501.114 (A) so that the table reads: (*note: periods used below to align columns*)

Minimum <u>EPA-registered label</u> Conc.	Minimum Temperature
.....MG/L	pH 10 or less, °C(°F)pH 8 or less, °C(°F)
.....25 - <u>49</u>	49(120)..... 49(120)
.....50 - <u>99</u>	38 (100)..... 24 (75)
<u>greater than or equal to</u> 100	13 (55)..... 13 (55)

3. Lowering the minimum temperature for iodine from 24°C (75°F) to 20°C (68°F) in 4-501.114 (B) to be consistent with science and harmonize with EPA registration protocols. Therefore 1-501.114(B) should read:

"An iodine solution shall have a:

(1)Minimum temperature of ~~24°C (75°F)~~ 20°C (68°F), ..."

4. Changing the term "exposure time" to "contact time" in 4-501.114 introduction, 4-703.11 (C) (1-4), and Annex 3 for 4-501.114 because "contact time" is used by EPA, and adding language to 4-703.11(C) to reflect the need to follow EPA-registered label use instructions. Section 4-703.11 should read:

"After being cleaned, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED in: ...

(C) Chemical manual or mechanical operations, including the application of SANITIZING chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under 4-501.114. Contact times shall be consistent with those on EPA-registered label use instructions or if time is not specified by providing: ..."

5. Adding a new 4-501.114 (F) reading:

"any chemical substance produced and used on-site as a food contact sanitizing solution must be in compliance with 40 CFR 180.940." to identify the regulatory authority for this type of system.

6. Deleting section 4-501.114 (C)(2): "~~Have a concentration as specified under 7-204.11 and as indicated by the manufacturer's use directions included in the labeling~~ " because it is redundant with the introductory paragraph of 4-501.114:

"A chemical SANITIZER used in a SANITIZING solution ... shall meet the criteria specified under 7-204.11 Sanitizers, Criteria, shall be used in accordance the ~~EPA-approved manufacturer's~~ EPA-registered label use instructions, and shall be used as follows:"

7. Delete all but paragraph 2 in Annex 3 for 4-501.14 (Warewashing Equipment, Cleaning Frequency) because it contains non-applicable information that is redundant with Annex 3 for 4-501.114 (Manual and Mechanical Warewashing Equipment, Chemical Sanitization - temperature, pH, Concentration, and Hardness) so that it reads: *(note: bold added for emphasis only)*

"During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day."

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Attachments:

- "Recommended Changes to Harmonize Food Code and EPA Sanitizer Provisions"

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.

Recommended Changes to Harmonize Food Code and EPA Sanitizer Provisions

Extracted from Table 1 of the 2006-08 CFP Sanitizer Committee Final Report, excluding Annex 3 for 4-501.114

Table 1. Recommended Food Code modification for consistency with EPA requirements

Food Code Reference	Specific Food Code 2005 Citation Language (verbatim)	Rationale for Recommendation	Recommended solution																														
4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitation – Temperature, pH, Concentration, and Hardness 4-501.114 (A)	<p>A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at exposure times specified under 4-703.11(C) shall meet the criteria specified under 7-204.11 Sanitizers, Criteria, shall be used in accordance with the EPA-approved manufacturer’s label use instructions, and shall be used as follows:</p> <table border="1" data-bbox="401 639 884 1105"> <thead> <tr> <th data-bbox="401 639 569 776">Minimum Conc.</th> <th colspan="2" data-bbox="569 639 884 776">Minimum Temperature</th> </tr> <tr> <th data-bbox="401 776 569 862">MG/L</th> <th data-bbox="569 776 716 862">pH 10 or less °C (°F)</th> <th data-bbox="716 776 884 862">pH 8 or less °C (°F)</th> </tr> </thead> <tbody> <tr> <td data-bbox="401 862 569 894">25</td> <td data-bbox="569 862 716 894">49 (120)</td> <td data-bbox="716 862 884 894">49 (120)</td> </tr> <tr> <td data-bbox="401 894 569 927">50</td> <td data-bbox="569 894 716 927">38 (100)</td> <td data-bbox="716 894 884 927">24 (75)</td> </tr> <tr> <td data-bbox="401 927 569 959">100</td> <td data-bbox="569 927 716 959">13 (55)</td> <td data-bbox="716 927 884 959">13 (55)</td> </tr> </tbody> </table>	Minimum Conc.	Minimum Temperature		MG/L	pH 10 or less °C (°F)	pH 8 or less °C (°F)	25	49 (120)	49 (120)	50	38 (100)	24 (75)	100	13 (55)	13 (55)	<p>All sanitizer formulations must be “registered” with EPA for regulatory compliance; technically they are not “approved”. Each specific label is registered, not just the manufacturer or the active ingredient. Clarification of wording is needed.</p> <p>As currently presented, the table may be interpreted to suggest that a sanitizer could be used at a concentration other than that specified on the EPA-registered label. This is not the case. Changing the column heading from “Minimum conc,” to “EPA-registered label conc.” is recommended to prevent misinterpretation.</p> <p>Manufacturers may or may not include temperature of use on the EPA label and sometimes refer the user to “local sanitation regulations” for contact times or temperatures. Because of this, information on temperature (included in this section) and contact time (included in section 4-703.11 (C)) is needed to provide guidance.</p> <p>Certification of chlorine sanitizing warewashing equipment under NSF Standard 3, section 6.1 specifies minimum temperature (120°F in general, 75°F for glassware), minimum sanitizer concentration (50 ppm), and other factors under which validation studies are conducted. This information is included on the warewashing machine data plate.</p>	<p>“A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at <u>exposure contact</u> times specified under 4-703.11(C) shall meet the criteria specified under 7-204.11 Sanitizers, Criteria, shall be used in accordance with the EPA-approved <u>manufacturer’s EPA-registered</u> label use instructions, and shall be used as follows: “</p> <p>“A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart;</p> <table border="1" data-bbox="1549 639 2053 1105"> <thead> <tr> <th data-bbox="1549 639 1717 776"><u>Minimum EPA-registered label</u> Conc.</th> <th colspan="2" data-bbox="1717 639 2053 776">Minimum Temperature</th> </tr> <tr> <th data-bbox="1549 776 1717 862">MG/L</th> <th data-bbox="1717 776 1885 862">pH 10 or less °C (°F)</th> <th data-bbox="1885 776 2053 862">pH 8 or less °C (°F)</th> </tr> </thead> <tbody> <tr> <td data-bbox="1549 862 1717 894">25 – <u>49</u></td> <td data-bbox="1717 862 1885 894">49 (120)</td> <td data-bbox="1885 862 2053 894">49 (120)</td> </tr> <tr> <td data-bbox="1549 894 1717 927">50 – <u>99</u></td> <td data-bbox="1717 894 1885 927">38 (100)</td> <td data-bbox="1885 894 2053 927">24 (75)</td> </tr> <tr> <td data-bbox="1549 927 1717 959">≤100</td> <td data-bbox="1717 927 1885 959">13 (55)</td> <td data-bbox="1885 927 2053 959">13 (55)</td> </tr> </tbody> </table>	<u>Minimum EPA-registered label</u> Conc.	Minimum Temperature		MG/L	pH 10 or less °C (°F)	pH 8 or less °C (°F)	25 – <u>49</u>	49 (120)	49 (120)	50 – <u>99</u>	38 (100)	24 (75)	≤100	13 (55)	13 (55)
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≤100	13 (55)	13 (55)																															
4-501.114 (B)	<p>An iodine solution shall have a:</p> <ol style="list-style-type: none"> (1) Minimum temperature of 24°C (75°F), (2) pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective, and (3) Concentration between 12.5 mg/L and 25 mg/L 	<p>NSF iodine sanitizing warewashing machine certification is conducted at 24°C (75°F). Iodophor EPA registration tests are run at 20°C (68°F). Since an assessment of efficacy is part of the EPA evaluation process, and not all applications are for warewashing; the minimum temperature stated in the Food Code should be lowered for consistency with EPA practice. This would not prevent NSF from using the higher temperature for equipment validation tests.</p>	<p>“An iodine solution shall have a:</p> <ol style="list-style-type: none"> (1) Minimum temperature of <u>24°C (75°F)</u>-20°C (68°F),”... 																														

Recommended Changes to Harmonize Food Code and EPA Sanitizer Provisions

Extracted from Table 1 of the 2006-08 CFP Sanitizer Committee Final Report, excluding Annex 3 for 4-501.114

Table 1 (continued) Recommended Food Code modification for consistency with EPA requirements

Food Code Reference	Specific Food Code 2005 Citation Language (verbatim)	Rationale for Recommendation	Recommended solution
4-501.114 (C)	A quaternary ammonium compound solution shall: (1) Have a minimum temperature of 24°C (75°F), (2) Have a concentration as specified under 7-204.11 and as indicated by the manufacturer's use directions included in the labeling, and (3) Be used only in water with 500mg/L hardness or less or in water having a hardness no greater than specified by the manufacturer's label;	No inconsistencies are noted between Food Code and EPA requirements; however, clause (2) is redundant with the initial paragraph. Deletion is recommended remove redundancy. Also modify wording regarding the manufacturer's label to reflect the standard EPA-registered label wording. There will be an inconsistency between the minimum temperature for quat and iodine; however, EPA registration temperatures for quat and iodine are 24°C and 20°C, respectively.	A quaternary ammonium compound solution shall: (1) Have a minimum temperature of 24°C (75°F), <u>and</u> (2) Have a concentration as specified under 7-204.11 and as indicated by the manufacturer's use directions included in the labeling, and (3) Be used only in water with 500mg/L hardness or less or in water having a hardness no greater than specified by the <u>manufacturer's EPA-registered label use instructions</u> ;
4-501.114 (D)	If another solution of a chemical specified under (A)-(C) of this section is used, the PERMIT HOLDER shall demonstrate to the REGULATORY AUTHORITY that the solution achieves SANITATION and the use of the solution shall be APPROVED; or	Sanitizers must be registered with EPA for their specific use following specific protocols recognized by EPA and they must be used per label instructions. This section of the Food Code should not provide flexibility to use other concentrations, potentially in conjunction with other treatments, as long as it is validated to be effective by the "permit holder," i.e. the legal entity operating the establishment. As long as the use is consistent with the EPA registered label, it should be allowed.	If another solution use condition (e.g. temperature, pH, water hardness, etc.) of a chemical specified under (A)-(C) of this section is used, the PERMIT HOLDER shall demonstrate to the REGULATORY AUTHORITY that the solution achieves SANITATION, and the use of the solution shall be APPROVED; or
4-501.114 (E)	If a chemical SANITIZER other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the manufacturer's use directions included in the labeling.	Sanitizers must be registered with EPA for compliance.	"If a chemical SANITIZER other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the <u>EPA-registered label manufacturer's use directions included in the labeling.</u>
4-501.114 (F)	New	The Food Code currently does not address on-site generation of sanitizing solutions. There is need to clarify what is allowed for this purpose for safety and efficacy.	<u>Any chemical substance produced and used on-site as a food contact sanitizing solution must be in compliance with 40 CFR 180.940.</u>

Reference for 4-501.114

- Miller, M.P. Principle Investigator, 1984. Relationship of factors affecting bactericidal effectiveness of chlorine sanitizing solutions. Final report. National Sanitation Foundation, Ann Arbor, MI. Subcontract No. 9013-092-108-H0620-101; Booz, Allen & Hamilton, Inc. Contract No. 223-80-2295.
- Miller, M.P. Principle Investigator, 1985. Relationship of factors affecting bactericidal effectiveness of chlorine sanitizing solutions. Addendum to Final report. National Sanitation Foundation, Ann Arbor, MI Subcontract No. 9013-092-108-H0620-101; Booz, Allen & Hamilton, Inc. Contract No. 223-80-2295.
- National Sanitation Foundation, Ann Arbor, MI November 1990. Report on the bacterial effectiveness of a chlorine sanitizing solution at contact times of less than 10 seconds. Purchase Order #FDA 665531-00-90-RB.

Recommended Changes to Harmonize Food Code and EPA Sanitizer Provisions

Extracted from Table 1 of the 2006-08 CFP Sanitizer Committee Final Report, excluding Annex 3 for 4-501.114

Table 1 (continued) Recommended Food Code modification for consistency with EPA requirements

Food Code Reference	Specific Food Code 2005 Citation Language (verbatim)	Rationale for Recommendation	Recommended solution
4-703.11 Sanitation of Equipment and Utensils - Hot Water and Chemical	After being cleaned, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED in:		
4-703.11(A)	Hot water manual...	Not relevant	
4-703.11(B)	Hot water mechanical...	Not relevant	
4-703.11(C)	<p>Chemical manual or mechanical operations, including the application of SANITIZING chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under 4-501.114 by providing:</p> <ol style="list-style-type: none"> (1) Except as specified under Subparagraph (C)(2) of this section, an exposure time of at least 10 seconds for a chlorine solution specified under 4-501.114(A) (2) An exposure time of at least 7 seconds for a chlorine solution of 50 mg/L that has a pH of 10 or less and a temperature of at least 38°C (100°F) or a pH of 8 or less and a temperature of at least 24°C (75°F), (3) An exposure time of at least 30 seconds for other chemical SANITIZING solutions, or (4) An exposure time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields SANITIZATION as defined in Subparagraph 1-201.10(B). 	<p>EPA uses the term “contact time” in a consistent manner with the term “exposure time”, meaning the time that the surface is submerged, sprayed, wiped, etc. with the solution. The committee recommends using “contact time” in place of “exposure time” throughout the Food Code for consistency.</p> <p>Sanitizer products must be used consistent with EPA registered labels; which frequently, but not always, specify a <u>contact</u> time. EPA registration tests use a 30 second contact time followed by immediate neutralization. As currently written, this section may be misinterpreted to allow shorter contact times than those specified on EPA-registered labels. Additional wording is proposed to avoid misinterpretation.</p> <p>Data to validate efficacy of the times in Subparagraphs (1) and (2) exist (Miller 1984, Miller 1985, NSF, 1990) and included contact times shorter than 30 seconds. A 7 second <u>application</u> time is used by NSF Standard 3 for low temperature commercial warewash machine certification based on these reports. While the sanitizer is “applied” for a minimum of 7 seconds, the sanitizer remains on the surface for a longer period of time because it is not rinsed off. These provisions were in the Food Code prior to transfer of jurisdiction to EPA. They have a long history of effective use and are in multiple state regulations. Therefore, retaining these provisions in the Food Code is important to ensure continued use of appropriate conditions for low temperature warewashing machine certification. At the same time, they do not conflict with EPA labels that have no time requirement specified for warewashing.</p> <p>The committee therefore recommends adding wording to clarify that times specified on EPA registered labels must be followed, while retaining the provision for shorter times.</p>	<p>Chemical manual or mechanical operations, including the application of SANITIZING chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under 4-501.114. <u>Contact times shall be consistent with those on EPA-registered label use instructions, or if time is not specified</u> by providing:</p> <ol style="list-style-type: none"> (1) Except as specified under Subparagraph (C)(2) of this section, an exposure <u>a contact</u> time of at least 10 seconds for a chlorine solution specified under 4-501.114(A) (2) An exposure <u>A contact</u> time of at least 7 seconds for a chlorine solution of 50 mg/L that has a pH of 10 or less and a temperature of at least 38°C (100°F) or a pH of 8 or less and a temperature of at least 24°C (75°F), (3) An exposure <u>A contact</u> time of at least 30 seconds for other chemical SANITIZING solutions, or (4) An exposure <u>A contact</u> time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields SANITIZATION as defined in Subparagraph 1-201.10(B).

Recommended Changes to Harmonize Food Code and EPA Sanitizer Provisions

Extracted from Table 1 of the 2006-08 CFP Sanitizer Committee Final Report, excluding Annex 3 for 4-501.114

Table 1 (continued) Recommended Food Code modification for consistency with EPA requirements

Food Code Reference	Specific Food Code 2005 Citation Language (verbatim)	Rationale for Recommendation	Recommended solution
7-204.11 Sanitizers, Criteria	Chemical SANITIZERS and other chemical antimicrobials applied to FOOD-CONTACT SURFACES shall meet the requirements specified in 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions).	This provision (7-204.11) is included to address chemical safety issues related to use of hazardous chemicals or hazardous levels of chemicals on food contact surfaces. When EPA registers a sanitizer under FIFRA, a review of 40 CFR 180.940 is done to ensure that the proposed chemical meets chemical safety issues for its intended use. Therefore, the inclusion of this provision is not intended to direct inspectors or operators to 40 CFR 180.940 to ascertain compliance of a product that is being used in a manner consistent with its EPA registered label. Instead, it is more appropriately used by EPA to check for tolerance levels allowed, and by manufacturers to understand what may be used as sanitizers.	No changes recommended.

Recommended Changes to Harmonize Food Code and EPA Sanitizer Provisions

Extracted from Table 1 of the 2006-08 CFP Sanitizer Committee Final Report, excluding Annex 3 for 4-501.114

Table 1 (continued) Recommended Food Code modification for consistency with EPA requirements

Food Code Reference	Specific Food Code 2005 Citation Language (verbatim)	Rationale for Recommendation	Recommended solution
<p>Annex 3 - Public Health Reasons/ Administrative Guidelines 4-501.14 Warewashing Equipment, Cleaning Frequency</p>	<p>With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Coordination Act of 1998, federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation has moved from 21 CFR 178.1010 to 40 CFR 180.940.</p> <p>During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day.</p> <p>With respect to chemical sanitization, section 4-501.114 addresses the proper make-up for the sanitizing <u>solution</u>, i.e., chemical concentration, pH, and temperature at the required <u>minimum</u> levels specified when considered together and, with respect to quaternary ammonium compounds (quats), the <u>maximum</u> hardness level. If these minimums (maximum hardness) are not as specified, then this provision is violated.</p> <p>By contrast, paragraph 4-703.11(C) addresses exposure time in seconds. For chemical sanitization, this paragraph is only violated when the specified exposure time is not met.</p> <p>Section 7-204.11 addresses two additional considerations. The first is whether or not the chemical agent being applied as a sanitizer is <u>approved</u> and listed for that use under 40 CFR 180.940. If the chemical used is not thus listed, this section is violated.</p> <p>The second consideration under this section is whether the product, if approved and listed, is being used in accordance with the "Limits" provided for that product under its 40 CFR 180.940 listing. The concern here is an indirect food additives concern, since chemical sanitizing solutions are not rinsed off in this country. For example, 40 CFR 180.940(a) lists several quaternary ammonium compounds as approved for "food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils," each listing adding a Limit that states, "When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound." If a sanitarian determined that a solution of any of these quats was 600 ppm, section 7-204.11 would be violated.</p> <p>To summarize, a too weak sanitizing solution would be a violation of section 4-501.114. A too strong solution would be a violation of section 7-204.11. Section 7-202.12 would not be violated due to the existence of section 7-204.11 that specifically addresses the use of chemical sanitizers.</p>	<p>With the exception of the second paragraph of Annex 3 section 4-501.14, all of the other wording repeats wording from Annex 3 section 4-501.114. This seems to be an error because 4-501.14 addresses frequency of cleaning, with no specific mention of sanitizers, whereas 4-501.114 specifically addresses sanitizers.</p> <p>Inclusion of the discussion of EPA in this section therefore creates redundancy and confusion, and should be deleted.</p>	<p>Delete all paragraphs except paragraph two, which follows.</p> <p>"During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day."</p>

**Conference for Food Protection
2008 Issue Form**

**Internal Number: 053
Issue: 2008 III-011**

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

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Title:

Quaternary Ammonium Compounds & Harmonization with EPA Practice

Issue you would like the Conference to consider:

The example provided in Food Code Annex 3 for 4-501.114 related to a maximum level of 200 ppm for quaternary ammonium compounds (quats) is no longer consistent with EPA regulations because EPA amended 40 CFR 180.940 in September 2007 to allow up to 400 ppm of certain quats for food service and other applications. This issue generated significant discussion during Sanitizer Committee deliberations, and the committee concluded that removing prescriptive examples like this that cite other regulations would prevent inconsistencies if regulations are amended. This example, as well as other inconsistencies between this section of Annex 3 and EPA practice are addressed in "Table 1 Recommended Food Code modification for consistency with EPA requirements" of the CFP 2006-08 Sanitizer Committee Final Report, and includes detailed rationale for the recommended solution below. All changes to Annex 3 for 4-501.114 are submitted in this Issue to prevent misinterpretation of information taken out of context. (see attached "*Quats and Harmonization with EPA practice - Recommended Changes*"; extracted from the CFP 2006-08 Sanitizer Committee Final Report).

Public Health Significance:

Use of effective concentrations of sanitizers is an important step to prevent cross contamination and food safety failures. It is also important that the concentration of sanitizer used is below the levels set by EPA to prevent use of potentially hazardous levels. Clarification of the Food Code requirements for sanitizers is essential to ensure proper use of these materials and to avoid unproductive confusion for inspectors and operators.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending changes to the Food Code Annex 3 for section 4-501.114 to read as follows:

"With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Coordination Act of 1998, federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation ~~has~~ moved from 21 CFR 178.1010 to 40 CFR 180.940. The Food Code contains provisions that were not captured in either 21 CFR 178.1010 or 40 CFR 180.940, such as pH, temperature, and water hardness. There is need to retain these provisions in the Code.

"The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. ~~All Sanitizers approved for use under 40 CFR 180.940 must be used under water conditions stated on the label to ensure efficacy. Provisions for pH, temperature, and water harness in 4-501.114 have been validated to achieve sanitization; however, these parameters are not always included on EPA-registered labels.~~ Therefore, it is critical to sanitization that the sanitizers are used consistently with the EPA-registered label, and, if pH, temperature, and water harness (for quat) are not included on the label, that properly and the solutions meet the minimum standards required in the Code.

"With respect to chemical sanitization, section 4-501.114 addresses the proper ~~make-up for use conditions for~~ the sanitizing solution, i.e., chemical concentration range, pH and temperature ~~at the required maximum~~ minimum levels ~~specified when considered together and, with respect to quaternary ammonium compounds (quats), the maximum hardness level. If these minimums (maximum hardness) parameters are not as specified in the Code or on the EPA-registered label, then this provision is violated.~~

"By contrast, paragraph 4-703.11(C) addresses ~~exposure~~ contact time in seconds. For chemical sanitization, this paragraph is only violated when the specified ~~exposure~~ contact time is not met.

"Section 7-204.11 addresses ~~two additional considerations. The first is whether or not the chemical agent being applied as a sanitizer is approved, and listed, and used in accordance with the "Limits" for that use under 40 CFR 180.940. If the chemical used is not thus listed, this section is violated.~~

~~"The second consideration under this section is whether the product, if approved and listed, is being used in accordance with the "Limits" provided for that product under its 40 CFR 180.940 listing. The concern here~~ This is an indirect food additives concern, since chemical sanitizing solutions are not rinsed off in this country the United States. EPA sanitizer registration assesses compliance with 40 CFR 180.940, therefore if the product is used at the appropriate concentration for the application on the EPA-registered label, it is not necessary to consult 40 CFR 180.940 for further compliance verification. For example, 40 CFR 180.940(a) lists several quaternary ammonium compounds as approved for "food-contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils," each listing adding a Limit that states, "When ready for use, the

~~end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound. If a sanitarian determined that a solution of any of these quats was 600 ppm~~ exceeded the concentration for the application on the EPA-registered label or is used for an application that is not on the EPA-registered label, section 7-204.11 would be violated.

"To summarize, a ~~too weak~~ sanitizing solution that is too weak would be a violation of section 4-501.114. A ~~too strong~~ solution that is too strong would be a violation of section 7-204.11. Section 7-202.12 would not be violated due to the existence of section 7-204.11 that specifically addresses the use of chemical sanitizers."

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Attachments:

- "Quats and Harmonization with EPA Practice - Recommended Changes"

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.

Quats & Harmonization with EPA Practice – Recommended Changes

Annex 3 for 4-501.114 extracted from Table 1 of the 2006-08 CFP Sanitizer Committee Final Report

Table 1 (continued) Recommended Food Code modification for consistency with EPA requirements

Food Code Reference	Specific Food Code 2005 Citation Language (verbatim)	Rationale for Recommendation	Recommended solution
<p>Annex 3 Public Health Reasons/ Administrative Guidelines 4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitation – Temperature, pH, Concentration, and Hardness</p>	<p>With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Coordination Act of 1998, federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation has moved from 21 CFR 178.1010 to 40 CFR 180.940.</p> <p>The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. All sanitizers approved for use under 40 CFR 180.940 must be used under water conditions stated on the label to ensure efficacy. Therefore, it is critical to sanitization that the sanitizers are used properly and the solutions meet the minimum standards required in the Code.</p> <p>With respect to chemical sanitization, section 4-501.114 addresses the proper make-up for the sanitizing <u>solution</u>, i.e., chemical concentration, pH, and temperature at the required <u>maximum</u> [should state “minimum”] levels specified when considered together and, with respect to quaternary ammonium compounds (quats), the <u>maximum</u> hardness level. If these minimums (maximum hardness) are not as specified, then this provision is violated.</p> <p>By contrast, paragraph 4-703.11(C) addresses exposure time in seconds. For chemical sanitization, this paragraph is only violated when the specified exposure time is not met.</p> <p>Section 7-204.11 addresses two additional considerations. The first is whether or not the chemical agent being applied as a sanitizer is <u>approved</u> and listed for that use under 40 CFR 180.940. If the chemical used is not thus listed,</p>	<p>With the shift in regulatory responsibility, transfer of certain sanitizer provisions in the Food Code did not occur and has led to confusion. The Food Code covers information relevant to application of sanitizers in food service operations that were not included in 21 CFR 178.1010. Specifically, the tables cited in 4-501.114 of the Food Code, and contact times cited in 4-703.11(C).</p> <p>Some products (e.g. low temperature dish machine sanitizers) comply with NSF certification criteria, and no EPA protocol exists for registration of such products in combination with factors such as temperature, pH, hardness, etc. Additionally, not all EPA-registered labels include a statement of water conditions for use. Therefore, this Annex needs to explain why provisions are retained in the Food Code.</p>	<p>With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Coordination Act of 1998, federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation has moved from 21 CFR 178.1010 to 40 CFR 180.940. <u>The Food Code contains provisions that were not captured in either 21 CFR 178.1010 or 40 CFR 180.940, such as pH, temperature, and water hardness. There is need to retain these provisions in the Code.</u></p> <p>The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. All sanitizers approved for use under 40 CFR 180.940 must be used under water conditions stated on the label to ensure efficacy. <u>Provisions for pH, temperature, and water hardness in 4-501.114 have been validated to achieve sanitization; however, these parameters are not always included on EPA-registered labels.</u> Therefore, it is critical to sanitization that the sanitizers are used <u>consistently with the EPA-label, and, if pH, temperature, and water hardness (for quat) are not included on the label, that properly and</u> the solutions meet the minimum standards required in the Code.</p> <p>With respect to chemical sanitization, section 4-501.114 addresses the proper make-up for use conditions for the sanitizing solution, i.e., chemical concentration range, pH and temperature at the required maximum minimum levels specified when considered together and, with respect to quaternary ammonium compounds (quats), the maximum hardness level. If these minimums (maximum hardness) parameters are not as specified <u>in the Code or on the EPA-registered label</u>, then this provision is violated.”</p> <p>By contrast, paragraph 4-703.11(C) addresses exposure <u>contact</u> time in seconds. For chemical sanitization, this paragraph is only violated when the specified exposure <u>contact</u> time is not met.</p>

Quats & Harmonization with EPA Practice – Recommended Changes

Annex 3 for 4-501.114 extracted from Table 1 of the 2006-08 CFP Sanitizer Committee Final Report

Table 1 (continued) Recommended Food Code modification for consistency with EPA requirements

	<p>this section is violated.</p> <p>The second consideration under this section is whether the product, if approved and listed, is being used in accordance with the “Limits” provided for that product under its 40 CFR 180.940 listing. The concern here is an indirect food additives concern, since chemical sanitizing solutions are not rinsed off in this country. For example, 40 CFR 180.940(a) lists several quaternary ammonium compounds as approved for “food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils,” each listing adding a Limit that states, “When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound.” If a sanitarian determined that a solution of any of these quats was 600 ppm, section 7-204.11 would be violated.</p> <p>To summarize, a too weak sanitizing solution would be a violation of section 4-501.114. A too strong solution would be a violation of section 7-204.11. Section 7-202.12 would not be violated due to the existence of section 7-204.11 that specifically addresses the use of chemical sanitizers.</p>	<p>The example provided for quaternary ammonium compounds is no longer consistent with 40 CFR 180.940, which has been amended to allow use of certain quats not to exceed 400 ppm. (Federal Register Volume 72, Number 172, September 6, 2007, page 51180-7). Inclusion of a specific example such as this provides an opportunity for inconsistency as regulations are amended. Removal of specific examples and citing consistency with the EPA-registered label would reduce the potential for inconsistency, confusion, and effort to understand what is allowed.</p>	<p>Section 7-204.11 addresses two additional considerations. The first is whether or not the chemical agent being applied as a sanitizer is approved, and listed, and used in accordance with the “Limits” for that use under 40 CFR 180.940. If the chemical used is not thus listed, this section is violated.</p> <p>“The second consideration under this section is whether the product, if approved and listed, is being used in accordance with the “Limits” provided for that product under its 40 CFR 180.940 listing. The concern here <u>This is an indirect food additives concern, since chemical sanitizing solutions are not rinsed off in this country the United States. EPA sanitizer registration assesses compliance with 40 CFR 180.940, therefore if the product is used at the appropriate concentration for the application on the EPA-registered label, it is not necessary to consult 40 CFR 180.940 for further compliance verification. For example, 40 CFR 180.940(a) lists several quaternary ammonium compounds as approved for “food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils,” each listing adding a Limit that states, “When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound. If a sanitarian determined that a solution of any of these quats was 600 ppm exceeded the concentration for the application on the EPA-registered label or is used for an application that is not on the EPA-registered label, section 7-204.11 would be violated.”</u></p> <p>To summarize, a too weak <u>too weak</u> sanitizing solution that is too weak would be a violation of section 4-501.114. A too strong <u>too strong</u> solution that is too strong would be a violation of section 7-204.11. Section 7-202.12 would not be violated due to the existence of section 7-204.11 that specifically addresses the use of chemical sanitizers.</p>
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**Conference for Food Protection
2008 Issue Form**

**Internal Number: 041
Issue: 2008 III-012**

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:

Support for Harmonizing the Food Code with EPA Sanitizer Provisions

Issue you would like the Conference to consider:

As clearly identified at the 2006 CFP Biennial Meeting, there are inconsistencies between the 2005 Food Code and EPA regulations and practices. The 2006-08 Sanitizer Committee has worked to develop suggestions that would harmonize the language between the Food Code and EPA provisions. We urge CFP to accept the recommendations of the Committee.

Public Health Significance:

Proper sanitization procedures and effective concentration levels of surfaces and equipment are necessary. Such levels must meet the recommendation of EPA to prevent higher levels used which may cause food safety concerns. Clarification of the Food Code requirements for sanitizers is essential to assure proper use of these materials. Additionally, elimination of any confusion as it relates to the code language makes for a more effective Food Code for all affected parties, both regulatory and the industry.

Recommended Solution: The Conference recommends...:

adoption of the recommendations of the Sanitizer Committee that would support harmonization of the Food Code with EPA sanitizer provisions.

Submitter Information:

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**Conference for Food Protection
2008 Issue Form**

**Internal Number: 114
Issue: 2008 III-013**

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

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Title:

Requirements for on-site generated electro-chemically activated sanitizers

Issue you would like the Conference to consider:

The Federal Insecticide, Fungicide, And Rodenticide Act (FIFRA, "The Act") is intended to regulate the marketing of economic poisons and devices, and for other purposes, according to its publication, dated Oct 9, 2007, as amended through P.L. 110-94.; **7 U.S.C. prec. 121.**

Sanitizers, disinfectants and sterilants are defined as "pesticides" in these regulations. Until now and in general terms, all chemicals registered with EPA as pesticides have had a double edge:

1. They are toxins; **economic poisons** according to FIFRA; and are "misbranded" if their package fails to be labeled with the international skull and crossbones symbol for poison:2q(2)(D)(i).
2. They have limits to efficacy that require specific concentrations, pH, and temperature. Indeed, when mixed with potable water it is well known that source water chemistry can limit their effectiveness. Primary limiting factors include turbidity and total dissolved solids (TDS) even though these source waters fit into the "potable" category.

Congress recognized that regulations were needed to define those concentrations and mixture characteristics needed for these toxic chemical admixtures to effectively reduce target pathogens whilst at the same time providing precautionary statements to protect the user, the public and the environment from risk factors associated with the use, discharge and disposal of such toxins and their containers.

Non-toxic solutions are generated on-site by a process first published in 1847 by Michael Faraday; the Laws of Electrolysis. The science is irrefutable. Otherwise, Faradays Laws would be titled the opinions, notions, or extrapolations of electrolysis. Their science and correlative mathematics is every bit as solid as those of magnetic field theory or the theory of relativity. In water electrolysis, potable water is mixed with salt (typically sodium chloride) to a concentration of approximately 2000 PPM NaCl (0.02%) to H₂O. Because these are

non-toxic solutions, they fall outside one of the two primary objectives of the rule; precautionary statements needed to protect animals, humans and the environment from exposure to registered economic poisons. Solutions generated by dilute brine electrolysis cannot be termed "poisons" as their generation in fact occurs within every higher life form. ECA is bioinspiration or, biomimicry at its best. It is a well known fact that ECA solutions are comprised largely of *non-toxic* hypochlorous acid (HOCl) in addition to many ionic bonds associated with free radicals and electron activity, both donors (anolyte) and acceptors (catholyte) associated with the strong electro-magnetic processing of "electrolyte" with resulting physicochemical properties being determined principally through the control of electrolytes conductivity, flow rate and energy input (E-).

Section 2. (h) of FIFRA defines "DEVICE" as "any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling or mitigating any pest or other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals(s); but not including equipment used for the application of pesticides when sold separately there from."

To date, U.S. EPA has interpreted the administration of The Act to include electro-chemical reaction equipment in the "Device" definition thereby exerting authority granted by The Act over the manufacture of such devices having categorized them as "pesticide generators". As such, on-site generation and application of electro-chemically activated (ECA) "pesticides" (sanitizers, disinfectants, sporicides and sterilants) have been interpreted to be EXEMPT from the more familiar pesticide registrations requirements for chemical concentrates pursuant to pesticide registration requirements.

Section 7 [7 U.S.C. 136e] of FIFRA contains the other criteria that are specific to the nuance of such electro-chemically activated electrolytes generated and applied on-site. These criteria are separate and distinct from those intended to protect us from exposures to the "economic poisons" that are packaged, labeled and then sold/distributed in interstate commerce.

Similarly, regulations promulgated in **40 CFR 180.940** were developed in part to protect the public and the environment from toxin exposures and separately to present concentration and reasonable threshold limit values (TLV's) for its chemical characteristics. The precautionary label requirements pertain only to these economic poisons, whether in concentrate or ready to use form.

When on-site generated ECA solutions first appeared in the U.S., EPA decided, whether for convenience or due to lack of scientific understanding, to treat them as "equivalent" to those poisonous admixtures already registered for the same intended uses. Thus, the TLV range of 50-200PPM free available chlorine(FAC) is applied to salt based ECA anolyte too, even though higher concentrations are still NON-TOXIC, and lower concentrations have been proven to be highly efficacious against a range of target pathogens on hard contact surfaces.

It is arbitrary and capricious to suggest imposition of labeling warnings and notifications to non-toxic substances generated on-site by electro-chemical activation to match those

required of the economic poisons responsible for many of the cancers and other diseases of humans attributable to life long exposures whose cumulative affects are just now coming into mainstream consciousness. So too is such an initiative a disingenuous restraint of trade promoted by those with vested interests in slowing ECA's speed to the commercial market as after all, they comprise the ONLY effective non-toxic cleaners and sanitizers known and thus pose a significant threat to the streams of revenues that the economic poison producers and their private and public dependants rely upon.

What is needed is a separate category into which any label requirements for the on-site generators and their solutions are placed. Said labels would logically be affixed directly to the on-site generator itself along with required MSDS for the range intended solutions generation.

For the sake of category conceptualization, I suggest that this new category is to be reserved for "**BLUE**" methods and means; BLUE being indicative of those non-toxic solutions, methods and means that are effective and at the same time non-toxic to all animals, birds, fish, reptiles and humans. Other such "BLUE" subcategories would include various mechanical or energy transfer methods or means, whether thermal destruction of organisms (Energy;steam, heat, electronic, photonic, radiologic, sonic) or of ultra high pressure or similar kinetics. This new BLUE category will then provide contrast compared to "GREEN" chemistry which is simply a lesser degree or less toxic form of the same "economic poison(s)" regulated by FIFRA.

Public Health Significance:

There is no adverse impact on public health

Recommended Solution: The Conference recommends...:

That a letter be sent to FDA recommending;

1. That the Sanitizer Committee be recreated and charged with the responsibility of investigating logical requirements for labelling ECA generators capable of generating on-site a range of unique, non-toxic metastabilized pesticides (sanitizers) in dynamic equilibrium for a range of intended uses and applications.
2. That the same Sanitizer committee investigate logical threshold limit values (TLV's) for potable water characteristics that are intended to used as base for economic poisons registered by EPA pursuant to FIFRA, and specifically and technically articulate the range of potable water characteristics necessary to assure all sanitizers efficacy with regard to temperature, TDS, turbidity and all other factors known to impact any sanitizers efficacy coefficients.

3. That the same Sanitizer Committee present the results of its investigation to Council II of the CFP so they in turn can be used to develop educational curriculum and risk communication opportunities to ensure that regulatory officials, food handlers and the public understand the unique attributes associated with both the economic poisons and their alternative non-toxic "BLUE" types of interventions including ECA, and those measures needed to assure efficacy of each given thier inteded use, application, discharge and disposal.

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**Conference for Food Protection
2008 Issue Form**

**Internal Number: 047
Issue: 2008 III-014**

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

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Title:

160°F Utensil Surface Temperature

Issue you would like the Conference to consider:

The 160°F utensil surface temperature referenced in 4-703.11 originated from an FDA-sponsored study by NSF International in the mid 1980's. The objective of the study was to develop a practical method to evaluate wash and rinse temperatures on dishwashers in the field. Although the 160°F surface temperature may have been easy to observe in the mid 1980's, the reduced water and energy consumption of today's machines makes it much more difficult to detect on a consistent basis. Additional factors that affect this criteria are the quality and accuracy of the temperature measuring device being used. The 160°F surface temperature has evolved over the years to become a performance standard rather than an observational guideline. The NSF International Standard 3 for Commercial Warewashing Equipment does not require a 160°F surface temperature. The requirement is a cumulative total of 3600 Heat Unit Equivalents with a 180°F final rinse temperature at the manifold. Theoretically a machine can provide effective sanitization without attaining a 160°F surface temperature. The FDA Food Code should not be design restrictive and should allow for technological advances, especially those that contribute to overall reduced energy consumption and smaller carbon footprints.

Public Health Significance:

There is no impact on public health.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that paragraph 4-703.11 be modified as follows:

4-703.11 Hot Water and Chemical.*

After being cleaned, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED in:

(A) Hot water manual operations by immersion for at least 30 seconds and as specified under § 4-501.111;

(B) Hot water mechanical operations by being cycled through EQUIPMENT that is set up as specified under §§ 4-501.15, 4-501.112, and 4-501.113 ~~and achieving a UTENSIL surface temperature of 71°C (160°F) as measured by an irreversible registering temperature indicator; or...~~

The Conference further recommends that the Public Health Reasons in Annex 3 be modified as follows:

Methods 4-703.11 Hot Water and Chemical.*

Efficacious sanitization depends on warewashing being conducted within certain parameters. Time is a parameter applicable to both chemical and hot water sanitization. The time hot water or chemicals contact utensils or food-contact surfaces must be sufficient to destroy pathogens that may remain on surfaces after cleaning. Other parameters, such as rinse pressure, temperature, and chemical concentration are used in combination with time to achieve sanitization. When surface temperatures of utensils passing through warewashing machines using hot water for sanitizing do not reach the required 71°C (160°F) ~~temperatures~~, it is important to understand the factors affecting the decreased surface temperature. A comparison should be made between the machine manufacturer's operating instructions and the machine's actual wash and rinse temperatures and final rinse pressure. The actual temperatures and rinse pressure should be consistent with the machine manufacturer's operating instructions and within limits specified in §§ 4-501.112 and 4-501.113. If either the temperature or pressure of the final rinse spray is higher than the specified upper limit, spray droplets may disperse and begin to vaporize resulting in less heat delivery to utensil surfaces. Temperatures below the specified limit will not convey the needed heat to surfaces. Pressures below the specified limit will result in incomplete coverage of the heat-conveying sanitizing rinse across utensil surfaces. The typical surface temperature for a utensil passing through a warewashing machine is 71°C (160°F). However, this is not a mandatory minimum performance criteria. If a machine is operating in accordance with the manufacturer's instructions and the final rinse temperature at the manifold is 180 °F, effective sanitization can be achieved.

Submitter Information:

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Attachments:

- "1986 letter from FDA to Hobart with highlights of NSF study."

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.

Food and Drug Administration
Washington DC 20204

May 29, 1986

Bill Paull
Agency/Design Policy
HOBART Corporation
Troy, Ohio 45374

Dear Mr. Paull:

In response to your request as to the Food and Drug Administration's (FDA) policy for checking hot water sanitization temperatures in mechanical dishwashing modems, the enclosed guidelines are provided for your information. The guidelines were initiated by FDA following acceptance of test data results for hot water sanitization temperatures from mechanical dishwashing machines as a result of a study contracted by FDA with the National Sanitation Foundation.

We hope this information will be of help to you.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "William P. Wollschlager".

William P. Wollschlager
Principal Food Consultant
Retail Food Protection Branch
Center for Food Safety
and Applied Nutrition

Enclosure

CHECKING TEMPERATURES IN DISHWASHING MACHINES

A study on developing and validating practical methods for evaluating wash and rinse temperatures in mechanical spray-type dishwashing machines was recently completed by the National Sanitation Foundation. This study was funded by a contract with the Division of Food Service, FDA. Briefly summarized are some of the more important findings.

1. Maximum registering, mercury filled thermometers and thermo-labels (paper thermometers that change color from silver to black when reaching specified temperatures) may be used and are relatively accurate. However, other factors should be taken into account for proper development of the required heat:
 - a. Scrap trays clean.
 - b. Wash and rinse nozzles clear of obstructions and lime deposits.
 - c. Flow pressure 20 psi + 5 psi.
 - d. Wash and rinse thermometers accurate or properly calibrated.
 - e. Overflow standpipe in place and not blocked or leaking.
 - f. No lime deposits in heating elements.
 - g. Rinse line strainer clear.
 - h. Machine tank gas heater jets not obstructed.
 - i. Pressure regulator operable.
 - j. Building water pressure adequate.
 - k. End caps in place on wash and rinse lines.
 - l. Rinse arm nozzle alignment correct.
 - m. Curtains intact and in proper position on conveyor-type machines.
 - n. Wash and rinse pump inlet unobstructed.
 - o. Conveyor speed according to manufacturer's specifications.
 - p. No excessive ventilation draft in the removal of steam and condensation.
 - q. Dishes properly racked.
2. Proper sanitization depends on heat accumulation from washing, power rinsing (on some types of machines) and final rinsing. Therefore, each of these cycles must be operating at the proper temperature.
3. The maximum registering, mercury filled thermometer, to give accurate readings, should be attached (rubber bands may be used) to the outside of an inverted glass in a vertical position. It should

also be taken out of any case or guard when used. Thermo-labels are attached by pressure sensitive adhesive tape (scotch tape)¹ preferably on a clean china plate.

4. A thermometer can be attached at the gage cock to check the calibration of the final rinse thermometer without removing the final rinse thermometer sensing bulb. However, the thermometer to be attached should have an immersion mark on it and must have a special connection that will allow movement of the stem through the opening presented when the valve is turned on. The sensor must be inserted into the flowing stream of water or serious errors in readings can occur since cooling will take place between the rinse flow line and the thermometer location. Be sure and check the thermometer that is being used as the calibrating thermometer. Immerse it in the hot water to the immersion mark on the thermometer and take a comparison reading. There will be a difference in reading if the bulb is not immersed to this depth each time.

Temperatures must be checked with the rinse activated and water flowing in the line.

5. As water falls through space after leaving the rinse spray arms, the drop off in temperature is rapid. Obviously, the temperature developed at the dish surface can be 10°F. to 20°F. lower than the temperature in the manifold. Therefore, a reading on the maximum registering thermometer of at least 160°F. or a color change in thermopaper at 160°F. should be acceptable.

6. Unless the machine is being used just prior to testing, run the machine through at least two complete wash and final rinse cycles before taking readings.
7. Close adherence to manufacturer's specifications as listed on the machine data plate is very important.

¹Scotch Brand No. 471, 3 M Company is one manufacturer.

**Conference for Food Protection
2008 Issue Form**

**Internal Number: 069
Issue: 2008 III-015**

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

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Title:

Potable water rinse after terminal sanitizing step

Issue you would like the Conference to consider:

Some approved sanitizers leave a residue on food contact surfaces after the required contact time for a terminal sanitizing step which imparts malodors and adverse tastes to the foods or beverages with which they contact. Accordingly, a rinse with potable water of any temperature after required contact time has elapsed can remove or reduce these residuals to a level where they are not objectionable to consumer taste and smell.

Public Health Significance:

1) As long as sanitizer contact times and parameters detailed on sanitizer labels are attained, there is no reasonable risk associated with a potable water rinse as any water called potable is safe to drink. Reference: Section 4-703.11(C)(4) "After being cleaned, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED in chemical manual or mechanical operations, including the application of SANITIZING chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under § 4-501.114 by providing an exposure time used in relationship with a combination of temperature, concentration, and PH that, when evaluated for efficacy, yields SANITIZATION as defined in Subparagraph 1-201.10(B).

2) Where a nonfood contact sanitizer must provide a 99.9+% reduction, a food contact sanitizer is required to provide a 99.999+% reduction. Section 7-204.11 of the FDA Food Code requires sanitizers applied to food contact surfaces to meet 40 CFR 180.940 tolerance exemptions for active and inert ingredients for use in antimicrobial formulations. After the required sanitizer contact time has elapsed, a potable water rise cannot alter its sanitary state in any reasonable way. Further, 40 CFR 180.940 allows "adequate draining before contact with food", though this statement is purely subjective as "adequate draining" is not a defined term, the statement is not relevant when the cleaning and sanitizing steps are effective.

3) European standards allow potable water rinse after a sanitizing step.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting changes as indicated below:

4-901.11 Equipment and Utensils, Air-Drying Required.

After cleaning and SANITIZING, EQUIPMENT and UTENSILS:

(A) ~~Shall~~ May be rinsed with potable water after sanitizer contact times are achieved pursuant to their label instructions and shall thereafter be air-dried or used after adequate draining as specified in the first paragraph of 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface SANITIZING solutions), before contact with FOOD; and

(B) May not be cloth dried except that UTENSILS that have been air-dried may be polished with cloths that are maintained clean and dry.

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**Conference for Food Protection
2008 Issue Form**

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Title:

Post-sanitizing, Potable Water Rinse for Commercial Dishwashers

Issue you would like the Conference to consider:

Commercial dishwashers that have been tested to a sanitizing performance standard should be allowed to utilize a potable water rinse step after completion of the sanitizing step. This will meet a customer need for:

- A) Reduced chemical sanitizer taste and odor on drinking glasses and,
- B) Greater comfort and safety for workers handling plates and utensils after hot-water sanitizing.

Rationale:

1) FDA Food Code paragraph 4-703.11(C)(4) states, "After being cleaned, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED in chemical manual or mechanical operations, including the application of SANITIZING chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under § 4-501.114 by providing an exposure time used in relationship with a combination of temperature, concentration, and PH that, when evaluated for efficacy, yields SANITIZATION as defined in Subparagraph 1-201.10(B)." Since the warewashing equipment must be tested to the 5-log sanitizing performance criteria with the post-sanitizing rinse in operation, the Food Code objective will be satisfied and public health will not be compromised.

2) FDA Food Code paragraph 7-204.11 requires chemical sanitizers applied to food contact surfaces to meet the requirements of 40 CFR (Code of Federal Regulations) 180.940 tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions). 40 CFR 180.940 allows "adequate draining before contact with food". The term "adequate draining" is subjective and not defined. However, this is not in conflict with potable water rinse since the dishes must still be air dried before use.

3) The NSF Joint Committee (JC) for Food Equipment Standards voted to submit wording to propose a change to NSF 3 for Warewashing Equipment to allow a post sanitizing potable water rinse. Note - the Warewashing Task Group struggled with the following concerns:

- a. Drying time/space for additional racks,
- b. Perceived conflict with the FDA Food Code,
- c. Conflict with the EPA labeling requirements for use instructions for chemical sanitizing agents,
- d. Boil water advisory/alert. Note - NSF International has stated that non-potable water is outside the scope of NSF International/American National Standard 3-2007 for Commercial Warewashing Equipment. Products certified to an NSF International sanitation standard are not intended to be used with anything other than potable water;

4) EPA use label - EPA has informed the NSF Joint Committee (JC) Task Group that "potable water rinse after food-contact surfaces have been treated with a sanitizing rinse is not acceptable for products intended for use as a terminal sanitizing rinse". Also, EPA requires the sanitizer to be used according to the label instructions. Some, but not all sanitizer labels instruct the user not to rinse equipment with water after sanitizing. (If this is an optional manufacturer recommendation rather than an EPA mandated label instruction it should be so noted.) If the science of a 5-log kill step is verified on a dishwasher with the post-sanitizing potable water rinse in operation, the objective of the EPA label requirements is clearly met.

5) European regulations do not prohibit potable water rinse after a sanitizing step. These European models are certified by an independent laboratory to a 5 log kill criteria.

6) The Codex Alimentarius guidelines require Chlorite or Chlorous Acid (III) solutions on seafood, fruits and vegetables to be rinsed with potable water before raw consumption. [1]

7) FDA Food Code paragraph 3-302.15 (A) states, "...raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form."

[1] Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Food Standards Programme, codex committee on food additives and contaminants, thirty-seventh session, The Hague, the Netherlands, 25 - 29 April 2005.

Public Health Significance:

There is no impact on public health.

Recommended Solution: The Conference recommends...:

that paragraph 4-901.11 be modified as follows:

Equipment and Utensils, Air-Drying Required.

After cleaning and SANITIZING, or after a potable water rinse for mechanical warewashing equipment that has been tested in accordance with an ANSI accredited sanitation standard, EQUIPMENT and UTENSILS:

(A) Shall be air-dried or used after adequate draining as specified in the first paragraph of 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface SANITIZING solutions), before contact with FOOD; and

(B) May not be cloth dried except that UTENSILS that have been air-dried may be polished with cloths that are maintained clean and dry.

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Attachments:

- "EPA Label requirements: "EPALabelrequirements.pdf""

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Label Requirements for Pesticides Used for Sanitation of Food Contact Surfaces

DIS/TSS-17 / Dec. 2, 1979

LABEL REQUIREMENTS FOR ANTIMICROBIAL PESTICIDES USED FOR SANITATION OF FOOD - CONTACT SURFACES

Directions For Use

Labeling must bear directions for each recommended use. The directions for use must include, but are not limited to*, the following:

1. The major areas in which the product is recommended for use (e.g. restaurants, dairies, food processing plants).
2. The identification of the types of hard surfaces, or objects, intended for treatment.
3. The necessity for removal of gross food particles and soil by a pre-flush, or pre-scrub and, when necessary, pre-soak treatment. In addition, instructions must be provided for thoroughly washing the surfaces or objects with a good detergent or compatible cleaner, followed by a potable water rinse prior to application of the sanitizing solution.
4. The recommended use dilution and instructions for preparing it. The units of measure (e.g. tablespoons, ounces, quarts, gallons) to be employed in diluting the product must be given, and must be understandable to the user. The concentration (ppm) of principal active ingredient (e.g. titratable iodine, available chlorine, active quaternary) provided by the recommended use solution should also be given.
5. The method of application (e.g. immersion, flooding, spraying) to wet all surfaces thoroughly. Additional instructions for in-place sanitizing may be required (e.g. filling piping with the sanitizing solution).
6. The contact time of **at least 1 minute** required for sanitization. The directions must also indicate if, and how, the product is to be removed from the surfaces after the recommended contact time. Instructions to **drain the use solution from the surface and air dry are appropriate** for product cleared for use on food contact surfaces under the Federal Food, Drug and Cosmetic Act. **A potable water rinse must be recommended for removal of the use solution from the food contact surface under any other circumstances.**
7. For mechanical operations, the limitation that the prepared use solution may not be re-used for sanitizing but may be re-used for other purposes such as cleaning. For manual operations, the recommendation that fresh sanitizing solution should be prepared at least daily or more often if the solution becomes diluted or soiled.

*Additional instructions may be necessary for certain use patterns and/or categories of products to ensure safe and effective use of a product. Such additional instructions may be recommended by the applicant, or required by the Agency, as determined on a case basis.

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Last updated on Tuesday, May 2nd, 2006
URL: http://www.epa.gov/oppad001/dis_tss_docs/dis-17.htm

**Conference for Food Protection
2008 Issue Form**

**Internal Number: 045
Issue: 2008 III-017**

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

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Title:

Modification of Time as a Public Health Control

Issue you would like the Conference to consider:

The 2007 Supplement to the 2005 FDA Food Code added cut tomatoes to the definition of potentially hazardous food (time/temperature control for safety food)(PHF/TCS). On October 5, 2007, The FDA's Center for Food Safety and Applied Nutrition published Retail Food Protection Storage and Handling of Tomatoes. This document informs retail foodservice operators that cut tomatoes may be held unrefrigerated for up to four hours if the tomatoes are 41°F or less when removed from temperature control. If a food establishment uses Time as a Public Health Control (4-hour limit) in lieu of temperature control to manage a supply of cut tomatoes, there are two options: (1) chill whole tomatoes (non-PHF) prior to cutting, or (2) cut ambient temperature tomatoes and subsequently cool to 41°F or less within four hours and prior to removal from temperature control.

Scientific evidence provided in the attached document shows that when raw, cut tomatoes were inoculated with *Salmonella enteritidis* and allowed to incubate at 72°F, maximum growth on the order of only 0.288 logs was observed in the first 4 hours. A full one-log increase was not observed to occur until 6.78 hours after being cut and inoculated. Based on the evidence from this study, it is recommended that Time as a Public Health Control be modified to allow tomatoes to be cut at ambient temperature and stored, unrefrigerated, for up to four hours.

Public Health Significance:

The proposed issue will enable food establishments to apply Time as a Public Health Control to a working supply of cut tomatoes without a regulatory variance. This eliminates confusion regarding the need to refrigerate foods (whole tomatoes) that do not meet the definition of PHF/TCS. This change is required since the current wording of Time as a Public Health Control requires an initial temperature of 41°F or less before removal from temperature control.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that the wording of §3.501.19 be changed as follows:

3-501.19 Time as a Public Health Control.*

(A) Except as specified under ¶ (D) of this section, if time without temperature control is used as the public health control for a working supply of potentially hazardous food (time/temperature control for safety food) before cooking, or for ready-to-eat potentially hazardous food (time/temperature control for safety food) that is displayed or held for sale or service:

1. Written procedures shall be prepared in advance, maintained in the food establishment and made available to the regulatory authority upon request that specify:

(a) Methods of compliance with Subparagraphs (B)(1)-(3) or (C)(1)-(5) of this section; and

(b) Methods of compliance with § 3-501.14 for food that is prepared, cooked, and refrigerated before time is used as a public health control.

(B) If time without temperature control is used as the public health control up to a maximum of 4 hours:

(1) ~~The food shall have: an initial temperature of 5°C (41°F) or less when removed from cold holding temperature control, or 57°C (135°F) or greater when removed from hot holding temperature control;~~

a. an initial temperature of 5°C (41°F) or less when removed from cold holding temperature control, or

b. an initial temperature of 57°C (135°F) or greater when removed from hot holding temperature control; or

c. any temperature for uncut tomatoes.

(2) The food shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the food is removed from temperature control or for tomatoes the time that they are cut;

(3) The food shall be cooked and served, served at any temperature if ready-to-eat, or discarded, within 4 hours from the point in time when the food is removed from temperature control; and

(4) The food in unmarked containers or packages, or marked to exceed a 4-hour limit shall be discarded.

(C) If time without temperature control is used as the public health control up to a maximum of 6 hours:

(1) The food shall have an initial temperature of 5°C (41°F) or less when removed from temperature control and the food temperature may not exceed 21°C (70°F) within a maximum time period of 6 hours;

(2) The food shall be monitored to ensure the warmest portion of the food does not exceed 21°C (70°F) during the 6-hour period, *unless an ambient air temperature is maintained that ensures the food does not exceed 21°C (70°F) during the 6-hour holding period;*

(3) The food shall be marked or otherwise identified to indicate:

(a) The time when the food is removed from 5°C (41°F) or less cold holding temperature control, and

(b) The time that is 6 hours past the point in time when the food is removed from cold holding temperature control;

(4) The food shall be:

(a) Discarded if the temperature of the food exceeds 21°C (70°F), or

(b) Cooked and served, served at any temperature if ready-to-eat, or discarded within a maximum of 6 hours from the point in time when the food is removed from 5°C (41°F) or less cold holding temperature control; and

(5) The food in unmarked containers or packages, or marked with a time that exceeds the 6-hour limit shall be discarded.

(D) A food establishment that serves a highly susceptible population may not use time as specified under ¶¶ (A), (B) or (C) of this section as the public health control for raw eggs.

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Attachments:

- "Retail Food Protection Storage and Handling of Tomatoes"

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October 5, 2007

Program Information Manual

Retail Food Protection Storage and Handling of Tomatoes

- [Questions](#)
- [Discussion and Rationale](#)
- [Recommendation](#)
- [References](#)
- [Attachment A](#)
- [Attachment B](#)
- [Attachment C](#)

Questions

- Are tomatoes potentially hazardous food requiring time/temperature control for safety?
- How should fresh whole tomatoes, cut fresh tomatoes and cut fresh tomatoes used as an ingredient in other foods (i.e., in salsa, in salads, topping a pizza, in sandwiches, etc.) be handled in a retail food establishment?

Discussion and Rationale

Recent foodborne illness outbreaks associated with tomatoes indicate the storage and handling practices of tomatoes and other fresh produce in food service operations and retail food stores must be re-examined. The FDA's Produce Safety Action Plan (6) recommended adding language to the Food Code to address produce safety at retail. The Conference for Food Protection (CFP) in 2006 recommended to FDA (2) to incorporate "cut tomatoes" into the definition of potentially hazardous food (time/temperature control for safety food) in the FDA Food Code (5).

A potentially hazardous food (PHF) or time/temperature control for safety food (TCS food) is defined in terms of whether or not it requires time/temperature control for safety to limit pathogen growth or toxin formation. The term does not include foods that do not support growth whether or not they contain a pathogenic

microorganism or chemical or physical food safety hazard. The progressive growth of all foodborne pathogens is considered whether slow or rapid. This definition takes into consideration a food's acidity (pH), water activity (a_w), or combination of pH and a_w interaction, heat treatment, and packaging for a relatively simple determination of whether the food requires time/temperature control for safety. (See [Attachment A](#))

When pH and/or a_w are not sufficient to control pathogen growth and/or toxin formation in the food, refrigeration may be the only viable alternative without changing the character of the food. Internal FDA research (see [Attachment B](#)) and other published references (1, 7, 9, 10, 11) have shown that the pH (4.2 - 4.8), a_w (0.99) and available nutrients of cut fresh tomatoes support the growth of *Salmonella* spp., the pathogen of concern for cut fresh tomatoes. While the pH and a_w of various varieties of tomato may vary somewhat (1) these values are still within the growth range of *Salmonella*. Therefore, cut tomatoes are considered a PHF (TCS food) because they support the growth of foodborne pathogens.

Historically, most fruits and vegetables have been considered non-PHF (non-TCS food) unless they were epidemiologically implicated in foodborne outbreaks. Since 1990, at least 12 large, multi-state foodborne outbreaks as well as small local outbreaks have been associated with different varieties of tomatoes (2, 3, 6). From 1998 - 2006, outbreaks reported to FDA associated with tomatoes made up 17% of the produce-related outbreaks. *Salmonella* has been the pathogen of concern most often associated with tomato outbreaks. Natural reservoirs for *Salmonella* spp. include birds, amphibians, reptiles, soil, pond sediment as well as infected and recovering human beings. *Salmonella* is viable in the environment (in soil, water, etc.) for months (5).

Biofilm formation by *Salmonella* allows bacterial cells to survive under adverse environmental conditions and also reduces the ability to remove pathogens by washing even with antimicrobial agents (7, 9). Once a *Salmonella* cell attaches to a surface such as the tomato skin, after 60-90 minutes it begins to secrete fibers of polysaccharide forming a biofilm in about 10 hrs. It can survive on tomatoes and does not die off during transportation, ripening and storage. The ability to fully decontaminate tomatoes is limited once they have become contaminated and the *Salmonella* cells have attached to the surface. Whole intact tomatoes with their protective waxy cuticle and low water activity on the surface do not support the growth of foodborne pathogens on the surface of the tomato.

Salmonella spp. can be carried by irrigation water, water flumes or wash water and has also been shown experimentally to enter the tomato plant and fruit through several different routes including through the flower, root, stem scar and cracks, cuts or bruises in the skin (5). Infiltration of microorganisms is also associated with negative temperature differentials between water and the tomato flesh. The temperature of wash water should be at least 10°F warmer than the tomato temperature to prevent infiltration. Cold water causes air cells in the tomato to contract and create a vacuum drawing water into the tomato. Contamination in water or on equipment can include bacteria, viruses, parasites and fungi such as molds and yeasts. In addition to spoilage, fungal contamination can raise the pH of the tomato and improve conditions for growth of foodborne pathogens (11). Once inside the tomato, bacterial pathogens cannot be removed by washing or sanitizing solutions, which in any case can only reduce pathogen levels 1-2 logs.

Other sources of contamination of tomatoes include storing or transporting the tomatoes under conditions subject to cross-contamination from other foods, especially raw meat or poultry. It includes use of dirty equipment and utensils that come in contact with the tomatoes such as dirty sinks or pans for washing, dirty cutting boards, dirty knives, slicers, choppers, etc (8). It also includes no or inadequate handwashing by food

employees and ill food employees with symptoms of vomiting, diarrhea or jaundice or a diagnosis of foodborne illness who continue to work with food.

Recommendation

The following recommendations are based on provisions of the 2005 FDA Food Code and the 2006 CFP recommendation to add "cut tomatoes" (e.g., sliced, diced) to the definition of PHF/TCS food in the 2007 Supplement to the 2005 FDA Food Code. They are being offered to prevent contamination in food service facilities and retail food stores and to minimize the impact when contamination of fresh tomatoes has already occurred (regardless of the location where the contamination occurred).

- Cut tomatoes should be considered PHF (TCS food) according to Interaction Table B in the definition of PHF (TCS food) in the 2005 FDA Food Code in Paragraph 1-201.10(B) and internal FDA research (See [Attachment B](#)) and therefore require refrigeration at 5°C (41°F) or less.
- Cut tomatoes used as an ingredient in another food will make that food PHF (TCS food) unless it is acidified or altered in some way to make the cut tomatoes non-PHF (non-TCS food). Example foods to consider:
 - Salsa with chopped tomatoes acidified with vinegar, lemon juice or lime juice to give a pH below 4.2 is non-PHF (non-TCS food). Salsa with cut tomatoes and without sufficient acidifying agent (acidulant) to give a pH below 4.2 is PHF (TCS food) and requires refrigeration at 41°F or less.
 - Chopped, sliced or cut tomatoes in a vinegar or lemon juice-based dressing so that the pH is less than 4.2 is considered non-PHF (non-TCS food) and does not require refrigeration.
 - Chopped, sliced or cut tomatoes with lettuce or other leafy greens in a salad without sufficient acidifying agent so the pH is less than 4.2 is considered PHF (TCS food) and requires refrigeration.
 - Chopped, sliced or cut up tomatoes in all sandwiches, on top of a pizza (with raw or cooked crust or dough) or added to any ready-to-eat food is considered PHF (TCS food) and requires refrigeration or other forms of time/temperature control.
- The food safety practices in Attachment C, "[Recommendations for Food Establishments Serving or Selling Fresh Tomatoes](#)" are recommended to prevent contamination and minimize the impact when contamination of fresh tomatoes occurs (regardless of the location where the contamination occurred), based on the 2005 FDA Food Code and 2007 Supplement to the FDA Food Code.

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ATTACHMENT A

Definition of Potentially Hazardous Food (Time/Temperature Control for Safety Food)

taken from the 2005 FDA Food Code, Section 1-201.10(B)

Table B. Interaction of pH and a_w for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged.

a_w values	pH values

	< 4.2	4.2 - 4.6	> 4.6 - 5.0	> 5.0
< 0.88	non-PHF*/non-TCS food**	non-PHF/non-TCS food	non-PHF/non-TCS food	non-PHF/non-TCS food
0.88 - 0.90	non-PHF/non-TCS food	non-PHF/non-TCS food	non-PHF/non-TCS food	PA***
> 0.90 - 0.92	non-PHF/non-TCS food	non-PHF/non-TCS food	PA	PA
> 0.92	non-PHF/non-TCS food	PA	PA	PA

* PHF means Potentially Hazardous Food

** TCS food means Time/Temperature Control for Safety food

*** PA means Product Assessment required

ATTACHMENT B

Growth of *Salmonella* spp. in Beefsteak and Roma Tomatoes at Room (72°F) and Refrigeration Temperature (41°F).

The 2005 version of the FDA Food Code defines Potentially Hazardous Food (PHF) as any food that requires time/temperature control for safety (TCS) to limit pathogenic microorganisms growth or toxin formation. As part of the recommendations following revision of the definition, a series of experiments was designed to determine if cut tomatoes need to be classified under the PHF/TCS Food category. In the last decade various *Salmonella* spp. outbreaks have been linked to consumption of cut tomatoes, which raises the question of whether fresh tomatoes should be refrigerated for safety.

In the FDA experiments, *Salmonella enterica* serovar Enteritidis and serovar Newport were grown in Beefsteak and Roma tomatoes at 72°F and 41°F to determine if growth occurs during a 24-hour time period.

Methodology

Bacterial strain. *Salmonella* Enteritidis and *S.* Newport (mango outbreak and tomato outbreak strains) were obtained from the Food and Drug Administration's culture collections.

pH and Water Activity (a_w). Measurements for pH and a_w were performed on blended tomatoes.

Growth Curves. Beefsteak and Roma tomatoes were purchased from a local grocery store as well as from a restaurant supplier and used for the experiments. In repetitions 1 through 4, tomatoes were purchased from a grocery store and for repetition 5, tomatoes were from a restaurant supplier. Cut and blended tomatoes were inoculated with an appropriate dilution of the inoculum to obtain an initial concentration of approximately $3 \log_{10}$ cfu/ml. Tomatoes were incubated at 72°F (room temp.) and 41°C (refrigeration temp.) and growth was followed for 24 hrs of incubation. *Salmonella* colonies were enumerated on XLD agar after 24 hrs of incubation.

Growth Parameters Calculations. Bacterial concentrations were transformed into \log_{10} values. Lag phase duration times (LDT) and exponential growth rates (EGR) were calculated by fitting data to a linear function that allows for a lag period before initiation of exponential growth.

Results and Recommendations

Results are presented in Table 1. *S.* Enteritidis and *S.* Newport were able to grow on both Beefsteak and Roma tomatoes at 72°C. For cut tomatoes, lag duration times (LDT) ranged from 2.88 to 3.81 hrs for the Roma tomatoes and from 5.29 to 7.49 hrs for the Beefsteak. Beefsteak blended tomatoes showed an average LDT of 6.91 hrs compared to 3.4 hrs for the Roma. Exponential growth rates (EGR) ranged from 0.185 to 0.266 logs/hr and from 0.166 to 0.297 logs/hr, for Roma and Beefsteak tomatoes, respectively. The low pH with a high water activity (>0.99) of the tomatoes was not found to inhibit *Salmonella* spp. growth in cut tomatoes (See Table B, ["Interaction of pH and \$a_w\$ for control of vegetative cells and spores in food not heat treated or heat treated but](#)

not packaged" in the definition of Potentially Hazardous Food (Time-Temperature Control for Safety Food), Section 1-201.10(B) in the 2005 Food Code). No growth was observed on the tomatoes incubated at refrigeration temperatures (41°C).

Table 1: Growth Kinetics of *Salmonella* Enteritidis and *Salmonella* Newport in Beefsteak and Roma Tomatoes at 72°F and 41°F.

Inoculation method/ Inc. temp	Beefsteak					Roma				
	Rep	pH	a _w	LDT ^a (h)	EGR ^b (log/h)	Rep	pH	a _w	LDT (h)	EGR (log/h)
Cut @ 72°F	1	4.27	0.996	5.29	0.2210	1 2 3 ^c	4.56 5.12 4.23	0.995 0.994 0.999	3.34 2.88 3.81	0.222 0.256 0.2657
	2	4.88	0.995	6.99	0.2972					
	3	5.04	0.993	7.49	0.2941					
	4 ^c	4.29	0.995	5.48	0.2438					
	5 ^d	4.23	0.995	5.41	0.2939					
Cut @ 41°F	1	5.04	0.993	indefinite	no growth	1	4.23	0.999	Indefinite	no growth
	2 ^c	4.29	0.995	indefinite	no growth					
	3 ^d	4.23	0.995	indefinite	no growth					
Blended @ 72°F	1	4.88	0.995	6.91	0.1658	1	5.12	0.994	3.40	0.1854

Source: Antonio De Jesús, CFSAN Microbiologist

^a LDT means Lag Phase Duration Time

^b EGR means Exponential Growth Rate

^c *Salmonella* Newport from a mango outbreak was used for this repetition using tomatoes from a local grocery store.

^d *Salmonella* Newport from a tomato outbreak was used for this repetition using tomatoes from a restaurant supplier.

ATTACHMENT C

Recommendations for Food Establishments Serving or Selling Fresh Tomatoes

Purchasing

1. Consider making purchase specifications to the supplier that tomatoes are grown using Good Agricultural Practices (GAPs). FDA's "[Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables](#)" provides useful information about GAPs and safely growing, harvesting, sorting, packing and distribution of produce.
2. Ripe tomatoes should be delivered to a food establishment in a refrigerated truck for both quality and safety.
3. Consider that purchase records may be needed for a traceback if a foodborne illness outbreak occurs.

Storage

4. After receiving fresh tomatoes, review and follow storage directions regarding temperature, "use by" dates, etc. Avoid using damaged and partially decayed tomatoes. Refrigerate cut tomatoes at 41°F or less.
5. Store whole fresh tomatoes, a raw agricultural commodity, in such a way that they do not contaminate other processed foods including ready-to-eat fresh produce with soil, etc. Store any fresh tomatoes, whole or cut, where other products especially raw meat and poultry cannot cross-contaminate them.
6. Segregate fresh produce from other refrigerated foods in refrigeration units by using a separate set of storage racks or separate cooler, if possible. Protect (by covering) and store washed, cut tomatoes above unwashed, uncut fresh produce. Store all produce off the floor.

Washing and Preparation.

7. Stop work immediately and report to the person in charge any symptoms of vomiting, diarrhea, jaundice (yellow eyes and skin), sore throat with fever or an exposed, infected lesion (cut, burn, boil, etc.) on hands or arms.
8. Wash hands thoroughly with soap and running water before and after handling fresh tomatoes and other produce.
9. All sinks, utensils, cutting boards, slicers, etc. should be washed, rinsed and sanitized before use with fresh tomatoes and other fresh produce.
10. Always wash whole tomatoes and other intact fresh produce under running, potable water before use. Soaking produce or storing it in standing water is not recommended for tomatoes or for most other types of fresh produce.
 1. Washing fruits and vegetables with soap or detergent is not recommended.

2. Scrubbing with a clean brush is only recommended for produce with a tough rind or peel such a cantaloupe or citrus that will not be bruised or penetrated by the brush bristles.
 3. Maintain the wash water temperature at 10°F warmer than the temperature of any produce being washed.
 4. "Fresh-cut" tomatoes and other produce have already been washed before processing and should be considered ready-to-eat with no further need for washing unless the label says otherwise.
11. After being washed and cut, tomatoes are considered potentially hazardous food requiring time/temperature control for safety (TCS) and should be refrigerated at 41°F or less to prevent any pathogens that may be present from multiplying.
- a. Any cut tomatoes that may be held refrigerated longer than 24 hours should be date marked.
 - b. Cut tomatoes may be held at ambient temperature for short periods of time (Time as a Public Health Control, Section 3-501.19 of the 2005 Food Code) if certain conditions are met:
 1. Cut tomatoes may be held un-refrigerated for up to 4 hours if the tomatoes are 41°F or less when removed from temperature control, a marking system is used to identify when the 4 hours is up and, if not consumed or cooked, the cut tomatoes should be discarded.
 2. Cut tomatoes may be held un-refrigerated for up to 6 hours if the tomatoes are 41°F or less when removed from temperature control, the temperature of the tomatoes is monitored and never rises above 70°F, a marking system is used to identify when the 6 hours is up and, if not consumed or cooked, the cut tomatoes are then discarded.
12. Foods which contain cut tomatoes are considered potentially hazardous food requiring time-temperature control for safety (TCS) or refrigeration at 41°F or less, unless:
1. Criteria for Time as a Public Health Control are met (see #11(b) above),
 2. Cut tomatoes or food containing cut tomatoes as an ingredient is acidified and reaches a pH below 4.2. The pH should be verified. Examples include:
 1. Salsa with cut tomatoes acidified with vinegar, lemon juice or lime juice.
 2. Marinated cut tomatoes with vinegar, acidified salad dressing, etc.

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**Conference for Food Protection
2008 Issue Form**

**Internal Number: 040
Issue: 2008 III-018**

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

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Title:

Change Hot Holding Temperatures from 135 F to 130 F

Issue you would like the Conference to consider:

Section 3-501.16. This section requires that potentially hazardous food (time/temperature control for safety food) be held at or over 135 F. Scientifically, if the potentially hazardous food or time/temperature control for safety food is properly reheated (to 165 F) and held hot, it can safely be held at 130 F indefinitely. Additionally, potentially hazardous foods (time/temperature control for safety foods which have been cooked to a temperature that meets the requirement in the food code as it relates to the particular food product can also be held safely at 130 F indefinitely.

The academic community, food scientists, and many in the regulatory community have agreed for years that 130 F is an absolutely safe hot holding temperature. The states of South Carolina, Arizona and Nevada have used 130 F for a number of years and have not seen any problems associated with time/temperature control for safety foods held at 130 F.

Public Health Significance:

The FDA Food Code is based on the recognition and application of technical and sound science by industry and levels of government to ensure the protection of the public's health. The recognition of hot holding of potentially hazardous foods (time/temperature control for safety food) at 130 F for foods cooked to the temperatures specified in Section 3-401 is supported by recognized sound science and does not compromise the health of the public.

Since 1983, South Carolina has recognized 130 F for hot holding of potentially hazardous foods (time/temperature control for safety foods). While improper hot holding is a recognized problem, a review of *Morbidity and Mortality Weekly Reports* for reported outbreaks revealed that those outbreaks were attributed to improper hot holding at room temperatures, not temperatures of 130 F or higher.

The USDA recognizes the health risk associated with the pathogens of concern and has established the minimum temperature for hot holding at 130 F. Similar requirements may be found in Section 3-501.16(A) of the 2005 Food Code and as referenced in Annex 2, References.

Recommended Solution: The Conference recommends...:

FDA amend Food Code section 3-501.16(A) to reflect the hot holding temperature for potentially hazardous food (time/temperature controls for safety foods) from 135 F to 130 F.

The 2005 FDA Food Code, section 3-501.16(A) should should read:

(A) Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under ' 3-501.19, and except as specified under ¶ (B) of this section, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) shall be maintained:

(1) At 57oC (~~135oF~~) (130 oF) or above, except that roasts cooked to a temperature and for a time specified in ¶ 3-401.11(B) or

reheated as specified in ¶ 3-403.11(E) may be held at a temperature of 54oC (130oF) or above; or...

Additionally, modify code language throughout the food code to reflect change to hot holding temperature.

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**Conference for Food Protection
2008 Issue Form**

**Internal Number: 061
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Council Recommendation:	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
Delegate Action:	Accepted _____	Rejected _____	

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Title:

Cooling and reheating of partially cooked meat and poultry products

Issue you would like the Conference to consider:

To section 3-501.14, add new section (E) to state:

(E) Partially cooked MEAT and POULTRY products shall be cooled: (1) Within 2 hours from a maximum temperature of 57°C (135°F) to 21°C (70°F); and (2) Within a total of 6 hours from a maximum temperature of 57°C (135°F) to 5°C (41°F) or less, followed by heating as specified in Section 3-403.11 (F).

AND....

To Section 3-403.11, add new section (F) to state:

(F) For MEAT and POULTRY that have been partially cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) for 15 seconds.

Public Health Significance:

The current version of the *Food Code* addresses cooling recommendations for cooked PHF/TCS foods (Potentially Hazardous Food/Time Temperature Control for Safety Food) under section 3-501.14 (A) as follows:

A) Cooked potentially hazardous food (time/temperature control for safety food) shall be cooled: (1) Within 2 hours from 57°C (135°F) to 21°C (70°F); and (2) Within a total of 6 hours from 57°C (135°F) to 5°C (41°F) or less.

In recent years, however, there has been an interest from retail food establishments to "partially cook" raw meat and poultry products, followed by cooling, followed by cold storage, followed by heating again for hot holding, display, or service. The current version

of the *Food Code* does not provide recommendations for handling, cooling, and/or heating (cooking or reheating) of partially cooked meat or poultry products.

There has been a long history of safety for meat and poultry products that have been partially cooked and properly cooled at a food manufacturing establishment, followed by proper heating (cooking) afterwards by the retailer or consumer. For these manufactured products, USDA-FSIS requires that the product be labeled to inform consumers that the food is Not-Ready-to-Eat (NRTE) and that it contains partially cooked meat products. Cooking instructions are also provided on the package to help insure that consumers achieve a safe minimum internal temperature of 165 °F (instantaneous time), which USDA has determined will deliver at least a 7-log reduction of *Salmonella* (the performance standard required for a ready-to-eat (RTE) product).

In addition, manufacturing establishments that produce partially cooked meat and partially cooked poultry products are required by USDA-FSIS to meet the stabilization performance standards for preventing growth of spore-forming bacteria. Criteria for cooling of these products are contained in Appendix B (Attached) - Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization). The most preferred method of cooling, described under Appendix B, is to ensure that the internal temperature of meat or poultry does not remain between 130 - 80°F (54 - 27°C) for more than 1.5 hours and from 80 - 40°F (27- 5°C) for more than an additional 5 hours. Since the publication of this document in 1999, USDA-FSIS has considered this an effective control measure for hazards likely to occur in meat and poultry products during cooling. Similarly, the *Food Code*, recommends cooling for 2 hours from 57°C (135°F) to 21°C (70°F); and within a total of 6 hours from 57°C (135°F) to 5°C (41°F) to control these same microbial hazards.

From a public health perspective, after the cooling process for partially cooked meat and poultry, there must be heating process to inactivate vegetative pathogens that could be present on or in the meat and poultry product (as the growth of sporeforming bacteria *Clostridium perfringens*, *Clostridium botulinum*, and *Bacillus cereus* are controlled using time and temperature measures during cooling and cold/hot holding). Such vegetative pathogens may include: *Campylobacter* spp., *Salmonella* spp, and shiga toxin-producing *Escherichia coli* (inherent to meat or poultry), *Staphylococcus aureus* (from food handler), and *Listeria monocytogenes* (from the environment). In any case, even high levels of each of these organisms are destroyed when the internal temperature of meat and poultry is heated to a minimum temperature of 74°C (165°F) for at least 15 seconds.

The recommendation provided in this Issue would meet the highest cooking time/temperature condition and the reheating time/temperature condition stated in the current version of the *Food Code*. This time and temperature recommendation also exceeds the performance standard provided by USDA-FSIS.

There may also be considerable value to a partial cook for raw meat and poultry products. Depending on the end temperature of the partial cook process, the population of vegetative pathogens is likely to decrease. This reduction may further minimize the risk of cross contamination from the partially cooked product vs. the raw product within a retail food establishment setting.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending the following additions to the 2009 FDA Model Food Code:

1) To section 3-501.14, add new section (E) to state:

(E) Partially cooked MEAT and POULTRY products shall be cooled: (1) Within 2 hours from a maximum temperature of 57°C (135°F) to 21°C (70°F); and (2) Within a total of 6 hours from a maximum temperature of 57°C (135°F) to 5°C (41°F) or less, followed by heating as specified in Section 3-403.11 (F).

2) To Section 3-403.11, add new section (F) to state:

(F) For MEAT and POULTRY that have been partially cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) for 15 seconds.

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Attachments:

- "Appendix B - Compliance Guidelines for Cooling Heat-Treated Meat and Poultr"

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Appendix B to Compliance Guidelines January 1999
Updated June 1999
Appendix B
Compliance Guidelines for Cooling Heat-Treated Meat and
Poultry Products
(Stabilization)

Introduction

Establishments producing ready-to-eat roast beef, cooked beef and corned beef products, fully cooked, partially cooked, and char-marked meat patties, and certain partially cooked and ready-to-eat poultry products are required by FSIS to meet the stabilization performance standards for preventing the growth of spore-forming bacteria (9 CFR §§ 318.17(a)(2), 318.23(d)(1), and 381.150(a)(2), respectively). Further, FSIS requires meat and poultry establishments, if they are not operating under a HACCP plan, to demonstrate how their processes meet these stabilization performance standards within a written process schedule validated for efficacy by a process authority (§§ 318.17(b) and (c); 318.23(d)(2) and (3); and 381.150(c) and (d)).

To assist establishments in meeting the stabilization requirements, FSIS is issuing these compliance guidelines, which are based upon FSIS Directives and the product cooling requirements contained in previous regulations. Establishments may choose to employ these guidelines as their process schedules. FSIS considers these guidelines, if followed precisely, to be validated process schedules, since they contain processing methods already accepted by the Agency as effective.

Also within these guidelines, FSIS has provided discussion regarding disposition of product following cooling deviations and advice for the development of customized procedures for meeting the stabilization performance standards.

Stabilization Guidelines

It is very important that cooling be continuous through the given time/temperature control points. Excessive dwell time in the range of 130° to 80°F is especially hazardous, as this is the range of most rapid growth for the clostridia. Therefore cooling between these temperature control points should be as rapid as possible.

1. During cooling, the product's maximum internal temperature should not remain between 130°F and 80°F for more than 1.5 hours nor between 80°F and 40°F for more than 5 hours. This cooling rate can be applied universally to cooked products (e.g., partially cooked or fully cooked, intact or non-intact, meat or poultry) and is preferable to (2) below.

2. Over the past several years, FSIS has allowed product to be cooled according to the following procedures, which are based upon older, less precise data: chilling should begin within 90 minutes after the cooking cycle is completed. All product should be chilled from 120°F (48°C) to 55°F (12.7°C) in no more than 6 hours. Chilling should then continue until the product reaches 40°F (4.4°C); the product should not be shipped until it reaches 40°F (4.4°C). This second cooling guideline is taken from the former ("Requirements for the production of cooked beef, roast beef, and cooked corned beef", 9 CFR 318.17(h)(10)). It yields a significantly smaller margin of safety than the first cooling guideline above, especially if the product cooled is non-intact product. If an establishment uses this older cooling guideline, it should ensure that cooling is as rapid as possible, especially between 120 °F and 80°F, and

monitor the cooling closely to prevent deviation. If product remains between 120 °F and 80 °F more than one hour, compliance with the performance standard is less certain.

3. The following process may be used for the slow cooling of ready-to-eat meat and poultry cured with nitrite. Products cured with a minimum of 100 ppm ingoing sodium nitrite may be cooled so that the maximum internal temperature is reduced from 130 to 80 °F in 5 hours and from 80 to 45 °F in 10 hours (15 hours total cooling time).

This cooling process provides a narrow margin of safety. If a cooling deviation occurs, an establishment should assume that their process has exceeded the performance standard for controlling the growth of *Clostridium perfringens* and take corrective action. The presence of the nitrite, however, should ensure compliance with the performance standard for *Clostridium botulinum*.

Establishments that incorporate a "pasteurization" treatment after lethality and stabilization treatments (e.g., applying heat to the surface of a cooled ready-to-eat product after slicing) and then re-stabilize (cool) the product should assess the cumulative growth of *C. perfringens* in their HACCP plans. That is, the entire process should allow no more than 1-log₁₀ total growth of *C. perfringens* in the finished product. When employing a post-processing "pasteurization," establishments may want to keep in mind that at temperatures of 130 °F or greater, *C. perfringens* will not grow.

Support documentation for this process was filed by the National Food Processors Association on April 14, 1999. It is available for review in the FSIS Docket Room, Room 102, Cotton Annex, 300 12th St., SW, Washington, DC 20250-3700.

Discussion

Cooling Deviations

In spite of the best efforts of an establishment to maintain process control, cooling deviations will occasionally occur. Power failures or breakdowns of refrigeration equipment cause situations that cannot always be anticipated. However, it is important that the establishment plan how to cope with such eventualities before they occur.

The recommended time/temperature combinations in these guidelines incorporate a small safety margin. Therefore, an occasional small lapse in and of itself may not cause a problem in every instance. If the cause of a small cooling deviation is not traced and corrected when first noticed, however, the problem will likely recur and possibly become more frequent and more severe. The processor should consider an occasional small deviation an opportunity to find and correct a control problem. Of course, a large deviation or continual small ones will always constitute unacceptable risk.

After it is determined that a cooling deviation has occurred, the processor should:

1. Notify the inspector, the QC unit, and other concerned units, such as refrigeration maintenance and production.
2. Hold the involved product and determine the potential adulteration by bacteria, particularly clostridial pathogens. If adulteration is confirmed or appears to be likely, inform the inspector.
3. Postpone further product manufacturing using that chill facility until the processor has:
 - a. determined the cause of the deviation;
 - b. completed adjustments to assure that the deviation will not recur; and
 - c. informed the inspector and the production units of the determinations and adjustments and make any needed amendments in the written processing procedures.

Computer modeling and sampling

In the event that a cooling deviation does occur, the product may often

be salvaged if the results of computer modeling and/or sampling can ensure product safety. Because of a lack of information concerning the distribution of *C. perfringens* in product, sampling may not be the best recourse for determining the disposition of product following cooling deviations. However, computer modeling can be a useful tool in assessing the severity of a cooling deviation. While computer modeling cannot provide an exact determination of the possible amount clostridial growth, it can provide a useful estimate.

A technical document (available from the FSIS Docket Room) provides description of the calculations that are used to estimate relative growth.

With careful continuous monitoring of the heating and cooling time/temperature profile of each lot, there will always be many available data points, enhancing the accuracy of computer modeling. Conversely, when there are few documented time/temperature data points, the accuracy of the modeling decreases markedly. If time/temperature monitoring has not been conducted through the end point internal product temperatures of 40° F or less, sampling is not an option and the product should be destroyed.

Options after computer determination of cooling deviation severity.

If computer modeling suggests that the cooling deviation would likely result in more than one log increase in *C. perfringens*, without any multiplication (remains in lag phase) of *C. botulinum*, then the establishment can choose to recook or sample the product.

Recook only when:

All product was either immediately refrigerated after the deviation or can be immediately recooked after the deviation; and

The recooking procedure can achieve a final internal product temperature of at least 149°F (65°C) for two minutes. Subsequent to recooking, the product must be cooled in strict conformance to existing guidelines. When the product is to be reworked with another raw product, the recooking procedure for the combined product must achieve a minimum internal temperature of 149°F, to address the cooling deviation, and further to an increased time\temperature if necessary to be in accord with any other requirement relative to microbiological safety for the intended final product. Subsequent to recooking, the product must be cooled in strict conformance to existing guidelines.

Custom Stabilization Processes

While compliance with the guidelines above will yield product that meets the cooling performance standards, some establishments may want to develop customized stabilization procedures. Because customized process schedules must be validated by process authorities for efficacy, most establishments will probably rely upon processing authorities to develop such procedures, demonstrate their efficacy, and attest to their safety. Process authorities may obtain information from the literature, or likely compare peer reviewed methods in determining safe procedures that meet the performance standards.

Probably one of the most definitive tools at the disposal of the processing authority is the inoculated pack study. Such studies should, of course, be conducted only in the laboratory, not in the plant. Further, such studies should be undertaken by individuals who have a thorough knowledge of laboratory methods used in clostridial research. *C. perfringens* can be used alone in an inoculated pack study to demonstrate that the cooling performance standard is met for both microorganisms, *C. perfringens*, and *C. botulinum*. This is because conditions of time/temperature that would limit the growth of *C. perfringens* to one log or less would also prevent multiplication of *C. botulinum*, which is much slower. A cocktail of various strains of *C. perfringens* spores is often used for this purpose. Relatively "fast" toxigenic strains should be used to develop a worst case. However, the strains selected should be among those that have been historically implicated in an appreciable number of

outbreaks, especially in products similar to those being prepared in the establishment.

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**Conference for Food Protection
2008 Issue Form**

**Internal Number: 004
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Title:

Cold Holding of Fish in Reduced Oxygen Packaging

Issue you would like the Conference to consider:

Clostridium botulinum type E is associated with aquatic environments. It is an anaerobic organism capable of producing a lethal toxin. Its potential growth and toxin formation must be taken into account during the production of reduced oxygen packaged fish products. It is capable of producing its toxin in environments as cold as 38°F.

Some commercially manufactured reduced oxygen packaged fish products are labeled "Keep refrigerated at 38°F or less," or language to that effect. Because of the risk of Clostridium botulinum type E in these products, it is possible that in some cases this language is a safety standard and that refrigerated storage at the labeled temperature in the retail store has been identified as a Critical Control Point (CCP) by the manufacturer. As a matter of practicality, it is not possible for retail food regulatory inspectors to be familiar with the details of the manufacturer's Hazard Analysis and Critical Control Points (HACCP) plan for every individual reduced oxygen packaged fish product. Therefore, when manufacturers of reduced oxygen packaged fish products have labeled their product with a refrigeration temperature below 41°F, retailers should be required to refrigerate the product at or below the labeled temperature.

The Food Code currently does not contain this requirement.

Public Health Significance:

The Food Code currently requires retailers to refrigerate reduced oxygen packaged fish products at or below 41°F, even when the products are labeled with a colder refrigeration temperature. A temperature of 41°F may not be sufficient to control the growth and toxin formation of Clostridium botulinum type E. Public health will be better protected by requiring that the products be refrigerated at or below their labeled temperature.

Recommended Solution: The Conference recommends...:

that the Conference Chair send a letter to the FDA recommending that section 3-501.16 be amended as follows:

3-501.16 Potentially Hazardous Food (Time/Temperature Control for Safety Food), Hot and Cold Holding.*

(A) *Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under §3 501.19, and except as specified under ¶¶(B)-(D) and in ¶(G) of this section, potentially hazardous food (time/temperature control for safety food) shall be maintained:*

(1) At 57°C (135°F) or above, except that roasts cooked to a temperature and for a time specified in ¶ 3 401.11(B) or reheated as specified in ¶ 3-403.11(E) may be held at a temperature of 54°C (130°F) or above; or

(2) At 5°C (41°F) or less.

(B) Eggs that have not been treated to destroy all viable **Salmonellae** shall be stored in refrigerated equipment that maintains an ambient air temperature of 7°C (45°F) or less.

(C) Potentially hazardous food (time/temperature control for safety food) in a homogenous liquid form *may be maintained outside of the temperature control requirements, as specified under ¶ (A) of this section, while contained within specially designed equipment that complies with the design and construction requirements as specified under ¶ 4-204.13(E).*

(D) Fish products that have been packaged in reduced oxygen packaging at a food processing plant and labeled with a holding temperature of less than 5°C (41°F) shall be held at the labeled temperature or less.

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**Conference for Food Protection
2008 Issue Form**

**Internal Number: 065
Issue: 2008 III-021**

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:

Storage Temperature of Certain Natural Cheeses

Issue you would like the Conference to consider:

This Issue was submitted as 2006-III-010 (Attachment 1), accepted as amended by Council III (Attachment 2) and approved by the Assembly of Delegates (Attachment #2). The amended Issue essentially asked "that FDA work with Stakeholders on scientific issues and product assessments related to food safety of certain cheeses (including Asiago (medium/old), Cheddar, Colby, Feta, Monterey Jack, Muenster, Parmesan, Provolone, Romano, Swiss/Emmentaler and Pasteurized Process Cheese manufactured to the Standard of Identity) that do not need temperature control for safety."

This 2006 Biennial Meeting recommendation was based on a scientific, unpublished study by the Wisconsin Center for Dairy Research attached to the 2006-III-010 issue. That study has now been peer reviewed and published in Food Protection Trends, October 2006 (Attachment 3) without significant changes from the initial version used for justification of the Issue in 2006. With the exception of Pasteurized Process Cheese, FDA has also indicated the safety of these cheeses by listing them as exempt from date marking provisions of 3-501.17 of the FDA Food Code (see Table in Annex 3 under 3-501.18) based on the FDA/USDA/CDC *Listeria monocytogenes* Risk Assessment. The meeting held with the National Cheese Institute (NCI), Food Marketing Institute (FMI) and FDA to meet the charge to FDA for this Issue essentially used the scientific study (Attachment 3) and suggested that a starting point would be to classify 6 cheeses (Asiago (medium/old), Cheddar, Colby, Provolone, Romano and Swiss/Emmentaler) as Tier 1 Cheeses with <39% Moisture. Parmesan was added to this group as a reference although it is generally accepted as a non PHF/TCS food. The Tier 1 cheeses represent the major cheeses that the industry has traditionally displayed unrefrigerated on an international level and would like to see uniform approval as a safe alternative for unrefrigerated display at retail food establishments.

Public Health Significance:

Unrefrigerated display of the cheeses named in this Issue is already approved by some State and local health agencies under the current criteria of using the Food Code's definition of Potentially Hazardous Food (Time/Temperature Control for Safety Food) and references within Table A and B of this definition. Attachment 3 already validates the safety of these cheeses with up to 50% moisture with traditional salt, pH, fat, etc. and even concludes that higher temperatures support further exclusion through bactericidal activity.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting they consult with the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) on the science presented in Attachment 3 that would support, as a minimum, that Tier 1 cheeses (Asiago (medium/old), Cheddar, Colby, Provolone, Romano and Swiss/Emmentaler) be classified as non-PHF/TCS food at storage temperatures not to exceed 30°C (86°F). In the interim, the Conference requests FDA continue to work with the National Cheese Institute (NCI) and the Food Marketing Institute (FMI) per the initial charge of the 2006-III-010 Issue on other cheeses that can be scientifically validated as being safe when held without refrigeration.

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Attachments:

- "2006-III-010, Storage Temperature of Certain Natural Cheeses-Attachment 1"
- "2006-III-010,Storage Temp. Certain Natural Cheeses-Amend/Approved-Attach #2"
- "Storage Temperatures Necessary to Maintain Cheese Safety, Bishop - Attach#3"

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ATTACHMENT #1

Conference for Food Protection 2006 Issue Form

Internal Number: 075
Issue: 2006 III-010

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

Delegate Action: Accepted _____ Rejected _____

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Title:

Storage Temperature for Certain Natural Cheeses

Issue you would like the Conference to consider:

Currently cheeses and other dairy products fall under the definition of potentially hazardous food (Time/Temperature for Safety Food). However, an exhaustive review of scientific literature provides substantial evidence that certain cheeses have inherent characteristics that create a hostile environment for bacterial pathogens, especially at elevated ripening and storage temperatures. This review is awaiting publication

Based on research studies that were reviewed, Asiago (medium/old), Cheddar, Colby, Feta, Monterey Jack, Muenster, Parmesan, Provolone, Romano, Swiss/Emmentaler and Pasteurized Process Cheese should be exempt from refrigeration requirements during ripening, storage, shipping and display. To qualify for this exemption, these cheeses must have a standard of identity in this or another country, include active cultures (with the exception of Pasteurized Process Cheese) and be manufactured under proper conditions of good hygiene practices, GMPs, HACCP principles and according to their Standard of Identity.

Public Health Significance:

These cheeses have not been implicated in outbreaks for foodborne illness. The inherent composition of these cheeses inhibits the growth of food pathogens at elevated temperatures. These cheeses are safe to store and display outside of refrigeration

Recommended Solution: The Conference recommends...:

That 3(f) be added under the definition of Potentially Hazardous Food (Time/Temperature Control for Safety Food) on page 16 of the 2005 Food Code.

3(f) Asiago (medium/old), Cheddar, Colby, Feta, Monterey Jack, Muenster, Parmesan, Provolone, Romano, Swiss/Emmentaler and Pasteurized Process Cheese manufactured to the Standard of Identity.

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Attachments:

- "Cheese Storage Temp Paper"

**Conference for Food Protection
2006 Issue Form**

Issue: 2006 III-010

Council Recommendation: Accepted as Submitted _____ Accepted as Amended X No Action _____

Delegate Action: Accepted X Rejected _____

All information above the line is for conference use only.

Title: Storage Temperature for Certain Natural Cheeses

Recommended Solution:

The Conference Recommends that FDA work with stakeholders on scientific issues and product assessments related to food safety to determine which cheeses (including Asiago (medium/old), Cheddar, Colby, Feta, Monterey Jack, Muenster, Parmesan, Provolone, Romano, Swiss/Emmentaler and Pasteurized Process Cheese manufactured to the Standard of Identity) do not need temperature control for safety. Scientific information presented in issue 2006 III – 010 indicates some cheeses may be safe when displayed at room temperature. The results will be reported back to the CFP Executive Board and included in the 2007 Food Code Supplement.

Storage Temperatures Necessary to Maintain Cheese Safety

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SUMMARY

Available information on bacterial pathogen growth, stasis, and death in cheeses was reviewed and evaluated to determine storage temperatures necessary to maintain product safety. In view of the variety and large volume of cheeses consumed throughout the world, the incidence of foodborne outbreaks associated with cheeses is extremely low. Research revealed that the inherent characteristics of most cheeses create a hostile environment for bacterial pathogens, especially at elevated ripening and storage temperatures. Therefore, it is recommended that the following cheeses, manufactured in the United States with pasteurized or heat treated ($\geq 63^{\circ}\text{C}$ for ≥ 16 seconds) milk, should be exempt from refrigeration requirements during ripening, storage, shipping, and display: Asiago (medium and old), Cheddar, Colby, Feta, Monterey Jack, Muenster, Parmesan, Pasteurized process, Provolone, Romano, and Swiss/Emmentaler. It must be stressed that the manufacture of these cheeses must be done under the proper conditions of Good Hygiene Practices, Good Manufacturing Practices, and HACCP principles, and according to CFR requirements. In addition, the natural cheeses must include active cultures, and the storage and display temperatures must not exceed 30°C .

INTRODUCTION

Temperature-dependent storage of most foods has three major roles – to allow for curing/ripening of foods that contain added active starter cultures and enzymes, to prevent quality defects, and to control pathogen growth. In making decisions on whether a food requires time/temperature control for safety, the properties of the food itself must be considered (3). The role of temperature-dependent aging and storage is similar for cheese and for other foods, but the targets differ significantly because of unique inherent characteristics of the finished food product.

Transformation of chalky, acid-tasting curd into ductile, full-flavored cheese is accomplished during ripening through the action of milk enzymes, rennet, and various organisms in the cheese, including those in the starter culture. The biochemical changes that occur during cheese ripening are complex and involve fermentation of the carbohydrate; hydrolysis of fats and proteins with subsequent decarboxylation, deamination, and/or hydrogenation; and production of carbonyls, nitrogenous compounds, fatty acids, and sulfur compounds, all of which contribute to the overall body, texture, and flavor of the final product (63). These inherent characteristics also create a hostile environment for pathogens (25). This re-

A peer-reviewed article

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view of scientific information on pathogen death and growth in cheeses at various storage temperatures will determine parameters necessary to ensure safety of cheeses in the marketplace. The United States cheese industry advocates the use of a science-based approach for assessing the risk posed by ready-to-eat foods for possible transmission of pathogens in the food supply (24). Applying HACCP principles enhances the manufacture of safe cheese (35).

In view of the variety and large volume of cheese consumed throughout the world, the incidence of outbreaks of food poisoning and foodborne disease associated with cheese are extremely low (36). Epidemiology studies of cheese-related outbreaks in the United States, Canada, and Europe have found no outbreaks linked to hard Italian varieties, e.g., Parmesan, Romano, and Provolone. Varieties such as Cheddar and Swiss were infrequently involved (38). In general, very few documented illness outbreaks have been linked to consumption of properly ripened hard cheese. Therefore, time/temperature control of hard cheese is primarily needed not for safety reasons, but to maintain the organoleptic quality of cheese (3).

INHERENT CHARACTERISTICS OF SAFE DAIRY FOODS

Numerous researchers have reported bactericidal and/or bacteriostatic effects on pathogenic bacteria in foods because of reduced moisture, low water activity, low pH as the result of organic acid production, salt, heat treatment, competing flora, biochemical metabolites, bacteriocins, and ripening, either singly or as part of hurdle technology (1, 3, 5, 6, 10, 11, 13, 15, 17, 22, 25, 26, 29, 34, 36, 37, 38, 39, 40, 43, 45, 48, 49, 51, 58, 59, 64, 65, 66, 68, 69, 70, 76). Refrigeration cannot be depended upon to reduce the number of pathogens, as it has been proven that *Listeria monocytogenes* (*L. monocytogenes*) and other psychrotrophic pathogens are capable of growth at these temperatures. Therefore, other factors, such as diligence with regard to good hygiene practices by the food industry, must be responsible for the lack of pathogen growth in fermented dairy foods. Results also confirm the low frequency of contamination by *L. monocytogenes* of pasteurized fluid milk products sold in the United States (24).

INHERENT CHARACTERISTICS OF CHEESE

Cheeses are one of the oldest types of prepared foods. Cheesemaking provided human kind with a means of concentrating and preserving milk at a time when refrigeration was unknown and principles of food preservation were vague empirical concepts at best (52).

The vast majority of cheese manufactured in the United States is made from pasteurized or heat-treated milk, which renders the product free of most pathogens (38, 39, 40). The inherent characteristics of cheeses made with starter culture addition provide multiple hurdles that inhibit pathogen growth (3, 47). A multiplicity of practices other than pasteurization or heat-treatment also contribute significantly to the microbiological safety of cheese (10, 11, 38). Some practices, such as milk quality management, lactic culture protocols, pH control, salt addition, and controlled curing conditions, are established technologies (38). Other factors may include natural inhibitory substances (e.g., lysozyme), starter metabolites and fermentation by-products (e.g., nisin), including organic acids (e.g., lactic, acetic, propionic, and formic). Water activity/moisture content imposes additional detrimental effects on foodborne pathogens during the manufacturing and ripening of cheese (10, 11, 38, 66).

During the manufacture of semi-soft, hard, and very hard cheeses, the cheese is subjected to relatively long exposure to ideal incubation temperatures for bacteria. For example, Cheddar and related varieties are maintained at 31–39°C during manufacture and are formed or hooped at temperatures in the 32–37°C range. Many Cheddar-type cheeses are cured or aged at temperatures up to 15.6°C. Swiss cheese is held for a period of 4–8 weeks at a temperature of 22.2–23.3°C to develop the characteristic eyes and flavor. If storage of Cheddar and Swiss cheese at room temperature had any inherent detrimental effect on safety of these cheeses, then neither would be safe to consume (51).

Specifically for *L. monocytogenes*, numerous studies suggest that the composition of cheese, ripening and storage conditions, lactic acid cultures, pH, salt, and moisture concentration influence its survival and growth (15, 29, 39, 40, 43). The fate of *L. monocytogenes* and other foodborne pathogens during cheese ripening is determined by the microbiological, biochemical, and physical properties

of the particular cheese (43, 64). Thus, cheese is a very complex system, with the following factors acting simultaneously to determine the behavior of *L. monocytogenes* during ripening: (a) type, amount, and activity of starter culture; (b) pH as determined by concentrations of lactic, acetic, formic, and other acids; (c) presence of hydrogen peroxide, diacetyl, and various antimicrobial agents (Nisin, diplococcin, and other bacteriocins); (d) levels of nutrients, salt, moisture, and oxygen; and (e) the cheese ripening temperature (64).

Fermentation is an age-old food preservation method used to inhibit the growth and survival of pathogenic bacteria (48). Lactic acid bacteria commonly used to produce fermented dairy products are antagonistic to foodborne pathogens and will either inhibit their growth or inactivate them (5, 13, 36, 59, 66, 70). In addition, research has shown that some starter cultures are detrimental to food spoilage organisms as well as various pathogens in these products (1, 17, 22, 51, 58, 69, 76). Responsible for this action are metabolites such as lactic and other acids, diacetyl, hydrogen peroxide, and various antibiotic-like substances produced by lactic acid bacteria, which are probably synergistic (34, 36, 37, 45, 49, 66).

Examples of pathogens that are susceptible to inactivation or growth inhibition by metabolites of lactic acid bacteria include *Salmonella* Typhimurium, enteropathogenic *Escherichia coli*, *Staphylococcus aureus*, and *L. monocytogenes* (66). Growth of *L. monocytogenes* is always inhibited appreciably in lactic acid cultured product when compared to that of the control, no matter how high the final pH of the fermented milk. Even when the final pH dropped only to 5.99, growth of the pathogen was inhibited by 84% relative to the control (65). This suggests that factors other than the hydrogen ion concentration are involved in the inhibition of *L. monocytogenes* by lactic acid bacteria (65). These observations have been documented by other researchers, who noted that lactic cultures inhibited pathogens such as salmonellae and staphylococci, even when pH was controlled at 6.6 (26). Modern lactic culture technology for cheese manufacturers has virtually eliminated *Staphylococcus*-caused outbreaks involving cheese (40). Vigorous starter growth should protect fermented milk products against the growth of pathogens and the formation of staphylococcal enterotoxin (36). Mathew and Ryser (48) reported increased injury of healthy *L. monocytogenes* cells during

TABLE I. Model *L. monocytogenes* exposure of cheese (2001)

	Contamination	Retail	Home storage	Home storage
Cheese	Frequency	Contamination	Growth rate	Time
Cheddar	Low	Low	Low	Long
Colby	Low	Low	Low	Long
Feta	Moderate	Moderate	Low	Long
Monterey Jack	Low	Low	Low	Long
Mozzarella	Low	Low	Moderate	Long
Parmesan	Low	Low	Low	Long
Processed	Low	Low	Moderate	Long
Provolone	Low	Low	Low	Long
Swiss	Low	Low	Low	Long

The evaluation revealed that there was a very low risk for listeriosis by Feta cheese, heat-treated natural and process cheeses, and aged cheeses (77).

Obtaining more information from research, industry, and regulatory experience, FDA/USDA (78) updated their *L. monocytogenes* risk analysis in 2003 with the following results (Table 2).

fermentation; at the end of the 24-h fermentation period, > 90% of the healthy *L. monocytogenes* cells were injured. Additionally, at the end of the product's shelf life, > 99% of the initial population was injured, and no significant decrease in the percentage of injury was observed. It was also discovered that the presence of *L. monocytogenes* did not adversely affect the growth of the starter culture at any inoculation level (48). Gengeorgis et al. (25) demonstrated that non-soft cheeses made with the use of starter cultures and pH values of ≤ 5.5 , as well as processed cheeses, will not support growth of *L. monocytogenes* at 4 to 30°C if the cheeses are contaminated from raw foods after the consumers open packages. Rapid acid production is the principal factor responsible for the elimination of pathogens from semi-hard cheese. The use of an effective starter culture is not only critical for preventing growth of pathogens, but also essential for the production of good quality cheese (6). The preservative effect of lactic acid bacteria can be attributed partly to the activation of the lactoperoxidase system and partly to bacteriocins (4).

Temperatures of curd cooking and aging/curing/ripening/storage have an impact on pathogen growth and survival in cheese. In hard cheese types with

higher curd cooking temperatures, growth is slight (68). There is considerable evidence showing that certain cheeses do not support growth of pathogens during the aging process and subsequent storage (11). A review of the literature related to the potential for growth of pathogens in hard cheeses that are aged for at least 60 days shows that such growth is not likely to occur because of factors inherent to these cheeses (31). Pathogens that survive the manufacturing process decrease faster at higher storage temperatures (14). The death rate of *Salmonella* in Samsøe cheese was slower at 10–12°C than at 16–20°C (36). It has been concluded that, for traditionally made hard cheeses, time/temperature control for safety is not required (3).

In most cheese varieties, salt concentrations attain levels of 1.6–3.0% of the total weight of the cheese, which would not affect most of the pathogenic bacteria in cheese. But it must be realized that salt is dissolved in the aqueous phase of the cheese only, the actual site of bacterial growth. Given the respective calculated values, salt concentrations in the aqueous phase reach levels of 2.2–6.5% or higher and will, in fact, at least slow down the growth rate of most bacteria and even have a detrimental effect on the more sensitive ones (68).

Where scientific data do not exist, all the inherent characteristics of cheese can serve as criteria in determining potential growth of pathogens by the use of mathematical modeling (16, 72, 79, 83). When two or more of these criteria are combined, the resultant effect is an additional hurdle to the outgrowth of pathogens of concern. It is this effect that makes it possible to store certain cheeses safely beyond either one of the two Food Code criteria for date marking and refrigeration (i.e., 7 days at 5°C or 4 days at 7.2°C). This led the US Food and Drug Administration to issue, on December 15, 1999 (11), a letter suggesting that regulatory agencies use their discretionary authority and defer enforcement action regarding date marking aged hard cheeses. In that letter, FDA granted a formal interpretation to the Food Code that hard and semisoft aged cheeses and pasteurized process cheese, each manufactured according to 21 CFR 133 as specifically cited above and maintained under refrigeration, are exempt from the Food Code's date marking provision related to refrigerated, ready-to-eat, potentially hazardous food. This interpretation has subsequently been incorporated into state statutes, such as Wisconsin's (2). Feta cheese was later added to this exemption list by FDA (in the case of Iowa Dept. Health vs. Shullsburg Creamery).

TABLE 2. Model *L. monocytogenes* exposure of cheese (2003)

	Contamination	Retail	Home storage	Home storage
Cheese	Frequency	Contamination	Growth rate	Time
Cheddar	Low	Low	Low	Long
Colby	Low	Low	Low	Long
Feta	Moderate	Moderate	Low	Long
Monterey Jack	Low	Low	Low	Long
Mozzarella	Low	Low	Moderate	Long
Muenster	Moderate	Low	Low	Long
Parmesan	Low	Low	Low	Long

The FDA/USDA evaluation classified cheeses as follows:

Fresh soft – Queso fresco, Queso de Crema, Queso de Puna

Soft unripened (> 50% moisture) – Cottage, cream, Ricotta

Soft ripened (> 50% moisture) – Brie, Camembert, Feta, Mozzarella

Semi-soft (>39–50% moisture) – Blue, Brick, Monterey Jack, Muenster, Provolone

Hard (≤ 39% moisture) – Cheddar, Colby, Parmesan, Processed

SPECIFIC CHEESES AND THEIR INHERENT CHARACTERISTICS

Cheeses are typically categorized according to their moisture content:

Soft	≥ 50%
Semi-soft	> 39 – < 50%
Hard	≤ 39% (4, 22)

Hard and semi-soft cheeses are the focus of this research review.

Research by Gengeorgis and colleagues (25) has yielded results indicative of those obtained by other researchers, which prove death of pathogens in nonsoft cheeses stored at various temperatures. In this study, 49 market cheeses representing 24 varieties were purchased commercially. Cheeses were inoculated with 10⁴ cells of *L. monocytogenes* per square cm. The inoculum was a cocktail of 5 strains — Scott A, V7, RM-1, VPH1, VPH2. Inoculated cheeses were stored at 4, 8 and 30°C for up to 36 hours. Certain cheeses (Queso Fresco, Panela Ranchero, Ricotta, Teleme, Brie, Camembert, and Cottage) supported *Listeria* growth in cheese at one of the storage temperatures. Cheeses not supporting growth but caus-

ing gradual death at all temperatures included Cotija, cream, blue, Cheddar, Monterey Jack, Swiss, Colby, string, Provolone, Muenster, Feta, and Kasserli with pH values of 4.3–5.6; process cheese (pH 5.7–6.4); and Limburger cheese (pH 7.2). Overall, this study demonstrated that nonsoft cheeses made with the use of starter cultures and at pH values of ≤ 5.6, as well as processed cheeses, will not support growth of *L. monocytogenes* at 4–30°C if contaminated from raw foods (meat, poultry, fish, vegetables) after the opening of the packages by consumers. In all cheeses that caused gradual death (Cotija, cream, Blue, Cheddar, Monterey Jack, Swiss, Colby, Provolone, Muenster, Feta, Kasserli, Process, Limburger), death at 30°C was greater than or equal to death at 4°C.

Asiago (medium and old)

Medium and old Asiago (aged at least 6 months and 12 months, respectively) are hard cheeses with characteristics very similar to those of Parmesan. FDA has previously exempted these cheeses from date-marking (11) and stated that hard cheeses aged at least 60 days are not likely to support pathogen growth (31).

Bachman and Spahr (6) found that Swiss-type hard cheeses are hygienically safe and that the technology used in manufacturing these cheeses does not support growth of pathogens and leads to a more rapid rate of death.

Cheddar

Cheddar is a hard cheese that does not support *L. monocytogenes* growth and that causes gradual death at all temperatures (25). This finding is confirmed by an FDA correspondence (11) and also agrees with work by Ryser and Marth (61), who reported that growth of *L. monocytogenes* during Cheddar cheese manufacture appeared to be inhibited by proper acid development resulting from an active starter culture. Behavior of other pathogens during Cheddar manufacture and ripening show similar results. With normal starter activity, inoculated *Staphylococcus aureus* died rapidly (60), as did *Yersinia enterocolitica* (67). Norholt (54) illustrated die-off of *Salmonella* spp. after 2 weeks. Wood et al. (84) found that, of 11 vats of *Salmonella*-contaminated Cheddar cheese curd, only 2 remained positive in the finished cheese immediately after manufacture. In 1 and 4 months,

these 2 vats were clear of the inoculated *Salmonella*. This result is supported by studies of Goepfert et al. (28) and Hargrove et al. (32) in artificially inoculated Cheddar. Both groups found a 75–80% reduction in *Salmonella* after hooping and pressing during manufacture.

Numerous researchers have reported kill of pathogens at higher ripening and storage temperatures. *Salmonella* spp. survived longer when Cheddar cheese was stored at 4.5°C rather than 10°C (82). In general, a low pH and a high ripening temperature result in a higher inactivation rate for pathogenic organisms (61). Using stirred-curd Cheddar cheese, Goepfert et al. (28) showed that the number of *S. Typhimurium* decreased by a factor of 10,000 during 10–12 weeks of ripening at 13°C, whereas a similar decrease required 14–16 weeks at 7.5°C. Park et al. (58) reported that salmonellae survived during ripening of Cheddar cheese for up to 7 months at 13°C and 10 months at 7°C. Ryser and Marth (61) reported an inactivation rate of *L. monocytogenes* 0.9 logs less at 6°C than at 13°C. International Dairy Federation researchers demonstrated that the decrease in numbers of staphylococci in Cheddar was greater at higher temperatures (10°C and 13°C) than at 7°C (36).

Colby

Colby is a hard to semi-soft cheese that does not support *L. monocytogenes* growth and causes gradual death at all temperatures (25), a finding confirmed by an FDA correspondence (11). Various researchers studying the behavior of inoculated pathogens during Colby cheese manufacture and ripening determined that *E. coli* generally decreased over a period of weeks and was not detected after 4–6 weeks (41) and that numbers of *Y. enterocolitica* generally decreased over a period of weeks at 3°C (51). Yousef and Marth (85) found that, early in storage of Colby cheese, numbers of *Listeria* in the cheese remained relatively constant for a time that depended on the strain used. Numbers of *Listeria* in cheese decreased steadily thereafter at a rate that depended mainly on composition of the cheese. It should be noted that 2 of the 6 lots of cheese manufactured in this study had moisture levels higher than CFR specifications. IDF researchers demonstrated that the decrease in numbers of staphylococci in Colby was greater at the higher temperatures (10°C and 13°C) than at 7°C (36).

Feta

The Greek regulatory standard for Feta cheese stipulates that it cannot contain more than 56% moisture and less than 43% FDM. No standard exists for the amount of salt, but the salting procedure is described in this regulation. Commercial Feta produced in Greece normally contains about 2.5% salt (75). Currently, there is no US standard of identity for Feta, a soft ripened cheese that does not support *L. monocytogenes* growth and that causes gradual death at all temperatures (25, 55). Other experiments have shown that *Listeria* not only failed to grow in Feta but was gradually inactivated in whey and skim milk brine containing 12% salt (NaCl) (57). Papageorgiou and Marth (55) observed that the pH value of 2-day old Feta cheese decreased to 4.6, after which the growth of *L. monocytogenes* ceased.

Monterey Jack

Monterey Jack is a hard to semi-soft cheese which does not support *L. monocytogenes* growth and causes gradual death at all temperatures (25). Other than this referenced study, there exists little published research with this cheese. However, it is very similar, with regard to pH, aqueous NaCl, and moisture, to other cheeses that have been heavily studied and proven not to support pathogen growth.

Mozzarella

Mozzarella is a soft to semi-soft cheese that has a manufacturing protocol detrimental to bacteria. Buazzi et al. (9) found that the typical cooking of Mozzarella curd at 40°C for 30 min caused a 38% decrease of *L. monocytogenes*, compared to numbers of the pathogen in curd after cutting. Placing of curd in hot water (77°C) and stretching for 3–4 min caused complete demise of the pathogen. The curd temperature during stretching was 58–65°C. In conclusion, no *L. monocytogenes* was found in the cheese at the end of stretching, start of brining, and end of storage. The heat treatment given to the curd freed the product of *L. monocytogenes*, even though the curd initially contained approximately 6.2×10^4 cells of the pathogen per g. Ryser and Marth (64) reported that the heat treatment given to Mozzarella cheese curd is clearly sufficient to inactivate small numbers of *L. monocytogenes* that might be present. Villani et al. (81) found similar results during manufacture of traditional Mozzarella cheese from buffalo milk.

Stecchini et al. (71) addressed the issue of post-process contamination by inoculating the surface and packaging fluid of Mozzarella cheese with *L. monocytogenes* and then storing the product at 5°C for 21 days. Under these conditions, numbers of *L. monocytogenes* increased about 10,000-fold. Mozzarella was implicated in an outbreak of salmonellosis in 1984. Post-processing contamination was thought to have caused the outbreak (19).

Muenster

Muenster is a semi-soft cheese that does not support *L. monocytogenes* growth and causes a gradual death at all temperatures (25). Other than this referenced study, there exists little published research with this cheese. However, it is very similar in pH, aqueous NaCl, and moisture, to other cheeses that have been heavily studied and proven not to support pathogen growth.

Parmesan

Parmesan is a hard cheese ripened at 12.8°C for 10 months, which does not support *L. monocytogenes* growth and which causes gradual death at all temperatures. No outbreaks in the United States have implicated any Italian-type hard cheeses, including Parmesan. This unblemished safety record may reflect conditions during manufacture and curing that inhibit or destroy pathogens (40). Yousef and Marth (86) observed that, during Parmesan cheese ripening, numbers of *L. monocytogenes* decreased almost linearly and faster than reported for other hard cheeses. *L. monocytogenes* was not detected in cheese after 2–16 weeks of ripening, depending on the strain of the pathogen and the lot of cheese. Parmesan made in this study was not a favorable medium for survival of *L. monocytogenes*. Decreased viability of the pathogen in Parmesan is probably related to a combination of factors, including (a) action of lipase added to the milk; (b) heat treatment that the curd receives during cheesemaking; and (c) lower moisture content and water activity of the fully ripened cheese.

Parmesan is more acidic than other cheeses, with a much lower water activity that inhibits microbial growth (35, 44). Pathogenic bacteria vary just as widely as the cheeses they contaminate, and their survival characteristics are equally varied. For example, Brie stored under refrigeration will support the growth of *L. monocytogenes*, while Parmesan stored at near-ambient temperature will not (35).

TABLE 3. Summary of data on cheeses reviewed, and compositional calculations (21, 68, 75)

Cheese Type	Typical % H ₂ O	CFR Limit % H ₂ O	A _w	Typical pH	Typical % NaCl	Typical % Aqueous NaCl	% FDM **	Active Culture	Age at sale (days)	Other inherent characteristics	Pathogen Kill+
Asiago	32-34	35	0.93	5.2-5.5	1.9-2.2	5.75	45	Thermophile	180-365	A/S Temp*	Ah, Cj, Ec, Lm, P, Sa, Sta, Ye
Cheddar	38	39	0.95	5.2	1.7	4.47	52	Mesophile	15-1,000	A/S Temp*	Lm, Sa, Sta, Ye
Colby	39	40	0.95	5.2	1.7	4.36	52	Mesophile	15-80	A/S Temp*	Ec, Lm, Sta, Ye
Feta	53	NA	0.95	4.5	3.0	5.66	29-52	Mesophile	7-90	A/S Temp*	Lm
Monterey Jack	38-42	44		5.25	1.7	4.05-4.47	52	Mesophile	15-150	A/S Temp*	Lm
Mozzarella	45-52	45-52		4.9-5.4	1.6	3.07-3.56	52	Thermophile	5-150	Hot water/steam treatment	Lm kill cook/stretch Lm, Sa growth
Muenster	43	46	0.98	5.2	1.8	4.18	52	Thermophile	10-150	A/S Temp*	Lm
Parmesan	31	32	0.92	5.4	2.6	8.38	38	Thermophile	300-600	A/S Temp* Aged ≥300d High temp curd cook Lipase activity	Lm
Process (sliceable)	40		0.92	5.6	2.2	5.50	50	None	14-180	A/S Temp* Heated ≥150°F/≥30 sec	Clb, Ec, Lm, Sa, Sta
Provolone	42.5	45	0.91	5.2	1.8	4.24	45	Thermophile	15-150	A/S Temp*	Lm
Romano	33.5	34	0.92	5.3	2.2	6.57	40	Thermophile	150-180	A/S Temp*	Lm
Swiss / Emmentaler	38	41	0.97	5.6	1.2	3.16	43	Thermophile	61-300	A/S Temp*	Ah, Cj, Ec, Lm, Pa, Sa, Sta, Ye
Brick	43	44		5.3	1.6	3.72	52	Mesophile	7-50	A/S Temp*	Ec, Lm
Blue	43	46	0.97	6.0	2.5	5.82	52	Mesophile	61-240		Lm

* A/S Temp => Increased pathogen kill at elevated aging/storage temperatures.

** %FDM=> Percent fat in dry matter.

+ Ah – *Aeromonas hydrophils*, Cj – *Campylobacter jejuni*, Clb – *Clostridium botulinum*, Ec – *Escherichia coli* O157:H7, Lm – *L. monocytogenes*,

P – *Pseudomonas aeruginosa*, Sa – *Salmonella* sp., Sta – *Staphylococcus aureus*, Ye – *Yersinia enterocolitica*.

Pasteurized Process (21CFR133.169)

Pasteurized process cheese is a soft to semi-soft cheese that does not support *L. monocytogenes* growth and that causes gradual death at all temperatures (25, 27). Pasteurized processed cheese and related products have an excellent safety record in the United States (39). During the past 50 years, very few disease outbreaks have been attributed to contaminated pasteurized process cheese products (27). The combined effects of pH, moisture, and salt in standardized process cheese may inhibit vegetative pathogen growth in a way

similar to the mechanism of inhibition for *Clostridium botulinum* (73, 74). If a pasteurized processed cheese is intended for use at ambient temperature, pH, water activity (a_w), moisture content, and antimicrobials should be appropriately adjusted to inhibit botulinal toxin formation (3). During manufacture, the product is heated for ≥ 30 s at a temperature of ≥ 65.6°C; this is sufficient to eliminate vegetative organisms but not the spores of *Clostridium botulinum*. As a formulated safe product with regard to *C. botulinum*, the combinations of moisture, salt, and pH act as multiple hurdles to inhibit botulinal growth and toxin production (42, 73).

While studying pathogen survival in pasteurized process cheese slices, Glass et al. (27) reported that populations of *Salmonella* serotypes and *E. coli* O157:H7 decreased by an average of 1.3 and 2.1 log CFU/g, respectively, by 36 h. *Salmonella* serotypes decreased an additional 0.6 log CFU/g during the remaining 60 h. Populations of *L. monocytogenes* also decreased, although to a lesser extent, exhibiting approximately 0.6 log CFU/g reduction in 96 h. *S. aureus* levels remained relatively constant during the testing period and were below levels that support detectable enterotoxin production. At 30°C, the pasteurized process cheese slices

allowed survival but did not support growth of *S. aureus*, whereas populations of *L. monocytogenes*, *E. coli* O157:H7, and *Salmonella* serotypes decreased during the 96 h storage. Water activity appears to contribute significantly to the inhibition of pathogen growth in these cheese slices. The a_w of the tested formulations (0.92–0.93) was at or below the minimum required for growth of most foodborne pathogens. Although low a_w may inhibit pathogen growth in these formulations, the synergistic effect of moisture, salts, and pH, or another factor such as sorbate, may also contribute to the safety of the product. The results suggest that properly formulated pasteurized process cheese could be exempt from the potentially hazardous food category because it does not support the rapid and progressive growth of pathogens tested. The results of the study suggested that unopened packages of properly formulated pasteurized process cheese can be safely stored unrefrigerated for certain time periods (53). In fact, reducing storage temperatures has been reported to actually enhance survival of *E. coli* O157:H7 in acidified media, apple cider, and mayonnaise (33, 50, 87).

Provolone

Provolone is a semi-soft cheese that does not support *L. monocytogenes* growth and that causes gradual death at all temperatures (25). No outbreaks that implicated any Italian-type cheese, including Provolone (40), have been found in the United States. Other than this referenced study, little published research with this cheese exists. However, with regard to pH, aqueous NaCl, and moisture, it is very similar to other cheeses that have been heavily studied and proven not to support pathogen growth.

Romano

Romano is a hard cheese that does not appear to support *L. monocytogenes* growth. In the United States, no outbreaks have been found that implicated any Italian-type cheeses, including Romano (40). Other than this referenced study, there exists little published research with this cheese. However, it is very similar to other cheeses with regard to pH, aqueous NaCl, and moisture, which have been heavily studied and proven not to support pathogen growth.

Swiss / Emmentaler

Swiss/Emmentaler is a hard to semi-soft cheese that does not support *L. monocytogenes* growth and that causes

gradual death at all temperatures (25). This finding is confirmed by an FDA correspondence (11). The ripening temperature of Swiss cheese is comparatively high (22°C). Buazzi et al. (10) reported a sharp decrease in numbers of *L. monocytogenes* during brining of Swiss blocks (7°C for 30 h). The population of *L. monocytogenes* continues to decrease during cheese ripening. *Listeria* was not detected after 80, 77, and 66 days of ripening of Swiss cheese made from inoculated milk. Bachmann and Spahr (6) discovered none of the inoculated potentially pathogenic bacteria, except for low numbers of *S. aureus*, could be found in the experimental Swiss cheese 1 day after manufacturing. All subsequent determinations showed that the cheese was free from potentially pathogenic bacteria and toxins. Baumgartner et al. (8) previously reported the same behavior of *S. aureus* in Emmentaler cheese. Bachmann and Spahr (6) also found that even in poor quality cheese that had been inoculated with *E. coli* and was exhibiting early blowing, no *E. coli* could be detected at the end of ripening. Additionally, results showed that 1 week after manufacturing, the inoculated pathogens (*Aeromonas hydrophila*, *Campylobacter jejuni*, *E. coli*, *L. monocytogenes*, *Pseudomonas aeruginosa*, *Salmonella* spp., *S. aureus*, and *Y. enterocolitica*) could no longer be detected.

El-Shenawy and Marth (18) suggested that production of propionate by eye-forming bacteria may have contributed to the demise of *L. monocytogenes* in Swiss cheese. In other work, < 2,000 ppm of sodium propionate inhibited growth of *L. monocytogenes* at pH 5.0 (10). At pH 5.0 and 3,000 ppm sodium propionate, the *Listeria* population decreased 1,000-fold during 67 days of incubation at 35°C and disappeared after 78 days. A 60-day-old Swiss cheese typically contains 3,750 ppm propionic acid (46). Acetate may also play a major role in inactivating *L. monocytogenes* in Swiss cheese (10); more lactate is fermented to acetate and CO₂ than to propionate (12). The rapid decrease of the redox potential of Swiss cheese probably supports the inhibitory effect on pathogenic bacteria (54).

Generally, manufacturing technology of Swiss cheese does not support the growth of pathogenic bacteria (6, 10). Because of the synergistic effect of active antimicrobial enzyme systems in fresh raw milk, antagonistic starter culture flora, fast acidification, antimicrobial effect of lactic acid, and high curd cooking temperatures,

potentially pathogenic bacteria do not survive the manufacturing of Swiss cheese produced under good manufacturing practices. In addition, intense brining and ripening at elevated temperatures for at least 2 months eliminate the occurrence of the tested strains. Pathogens that may survive the manufacturing process decrease faster at higher storage temperatures (14). Swiss cheese appears to pose a very low risk for transmission of foodborne diseases (40).

Brick

Brick is a semi-soft cheese. In studies of the behavior of pathogens during Brick cheese manufacture and ripening, *L. monocytogenes* numbers decreased during 20–22 weeks of curing at 10°C (67), and *E. coli* grew during manufacture and then died off during curing (23).

Blue

Blue is considered a semi-soft cheese that has been proven to not support *L. monocytogenes* growth and that causes gradual death at all temperatures (25). Papageorgiou and Marth (59) reported that growth of *L. monocytogenes* ceased when the pH of blue cheese dropped below 5.0. Populations of *L. monocytogenes* decreased significantly ($P \leq 0.005$) during the first 50 days of ripening, by an average of 2.6 logs CFU/g compared to populations of 1-day old cheese. The high salt content in blue cheese is likely the main reason for the lack of growth of *Listeria*. Productions of fatty acids and methyl ketones derived from fatty acids via the beta-oxidation pathway, and their corresponding secondary alcohols, may contribute to the unfavorable environment for *L. monocytogenes* (32). Blue cheese on the market has a pH >5.0; therefore, conclusive pathogen death is not verified.

Soft / Hispanic

This category includes Queso Blanco, Queso Fresco, Ricotta, Teleme, Brie, Camembert, Panela, Ranchero, cream, and cottage. Gengeorgis et al. (25) evaluated the fate of *Listeria* as a post-processing contaminant and found that *Listeria* growth was primarily confined to high-moisture varieties, including Brie, Camembert, Ricotta, and the soft Hispanic cheeses, all of which had a pH ≥ 6.0 and low to moderate levels of salt in the moisture phase. Back et al. (7) noted that *L. monocytogenes* survived, and under most conditions multiplied, when inoculated directly into the cheese milk of laboratory-made Camembert cheese.

REGULATORY EVALUATION

In a series of correspondences, in a letter form as an inclusion to the US FDA Program Information Manual on retail Food Safety and in a subsequent correspondence (11, 31), FDA exempted the following cheeses from the date marking mandate within the US Food Code:

Asiago	Limburger
Blue	Monterey Jack
Brick	Muenster
Cheddar	Parmesan
Colby ($\leq 40\%$ moisture)	Pasteurized process
Edam	Provolone
Feta	Reggiano
Gorgonzola	Romano
Gouda	Sapsago
Gruyere	Swiss/Emmentaler

In 2001, FDA/USDA (77) conducted a risk analysis of foodborne outbreaks of *L. monocytogenes* from ready-to-eat foods (Table 1).

The evaluation revealed that there was a very low risk for listeriosis by Feta cheese, heat-treated natural and process cheeses, and aged cheeses (77).

Obtaining more information from research, industry, and regulatory experience, FDA/USDA (78) updated their *L. monocytogenes* risk analysis in 2003 with the following results (Table 2).

Utilizing a cluster analysis of predicted risk that takes into account the relative risk of listeriosis for the total population on a per serving and per annum basis, the following risk categories were developed for cheese:

- High risk – soft unripened cheeses (cottage, cream)
- Moderate risk – fresh soft cheeses (Queso Fresco) soft ripened cheeses (Brie, Camembert, Feta, Mozzarella) semi-soft cheese (Blue, Brick, Monterey Jack)
- Very low risk – hard cheeses (Cheddar, Swiss, Parmesan)
- Process cheeses

FDA/USDA actually decreased the predicted risk of soft ripened and certain semi-soft cheeses to “Moderate” due to increased use of pasteurized or otherwise heat-treated milk, and effective food safety control programs.

The very low risk cheeses have similar characteristics of being subjected to bactericidal treatment, having very low contamination rates, and possessing an inherent characteristic (or two) that either inactivates *L. monocytogenes* (hard

cheese) or prevents its growth (process cheese). As can be noted from this review, many more cheeses fit this category than recognized by USDA. The relative risk indices used may not give a clear picture of the range of risk potential that exists. The differential between per-serving risks associated with deli meats (relative risk rank of 1) and hard cheeses (relative risk rank of 23) is almost 10,000,000-fold (78).

CONCLUSIONS

Science-based data presented herein adequately illustrate the fact that most cheeses containing $< 50\%$ moisture (or more, in the case of Feta) and active lactic acid starter cultures, along with traditional levels of salt, pH, fat, etc., do not allow the growth of pathogens at temperatures between 4 and 30°C. In fact, in the vast majority of the cheeses, a higher temperature during ripening/aging and storage leads to significant bactericidal activity. A summary of the reviewed science and data is available in Table 3.

Mathematical models were generated using the USDA Pathogen Modeling Program, but given that this system is in nutrient broth, not in a limited moisture solid food (cheese), growth/death curves generated were meaningless. No other models reviewed were found to be appropriate.

RECOMMENDATIONS

For cheeses manufactured in the United States with pasteurized or heat-treated ($\geq 63^\circ\text{C}$ for ≥ 16 s) milk, under hygienic conditions outlined in Good Hygienic Practices, Good Manufacturing Practices, and HACCP systems, using active lactic acid cultures, and according to CFR specifications, the following cheese should be considered by regulatory agencies (FDA, USDA, state, local, etc.) exempt from any and all refrigeration requirements for aging, storage, shipping, and retail display, with a maximum temperature of 30°C:

Asiago (medium and old)
Cheddar
Colby
Feta
Monterey Jack
Muenster
Parmesan
Pasteurized process cheese
Provolone
Romano
Swiss / Emmentaler

If this exemption would apply only to pre-packaged cheeses, Parmesan and Romano, and possibly medium and old Asiago — because of their inherent characteristics — would not have to be pre-packaged for this refrigeration exemption. Soft/fresh Asiago, Blue, Brick, cream and Mozzarella require further investigation before a recommendation for exemption could be made.

There is one common thread among all the ripened cheeses evaluated (this would exclude Mozzarella); the curing/ripening/aging step is detrimental to bacterial pathogens, especially at elevated temperatures up to 30°C. Therefore, for safety purposes, refrigerated storage of the cheeses would appear to be unnecessary and possibly counterproductive.

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**Conference for Food Protection
2008 Issue Form**

**Internal Number: 022
Issue: 2008 III-022**

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

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Title:

Time/Temperature Control for Safety for Cut Leafy Greens

Issue you would like the Conference to consider:

Research shows that cut lettuces and other cut leafy greens support the growth of pathogens commonly associated with foodborne illness outbreaks when stored outside of temperature control. Requiring that these foods be stored under refrigeration in retail and foodservice establishments should significantly limit the growth of pathogens that may be present on the product and therefore represents an important step in preventing foodborne illness in the U.S.

Public Health Significance:

Note: Where reference numbers are noted in parentheses, see Attachment A

Since 1996, at least 21 confirmed foodborne illness outbreaks have been attributed to consumption of various types of leafy greens (11) that were contaminated prior to the point of service, most likely on the farm. Additional outbreaks are likely to have occurred due to contamination at the point of service. These illnesses can produce severe gastrointestinal distress long-term chronic sequelae, and death. (Attachment B).

Cut leafy greens with a pH of 5.8 or more (1, 4) and a_w of 0.99 or more (3) have been shown to support pathogenic growth (1, 2, 3, 7, 8, 9, 12) once the product is cut and internal liquid and nutrients are made available to pathogens that may be present.

Laboratory studies have shown that storage of cut leafy greens at 41°F or less effectively limits the growth of pathogens such as *E. coli* O157:H7, *Salmonella spp.* and *Listeria monocytogenes*. Refrigeration of cut leafy greens at 5°C/41°F or less has been shown to limit the growth of *E. coli* O157:H7 as well as promote a general die-off of the pathogens over time (1, 2, 3, 8, 9).

It is common industry practice to refrigerate cut produce to preserve the crispness and to prevent browning, decomposition and sliminess from spoilage organisms. Changing state and local retail food codes and ordinances to mandate that cut leafy greens be stored and displayed at a temperature of 41°F or less in retail and foodservice establishments will help to ensure that these products are not held for extended periods within the lower temperature limit of growth for *E. coli* O157:H7 (8°C/46.4°F), *Salmonella* spp. (7°C/44.6°F) and other pathogens identified in illness outbreaks associated with lettuce and other leafy greens. Storage at temperatures above 41°F can negate pathogen reductions achieved from prior washing in cold or warm chlorinated water and allow surviving pathogens to multiply.

In the FDA *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, subparagraph VII (C)(3) and paragraph VIII (D), FDA recommends that finished, fresh-cut produce be held, stored, transported, and displayed at 40°F or lower. (5)

Once the pathogens have been in contact with the leaves, they are able to attach to the leaves, especially at cut surfaces and openings such as stomatal pores. Under adverse conditions, *E. coli* O157:H7, *Salmonella* and *Listeria monocytogenes* can also form biofilms for additional protection. Contamination, which may occur anywhere from the field to the kitchen (6), cannot be effectively removed from the leaves once the pathogen has attached or internalized through cut surfaces. For example, studies have shown that once *E. coli* O157:H7 becomes internalized in cuts in the plant tissue, it becomes inaccessible to chlorinated or other chemical washes and can survive the disinfection or sanitizing process (13). Other controls such as different atmospheres (anaerobic or other gases) or competing microflora (Standard Plate Count (SPC) of 5-8 million are normal) have not been proven effective at preventing pathogenic growth on cut leafy greens (7).

Recommended Solution: The Conference recommends...:

1. The FDA Food Code and state and local regulations applicable to retail and foodservice establishments be amended to include cut leafy greens among the foods that require time/temperature control for safety, including cold holding at 41°F or less; and

2. The intended meaning of the term "cut leafy greens" should be made clear by including appropriate definitions in Chapter 1 of the FDA Food Code. For the purposes of this recommendation, the term "cut leafy greens" refers to 1) leafy greens that are considered "fresh-cut produce" as defined in FDA *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables* (5), and 2) fresh leafy greens whose leaves have been cut, shredded, sliced, chopped or torn at the point of sale or service. For the purposes of this recommendation the term "leafy greens" refers only to iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula and chard. The term "leafy greens" does not include herbs such as cilantro or parsley.

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Attachments:

- "Attachment A - References"
- "Attachment B - Outbreaks and Illnesses Associated with Leafy Greens"

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Time/Temperature Control for Safety for Cut Lettuce and Leafy Greens Issue

Attachment A - References

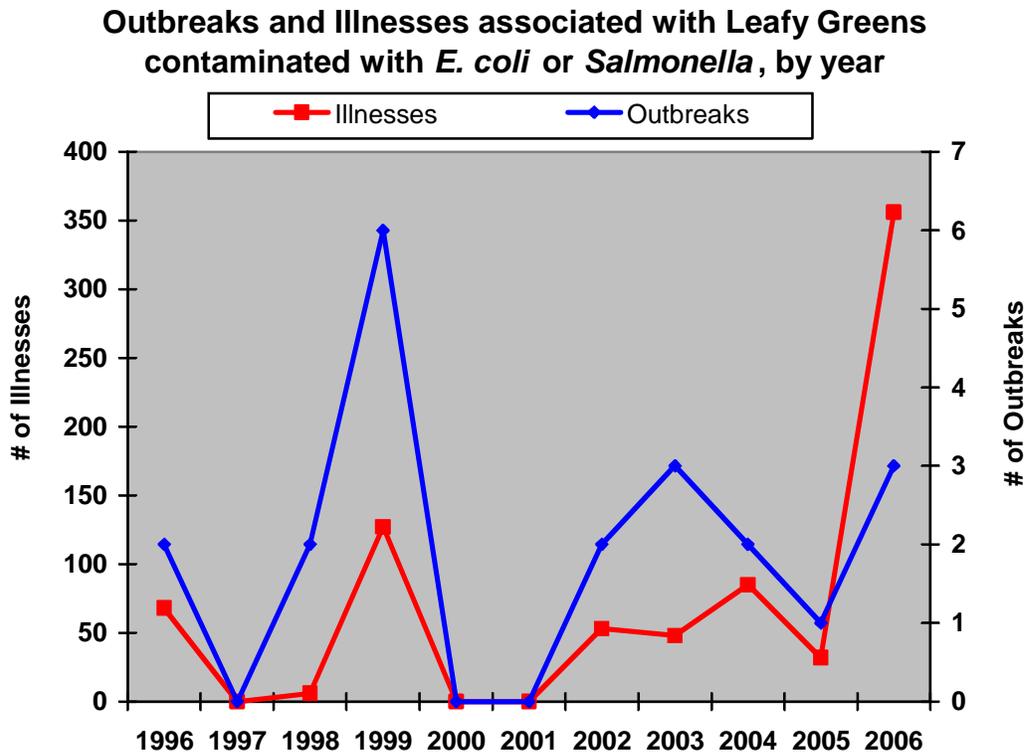
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Time/Temperature Control for Safety for Cut Lettuce and Leafy Greens

Attachment B- Outbreaks & Illnesses Associated with Leafy Greens Contaminated with *E. coli* or *Salmonella*, 1996-2006*

* Source: CFSAN Outbreak Surveillance Database

- Types of leafy greens associated with these outbreaks/illnesses:
 - Mesclun lettuce
 - Lettuce
 - Romaine lettuce
 - Spinach
 - Cabbage (coleslaw outbreak associated with contaminated cabbage – 22 ill)
- # of outbreaks associated with Leafy Greens, 1996-2006: 21
- # of illnesses associated with Leafy Greens, 1996-2006: 775
- # of deaths associated with Leafy Greens, 1996-2006: 5
- *E. coli* O157:H7 was associated with all of the outbreaks and illnesses of leafy greens except for one lettuce outbreak (79 ill) due to *Salmonella Newport* in 2004.



2006 Leafy Green Outbreaks:

1. Spinach and *E. coli* O157:H7

Outcome	N (%)
Total ill	205
Hospitalized	104 (51)
HUS	31 (15)
Death	3 (1)

State	Number of Confirmed Cases
AZ	8
CA	2
CO	1
CT	3
ID	8
IL	2
IN	10
KY	8
MD	5
ME	3
MI	4
MN	2
NE	11
NM	5
NV	2
NY	11
OH	26
OR	6
PA	10
TN	1
UT	19
VA	2
WA	3
WI	50
WV	1
WY	1
Total	204

2. Lettuce and *E. coli* O157:H7 (Facility A)

Outcome	N (%)
Total ill	71
Hospitalized	53 (75)
HUS	8 (11)
Death	3 (1)

State	Number of Confirmed Cases
DE	2
NJ	33
NY	22
PA	13
SC	1
Total	71

3. Lettuce and *E. coli* O157:H7 (Facility B)

Outcome	N (%)
Total ill	81
Hospitalized	26 (32)
HUS	1 (1)

Data Limitations:

The CFSAN Outbreak Surveillance Database was developed by the Epidemiology Team and the Emergency Coordination and Response Team to capture and retrieve data on foodborne and cosmetic illnesses associated with FDA-regulated products. **The following caveats are to be cited when providing data from the CFSAN Outbreak Surveillance database:**

1. The data only represent those outbreaks and illnesses associated with FDA-regulated foods and cosmetics.
2. The data do not contain information on outbreaks/illnesses where the point of contamination is the retail food setting or home.
3. The data do not include illnesses transmitted from person-to-person.
4. Illness data represent only the number of illnesses reported to CDC, FDA, and state/local health departments in association with an outbreak. The data do not include illnesses that may have occurred but were not reported, sporadic cases of illness, and illnesses not associated with a food vehicle.
5. Information on outbreaks/illness reported prior to 2004 has been compiled from paper records; information on outbreaks/illnesses since 2004 has been entered into the CFSAN Outbreak Surveillance Database.
6. The outbreaks tracked by FDA are a subset of all the outbreaks tracked by CDC. CDC also tracks outbreaks/illnesses where the point of contamination is the retail food setting or the home. Due to lags in reporting of illnesses, some differences in numerical tallies may exist between FDA and CDC data.

**Conference for Food Protection
2008 Issue Form**

**Internal Number: 031
Issue: 2008 III-023**

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

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Title:

Fresh Pressed/Squeezed Juice

Issue you would like the Conference to consider:

I would like the Conference to recommend that the Food Code requirements for treating juice packaged in a food establishment be expanded to include juice that is served in a food establishment but not packaged.

Public Health Significance:

Many food establishments that press/squeeze juice are breakfast establishments. Many of their patrons are either families with small children (under 9 years of age) or elderly populations. Both of these groups are considered highly susceptible populations.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting the following changes:

3-404.11 Treating Juice.

Juice packaged or served in a food establishment shall be:

(A) Treated under a HACCP plan to attain a 5-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance; or

(B) Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of public health significance:

(1) As specified under § 3-602.11, and

(2) As specified in 21 CFR 101.17(g) Food labeling, warning, notice, and safe handling statements, Juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens with the following,

"WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."

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**Conference for Food Protection
2008 Issue Form**

**Internal Number: 063
Issue: 2008 III-024**

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

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Title:

Wild Mushrooms

Issue you would like the Conference to consider:

There are currently no national standards for the approval of wild mushrooms. As a result there is an extensive underground network for distribution and sales of wild mushrooms generated from unapproved sources to the general public.

Public Health Significance:

Some wild mushroom species are easily identifiable and pose minimal public health risks. The FDA Food Code prohibits all wild mushrooms from being served to the public unless they are identified by a wild mushroom expert.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that section 3-201.16 wild mushrooms be modified to read:

"(B) This section does not apply to the following wild mushrooms if a consumer advisory is provided:

- Boletus edulis - Cepe, Porcini, King Bolete
- Cantherellus cibanius - Golden Chanterelle
- Cantherellus subalbidus - White Chanterelle
- Cantherellus tubaeformus - Yellow foot
- Cantherellus cornucopiodes - Black Trumpets
- Gomphus clavatus - Pig's Ears
- Hericium abietus - Pom Pom
- Hericium erinaceus - Lion's Mane, Bear's Head

- Polyozellus multiplex - Blue Chanterelle
- Hydnum repandum - Sweet Tooth
- Hydnum umbilicatum - Belly Button Hedgehog
- MOREL species complex - morels
- Sparassis crispa - Cauliflower mushroom
- Tricholoma magnivelare - Matsutake

(3) Wild mushroom species that are easily identifiable, are of minimal public health risk and a consumer advisory is provided. The consumer advisory shall include a reminder and disclosure of the severe consequence associated with consuming wild mushrooms that are from an unapproved source, and

a) The wild mushroom is identified by the Latin binomial and common name (identification in the fresh state), and

b) The name of the person making the identification, statement of their qualifications and training".

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**Conference for Food Protection
2008 Issue Form**

**Internal Number: 068
Issue: 2008 III-025**

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:

A quantifiable definition for "CLEAN"

Issue you would like the Conference to consider:

The FDA Food Code Chapter 1-2 presents Definitions, and subpart 1-201 Applicability and Terms for the various words and phrases whose clear definitions are important to risk communication relating to food safety. Though definitions exist for such phrases as "easily cleanable", a definition for "CLEAN" itself is and has for many years been conspicuous in its absence.

Public Health Significance:

There is no adverse affect to public health, though the consequence for having a quantifiable definition for CLEAN will be exponential in its benefit to risk communication.
>

Additionally, the failure to define CLEAN is at the crux of many prerequisite system failures. Though a slicer, cutting board or other food contact surface may be clean to "sight and touch", the invisible layers of fats and proteins present an organic load which works to inactivate sanitizers and may thus fail to reduce target organisms below their infective dose. New AOAC International (formerly known as the Association Of Analytical Chemists) validated detection methods that are or will soon be available to enable reasonably accurate measure of a surface's organic load/bio-burden.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting

1. the following be added as a definition in subpart 1-201 after "CIP" and before "commingle":

CLEAN: A condition reached when a food or food contact surface has a foreign organic load equal to or below that needed to be reasonably sure that sanitizers approved for such applications and use will reduce remaining target organisms below their infective dose.

2. the Sanitation Committee be charged to develop reasonable threshold limit values for organic loads on various food contact surfaces given intended use using validated detection methods and means.

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Attachments:

- "FOODSAFE CLEAN"

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FOODSAFE "CLEAN"

A position paper calling for development of validated international standardized test method for measuring hygiene relative to food operations

By Thomas W. Johnson, 12/14/2007

<http://www.jdpinc.com>

There exist many methods of assay for determining the cleanliness of surfaces in preparation for sanitization, disinfection and sterilization. The fact that none of these have been validated may be due to our past inability to use a cross disciplinary approach to define CLEAN thereby providing quantifiable criteria for a surfaces availability to be sanitized.

It is a matter of reasonable thresholds given same or similar circumstance to mitigate risk associated with contamination. Risk assessment, communication and management are couched in statistics whereby the probability of contamination to the level that a health safety hazard exists is on a curve based upon observation and measurement. Our collective failure to have any validated test methods for determining CLEAN is testament to the frustration experienced in many diverse industries and market segments. With recent advancements in detection and measurement technologies we have before us the opportunity to develop practical standardized test methods capable of validation for specific applications of intended use.

The efficacy of sanitizers is reported in terms of specific log reductions for specific target organisms given their assay environments and factors of time, concentration and energy transfers. But all of this is relative to presumed organic loads or their absence. Many AOAC International, JIS (Japanese Industrial Standards) or other validated international standardized test methods presume specific organic loads such as the 5% bovine serum common for testing solutions intended to be used as pesticides pursuant to registrations for Federal Insecticide, Rodenticide and Fungicide Act (FIFRA) compliance. We talk about "residuals" in the context of a solutions efficacy given a specific level of organic load challenge yet we have no validated measure of these specific organic loads on various contact surfaces which reduces the likelihood of a successful sanitizing step.

HACCP program success can not be achieved without effective prerequisite programs and verification regimes to constantly reassess risks of contamination to our foods and beverages. The very act of identifying a hazard to foods and beverages presumes quantifiable measure for reasonable threshold limits as ZERO risk is known to not exist. It is important to have clear definitions for the various categories of safety we conceive. In the vernacular of hygiene we use such words as decontaminated and clean as synonyms, or are they? After all, it is well known that you cannot expect to be effective in sanitizing surfaces that are not first clean.

For purposes of infection control and hygienic safety, CLEANING is a separate and prerequisite step to sanitizing which is precursor to sterilization. The current state of the art is to perform cleaning checks using simple "soil" detection or Protein Assay's. Aerobic and total plate count (APC and TPC) methodologies have been available for decades but their convenience, cost and speed have been limiting factors to their commercial acceptance as audit or quality control (QC) tools. Then there are the

photo-metric measurement and a range of competitors in the field of chemiluminescence and bioluminescence, all of which may be accurate enough but each is expensive and all lack practicality for field audit and or QC inspection.

The measure of a given organic loads reasonability is a function of both the bio-burdens characteristics and those of the interfacial surface for any particular intended use. It is therefore necessary to present a matrix of risk categories based upon multi-dimensional axis; e.g., intended food/beverages characteristics, along with those of food contact surfaces/stainless steel, the use environment, vitrified china or glass stem ware, anodized aluminum, cast iron, ceramic tile, quarry tile, tile grout, schedule 80 black iron pipe, or any of a range of approved food contact polymers and elastimers, etc. Other surfaces must have their own reasonably clean characteristics, such as the epidermis of the hands, or green leafy produce, a wooden pizza peel, cutting board, door pull on a freezer or a front door, the keys on a cash register, the surface of a gloved hand, the surface of meats, nuts, egg's, film food wraps, the coil of a refrigerator, etc. In infection control circles, the surface of an endoscope, a stent or surgical implement must be sterile to reduce probability of cross contamination, just as the air itself is purified and its characteristics controlled to reduce airborne transmissible agents that may provide infective dose upon contact with an open wound of a healthy or immuno compromised person or animal.

The first step is to categorize FOODSAFE cleans' applicability and one logical place to start is hard surfaces intended for food/beverage contacts. These surfaces and materials compatibility are spelled out in NSF International's American National Standard Institute (ANSI) Std 2, with reference to Std 51. If this first category is defined, then reasonable thresholds for organic load can be determined based upon target organisms and their expected environments given their food/beverage processes. Such methodology would also take into account biofilms which have plagued process piping and drains throughout recorded history.

In recent years adenosine triphosphate (ATP) assay instruments have found their way into the QC market as convenient, fast and relatively inexpensive means of quantifying the presence of adenosine triphosphate. It is well known that the presence of ATP is a reliable indicator of organics, alive or otherwise. There are a number of competitors in the field and together they have simplified and dramatically improved the ability of field audit/inspection personnel to quickly determine with relative accuracy the "cleanliness", e.g. reasonable lack of organic load on a given surface.

The National Sanitation Foundation International (NSF) is sponsor to the Joint Committee for Food Equipment (JC), which is an ANSI standards development organization. I have been a voting member of the JC representing the North American Food Equipment Manufacturers (NAFEM) association since 2001, and serve on many task groups. The NSF JC complies with ISO65/IEC criteria for industry consensus standards development and is thus comprised of three distinct groups. Regulatory has representation from Federal, State and local levels, and a few representatives from Canadian Health agencies too. Industry is represented by persons employed by the manufacturers, some of food products and others of food equipment along with representatives of affected trade associations. Consumers are represented to the NSF JC by academia and by consultants and other ANSI certifying body personnel, together

NSF's JC is a likely candidate for consideration as the developer of a standard to define CLEAN, from a FOODSAFE perspective, i.e., what quantifiable level of organics on a food contact surface is reasonably defined as FOODSAFE CLEAN in preparation for a separate sanitizing step.

The Association of Analytical Chemists International (AOAC International) is committed to be a proactive worldwide provider and facilitator in the development use and harmonization of validated analytical methods and laboratory quality assurance programs and services. AOAC's "Official Methods of Analysis" have been defined as "official" by regulations promulgated for enforcement of the Food, Drug and Cosmetic Act (21 CFR 2.19), recognized in Title 9 of USDA-FSIS Code of Federal Regulations and in many cases by the US Environmental Protection Agency (EPA). US EPA is the authority having jurisdiction for the maintenance and enforcement of FIFRA, an act of Congress containing all pesticide regulations; all sanitizers, disinfectants and sterilants being categorized as pesticides.

The timing of this initiative coincides with a brand new AOAC International project working towards validating ATP instrumentation and regimes. If and when ATP detection methods become validated in this manner we will then have the speed, convenience, accuracy and reasonably priced and validated tool we need to do field audit and inspection to quantify cleaning processes to further improve our food handler training programs and cleaning and sanitizing regimes. So too will we have the tool needed to reexamine other performance standards whose criteria were developed without such tools and may be found to lack correlation limiting innovation and optimization.

I invite you and other interested stakeholders, public and private, NGO or GO to collaborate in the pursuit for reliable, replicable and reasonable test methods for determining "FOODSAFE" food contact surface cleanliness.

Please send you enquiries to:

tomj@jdpinc.com or call, 651-203-2462

**Conference for Food Protection
2008 Issue Form**

**Internal Number: 067
Issue: 2008 III-026**

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 Antiseptic Protocol to Clean Hands in No Water or Remote Locations

Issue you would like the Conference to consider:

FDA Food Code, Section 2-301.16 states employees may use a hand antiseptic to clean hands when food exposure is limited and handwashing sinks are not conveniently available. Section 5-203.11(C) allows the use of chemically treated disinfectant towelettes only when authorized by the regulatory authority.

Effective hand cleaning without water, using alcohol-based hand antiseptics, has been demonstrated as equivalent to handwashing with soap and water as required in Section 2-201.12(B) when the application of antiseptic is accompanied by friction, wiped with a dry towel, and followed by a second application of antiseptic that is allowed to dry in accordance with the manufacturers label in a protocol similar to Section 2-101.12(B).

The use of this technique when food is prepared or served in temporary or remote location where water or electricity is not conveniently available is an advance in worker hygiene in that it eliminates ambiguities associated with portable hand sinks, other techniques, and is easier for the employee.

This technique is neither a substitute for handwashing at permanent facilities, a substitute for handwash sink requirements in Section 5-202.12, nor a substitute for towelettes. It is another option.

Public Health Significance:

Everyone has attended an outdoor or remote catering, beverage, or temporary food service affair and observed the lack of hand hygiene by employees when handwashing facilities, including portable hand sinks are not available, conveniently located, or malfunction. At certain locations, water or electricity may not be readily available. A codified protocol for the use of hand antiseptic cleaning will allow hand cleaning stations to be located exactly

where needed by the employee, increase hand cleaning, permit accurate employee training, and minimize hand transfer of harmful microbes to the public.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting the addition of sub-paragraph C to Section 2-301.12 of the Model Food Code to read as follows with renumbering of existing Sections 2-301-12 (C) and (D).

Section 2-201.12 Cleaning Procedure

(A) No Change

(B) No Change

(C) When food exposure is limited and handwashing sinks are not available, such as outdoor events, catered events, mobile, and temporary service, employees may use a hand antiseptic procedure in which:

(1) The first application of antiseptic is used as hand cleaning wherein the employee rubs hands together vigorously for at least 10-15 seconds,

(2) A single use towel is used to dry hands; and

(3) A subsequent application of hand antiseptic is immediately applied which is allowed to dry in accordance with the manufacturers label instruction.

Submitter Information:

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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
2008 Issue Form**

**Internal Number: 058
Issue: 2008 III-027**

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:

Sequential Application of Hand Antiseptic for Use in No-Water Situations

Issue you would like the Conference to consider:

Effective hand hygiene for situations where soap and water are unavailable remains a challenge for food safety. The 2005 FDA Food Code, Section 2-301.16, outlines the parameters for hand antiseptics, but specifies that hand sanitizers "be applied only to hands that are cleaned as specified in § 20301.12." Per Section 5-203.11(C), employees may use chemically treated disinfectant towelettes when food exposure is limited and handwashing sinks are not conveniently available, such as in some mobile or temporary food establishments or at some vending machines. This leaves a gap in the Code for effective hand decontamination in situations where food exposure is limited and handwashing sinks are not available. It has now been found that an effective hand cleansing, equivalent in degerming to handwashing with soap and water as specified in Section 2-301.12(B), can be achieved by sequential use of alcohol-based hand antiseptics, wherein a first application is wiped off with a dry towel, followed immediately by a second application that is allowed to dry as per normal alcohol sanitizer use directions. This protocol is not a substitute for handwashing in stationary facilities where cleaning can be accomplished per 2-301.12.

Public Health Significance:

Potential contamination of ready-to-eat foods is increased in situations where access to soap and water are limited or simply unavailable. The new proposed option can significantly increase the level of effective hand degerming in those situations.

Recommended Solution: The Conference recommends...:

that a letter to FDA urging the following addition to the Model Food Code:

5-203.11 Handwashing Sinks

(D) When food exposure is limited and handwashing sinks are not conveniently located, such as at outdoor events, mobile or temporary food service and some vending machine locations, employees may use a regimen of sequential application of hand antiseptic wherein the first application is treated as a handwash with full scrubbing action and then, while wet, wiped off with a dry towel, immediately followed by a second application which is allowed to dry per standard label instruction.

(i) Said hand antiseptic shall meet requirements of 2-301.16

(ii) Said hand antiseptic shall have supporting test data indicating statistical equivalence to a standard handwash in hand degerming.

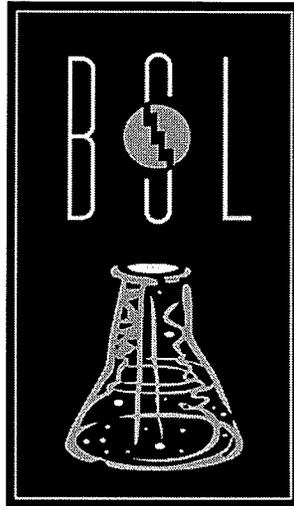
Submitter Information:

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Attachments:

- "Determination of the Antimicrobial Efficacy ... Handwash Procedure"

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.



January 17, 2008

FINAL REPORT #070723-150

**DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF THREE (3) TEST ARTICLES
USING A VARIATION OF THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE**

Prepared for:

(SPONSOR)

Prepared by:

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EXECUTIVE SUMMARY

The purpose of this study was to evaluate the antimicrobial efficacy of three (3) test articles using a modification of the Health Care Personnel Handwash evaluation. The indicator microorganism used for hand contaminations was *Escherichia coli* (ATCC #11229). Eleven (11) subjects used each of the three (3) test articles (reference Section 14.0 of this Final Report and a Protocol and/or SOP Deviation Recording Form [Form No. 99-QA-004] in Addendum I of this Final Report), one (1) at a time. Subjects performed two (2) consecutive hand contaminations with the challenge suspension in a beef broth medium, the first followed by a sample for baseline, and the second by a product application. Subjects then decontaminated their hands with a 70% Ethanol rinse and a nonmedicated soap wash, and then used a second Test Article. This procedure was repeated again with the remaining Test Article. The baseline and post-application samples were evaluated for the presence of *Escherichia coli* (ATCC #11229). The testing methods were based on the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash*. (FR59:116, 17 June 94) and ASTM E1174-06, *Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations*.

The critical index for this study was a two (2) log₁₀ reduction in baseline populations after product application.

STATISTICAL ANALYSIS #1

For Test Article #1, Bland Foaming Handwash (Lot Number 275543), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean log₁₀ reduction of 2.80 after product application and met the critical index of the study.

For Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2 produced a mean log₁₀ reduction of 2.64 after product application and met the critical index of the study.

For Test Article #3, Sanitizing Hand Wipes (68.15% Ethanol; Lot Number 973-12), followed by Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), applied per Test Article #3 Application Procedure, the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 followed by Test Article #2, applied per Test Article #3 Application Procedure, produced a mean log₁₀ reduction of 2.47 after product application and met the critical index of the study.

STATISTICAL ANALYSIS #2

Upon completion of the statistical analysis, Subject #12's data were determined to be outliers. Further investigation revealed that the subject appeared to have a learning disability and needed repeated instruction by the monitoring laboratory technician to be able to perform each of the steps required by the study protocol. The conclusions below results from a statistical analysis excluding data from testing of Subject #12.

For Test Article #1, Bland Foaming Handwash (Lot Number 275543), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean log₁₀ reduction of 2.93 after product application and met the critical index of the study.

Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2 produced a mean log₁₀ reduction of 2.83 after product application and met the critical index of the study.

Test Article #3, Sanitizing Hand Wipes (68.15% Ethanol; Lot Number 973-12), followed by Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), applied per Test Article #3 Application Procedure, the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 followed by Test Article #2, applied per Test Article #3 Application Procedure, produced a mean log₁₀ reduction of 2.63 after product application and met the critical index of the study.

January 17, 2008

FINAL REPORT # 070723-150

1.0 **TITLE:** **DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF THREE (3) TEST ARTICLES USING A VARIATION OF THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE**

2.0 **TESTING FACILITY:** **BIOSCIENCE LABORATORIES, INC.**
300 N. Willson Avenue
Bozeman, Montana 59715

3.0 **STUDY DIRECTORS:**

Robert R. McCormack - Principal Study Director
Kendra F. Drake - Associate Study Director

4.0 **PURPOSE OF STUDY:**

The purpose of this study was to evaluate the antimicrobial efficacy of three (3) test articles for use in the food service industry. Testing was performed per methodology based on the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash* (FR59:116, 17 June 94, pp. 31448-31450) and ASTM E1174-06, *Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations*.

5.0 **SCOPE:**

The purpose of this study was to evaluate the antimicrobial efficacy of three (3) test articles using a modification of the Health Care Personnel Handwash evaluation. The indicator microorganism used for hand contaminations was *Escherichia coli* (ATCC #11229). Eleven (11) subjects used each of the three (3) test articles, one (1) at a time. Subjects performed two (2) consecutive hand contaminations with the challenge suspension in a beef broth medium, the first followed by a sample for baseline, and the second by a product application. Subjects then decontaminated their hands with a 70% Ethanol rinse and a nonmedicated soap wash, and then used a second Test Article. This procedure was repeated again with the remaining Test Article. The baseline and post-application samples were evaluated for the presence of *Escherichia coli* (ATCC #11229). The testing methods were based on the Food and Drug Administration Tentative Final Monograph (TFM) for *Effectiveness Testing of an Antiseptic Handwash or Health Care Personnel Handwash*. (FR59:116, 17 June 94) and ASTM E1174-06, *Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations*. The Study Protocol was approved by the Gallatin Institutional Review Board (GIRB) on 12/04/07 (See Addendum I of this Final Report). One (1) deviation from the methodology described in the Study Protocol occurred (reference Section 14.0 of this Final Report), and as is detailed on a Protocol and/or SOP Deviation Recording Form (Form No. 99-QA-004) in Addendum I of this Final Report, it had no adverse effect upon the study outcome. No deviations from BioScience Laboratories, Inc., Standard Operating Procedures occurred during the course of this evaluation.

6.0 **STUDY DATES:**

STUDY INITIATION DATE: 11/30/07
EXPERIMENTAL START DATE: 12/19/07
EXPERIMENTAL END DATE: 01/07/08
STUDY COMPLETION DATE: 01/17/08

7.0 **TEST MATERIALS:**

The test articles were provided to the Testing Facility by the Sponsor. Responsibility for determination of the identity, strength, purity, composition, stability, and solubility of the test articles, as well as responsibility for retention of the test articles, remained with the Sponsor. All documentation provided with the test articles is included in Addendum IX of this Final Report.

Test Article #1: Bland Foaming Handwash
Lot Number: 275543
Expiration Date: 01/2010

Test Article #2: Instant Hand Sanitizer Gel
Active Ingredient: 62% Ethanol
Lot Number: 240041 5179
Expiration Date: 06/2008

Test Article #3: Sanitizing Hand Wipes
Active Ingredient: 68.15% Ethanol
Lot Number: 973-12
Expiration Date: 04/19/08

8.0 **TEST ARTICLE APPLICATION PROCEDURES:**

Test Period

8.1 Each subject was in testing for approximately four (4) hours on a single day and used each of the three (3) test articles. Prior to being admitted into testing, subjects were questioned regarding their adherence to the Protocol requirements. Subjects clipped their fingernails to a free edge of ≤ 1 mm, if they had not already done so. All jewelry was removed from the hands and arms prior to washing.

NOTE: Each subject used each of the three (3) test articles, one (1) at a time, per specified application procedures. After the Glove Juice Sampling Procedure was performed following test article application and prior to use of another test article, the subjects were required to decontaminate their hands by performing a one (1) minute rinse with 70% Ethanol and an air-dry, followed by a thirty (30) second handwash using a nonmedicated soap. The subjects waited a minimum of twenty (20) minutes following the use of the nonmedicated soap and prior to use of another test article.

8.2 A handwash was performed using a nonmedicated soap to remove dirt and oil from the hands. A technician instructed subjects in the appropriate technique and verified its proper execution by subjects. The temperature of the water used for all wash or rinse procedures was controlled at $40^{\circ} \pm 2^{\circ}\text{C}$ (see Water Temperature Monitoring Sheets [Form No. 96-CT-017] in Addendum VII of this Final Report]).

Inoculum Application Procedure

- 8.3 Four and one-half (4.5) mLs of the beef broth suspension containing at least 1×10^9 CFU/mL of *Escherichia coli* (ATCC #11229) were transferred into each subject's cupped hands in three (3) aliquant amounts of one and one-half (1.5) mLs.
- 8.4 The suspension was distributed over the entire surface of the hands (front and back), not reaching above the wrists, for twenty (20) \pm five (5) seconds. Following distribution of the inoculum, the hands were held motionless, away from the body, and allowed to air-dry for thirty (30) \pm five (5) seconds.
- 8.5 The procedure in Section 8.4 was repeated.
- 8.6 A final one and one-half (1.5) mL aliquant amount of the challenge suspension was dispensed into the subject's cupped hands and distributed over the entire surface of the hands (front and back), not reaching above the wrists, for twenty (20) \pm five (5) seconds. The hands were allowed to air-dry for ninety (90) seconds.
- 8.7 After the timed ninety (90) second air-dry, the Glove Juice Sampling Procedure was performed. This first contamination cycle provided the baseline population level. It was followed with a thirty (30) second handwash using nonmedicated soap.
- 8.8 The challenge suspension was again dispensed into each subject's cupped hands and distributed as described above. After a timed ninety (90) second air-dry, the subjects applied their randomly assigned test article according to the directions below.

Test Article #1 Application Procedure

- 8.9 The subject wet hands within ten (10) seconds of completing the drying step.
- 8.10 Two (2) pumps (1.4 mL) of Test Article #1 were placed in the subject's cupped hands.
- 8.11 The subject lathered Test Article #1 for fifteen (15) seconds, followed by a ten (10) second rinse with water.
- 8.12 Following the water rinse, the subject used two (2) paper towels to pat-dry hands for ten (10) seconds.

Test Article #2 Application Procedure

- 8.13 Two (2) pumps (3.0 mL) of Test Article #2 were placed in the subject's cupped hands within ten (10) seconds of completing the drying step.
- 8.14 The subject rubbed Test Article #2 into the hands in a vigorous manner for fifteen (15) seconds.
- 8.15 Following Test Article #2 application, the subject used two (2) paper towels to pat-dry hands for ten (10) seconds.
- 8.16 An additional one (1) pump of Test Article #2 was placed in the subject's cupped hands (1.5 mL), and the hands were rubbed together until dry.

Test Article #3 Application Procedure

- 8.17 Within ten (10) seconds of completing the drying step, the subject wiped both hands with Test Article #3 in a standardized fashion for twenty-five (25) seconds.
- 8.18 Following the wiping procedure, one (1) pump of Test Article #2 was placed in the subject's cupped hands, and hands were rubbed together until dry.

9.0 EQUIPMENT AND SUPPLIES:

The equipment and supplies used for this study are summarized in the Study Protocol, included in Addendum I of this Final Report, and are also detailed on Clinical Trials Equipment Tracking Forms (Form No. 01-L-009) and Clinical Trials Supplies Tracking Forms (Form 01-L-008) in Addendum VII of this Final Report.

10.0 MEDIA:

The growth media and diluting fluids used in this study are as described in the Study Protocol in Addendum I of this Final Report. Additional details are recorded on Media/Diluent Tracking Forms (Form No. 97-L-007) in Addendum VIII of this Final Report.

11.0 SUBJECT DEMOGRAPHICS:

Twenty-seven (27) overtly healthy subjects, at least eighteen (18) years of age were admitted into the study. Eleven (11) subjects completed the study (reference Protocol and/or SOP Deviation Recording Form [Form No. 99-QA-004] in Addendum I of this Final Report). Insofar as possible, the group of subjects selected was of mixed sex, age, and race. Hands and forearms were free from clinically evident dermatoses, other injuries to the area, and/or any other disorders that may have compromised the subject and the study. All subjects who participated in the Study signed the Study Description and Informed Consent Form, Subject Confidential Information and Acceptance Criteria, and Authorization to Use and Disclose Protected Health Information Form (Appendix I of Addendum I of this Final Report) and List of Restricted Products (Appendix II of Addendum I of this Final Report) prior to participating in the study. The demographics of the study are presented in the table below.

DEMOGRAPHIC SUMMARY	ALL SUBJECTS	
	Recruited	Received Product
AGE		
Minimum Age	19	19
<i>Median Age</i>	35	45
Maximum Age	69	69
SEX		
Males (M)	14	5
Females (F)	13	6
<i>Total</i>	27	11
RACE		
White/Caucasian (C)	26	10
Latino (L)	1	1
<i>Total</i>	27	11

DID NOT PARTICIPATE IN TESTING	
SC = Schedule Conflict	1
QC = Qualification (Inclusion/Exclusion) Criteria Failure	10
NS = No Show	5

12.0 ADVERSE EVENTS:

No subject experienced an adverse event during or following completion of this study.

13.0 NEUTRALIZATION EVALUATION :

The results of a neutralization evaluation (BSLI SOP CT-1006) indicated that the neutralizer(s) used in the recovery medium successfully quenched the antimicrobial activity of the test articles. Study procedures followed guidelines set forth in ASTM E 1054-02, *Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents*, except that the microorganism was added to the neutralizer prior to the addition of the test articles. *Escherichia coli* (ATCC #11229) was used as the challenge species in the neutralizer validation study. All data resulting from the Neutralization Assay are included in Addendum VI of this Final Report.

14.0 DEVIATION FROM PROTOCOL:

Section 12.40 in Protocol 070723-150 states, "Within ten (10) seconds of completing the drying step (Section 12.31), the subject will wipe both hands with Test Article #3 in a standardized fashion for twenty-five (25) seconds." Subject 21 did not use Test Article #3 on both hands in a standardized fashion nor for the full twenty-five (25) seconds. Subject 21 dropped wipe with three (3) seconds left on the rub, continued without wipe, and one (1) pump of Test Article #2 was then placed in the subject's cupped hands. Subject 21 failed to follow applications instructions as directed by the monitoring laboratory technician. Subject 21's data for Test Article #3 were disregarded from the analysis, so there is no effect on the outcome of the study.

15.0 RESULTS - TABLES I THROUGH XII:

15.1 Table I presents the statistical summary of the log₁₀ values following performance of Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]).

Table I: Statistical Summary of the log₁₀ Recovery Values following Performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543])

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	22	8.18	0.24	8.08 to 8.29
Application 1	22	5.38	0.58	5.13 to 5.64
Application 1 Log ₁₀ Reduction	22	2.80	0.68	2.50 to 3.10

15.2 Table II presents the log₁₀ values and log₁₀ reduction from baseline values, by subject, following performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]).

Table II: Log₁₀ Values and Log₁₀ Reduction from Baseline Values, by subject, following Performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543])

Subject	Side	Baseline log ₁₀ Values	Application 1 log ₁₀ Values	Application 1 log ₁₀ Reduction from Baseline
1	Left	8.31	5.66	2.65
	Right	8.12	5.81	2.31
16	Left	8.34	4.33	4.01
	Right	8.34	5.27	3.07
3	Left	8.23	5.12	3.11
	Right	8.11	5.60	2.51
9	Left	8.43	4.97	3.46
	Right	8.19	5.11	3.07
20	Left	8.04	4.82	3.22
	Right	8.11	4.69	3.42
7	Left	8.19	4.14	4.05
	Right	8.14	4.69	3.45
18	Left	8.01	6.00	2.01
	Right	8.04	6.09	1.95
12	Left	7.66	5.87	1.79
	Right	7.58	6.22	1.36
21	Left	8.58	5.64	2.94
	Right	8.48	5.96	2.52
27	Left	8.21	5.55	2.67
	Right	8.21	5.76	2.44
26	Left	8.32	5.47	2.85
	Right	8.38	5.60	2.78

15.3 Table III presents the statistical summary of the log₁₀ values following performance of Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]).

Table III: Statistical Summary of the log₁₀ Recovery Values following Performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179])

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	22	8.14	0.31	8.00 to 8.28
Application 1	22	5.50	0.79	5.15 to 5.85
Application 1 Log ₁₀ Reduction	22	2.64	0.89	2.24 to 3.03

15.4 Table IV presents the log₁₀ values and log₁₀ reduction from baseline values, by subject, following performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]).

Table IV: Log₁₀ Values and Log₁₀ Reduction from Baseline Values by subject following Performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179])

Subject	Side	Baseline log ₁₀ Values	Application 1 log ₁₀ Values	Application 1 log ₁₀ Reduction from Baseline
1	Left	8.14	5.96	2.18
	Right	8.23	5.80	2.43
16	Left	8.28	5.99	2.29
	Right	8.25	6.45	1.80
3	Left	8.02	5.36	2.67
	Right	8.21	5.34	2.87
9	Left	8.43	4.96	3.47
	Right	8.39	5.56	2.84
20	Left	8.11	4.74	3.37
	Right	8.03	5.82	2.21
7	Left	8.29	4.19	4.10
	Right	8.20	4.85	3.35
18	Left	7.74	4.33	3.40
	Right	7.88	3.66	4.22
12	Left	7.25	6.47	0.78
	Right	7.45	6.90	0.55
21	Left	8.44	5.85	2.59
	Right	8.27	5.90	2.37
27	Left	8.27	6.21	2.06
	Right	8.31	5.61	2.69
26	Left	8.42	5.77	2.66
	Right	8.42	5.34	3.08

- 15.5 Table V presents the statistical summary of the log₁₀ values following performance of Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]).

Table V: Statistical Summary of the log₁₀ Recovery Values following Performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Log Number 240041 5179])

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	20	8.07	0.34	7.92 to 8.23
Wash 1	20	5.60	0.64	5.30 to 5.90
Wash 1 Log ₁₀ Reduction	20	2.47	0.76	2.12 to 2.83

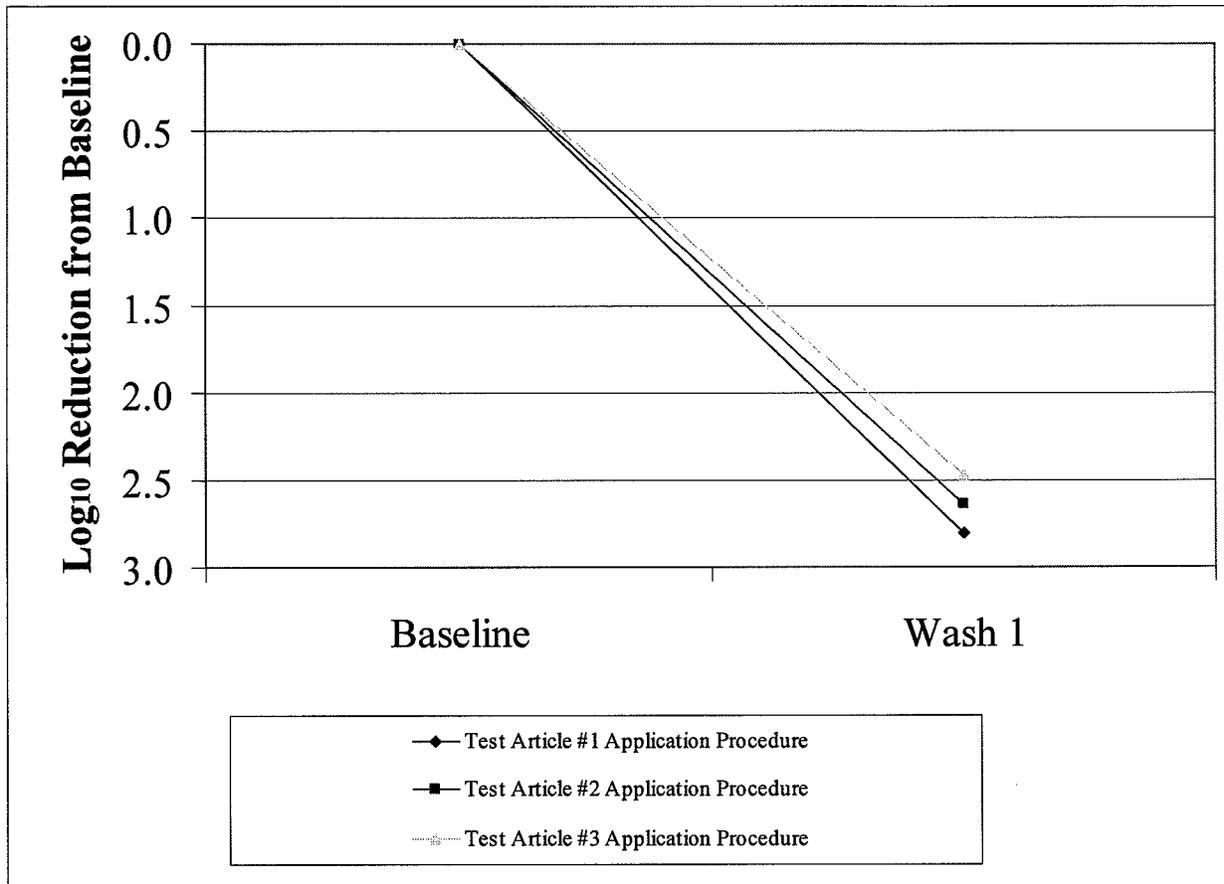
- 15.6 Table VI presents the log₁₀ values and log₁₀ reduction from baseline values, by subject, following performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]).

Table VI: Log₁₀ Values and Log₁₀ Reduction from Baseline Values by subject following Performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Log Number 240041 5179])

Subject	Side	Baseline log ₁₀ Values	Application 1 log ₁₀ Values	Application 1 log ₁₀ Reduction from Baseline
1	Left	8.37	6.20	2.17
	Right	8.33	6.37	1.97
16	Left	8.13	5.31	2.82
	Right	8.29	5.81	2.48
3	Left	8.09	4.88	3.21
	Right	8.22	4.14	4.08
9	Left	8.41	5.18	3.23
	Right	8.35	5.33	3.02
20	Left	7.69	4.75	2.94
	Right	7.70	5.48	2.22
7	Left	8.16	5.07	3.09
	Right	8.23	6.32	1.91
18	Left	7.79	5.65	2.14
	Right	8.25	5.18	3.07
12	Left	7.23	6.21	1.03
	Right	7.35	6.30	1.05
21	Left	*	*	*
	Right	*	*	*
27	Left	8.16	5.33	2.83
	Right	8.23	5.86	2.38
26	Left	8.24	6.28	1.96
	Right	8.27	6.39	1.88

15.7 Figure 1 presents the graphical presentation of the mean log₁₀ reductions from baseline from each of the three (3) test article application procedures.

Figure 1: Graphical Presentation of the Mean log₁₀ Reductions from Baseline From the Three (3) Test Article Application Procedures



15.8 Table VII presents the statistical summary of the log₁₀ values following performance of Test Article #1 Application Procedure (Bland Foaming Handwash (Lot Number 275543)) excluding data from Subject 12.

Table VII: Statistical Summary of the log₁₀ Recovery Values following Performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]) excluding Data from Subject #12

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	20	8.24	0.16	8.17 to 8.31
Application 1	20	5.32	0.56	5.05 to 5.58
Application 1 Log ₁₀ Reduction	20	2.93	0.58	2.66 to 3.19

15.9 Table VIII presents the log₁₀ values and log₁₀ reduction from baseline values, by subject, following performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]) excluding data from Subject #12.

Table VIII: Log₁₀ Values and Log₁₀ Reduction from Baseline Values, by subject, following Performance of the Test Article #1 Application Procedure (Bland Foaming Handwash [Lot Number 275543]) excluding Data from Subject #12

Subject	Side	Baseline log ₁₀ Values	Application 1 log ₁₀ Values	Application 1 log ₁₀ Reduction from Baseline
1	Left	8.31	5.66	2.65
	Right	8.12	5.81	2.31
16	Left	8.34	4.33	4.01
	Right	8.34	5.27	3.07
3	Left	8.23	5.12	3.11
	Right	8.11	5.60	2.51
9	Left	8.43	4.97	3.46
	Right	8.19	5.11	3.07
20	Left	8.04	4.82	3.22
	Right	8.11	4.69	3.42
7	Left	8.19	4.14	4.05
	Right	8.14	4.69	3.45
18	Left	8.01	6.00	2.01
	Right	8.04	6.09	1.95
12	Left	*	*	*
	Right	*	*	*
21	Left	8.58	5.64	2.94
	Right	8.48	5.96	2.52
27	Left	8.21	5.55	2.67
	Right	8.21	5.76	2.44
26	Left	8.32	5.47	2.85
	Right	8.38	5.60	2.78

15.10 Table IX presents the statistical summary of the log₁₀ values following performance of Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding data from Subject #12.

Table IX: Statistical Summary of the log₁₀ Recovery Values following Performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding Data from Subject #12

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	20	8.22	0.19	8.13 to 8.30
Application 1	20	5.38	0.73	5.05 to 5.72
Application 1 Log ₁₀ Reduction	20	2.83	0.66	2.53 to 3.14

15.11 Table X presents the log₁₀ values and log₁₀ reduction from baseline values, by subject, following performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding data from Subject #12.

Table X: Log₁₀ Values and Log₁₀ Reduction from Baseline Values by subject following Performance of the Test Article #2 Application Procedure (Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding Data from Subject #12

Subject	Side	Baseline log ₁₀ Values	Application 1 log ₁₀ Values	Application 1 log ₁₀ Reduction from Baseline
1	Left	8.14	5.96	2.18
	Right	8.23	5.80	2.43
16	Left	8.28	5.99	2.29
	Right	8.25	6.45	1.80
3	Left	8.02	5.36	2.67
	Right	8.21	5.34	2.87
9	Left	8.43	4.96	3.47
	Right	8.39	5.56	2.84
20	Left	8.11	4.74	3.37
	Right	8.03	5.82	2.21
7	Left	8.29	4.19	4.10
	Right	8.20	4.85	3.35
18	Left	7.74	4.33	3.40
	Right	7.88	3.66	4.22
12	Left	*	*	*
	Right	*	*	*
21	Left	8.44	5.85	2.59
	Right	8.27	5.90	2.37
27	Left	8.27	6.21	2.06
	Right	8.31	5.61	2.69
26	Left	8.42	5.77	2.66
	Right	8.42	5.34	3.08

15.12 Table V presents the statistical summary of the log₁₀ values following performance of Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding data from Subject #12.

Table XI: Statistical Summary of the log₁₀ Recovery Values following Performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Log Number 240041 5179]) excluding Data from Subject #12

Sample	Sample Size	Mean	Standard Deviation	95% Confidence Interval
Baseline	18	8.16	0.22	8.05 to 8.27
Wash 1	18	5.53	0.63	5.21 to 5.85
Wash 1 Log ₁₀ Reduction	18	2.63	0.61	2.33 to 2.93

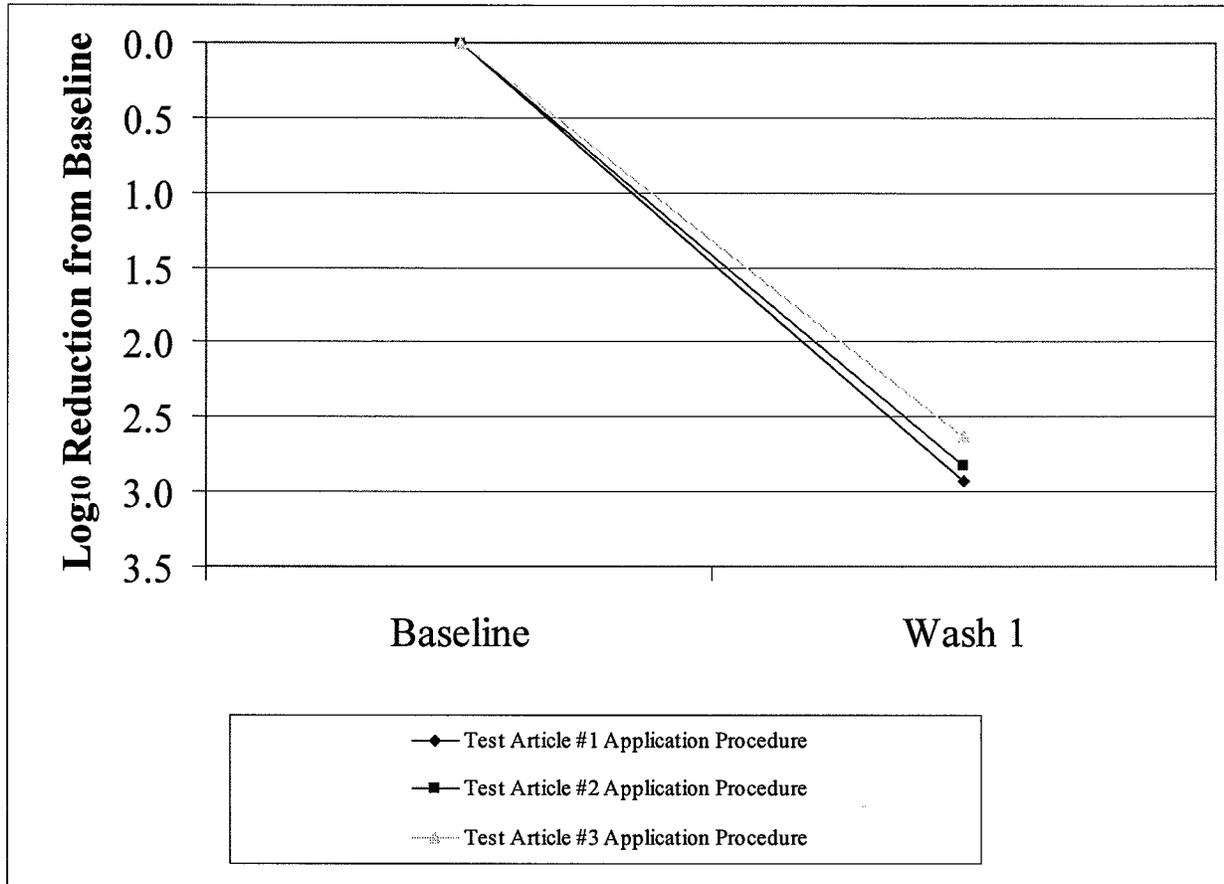
15.13 Table XII presents the log₁₀ values and log₁₀ reduction from baseline values, by subject, following performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Lot Number 240041 5179]) excluding data from Subject #12.

Table XII: Log₁₀ Values and Log₁₀ Reduction from Baseline Values by subject following Performance of the Test Article #3 Application Procedure (Sanitizing Hand Wipes [68.15% Ethanol; Lot Number 973-12] followed by Instant Hand Sanitizer Gel [62% Ethanol; Log Number 240041 5179]) excluding Data from Subject #12

Subject	Side	Baseline log ₁₀ Values	Application 1 log ₁₀ Values	Application 1 log ₁₀ Reduction from Baseline
1	Left	8.37	6.20	2.17
	Right	8.33	6.37	1.97
16	Left	8.13	5.31	2.82
	Right	8.29	5.81	2.48
3	Left	8.09	4.88	3.21
	Right	8.22	4.14	4.08
9	Left	8.41	5.18	3.23
	Right	8.35	5.33	3.02
20	Left	7.69	4.75	2.94
	Right	7.70	5.48	2.22
7	Left	8.16	5.07	3.09
	Right	8.23	6.32	1.91
18	Left	7.79	5.65	2.14
	Right	8.25	5.18	3.07
12	Left	*	*	*
	Right	*	*	*
21	Left	*	*	*
	Right	*	*	*
27	Left	8.16	5.33	2.83
	Right	8.23	5.86	2.38
26	Left	8.24	6.28	1.96
	Right	8.27	6.39	1.88

15.14 Figure 2 presents the graphical presentation of the mean log₁₀ reductions from baseline from each of the three (3) test article application procedures excluding data from Subject #12.

Figure 2: Graphical Presentation of the Mean log₁₀ Reductions from Baseline From the Three Test Article Application Procedures excluding Data from Subject #12



16.0 CONCLUSION:

The critical index for this study was a two (2) log₁₀ reduction in baseline populations after product application.

STATISTICAL ANALYSIS #1

For Test Article #1, Bland Foaming Handwash (Lot Number 275543), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean log₁₀ reduction of 2.80 after product application and met the critical index of the study.

For Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2 produced a mean log₁₀ reduction of 2.64 after product application and met the critical index of the study.

For Test Article #3, Sanitizing Hand Wipes (68.15% Ethanol; Lot Number 973-12), followed by Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), applied per Test Article #3 Application Procedure, the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 followed by Test Article #2, applied per Test Article #3 Application Procedure, produced a mean log₁₀ reduction of 2.47 after product application and met the critical index of the study.

STATISTICAL ANALYSIS #2

Upon completion of the statistical analysis, Subject #12's data were determined to be outliers. Further investigation revealed that the subject appeared to have a learning disability and needed repeated instruction by the monitoring laboratory technician to be able to perform each of the steps required by the study protocol. The conclusions below results from a statistical analysis excluding data from testing of Subject #12.

For Test Article #1, Bland Foaming Handwash (Lot Number 275543), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #1 produced a mean log₁₀ reduction of 2.93 after product application and met the critical index of the study.

Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #2 produced a mean log₁₀ reduction of 2.83 after product application and met the critical index of the study.

Test Article #3, Sanitizing Hand Wipes (68.15% Ethanol; Lot Number 973-12), followed by Test Article #2, Instant Hand Sanitizer Gel (62% Ethanol; Lot Number 240041 5179), applied per Test Article #3 Application Procedure, the bacterial populations recovered after product application were reduced significantly from baseline populations. Test Article #3 followed by Test Article #2, applied per Test Article #3 Application Procedure, produced a mean log₁₀ reduction of 2.63 after product application and met the critical index of the study.

17.0 LABORATORY PERSONNEL:

The following employees of BioScience Laboratories, Inc., were involved in the testing or ancillary support of this Study. The laboratory personnel have been appropriately trained, and their training records are on file in the Quality Assurance Unit at the Testing Facility.

STUDY DIRECTOR:	Robert R. McCormack Microbiologist
Sabrina Bakich Marketing Manager/Product Handling	Paul O' Brien Clinical Laboratory Technician
Amanda Berry Subject Recruitment	Alicia Pfile Microbiologist
Stephanie Cebulla Laboratory Support Technician	Christine Roath Microbiologist
Kendra F. Drake Associate Study Director, Microbiologist	Lori Schlotfeldt Supervisor of Laboratory Support

LABORATORY PERSONNEL (Continued)

Collette Duley
Microbiologist

Jessica Sheehy
Laboratory Support Technician

Erika Ecton
Subject Recruitment

Carl Schmidt
Microbiologist

Amanda Henry
Microbiologist

Brian Stancil
Clinical Laboratory Technician

August Grace Johnson
Microbiologist

Robert H. Stancil
Microbiologist

Jacqueline Joyner
Subject Recruitment

Clare Wilson
Microbiologist

Lisa Lehman
Microbiologist

Annette C. Woods
Microbiologist

Ron Neibauer
Manager of Clinical Laboratories

Kristy Wuebber
Microbiologist

18.0 QUALITY ASSURANCE PERSONNEL:

Liv Graving
Quality Assurance Associate

John A. Mitchell, Ph.D.
Director of Quality Assurance

Amy Juhnke
Manager of Quality Assurance/Document
Control

Janis Smoke
Quality Assurance Associate

Scott McCommon
Manager of Quality Control

19.0 DOCUMENTATION AND RECORD-KEEPING:

All documentation and records were compiled, analyzed, and will be retained by BioScience Laboratories, Inc., at its facility in Bozeman, Montana. All raw data for this study, as well as the Final Report, will be retained in safe storage by the Testing Facility for a period of at least three (3) years.

20.0 **ACCEPTANCE:**

QUALITY ASSURANCE STATEMENT:

This study was inspected by the Quality Assurance Unit, and reports were submitted to the Study Director and Management in accordance with Standard Operating Procedures, as follows:

<u>Phase</u>	<u>Date</u>
Neutralization Assay	01/04/08
Product Testing	12/19/07 and 12/26/07
Data Audit	01/14/08
Final Report Review	01/17/08
Reports to Study Director and Management	12/19/07, 12/26/07, 01/04/08, and 01/17/08

This study was conducted in compliance with Good Laboratory Practices standards, as described by the FDA (reference CFR 21 Parts 50, 56, 312, and 314), with the following exception: test article preparations were not analyzed at BioScience Laboratories, Inc., to confirm concentration, stability, or homogeneity.

INDEX OF ADDENDA

- I GIRB-Approved Protocol #070723-150
Protocol and/or SOP Deviation Recording Form (Form No. 99-QA-004)

- II Qualification Criteria for Study 070723-150

- III Sampling Data Sheets for Healthcare Personnel Handwash Study 070723-150
Irritation Evaluations for Study 070723-150

- IV Q-Count™ Plate Counter Data Sheets (Form No. 00-L-009)
Q-Count™ Plate Count Data and Calculations

- V Statistical Analysis

- VI Neutralization Evaluation
 - Project Notes (Form No. 95-G-001) for Neutralization Assay
 - Neutralization Evaluation Data Sheets for Study 070723-150
 - Neutralization Statistics

- VII Study Notes and General Records
 - Age Calculation and Demographics Worksheet
 - Project Notes (Form No. 95-G-001)
 - Protocol 070723-150 Randomization Scheme
 - Clinical Trials Equipment Tracking Forms (Form No. 01-L-009)
 - Clinical Trials Supplies Tracking Forms (Form No. 01-L-008)
 - Water Temperature Monitoring Sheets (Form No. 96-CT-017)
 - Incubator Log Forms (Form No. 96-L-008)
 - Refrigerator Log Form (Form No. 96-L-015)
 - Inoculum Preparation Tracking Forms - Flask Preparation (Form No. 07-CT-001)
 - Inoculum Preparation Tracking Forms - Solid Media Preparation (Form No. 07-CT-002)
 - Autoplate® 4000 Data Sheets for Healthcare Personnel Handwash Study 070723-150

- VIII Media/Diluent Tracking Forms (Form No. 97-L-007)

- IX Product Information
 - Product Receipt Log (Form No. 92-L-023)
 - Sample Submission Form and Document Compliance Statement (Form No. 94-G-007)
 - Material Safety Data Sheets (MSDS)
 - Product-Tracking Forms (Form No. 93-L-029)

**Conference for Food Protection
2008 Issue Form**

**Internal Number: 060
Issue: 2008 III-028**

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:

Elimination of Open, Refillable Soap Dispensers

Issue you would like the Conference to consider:

The Food Code emphasizes the very important role of hygiene in prevention of foodborne illness. Various Sections of the 2005 Food Code address the specifications and requirements for water quality, air supply, surface and utility cleanliness, and cleaning materials. In a similar manner, numerous Code Sections, including 2-102.11(C)(8), 2-301.11-16, 5-202.12, 5-203.11, 5-204.11, and 5-205.11, delineate sink and faucet parameters, handwashing procedures, and other aspects for proper handwashing in food handling operations. However, the Code lacks specification for the type of dispensing systems suitable for handwashing products in food handling situations. This gap creates a potential for increased microbiological contamination due to the use of open, refillable reservoir-type dispensing systems. It has been known for decades that contaminated soap can lead to disease transfer. Following a number of infectious outbreaks, the use of open, refillable soap systems in Healthcare facilities was essentially eliminated in the 1990's, and codified in the 2002 CDC Guideline for Hand Hygiene in Health-Care Settings. Recent research by the University of Arizona has demonstrated that high level bacterial contamination of open, refillable soap dispensers is still widespread, including foodservice settings. A ready solution to this situation is widely available and should be specified in the Food Code.

Public Health Significance:

High level contamination of open, refillable soap dispensers with coliforms and other organisms represents an unnecessary risk of infection to foodservice workers and patrons

Recommended Solution: The Conference recommends...:

that a letter to FDA requesting the following changes to the Model Food Code:

5-202.11 Approved System and Cleanable Fixtures.*

(C) A dispensing system for hand soap and/or hand antiseptic shall be of a sealed design and not susceptible to refilling from a secondary container, "topping off", or dilution with water or other materials. If used, individual bottles of hand soap or hand disinfectant shall be of similar design and disposed of after use of the initial contents and not refilled.

Submitter Information:

Name: Jim Mann
Organization: Handwashing For Life Institute
Address: 1216 FLAMINGO PKWY
City/State/Zip: Libertyville, IL 60048
Telephone: 847-918-0254 Fax: 847-918-0305
E-mail: jmann@handwashingforlife.com

Attachments:

- "Bacterial Contamination of Soap from Open Refillable Bulk Dispensers"

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.

How Safe is Your Soap?

Bacterial Contamination of Soap from Open Refillable Bulk Dispensers

Charles P. Gerba, PhD

Marisa B. Chattman

Sheri L. Maxwell

**An overview and summary of research studies conducted by
The University of Arizona, Tucson, AZ, and presented to:**

- **The American Society for Microbiology 107th General Meeting
Toronto, ON, Canada; May 21-25, 2007**
- **The National Environmental Health Association 71st Annual
Educational Conference & Exhibition
Atlantic City, NJ; June 18-21, 2007**

Do you know the difference?



**Open Refillable
Bulk Soap Dispenser**

**Sealed Soap
Dispensing System**

Design	<ul style="list-style-type: none"> • Open to the environment • Permanent nozzle is reused 	<ul style="list-style-type: none"> • Factory sealed • New nozzle with each refill
Refilling Method	<ul style="list-style-type: none"> • Pour soap into dispenser from bottle 	<ul style="list-style-type: none"> • Snap new cartridge into dispenser
Maintenance	<ul style="list-style-type: none"> • Labor intensive • Extensive cleaning and sanitizing required 	<ul style="list-style-type: none"> • Labor-free • No need for cleaning and sanitizing
Contamination	<ul style="list-style-type: none"> • Prone to contamination 	<ul style="list-style-type: none"> • Safe from contamination

Bacterial Contamination of Soap from Open Refillable Bulk Dispensers

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**POSTER: Bacterial Contamination of Liquid Hand Soaps
Used in Public Restrooms**

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8

Bulk Soap Contamination Research Study Summary

Background

Several studies conducted during the last 25 years have demonstrated that liquid soaps can become contaminated with microorganisms and multiple instances of infections and nosocomial outbreaks associated with such contamination have been reported (1-4). Contamination often occurs after the product reaches the user (extrinsic contamination) (1;3;5) and has been observed in both nonmedicated (1) and antimicrobial products including those with the active ingredients Chloroxylenol (PCMX) (3), Benzalkonium chloride (5;6), Triclosan (4), and Chlorhexidine gluconate (2;5;7-10). All types of liquid soap, regardless of the active ingredient or preservative system, are susceptible to contamination when exposed to adverse circumstances. Soap dispensers with sealed disposable refills are an alternative to this contamination challenge. By contrast, open refillable ("bulk") soap dispensers continue to present significant risk of contamination during use. Because the addition of soap

to a partially empty dispenser ("topping off") can lead to bacterial contamination in healthcare settings, the CDC recommends the use of soap dispensed from disposable containers or containers that are thoroughly washed and dried prior to refilling (11;12).

Recent studies conducted at the University of Arizona by prominent microbiologist, Dr. Charles P. Gerba, revealed that liquid hand soap collected from open refillable dispensers are a public health risk. Dr. Gerba determined the levels of bacteria in soap sampled from various types of dispensers. He found unsafe levels of bacterial contamination in soap from open refillable dispensers, whereas no bacterial contamination was found in soap from dispensers with sealed disposable refills. This research has been presented at two recent scientific conferences (13;14).

National Environmental Health Association 71st Annual Educational Conference & Exhibition

Atlantic City, NJ; June 18-21, 2007

Title: Bacterial Contamination of Liquid Hand Soaps Used in Public Restrooms

Authors: C. P. Gerba and S. Maxwell; University of Arizona, Tucson, AZ

Abstract

The objective of this study was to determine the occurrence of heterotrophic and coliform bacteria in liquid hand soaps collected from public restrooms across the United States. Sample locations included public restrooms in restaurants, health clubs, office buildings and retail stores. The liquid soap samples collected were from refillable dispensers (also referred to as "open systems" or "bulk soap" systems). Of 541 samples, 133 (25%) had bacterial numbers greater than 500 CFU/mL and 87 samples (16%) contained coliform bacteria. Approximately 65% of the bacteria isolated from the soap belonged to the coliform group.

The average number of bacteria detected in the soap was 3.02×10^6 CFU/mL with a range of 590 to 5.3×10^7 CFU/mL. The average number of coliform bacteria was 3.94×10^6 CFU/mL with a range of <10 to 6.5×10^7 CFU/mL. Opportunistic pathogens identified in the liquid soap samples included *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Serratia marcescens*, *Pseudomonas aeruginosa* and *Enterobacter sakazakii*. No bacteria were detected in dispensers that required sealed soap replacements. All of the organisms detected in the soap samples were Gram-negative bacteria. This is most likely because of the presence of sodium lauryl sulfate in the soap, which inhibits the growth of Gram-positive bacteria. The results suggest that some liquid soap dispensers become colonized by Gram-negative bacteria over time, possibly because of the degradation of preservatives in the liquid soap.

American Society for Microbiology 107th General Meeting

Toronto, ON, Canada; May 21-25, 2007

Title: Bacterial Contamination of Liquid Hand Soaps

Authors: M. Chattman, S. Maxwell and C. P. Gerba; University of Arizona, Tucson, AZ

Abstract

The occurrence of heterotrophic bacteria (HPC) and coliform bacteria in liquid hand soap from 130 refillable unsealed (a.k.a. open or bulk) dispensers collected from employee break rooms, airplane restrooms, kitchens and public restrooms was determined. The percentage of samples that contained HPC numbers above 500 CFU/mL was 23%, averaging 4.5×10^6 CFU/mL. Total coliform bacteria were detected in 22% of the samples, averaging 2.2×10^6 CFU/mL. Bacterial species most frequently identified included *Serratia marcescens*, *Enterobacter aerogenes*, and *Klebsiella pneumoniae*. One of the soap dispensers containing contaminated soap was monitored over a three month period. Various levels and types of bacterial contamination were observed. When bacteria were added to uncontaminated, factory-sealed, liquid hand soap the bacteria quickly died. Liquid hand soap from a public restroom, that contained large numbers of bacteria was pasteurized

and inoculated with *K. pneumoniae*. Growth was observed, indicating that degradation of preservatives must occur in the soap dispenser over time, allowing for the growth of bacteria. These results demonstrate that bacteria growing in soap dispensers are not resistant to the preservatives and that preservative degradation takes place, likely after introduction of the soap in the dispensers.

Contaminated Bulk Soap is a Public Health Risk

Dr. Gerba's studies demonstrate that soap from open refillable dispensers in public restrooms in the US are routinely contaminated with opportunistic pathogens. Soap users are exposed to an average of over 1,000,000 of these bacteria approximately 1 in 4 times they wash with soap from an open refillable soap dispenser. This level of contamination is 1000 times greater than upper limit recommended by cosmetic industry standards (15) and presents a potential health risk to the soap users as well as to others they may have contact with. Hands are known to be a common transmission vector and it has been shown that bacteria remain on the hands after using contaminated soap (1). The risk of acquiring an infection is greatest for anyone who has a defect in their body's normal defense mechanisms. Up to 20% of the US general public have impaired immune function and this percentage is growing due to advances in medicine which are prolonging life as well as the increase in the proportion of elderly in the population (16-18). The immunocompromised population includes a diverse group with a wide variety of conditions ranging from the severely immunocompromised (HIV/AIDS, cancer, organ or bone marrow transplant recipients) to pregnant women, young children and the elderly which exhibit non-specific general reduced immune function (19;20). The fetus, neonate

and young children have reduced immune function for the first few years of life until their immune systems mature (19). Over 12% of the US population is over the age of 65 and are at a greater risk of acquiring infections due to their age-related diminished immunity (16;21). In addition, many common chronic conditions weaken the immune system including diabetes (which affects 10% of the population) (18), cirrhosis/alcoholism, chemical dependency, nutritional deficiencies, and any defects resulting in skin barrier function loss (burns, ulcers, or dermatitis) (17;20).

Illnesses Caused by the Contaminating Bacteria

In the recent study by Dr. Gerba, several of the bacterial species isolated from the contaminated soap (e.g. *Klebsiella*, *Enterobacter*, *Citrobacter*, *Serratia*, and *Pseudomonas*) are medically important opportunistic pathogens. These organisms cause a variety of illnesses including respiratory tract infections, pneumonia, urinary tract infections, bloodstream infections, surgical site infections, meningitis, skin ulcers, gastroenteritis as well as wound and soft tissue infections (22-24). *Klebsiella pneumoniae*, for example, is responsible for 1-5% of community-acquired pneumonia (25). *Enterobacter sakazakii* causes neonatal meningitis (26). *Citrobacter* causes sepsis, meningitis and central nervous system abscesses in neonates and young infants (27) and there has been one report of *Citrobacter koseri* causing a central nervous system infection in a healthy person with a fully functional immune system (28). *Citrobacter freundii* was also implicated as a potential cause of an outbreak of diarrheal disease (24). *Pseudomonas aeruginosa* is a common nosocomial pathogen causing urinary tract infections, sinusitis, wound infections, and pneumonia. Occasionally it has been known to cause a rare form

of community-acquired pneumonia with a 33% mortality rate that can affect persons with healthy immune systems (29). *Serratia* has been implicated in multiple outbreaks due to contaminated soaps in healthcare facilities (1;3;4). *Pantoea* is a rare pathogen that was reported to be responsible for 7 infant deaths in a neonatal outbreak (30). The frequent presence of such high numbers of organisms known to be medically significant both in the community and in healthcare settings is quite alarming.

Reducing the Risks of Bulk Soap Contamination

Unsafe levels of contamination were found in 23% – 25% of soap samples collected from open refillable dispensers. In contrast, no contamination was found in soap samples collected from dispensers containing sealed disposable refills. It is recommended that all open refillable dispensers should be switched to dispensers with sealed disposable refills, which are a safer alternative and avoid unnecessary health risk.

Bacterial Contamination of Liquid Hand Soaps

Introduction

Liquid hand soap is used daily by millions of people worldwide. Hand washing, with soap and water, is a universally accepted method to reduce the microbial load on the hands. People encounter situations in which they are exposed to a variety of bacteria that have the ability to cause infection. In response to these situations, many people wash their hands with soap and water. Society recognizes that good hygiene can reduce the risk of bacterial infection. Some public facilities have soap dispensers that require sealed bags or cartridges while others have dispensers that are refillable by using stock soap solutions that are often diluted with tap water. Bulk open refillable liquid soap dispensers in many public restrooms and restaurants, offer a suitable environment for the growth of potentially disease causing microorganisms.

Materials and Methods

Soap was collected into sterile 50mL centrifuge tubes through the dispenser mechanism. One mL of Dey-Enger (DE) neutralizing broth (Remel, Lenexa, KS) was added to each sample tube and shaken for 30 seconds. Heterotrophic plate counts (HPC) were obtained by spread plating 0.1mL onto duplicate petri dishes containing R2A media (Difco, Sparks, MD) and incubated at 30°C for 5 days.

Coliform enumeration was performed by spread plating on mEndo agar plates (Difco, Sparks, MD) and incubating at 37°C for 24 hours. Representatives of each colony type were streaked for isolation on petri dishes containing Tryptic Soy Agar (TSA) (Difco, Sparks, MD). Identification of bacteria was performed by using API20E strips (BioMerieux, Marcy-l'Etoile, France).

Results

Table 1: Occurrence of Bacteria in Liquid Hand Soap from Refillable Dispensers

Type of soap dispenser	Total number of liquid soap samples tested	Number >500 CFU/mL	Coliform bacteria	Average number HPC CFU/mL	Average number coliform bacteria CFU/mL
Refillable	132	30	29	4.5 x 10 ⁶	2.2 x 10 ⁶
Disposable bag	20	0	0	0	0

Figure 1: Frequency of Detection of Various Bacteria in Soap Samples

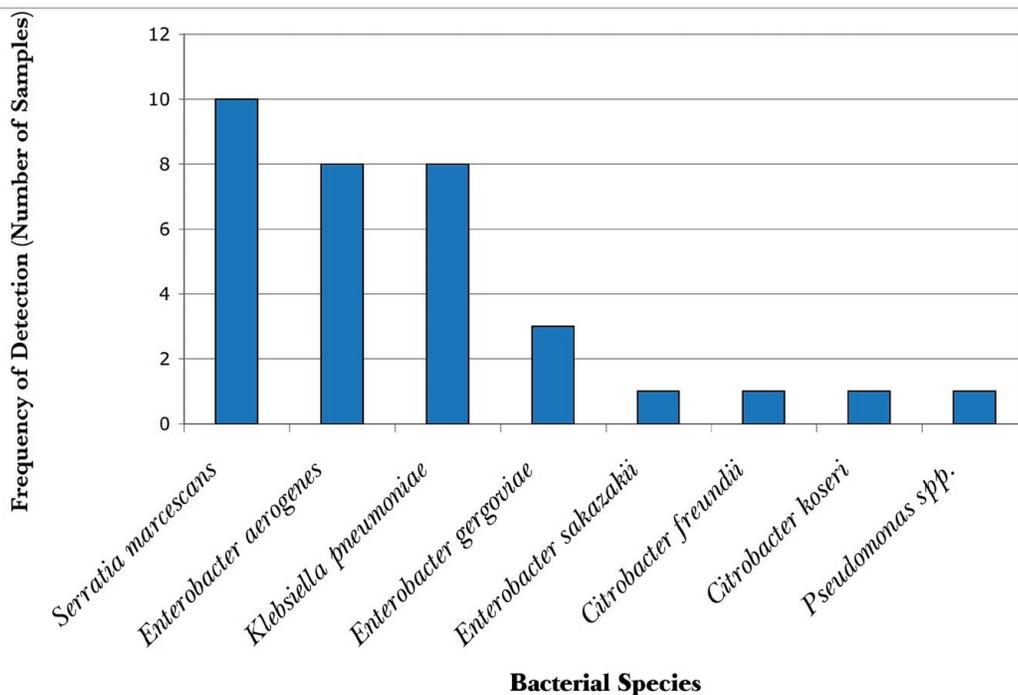


Table 2: Occurrence of HPC and Coliform Bacteria Over Time in a Restaurant Soap Dispenser

Date	HPC (CFU/mL)	Coliform bacteria (CFU/mL)
5/29	4.3 x 10 ⁷	2.0 x 10 ⁷
6/21	9.3 x 10 ³	<1
7/17	1.9 x 10 ⁷	8.2 x 10 ⁶
7/31	9.5 x 10 ⁶	7.3 x 10 ⁶
8/14	1.2 x 10 ⁷	9.0 x 10 ⁶
8/28	<1	<1
9/12	3.2 x 10 ⁷	2.6 x 10 ⁷

Table 3: Growth of *Klebsiella pneumoniae* in Pasteurized Contaminated Soap (CFU/mL)

Sample	Time (Days)			
	0	1	4	8
9/12	6.3 x 10 ²	3.4 x 10 ⁴	5.9 x 10 ⁵	2.5 x 10 ⁶
Negative Control*	<1	<1	<1	<1

* Undiluted, pasteurized soap inoculated with same amount of bacteria as sample. Number of *Klebsiella pneumoniae* added to each soap sample was 5.6 x 10³ (9.3 x 10² CFU/mL).

Table 4: Minimum Inhibitory Concentration of a Liquid Soap against *Klebsiella pneumoniae* (CFU/mL)

Dilution	Time (Days)				
	0	60 min	1	5	10
No Dilution	50	<1	<1	<1	<1
1:1	330	<1	<1	<1	<1
1:2	490	<1	<1	<1	<1
1:4	480	160	<1	<1	<1
1:10	410	320	<1	<1	<1
1:100	350	580	240	<1	<1
1:1000	410	550	240	1.5 x 10 ⁴	1.5 x 10 ⁵
Negative Control*	500	520	150	1.5 x 10 ³	2.3 x 10 ³

* No soap added.

Conclusions

- 22.7% of samples taken from refillable bulk dispensers contained >500 CFU/mL HPC, and 22% contained coliform bacteria, averaging 10⁶ CFU/mL.
- Bacterial species identified were all opportunistic pathogens.
- No bacteria were found in sealed system soap dispensers.
- A soap dispenser monitored over a three-month period, demonstrated that bacterial contamination was prolonged although the levels and types of bacteria varied.
- Eight types of uncontaminated, factory-sealed, liquid hand soaps were inoculated with various species of bacteria. All of the bacteria quickly died in the soaps after addition, even when the soap was diluted.
- The minimum inhibitory concentration of a specific brand of soap used at a restaurant that had bacterial contamination in the soap indicated that it contained sufficient concentrations of preservatives to inhibit bacterial growth.
- Liquid soap from a public restroom, that contained large numbers of bacteria was pasteurized and inoculated with *Klebsiella pneumoniae*. Growth was observed, thus it appears that degradation of preservatives must occur in the soap dispenser, allowing for the growth of bacteria.
- Bacteria growing in the soap dispensers are not resistant to the preservatives and that preservative degradation takes place, likely after introduction of the soap into the dispensers.

Bacterial Contamination of Liquid Hand Soaps Used in Public Restrooms

Introduction

Washing hands with soap and water is a universally accepted method to reduce the microbial load on the hands and is used daily by millions of people worldwide. However, the majority of public facilities have soap dispensers that are refillable using a stock soap solution. The CDC recognized in 1975 that the use of these types of dispensers can result in a suitable environment for the growth of potentially disease causing microorganisms. Current health-care hand hygiene guidelines do not recommend the use of open refillable dispensers. The liquid soap used in these dispensers can become contaminated regardless of the preservative used when the microbial population exceeds the preservatives defenses. When product contamination has been reported, contamination was more likely to have occurred extrinsically (after product had been used) than intrinsically (during manufacturing). The likelihood of extrinsic contamination is greatest when the product is open to repeated exposure to bacteria from the user or the environment, hence, the packaging and the dispensing method plays a significant role in product safety.

Materials and Methods

Liquid soap samples were collected from public restrooms in five cities [Boston, MA (107), Atlanta, GA (120), Columbus, OH (109), Los Angeles, CA (94), and Dallas, TX (111)]. Samples were organized into 5 categories: office, health clubs, food service, retail locations and other (education, leisure, etc.). The total number of liquid soap samples analyzed in this report were 541, consisting of 428 soap samples from the sink area and 113 soap samples from the shower area at health clubs, 65 from men's showers and 48 from women's showers. A total of 428 liquid soap samples from the sink area, 226 from men's restroom sink areas and

202 from women's restroom sink areas, were analyzed for this report. Samples with <500 CFU/mL were not considered since industry standards allow for this amount of bacteria in liquid soap. All samples were confirmed to be from open refillable systems.

The samples were collected in sterile 50 mL conical tubes and shipped to the laboratory on ice. 1 mL of DE neutralizing broth (Remel, Lenexa, KS) was added to each sample tube and shaken vigorously for 60 seconds. Heterotrophic plate counts (HPC) were obtained by the spread plate method on R2A media (Difco, Sparks, MD). Plates were incubated at 30°C for 5 days. Any sample showing bacterial content was reexamined for Coliform bacteria.

Coliform analysis and enumeration was performed using the spread plate method on mEndo agar (Difco, Sparks, MD) and incubated at 35°C for 24 hours. Bacterial colonies were counted and recorded, representatives of all colony types were subcultured to TSA plates (Difco, Sparks, MD) for oxidase tests and identification. TSA plates were incubated at 35°C for 24 hours. Identification of bacteria was obtained using API20E strips (BioMerieux, Marcy-l'Etoile, France). *S. aureus* analysis was performed by using the spread plate method on TSA amended with 5% Sheep Blood (BA) (Hardy Diagnostics, Phoenix, AZ) to check for hemolysis. Plates were incubated for 24-48 hours at 35°C. Beta hemolytic isolates were enumerated and streaked onto a TSA plate and incubated for 24 hours at 35°C. Isolated colonies underwent further confirmation testing utilizing catalase production, microscopic morphology, coagulase production (tube and slide tests) and antibiotic (polymyxin) sensitivity.

Results

Figure 1: Locations Containing HCP and Percent of HCPs that were Coliforms

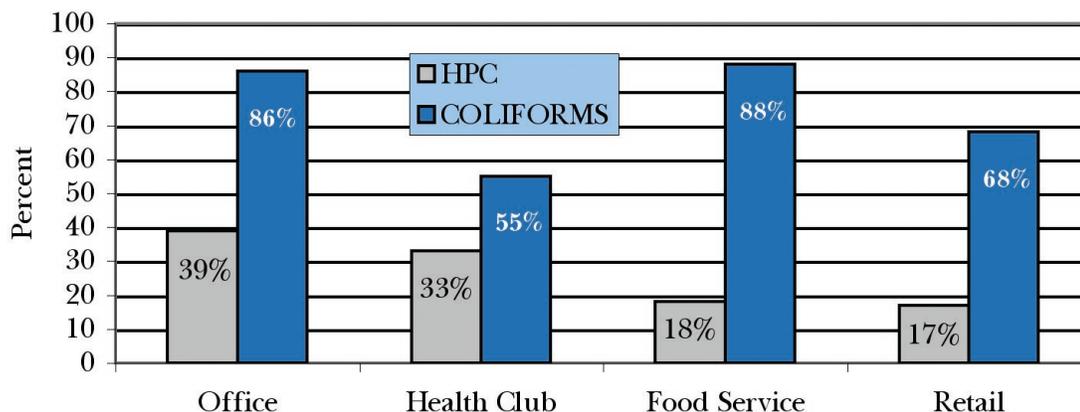


Figure 2: Frequency of Bacterial Species Isolated from Refillable Liquid Soap Dispensers

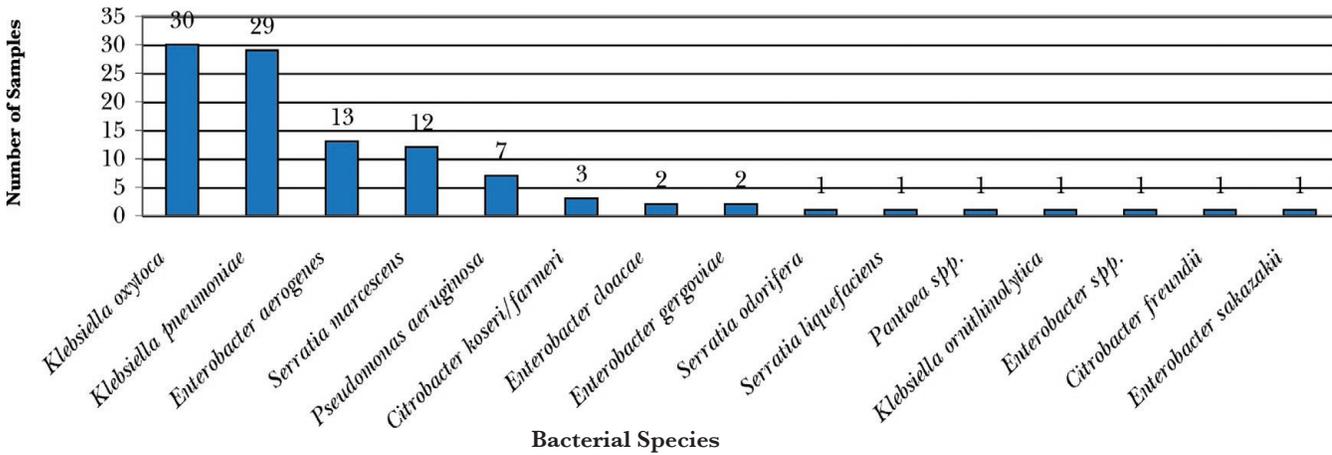


Figure 3:



Sealed System
0% Contaminated

Open Refillable Bulk Soap Dispenser Being Refilled
25% Contaminated

Table 1:

Total number of open refillable soap samples	Number of samples with bacteria	Number of samples with Coliforms
541	133 (25%)	87 (16%)

Summary

A total of 541 open refillable liquid soap samples were analyzed for bacteria, coliforms and *Staphylococcus aureus*. Of the 541 samples, 133 (25%) contained bacteria, 87 samples (16%) contained coliforms. The percent of bacteria isolated from open refillable liquid soap samples that were identified as coliforms was 65%. Heterotrophic bacterial numbers detected in the liquid soap samples ranged from 590 to 5.3×10^7 CFU/mL. The average number of bacteria found in one mL of soap was 3.02×10^6 CFU/mL. Coliform bacteria ranged from <10 to 6.5×10^7 CFU/mL, with an average of 3.94×10^6 per mL of soap. The frequency of contamination was similar for all cities tested, for both men and women’s restrooms and for both wall mounted and counter-mounted dispensers. *Klebsiella* was the most frequently isolated genus of bacteria, followed by *Enterobacter* and *Serratia*. No *Staphylococcus aureus* were detected in any of the liquid soap samples analyzed.

Conclusions

High levels of bacterial contamination (average 3.02×10^6 CFU/mL) were found in 25% of the liquid soap samples in this study. Previous reports found no contamination in soap from sealed systems (figure 3). Since these samples represent a diverse cross section of geographical locales and individual sites, it is concluded that refillable open, or “bulk”, liquid soap systems commonly found in the U.S. are routinely contaminated with bacteria. Many of the bacteria isolated are opportunistic pathogens which can cause a variety of health issues including respiratory infections, bloodstream infections, urinary tract infections and skin infections. The type and level of bacteria found in these systems represent a potential health risk to users, especially to any immunocompromised individuals.

Footnotes

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