
**Food and Drug Administration
Center for Food Safety and Applied Nutrition
September 1999**

Evaluation of Risks Related to Microbiological Contamination of Ready-to-eat Food by Food Preparation Workers and the Effectiveness of Interventions to Minimize Those Risks

**JACK GUZEWICH, RS, MPH
MARIANNE P. ROSS, DVM, MPH**

INTRODUCTION:

The Food and Drug Administration (FDA) publishes the Food Code which provides guidance on food safety, sanitation and fair dealing that can be uniformly adopted by jurisdictions for regulating the retail segment of the food industry. The model Food Code is the cumulative result of the efforts and recommendations of many contributing individuals, agencies, and organizations. Section 3-301.11 of the 1999 Food Code, entitled "Preventing Contamination from Hands" was added to the code in response to outbreaks of foodborne illness caused by food that had been contaminated with pathogens transmitted by food preparation workers. FDA believes that the considerable number of illnesses transmitted by food worker contamination of food demands rigorous intervention measures.

The following is a summary of current information from scientific literature or provided to FDA that evaluates the factors related to contamination of foods by food workers and the effectiveness of interventions to prevent or minimize contamination of ready-to-eat food by food workers. Three major intervention areas are addressed: exclusion of ill food workers from the workplace, removal of pathogens from the hands of food workers, and the use of barriers to prevent bare-hand contact with ready-to-eat foods. Information provided in this review includes all applicable submissions that were received in response to Federal Register Notice, Vol. 64, No. 63, Friday, April 2, 1999. On September 16, 1999, CDC released data on the [incidence of foodborne disease in the United States](#).

WHITE PAPER, SECTION ONE

A LITERATURE REVIEW PERTAINING TO FOODBORNE DISEASE

OUTBREAKS CAUSED BY FOOD WORKERS, 1975-1998.

**Jack Guzewich, RS, MPH
Marianne P. Ross, DVM, MPH**

ABSTRACT:

A search was conducted of the published scientific literature for the period 1975-1998 to identify articles that described outbreaks of foodborne disease that were believed to have resulted from contamination of food by food workers. A total of 72 articles that described 81 outbreaks involving 16 different pathogens were

identified.

Viral agents, specifically hepatitis A and Norwalk-like virus, accounted for 60% (49) of the outbreaks in this review. Ninety-three percent (75) of the outbreaks involved food workers who were ill either prior to or at the time of the outbreak, depending on the organism involved. In most of the remaining outbreaks, an asymptomatic food worker was believed to be the source of the infections. Eighty-nine percent of the outbreaks (72) occurred in food service establishments as compared to 11% (9) that were attributed to foods prepared in domestic settings. Sandwiches, salads, and miscellaneous hot food items that required extensive hand contact during preparation accounted for the majority of foods involved in the outbreaks. This review provides evidence that food workers, particularly ill food workers, can serve as the source of infection in foodborne outbreaks and that hand contact with foods represents a mode by which contamination may occur.

INTRODUCTION:

Outbreaks of foodborne disease are caused by foods that are contaminated intrinsically or that become contaminated during harvesting, processing, or preparation (Torok et al., 1997). It has been estimated that seven pathogens found in animal products (*E. coli* O157:H7, *Listeria monocytogenes*, *Campylobacter jejuni*, *Clostridium perfringens*, *Toxoplasma gondii*, *Salmonella* spp., and *Staphylococcus aureus*) account for approximately 3.3-12.3 million cases of illness and 3,900 deaths in the United States each year (Buzby & Roberts, 1997). The annual cost of these foodborne illnesses, which includes costs to individuals, industry, and the public health sector, is estimated to be \$6.5-\$35 billion (Buzby & Roberts, 1997).

Foodborne diseases are known to contribute to both human morbidity and mortality as well as to health care costs (Campbell et al., 1998). These costs include the expenses entailed in controlling the disease, medical treatment costs, business losses, and losses in productivity. A recent study estimated the total societal cost of one particular foodborne outbreak of hepatitis A to be \$809,706 (Dalton et al., 1996). This included the costs associated with the infected food worker believed to be the source case, 43 secondary cases, and the potential exposure to 5000 patrons. The study suggested that the cost of outbreaks due to food workers can in some instances far exceed the costs associated with outbreaks due to person-to-person transmission of infectious agents.

According to a report by the Centers for Disease Control and Prevention (CDC), hands may be the most important means by which enteric viruses are transmitted (LeBaron et al., 1990). Further, contamination of food by an infected food worker is the most common mode of transmission of hepatitis A in foodborne disease outbreaks. In these outbreaks, the vehicles involved have most often been foods that were not cooked or that were handled improperly after cooking (Centers for Disease Control, 1990, 39(14):228-32).

Food workers may transmit pathogens to food from a contaminated surface, from another food, or from hands contaminated with organisms from their gastrointestinal tract (British Medical Journal, 1990). Therefore, hand contact with ready-to-eat foods (defined as food that is edible without washing, cooking, or additional preparation by the consumer or by the food establishment and that is reasonably expected to be consumed in that manner -U.S. Public Health Service, 1999), represents a potentially important mechanism by which pathogens may enter the food supply.

During the five-year period from 1988-1992, 2,423 outbreaks of foodborne disease were reported to the CDC (Bean et al., 1996). Of these outbreaks, 1,435 had information reported concerning contributing factors. During this period, the two most commonly reported practices that contributed to foodborne disease were improper holding temperatures of foods and poor personal hygiene of food workers, reported in 59% and 36% of outbreaks, respectively. Delicatessens, cafeterias, and restaurants were the most common places where contaminated food was reportedly eaten (Bean et al., 1996). For the period 1983-1987, there were 2,397 outbreaks reported with 1,257 of these outbreaks reporting contributing factors (Bean et al., 1990). Improper

holding temperatures were reported in 63% of the outbreaks and poor personal hygiene were reported in 28% of the outbreaks.

In New York State during the period 1980-1993, among the outbreaks where contributing factors were reported, the most commonly reported contributing factor was contaminated ingredients (23%) (Guzewich, 1995). Inadequate refrigeration was reported 20% of the time and infected food workers were reported 17.6% of the time (Guzewich, 1995).

Enteric pathogens that are believed to be capable of being transmitted by food workers include, but are not limited to: *E. coli*, hepatitis A virus, *Salmonella* spp., *Shigella* spp., and *Clostridium perfringens* (Paulson, 1994; Restaino & Wind, 1990; Snyder, 1997). In addition, pathogens such as *Yersinia*, *Proteus*, *Campylobacter*, and *Klebsiella*, originating from raw animal products, can contaminate hands and then be transferred to foods, equipment, and other workers (Paulson, 1994; Restaino & Wind, 1990; Snyder, 1997). The purpose of this review was to search the published scientific literature for examples of foodborne disease outbreaks believed to have resulted from the introduction of pathogens by food workers.

METHODS:

We conducted a search of the published English-language scientific literature for the period 1975-1998 for articles that described foodborne disease outbreaks believed to have resulted from the introduction of pathogens into food by food workers. In order for an outbreak of foodborne disease to be classified as one resulting from the contamination of food by a food worker, we required that at least one of the following 2 criteria be presented convincingly in the published report. The first criteria: sufficient epidemiologic evidence was presented to link the food worker with the outbreak. Factors considered here included whether the putative time of the employee's contact with the implicated food was consistent with the incubation period for the illness experienced by those persons who ate the food; the strength of the association between the food(s) prepared by the employee and the illness that followed consumption of the food(s); the biologic plausibility of the food(s) serving as the vehicle; whether the cessation of contact of the food worker with the food(s) in question resulted in a reduction in illness; consistency of findings with previous reports; and, finally, the likelihood that alternative explanations could account for the illnesses. The second criteria: laboratory evidence implicating a food worker as the source of contamination had to include either the identification of the etiologic agent from an anatomical site of the food worker suggesting colonization or infection or, in the case of hepatitis A infection or Norwalk-like virus infection, serologic evidence had to suggest acute infection at the time of food preparation.

The following electronic databases were searched: PubMed, Grateful Med (MEDLINE), Educational Resources Information Centre (ERIC), Agriculture Online Access (Agricola), Food Science Technology Abstracts (FSTA), Biological Abstracts (BIOSIS PREVIEWS), and the Centers for Disease Control and Prevention (CDC) publication website. Keywords used for the search included terms such as 'foodborne disease', 'food handler', 'foodborne outbreak' and 'food preparer'. Outbreaks of foodborne disease that occurred in countries other than the United States and that met the above criteria were included to emphasize the global importance of sanitary food preparation practices.

Viruses of the Norwalk and Norwalk-like group are in the family of viruses known as Caliciviridae. For simplicity, we categorized all such viruses (such as Snow Mountain Agent and Small Round Structured Virus) as Norwalk-like viruses.

RESULTS:

Using the criteria described in the Methods, we identified a total of 72 articles for review. Several articles described more than one outbreak; consequently, a total of 81 foodborne outbreaks were incorporated in our

review.

In the 72 articles reviewed, 16 organisms were identified as the etiologic agents. Hepatitis A and Norwalk-like viruses were the most frequently reported organisms (Table 1).

Outbreaks ranged in size from five persons to 3,175 persons. A total of 14,712 persons were affected in these 81 outbreaks. Three percent (440) of the case-patients required hospitalization. Two case-patients died, both as a result of infection with *Salmonella enteritidis*. One of the fatalities was a 70-year old man who had had cardiac surgery while the other patient recently underwent a laparotomy.

Seventy-eight percent (63) of the outbreaks occurred in the United States, 11% (9) in the United Kingdom, and 4% (3) in Canada. One outbreak took place in Singapore (Goh et al., 1984) and one in Jordan (Khuri-Bulos et al., 1994). One outbreak occurred on a cruise ship sailing from the U.S. to the Bahamas (Dalton et al., 1996). Three outbreaks occurred on international flights: one originating in the U.S. (Hedberg et al., 1992), one originating in the U.K. (Burslem et al., 1990), and one originating in Tokyo (Centers for Disease Control, 1975). The two flights originating abroad had connections in the U.S. and one of these outbreaks was traced back to a food worker in the U.S.

Several large outbreaks where food workers were implicated were captured in our search. These include an outbreak of *Shigella sonnei* in 1991 that involved approximately 3,175 persons (Lee et al., 1991); an outbreak of Norwalk-like virus in 1984 in which approximately 3,000 persons became ill (Kurtisky et al., 1984); and an outbreak of *Salmonella enteritidis* in 1980 involving 866 persons (Burslem et al., 1990).

Specific food items were implicated as vehicles for transmission in 89% (72) of the outbreaks (Table 2). Sandwiches, salads, and miscellaneous hot food items, such as mashed potatoes and ham, accounted for the majority of foods involved in the outbreaks. In cases where multiple foods were implicated, these items were counted separately. Other foods implicated in outbreaks included baked goods, beverages, fruit salads, and miscellaneous cold foods such as aspic glaze (obtained from powdered gelatin, used to retain the fresh look of food products while extending shelf life), rice dressing, and canned salmon. Of the nine remaining outbreaks where a specific food item was not identified, five were hepatitis outbreaks that were associated with eating at the establishment where the food worker was ill with hepatitis A during the appropriate time frame. The remaining 4 outbreaks involved bacterial illnesses (2 *Salmonella typhi*, 1 *Salmonella enteritidis*, and 1 *Shigella sonnei*) where a food worker was ill with the outbreak bacteria just prior to the outbreak and acquisition of the illness was associated with eating at the establishment at times when the implicated food worker was on duty.

Eighty-two percent (66) of outbreaks provided sufficient epidemiologic and laboratory evidence to implicate a food worker as the source of infection; 17% (14) relied on epidemiologic evidence alone whereas for the remaining 1% (1) of outbreaks, laboratory findings alone contributed the evidence.

Ninety-three percent (75) of the outbreaks involved food workers who were infectious either prior to or at the time of the outbreak, depending on the organism (i.e., Norwalk-like virus is thought to be shed primarily at the time of symptoms whereas hepatitis A, with an incubation period of 15-50 days, had maximum infectivity during the latter half of the incubation period). In the remaining 6 outbreaks, 1 food preparer denied illness and refused testing, 1 food preparer was not clinically ill but was responsible for contaminating foods with hands after changing diapers, 4 articles provided insufficient information concerning laboratory testing and the implicated food workers denied illness.

The majority of the outbreaks associated with food workers involved transmission of the pathogen to food by the food worker's hands. In the description of the findings from the outbreak investigations, authors specifically listed hand contact as a factor in the transmission of the pathogen in 34 outbreaks (and

specifically mentioned that the food worker was not wearing gloves in 14 of these outbreaks) or implied that hand contact was a factor in the transmission of the pathogen by discussing one or more of the following factors in an additional 38 outbreaks: handwashing, poor personal hygiene, food workers "handling" ready-to-eat foods such as adding parsley to dishes, open sores on hands or arms, and food workers snacking on food. The remaining 9 outbreaks associated with food workers did not specifically mention how the food worker transmitted the organism to the food. In this latter group, all food workers were ill.

Four of the 72 articles specifically mentioned that food workers were wearing gloves; however, gloves were worn improperly (i.e., not worn consistently or not worn to cover lesions) or were not worn during food preparation and handling. Several scenarios by which food contamination occurred from bare-hand contact were described in the 72 articles. In an outbreak of Norwalk-like virus gastroenteritis that infected 67 persons, the food vehicle was food prepared by an asymptomatic food worker who reported recovering from mild gastrointestinal illness 48 hours prior to the outbreak. The worker used bare hands to slice meats and de-bone cooked chicken (Patterson, et al., 1993). Staff members involved in an outbreak of *Shigella sonnei* gastroenteritis in the week prior to an outdoor festival prepared cold ready-to-eat foods that led to an outbreak involving 3,175 persons. A few food preparers were still symptomatically ill with febrile diarrheal illness during food preparation for the festival. An uncooked tofu salad had been thoroughly mixed by hand by these staff members and there was limited access to proper handwashing facilities (Lee et al., 1991). Four employees of a hotel bar developed hepatitis A due to mixed drinks prepared by a bartender who was asymptomatic at the time he prepared the drinks; in addition to mixing drinks, he placed garnishes as well. This bartender reported experiencing cough, nausea, and vomiting 3 weeks prior to the outbreak and was subsequently diagnosed with hepatitis A infection (Kosatsky & Middaugh, 1986). A bakery worker experienced vomiting and diarrhea while preparing butter cream frosting. The employee prepared frosting by submerging his bare arm up to the elbow in the frosting as it was being mixed in order to scrape the sides of the vat. A subsequent outbreak of Norwalk-like virus infection involving 129 ill persons resulted from ingestion of frosted items that were contaminated by the suspected source case (Kurtisky et al., 1986).

In addition to the hands of food workers being a source of contamination of the implicated foods, other contributing factors were identified during the investigations. Inadequate food storage or other problems with preparation practices were described, including unsanitary food-contact surfaces, cross-contamination, and improper holding temperatures for foods. After contamination of foods by the hands of food workers, temperature abuse may have enhanced the growth and multiplication of bacteria in the implicated products.

DISCUSSION:

In our search of the published scientific literature for reports of foodborne disease believed to have resulted from contamination of food by food workers, we found more instances of disease caused by viral agents than bacterial agents. Specifically, hepatitis A and Norwalk-like viruses accounted for 60% (49) of all the outbreaks included in this review. During the 81 outbreaks, 14,712 persons were infected.

Ninety-three percent of these outbreaks involved food workers who were ill either prior to or at the time of the outbreak. Eighty-nine percent (72) of the outbreaks occurred at food service establishments, such as restaurants, cafeterias and catered functions as compared to 11% (9) of the outbreaks which were attributed to foods prepared in domestic settings. The majority of foods involved in the outbreaks included sandwiches, salads, and miscellaneous hot items. Foods such as sandwiches and salads often involve intensive hand contact during preparation and are not cooked prior to consumption. Contaminated hot foods suggest that hand contact occurred after cooking.

There were several limitations inherent in this review: first, the reports of foodborne disease outbreaks identified in the published literature represent only a small fraction of foodborne disease outbreaks and an even smaller fraction of all foodborne disease. The likelihood of an outbreak being brought to the attention of

health authorities depends on consumers' and physicians' awareness, interest and motivation to report the incident, and the surveillance activities of state and local health agencies. Diseases with short incubation periods are more likely to be recognized as foodborne disease outbreaks than those with longer incubation periods. Pathogens that cause mild illness may be underreported.

A second limitation of the review is that the studies included often differed in the extent to which the outbreaks of disease were investigated or reported. As a result, uniform data were not presented regarding the role of hand contact in all of the outbreaks. For example, some factors that make foodborne disease detection inherently difficult are the fact that foods are often not available for testing, food workers may refuse to submit stool or blood samples for analysis, and samples may not be collected until days or weeks have elapsed following contamination of the implicated food. Food consumption histories are often impracticable; therefore the link between illness and the consumption of contaminated food may not be ascertained.

Viral foodborne diseases are exceptionally challenging. Viruses have small infective doses and infection, especially of immunocompromised individuals, can occur with low-dose contamination (Stolle & Sperner, 1997). Virus excretion is of short duration, which may make diagnosis difficult. Because hepatitis A has a mean incubation period of 30 days, poor recall and recall bias can be substantial problems in investigations (Warburton et al., 1991). Foodborne outbreaks due to hepatitis A are most often caused by food contaminated during preparation by an infected food worker (Centers for Disease Control, 1993). Therefore, food workers in retail settings with acute hepatitis A infection constitute a great risk for consumers since one person has the potential to transmit the virus to a large number of people (Angelillo et al., 1996). Since thorough cooking inactivates hepatitis A virus, outbreaks almost always involve foods that are not cooked between contamination and consumption (Centers for Disease Control, 1983).

Because of the limitations described above, it is most likely that this review markedly under-represents the true number of foodborne outbreaks related to food workers. Additionally, one cannot establish from this review what the true role of hand contact of food by food workers is in the total burden of foodborne disease. Nevertheless, despite these limitations, several themes became apparent: first, numerous examples of foodborne disease outbreaks were identified in which hand contact of foods by food workers was believed to be the source of infection. Second, both viral agents as well as bacterial pathogens were involved, with parasitic agents being less common. Third, in addition to contamination of foods by food workers, a number of other substandard food practices were often involved. In sum, our review of the literature provides evidence that ill food workers can be the source of infection in foodborne outbreaks and that hands of food workers can transmit pathogenic organisms to foods. It has been suggested that food establishments that mass-produce cold, ready-to-eat food items should exclude ill workers from food preparation responsibilities and provide strict oversight of food preparation and handwashing practices (Hedberg et al., 1992). Exclusion of food handlers from duties for 48-72 hours after termination of diarrhea and vomiting may be adequate to prevent and control Norwalk-like virus outbreaks (Parashar et al., 1998).

Table 1:
Organisms identified in foodborne outbreaks, 1975-1998.

AGENT	# OUTBREAKS
Hepatitis A	28 (34.57%)
Norwalk-like virus	21 (25.93%)
Staphylococcus aureus	6 (7.41%)

Shigella sonnei	5 (6.17%)
Salmonella typhimurium	5 (6.17%)
Salmonella enteritidis	4 (4.94%)
Group A streptococcus	4 (4.94%)
Giardia	2 (2.47%)
Salmonella paratyphi	1 (1.23%)
Salmonella javiana	1 (1.23%)
Vibrio cholera	1 (1.23%)
Shigella flexneri	1 (1.23%)
Cryptosporidium parvum	1 (1.23%)
Yersinia enterocolitica	1 (1.23%)
	Total: 81 (100%)

Table 2:
Foods identified in foodborne outbreaks, 1975-1998.

FOOD ITEM(S) IMPLICATED	# OF TIMES THIS ITEM WAS IMPLICATED IN AN OUTBREAK
Hot food items such as mashed potatoes, ham and turkey	24
Cold salads	19
Cold sandwiches	16
Other cold foods such as canned salmon and rice dressing	9
Bakery goods such as glazed products	6
Beverages such as mixed drinks and ice	6

slush beverages	
Fruit including fruit salads	6
Combination of salad and sandwich	4

REFERENCES:

1. Al-Lahham AB, Abu-Saud M, Shehabi AA. Prevalence of *Salmonella*, *Shigella* and intestinal parasites in food handlers in Irbid, Jordan. J Diarrhoeal Dis Res 1990;8(4):160-62.
2. Angelillo IF, Nobile CGA, Talarico F, Pavia M. Prevalence of hepatitis A antibodies in food handlers in Italy. Infection 24 1996;2:147-50.
3. Bean NH, Griffin PM, Goulding JS, Ivey CB. Foodborne disease outbreaks, 5-year summary, 1983-1987. J Food Protect 1990;53(8):711-728.
4. I. Bean NH, Goulding JS, Lao C, Angulo FJ. Surveillance of foodborne-disease outbreaks-United States, 1988-1992. MMWR 1996; 45(SS-5):1-55.
5. II. Birkhead GS, Morse DL, Levine WC, Fudala JK, Kondracki SF, Chang H, et al. Typhoid fever at a resort hotel in New York: A large outbreak with an unusual vehicle. J Infect Dis 1993;167:1228-32.
6. III. Blaser MJ, Rafuse EM, Wells JG, Pollard RA, Feldman RA. An outbreak of salmonellosis involving multiple vehicles. Am J Epidemiol 1981;114(5):663-669.
7. Briley RT, Teel JH, Fowler JP. Investigation and control of a *Shigella sonnei* outbreak in a day care center. J Environ Health 1994;56(6): 23-25.
8. British Medical Journal 1990; 300:208. Food handlers and food poisoning.
9. Brockman RA, Lenaway DD, Humphrey CD. Norwalk-like viral gastroenteritis: A large outbreak on a university campus. J Environ Health 1995;57(10):19-22.
10. Brondum J, Spitalny KC, Vogt RL, Godlewski K, Madore HP, Dolin R. Snow Mountain agent associated with an outbreak of gastroenteritis in Vermont. J Infect Dis 1985;152(4):834-37.
11. Burslem CD, Kelly MJ, Preston FS. Food poisoning- A major threat to airline operations. J Soc Occup Med 1990;40:97-100.
12. Buzby JC, Roberts T. Economic costs and trade impacts of microbial foodborne illness. World Health Stat Quarterly 1997;50(1/2):57-66.
13. Campbell ME, Gardner CE, Dwyer JJ, Isaacs SM, Krueger PD, Ying JY. Effectiveness of public health interventions in food safety: a systematic review. Can J Public Health 1998; 89(3):197-202.
14. Campbell M, Sahai V, Vettoretti I, Northan A. *Shigella sonnei* outbreak in Mindemoya, Ontario. PHERO 1993;Feb 26:40-44.
15. Can Comm Dis Rep April 1998. Hepatitis A in restaurant clientele and staff-Quebec.
16. Centers for Disease Control, Foodborne hepatitis A- Alaska, Florida, North Carolina, Washington. MMWR 1990, 39(14):228-32.
17. Centers for Disease Control, Foodborne hepatitis A- Oklahoma, Texas. MMWR 1983;32(50):652-54, 659.
18. Centers for Disease Control, Foodborne outbreak of diarrheal illness associated with *Cryptosporidium parvum*-Minnesota, 1995. MMWR 1996;45(36):783-84.
19. XII. Centers for Disease Control, Foodborne hepatitis A-Missouri, Wisconsin, and Alaska, 1990-1992. MMWR 1993;42(27):526-29.
20. XIII. Centers for Disease Control, Outbreak of food-borne hepatitis A-New Jersey. MMWR 1982;31(12):150-2.
21. Centers for Disease Control, shigellosis in a children's hospital-Pennsylvania. MMWR 1979;Oct 26:498-99.

22. Centers for Disease Control, Typhoid fever-Michigan. MMWR 1982;31(40):544, 549-50.
23. Centers for Disease Control, Typhoid fever-Skagit County, Washington. MMWR 1990;39(42):749-51.
24. Centers for Disease Control, *Staphylococcal* food poisoning from turkey at a country club buffet-New Mexico. MMWR 1986;35(46):715-22.
25. Centers for Disease Control, staphylococcal food poisoning-West Virginia. MMWR 1980;Aug 1:367-69.
26. Centers for Disease Control, Epidemiologic notes and reports. Outbreak of staphylococcal food poisoning aboard an aircraft. MMWR 1975;24(7):57-9.
27. Centers for Disease Control, Epidemiologic notes and reports. Staphylococcal food poisoning-Colorado. MMWR 1977;Jan 28:22-3.
28. Centers for Disease Control, Staphylococcal Food Poisoning-Delaware. MMWR 1979;September 21:445-446.
29. Chaudhuri AKR, Cassie G, Silver M. Outbreak of food-borne type-A hepatitis in greater Glasgow. Lancet 1975;ii:223-25.
30. Dalton CB, Haddix A, Hoffman RE, Mast EE. The cost of a food-borne outbreak of hepatitis A in Denver, Colo. Arch Intern Med 1996;156:1013-16.
31. Decker MD, Lavelly GB, Hutcheson RH, Schaffner W. Food-borne streptococcal pharyngitis in a hospital pediatrics clinic. JAMA 1985;253:679-81.
32. Denes AE, Smith JL, Hindman SH, Fleissner ML, Judelsohn R, Engender SJ, et al. Foodborne hepatitis A infection: A report of two urban restaurant-associated outbreaks. Am J Epidemiol 1977;105(2):156-62
33. Dryden MS, Keyworth N, Gabb R, Stein K. Asymptomatic foodhandlers as the source of nosocomial salmonellosis. J Hosp Infect 1994;28:195-208.
34. Farley TA, Wilson SA, Mahoney F, Kelso KY, Johnson DR, Kaplan EL. Direct inoculation of food as the cause of an outbreak of Group A streptococcal pharyngitis. JID 1993;167:1232-5.
35. Fleissner ML, Herrman JE, Booth JW, Blacklow NR, Nowak NA. Role of Norwalk virus in two foodborne outbreaks of gastroenteritis: Definitive virus association. Am J Epidemiol 1989;129(1):165-72.
36. Francis S, Rowland J, Rattenbury K, Powell D, Rogers WN, Ward L, et al. An outbreak of paratyphoid fever in the UK associated with a fish-and-chip shop. Epidem Inf 1989;103:445-48.
37. Goh KT, Lam S, Kumarapathy S, Tan JL. A common source foodborne outbreak of cholera in Singapore. Int J Epidemiol 1984;13(2):210-15.
38. Griffin MR, Surowiec JJ, McCloskey DI, Capuano B, Pierzynski B, Quinn M, et al. Foodborne Norwalk virus. Am J Epidemiol 1982;115(2):178-84.
39. Gross TP, Conde JG, Gary GW, Harting D, Goeller D, Israel E. An outbreak of acute infectious nonbacterial gastroenteritis in a high school in Maryland. Public Health Reports 1989;104(2):164-69.
40. Guest C, Spitalny KC, Madore HP, Pray K, Dolin R, Hoffmann JE, et al. Foodborne Snow Mountain agent gastroenteritis in a school cafeteria. Pediatrics 1987;79:559-63.
41. Gustafson TL, Hutcheson RH, Fricker RS, Schaffner W. An outbreak of foodborne hepatitis A: The value of serologic testing and matched case-control analysis. Am J Public Health 1983;73:1199-1201.
42. Guzewich JJ. The anatomy of a "glove rule". Environ News Digest Fall 1995: 4-13.
43. Hanrahan JP, Zimmerman KL, Toly MH, Prowda RL, Grabau JC, Morse DL. An outbreak of hepatitis A linked to a food handler in a cafeteria. NY State J of Med 1984;84:10-13.
44. Hedberg CW, Levine WC, White KE, Carlson RH, Winsor DK, Cameron DN, et al. An international foodborne outbreak of shigellosis associated with a commercial airline. JAMA 1992;268(22):3208-12.
45. Hedberg CW, White KE, Johnson JA, Edmonson LM, Soler JT, Korlath JA, et al. An outbreak of *Salmonella enteritidis* infection at a fast-food restaurant: implications for foodhandler-associated transmission. J Infect Dis 1991;164:1135-40.
46. Herwaldt BL, Lew JF, Moe CL, Lewis DC, Humphrey CD, Monroe SS. Characterization of a variant strain of Norwalk virus from a food-borne outbreak of gastroenteritis on a cruise ship in Hawaii. J Clin

- Microbiol 1994;32(4):861-66.
47. Heun EM, Vogt RL, Hudson PJ, Parren S, Gary W. Risk factors for secondary transmission in households after a common-source outbreak of Norwalk gastroenteritis. *Am J Epidemiol* 1987;126(6):1181-86.
 48. Iverson AM, Gill M, Bartlett CLR. Two outbreaks of foodborne gastroenteritis caused by a small round structured virus: evidence of prolonged infectivity in a food handler. *Lancet* 1987;i.i.:556-58.
 49. Johnston MC, Arthur J, Campbell I, Foodhandling practices of Dunedin caterers: a cause for concern. *NZ Med J* 1992;105:289-91.
 50. Khuri-Bulos, NA, Khalaf MA, Shehabi A, Shami K. Foodhandler-associated *Salmonella* outbreak in a university hospital despite routine surveillance cultures of kitchen employees. *Infect Control Hosp Epidemiol* 1994;15:311-14.
 51. Kosatsky T, Middaugh JP. Linked outbreaks of hepatitis A in homosexual men and in food service patrons and employees. *West J Med* 1986;144:307-10.
 52. Kurtisky JN, Osterholm MT, Greenberg HB, Korlath JA, Godes JR, Hedberg CW, et al. Norwalk gastroenteritis: A community outbreak associated with bakery product consumption. *Ann Intern Med* 1984;100:519-21.
 53. Latham RH, Schable CA. Foodborne hepatitis A at a family reunion. Use of IgM-specific hepatitis A serologic testing. *Am J Epidemiol* 1982;115:640-5.
 54. LeBaron CW, Furutan NP, Lew JF, Allen JR, Gouvea V, Moe C, et al. Viral agents of gastroenteritis. *MMWR* 1990; 39(No. RR-5): 1-24.
 55. Lee LA, Ostroff SM, McGee HB, Johnson DR, Downes FP, Cameron DN. An outbreak of shigellosis at an outdoor music festival. *Am J Epidemiol* 1991; 133:608-15.
 56. Lee R, Peppe J, George H. Pulsed-field gel electrophoresis of genomic digests demonstrates linkages among food, food handlers, and patrons in a food-borne *Salmonella javiana* outbreak in Massachusetts. *J Clin Microbiol* 1998;36(1):284-5.
 57. Levy BS, Fontaine RE, Smith CA, Brinda J, Hirman G, Nelson DB, et al. A large food-borne outbreak of hepatitis A. Possible transmission via oropharyngeal secretions. *JAMA* 1975;234(3):289-94
 58. Lew JF, Swerdlow DL, Dance ME, Griffin PM, Bopp CA, Gillenwater MJ, et al. An outbreak of shigellosis aboard a cruise ship caused by a multiple-antibiotic-resistant strain of *Shigella flexneri*. *Am J Epidemiol* 1991;134(4):413-20.
 59. Lo SV, Connolly AM, Palmer SR, Wright D, Thomas PD, Joynson D. The role of the pre-symptomatic food handler in a common source outbreak of food-borne SRSV gastroenteritis in a group of hospitals. *Epidemiol Infect* 1994;113:513-521.
 60. Lossos IS, Felenstein I, Breuer R, Engelhard D. Food-borne outbreak of Group A -hemolytic streptococcal pharyngitis. *Arch Intern Med* 1992;152:853-5.
 61. Lowry PW, Levine R, Stroup DF, Gunn RA, Wilder MH, Konigsberg C. Hepatitis A outbreak on a floating restaurant in Florida, 1986. *Am J Epidemiol* 1989;129(1):155-64.
 62. Martin TA, Hoff GL, Gibson V, Biery RM. Foodborne streptococcal pharyngitis Kansas City, Missouri. *Am J Epidemiol* 1985;122(4):706-9.
 63. Meehan PJ, Atkeson T, Kepner DE, Melton M. A foodborne outbreak of gastroenteritis involving two different pathogens. *Am J Epidemiol* 1992;136:611-16.
 64. Meyers JD, Romm FJ, Tihen WS, Bryan JA. Food-borne hepatitis A in a general hospital. Epidemiologic study of an outbreak attributed to sandwiches. *JAMA* 1975;231:1049-53.
 65. Morse DL, Shayegani M, Gallo RJ. Epidemiologic investigation of a *Yersinia camp* outbreak linked to a food handler. *AJPH* 1984;74(6):589-92.
 66. Nelson M, Wright TL, Case MA, Martin DR, Glass RI, Sangal SP. A protracted outbreak of foodborne viral gastroenteritis caused by Norwalk or Norwalk-like agent. *J Environ Health* 1992; 54(5):50-55.
 67. Osterholm MT, Forfang JC, Ristinen TL, Dean AG, Washburn JW, Godes JR. An outbreak of foodborne giardiasis. *N Engl J Med* 1981;304(1):24-28.
 68. Parashar UD, Dow L, Frankhauser RL, Humphrey CD, Miller J, Ando T et al. An outbreak of viral

- gastroenteritis associated with consumption of sandwiches: implications for the control of transmission by food handlers. *Epidemiol Infect.* 1998;121:615-621.
69. Patterson T, Hutchings P, Palmer S. Outbreak of SRSV gastroenteritis at an international conference traced to food handled by a post-symptomatic caterer. *Epidemiol Infect* 1993;111:157-62.
 70. Paulson DS. A comparative evaluation of different hand cleansers. *Dairy Food Environ Sanit* 1994; 14:524-28.
 71. Pether JVS, Caul EO. An outbreak of food-borne gastroenteritis in two hospitals associated with a Norwalk-like virus. *J Hyg Camb* 1983;9:343-50.
 72. Reid JA, White DG, Caul EO, Palmer SR. Role of infected food handler in hotel outbreak of Norwalk-like viral gastroenteritis: implications for control. *Lancet* 1988;i.i.:321-323.
 73. Restaino L, Wind CE. Antimicrobial effectiveness of handwashing for food establishments. *Dairy Food Environ Sanit* 1990; 10:136-41.
 74. Riordan T, Craske J, roberts JL, Curry A. Food borne infection by a Norwalk like virus (small round structured virus). *J Clin Pathol* 1984;37:817-20.
 75. Rubertone MV, DeFraitres RF. An outbreak of hepatitis A during military field training exercise. *Mil Med* 1993;158:37-41.
 76. Sekla L, Stackiw W, Dzogan S, Sargeant D. Foodborne gastroenteritis due to Norwalk virus in a Winepeg hotel. *CMAJ* 1989;140:1461-64.
 77. Snyder OP. A "safe hands" hand wash program for retail food operations. St. Paul, MN: Hospitality Institute of Technology and Management; 1997.
 78. Snyderman DR, Dienstag JL, Stedt B, Brink EW, Ryan DM, Fawaz KA. Use of IgM-hepatitis A antibody testing. *JAMA* 1981;245(8):827-30.
 79. Stolle A, Sperner B. Viral infections transmitted by food of animal origin: the present situation in the European Union. *Arch Virol* 1997;13-suppl:219-28.
 80. Taylor JP, Shandera WX, Betz TG, Schraitle K, Chaffee L, Lopez L, et al. Typhoid fever in San Antonio, Texas: An outbreak traced to a continuing source. *J Infect Dis* 1984;149(4):553-57.
 81. Tebbutt GM. Development of standardized inspections in restaurants using visual assessments and microbiological sampling to quantify the risks. *Epidemiol Infect* 1991; 107:393-404.
 82. Torok TJ, Tauze RV, Wise RP, Livengood JR, Sokolow R, Mauvais S, et al. A large community outbreak of *Salmonellosis* caused by intentional contamination of restaurant salad bars. *JAMA* 1997; 278(5):389-95.
 83. United States Public Health Service, Food and Drug Administration, Food Code, 1999. Springfield, VA.: National Technology Information Service. Chapter 3: 43.
 84. Warburton ARE, Wreghitt TG, Rampling A, Buttery R, Ward KR, Perry KR, et al. Hepatitis A outbreak involving bread. *Epidemiol Infect* 1991;106:199-202.
 85. Weltman AC, Bennett NM, Ackman DA, Misage JH, Campana JJ, Fine LS, et al. An outbreak of hepatitis A associated with a bakery, New York, 1994: The 1968 'West Branch, Michigan' outbreak repeated. *Epidemiol Infect* 1996;117:333-41.
 86. White KE, Osterholm MT, Mariotti JA, Korlath JA, Lawrence DH, Ristinen TL, et al. A foodborne outbreak of Norwalk virus gastroenteritis. *Am J Epidemiol* 1986;124(1):120-6.
 87. White KE, Hedberg CW, Edmonson LM, Jones DBW, Osterholm MT, MacDonald KL. An outbreak of giardiasis in a nursing home with evidence for multiple modes of transmission. *J Infect Dis* 1989;160(2):298-304.

WHITE PAPER, SECTION TWO

INTERVENTIONS TO PREVENT OR MINIMIZE RISKS ASSOCIATED WITH BARE-HAND CONTACT WITH READY-TO-EAT FOODS.

Jack Guzewich, RS, MPH

Marianne P. Ross, DVM, MPH

INTRODUCTION:

In the food industry, contamination from microorganisms can be responsible for infectious disease outbreaks passed from food employees to consumers via food (Paulson, April 1996). In a report by the Hospitality Institute of Technology and Management (Docket C-3), it was stated that, "due to lack of adequate handwashing by employees who prepare, process, and handle food in a retail setting, the potential for foodborne illness of fecal-oral nature continues to be problematic". The origins of microbial contaminants in food service facilities include the environment, the food worker, the source of the food, and the food itself (Docket C-8). Food may also be contaminated by food employees via exposure to raw animal products during processing (Paulson, 1994; Coates, et al. 1987; Docket C-8). The number of pathogenic cells on a food employee's hands is presumed to be directly related to the probability of transfer of microorganisms from hands to cooked food products (Restaino and Wind, 1990). It has been stated that handling cooked products with bare hands is one of the major hazards of cooked foods (Bryan, 1995).

This review will address the many different interventions that can be used to minimize or eliminate the contamination of ready-to-eat foods by food workers. Two major areas have been presented in this section: removal of pathogens from the hands of food workers, and barriers to bare-hand contact with ready-to-eat foods.

METHODS:

The information presented here is the result of a literature search of the past five years on PubMed by using keywords 'handwashing', 'hand washing', and 'handwash products'. Other reference items included in this document were submitted to the FDA before and during the development of this paper, and in response to a Federal Register Notice. The information presented in this paper forms the basis for current opinion and judgements made on these topics. Value judgements were not made concerning the quality of the data or the methods used to generate the data.

REMOVAL OF PATHOGENS:

Background and Definitions:

Handwashing is the removal of soil and transient microorganisms from the hands (Larson, 1995). Hand antisepsis is the removal or destruction of transient microorganisms (Larson, 1995). Degerming, or hygienic hand disinfection, refers to the reduction of predominantly transient microorganisms with the use of germicidal agents or antiseptic detergent formulations (Sheena and Stiles, 1982; Ayliffe et al., 1987; Nicoletti et al., 1990). Hygienic hand disinfection is also called healthcare personnel wash, which is a term that describes the washing of hands by food employees and healthcare personnel in order to eliminate transient microorganisms. (Bartzokas et al., 1987; Sattar and Springthorpe, Cambridge Univ Press, 1996). Plain or nonantimicrobial, nonantiseptic soaps are detergent-based cleansers that have no bactericidal activity and, by mechanical action, are used for physical removal of dirt (Larson, 1995). Antimicrobial or antiseptic soaps, on the other hand, contain ingredients with *in vitro* and *in vivo* activity against microorganisms on the skin (Larson, 1995). Antimicrobial soaps are considered drugs and are regulated by the Food and Drug Administration since they are intended to inhibit or kill certain skin flora.

Microflora of skin are categorized into two types: resident and transient. Resident bacteria are those organisms that normally reside on the skin, in this case, the skin of the hands. Ninety percent of resident flora of the hands are coryneform and coagulase negative staphylococci (Miller, 1994). Among the resident microflora, *Staphylococcus aureus* is the only true pathogenic organism of food safety concern (Docket

C-3; Miller, 1994; Lowbury et al., 1964). Resident flora are not easily removed by mechanical friction (Docket C-3; Larson, 1995) since they are buried deep within the pores where they are protected by sebaceous gland secretions (Restaino and Wind, 1990; Miller, 1994). The variety of resident organisms is significantly less than the kinds of microorganisms that can serve as transient organisms (Restaino and Wind, 1990).

Transient organisms are of concern because they are readily transmitted by hands unless removed by the mechanical friction of washing with soap and water, or destroyed by the use of an antiseptic solution (Larson, 1995). Transient organisms can be considered skin contaminants that are acquired from environmental sources and become attached to the outer epidermal skin layer (Docket C-3; Restaino and Wind, 1990).

Hands, as well as contaminated gloves, serve as vectors for transmission of transient microorganisms (Fendler et al., Part I, 1998; Docket RPT-1). According to Miller (1994), transient bacteria cause great concern to the food service industry because these organisms are loosely attached to the surface of the skin and can easily contaminate food products if employees do not wash their hands adequately.

Hands, arms and fingers of food employees may become contaminated with fecal microorganisms after using the toilet. These organisms include salmonellae, *E. coli*, *Staphylococcus aureus* (Snelling, 1991), *Clostridium perfringens*, shigellae, and hepatitis A virus (Docket C-3; Restaino and Wind, 1990). Organisms from animal sources such as *Yersinia*, *Proteus*, *Campylobacter*, and *Klebsiella*, can be transmitted to hands and thus transferred to foods, equipment, and other workers (Paulson, 1994).

Transfer of Organisms:

Hand transfer can be a significant mode of transmission of bacteria and viruses from person to person, from person to surface or vice-versa, and from person to food (Docket C-8). Touch-contact-associated bacterial transfer is facilitated by wet hands as compared to dry hands (Docket C-8). Transfer of organisms and viruses occurs less frequently when the contaminated material or hands are dry (Larson, 1985; Ansari et al., 1988). Residual moisture on hands after handwashing has been found to play an important role in the transfer of bacteria and viruses (Springthorpe and Sattar, 1998). The longer the duration of hand drying, the fewer bacteria were transferred to other surfaces (Springthorpe and Sattar, 1998).

Viral Transfer:

Frequent and thorough handwashing has been found to help prevent and control the transfer of viruses and other infections from food employees in field settings (Sattar and Springthorpe, Cambridge Univ Press, 1996). However, handwashing agents vary in their ability to eliminate viruses on hands; they tend to eliminate bacteria more effectively than they do viruses (Sattar and Springthorpe, Cambridge Univ Press 1996). Non-enveloped viruses, such as rotavirus, calicivirus and hepatitis A virus, survive better on skin than enveloped ones, such as herpes virus and influenza virus (Sattar and Springthorpe, Infect Control & Sterilization Technique, 1996; Joklik, 1988). Most of the *in vivo* evaluations of handwashing products have been conducted with bacteria; whereas, very few published reports evaluate the agents against viruses.

Rotaviruses are transmitted by the fecal/oral route and usually cause gastroenteritis in infants and small children. They can also be problematic for the elderly and immunocompromised individuals. Caretakers of infants must practice proper handwashing techniques after changing diapers. Rotaviruses survive for long periods in contaminated water, on hard surfaces, and on hands (Benenson, 1995). Rotaviruses are capable of surviving on human hands for up to 4 hours (Sattar and Springthorpe, Infect Control & Sterilization Tech, 1996; Ansari et al., 1989; Sattar et al., 1994) and can be readily transferred between hands and inanimate objects (Ansari et al., 1989).

Infectious rotavirus on hands can be readily transferred to other surfaces and vice versa. The amount of virus transferred is related to the duration of contact and the amount of pressure applied during contact (Sattar and

Springthorpe, Infect Control & Steriliz Tech, 1996). Contamination can occur from the preparation of various types of foods by persons with rotavirus-contaminated hands (Ansari et al., Rev Infect Dis, 1991). Lack of data on the role of foods as a vehicle may be due to investigation insufficiencies following foodborne outbreaks of gastroenteritis rather than the inability of rotaviruses to be distributed via food (Ansari et al., Rev Infect Dis, 1991).

In a study by Ansari et al. (1988), hands contaminated with rotavirus were then allowed to dry for 20 or 60 minutes and then touched to clean metal surfaces and vice versa, for 10 seconds at a pressure of 1 kg/cm². Virus transfer from hands to surfaces and from surfaces to hands was similar. After 20 minutes the mean percent of transfer ranged from 16.1-16.8%. At 60 minutes, the mean percent of transfer was 1.6-1.8%. Transfer from contaminated hands to clean hands was 6.6% at 20 minutes and 2.8% at 60 minutes. The author concluded that virus transfer after 20 minutes was quite high compared to that at 60 minutes. This suggests that the inocula were not completely dry after 20 minutes. The author concludes that hands may play a vehicular role in the transfer of rotavirus. Repeated experiments did not show detectable human parainfluenza virus transfer from fingers to inanimate objects when using pressure of 1 kg/cm² for 5 seconds, although the virus could be transferred from inanimate objects to fingers (Ansari et al., J Clin Microbiol, 1991).

Hepatitis A virus survives well on environmental surfaces and on human hands for up to 7 hours (Sattar and Springthorpe, Infec Control & Steriliz Tech, 1996), can be easily transferred to and from hands and surfaces, and is resistant to many disinfectants used in food establishments (Mbithi et al., 1993). In a study of 10 handwashing agents (Alcare, Aquares, Bacti-stat soap, Dettol, Ethanol 70%, Savlon, Scrub Stat IV, Septisol soap, Triclosan hand soap), alcohol solutions were effective in preventing the transfer of hepatitis A virus from washed hands to metal surfaces (Mbithi et al., 1993).

In a study by Bardell (1995), it was found that the presence of Herpes Simplex Virus-1 (HSV-1) on gloved hands led to the contamination of lettuce and ham. This might not be expected with virus in a dry state that was adhering to the fingertips. Since the transfer of HSV-1 to the foods occurred when the virus inoculum was dry and the surfaces of the foods were moist, the moist surface of the foods apparently enhanced viral transfer.

Bacterial Transfer:

According to a study by Scott and Bloomfield (1990), if surfaces are contaminated with low numbers of organisms (120 organisms/cm²) such as *E. coli*, *Salmonella*, and *S. aureus*, contact with fingers can transfer organisms in sufficient numbers to pose a potential infection hazard. The ability to transfer staphylococci to cooked potatoes during handling, peeling, cutting and garnishing has been recognized (Bryan, 1995).

Listeria spp. Have been found to survive on the fingertips for over 11 hours, thus food may be contaminated with *Listeria* via the fingers of food employees (Snelling et al, 1991). Since *L. monocytogenes* has a long survival time, this may have serious implications for food processing establishments (Snelling et al, 1991). Chlorhexidine gluconate in alcohol was found to be effective in reducing *Listeria* from fingertips (Snelling et al, 1991).

Cooked foods are vulnerable if touched by *Salmonella*-contaminated fingers that have been contaminated by low numbers of the bacteria (Pether and Gilbert, 1971). *Salmonella* spp., as well as *E. coli*, can be transferred between hands, raw foods, and cooked or processed foods (Pether and Gilbert, 1971). In a study by Pether and Gilbert (1971), it was found that washing with soap and water, followed by drying with paper towels, reduces transient carriage of *Salmonella* spp. on hands unless the bacterial contamination is very high. This study showed that standard handwashing techniques did not remove inocula of 10⁶ organisms but did remove some

organisms with inocula of 10^3 - 10^4 . All Salmonella organisms were removed after handwashing with inocula below 10^3 .

Transmission via hands contaminated with *Campylobacter* can be a major route of infection. Transmission to hands may take place through cross-contamination of foods and utensils when food workers process raw foods (Coates et al., 1987). In a study by Coates et al. (1987), *Campylobacter* spp. were effectively removed by handwashing with either soap and water or water alone, followed by drying with paper towels, yet the organism existed on wet hands. *Campylobacter* was also eliminated by 70% isopropyl alcohol. This study demonstrates the importance of hand drying to reduce the incidence of sporadic *Campylobacter* infections.

Parasite Transfer:

The literature search produced only one article that briefly mentioned parasitic infections. Detergent and soap products can inactivate parasites, such as lice and pinworms. The ova are more resistant but can be easily removed by mechanical action of handwashing (Borgatta, 1989).

Handwash Technique:

According to Springthorpe and Sattar (1998), proper hand hygiene requires three components: a proper protocol, an appropriate handwashing/cleansing agent, and compliance. Fingers are thought to be the most important part of the hand in terms of the transfer and spread of pathogenic microflora (Ansari et al., J Clin Microbol, 1991). An evaluation of handwashing techniques reveals many different schools of thought. Discrepancy in duration of the procedure, type of product used, and temperature and pressure of the water are just a few of the variations presented in the literature.

Quantity of soap varied from study to study. It was found that 3-5 ml. was sufficient (Larson, 1987; Ayliffe, 1988) when using antiseptic soap. Larson states that there is no advantage of using more than 1 ml. when using nonantiseptic soap (Larson, 1987).

The methods and duration of handwashing were variable among the many articles reviewed. A range of 5-30 seconds was noted (Paulson, 1994; Nicoletti et al, 1990; Miller, 1994; Butz et al, 1990; Larson, 1987; Larson et al, 1989; Paulson, 1992; Namura et al., 1994, Docket C13). Duration of handwashing is important for mechanical action as well as to allow sufficient contact time with antimicrobial products (Larson, 1995). Increased friction by rubbing hands together or using a scrub brush allows for greater reduction of transient bacteria even with the use of plain soaps or detergents (Restaino and Wind, 1990; Docket C-3).

Butz, et al. (1990) performed a comparative study of the immediate antimicrobial effectiveness of four handwash products for health care personnel. Immediate effectiveness was determined by sampling hands immediately after handwash compared with samples taken prior to handwash. In this study, they adapted the handwashing protocol set forth by the American Society for Testing and Materials (ASTM). The ASTM protocol is as follows: wet hands under warm water (100 -108 F); apply 3 ml. handwash product; rub vigorously over all hand surfaces, concentrating on interdigital spaces and nailbeds; apply a small amount of water and lather for 15 seconds; rinse for 30 seconds; dry with a clean paper towel. The 1986 CDC Guidelines for Hand Washing and Hospital Environmental Control recommended that, for routine handwashing, plain soap can be used with a vigorous rubbing of all surfaces of lathered hands for at least 10 seconds, followed by thorough rinsing under a stream of water (Docket C-3). The American Society for Microbiology (ASM) recommends vigorous scrubbing for 10-15 seconds and the Association for Professionals in Infection Control and Epidemiology (APIC) recommends 15-20 seconds of vigorous hand washing (Docket C-13). In a study by Ojajarvi (1979), it was found that a handwash of 2 minutes' duration removed only 3% more transient microorganisms than did a 15-second wash (Docket C-13).

Handwashing with warm water is thought to exacerbate the damage done to the skin's barrier function (Springthorpe and Sattar, 1998). However, it has been suggested that warm water (110° F-120° F) at a water flow of 2 gallons/minute is sufficient to wash off the pathogens that have been loosened by handwashing with plain soap or detergents (Docket C-3). The activation energy of antimicrobial agents is easier to achieve at higher temperatures, thus surfactants and other antimicrobial components in handwashes work more efficiently (Docket C-13).

In a study of handwashing at various water temperatures, a significant difference in resident microflora removal was seen between washing and rinsing with 70° F and 120° F water (Docket C-8). There were no resident microflora removed at 40 F, despite the use of soap and manual handwashing. Washing and rinsing with warm water brings resident flora from deep skin layers to the surface where they are removed with washing or drying (Docket C-8). Since transient microorganisms are not normally located in deep skin layers and are more easily removed by routine handwashing, water temperature may not play a role in the removal of these organisms from the skin (Docket C-8). In any case, water temperatures must be within a comfortable range to the user in order to be effective and practical.

Numbers of organisms decrease as the duration of handwashing increases but this occurs only to a certain point. Chamberlain et al. (1997) demonstrated increased bacterial counts of both naturally-occurring and artificially-inoculated organisms after a 3-minute handwash as compared to a 10-second regimen. Mean bacterial counts for unwashed hands was significantly greater ($p=0.04$) than for hands washed for 10 seconds. Mean data for hands washed at 3 minutes was not significantly different from unwashed hands ($p=.30$). Mean data for hands washed at 3 minutes was also not significantly different from hands washed for 10 seconds ($p=.22$) (Chamberlain et al., 1997). Washing for 10 seconds removes transient bacteria from hands and results in decreased recovered organisms. Washing for 3 minutes removes transient bacteria but brings residual flora to the surface, thus increasing recovered organisms from hands.

Very high frequency (>25 times/day) of handwashing shows increased skin irritation (Bartzokas et al., 1987) and increased bacterial counts, possibly due to the defatting of skin, which has been shown to increase the survival of *Staphylococcus aureus* on hands (Larson, 1985). Excessive handwashing can interrupt the skin's normal protective barrier function by cracking or damaging the skin, altering the skin's pH, removing skin lipids, decreasing moisture, or changing its normal flora (Larson, 1995; Springthorpe and Sattar, 1998; Larson, 1985; Larson et al., 1989; Borgatta, 1989). As handwashing frequency, duration and aggressiveness increases, damage to the stratum corneum layer can cause dry skin, chapping, pain, cracking and fissures. Dry skin then causes increased shedding of both skin cells and skin microflora (Docket C-8).

One study found that a double handwash of 15 seconds provided a 20% greater reduction in resident bacteria than a single wash; whereas, the second wash provided 0.25%-2.25% greater reduction in transient organisms (Docket C-13). Transient organisms, rather than resident microorganisms, and cross contamination via hands are of greatest concern in food establishments.

In a study by Stiles and Sheena (1987) in a meat processing plant, levels of hand contamination varied between work stations. For workers in the kitchen and packaging areas, no differences in reduction of bacteria could be noted among handwash agents. Transient bacteria were found after handwashing during in-use operations, indicating that handwash techniques were not effective. However, the visible contamination of hands in the meat cutting areas may have prompted these workers to perform a more extensive handwash, which then resulted in significant differences in reduction of bacterial counts.

Rings and Fingernails:

In a hospital study by Jacobson et al., a one-minute wash with Ivory soap and a surgical scrub brush, followed by a one-minute rinse, was used to determine bacterial counts on subjects with rings versus those without

rings (1985). It was found that, although wearing rings increased the number of microbes found on the skin, thorough handwashing produced no statistically significant difference in bacterial counts for subjects with rings as compared to subjects without rings (Jacobson et al., 1985). In another study in the healthcare setting, a 10-second handwash and 10-second rinse were used to demonstrate differences in microbial counts in subjects with and without rings (Salisbury, 1998). The authors concluded that there was a greater reduction in microbial counts after handwashing for those persons without rings (Salisbury, 1998). This effect was more apparent when the initial microbial load was greater than 1000 cfu/ml before handwashing. One article from the healthcare setting determined that nurses with artificial nails concealed greater numbers of gram-negative rods before and after handwashing as compared to nurses without artificial nails (Pottinger et al., 1989). The authors suggested that a 10-second handwash alone may be inadequate to prevent bacterial shedding.

Rings and jewelry are thought to harbor food debris, microbial contaminants, food allergens, and caustic sanitizers or disinfectants; all of these items may be irritating and react with ring metals, which may result in decreased or inadequate handwashing (Docket C-8).

Methods of Evaluation:

This literature search provided studies on various handwash products. However, it should be noted that no standard, approved method exists to evaluate and analyze handwash products. Methods used to analyze products vary in relation to: setting, technique and duration of handwash, number of handwashes, water temperature and pressure, use of a prewash, amount and type of product tested, *in vivo* versus *in vitro* studies, microbiological analysis, and microorganisms used for testing purposes. This makes it difficult to compare the various products. The proposed Healthcare Continuum Model addresses the need for a uniform means of evaluation and classification of topical antimicrobial formulations (Jones, 1998). For the category of food employee handwash products, this model suggests specific *in vitro* and *in vivo* testing methods for efficacy, performance, and use pattern. An approach to testing the efficacy of food employee handwash products, based on the Healthcare Personnel Handwash Evaluation, has recently been developed (Docket RPT-1). Paulson believes that topical antimicrobial handwash products used for healthcare personnel are chemically and antimicrobially similar to those used in food service; however, food service products should also effectively remove the organic load of food ingredients and fat (Docket RPT-1).

There are currently no chemicals or formulations capable of reducing virus infectivity by at least 99%, which is the standard measure of effectiveness of chemical disinfectants. To date, there is no such criterion for the efficacy of *in vivo* testing of antiseptics for viruses (Sattar and Springthorpe, Cambridge Univ Press 1996; Sattar and Springthorpe, Infect Control & Steriliz Technique, 1996).

Handwash Products:

1. Soaps and Detergents:

Different conclusions have been drawn concerning the effectiveness of plain soaps. Handwashing with plain detergent soap and water can physically remove microbes, but antiseptic agents are necessary to kill or inhibit microorganisms (Larson, 1995; Ehrenkranz, 1992). Plain soap is used primarily in the mechanical removal of transient microorganisms whereas antimicrobial products are used for the mechanical removal and killing or inhibition of both resident and transient flora (Larson, 1995). Handwashing with plain soap should be sufficient to remove transient microflora from the hands of food service employees (Docket C-3; Paulson, 1994). However, antimicrobial soap is statistically more effective in both immediate and residual properties (Paulson, 1994). One study demonstrated that plain soap was as effective as alcohol or chlorhexidine, but only in terms of activity against Gram-negative bacilli (Ayliffe et al., 1987). It is unclear if plain soaps are more effective than antimicrobial soaps, since there is literature to support both types of products. However, the review of the literature seems to indicate that plain soaps are effective for the physical removal of transient

organisms and that antimicrobial products are needed for the inhibition of transient and resident flora. Apparent increases in bacterial counts associated with sanitizers as well as handwashing alone may be due to methodology accuracy and precision, inherent variability in individual dermal parameters, and data scatter due to insufficient controls (Docket C-13). When handwashing frequency is low (<6 washes per day), there is less advantage of using antimicrobial soaps compared to nonantimicrobial soaps (Larson et al., 1989). Antimicrobial soaps are recommended at higher frequency handwashes when long-term reduction in colonizing microflora is needed (Larson et al., 1989).

Debate has ensued concerning the presence of bacteria on bar soaps. Bar soaps were found to have higher bacterial cultures after use than liquid soaps (McBride, 1984) but several studies found that the bacteria were not transferred to hands on subsequent use (Heinze, 1985; Bannan and Judge, 1965; Heinze and Yackovich, 1988).

2. Chlorhexidine

Chlorhexidine gluconate (CHG) was found to be an effective product in terms of residual effects against bacteria (Docket C-3; Larson, 1995; Bartzokas, et al., 1987; Ayliffe et al., 1988). Bartzokas et al. (1987) found that CHG had a residual efficacy of log₁₀ reduction factor of 4.15. Chlorhexidine gluconate was found to be effective against nosocomial infections (Sheena and Stiles, 1982; Doebbeling et al., 1992; Aly and Maibach, 1979) and fungi (Nicoletti et al., 1990; Namura et al., 1994; Stiles and Sheena, 1985; Larson et al., 1986), although it is not effective against viruses (Mbithi et al., 1993; Sheena and Stiles, 1983). A study by Stiles and Sheena (1985) found that 4% CHG had a 99% reduction in transient organisms. Aly and Maibach (1979) determined that 4% CHG had immediate activity (85% reduction) and residual activity (98.2% reduction) of resident bacteria. In a study by Ayliffe et al. (1988), it was found that CHG had a log₁₀ reduction factor of 4.92. Therefore, CHG was more effective in terms of residual activity than 7 other products tested. A test configuration using 0.75% CHG formulation demonstrated a 3 log₁₀ difference between the treatment group and a control group (untreated) at the immediate and one hour sample (Docket RPT1). Recovery populations for the group using 0.75% CHG were 4.45 log₁₀ for the immediate sample and 3.37 log₁₀ for the 1-hour sample. Recovery populations for the untreated group were 7.49 log₁₀ for the immediate sample and 6.16 log for the 1-hour sample. In this study, CHG demonstrated statistically significant immediate and persistent antimicrobial activity (Docket RPT1).

3. Alcohols

Alcohol was the most immediately effective product against bacteria but had limited residual activity (Docket C-3; Paulson, 1994; Coates et al., 1987; Larson, 1995; Butz et al., 1990; Ayliffe et al., 1988; Aly and Maibach, 1979; Larson et al., 1986; Paulson, 1994; Ly et al., 1997). Alcohols and formulations containing 70% alcohols were most effective in reducing the numbers of *E. coli* and rotavirus (Ansari et al., 1989). In contrast, they were not as effective against viruses such as hepatitis A (Mbithi et al., 1993). Alcohol applied to hands for as short as 15 seconds has been found to be effective in preventing transmission of Gram-negative bacteria (Larson, 1995). Products containing isopropanol or ethanol are very effective in decreasing bacteria in areas around and under the fingernails (Mahl, 1989).

Bacterial counts were found to increase after very frequent washing and with the use of alcohol sanitizers (Miller, 1994). Alcohol gel sanitizers that do not require rinsing may be ineffective on their own due to the fact that there is no mechanical action to wash away bacteria (Paulson, 1994; Miller, 1994; Docket C-8). Thus the end result may be increased resident bacteria, including pathogenic *S. aureus*, on the hands. As they dry, alcohol products may pull resident bacteria from deeper skin layers, thus an increase in resident bacterial counts may be noticed (Docket C-8). Antiseptic handrubs, such as alcohol gel sanitizers, can be used only to inhibit microorganisms, without any mechanical effect on soil removal (Larson, 1995). It has been reported that the detergent base in these handrubs, and not necessarily the antiseptic product, is the cause of greater

damage to the skin when compared to plain soaps (Larson, 1995). These detergents can irritate the skin by removing normal skin oils and impairing the skin's normal barrier function (Paulson, 1998).

Aly and Maibach (1979) found that alcohol had immediate activity (84% reduction) but had limited residual activity (90% reduction) as compared to other products. A study by Ayliffe et al. (1988) determined that the most immediately effective products for hygienic hand disinfection were those containing alcohols (log₁₀ reduction factors of 2.5-3.8) but alcohols showed little or no residual effect. In a study to demonstrate immediate and persistent antimicrobial activity of a commercially available alcohol gel product, recovery populations were 7.85 log₁₀ for the immediate sample and 6.81 log₁₀ for the 1-hour sample (Docket RPT1). Recovery populations for the control group (untreated) were 7.49 log₁₀ for the immediate sample and 6.16 log₁₀ for the 1-hour sample. There was no significant difference in antimicrobial activity between the group that used the alcohol gel and the control group (Docket RPT1).

Alcohols are not cleaning agents; therefore, they are not recommended for use in the presence of physical dirt (Larson, 1995; Docket C-8). Due to the shortcomings of alcohol sanitizers in the presence of soil, the build-up of emollients after repeated use, and the lack of effectiveness against certain viruses, it is recommended that hands be washed before alcohol application (Docket C-3; Restaino and Wind, 1990; Docket C-8). A combination of the rapid effects of alcohol and the persistent effect of chlorhexidine gluconate could serve as a template for a desirable antiseptic product (Paulson, 1994; Larson, 1995; Snyder, 1993).

4. Iodophor

Stiles and Sheena (1985) determined that iodophor was effective for reduction of several transient bacteria (99.2-99.5% reduction). Using a procedure involving 6 handwash treatments over a period of 2 successive days, Sheena and Stiles (1983) determined that chlorhexidine gluconate had a residual effect whereas iodophor (0.75% available iodine) did not indicate a residual effect. Iodophors are generally accepted as antibacterial agents for hand hygiene but products containing high iodine concentrations (i.e. >0.75%) create some hesitation among users due to product odor and staining of skin (Stiles and Sheena, 1985). In addition to its broad-spectrum activity against bacteria, viruses, spores, and protozoa cysts, 0.5% active iodine has a low toxicity to humans (Docket C-4). A handwash towel that is comprised of a 5% Povidine-Iodine solution (PVP) represents new technology for application to the hands of food preparation/food processing personnel (Docket C-4). The antimicrobial properties of PVP, along with its low toxicity to humans, suggests that its compound will contribute to the reduction of microbial levels in food processing facilities (Docket C-4).

5. Triclosan

Triclosan has a broad spectrum of activity against gram-positive and most gram-negative bacteria. It has immediate antibacterial effects as well as persistent activity on the skin and is only minimally affected by organic matter (Larson, 1995). Triclosan 1.5% was found to have residual efficacy (3.78 log₁₀ reduction factor) against transient bacteria (Bartzokas et al, 1987). A study using 0.3% triclosan found that after 6 washes per day for 5 days, there was no significant difference in mean log₁₀ colony-forming units compared to other products. After 18 washes per day for 5 days, the control group (nonantimicrobial soap) mean count decreased 0.30 logs while the triclosan group decreased 1.55 logs. In this study, triclosan performed significantly better than the control soap after high-frequency handwashing (Larson et al., 1989).

6. Para-chloro-meta-xyleneol (PCMX)

PCMX is considered to have good activity against gram-positive organisms, is less active against gram-negative organisms, and has fair activity against viruses, some fungi and against the tubercle bacillus (Larson, 1995). Its activity is minimally affected by organic matter and it has a persistent effect over several

hours (Larson, 1995). In a study comparing handwash products at two different handwashing frequencies, 0.6% PCMX demonstrated no difference in mean log₁₀ colony-forming units when compared to control (nonantimicrobial) soap after 6 washes per day for 5 days. After 18 washes per day for 5 days, the control group mean count decreased 0.30 logs while the mean count for PCMX decreased 1.74 logs. After 18 washes, the effectiveness of PCMX was significantly better than that of the control soap; however, triclosan and PCMX were not significantly different from each other (Larson et al., 1989).

7. United States Department of Agriculture (USDA) List of Proprietary Substances and Nonfood Compounds

Employee, or simply "E", classifications were used to describe and categorize antimicrobial hand soaps and sanitizing compounds. This classification system applied to USDA-approved handwash products to be used in meat processing plants. This system was discontinued by the USDA in 1998. The USDA classification is mentioned in this review since this system may still be familiar to the intended audience. When in use, this classification system was based on manufacturer's research claims and recommendations rather than on research conducted by USDA.

E2 compounds were those used for handwashing and sanitizing. For purposes of E2 classification, hands did not need to be washed prior to the use of such compounds but must have been thoroughly rinsed after use (Paulson, 1994; Miller, 1994). E2 soaps usually contain triclosan or parachlorometaxyleneol (PCMX) and had immediate antimicrobial effects primarily due to mechanical action (Paulson, 1994). Examples of these products included Clean & Smooth, Purell Antibacterial Lotion Soap, and Derma Klens (Miller, 1994). E2 products were effective in terms of immediate and persistent antimicrobial effects but were very irritating to the skin (Paulson, 1994). E2 products showed a more significant reduction in resident and transient (Miller, 1994) organisms compared to antibacterial soaps.

8. Fingernail brushes:

From this literature search, only one author published information concerning the use of fingernail brushes (Docket C-3). The author concludes that fingernail brushes are necessary in order to remove debris from fingertips and under and around nails, since the subungual area of the hand (area under fingernail) contains the highest numbers of microorganisms. However, the use of a brush that is too stiff or excessive use of fingernail brushes may damage the epidermal layer of the fingertips. The author recommends the double hand wash method when food service employees begin a shift and then again after using the restroom. A single hand wash, without the use of a nailbrush, is adequate for the removal of most transient bacteria during routine food preparation operations. The outline of the double hand wash is as follows: 1) using warm water, and with water flowing over fingertips, brush the fingertips and beneath nails for 10-12 seconds; 2) after using brush, store brush side up, without the use of sanitizing solutions; 3) apply soap to hands, lathering all surfaces for 5-7 seconds; 4) rinse; 5) dry with paper towel.

Studies were conducted with an inoculated finger washing experiment using a 0.1 ml. solution of *Serratia marcescens*, containing 20,000,000-100,000,000 organisms/ml. (Docket C-3). These studies have shown a 1,000:1 reduction in bacterial counts after the first wash, with an additional 100:1 reduction after the second wash and then even further reductions after paper towel use. After use of the nail brush, it was determined that fewer residual organisms remained on the brush as compared to fingertips. The residual microorganisms that remain on the fingernail brush could be transferred to the next person using the brush; however, there would be another 99.98% reduction once the subsequent user begins washing. The author believes that door knobs and other fomites present a greater risk for cross-contamination than the common use of a nail brush; however, no scientific data were presented to support this statement.

Hand Drying:

1. Hot Air Dryers

Measures of hand drying effectiveness include such things as speed of drying, effective removal of microorganisms, degree of dryness, and prevention of cross-contamination (Docket C-8). One study of hot air dryers revealed an increase in the number of bacteria on hands after dryer use, as well as the presence of bacteria in the nozzles of hot air dryers themselves (Blackmore, 1989). A comparison of three models of dryers demonstrated an increase in numbers of bacteria remaining on hands after drying from 136% to 187% (Blackmore, 1989). After using hot air dryers with insufficient cycle length or heat, there may be a tendency for persons to finish drying hands on clothes (Blackmore, 1989; Matthews & Newsom, 1987). This could serve to increase the chances of organism transfer and cross-contamination (Blackmore, 1989). Matthews and Newsom (1987) found that a 30-second cycle drying time was insufficient to dry hands thoroughly. They also concluded that, of the four commercial dryers that were tested, hot air dryers appear to be safe from a microbiological standpoint.

A study by Ansari et al. (Am J Infect Control, 1991) found that, irrespective of the handwashing agent used, electric air drying produced the highest reduction in numbers of *E. coli* and rotavirus when compared to either paper towels or cloth towels. For example, after washing with soap and water with no drying, there was a 77% reduction of rotavirus on hands; whereas, a reduction of 91.74% was noted with warm air drying, 86.8% with paper towels, and 80.4% with cloth drying. It was also noted that the use of 70% isopropanol can reduce the transient microflora to undetectable levels and in such instances, any of the methods of hand drying could be used. The author concluded that, in terms of washed hands, the reduction in contamination during drying is more critical when less effective hand washing agents are used.

2. Paper Towels

Several studies demonstrated a significant reduction in bacterial counts when hands were dried with paper towels (Blackmore, 1989; Georgia-Pacific, 1996) and with cloth towels (Blackmore, 1989) since the friction effect physically removes bacteria from hands. A comparison of calculated mean values of bacteria from hands before and after drying revealed a 29% reduction when hands were dried with paper towels and a 26% reduction when dried with a continuous cotton towel (Blackmore, 1989). However, the bacteriologic quality of continuous cloth towels is inferior to that of paper towels (Blackmore, 1989). This can be due to the laundering process as well as the fact that bacteria can be transferred from one user to the next as the towel is rotated and pulled in order to obtain a clean area.

The paper making process leads to substantial reduction, if not elimination, of microorganisms in paper towels (Georgia-Pacific, 1996). Paper towels are considered to be the most sanitary hand drying method (Georgia-Pacific, 1996). It was noted that the number of bacteria on paper towels was low before use but markedly increased after hands were dried indicating physical removal of microbes from the hands (Georgia-Pacific, 1996). The friction applied when drying with paper towels further reduces bacterial counts. Under experimental conditions, an average of 95% reduction in contamination with *S. aureus* was obtained after rinsing with tap water alone and drying hands with paper towels (Georgia-Pacific, 1996). This frictional removal of transient bacteria from hands takes on greater importance if handwashing is not performed properly (Georgia-Pacific, 1996). Paper towels can also be useful in situations where foot pedals are not available such that faucets and door handles can avoid being touched with cleaned hands (Georgia-Pacific, 1996). Although there are advantages offered by paper towels, there are issues of hand contamination with pathogens from paper towel exit areas as well as dispensers that utilize cranks, buttons, and levers (Docket C-8).

3. Handwash Machines:

The major advantage of handwash machines is consistency of the handwash procedure (Vesley et al., 1985;

Paulson, 1993). Another side benefit may include the monitoring of employees' handwash frequency. The antimicrobial efficacy of handwash machines is equivalent to that of manual handwashing procedures (Paulson, 1992; Vesley et al., 1985). A study of the efficacy of antiseptic handrub lotions with handwashing machines revealed that a 30-second soap wash prior to use of handwashing machines with a chlorhexidine/alcohol combination (0.5% CHG and 77% ethyl alcohol) resulted in 90% reduction of bacteria from hands (Namura et al., J Derm, 1994;21:481-485).

In a study comparing a plain soap manual handwash with chlorhexidine gluconate machine wash, it was found that automated handwashing has more standardized and consistent wash results than did the manual wash (Paulson, 1993). After the first handwash, the variability of wash results was .719 logs for the manual wash and .53 logs for the automated wash. The manual wash variability was not significantly different from baseline measurements (0.749 logs) while the automated wash had less variability than baseline measurements (1.225 logs). After 5 washes, the manual wash variability was .74 logs which was not statistically different from baseline measurements. However, the automated wash variability was .505 logs, which was statistically significantly less than baseline.

A standard handwashing machine comparing manual handwash with plain soap and 0.3% triclosan with machine wash using 2% chlorhexidine gluconate, it was noted that both the manual wash and chlorhexidine gluconate wash were statistically equivalent in degerming effectiveness (Docket RPT1). After the first manual wash there was a log₁₀ reduction of 2.07 from baseline and a 2.03 log₁₀ reduction after the fifth manual wash. The chlorhexidine gluconate machine wash revealed a 1.84 log₁₀ reduction from baseline after the first wash and 1.88 log₁₀ reduction after the fifth wash. The machine wash was effective in degerming the skin while having the advantage of increased wash control (Docket RPT1). This study also determined that users need not have any specific training in handwashing techniques to properly use the automated handwash system. A system employing brushes with the automated wash was not more effective than systems without brushes. This may be due to the fact that fingers were not placed far enough into the machine to make sufficient physical contact and that brushes are unable to clean between fingers (Docket RPT1).

BARRIERS:

Barriers to bare-hand contact with ready-to-eat foods include such things as gloves, deli wraps and utensils. In this review, gloves were the only barriers that were included due to lack of available data regarding other barrier methods.

Gloves:

Most glove studies have been conducted in the healthcare setting. In terms of food establishments, the main purpose of wearing gloves is to prevent pathogenic organisms from being transmitted to foods via hand contact from food workers (Paulson, Food Quality, 1996). An intact vinyl or latex glove (i.e., one with no punctures, tears, or holes) will provide protection from transmission of contaminating microorganisms from hands (Paulson, Food Quality, 1996).

Ehrenkranz believes that glove use promotes a false sense of security among healthcare workers since contaminated gloves have led to patient-to-patient spread of nosocomial infections (Ehrenkranz, 1992). Considering the glove to be protective can promote poor handwashing practices and increased microbial growth on the hands (Fendler et al., Part I, 1998). According to Bardell (1995), it is not uncommon for gloves to be worn for long periods of time without being changed and it is not unusual for food employees to put gloved hands to their mouths or noses without changing their gloves. It is the opinion of one author that the wearing of gloves to prepare and serve food does not prevent cross-contamination since glove wearers continue to touch contaminated surfaces or raw foods, thereby inoculating the glove surfaces with microorganisms (Docket C-3). The use of gloves alone does not provide a sufficient barrier against

transmission of pathogenic microorganisms from food employees to consumers (Fendler et al., Part II, 1998).

Handwashing was strongly encouraged prior to gloving (Snyder, 1997; Fendler et al., Part I, 1998; Docket RPT-1; Paulson, April 1996) and after removal of gloves (Larson, 1995; Doebbleling et al., 1988; Olson et al., 1993). *E. coli* counts increased on hands that were not washed prior to gloving (Paulson, June/July, 1996). This occurred after glove changes at one-hour and three-hour intervals. No significant growth of contaminating microorganisms was found on hand surfaces after 3 hours of consecutive glove wearing when hands were effectively washed prior to gloving (Paulson, June/July 1996).

It has been demonstrated that both the interior and exterior of gloves can become contaminated with surface hand microorganisms if the hands are not washed prior to gloving (Docket C-3). Hands themselves can also be contaminated with organisms found on the glove surface. Microbial contamination of hands occurred more frequently with vinyl than with latex gloves (Olsen et al., 1993). According to Paulson (June/July, 1996), wearing gloves can present an even greater potential for transmission of disease. The author feels that microorganisms residing on skin are provided a more favorable environment for growth on gloved hands as compared to ungloved hands due to increased levels of moisture and nutrients. The author recommends that when gloves are worn, hands must be washed with an effective product prior to donning the gloves. The author also suggests that both handwashing with an antimicrobial product and gloving will provide more protection to those performing high-risk tasks (e.g., preparing, cooking, or wrapping food) than either method used alone (Paulson, 1997). According to Larson et al. (1989), handwashing is often omitted when gloves are used and organisms on the hands can multiply rapidly inside the moist and warm environment of the gloves. The use of gloves does not replace handwashing, especially since bacteria and viruses can leak through gloves (Larson et al., 1989). It has been shown that up to 18,000 *Staphylococci* organisms can pass through a single glove hole during a 20-minute period despite the fact that hands were washed for 10 minutes prior to gloving (Docket C-8). When a glove break occurs, a liquid bridge of microbial contamination can flow from hands to surfaces and foods (Docket C-8).

Loose-fitting gloves may increase the risk of microbial contamination and transfer, as well as rendering them cumbersome. Gloves that are too tight can cause discomfort and may result in multiplication of microorganisms due to incubation and sweating inside the gloves (Docket C-8).

Vinyl and latex gloves were tested in the hospital environment by mimicking patient care (Korniewicz et al., 1990). At "lower use levels", which included donning and removing gloves or rubbing the gloved hand with a washcloth, there was no statistically significant difference found between latex and vinyl gloves in terms of leakage. However, at "higher use levels", which included attaching capped needles to syringes and removing needles several times, or wrapping and taping blunt objects, 63% of vinyl gloves leaked compared to 7% of latex gloves. Glove leaks were more frequent with vinyl than with latex gloves (Olsen et al., 1993; Korniewicz et al., 1990; Kotilainen et al., 1989). In a hospital study, 43% of unused vinyl gloves had perforations (Best, 1992). In a hospital study using both vinyl and latex gloves, leaks occurred more frequently at the tip of the index and middle fingers (Kotilainen et al., 1989). This same study found that vinyl gloves were more likely to have multiple leaks as compared to latex gloves. One author stated that packaging for nonsterile use was the major factor associated with an increased glove leakage rate, implying that less care is taken in the molding of gloves for nonsterile use or that such gloves are not adequately tested for leakage (DeGroot-Kosolcharoen and Jones, 1989). Another potential problem with latex gloves is that some persons exhibit an allergic reaction to latex (Muller et al., 1998; Schwartz, 1995).

Several studies reported the effectiveness of various products in removing bacteria from latex and vinyl gloves (Doebbling et al., 1988; Newson and Roland, 1989; McCarthy, 1996; Best, 1992). Best (1992) concluded that latex contributes to the trapping of microorganisms, possibly due to the three-dimensional lattice structure of latex, which allows for elasticity. It was found that after washing with several different commercial products, recovery of *Staphylococcus aureus* was minimal or negative (ranging from 0 cfu/ml to

39 cfu/ml).

In a hospital study by Doebbeling et al., it was found that microorganisms adhere to latex gloves and are not easily washed off despite friction and cleaners (1988). A 3x2 factorial design tested a standard concentration of one of four nosocomial pathogens and one of three different handcleansing agents to cleanse gloves. The agents reduced the median log₁₀ counts of organisms on gloves to 2.1 to 3.9 after an initial inoculation of 10⁷ colony forming units. The proportion of positive glove cultures was as follows: *Staphylococcus aureus*, 8%-100%; *Serratia marcescens*, 16%-100%, and *Candida albicans*, 4%-60%. These results varied greatly after use of different handcleansers

(P <0.001). There was considerable variability for *Pseudomonas aeruginosa*, 20%-48% (P=0.085). After glove removal, the observed proportions of hands contaminated with the nosocomial organisms varied from 5%-50% with variability depending on the particular handwashing agent used (P<0.001) (Doebbeling et al., 1988). The authors recommended handwashing after glove removal and suggested that it may not be beneficial to wash and reuse gloves in a hospital setting.

SUMMARY:

This review has addressed the many different interventions that can be used to minimize or eliminate the contamination of ready-to-eat foods by food workers. Three major areas have been presented: exclusion of ill food workers from the workplace, removal of pathogens from the hands of food workers, and barriers to bare-hand contact with ready-to-eat foods.

Part One of the White Paper discussed the transmission of pathogens from food workers to foods. Exclusion of ill or infected food workers from the workplace is one intervention that can be applied in response to the information presented.

Removal of pathogens from the hands of food workers can be accomplished by various modalities. Handwashing technique, including duration of handwash, water temperature, hand drying method, and frequency of handwash, play an important role in pathogen removal. Handwashing agents, such as detergents, soaps, sanitizers, and antimicrobial agents, vary in their ability to remove pathogens. Factors such as type of pathogen, duration of contact with hands, and characteristics of organic material present on hands must be considered when selecting an appropriate handwashing agent. Hand drying methods range from hot air dryers to cloth and paper towels. Factors such as cycle length of air drying, friction used with towel drying, and type of towel used can all influence the removal of pathogens from hands. Handwashing machines are also used to remove pathogens from hands. They are found to offer consistency and compliance monitoring capabilities but must be evaluated based on their mechanism of action, such as cycle length, water pressure and quantity, as well as the products utilized in the handwash procedure.

Barriers to bare-hand contact with ready-to-eat foods include such things as gloves, deli wraps and utensils. In this review, gloves were the only barriers that were included due to lack of available data regarding other barrier methods. Issues related to the use of gloves as barriers include the glove material, glove permeability, duration of wearing, and handwashing techniques prior to and after wearing.

REFERENCES:

1. Aly R, Maibach HI. Comparative study on the antimicrobial effect of 0.5% chlorhexidine gluconate and 70% isopropyl alcohol on the normal flora of hands. *Appl Environ Microbiol* 1979;37(3):610-613.
2. Ansari SA, Springthorpe VS, Sattar SA, Rivard S, Rahman M. Potential role of hands in the spread of respiratory viral infections: studies with human Parainfluenza virus 3 and Rhinovirus 14. *J Clin Microbiol* 1991;29(10):2115-2119.

3. Ansari SA, Sattar SA, Springthorpe VS, Tostowaryk W, Wells GA. Comparison of cloth, paper and warm air drying in eliminating viruses and bacteria from washed hands. *Am J Infect Control* 1991;19:243-249.
4. Ansari SA, Sattar SA, Springthorpe VS, Wells GA, Tostowaryk W. In vivo protocol for testing efficacy of hand-washing agents against viruses and bacteria: experiments with rotavirus and *E. coli*. *Appl. Environ. Microbiol.*,1989;55(12):3113-3118.
5. Ansari SA, Springthorpe VS, Sattar SA. Survival and vehicular spread of human rotaviruses: possible relation to seasonality of outbreaks. *Rev Infect Dis*1991;13:448-61.
6. Ansari SA, Sattar SA, Springthrope VS, Wells GA, Tostowaryk W. Rotavirus survival on human hands and transfer of infectious virus to animate and nonporous inanimate surfaces. *J Clin Microbiol* 1988;26(8):1513-1518.
7. Ayliffe GAJ, Babb JR, Quoraishi AH. A test for 'hygienic' hand disinfection. *J Clin Path* 1987;31:923-928.
8. Ayliffe GAJ, Babb JR, Lilly HA. Hand disinfection: a comparison of various agents in laboratory and ward studies. *J Hosp Infect* 1988;11:226-243.
9. Bannan EA, Judge LF. Bacteriological studies relating to hand washing. *AJPH* 1965;55(6):915-921.
10. Bardell D. Herpes simplex virus type 1 applied experimentally to gloves used for food preparation. *J Food Protect* 1995;58:1150-1152.
11. Bartzokas CA, Corkill JE, Makin T. Evaluation of skin disinfection activity and cumulative effect of chlorhexidine and triclosan handwash preparations on hands artificially contaminated with *Serratia marcescens*. *Infect Control* 1987;8:163-167.
12. Bennenson, AS, editor. *Control of Communicable Diseases*. Washington, DC: American Public Health Association.
13. Best M. Effectiveness of handwashing agents in eliminating *Staphylococcus aureus* from gloved hands. *J Appl Bacteriol* 1992;73:63-66.
14. Blackmore MA. A comparison of hand drying methods. *Catering & Health* 1989;1:189-198.
15. Bryan FL. Hazard analysis: the link between epidemiology and microbiology. *J Food Prot* 1995;59(1):102-107.
16. Borgatta L. Hand protection and protection from hands: Handwashing, germicides, and gloves. *Women and Health* 1989;15:77-92.
17. Butz AM, Laughon BE, Gulette DL, Larson EL. Alcohol-impregnated wipes as an alternative in hand hygiene wipes as an alternative in hand hygiene. *Am J Infect Control* 1990;18:70-76.
18. Chamberlain AN, Halablad MA, Gould DJ, Miles RJ. Distribution of bacteria on hands and the effectiveness of brief and thorough decontamination procedures using non-medicated soap. *Zentralblatt fur bakteriologie*. 1997; 285:565-575.
19. Coates D, Hutchinson DN, Bolton FJ. Survival of thermophilic *Campylobacters* on fingertips and their elimination by washing and disinfection. *Epidemiol Infect* 1987;99:265-274.
20. DeGroot-Kosolcharoen J, Jones JM. Permeability of latex and vinyl gloves to water and blood. *Am J Infect control* 1989;17(4):196-200.
21. Doebbeling BN, Stanley GL, Sheetz CT, Pfaller MA, Houston AK, Annis L., et al. Comparative efficacy of alternative hand-washing agents in reducing nosocomial infections in intensive care units. *NEJM* 1992;327(2):88-93.
22. Doebbeling BN, Pfaller MA, Houston AK, Wenzel RP. Removal of nosocomial pathogens from the contaminated glove: Implications for glove reuse and handwashing. *Ann Intern Med* 1988;109:394-398.
23. Dyer DL, Gerenraich KB, Wadhamas PS. Testing a new alcohol-free hand sanitizer to combat infection. *AORN* 1998;68:239-301.
24. Ehrenkranz NJ. Bland soap hand wash or hand antiseptis? The pressing need for clarity. *Infect Control Hosp Epidemiol* 1992;13:299-301.
25. Fendler EJ, Dolan MJ, Williams RA. Handwashing and gloving for food protection Part I: Examination

- of the evidence. Dairy, Food and Environ Sanit 1998;18(12):814-823.
26. Fendler EJ, Dolan MJ, Williams RA, Paulson DS. Handwashing and gloving for food protection Part II: Effectiveness. Dairy, Food Environ Sanit 1998;18(12):824-829.
 27. Georgia-Pacific Corporation, Commercial Products Division. Results of G-P sponsored field study of hand contact surfaces. 1996. Proceedings of the FDA/USDA meeting; 1996 Oct. 3; Washington, DC
 28. Heinze JE. Bar soap and liquid soap. JAMA 1985;253:1561
 29. Heinze JE, Yackovich FY. Washing with contaminated bar soap is unlikely to transfer bacteria. Epidemiol Infect 1988;101:135-142.
 30. Jacobson G, Thiele JE, McCune JH, Farrell LD. Handwashing: Ring wearing and number of microorganisms. Nurs Research 1985;34:186-188.
 31. Joklik WK (1988). "The structure, components, and classification of viruses", In WK Joklik (Ed), Virology, 3rd edition (pp. 8-38). Norwalk: Appleton and Lange.
 32. Jones RD. The healthcare continuum: A classification model for topical antimicrobial products including those used in the food industry. Dairy Food Environ Sanit 1998;18:352-358.
 33. Korniewicz DM, Laughton BE, Cyr WH, Lytle CD, Larson EL. Leakage of virus through used vinyl and latex examination gloves. J Clin Microbiol 1990;28(4):787-788.
 34. Kotilainen HR, Brinker JP, Avato JL, Gantz NM. Latex and Vinyl Examination Gloves. Arch Intern Med 1989;149:2749-2753.
 35. Larson EL. APIC guidelines for handwashing and hand antisepsis in health care settings. Am J Infect Control 1995;23:251-269.
 36. Larson EL. Quantity of soap as a variable in handwashing. Infect Control 1987;8:371-375.
 37. Larson EL, Mayur K, Laughon BA. Influence of two hand washing frequencies on the reduction in colonizing flora with three hand washing products used by health care personnel. Am J Infect Control 1989;17:83-88.
 38. Larson EL. Handwashing and skin physiologic and bacteriologic aspects. Infect Control 1985;6:14-23.
 39. Larson EL. Hand washing: It's essential—even when you use gloves. Am J Nurs 1989;934-939.
 40. Larson EL, Eke PI, Laughon BE. Efficacy of alcohol-based hand rinses under frequent-use conditions. Antimicrob Agents & Chemother 1986;30:542-545.
 41. Lowbury EJJ, Lilly HA, Bull JP. Disinfection of hands: removal of transient organisms. Brit Med 1964;2:230-233.
 42. Ly VT, Simmons PA, Edrington TB, Weschler S, De Land PN. Efficacy of hand washing procedures on bacterial contamination of hydrogel contact lenses. Optometry and Vision Science 1997;74:288-292.
 43. Mahl MC. New method for determination of efficacy of health care personnel hand wash products. J Clin Microbiol 1989;27(10):2295-2299.
 44. Matthews JA, Newsom SWB. Hot air electric driers compared with paper towels for potential spread of airborne bacteria. J Hosp Infect, 1987;9:85-88.
 45. Mbithi JN, Springthorpe VS, Sattar SA. Comparative in vivo efficiencies of hand-washing agents against hepatitis A virus (HM-175) and poliovirus type 1 (Sabin). Appl Environ Microbiol 1993;59(10):3463-3469.
 46. McBride ME. Microbial flora of in-use soap products. Appl Environ Microbiol 1984;48:338-341.
 47. McCarthy SA. Effect of sanitizers on *Listeria monocytogenes* attached to latex gloves. J Food Safety 1996;16:231-237.
 48. Miller ML. A field study evaluating the effectiveness of different hand soaps and sanitizers. Dairy Food Environ Sanit 1994;14:155-160.
 49. Muller BA, Steelman VM, Hartley PG, Casale TB. An approach to managing latex allergy in the health care worker. Environ Health July/August 1998:8-16.
 50. Namura S, Nishijima S, Asada Y. An evaluation of the residual activity of antiseptic handrub lotions: an 'in use' setting study. J Derm 1994;21:481-485.
 51. Namura S, Nishijima S, Mitsuya K, Asada Y. Study of the efficacy of antiseptic handrub lotions: an 'in use' setting study. J Derm 1994;21:405-410.

52. Newsom SWB, Rowland C. Application of the hygienic hand-disinfection test to the gloved hand. *J Hosp Infect* 1989;14:245-247.
53. Nicoletti G, Boghossian V, Borland R. Hygienic hand disinfection: a comparative study with chlorhexidine detergents and soap. *J Hosp Infect* 1990;15:323-337.
54. Olsen RJ, Lynch PL, Coyle MB, Cummings J et al. Examination gloves as barriers to hand contamination in clinical practice. *JAMA* 1993;270(3):350-353.
55. Paulson DS. Get a handle on contamination. *Food Quality* April 1996:42-46.
56. Paulson DS. A comparative evaluation of different hand cleansers. *Dairy Food Environ Sanit* 1994;14:524-28.
57. Paulson DS. Evaluation of three handwash modalities commonly employed in the food processing industry. *Dairy, Food Environ Sanit* 1992;12:615-618.
58. Paulson DS. To glove or to wash: A current controversy. *Food Quality* June/July 1996:60-64.
59. Paulson DS. Foodborne disease: Controlling the problem. *Environ Health* May 1997;15-19.
60. Paulson DS. Variability evaluation of two handwash modalities employed in the food processing industry. *Dairy Food Environ Sanit* 1993;13:332-335.
61. Pether JVS, Gilbert RJ. The survival of salmonellae on finger-tips and transfer of the organisms to food. *J Hyg Camb* 1971; 69:673-681.
62. Pottinger J, Burns S, Manake C. Bacterial carriage by artificial versus natural nails. *Am J Infect Control* 1989;17:340-344.
63. Restaino L, Wind CE. Antimicrobial effectiveness of hand washing for food establishments. *Dairy Food Environ Sanit* 1990;10:136-141.
64. Salisbury DM, Hufilz P, Treen LM, Bollin GE, Gautam S. The effect of rings on microbial load of health care workers' hands. *Am J Infect Control* 1998;25:24-27.
65. Sattar SA, Springthorpe VS. Transmission of viral infections through animate and inanimate surfaces and infection control through chemical disinfection. In: Hurst CJ, ed. *Modeling disease transmission and its prevention by disinfection*. Cambridge University Press;1996. p. 224-257.
66. Sattar SA, Springthorpe VS. Environmental spread and germicide control of viruses in hospitals. *Infect Control & Sterilization Tech* 1996;2(7):30-36.
67. Sattar SA, Springthorpe VS, Ansari SA. Rotavirus. In:Hui, YH, Gorham JR, Murrell KD, Cliver DO, editors. *Foodborne Disease Handbook. Diseases caused by viruses, parasites, and fungi. Volume 2*. New York: Marcel Dekker, Inc.; 1994. p. 81-111.
68. Scott E, Bloomfield S. The survival and transfer of microbial contamination via cloths, hand and utensils. *J Appl Bacteriol* 1990;68:271-277.
69. Schwartz HJ. Latex: a potential hidden "food" allergen in fast food restaurants. *J Allergy Clin Immunol* 1995;95:139-40.
70. Sheena AZ, Stiles ME. Efficacy of germicidal hand wash agents in hygienic hand disinfection. *J Food Protect* 1982;45(8):713-720
71. Sheena AZ, Stiles ME. Efficacy of germicidal hand wash agents against transient bacteria inoculated onto hands. *J Food Protect* 1983;48:722-727.
72. Sheena AZ, Stiles ME. Immediate and residual efficacy of germicidal hand wash agents. *J Food Protect* 1983;46:629-632.
73. Snelling AM, Kerr KG, Heritage J. The survival of *Listeria monocytogenes* on fingertips and factors affecting elimination of the organism by hand washing and disinfection. *J Food Protect* 1991;54:343-348.
74. Springthorpe S, Sattar S. Handwashing: what can we learn from recent research? *Infect Control Today* 1998;2(4):20-28.
75. Stiles ME, Sheena AZ. Efficacy of low-concentration iodophors for germicidal hand washing. *J Hyg Camb* 1985;94:269-277.
76. Stiles ME, Sheena AZ. Efficacy of germicidal hand wash agents in use in a meat processing plant. *J Food Protect* 1987;50(4):289-295.

77. Vesley D, Lilliquist DR, Le CT. Evaluation of non-germicidal hand washing protocols for removal of transient microbial flora. *Appl Environ microbiol* 1985;49:1067-1071.

Dockets submissions:

99N-0438 RPT1, submitted by BioScience Laboratoires, Inc.

99N-0438 C3, submitted by the Hospitality Institute of Technology and Management

99N-0438 C4, submitted by Contec, Contamination Control Technology.

99N-0438 C8, submitted by the Georgia-Pacific Corporation.

99N-0438 C13, submitted by the Soap and Detergent Association.

[Home](#)

Hypertext updated by ces/ear 1999-OCT-06