

DAIRY, FOOD AND ENVIRONMENTAL

Sanitation

A PUBLICATION OF THE INTERNATIONAL ASSOCIATION OF MILK, FOOD AND ENVIRONMENTAL SANITARIANS, INC. DECEMBER 1998

- **Handwashing and Gloving for Food Protection: Part 1 and Part II**
- **Index to Volume 18**

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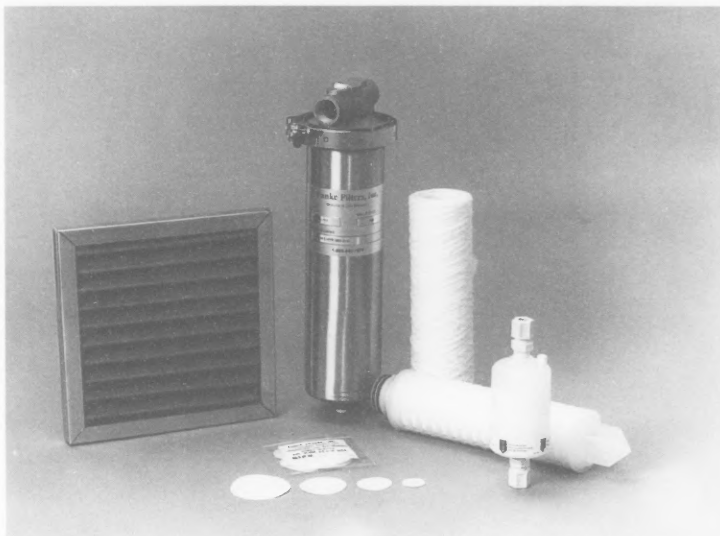
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VIEWS

FROM YOUR PRESIDENT



By ROBERT E. BRACKETT
IAMFES President

“What do you
get for your
dues?”

By the time you read this column, many of you will have already received your Membership dues notice. If you have, you undoubtedly noticed that the dues have increased. The good news is that IAMFES has offered a discount equivalent to the increase to Members who renew within 30 days of the invoice date. The effect of this discount is an exemption from the dues increase for those individuals who pay their dues promptly. The rationale behind this decision is really quite simple. IAMFES must spend considerable money and effort to send out multiple renewal notices and to process new applications for those Members who allow their Membership to lapse. Hence, Members who pay their dues timely save IAMFES money and this savings is passed back to Members. Regardless of whether you take advantage of the discount or not, the necessity for a dues increase still exists in the minds of many Members. In this month's column, I want to provide you with some of the financial reasons for such increases.

Just where do your dues go? You may not think that it could cost \$85 (or \$140 if you receive *Journal of Food Protection*) to maintain the services of your Membership but you might be surprised. Last year, IAMFES spent over \$145,000 for Membership expenses. These expenses include all the basic essentials necessary to provide you with your Membership services, which Members usually take for granted. For example, they include leasing or purchasing of the computers and software needed to maintain our Membership and financial records, stationery and postage used to communicate with

IAMFES Members (including sending out dues notices), rental of office space, telephones (including the 800 line that enables Members to call IAMFES toll-free), and a variety of other similar expenses. However, these costs do not even reflect the costs involved with providing you with *Dairy, Food and Environmental Sanitation* and, for some Members, *Journal of Food Protection*.

Producing quality journals is very expensive. Last year, the costs for printing *Dairy, Food and Environmental Sanitation* and *Journal of Food Protection* were roughly \$70,000 and \$175,000, respectively. However, printing is not the only expense involved in producing our publications. There are significant pre-printing expenses as well. These pre-printing costs include salaries for IAMFES employees involved in journal production, payments to copy editors, and distribution costs. These pre-printing expenses amounted to over \$75,000 for *Dairy, Food and Environmental Sanitation* and just under \$150,000 for *Journal of Food Protection*. Hence, the total cost for producing our journals was just short of a whopping \$470,000.

After allowances are made for nonmembers, such as libraries, who subscribe to one or both of the journals, the total direct costs of Membership to Members who receive *Dairy, Food and Environmental Sanitation* is about \$219,000 and an additional \$256,000 for those Members who also receive *Journal of Food Protection*. This means that last year's average cost of providing services and *Dairy, Food and Environmental Sanitation* was

about \$81 per Member. The average cost for providing both journals was about \$224 per Member. So, as you can see, our previous dues structure of \$75 and \$120 did not even cover the most basic of expenses for providing Members with their services and benefits. To make up for this shortfall, your Executive Board made the decision to raise dues slightly to make sure that we were not forced into the position of operating at a deficit. In addition, other related fees, such as page charges, were also increased to help cover our expenses.

The overall view of our finances I've just provided should give you a better idea of how your dues are being spent and why an

adjustment in dues was necessary. However, that is still not the whole picture! There are many other intangible services and benefits provided by IAMFES and enjoyed by Members. For example, our free Audio Visual Lending Library is one of the best sources of food sanitation and safety materials that you can find. Similarly, the many outstanding articles printed in our journals exist thanks in part to a pool of outstanding reviewers who unselfishly volunteer their time and expertise for the good of the Association and the reputation of the journals. Many Members do not realize that most Members of our Affiliates are not also Members of IAMFES. Nevertheless, Affiliates still enjoy an internationally

respected parent Association that supports their goals and efforts and is committed to their success. Finally, IAMFES Membership has provided the framework and opportunity for development of both professional networking AND personal friendships. These are benefits of Membership for which one cannot place a price.

What do you get for your dues? You get far more than you pay for. You get high quality journals, a dedicated and hard-working IAMFES staff, scientific expertise, and the knowledge that your dues are being used to further the IAMFES goal, "Advancing Food Safety Worldwide." In other words, IAMFES Membership is a bargain.

As you may know, IAMFES will present a proposal to the Membership to change the name of the Association. Listed below is a general timeline for input and approval regarding this proposal.

Fall 1998	Research legal issues of changing IAMFES' name	September 1999	Mail ballot to entire Membership for vote to amend the IAMFES Constitution and Bylaws and change the Association name to "International Association for Food Protection"
Winter 1998	Communicate regularly with IAMFES Members giving updates and progress reports on name change issues	Fall 1999	Tabulate votes and announce results in <i>Dairy, Food and Environmental Sanitation</i>
Spring 1999	Publish in <i>Dairy, Food and Environmental Sanitation</i> , an official notice to amend the IAMFES Constitution and Bylaws	January 2000	After Membership approval, begin using the new name: "International Association for Food Protection"
August 1999	Vote at the IAMFES Annual Business Meeting to amend the IAMFES Constitution and Bylaws and change the Association name to "International Association for Food Protection"		

Input to this process is always welcome. Any questions or comments regarding the name change should be forwarded to Bob Brackett, IAMFES President or David Tharp, IAMFES Executive Director (contact information listed on page 806).

COMMENTARY

FROM THE EXECUTIVE DIRECTOR



By DAVID W. THARP
IAMFES Executive Director

“As we look back over 1998, we can note a number of ways in which we met our Association mission”

December brings to close the year of 1998 and makes for a good time to review our accomplishments of the last year and an opportunity to look forward to goals for next year. As we look back over 1998, I believe we can note a number of ways in which we met our Association mission of *providing food safety professionals worldwide with a forum to exchange information on protecting the food supply*. The most noteworthy is, of course, the IAMFES 85th Annual Meeting where over 1,150 attendees gathered to discuss the latest information and research involving our food supply. Next year, we are planning for more than 1,200 attendees in Dearborn, Michigan. With your help, we can easily achieve this goal.

We co-sponsored many conferences and meetings during 1998, but the one we were most closely associated with was ILSI's Conference on *The National Food Safety Initiative: Implications for Microbial Data Collection, Analysis, and Application* held in Washington, D.C. in October. This was an excellent 3-day conference and a great opportunity to work closely with the International Life Sciences Institute (ILSI) in promoting food safety. There were 240 attendees that came from around the world to attend this conference.

Last April, we held a workshop in the San Francisco area to discuss resources to assist plant managers and food preparation managers in implementing HACCP plans in their operations.

If you organize conferences or know of conferences that fit with the IAMFES mission and would like co-sponsorship assistance, please contact our office for details. We feel that co-sponsorship can benefit both IAMFES and conference organizers in promoting food safety worldwide!

Another way in which we meet our mission is through the publishing of our monthly journals, *Dairy, Food and Environmental Sanitation* and the *Journal of Food Protection*. Both have increased in size and content during 1998 and submissions continue to be received at a rapid pace. We've worked hard to remain on schedule throughout 1998 and have succeeded in doing so. Our processing time for *Journal of Food Protection* manuscripts was reduced by two months during the year and our authors can now expect their papers to appear in print quicker than ever.

Some advancements were made at the IAMFES office during the year. We completed the installation of our network computer system and Membership management software. Now all IAMFES staff members have access to Membership records, which is a great efficiency in the office. We are also all using the same versions of word processing and other software that allows us to assist each other when software questions arise. Just a year ago, we had five versions of word processing software in use and each handled information a little differently. Now we are standard-

ized and determined to keep it that way.

With the change in Membership software, we are now able to provide IAMFES Members with a Membership card and a certificate of Membership suitable for framing. Also, we are attempting to improve the accuracy of our Membership database by asking Members to complete a "Member Information" form and return it to our office. The response has been overwhelming and we appreciate your assistance in keeping your Member record up to date. This saves us time and saves you money (through your dues) by keeping your address and other information current.

Speaking of Membership dues, yes they were increased during 1998, but you have the opportunity, through prompt

payment of your dues, to eliminate the dues increase. The Executive Board voted to allow Members who pay their dues promptly, within 30 days of the invoice date, to take a \$10 discount (\$15 if you receive both Journals). You have the opportunity to save the Association expense and thus, save yourself or your employer money by paying your dues on time. So far, we have seen a very positive response to this program.

Looking forward to 1999, the Executive Board would like to see IAMFES increase our Association visibility in the food safety arena and increase our Member base. One major item to focus on is changing our Association name to the International Association for Food Protection. Watch this issue and future issues of *DFES* for timelines and updates regarding the name change issue. Something else

to watch for in 1999 is a change of printers for the *Journal of Food Protection*. Over the last three years, MACK Printing/Science Press Division has done an excellent job for the Journal. Beginning in January, our printing for the Journal will be performed by Allen Press. There are many advantages to making this change and we look forward to a long and beneficial relationship with Allen.

We hope that 1998 has been a year that you can look back on with a sense of pride for your own accomplishments and for the accomplishments of the Association. 1998 was a very good year for IAMFES, and we look forward to 1999 with the knowledge we have gained and the promise of better things to come. Best wishes for a prosperous and rewarding New Year!

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Handwashing and Gloving for Food Protection Part I: Examination of the Evidence

Eleanor J. Fendler, Michael J. Dolan, and Ronald A. Williams

SUMMARY

The potential for foodhandlers to be a factor in transmitting foodborne disease continues to be a significant issue. In a number of situations, foodhandlers have been implicated as a primary vector in contributing to foodborne illness. The most effective method to break the contamination vector between foodhandlers and consumers is intensely debated. One view holds that food servers must eliminate bare hand contact with ready-to-eat food (by use of gloving) to insure protection, while the other position is that a well managed handwashing and hand sanitizing program is sufficient to insure protection. This paper explores the evidence for these widely differing opinions via a literature review.

INTRODUCTION

Handwashing has been universally accepted for more than a century as a means of reducing contact transmission of microorganisms. The effectiveness of handwashing as a primary infection control measure in healthcare has been reviewed and extensively documented (75, 76). Its effectiveness in preventing the transmission of microorganisms to food via the hands is well established in the food service industry (85, 88).

The FDA Food Code (37) introduced in 1993 requires double handwash, use of a nail brush, and no hand contact with ready-to-eat food. These requirements reflect the premise that use of a physical barrier (gloves) on the hands of food handling personnel minimizes the transfer of pathogens to food. However, it is questionable whether the scientific evidence is sufficient to support these requirements. To answer this question, a review of the published literature re-

lated to all aspects of handwashing and gloving was undertaken.

METHODS

Published studies related to gloving were sought in three areas: (1) the medical literature, including healthcare, infection control, and dermatology; (2) the microbiology literature; and (3) food industry literature, including scientific and trade publications. Information sources used include the following:

- (1) Dialog search of technical databases,
- (2) Dialog search of Trade and Industry Database,
- (3) Literature review publications and books, and
- (4) Bibliography of literature on gloves, E. D. Leach, Associated Enterprises, Inc., 1994.

Articles reviewed were classified under seven major headings according to their primary focus: (1) Food, articles on the general problems of food protection (1-32); (2) Food Code/Regulatory, articles related to the Food Code and regulatory issues (33-45); (3) Microbiology-Skin, articles reporting studies of the microflora of the skin under various conditions (46-63); (4) Micro-

biology-Efficacy, articles reporting the efficacy of handwashing and gloving in microbial control (64-93); (5) Microbiology-Gloves, articles related to microorganisms and gloves (94-110); (6) Gloves-Leakage, articles reporting the methods of glove testing, and the incidence and consequences of glove leakage (111-137); and (7) Gloves-Contact Dermatitis and Allergy, articles reporting the dermatological consequences of glove contact and skin occlusion (138-226).

RESULTS

Medical literature

Extensive medical literature on the effectiveness of handwashing/gloving regimens exists, dating from the demonstration of the importance of antiseptics by Semmelweis in 1847 and Lister in 1867. Literature on the relationship between handwashing and risk of infection from microbes has been reviewed by Larson (75, 76) for the period from January 1879 to June 1993. This literature clearly demonstrates the effectiveness of handwashing in the reduction of nosocomial infections and the value of handwashing as a primary infection control measure. In 1980, the Centers for Disease Control and Prevention (CDC) began developing a series of guidelines entitled *Guidelines for the Prevention and Control of Nosocomial Infections*, and in 1985 the CDC released the *Guideline for Handwashing and Environmental Control* (69). These publications reflect the importance of compliance with handwashing/gloving regimens; however, several studies show that in general, compliance is poor. The CDC Isolation Guidelines are a reflection of poor handwashing compliance in healthcare facilities. The effectiveness of Universal Precautions and Body Substance Isolation practices tend to validate the use of gloves in conjunction with a handwashing regimen. Gloves alone have never been demonstrated to be effective in controlling microbial transmission.

In addition to demonstrating the effectiveness of handwashing and

gloving in preventing microbial transmission, the medical literature serves to identify and define issues related to the practice of glove use, such as compliance, importance of handwashing, single use, glove quality standards, leakage/puncture, and irritation/allergy. Recommendations and guidelines for handwashing and gloving regimens have been established and endorsed by regulatory agencies for healthcare settings (69, 76, 91). These guidelines specify thorough handwashing and hand antisepsis with antimicrobial-containing soaps or detergents or with alcohol-based hand rubs whenever hands are soiled as well as before and after patient contact. Guidelines for glove use specify the following:

- a. Gloves should be used as an adjunct to, not a substitute for, handwashing.
- b. Gloves should be used for hand-contaminating activities. Gloves should be removed and hands washed when such activity is completed, when the integrity of the gloves is in doubt, and between patients. Gloves may need to be changed during the care of a single patient, for example when moving from one procedure to another.
- c. Disposable gloves should be used only once and should not be washed for reuse.
- d. Gloves made of other materials should be made available for personnel with sensitivity to usual glove material (such as latex) (76).

Research indicates that gloves should be changed after 3 to 5 minutes when used for prolonged procedures that result in high levels of glove stress (102, 106).

Glove quality standards (127) have been established by the FDA based on a sampling scheme and a quality assurance test known as the "1000 ml water leak test" described in the Code of Federal Regulations, 21 CFR 800.20. The Final Rule was published in the December 12, 1990, *Federal Register* and became effective

March 12, 1991. The acceptable quality level is a maximum failure rate of 2.5% for surgeons' gloves and of 4.0% for patient examination gloves as determined in this water leak test.

Since the recent widespread increase in glove use due to the implementation of Universal Precautions and Body Substance Isolation, problems associated with glove use, such as leakage and contact dermatitis, have become more evident. Considerable attention and research have been devoted to glove integrity and leakage both before and during use (111-137). Numerous investigations have revealed a high frequency of defects as high as 60% or more in unused latex and vinyl gloves as determined by air inflation-visual detection, air inflation-submersion, electrical conductivity, and fluorescein dye detection.

It is important to note that these high initial defect rates are for presumably high quality surgical and exam gloves and that the defect rate increases sharply with use (122-126). Penetration and leakage of gloves destroy their barrier effectiveness to prevent transmission of microorganisms (129-131, 133, 135). Yangco and Yangco found that 96.4% of unused gloves allowed the passage of infected fluids (137). Conclusions and recommendations from these studies include more stringent guidelines for manufacture with verification of compliance and more careful observation of elements of "universal precautions" such as changing gloves after each patient contact and good handwashing before and after using gloves.

The dramatic increase in the number of individuals using gloves following the adoption of the Centers for Disease Control and Prevention (CDC) "universal precautions" 16 years ago coincides with an explosion of reports in the medical literature of hypersensitivity reactions to latex products. During this same time period, the reported cases of irritant contact dermatitis, allergic reactions to plastic gloves and glove powder, and occupational asthma precipitated

TABLE 1. Definitions of dermatologic terms

Allergic contact dermatitis:	Sensitization or allergic contact dermatitis is a delayed, immunologically mediated response to a chemical. Initial contact with the chemical does not appear to have any effect on the skin, but after a short delay (ca. 5 days), reexposure to the chemical causes an acute inflammatory reaction with an homogeneous "rash".
Irritant contact dermatitis:	Irritant dermatitis is a non-immunological, local inflammatory response at the site on single, repeated, or continuous contact with a chemical. It results in erythema (reddening of the skin) and edema (accumulation of fluid) which is often irregular or patchy in nature.
Contact urticaria:	Contact urticaria is a specific dermal reaction, usually appearing within minutes to an hour after contact with a substance and disappearing by 24 hours, characterized by itching, tingling, or burning sensations, erythema/edema, and urticaria (itching wheals).

TABLE 2. Classification of glove reactions

Reaction	References
Barrier reduction and increased penetration of irritants/allergens by occlusion	173, 194, 201, 202 208
Irritation from occlusion, friction, and maceration	208
Allergic reactions to glove materials (natural and synthetic latex, plastic, polymer additives, dyes, glove powder)	159
Contact dermatitis	213
Contact urticaria, angioedema, and anaphylaxis	208
Penetration of irritants through gloves	208
Others: Endotoxin reactions, Ethylene oxide, Chemical leukoderma	208

by glove powders and airborne latex allergens rose sharply among health-care workers and patients.

It is now widely recognized that natural and synthetic latex, rubber additives, plastics (PVC, vinyl), organic pigments in gloves, and glove

powders cause allergic contact dermatitis and contact urticaria (definitions of dermatologic terms are given in Table 1). Up to 30% of frequent glove wearers are believed to have some degree of acquired hypersensitivity to latex chemicals or proteins

and various additives in synthetic gloves (161).

In addition to allergic contact dermatitis, protective disposable gloves can result in irritant contact dermatitis and skin barrier damage (161, 208). Gloves have been shown to result in reduced protective barrier properties of the stratum corneum due to the physical and chemical effects of skin occlusion (173, 194, 208). Skin occlusion by hypoallergenic non-latex gloves for short exposure periods (6 hours/day for 3 days) was found to have a significant negative effect on the barrier function of surfactant-compromised skin, but no effect on normal skin over the same time period (201). However, longer term exposure (6 hours/day for 14 days) resulted in a significant negative effect on the barrier function of normal skin (202). It was concluded that occlusion by gloves may be a substantial factor in the pathogenesis of cumulative irritant contact dermatitis (201, 202). Glove usage has also been found to result in all of the clinical types of irritant dermatitis classified by Lammintausta and Maibach (185): (1) acute irritant dermatitis (primary irritation), (2) irritant reactions, (3) delayed acute irritant dermatitis, (4) cumulative irritant contact dermatitis, (5) traumatic irritant dermatitis, (6) pustular and acneiform dermatitis, (7) nonerythematous irritation, and (8) subjective irritation.

Microbiology literature

The microbiological literature relevant to handwashing and gloving practices includes studies of the transient and resident microflora of the skin, the effects of glove occlusion on skin microflora, hand and glove carriage, the transmission of microbes, and the antimicrobial effectiveness of handwashing agents and regimens. The microflora of normal skin, including that of foodhandlers, has been well documented (49, 54, 57, 59, 62, 63). These resident microbes present in normal skin are generally non-pathogenic and are not responsible for healthcare or foodborne illness. Hands and contami-

nated gloves, however, are a primary vector for transmission of transient microbes, both pathogenic and non-pathogenic, acquired from the environment (58, 61).

Occlusion of skin by gloves affects the microbial flora on hands by greatly increasing growth rates and populations (47, 48, 50, 59). Price found that "beneath rubber gloves, bacteria remaining on the skin multiply rapidly, their numbers doubling every forty (40) minutes if the hands are dry or every fifty (50) minutes if the gloves have been put on wet. If gloves are worn long enough, the cutaneous [transient] flora may increase until it exceeds by far the ordinary flora. I found that on one occasion the bacterial count of my hands and arms had increased to more than 31,000,000" (59). Microbiological studies have also shown that viable bacteria emerge through pinholes in surgeons' gloves (56).

An enormous number of studies have been devoted to the antimicrobial effectiveness of handwashing products and their role in preventing the transmission of pathogenic microorganisms (55, 56, 71, 72, 75, 76, 79). The literature clearly demonstrates that antimicrobial handwashing agents can be highly effective in killing pathogens and can provide residual antimicrobial activity over a period of several hours. The importance of handwashing when using gloves is widely recognized and accepted in the healthcare field (55, 76). Antimicrobial and antiseptic products have been found to result in greater reduction in microorganisms after 3 hours of wearing gloves than immediately following the antiseptic treatment, whereas microbial counts increased when hands were washed with non-antimicrobial soap (56).

Food industry literature

Although the healthcare setting has been the primary focus of attention for research and field studies of antimicrobial efficacy, some studies have been carried out that demonstrate the effectiveness of handwash-

ing with antimicrobial products in the food industry (65-69, 74, 77, 80, 82-85, 87-90, 92). New York State instituted the first statewide policy of no bare hand contact with ready-to-eat foods (41). The state's rationale for this policy, considered radical by many in both government and industry, was described by Guzewich in a presentation at the 1995 Annual Meeting of the International Association of Milk, Food and Environmental Sanitarians. The policy is based on correcting the problem caused by food workers working when they are ill, not properly washing their hands, and preparing ready-to-eat food, thereby spreading bacterial and viral diseases (14, 15). In spite of the no bare hand contact with ready-to-eat food policy in the Food Code, there is no direct information on the effectiveness of hand hygiene and gloving regimens in the food industry. All of the information available to-date is anecdotal. Additionally, no clean epidemiology data has been found. The recent Idaho hepatitis case serves as a clear illustration.

The food industry also lacks glove quality standards. Studies indicate that the gloves used in food service are generally poor quality and have higher leakage rates than gloves used in healthcare. Although there is a keen awareness of the importance of food protection and the risks of microbial contamination and transmission, there is also a low general awareness of the importance of hand hygiene regimens by foodhandlers. Education and training programs and measures to promote compliance are needed in the food industry.

DISCUSSION

The premise that use of a physical barrier (gloves) on the hands of food handling personnel prevents transfer of pathogens to food is intuitively attractive. At first glance it appears to be a simple solution, and it can be effective when practiced as part of a hand hygiene regimen, as evidenced by the healthcare experience. There are, however, numerous

disadvantages and complications involved in the use of gloves for food protection from contamination by foodhandlers. Counter-intuitive effectiveness issues arise from gloving misuse practices, such as the lack of compliance with single-use and a low frequency of changing gloves. Effectiveness is also compromised by poor glove quality and the resulting high defect and leakage rates. Considering the glove to be protective can lead to low handwashing compliance and accelerated microbial growth on the occluded (gloved) hands. The glove functions as a second skin and can easily become contaminated from the activities of well or ill workers. Gloves, unlike hands washed persistently with antimicrobial skin cleansers lack the ability to continue killing microbes on contact. Other disadvantages of gloving, in addition to the questionable effectiveness, are the cost and the clumsiness of some manipulations when wearing gloves. An additional complication of gloving is the high potential in foodhandlers and customers alike for allergic reactions (contact dermatitis and urticaria) to latex and plastic gloves. Occlusion of the skin by gloves not only leads to enhanced microbial growth, but also results in a decrease in skin barrier function and irritant contact dermatitis.

From this literature review, it appears that the current status of gloving is the following:

1. Gloving is a well-established infection control practice in healthcare environments.
2. Gloving is generally recognized as an adjunct to, not a replacement for, handwashing.
3. The value of gloving in food handling settings is assumed, but has not been proven.
4. Indirect data indicates the potential for health hazards from gloving.
5. A total regimen for hand hygiene needs to be considered and standards need to be established to ensure safe food handling.

CONCLUSION

This literature review clearly demonstrates that the scientific evidence is insufficient to support the premise that the use of a physical barrier (gloves) on the hands of food handling personnel prevents the transfer of pathogens to food and consequently to support the requirement for no hand contact with ready-to-eat food. It is our recommendation that gloving studies be performed under food service conditions to establish data to support the most effective hand hygiene regimens for food protection and minimized risk of health hazards.

ABOUT THE AUTHORS

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Handwashing and Gloving for Food Protection Part II. Effectiveness

Eleanor J. Fendler,¹ Michael J. Dolan,¹ Ronald A. Williams,¹ and Daryl S. Paulson²

SUMMARY

Currently, there are insufficient scientific data to define and substantiate effective hand cleaning hygiene regimens for food protection and minimized risk of health hazards. No direct scientific evidence has been published to support the premise that use of a physical barrier (gloves) on the hands of food handling personnel prevents transfer of pathogens to food and, consequently, to support a requirement for no hand contact with ready-to-eat food. This study was carried out to obtain data under simulated food service conditions to define and support the most effective hand hygiene regimens for food protection and minimized risk of health hazards for the customer.

INTRODUCTION

The potential for food workers to be a factor in transmitting foodborne disease continues to be significant; however, the most effective method to break the contamination vector between food workers and consumers is a topic of intense debate. One view maintains that food workers must eliminate bare hand contact with ready-to-eat food (by the use of gloves, utensils, etc.) to insure protection, while the other position holds that a well managed hand-washing and sanitizing program is sufficient to insure protection. Previously,

we explored the evidence for these widely differing opinions via a review of the published literature related to all aspects of handwashing and gloving (2), and clearly demonstrated that there is insufficient evidence to support the premise that use of gloves on the hands of food workers prevents the transfer of microorganisms to food and consequently to support the requirement for no hand contact with ready-to-eat food. The present study was carried out to establish data under simulated food service conditions to support the most effective hand hygiene regimens for food pro-

tection and minimized risk of health hazards.

Disease transmission via the hands from food workers to consumers can involve various types of microorganisms. "Resident" microorganisms that normally colonize the skin pose little threat of infectious disease (3, 4). There are situations, e.g., an infected cut, in which resident microorganisms may cause disease. In such situations, however, washing serves to degerm the infected area, cleansing it of dead cells and exudate material (5). The threat, comes instead, from "transient" pathogenic microorganisms that temporarily reside on the skin of the hands. Transient microbial contamination occurs when a person makes hand contact with contaminate materials such as mucous, blood, soil, urine, feces, or food. In the food industry, contamination usually occurs from contact with excretions or infected areas of one's own or of others, most commonly through hand transmission. Additionally, food workers can contaminate the food they prepare or serve others, through hand contact with microbial contaminated materials such as money, raw and discarded food, tableware, countertops, soiled clothing, and other items in the work environment. Both of these types of transmission are examined in this study.

First, consider the situation of infected food workers who pass their

infectious diseases by directly contacting food with contaminated hands. For infectious diseases to be spread to others via a carrier, several events must take place. The first two of these events are:

1. The contaminating microorganisms must be physically transmitted to others. This can occur when food workers contaminate their hands during defecation and pass the disease-causing microorganisms to consumers via hand contact.
2. The contaminating microorganisms must physically enter a person. This is particularly easy when the food has been contaminated by enteric (intestinal) disease-causing microorganisms.

An effective handwash or intact barrier gloves disrupt the disease process after event 1 either by removing the contaminating microorganisms from the hand surfaces or using a physical barrier to prevent them from being transmitted to the prepared food.

To evaluate the effectiveness of handwashing compared to gloving, a two-phase study was designed. The first phase evaluated the ability of hand contaminant bacteria to penetrate through compromised vinyl glove barriers. The second phase evaluated the microbial contamination level picked up on the hands from handling contaminated hamburger.

METHODS

Materials

Ambidextrous disposable polyethylene gloves were used throughout the studies. Hand cleansing and sanitization were carried out using an antibacterial lotion soap and an alcohol (gel) hand sanitizer. Ground beef, buns, vegetables, and paper wrap were used in the simulated food handling.

Before the initiation of this study, the Protocol study description was given to the subjects and Informed

Consent Forms were completed. The Protocol, Informed Consent Form, and any other supportive materials relevant to the safety of the subjects were reviewed and approved by an Institutional Review Board (IRB). No subject was admitted into the study who was using topical or systemic antimicrobials, or any other medication known to affect the normal microbial flora of the skin.

The seven days prior to the test portion of the study comprised the pre-test period. During this time, subjects avoided the use of medicated soaps, lotions, deodorants and shampoos, as well as avoiding skin contact with solvents, detergents, acids, and bases. They avoided contact with products on the restricted list. Subjects were provided a personal hygiene kit containing non-antimicrobial products to be exclusively used during the course of this study. Subjects also avoided using UV tanning beds and bathing in chlorinated pools and/or hot tubs. This regimen allowed for stabilization of the normal microbial populations residing on the hands.

Glove juice sampling method (1)

Following the prescribed procedure, powder-free sterile gloves were put on. At the designated sampling time, 75.0 ml of Sterile Stripping Fluid (SSF) were instilled into the glove. The wrist was secured and an attendant massaged the hand through the glove in a standardized manner for 60 seconds. Aliquots of the glove juice (dilution 10^0) were removed and serially diluted in Butterfield's Buffered Phosphate Diluent (BBP).

Duplicate spread plates were prepared from each dilution, using MacConkey's Agar. The plates were incubated at 30 to 35°C for 24 to 48 hours. Those plates providing colony counts between 25 and 250 were preferentially utilized in this study. If no plates provided counts in the 25 to 250 range, the plates closest to that range were counted and used in determining the number of viable microorganisms. If 10^0 plates gave an average count of zero (0), the average plate count was expressed as

1.00. This was done because the \log_{10} of zero (0) is undefined, but the \log_{10} of 1.00 is zero (0). The number of viable bacteria recovered was obtained from the formula $75 \times$ dilution factor \times mean plate count for the two plates.

A statistical analysis, two-factor analysis of variance (ANOVA), was performed on the collected data. The significant level was set at 0.05. The optimum levels of two test configurations evaluated were determined, as well as which glove type to use in the remainder of the study (Phases 1 and 2).

Phase 1

Nineteen human subjects were utilized in this evaluation segment. Punctured gloves were simulated by introducing four holes into the fingertips of the glove with a 21-gauge hypodermic needle. Subject treatment was randomized. Subjects underwent a seven day pre-trial restriction period in which they avoided skin contact with products and/or processes which are known to affect the normal microbial populations of the skin.

On the day of the evaluation, the subjects' hands were inoculated with 5 ml of 9.50×10^8 CFU/ml *Escherichia coli* (ATCC #11229). After air drying the inoculated hands for approximately one minute, technicians placed the assigned test glove configuration on the subject, taking precautions to avoid contaminating the outer surface of the glove. Sterile latex gloves were then placed over the test gloves, and one of the gloved hands, randomly selected, was sampled (zero time sample) using the Glove Juice Sampling Procedure. If the hand selected for time zero time sampling bore a punctured-glove configuration, the punctures were taped prior to the sampling. Subjects then proceeded to their assigned activity (or nonactivity) for one hour.

Four test configurations were used; each with five subjects:
Test configuration #1 (Inactive/intact):

The subjects assigned to this configuration remained "inactive" (sitting in a chair reading) wearing an "intact" glove for one hour.

TABLE 1. Two factor analysis of variance design

	B ₁	B ₂
A ₁	n = 5	n = 5
A ₂	n = 5	n = 5

where: A = Activity level

A1 = Inactive

A2 = Active

B = Glove status

B1 = Intact

B2 = Punctured

Test Configuration #2 (Inactive/punctured):

The subjects remained "inactive" wearing a "punctured" glove for one hour.

Test Configuration #3 (Active/intact):

The subjects were "active" (performed food service activities; specifically, handling buns and vegetables, and folding paper wrap) wearing an "intact" glove for one hour. The vegetables were pre-screened for *Escherichia coli* and other coliform contamination.

Test Configuration #4 (Active/punctured):

The five subjects were "active" (performed food service activities; specifically, handling buns and vegetables, and folding paper wrap) wearing a "punctured" glove for one hour.

All subjects were sequestered and closely monitored in the laboratory during the duration of the test. The subjects were sampled, using the glove juice sampling method, one hour after donning the test barrier glove. After the samples were collected, the subjects were required to perform a supervised surgical scrub with a 4% chlorhexidine gluconate (CHG) solution for four minutes, then wash their hands with 70% isopropyl alcohol for one minute and air dry the hands for an additional five minutes.

A statistical analysis was performed on the collected data. The 0.05 level of significance was utilized in a two factor analysis of variance (ANOVA), the ANOVA design of which is given in Table 1.

Phase 2

Thirty subjects were randomly assigned to an evaluation segment (five subjects to each of the six test configurations). Subjects underwent a 7-day pre-trial restriction period in which they avoided skin contact with products and/or processes known to affect the normal microbial populations of the skin.

Assay of the ground beef for *Escherichia coli*, prior to its experimental use, revealed loads of 1.30×10^3 to 2.00×10^4 CFU per ounce of ground beef. The ground beef was then inoculated with aliquots of an *Escherichia coli* (ATCC #11229) suspension to provide a final *Escherichia coli* concentration of 1.1×10^5 to 9.6×10^5 CFU per ounce of ground beef.

The five subjects assigned to each test configuration performed a simulated food service task (kneading ground beef) over the course of three consecutive, 1-hour periods.

Test Configuration #5 (Bare hands/No washing):

No handwashing was conducted by these subjects during the three 3-hour course of the study. A baseline (pre-marker bacteria exposure) sample of the hands as well as sampling at the end of the test period was conducted.

Test Configuration #6 (Gloved hands/No washing and no glove changes):

No glove changes or handwashes were conducted over the 3-hour course of the study. A baseline (pre-marker bacteria exposure) sample of the hands and of the test

glove outer surfaces as well as sampling at the end of the 3-hour test period were conducted.

Test Configuration #7 (Bare hands/Hourly washing):

Subjects washed their hands with only the assigned antimicrobial soap product immediately before beginning the simulated food service tasks (time 0), as well as at hours one (1), two (2), and three (3). A baseline (pre-marker bacteria exposure) sample of the hands as well as sampling at the end of the 3-hour test period were conducted.

Test Configuration #8 (Bare hands/Hourly washing and sanitizing):

Subjects washed their hands with the assigned antimicrobial soap followed by a hand sanitizer application immediately before beginning the simulated food service tasks (time 0), as well as hours one (1), two (2), and three (3), a baseline (pre-marker bacteria exposure) sample of the hands as well as sampling at the end of the test period were conducted.

Test Configuration #9 (Gloved hands/Hourly glove changes, and no handwashing):

Subjects changed their gloves at hourly intervals but did not wash their hands between the glove changes. A baseline (pre-marker bacteria exposure) sample of the hands and outer glove surfaces was conducted. Additionally, a sample of the hands and outside glove surfaces were conducted at the end of the marker bacteria exposure period.

Test Configuration #10 (Gloved hands/Hourly glove changes and handwashing between changes):

Subjects changed their gloves at hourly intervals and washed their hands between glove changes with the assigned product. A baseline (pre-marker bacteria exposure) sampling of the outer glove surfaces was conducted. Also, a sampling of outside glove surfaces was conducted at the end of the 3-hour marker bacteria exposure period.

After the samples were collected, subjects performed a surgical scrub with a 4% Chlorhexidine glu-

Figure 1. Glove study concept of phase 1

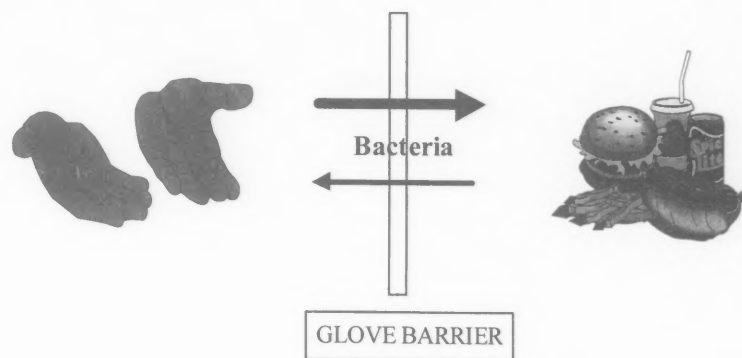


TABLE 2. Effect of glove condition and activity on microbial penetration through gloves

Test configuration	Microbial level on test glove	
	Mean Log ₁₀ (S.D.)	
	Zero hour	One hour
#1 Inactive/Intact	2.05 (1.43)	0.00 (0.00)
#2 Inactive/Punctured	0.48 (1.08)	0.87 (1.21)
#3 Active/Intact	1.87 (1.29)	0.47 (0.94)
#4 Active/Punctured	1.24 (1.21)	0.85 (1.16)

conate (CHG) product for four minutes and then washed their hands with 70% isopropyl alcohol for one minute and air dried for an additional five minutes.

NOTE: All hand sampling was conducted utilizing the glove juice sampling method.

A statistical analysis was performed on the collected data. The 0.05 level of significance was utilized. A two-factor analysis of variance (ANOVA) statistic was used to compare bare hand and outer glove microbial count differences between the zero and three hour samples times.

RESULTS

Phase 1

The concept underlying Phase 1 of the study is illustrated in Figure 1.

All values obtained for Phase 1 were obtained from the 10⁰ dilution. If plates yielded no counts, the log₁₀ value was designated 0.00 and used in the statistical analysis. The glove juice procedure can detect microorganism populations only down to a log₁₀ value of 1.57, because the multiplication of the average plate count by 75 ml (log₁₀ [75 × 0.5] = 1.57). As the data demonstrate, the test gloves housed within the latex gloves, regardless of test configuration, yielded contaminative bacteria at zero (0) and one (1) hour sampling.

Phase 2

The concept underlying Phase 2 of the study is illustrated in Figure 2. The results from Phase 2 are presented in Table 3. A two (2) factor ANOVA model was used to compare times and product configurations.

Figure 3 graphically displays the data obtained from the surfaces directly exposed to the inoculated ground beef for each product configuration.

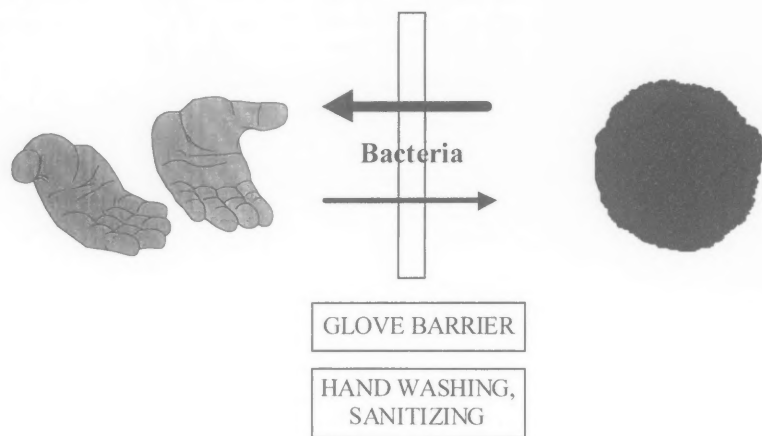
DISCUSSION

Phase 1

Although the counts were not high, clearly the *Escherichia coli* contaminated some of the outer surface of the test gloves, whether the subject was engaged in food preparation activities or not. Admittedly, the variables producing these results were several, but significantly, all potential sources of contamination in this test bear direct relevance to use of gloves by food-handlers as barriers to transmission of infectious agents. For example, bacteria could have moved from the contaminated hand to the glove surface via breaches whether experimentally created or because of defects of manufacture in the gloves. Indeed, results of preliminary testing of glove integrity, using the FDA Water Leak Test and the Glove-Chek method, indicated that manufacturing defects in the vinyl gloves commonly used in food preparation were remarkably high (unpublished data, GOJO Industries, Inc.). Secondly, the test gloves may have been contaminated with *Escherichia coli* during the process of their application by the technician, despite extreme measures to prevent this. The dire implications for the sterility of gloves donned by a food-handler after using the toilet without a handwash are obvious. Finally, *Escherichia coli* contaminating the food handled by subjects in the "active" test configurations may have penetrated the latex outer gloves through manufacturing defects, such as pinholes. Although unpublished data (GOJO Industries, Inc.) show latex gloves to be superior to vinyl gloves commonly used by food-handlers, manufacturing defects are occasionally present. Hence, in all cases, the presence of bacteria on the surfaces of test gloves suggest that their value as "barriers" to disease is equivocal.

These results clearly have implications for gloving policies in the

Figure 2. Glove study concept of phase 2



food industry. Use of gloves, alone, provides insufficient protection from transmission of pathogenic disease-causing microbes from food workers to consumers. Phase 2 of this study was carried out to determine the relative effectiveness of various handwashing and gloving regimens in preventing transmission.

Analysis of the data for the different handwashing and gloving regimens was carried out using a two fac-

tor ANOVA model. Both the time and product factors as well as the product versus factor interaction term were significant ($P < 0.05$). The interaction is significant because each product began at the same baseline microbial level, but the levels were different from one another at the three 3-h study completion time.

As illustrated graphically in Fig. 4, Bare hands/No washing (#5), Gloved hands/No washing (#6),

Gloved hands/Hourly washing (#9), and Gloved hands/Hourly glove changes and handwashing between changes (#10) are equivalent in microbial levels picked up from the inoculated ground beef ($P < 0.05$). Notably, results for Bare hands/Hourly washing (#7) and Bare hands/Hourly washing and sanitizing (#8) were statistically less than the results for the other four groups just mentioned ($P < 0.05$) with #8 (Bare hands/Hourly washing and sanitizing) being more highly statistically significant than regimen #7 (without the sanitizing).

The significantly lower microbial levels on the hands for regimens #7 and 8 as compared with that on hands with no washing (#5) and on the outer surfaces of the gloves (#6, 9, and 10) can be attributed to the residual antimicrobial activity from binding of the active in the antimicrobial handwashing product to the skin (Fig. 4).

The microbial values obtained (Table 3) from the hands for the regimens employing gloves, (#6, 9, and 10), clearly demonstrate that the polyethylene barrier gloves were unable to prevent contamination of the hands over the three hour course of the study. However, the microbial

TABLE 3. Microbial levels of *Escherichia coli* from contaminated ground beef using different washing/gloving regimens

Configuration (Regimen)		Microbial level on hands/outside of gloves Mean log ₁₀ (S.D.)		
		Time 0	Time 3	Time 3-Time 0
#5 Bare hands/No washing	Hands	0.53 (0.86)	6.25 (0.53)	5.72
#6 Gloved hands/No washing and no glove changes	Hands	0.21 (0.65)	2.39 (2.65)	2.18
	Gloves	0.00 (0.00)	5.70 (1.00)	5.70
#7 Bare hands/Hourly washing	Hands	0.65 (1.40)	4.16 (1.43)	3.51
#8 Bare hands/Hourly washing and sanitizing	Hands	0.00 (0.00)	0.80 (1.21)	0.80
#9 Gloved hands/Hourly glove changes and no handwashing	Hands	0.16 (0.50)	3.04 (1.75)	2.88
	Gloves	0.00 (0.00)	6.06 (0.31)	6.06
#10 Gloved hands/Hourly glove changes and handwashing between changes	Hands	0.91 (1.49)	1.77 (2.37)	0.86
	Gloves	0.00 (0.00)	5.60 (0.86)	5.60

A two factor ANOVA model was used to compare times and product configurations.

Figure 3. Graphically displays the data obtained from the surfaces directly exposed to the inoculated ground beef for each product configuration

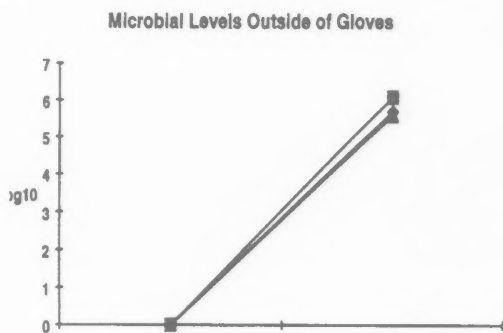
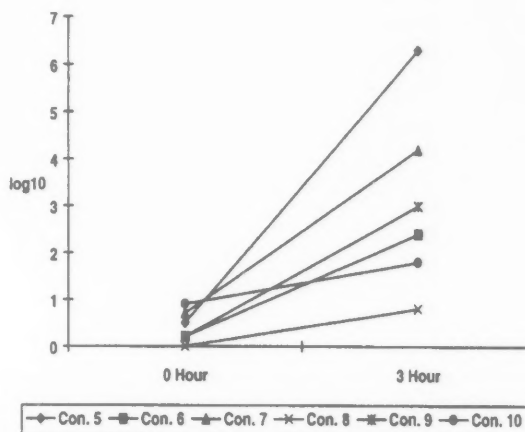
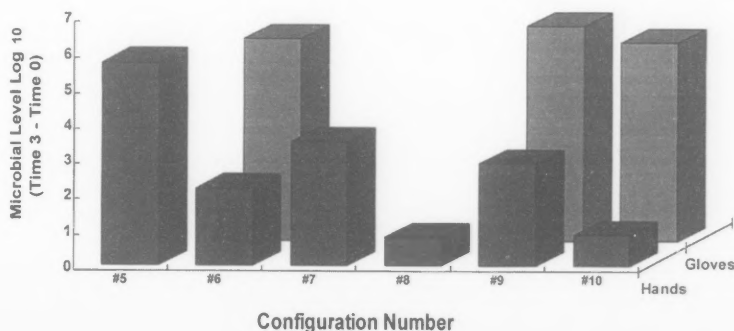


Figure 4. Microbial levels of *E. coli* on hands from contaminated ground beef using different washing/gloving regimens



level found on the hands was lower when handwashing was employed between glove changes (#10). This is also probably the consequence of the residual antimicrobial activity of the handwashing product on the hand.

In conclusion, bare hands with a regimen of hourly handwashing and sanitizing provided significantly higher hand sanitization levels than any of the five other regimens, including those employing gloves.

CONCLUSION

The choice of and compliance with an effective regimen is essential for food protection. It is clear that a policy where gloves are employed to provide no bare hand contact with ready-to-eat food is not a panacea and may only serve to provide a dangerous false sense of security. Caution should be exercised in the selection of the most effective regimen for food protection. Additional studies should be conducted in food industry settings to validate the most effective regimen of hand sanitization for food protection.

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FoodNet Update: 1997 Preliminary Foodborne Illness Data

Ralph R. Meer and Scottie L. Misner

SUMMARY

FoodNet is a cooperative effort between the CDC, USDA, FDA, and national Emerging Infections Program (EIP) sites. EIP sites consist of local health departments, academic institutions and organizations of health professionals. The goals of FoodNet are to (1) better assess the incidence of foodborne disease in the U.S., (2) identify specific foodborne diseases that are associated with specific foods or other exposures, (3) provide a network to allow for a rapid and cooperative response to foodborne disease outbreaks, and (4) evaluate whether new food safety programs have an effect on the incidence of foodborne illness. FoodNet tracks the incidence of diarrheal disease associated with seven primary foodborne pathogens (i.e., *Campylobacter*, *E. coli* O157:H7, *Salmonella*, *Shigella*, *Listeria*, *Vibrio*, and *Yersinia*). In 1996, FoodNet data was collected from two states, Oregon and Minnesota, and from selected counties in California, Georgia, and Connecticut. The population for the 1997 survey totaled 15,926,304 persons, up 11% from 1996. The number of laboratory-confirmed diarrheal cases associated with the seven bacterial pathogens was 8,031 in 1997. Although this represented an increase of 709 cases (9.6%) from 1996, when adjusted for the additional population surveyed, the rate per 100,000 persons actually decreased, from 51.3 in 1996 to 50.4 in 1997. *Campylobacter* was the most frequently isolated target bacterium isolated from cases of diarrhea, followed by *Salmonella*, *Shigella*, *E. coli* O157:H7, *Yersinia*, *Listeria*, and *Vibrio*. A seasonal variation was seen, with isolation of most of the pathogens increased during the summer months. The greatest number of cases involved children between one and ten years of age. With regard to the total 33 known deaths in 1997, *Listeria* was isolated from 45% of the cases, followed by *Salmonella* at 36% and *E. coli* at 12%. The total number of known deaths per 100,000 population in 1997 (0.21) was similar to that seen in 1996 (0.24).

Figure 1. Cases per 100,000 by pathogen (all sites) – 1996-left bar, 1997-right bar for each pathogen
*final 1996 data

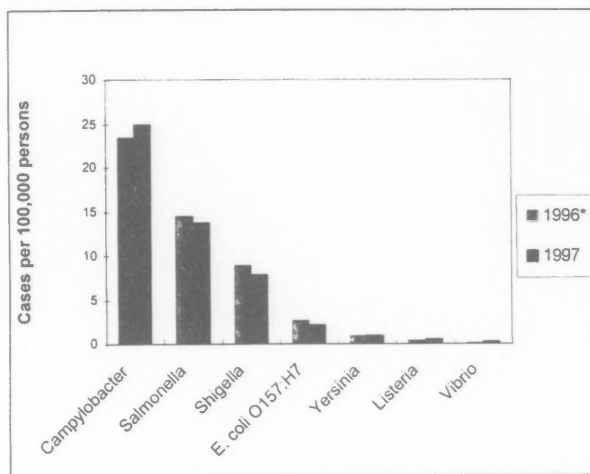
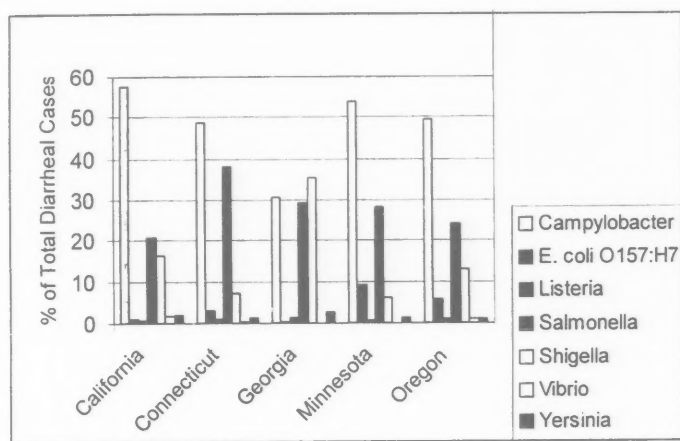


Figure 2. Percent pathogen by site



INTRODUCTION

The foodborne disease component of the CDC's Emerging Infections Program (EIP) is known as the Foodborne Disease Active Surveillance Network, or FoodNet. FoodNet is a cooperative effort between the CDC, United States Department of Agriculture (USDA), Food and Drug Administration (FDA), and national EIP sites. EIP sites consist of local health departments, academic insti-

tutions and organizations of health professionals. The initial goals of FoodNet were to (1) better assess the incidence of foodborne disease in the U.S., (2) identify specific foodborne diseases that are associated with specific foods or other exposures, and (3) provide a network to allow for a rapid and cooperative response to foodborne disease outbreaks (3). Additionally, data from subsequent years will be used to

evaluate whether new food safety programs (e.g., HACCP implementation by meat and poultry processors) has an affect on the incidence of foodborne illness (5).

The problem of underreporting cases of foodborne illness in "passive" or self-reporting surveillance systems is significant (5, 6, 7). Unlike passive surveillance systems, which rely on the voluntary reporting of foodborne illnesses (by physicians, other health care providers, and health departments), FoodNet is an active surveillance system in which public health officials regularly contact EIP sites to identify potential cases of foodborne disease. FoodNet tracks the incidence of diarrheal disease associated with the isolation of seven primary foodborne pathogens: *Campylobacter*, *E. coli* O157:H7, *Salmonella*, *Shigella*, *Listeria*, *Vibrio*, and *Yersinia*.

The collection of FoodNet data began January 1, 1997. A summary of the 1996 data has previously been published (4). In 1996, FoodNet data was collected from five sites (the states of Oregon and Minnesota, and selected counties in California, Georgia, and Connecticut). Data from 1997 includes additional counties in Connecticut and Georgia. Also in 1997, data collection for illness caused by the parasites *Cyclospora* and *Cryptosporidium* began in four sites.

METHODS

Preliminary data from the USDA's April 1998 report to congress entitled "FoodNet: An Active Surveillance System for Bacterial Foodborne Disease in the United States" was reviewed and summarized in the subsequent sections. The survey period covered January 1, 1997, to December 31, 1997.

RESULTS

The population total for the 1997 survey was 15,926,304 persons (based on 1996 census figures). The total population base increased 11% from 1996 because of the addition of

Figure 3. Seasonal variation

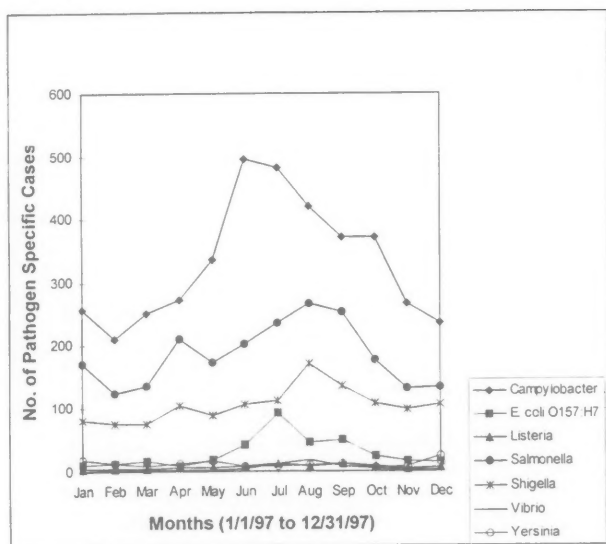
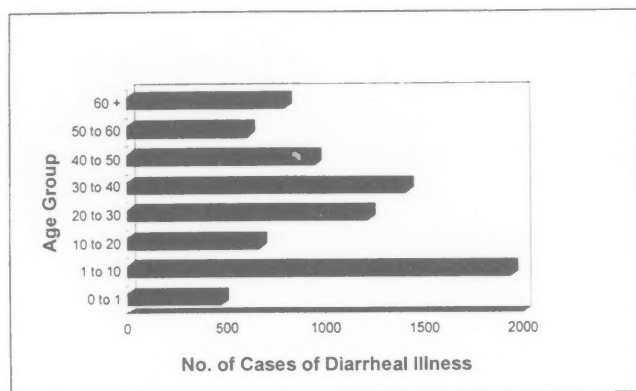


Figure 4. Age distribution for all pathogens



counties in Connecticut and Georgia. The number of laboratory-confirmed diarrheal cases associated with the isolation of the seven bacterial pathogens was 8,031 in 1997, compared with 7,322 in 1996. Although this represented an increase of 709 cases (9.6%), when adjusted for the increased population surveyed, the rate per 100,000 persons actually decreased from 51.3 in 1996 to 50.4 in 1997. A total of 517 cases of illness were associated with the two parasites (468 *Cryptosporidium* and 49 *Cyclospora*).

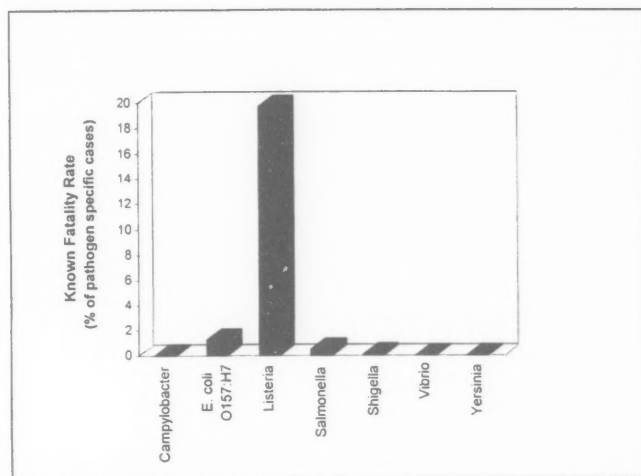
During 1997 as well as 1996, *Campylobacter* was the most frequently isolated target bacterium isolated from cases of diarrhea, followed by *Salmonella*, *Shigella*, *E. coli* O157:H7, *Yersinia*, *Listeria*, and *Vibrio* (Fig. 1). Figure 2 depicts the percent of diarrheal cases per EIP site in which the respective pathogens were identified. *Salmonella* was the second most commonly isolated pathogen in diarrheal cases at all sites except in Georgia. Where *Shigella* was the second most commonly isolated pathogen. Similar to the

pattern seen with the 1996 data, a seasonal variation was demonstrated, with an increase in the isolation of most of the pathogens during the summer months (Fig. 3). The exception to this trend was the isolation of *Yersinia* from more diarrheal cases during December, January, and February than during the next highest three-month period of March, April, and May (53 versus 29 cases, respectively). Figure 4 shows the distribution by age of diarrheal cases from which the target pathogens were isolated. The 1997 distribution was similar to that of 1996, with the greatest number of cases involving children between one and ten years. Depicted in Fig. 5 is the number of known deaths as a percent of the total number of pathogen-specific cases. Of the total 33 known deaths in 1997, *Listeria* was isolated from 45% of the cases, followed by *Salmonella* (36%) and *E. coli* (12%). In comparison, of the total 34 known deaths in 1996, *Salmonella* was isolated from 47% of the cases, followed by *Listeria* (26%), and *Campylobacter* (12%). The total number of known deaths per 100,000 population in 1997 (0.21) was similar to that seen in 1996 (0.24). It is important to note that the deaths may or may not have been caused by the pathogen rather than an underlying illness. In addition, no outcome was known in 20% of the cases.

DISCUSSION

Data pertaining to FoodNet will continue to be collected over a number of years in order to observe and establish trends and to attempt to evaluate the effectiveness of control strategies. FoodNet data will also be used for other surveillance strategies to better understand the extent and etiology of foodborne illness. With regard to additional plans for FoodNet, starting in January of 1998 all sites are scheduled to begin surveying cases of diarrheal

Figure 5. Known fatality rate for pathogen positive persons



disease associated with the isolation of *Cryptosporidium* and *Cyclospora*. Population surveys and case-control studies are being conducted on the above data to identify specific behaviors, such as types of foods consumed and preparation practices, that are associated with development of pathogen-specific illnesses. In 1998, seven counties in the state of New York and five counties in Maryland will be added to the survey population base.

The true occurrence of foodborne disease and its burden to health

and economics continues to be an area of controversy and debate. One of the limitations to obtaining this information is the lack of sufficient surveillance support and information (1, 2). FoodNet is a step toward the development of appropriate surveillance programs that will ultimately provide the data necessary to assess the impact of foodborne illness and provide direction for prevention and control measures. Since the preparation of this manuscript other information on the FoodNet 1997 data has been reported (3). In addition, the

1997 FoodNet summary report is now available on the World Wide Web at www.cdc.gov/ncidod/dbmd/foodnet/foodnet.htm.

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BASIC SANITARY CRITERIA FOR FOOD AND DAIRY EQUIPMENT

Thomas M. Gilmore,¹ Lyle Clem,² and Vince Mills³

SUMMARY

The basic criteria for hygienic food and dairy equipment to meet U.S. expectations follow. Guidelines for material selection, fabrication, and design are included. These basic criteria can serve as an informal inventory of sanitary criteria that should be accounted for when reviewing equipment. The criteria are largely based on those found in 3-A Sanitary Standards but also refer to those of the European Hygienic Equipment Design Group. These basic design features should be included in standards used for specific processes and products.

INTRODUCTION

The sanitary or hygienic design of dairy and food processing, handling, and packaging equipment (hereafter, "equipment") is the equipment manufacturer's obligation. The obligation may also be considered a trade obligation, a moral obligation, and, of course, the requisite legal obligation. Self-interest and pride are also motivating forces for suppliers to provide sanitary equipment.

The desire and indeed the requirement for the food industry is to provide wholesome, clean products that are free from health hazards, so that as a result, consumers have trust in the plants and personnel processing the food they consume; this, in turn, is good for trade. Companies rely on their reputations and are morally obliged to uphold consumer trust. There is also the obvious legal obligation to protect their customers and ultimately the consumer by constructing equipment that improves the quality and assures the safety of products ultimately sold for consumption. In instances where health and safety of food products is in doubt, litigation often entangles processors, equipment manufacturers, marketers, and anyone else associated with the particular products. Results of these proceedings may be very damaging, in some cases causing a company to cease operating altogether. Due dili-

gence exercised by manufacturers to meet legal requirements, maintain high sanitary design standards, and keep thorough records of production will pay dividends of high consumer trust and enhanced ability to compete in the marketplace.

This article will outline the basic sanitary criteria and can serve as an informal check list of sanitary criteria that form the essential framework of 3-A Sanitary Standards. The individual 3-A Sanitary Standards and 3-A Practices should be consulted for details. Currently, there are 63 3-A Sanitary Standards for various types of equipment and nine 3-A Accepted Practices covering as many systems.

OBJECTIVES

The objectives of 3-A Sanitary Standards or any other hygienic guidelines are to provide criteria applicable to food and dairy equipment to insure that: (1) it is either cleanable by circulating chemical solutions and water rinses, manually (after complete or partial disassembly) using chemical solutions and water, or cleanable by a combination of these methods; (2) the product contact surfaces can be easily inspected; and (3) the product is protected from contamination. In short, the public health protection of product contact surfaces is the main concern, and 3-A Sanitary Standards are written with these objectives paramount, using the best available technology. By suitable understanding and application of these principles, the manufacturer can fabricate equipment meeting state-of-the-art hygienic criteria.

The following discussion is limited to general sanitary specifications for equipment. It is mainly concerned with the intimate substantive criteria for product contact surfaces.

DEFINITION OF TERMS

To understand the basic sanitary criteria in this article, definitions of terms commonly used in 3-A Sanitary Standards are necessary. Surfaces are defined as follows:

- "Product contact surfaces shall mean all surfaces which are exposed to the product and surfaces from which liquids or materials may drain, drop, diffuse, or be drawn into the product."

- "Solution contact surfaces shall mean the interior surfaces of the equipment or system which are used exclusively for supply and recirculation of cleaning and/or sanitizing solutions, except those used to supply concentrated cleaning and/or sanitizing materials to the point of use."
- "Splash contact surfaces shall mean other nonproduct contact surfaces that during normal use are subject to accumulation of soil and which require routine cleaning."
- "Nonproduct contact surfaces shall mean all other exposed surfaces."

The following definitions found in 3-A Sanitary Standards are unique to usage in the United States:

- "Mechanical cleaning or mechanically cleaned shall mean soil removal by impingement, circulation, or flowing chemical detergent solutions and water rinses onto and over the surfaces to be cleaned by mechanical means in equipment or systems specifically designed for this purpose."
- "Cleaned in place (CIP) shall mean mechanical cleaning of equipment, the cleanability of which has been sufficiently established such that all product or solution contact surfaces do not have to be readily accessible for inspection (for example, silo-type tanks or welded pipelines)."
- "Manual (COP) cleaning shall mean soil removal when the equipment is partially or totally disassembled. Soil removal is effected with chemical solutions and water rinses with the assistance of one or a combination of brushes, nonmetallic scouring pads and scrapers, high or low pressure hoses and tank(s) which may be fitted with recirculating pump(s), and with all cleaning aids manipulated by hand."

CIP cleaning is considered a special case of mechanical cleaning of equipment that cannot be dismantled, so that only representative product contact surfaces are exposed for visual inspection and verification of cleaning effectiveness. In contrast, mechanical cleaning of equipment, although done by circulating fluids, requires periodic disassembly to expose all or nearly all of the product contact area for visual inspection.

Additional terms related to equipment design are the following:

- "Close coupled shall mean mating surfaces or other juxtaposed surfaces that are less than twice the nominal diameter or cross section of the mating surfaces or a maximum of 5 in. (127 mm)."
- "Corrosion resistant shall mean the surface has the property to maintain its original surface characteristics for its predicted service period when exposed to the conditions encountered in the environment of intended use, including expected contact with product and cleaning, sanitizing, or sterilization compounds or solutions."
- "Dead end shall mean an area or space wherein a product, ingredient, cleaning, or sanitizing agent,

or other extraneous matter may be trapped, retained, or not completely displaced during operational or cleaning procedures."

- "Easily or readily accessible shall mean a location which can be safely reached by an employee from the floor, platform, or other permanent work area."
- "Readily or easily removable shall mean quickly separated from the equipment with the use of simple hand tools if necessary."
- "Simple hand tools shall mean implements normally used by operating and cleaning personnel such as a screwdriver, wrench, or mallet."
- "Substantially flush shall mean mating surfaces or other juxtaposed surfaces shall be within 1/32 in. (0.794 mm)."

MATERIALS

The selection of corrosion-resistant, nonabsorbent, and nontoxic materials suitable for the environment of intended use is the prerequisite to fabricating hygienic food and dairy equipment. Most 3-A Sanitary Standards contain the following criteria as suitable for the majority of the product contact area:

"Product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI) 300 Series¹ or corresponding Alloy Cast Institute (ACI) types², or metal which under conditions of intended use is at least as corrosion resistant as stainless steel of the foregoing types, and is nontoxic and nonabsorbent."

The following allowance is made when 300 Series Stainless Steels are not functionally suitable:

"Optional metal alloy may be used in specified areas of the equipment, but only in applications requiring disassembly and manual cleaning."

The AISI 300 Series Stainless Steels are frequently selected as the metal of choice in the manufacture of food processing equipment. Type 304 Stainless Steel is most prevalent, with Type 316 or Type 316L being selected for use in moderate to corrosive environments. Where welding is done, carbon content should not exceed 0.08% and, although not currently covered in 3-A Sanitary Standards, sulfur content should not exceed 0.03%.

The criteria as worded allow metals equivalent to the AISI 300 Series to be used. Table 1 is a listing of typical equivalent metals. To use metals other than the AISI 300 Series, ACI types, or those in Table 1, it is incumbent upon the fabricator to verify the required equivalence or to assure that the requirements for nontoxicity, nonabsorbency, and corrosion resistance have been met.

In addition to the above, electroplating with chromium and nickel is allowed on specified components when necessary for functional reasons. The use of "dairy metal" or nickel-bronze alloy is prohibited.

Certain nonmetals may be used for product contact where necessary for functional reasons and only on specified components. For rubber and plastic materials, there are 3-A Sanitary Standards that these materials must meet.

TABLE 1. Optional Metal Alloy³

Optional metal alloys having the following compositions are examples considered in compliance with Section C1.1 herein. (Percentages are maximum unless range is given.)

	UNS N08367	UNS S21800	UNS S20161	UNS N26055	UNS N26455	UNS S17400	UNS S15500	UNS S32900	UNS R20500	UNS R50400
	ASTM A743 Grade	ASTM A743 Grade		ASTM A494 Grade	ASTM A494 Grade	ASTM A747 Grade	ASTM A747 Grade		ASTM A560 Grade	ASTM B67 Grade
	CN-3MN	CF-10 SMnN		CYSSnBIM	CW-2M	CB7Cu-1	CB7Cu-2		50Cr-50Ni	C-2
C	0.03	0.10	0.15	0.05	0.02	0.07	0.07	0.20	0.10	0.10
Mn	2.00	7.00-9.00	4.00-6.00	1.5	1.00	0.70	0.70	1.00	0.30	
Si	1.00	3.50-4.50	3.00-4.00	0.5	0.80	1.00	1.00	0.75	1.00	
P	0.040	0.040	0.040	0.03	0.03	0.035	0.035	0.040	0.02	
S	0.010	0.030	0.040	0.03	0.03	0.03	0.03	0.030	0.02	
Cr	20.0-22.0	16.00-18.00	15.0-18.0	11.0-14.0	15.0-17.5	5.50-17.7	14.0-15.50	23.0-28.0	48.0-52.0	
Ni	23.5-25.5	8.00-9.00	4.00-6.00	Balance	Balance	3.60-4.60	4.50-5.50	2.50-5.00	Balance	
Mo	6.0-7.0			2.0-3.5	15.0-17.5			1.00-2.00		
Cb						0.15-0.35	0.15-0.35			
Cu	0.75					2.50-3.20	2.50-3.20			
N	0.18-0.26	0.08-0.18	0.08-0.20			0.05	0.05		0.30	
Fe	Balance	Balance	Balance	2.00	2.00	Balance	Balance	Balance	1.00	0.30
Sn				3.0-5.0						
Bi				3.0-5.0						
W					1.0					
Ti									0.50	Balance
Al									0.25	
Other										H = 0.015 N = 0.03 O = 0.25

Metal alloys or metals other than the above may be as corrosion resistant as 300 Series Stainless steel. This may be shown when metal alloys or metals are tested in accordance with ASTM G31 Laboratory Immersion Corrosion Testing of Metals and have a corrosion rate of less than 10 mil per year. The test parameters such as the type of chemical(s), their concentration(s), and temperature(s) should be representative of cleaning and sanitizing conditions used in dairy equipment. Alloys containing lead, leachable copper, or other toxic metals should not be used.

FABRICATION

This section considers design features necessary to insure that product contact surfaces are cleanable, drainable, and inspectible, and that the equipment product from contamination. The most important fabrication criterion is surface finish or, more correctly, surface texture. A suitably smooth finish is synonymous with the ability for unwanted soil to be removed from a surface. For food and dairy equipment, field experience has demonstrated that a finish at least as smooth as a No. 4 finish on stainless steel sheets that are free of surface imperfections is acceptable. There are various methods to meet the No. 4 requirement. One is successive polishing to a final finish as obtained with 150 grit silicone-carbide. A combination of grit finish and electropolish may be used or another method so long as the finish is equivalent to a No. 4. An additional quantitative specification on finish is a maximum roughness average (R_a) of 32 microinch or 0.80 micron. A 2B cold rolled finish is acceptable so long as the final fabricated form is free of imperfections.

The preferred method of joining metallic components is by butt welding (Fig. 1). The welded area and deposited weld metal shall be as substantially corrosion resistant as the parent metal and welded areas on product surfaces must be as smooth as the parent material, i.e., No. 4 finish (32 microinch or 0.80 micron R_a). This means grind-

Figure 1. Square corner/radius



ing is usually required to produce a flush, smooth joint. If welding is not possible, interference fits may be used, but they must also produce a finish at least equivalent to a No. 4 and be free of imperfections.

Sanitary stainless steel tubing joined by butt welding is a particular challenge, because the product contact surface of the finished welded joint cannot be polished. For sanitary applications, Gas Tungsten Arc Welding (GTAW) commonly referred to as TIG (Tungsten Inert Gas) welding, is the most appropriate process for sanitary welds for equipment and pipework. The welding procedures, whether manual or automated orbital, must insure uniform and complete penetration of the welded surfaces. Penetration of the root head into the bore shall be kept to a minimum. Unpolished TIG welds of high quality have surface roughness of 3 to 4 micron R_a , whereas values of 7 to 8 micron R_a are more likely on industry standard

Figure 2. Internal angles and corners

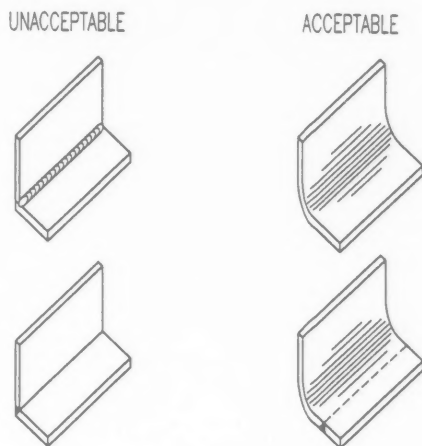


Figure 3. Permanent joints – welded

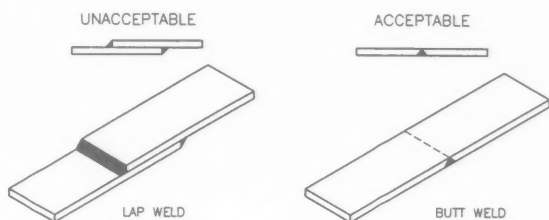


Figure 4. Drainage of vessels

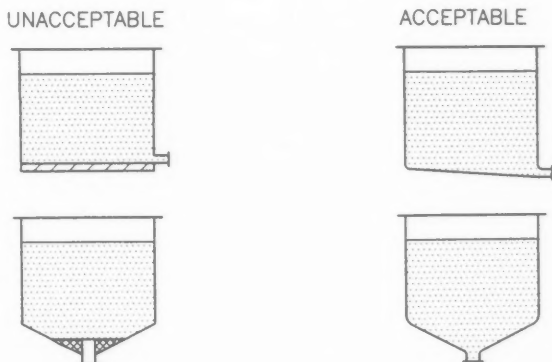


Figure 5. Drainage of pipes

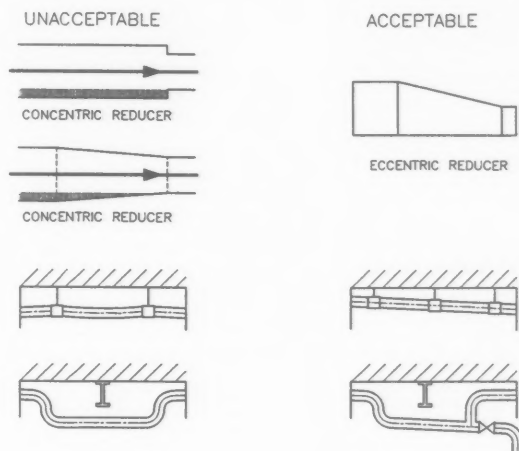
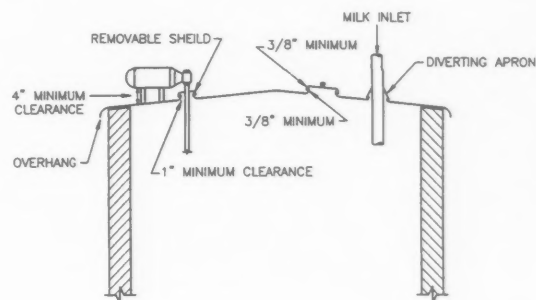


Figure 6. Acceptable shields and covers



welds. Welds with these higher values, which are higher than ideal, may require additional time to be mechanically cleaned. Welds with roughness of $R_a > 8$ micron are not acceptable for hygienic application.

A major concern for the processor and fabricator is ability to clean and inspect the equipment. In addition to the finish, the other important parameters to be considered are corners (angles), radii, drainage, ease of disassembly, shielding, use of springs and threads in contact with product and supports, and exterior surfaces (Fig. 2 and 3).

Being able to drain all product contact surface except for normal surface adherence is necessary. Ideally, all surfaces, including appurtenances and weldments should be self-draining; that is, drainable without operator intervention (Fig. 5). If this is not possible, then minimal interaction by the operator to cause drainage to occur is acceptable. Proper slope in piping, tank bottoms (Fig. 4) and bridges (Fig. 6) are necessary for proper drainage. If mounting of a valve or other appurtenance is crucial to draining, they should be labeled to show the correct mounting angle. Large flat surfaces are not acceptable.

TABLE 2. Groove radii dimensions for standard O-rings

O-Ring Cross Section, Nominal (AS 568 ⁴)	O-Ring Cross Section, Actual (AS 568)	O-Ring Cross Section, Actual (ISO 3601-1 ⁵)	Minimum Groove Radius
1/16 in.	0.070 in.	1.80 mm	0.016 in. (0.406 mm)
3/32 in.	0.103 in.	2.65 mm	0.031 in. (0.787 mm)
1/8 in.	0.139 in.	3.55 mm	0.031 in. (0.787 mm)
3/16 in.	0.210 in.	5.30 mm	0.062 in. (1.575 mm)
1/4 in.	0.275 in.	7.00 mm	0.094 in. (2.388 mm)

Because visual inspection is usually necessary and manual cleaning may be required at times, equipment and associated parts must be readily accessible and easily removable. The functional definitions previously stated are useful. Additionally, it is important that there be as few removable parts as necessary and that these should require few operations to dismantle. Ideally, dismantling can be done without tools. If tools are required, they should be limited to screwdrivers, wrenches, soft-faced mallet and pliers—that is to say, tools normally found in the processing area. Equipment designed to be frequently dismantled should not require the operator to search for special tools or utilize specialized mechanical skills.

Corners and radii are other concerns as they are used in the design and fabrication processes. First, let us define a corner, using mathematic concepts. An inside corner is one formed by the conjunction of two or more plane surfaces that form the angle(s) of less than 135°. An outside corner is one formed by the conjunction of two or more plane surfaces with exterior (nonincluded angle[s]) less than 225°. In general, it is the practice that inside angles are rounded and smooth, having radii as large as possible for practical operation and fabrication, and shall be so located as to be readily accessible for cleaning (Fig. 6 and 7). No minimum requirements are demanded for outside corners except that there be no sharp external edges. Examples of acceptable design technique for corners and radii are shown in Figures 1 and 2.

The radii requirements for inside angles of less than 135° may range from 0.75 in. (19.1 mm) where tank heads join the lining to 0.125 in. (3.18 mm) in other product areas. Usually, a 0.25 in. (6.35 mm) radius is the largest preferred one required for sanitary reasons. If smaller radii are required, they must be limited to specified areas of the equipment and usually require mechanical cleaning.

O-ring grooves and gasket grooves are also important to hygienic design. Typical sanitary O-ring grooves are listed in Table 2. In general, grooves in other gaskets shall be no deeper than their width and gasket retaining grooves shall not exceed 0.25 in. (6.35 mm) in depth or be less than 0.25 in. (6.35 mm) wide. The use of O-ring seals in the U.S. is accepted if they are properly positioned and the grooves machined to allow cleaning. This means the O-ring and its groove can be exposed to circulating cleaning solutions or manually cleaned. It is usually necessary to have movement of the seal, such as pulsing a valve stem,

Figure 7. Equipment supports and mountings

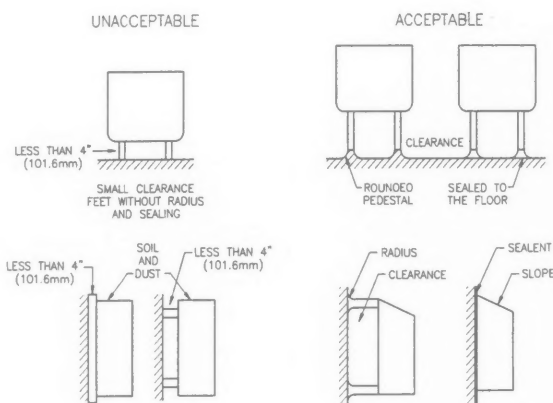
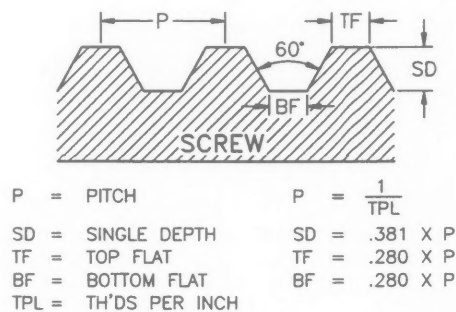


Figure 8. Acceptable Sanitary Thread



to mechanically clean O-rings. Static O-rings require manual cleaning. The European Hygienic Equipment Design Group (EHEDG), representing European hygienic interests, recommends against O-rings usage unless they give a flush, static seal and are mounted in such a way as to ensure to that the area of steel covered by the rubber on the product side is not influenced by thermal expansion. As stated previously, the preferred method of joining is welding, with nonpermanent joints used only when necessary.

Figure 9. Mounting of sensors

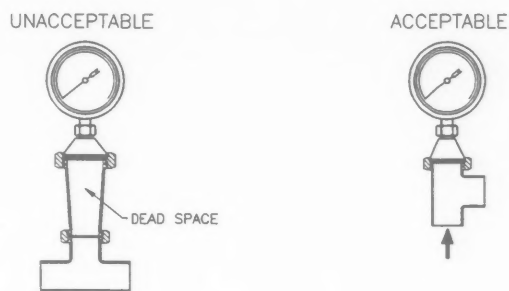
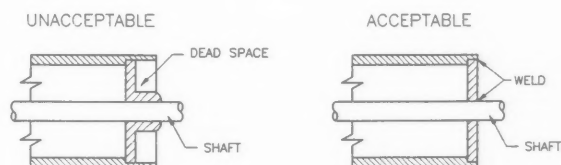


Figure 10. Conveyor roller construction



Threads shall not be used in contact with the product. There are a few exceptions to this, for example in pumps. If threads must be used, they shall be the American Standard Stub ACME Thread (Fig. 8). The threaded angles shall be not less than 60° and shall have not more than eight threads to the inch (25.4 mm), nor less than 0.625 in. (15.88 mm) major basic diameter. The length of the nut shall not exceed 3/4 of the basic thread diameter. The nut shall be of the open type. Equipment with these exposed threads must be designed for manual cleaning. Another acceptable option is to use enclosed threads, in which case thread type is optional.

The use of springs and bearings in product contact zones is at times unavoidable. If springs are used, they must be smooth and have at least 0.09375 in. (2.38 mm) opening between all coils when the spring is in the free position. Bearings, often a hygienic challenge, must be either sealed or self-lubricating bearings and should be located outside the product contact zone. If bearings must be in the product zone, one should use food-grade materials such as plastic or polytetrafluoroethylene polymers, which require no lubrication.

Mechanical seals are sometimes required on rotating shafts and are used in pumps. A project to develop 3-A Sanitary Standards for mechanical seals was initiated in October 1996. For now, mechanical seals with product contact should be nonabsorbent, nontoxic, and easily removable and cleanable.

Many food and dairy operations require agitation. Horizontal agitators shall be easily demountable and have a rotary seal. When removed, the sleeve through the vessel shall be free from obstruction and accessible. The vertical type may be removable. This agitator shall have accessible sanitary couplings and interior angles shall be

radius. When a bottom support is required, it shall not interfere with vessel draining and all surfaces of the bottom of the support shall be accessible for cleaning and inspection. The opening through the bridge or cover for the agitator shaft shall be of sufficient size to allow cleaning and shall be protected against the entrance of foreign material. Direct connected or nonremovable agitators shall have an annular space of at least one inch (25.4 mm) between the shaft and the inside diameter of the opening to the tank. The blades shall be so shaped and located to allow cleaning and visual inspection.

Because product contact surface definitions include "...and surfaces from which liquids may drain, drop...into the product," shielding is often necessary, especially if the product zone is open. When designing equipment, one needs to imagine the worst case scenario in determining where to locate shielding (Fig. 6).

Dead ends should be avoided if at all possible. If a dead end is unavoidable, it must be as short as possible. 3-A requirements, with one exception, specify that dead legs "...be not more than the smaller of twice the nominal diameter of the piping or inlet passage or 5 in. (127 mm)." The EHEDG recommends that, for pipe diameters of 25 mm or larger, the dead leg shall be less than 28 mm. For smaller pipe diameters, the dead leg should be smaller than the pipe diameter (Fig. 9). Close coupled valves follow the same 3-A recommendations.

Another potential harborage of organic matter is the shadow area. Shadow areas may be caused by misalignment or may be due to faulty design. Although not a dead leg, shadow areas do not allow for complete displacement of product or other liquids and hence are not cleanable. They may also not allow proper fluid contact during mechanical cleaning. The EHEDG has several test methods to evaluate in-place cleanability and are useful in identifying dead legs or shadow areas.

Equipment framing and supports should be simply designed to eliminate complex angles or inaccessible areas. The objective is to eliminate flat surfaces, cracks, crevices, or other depressions that can harbor organic residue (Fig. 7 and 10). It is also necessary to have sufficient clearance, usually 4 in. (101.6 mm), between the lowest part of the frame and the floor to allow for cleaning. If the equipment is permanently mounted, it should be sealed to the base and be located so as to provide a minimum clearance of one inch (25.4 mm) from the nearest adjacent part. Legs should be smooth, with rounded ends, and have no exposed threads. Legs made of hollow stock are sealed (Fig. 7).

Nonproduct zones are made up of exterior surfaces and other surfaces isolated from product contact as defined herein. These surfaces should be relatively smooth, without pockets or crevices, and nonabsorbent – that is, fabricated, finished, and arranged to prevent liquid or soil accumulation. These surfaces should be easy to clean. The materials should be corrosion-resistant or rendered corrosion-resistant. If painted or coated, the materials should be suitable for food contact and appropriate for the environment of intended use. All exterior surfaces shall be self-draining.

Although this article contains some design criteria for hygienic equipment, it is largely an attempt to provide the fundamentals from a goal-oriented perspective. The most important criteria are (1) selection of materials suitable for the product, process and cleaning regimen; (2) design and fabrication that allows all surfaces, especially product surfaces, to be cleaned and easily inspected; (3) design and installation to provide for self-draining or for being easily drainable; and (4) design and fabrication to protect the product. Because of the wide variety of products and processes, it is easy to see that many different types of equipment each requiring its own peculiar sanitary characteristics, are necessary. These differing sanitary characteristics are related to an understanding of the risks and microbial sensitivities of the products. It is therefore necessary to select the fundamentals that apply to a specific product and process and then choose the appropriate material and detailed design criteria from recognized sources.

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[‡]Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016; 708.299.9160.

[§]Metal alloys or metals other than the above may be as corrosion resistant as 300 Series Stainless steel. This may be shown when metal alloys or metals are tested in accordance with ASTM G31 Laboratory Immersion Corrosion Testing of Metals and have a corrosion rate of less than 10 mil per year. The test parameters such as the type of chemical(s), their concentration(s), and temperature(s) should be representative of cleaning and sanitizing conditions used in dairy equipment. Alloys containing lead, leachable copper, or other toxic metals should not be used.

[¶]The document establishing these standard dimensions is Aerospace Standard (AS) 568, published by SAE, 400 Commonwealth Drive, Warrendale, PA 15086; 412.776.4970.

^{¶¶}The document establishing these standard dimensions is ISO 3601-1: 1988 (E), published by the International Organization for Standardization (ISO), 1 Rue de Varembe, Case Postale 58, CH 1 1211, Geneva, Switzerland; 41.22.734.1240.

^{¶¶¶}This list is not to be considered complete.

^{¶¶¶¶}Both CEN and ISO are developing standards covering the hygienic design of equipment.

Reprinted from *Guelph Food Technology Centre Newsletter*, October 1998, Number Fifteen

Auditing Your Food Safety System

by Jane Dummer

The food service sector is very diverse; extensively documented quality management systems that conform to ISO 9000 standards are far less common than in food manufacturing. However, the food service sector is implementing food safety systems and HACCP principles in their operations. As you can imagine, you need a safe food before you can have a quality food, so it makes sense to build ISO on top of solid HACCP!

So, now that you have a Food Safety System and HACCP principles in place, how do you know it is working effectively? By conducting a Systems Audit.

What is an Audit?

A systematic and independent examination to determine whether activities and results comply with the documented procedures; also whether these procedures are implemented effectively and are suitable to achieve the objectives.

The benefits of auditing a Food Safety System include:

- providing documented evidence of due diligence in managing food;
- an independent and objective review of the effectiveness of your system;
- maintaining confidence in the system through verifying the effectiveness of the controls;

- identifying areas for improving and strengthening the system; and
- reinforcing awareness of food safety management.

How do you Conduct a Systems Audit?

The purpose of a systems audit is to find any weakness in the system and to ensure that corrective action is taken. This will entail taking a thorough, systematic and independent review of all or part of the Food Safety System.

1. **Record reviews** including sanitation, food safety training, equipment calibration and HACCP records.
2. **Analyzing records** to determine if food safety is in control.
3. **Review the facility** to determine if the records are in compliance with what is actually happening on the floor.
4. **Review documentation** uses in process.
5. **Communicate the results** to the facility both verbally and in a formal written report.
6. **Obtain** corrective action dates.
7. **Closing** meeting.

At the end of the seven steps of a systems audit you will be better able to ensure that your food safety plan achieves your policy and activity objectives, and that your food safety system meets the requirements of your customers.

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Organized by the International Life Sciences Institute North America (ILSI N.A.)
and the ILSI N.A. Technical Committee on Food Microbiology
In Collaboration with CDC, FDA, IAMFES, NIH, and USDA
October 14-16, 1998, Arlington, Virginia

SUMMARY REPORT: A PERSONAL PERSPECTIVE

Prepared by Michael Brodsky

Ontario Ministry of Health, P.O. Box 9000, Terminal A, Toronto, Ontario, Canada M5W 1R5

Approximately 250 food safety professionals from around the world attended this 3-day conference. There was a limited amount of new information for those of us who have been intimately involved with these issues for the past few years. But those who are newly exposed certainly had their eyes opened.

The issues associated with trying to reasonably assess the magnitude of the public health problem were addressed in the first session, which I co-chaired. All speakers made the quiet assumption that clinically confirmed cases of gastroenteritis were foodborne. There was no attempt by anyone to actually define "foodborne" in terms of relating the etiological agents of clinical illness to food isolates. An active surveillance program such as FoodNet, with strategically located sentinel sites, appears to be the most reasonable way of gathering data on gastrointestinal (aka foodborne) illness on a national scale. The limitation, of course, is that one must still extrapolate the data from a limited number of sites in order to assess the national picture. The numbers obtained, however, are still estimates. The importance of having a stronger collaboration between epidemiology and public health laboratories was emphasized by many speakers. Experience has shown that health agencies need to rely more heavily on epidemiological data and be less reliant on laboratory data when making decisions about removing

suspect hazardous food from the marketplace. The data generated by food analysis, even when using extensive sampling plans is often unreliable due to a variety of factors including: the heterogeneous distribution of the organisms in the products, the nature of the etiological agent, the virulence characteristics of the organism and the availability of reliable methods for isolation and identification. Dr. Andrew Plaut from Tufts School of Medicine gave a most interesting presentation on the clinical pathology of foodborne (gastrointestinal) illness. We should hear more presentations like this.

The second session focused on case studies and the difficulties of trying to definitively relate foodborne illness to a specific type or lot of food product. The lack of communication between various agencies, individuals and organizations involved in investigation and trace backs was cited a number of times as a critical impediment to minimizing the spread and achieving a successful and timely resolution of foodborne outbreaks.

Following this session, there was a somewhat formal discussion on the creation of "The Food Safety Risk Assessment Clearing House." This clearing house is being guided by the Food Safety Initiative Risk Assessment Consortium and is being developed by the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). The intent of the clearing house is to compile and consolidate microbial data from government, academia and industry

sources and to make such information available to risk assessors. There was a lively discussion on incentives for data submission, confidentiality, accessibility, reliability and usefulness of such information. For more information, the Food Safety Risk Assessment Clearing House can be accessed at their Web site: www.life.umd.edu/jifsan.



The second day began with a session using specific examples of *Salmonella enteritidis* in eggs and *Escherichia coli* O157:H7 in ground beef to illustrate the benefits of using molecular typing and PulseNet for linking food microbial data to human health. The application of this technology to the emerging waterborne parasitic agents, *Cryptosporidium* and *Giardia* was also discussed. The need for dose response data for risk assessment was discussed by a number of the speakers.

This session concluded with a panel of risk assessors. Each member of the panel was given about 10 minutes to summarize their thoughts with respect to exposure and dose-response assessment. Concerns were expressed about the quality of the available data. Many felt much of the information was incomplete or inaccurate and rarely included any information on the variability of the data. A number of speakers suggested that better use should be made of predictive modelling to get a better understanding of microbial ecology and physiology. The paradigm of microbial risk assessment is complicated by etiological agents with differing virulence characteristics, the lack of available animal models, the role of the carrier status of food handlers, acquired immunity of human hosts to low dose exposure and hence exposure without illness and the need for a more reliable means to identify sensitive sub-populations. Surveillance data is still critical, but, in any communication to the public at large, these limitations must be recognized so that expectations are not exaggerated.

The afternoon session of the second day (session 4) addressed the role of microbial testing in HACCP from the perspective of academia, government and industry and was followed by a panel discussion. There was general agreement that microbiological data was needed to verify HACCP plans and to validate critical control point outcomes. In this context, indicator or index organisms

may be more appropriate than analyses for specific pathogens for CCP assessment. Similarly, end product testing for critical pathogens of concern, following a reasonable sampling plan, may still generate useful information for the microbiological safety of the overall process. Defining appropriate CCPs and establishing reasonable food safety objectives were seen as critical issues in developing successful HACCP plans. In addition, obtaining accurate data using reliable methods was paramount in order to establish a link between risk assessment and HACCP.

Current analytical methods and future prospects were addressed on the third day in session 5. It was evident that without proper sampling plans, even the most sensitive of methods is doomed to failure in terms of providing reliable data. Methods that are too specific e.g. focused on *E. coli* O157:H7, may not be sensitive enough to detect related microbial pathogens, such as other Shiga toxin producing *E. coli* (STEC). It is evident that more rapid, real-time, microbiological analyses are needed if we are going to optimize the availability of useful data for on-line risk assessment. In this regard, the development and use of biosensors for controlling HACCP plans through continuous CCP validation appears to be the way of the future.

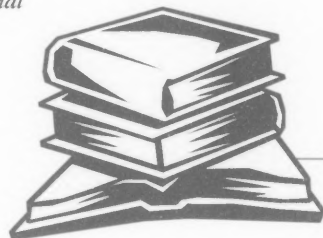
The conference concluded with a panel discussion on future research and development needs. Panelists gave their views on data and knowledge gaps and hence needs, based on what they had heard during the conference and their own experience. The need for more reliable microbial data upon which to base scientific decisions for risk assessment was reiterated by a number of panelists. Such information is predicated on developing new or improving current analytical methods, having a better understanding of microbial ecology and adaptation and the develop-



ment of appropriate animal models. It will also be critical to define "acceptable risk." As a final comment, the National Academy of Sciences has prepared a report to the U.S. Congress recommending the establishment of a single food safety agency to coordinate the 12 agencies and 35 primary statutes which are responsible for food safety enforcement in the United States. It will be interesting to see what they have learned from the Canadian experience.

Book reviewed by: Ebenezer R. Vedamuthu, Ph.D., Chief Microbiologist, Quest International Flavors & Food Ingredients Co., Rochester, MN

Book Review



Lactic Acid Bacteria

Edited by: Seppo Salminen and Atte Von Wright

Lactic acid bacteria, which have been almost a preserve of dairy microbiologists over the past several decades have come to occupy center stage in microbial research since the pioneering work of Dr. Larry McKay in the 1970s on the physiology and genetics of these important group of microorganisms. The "adaptive physiological and genetic traits" acquired by their transition from their natural habitats (mainly plant and vegetable material) to their unique ecological niches in which they are now found and used (for example milk, enteric microbiota, and fermentations) have conferred a variety of genetic elements within these bacteria (plasmids, insertion sequences, interons and bacteriophages) to cope with their "adaptive challenges." With the advent of biotechnology, and modern analytical and computational tools, interest in unravelling the genetic and physiological organization in this group of bacteria has created a world-wide impetus to research on lactic acid bacteria. The industrial and possible medical significance of lactic acid bacteria have further added to these efforts. The "information explosion" that has been the fall-out of intense research on lactic acid bacteria has spawned a spate of symposia, reviews, treatises and books on these bacteria. The book under review, a second expanded and updated edition presents the current knowledge on lactic acid bacteria from a unique perspective.

The book under review has 19 chapters, of which 10 deal with probiotic aspects of lactic acid bacteria in humans and animals. So, the major portion of the book is devoted to probiotic characteristics of these bacteria. The subject matter is covered thoroughly and extensively. Although there is considerable overlap in the various chapters, the book brings together cogently widely scattered information that will be of immense value to students and researchers interested in probiotics. The chapter on the potential of propionibacteria as probiotic supplements will stimulate research on novel applications for these bacteria. The chapter on *Lactobacillus reuteri* contains a lot of unpublished material, that will be of interest to those working in poultry probiotics, especially in the light of recent commercial introduction of mixed culture probiotic spray for poultry, based on USDA sponsored studies. Many of the studies reported in that chapter, however, have not included other possible lactic acid bacterial candidates as a parallel comparison to really prove the unique probiotic efficacy of *Lactobacillus reuteri* that the authors wish to convey.

The chapters dealing with the classification and physiology and bacteriophages are excellent and summarize the recent developments in an elegant style. Antimicrobial components derived from lactic acid bacteria have considerable industrial and research significance. Research in this

area has exploded and several reviews and books have appeared exclusively on this subject. The chapter dealing with this subject is brief and has not adequately covered the entire spectrum of research related to structure, function, mechanism of action, genetics, possibilities in engineering hybrid bacteriocins, mechanisms of resistance developed by susceptible microorganisms, protein engineering to extend the spectrum of activity and applications in protection of foods against pathogenic, and/or spoilage flora, and extension of shelf-life. Because of the availability of several recent books and symposia proceedings on bacteriocins and genetics of lactic acid bacteria (Chapter 6), the editors have justifiably chosen to present these aspects in brevity. The weakest chapters in the book are Chapters 2 and 3. The chapter on "Industrial use and production of lactic acid bacteria" does not cover the industrial

production of starters adequately. Much of this information is found in patent literature, and this valuable source of information has not been included. Several grammatical and spelling errors appear in this chapter. Chapter 3 contains a few factual and spelling errors in Table 1 and in the text. The importance of handling cultures in ensuring plasmid stability in starter strains which is often reflected in lack of functionality is not brought out in the discussion. Recent developments in the expression of stress proteins and their possible role in the function of starters under adverse conditions and practical measures to manage phage-related instability of fermentations and manufacturing processes are not covered.

The book on the whole is a valuable addition to the growing literature on lactic acid bacteria, and is an especially noteworthy contribution to the nascent field of "scientifically credible" probiotics.

For copies of *Lactic Acid Bacteria*—

Mail requests to: Morcel Dekker, Inc., 270 Madison Ave., New York, NY 10016-0602; Phone: 212.696.9000; Fax: 212.685.4540.

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- ◆ Animal Waste Management and Its Relationship to Food Safety
- ◆ A Dairy Plant HACCP Program
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New IAMFES Sustaining Member

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UpDates

Osmonics Names New General Manager

Osmonics has named Robert Geiselman General Manager of the company's Minnetonka Operations, its largest manufacturing facility. Geiselman will take on responsibility for all manufacturing, production control, purchasing, sustaining product engineering, and facilities operations associated with the Minnetonka site.

Geiselman served as a Manufacturing Manager, Process Engineering Manager, and Engineering Manager for the Measurement Division of Rosemount, Inc. He also held positions with Sperry Semiconductor Operations and Motorola.

Geiselman holds bachelor degrees in chemistry and chemical engineering from the University of Minnesota, Duluth, and the University of Minnesota, Institute of Technology, respectively. He also earned an MBA with an emphasis in manufacturing systems engineering from the University of St. Thomas.

Dorner Names Lucas to Lead Standard Products Division

Dorner Mfg. Corp. has announced the appointment of Scott W. Lucas as President of its Standard Products Division.

In his new capacity, Lucas will head sales, marketing, engineering, and operations pertaining to the company's broad lines of low-profile conveyors and accessories for numerous parts handling applications. The company's

conveyors are widely used in metalworking, assembly, automated production and packaging applications worldwide.

Lucas joined Dorner Manufacturing in 1994 and most recently served as the company's Vice President of Marketing and Sales. He also has more than 17 years of marketing and management experience, having served as Vice President of Sales/Marketing and General Manager of the Production Automation Division of the Enerpac unit of Applied Power Inc., Butler, WI.

Busch Joins Bell Laboratories as Inside Technical Sales Representative

Sara Busch joined Bell Laboratories' sales and marketing team recently as an Inside Technical Sales Representative.

Busch provides sales support to Bell in-house accounts and to other Bell distributors and PCOs, as needed. She serves as a resource for technical questions from PCOs and follows up on inquiries generated from Bell's advertising program.

Busch also coordinates the sales activities of Bell's outside technical representatives, including scheduling and providing them with materials for PCO training seminars, distributor trade shows and related conferences. She also assists them with customer requests for product and product information. In early 1999, Busch will provide technical sales support for Bell accounts in Canada.

Universal Flavors Names Vice President and Sales Director

Universal Foods Corporation has appointed William Beglin as Vice President-General Manager, Food and Beverage USA. Beglin, who joined Universal Flavors in 1996 from G.D. Searle's NutraSweet division, most recently served as Vice President, Operations.

Bob Burns has been appointed as Director Sales, Food and Beverage USA at its Indianapolis-based Universal Flavors division. In his new role, Burns will be responsible for the development and execution of the sales revenue and objectives supporting the Universal Flavors Food and Beverage group.

Vidlock Named to Head ADPI Cheese Division

Gary Vidlock has been named to direct the Cheese Division of the American Dairy Products Institute. The announcement was made jointly by Larry L. Claypool, President, American Dairy Products Institute and Kevin J. Ruda, Cheese Division Chairman.

Vidlock will join the Institute from his current position as Director of Cheese Sales for Dairy Farmers of America, Inc. Previously, he was employed with Waterford Food Products, Inc. and Michigan Milk Producers Assn. Vidlock is a graduate of the University of Wisconsin-Eau Claire, where he majored in business management. Vidlock succeeds Richard K. Smith, who retired as Cheese Division Director.

Schroeder Heads R&D Efforts at DFA's "Technology Center"

Dr. Craig Schroeder, Ph.D. has been named Vice President of research and development and quality assurance for Dairy Farmers of America (DFA). Schroeder was promoted to spearhead DFA technology, product development and quality assurance efforts at the cooperative's research and development facility, now sporting the new name, DFA's "Technology Center."

The Technology Center, located in Springfield, MO, is a state-of-the-art laboratory and testing facility that offers product innovation and research and development services supporting DFA manufacturing groups and customers. The facility houses R&D laboratories, a small scale pilot plant that allow scientists to perform all current plant processes, "customer-friendly" offices for client use, and a sensory lab for consumer testing.

The Iowa native says his greatest challenge is to build upon the strengths that already exist within DFA's R&D team and to capitalize on exciting new opport-

unities available through DFA, its customers and its joint venture relationships. He says those initiatives lead to the center's name change from Product Development Center to Technology Center.

Alfa Laval Flow Inc. Names Vice President and General Manager of Industrial Valve Division

Alfa Laval Flow Inc., has named Brian Tripoli Vice President and General Manager, Industrial Valve Division.

G&H Products Corp., of Pleasant Prairie, WI; Alfa Laval Pumps, of Kenosha, WI; and Alta Laval Saunders, of Houston, TX, will come together to form Alfa Laval Flow Inc. The new company's headquarters will be at the present location of G&H Products.

Tripoli is the current President of Alfa Laval Saunders Inc. He began working at Alfa Laval Saunders in 1984 as a Regional Sales Manager. Tripoli became the company's Business Development Manager for industrial valve products in 1991 before becoming President in 1995. He has been in the valve

distribution business for more than two decades.

Rick Murtaugh Promotion to Senior Technical Support Specialist

Hydro Systems and NOVA Controls are pleased to announce the appointment of Rick Murtaugh to the newly created position of Senior Technical Support Specialist for NOVA products.

In this new position, Rick will be responsible for leading comprehensive training programs relating to the installation, operation and maintenance of the full line of NOVA Controls products. Rick will be available for training and technical support for NOVA customers in the field, and will lead and organize training sessions at Hydro, and NOVA facilities worldwide.

Rick brings over 25 years of experience in the warewash and laundry dispensing systems industry to his new role. Hydro and NOVA management are excited about the additional capability which this new position brings to their total customer support package.

Scientists at Rutgers Develop System to Improve Microwave Cooking

Rutgers scientists have "cooked up" a unique but very practical blend of food, packaging and information technologies called the Intelligent Microwave Oven system (IMWO). The new system allows food manufacturers to encode information on microwavable food packages to automatically provide cooking instructions to the oven, resulting in improved food quality and a more convenient and safer product for the consumer.

In addition to the ability to read encoded information, the current IMWO prototype also provides real-time Web communication between consumers and manufacturers via a small panel on the front of the oven. This presents opportunities for consumers to bring any questions or concerns directly to manufacturers as they arise.

The development of the IMWO is a technology application of the Intelligent Product Delivery System (IPDS), a program of the Nutraceuticals Institute at Rutgers. The Institute is supported by the New Jersey Agricultural Experiment Station and the food science department of Rutgers' Cook College.

"Our development strategy was to give the food manufacturer the capability to help the consumer prepare the highest quality meal possible, with more convenience and safety than ever before," says Raymond Saba, Associate Director of IPDS and a Co-inventor of the technology.

The IMWO technology allows consumers to instruct the microwave oven to prepare packaged microwavable food by simply passing the information code on the package in front of a scanner built into the oven. This eliminates the need to read instructions, program information into the microwave oven control panel,



NEWS

convert instructions from the food manufacturer's oven size to the consumer's oven size, or take intermediate steps of turning the product or changing power levels.

"Manufacturers tell us the market growth of microwavable foods has been constrained for many years," says Saba. "Consumers are not using their microwave ovens for meal preparation as much as expected because of the unpredictability of results. Consequently, food manufacturers have not been developing many new microwavable foods."

The new technology allows food manufacturers to assure that consumers can prepare food of the highest quality possible in a microwave oven. This provides manufacturers with the opportunity to develop new food products that meet consumer needs. The technology also benefits the customer by making the microwave oven a much more convenient and valuable home appliance.

The IMWO technology is a part of a proposal recently submitted by Rutgers to NASA for the development of a Food Technology Commercial Space Center. The microwave oven is a key piece of equipment in meal preparation for astronauts.

"This technology is a giant step forward in making the microwave

oven convenient for all types of cooking uses," says Paul A. Lachance, Professor of Food Science and Director of the Nutraceuticals Institute.

HACCP Regulations Viewed as Not Significantly Improving Food Safety

According to a recent survey of food processors and manufacturers, nearly two-thirds (65%) of participants say Hazard Analysis Critical Control Point (HACCP) regulations do not significantly improve food safety. Despite this skepticism, nearly 50% of the nation's processed food products come under HACCP inspection as well as approximately 75% of the nation's raw meat and poultry products, according to the USDA Food Safety and Inspection Service (FSIS). These are just some of the findings from Master Food Group's Survey on Plant Sanitation Among Food Processors and Manufacturers. Other survey findings include: due to "unnecessary paperwork," some survey respondents say HACCP is not a cost-effective method for improving safety. Nearly a quarter (24%) report that HACCP is not cost-effective; more than a quarter (27%) of participating food processors and manufacturers say they do not have an HACCP system in place. By the year 2000, such systems will be required in all food plants; and the majority (76%) of participating food processors and manufacturers identifies plant sanitation as one of their greatest challenges. One participant says, "Plant sanitation challenges never end."

3-A Symbol Council Amends Non-compliance Procedures

Board of Trustees of the 3-A Sanitary Standards Symbol Administrative Council has reviewed its procedure for invest-

igating reports of equipment allegedly in non-compliance with 3-A Sanitary Standards. As a result, the following policy has been established and will be followed:

If a non-compliance report is substantiated, the equipment manufacturer must bring the equipment and all other known manufactured units which bear the 3-A Symbol, into compliance if it wishes to retain the authorization to use the 3-A Symbol; if the reason for non-compliance is one of faulty manufacturing procedure (finish, poor polishing, etc.), the manufacturer shall demonstrate to the 3-A Symbol Council that its quality control and inspection procedures have been strengthened to prevent further occurrences; and if the equipment is in non-compliance because of design, the manufacturer must correct the design flaw for the piece of equipment in question, as well as correcting all other units bearing the 3-A Symbol that have been manufactured with the same design flaw.

Failure to comply with any substantiated non-compliance report, or for violation of any 3-A Symbol Council provisions regarding use of the 3-A Symbol, may subject the manufacturer to loss of authorization to use the 3-A Symbol.

Scientists Comment on Proposed EPA Plant Pesticide Rule

What are the possible consequences of the U.S. Environmental Protection Agency (EPA) proposed plant pesticide rule? The Council for Agricultural Science and Technology (CAST), an international consortium of 36 scientific and professional societies, released an issue paper *The Proposed EPA Plant Pesticide Rule* in which a CAST panel of five members of the National Academy of Sciences discusses this proposal. In 1996 and 1997, two reports were published in which eleven professional scientific societies and

an advisory panel of the Biotechnology Industry Organization (BIO—representing over 550 companies and affiliated organizations) discussed the issues relative to the EPA proposal. The CAST panel formed in 1998 was charged with examining the scientific merits of the differing viewpoints based solely on scientific principles.

Under statutes developed for chemicals applied externally to plants, the EPA proposes to regulate genetically engineered plants containing genes for pest resistance that have been introduced by techniques of recombinant deoxyribonucleic acid (rDNA). Plants with such genes would be designated pesticides.

The CAST panel member, as well as other scientists, say designation of plants as pesticides is indefensible on scientific grounds for the following reasons: Pest resistant plants produced by genetic engineering may be indistinguishable from plants bred for pest resistance by conventional methods. These latter plants are exempt from the EPA proposed guidelines even though the end results of recombinant DNA strategies are the same as conventional breeding; scientific panels have stated that genetically modified crops should be judged on their safety, allergenicity, toxicity, and other properties, and not the means by which the trait has been introduced. Thus, the properties of the modified plant, in terms of risk, are important, not the technique used to modify the plant; numerous mechanisms, which confer resistance to pests, exist in plants. It is scientifically illogical to combine these various mechanisms in plants into one category and state that they must be regulated if they result from recombinant DNA technology; and no evidence exists that the plant's level of resistance to pests creates hazards in the environment.

If the EPA rules go into effect, the CAST panel foresees the likelihood of serious economic consequences in the food industry: Labeling plants as pesticides would undermine public confidence in

the safety of the food supply. If plants are safe for human consumption, there is no reason to label them as pesticidal; adoption of the proposed EPA regulations would discourage development of pest resistant minor crops or crops resistant to minor pests, which would delay the time until chemical pesticide use can be decreased; and enforcing the EPA regulations would increase the regulatory burden on all companies as well as on the EPA. Small companies, who are the ones most likely to develop pest resistance in those minor crop plants, could be forced out of business or find it necessary to change their business plans by the increased paperwork and scientific data gathering.

Reprinted from the Council for Agricultural Science and Technology (CAST), Oct. 19, 1998.

Dairy Farmers May Switch to Cows with Short Tails

Dairy producers interested in better farming efficiency and improving herd health may want to consider docking their cows' tails, a veterinarian says in Penn State's College of Agricultural Sciences.

According to Larry Hutchinson, Professor of Veterinary Science, removing two thirds of a cow's tail, a practice called "docking," is catching on in Pennsylvania as producers with large herds change over to parallel milking parlors. In parallel parlors, milking equipment is attached between the cow's hind legs, and the animal's tail becomes an obstacle to efficient milking.

Hutchinson explains that a cow's tail often can be the dirtiest part of the animal. The tail often is dropped into the milking gutter, manure or mud. When the cow swings its tail, mud and filth is sprayed onto her back, onto the udder or into the face of the person milking the cow.

"One of the biggest questions about tail docking is how the cow

can control flies without a tail," Hutchinson says. "In reality, the cow's tail is pretty ineffective fly control. In fact, when a cow flicks a manure-laden tail onto its back, it tends to attract more flies."

Hutchinson emphasizes that farmers who choose to dock their cows' tails must be extra vigilant about fly control and cleanliness. "A cow with a docked tail can get just as dirty if she is lying in manure and mud," Hutchinson says. "Tailless cows should be kept in clean and dry areas, and farmers should take fly control as a serious responsibility."

Cows can have their tails surgically removed by a veterinarian, or producers can remove the tail by using elastrators, rubber bands that are placed around the tail, cutting off circulation to the remaining part. "The tail will fall off within two to four weeks," Hutchinson says. "It's better for the cows if the tails are docked within the first few months of life, because the blood vessels in the tail are less developed in young calves. But you can use this method on adult cows as well."

Hutchinson suggests that producers who have no experience in docking tails should consult with their veterinarian for a recommended docking procedure.

Hutchinson says studies have shown that cows experience little stress when their tails are docked using the elastrator method. "There are no observable signs of stress or pain, and cortisol, an enzyme that indicates pain levels, remains unchanged," he says.

Hutchinson recommends leaving one-third of the tail. For young heifers, that means placing the band approximately two finger-widths below the calves vulva. For older heifers and cows, place the band two hand-widths below the vulva.

"Cutting the tail too short may result in vaginal infections,"

Hutchinson says. "If it is cut too long, the tail can act as a club. It can knock a person unconscious or flick equipment out of the hands of a farmer."

Commerce Department Provides Award to Support Food Processing and Packaging Exports

Commerce Secretary William M. Daley announced that the International Association of Food Industry Suppliers (IAFIS) of McLean, VA, has been selected to participate in the Market Development Cooperator Program (MDCP), a public-private partnership developed to help small-and-medium-sized U.S. firms expand exports that support jobs for Americans.

IAFIS' Latin America Export Assistance Program (LEAP) focuses on the Latin American Big Emerging Markets of Argentina, Brazil, and Mexico and is comprised of the following activities: promoting the use and acceptance of 3-A Sanitary (Food Equipment) Standards in Latin America through standards translation into Spanish and Portuguese and through educational programs; performing primary research on supplier exporting attitudes and readiness; hosting trade missions and trade show pavilions; developing a Spanish IAFIS Web site; sponsoring customized, industry specific international market research, and qualified agent/distributor lists; opening a Latin American liaison office in Brazil.

Animal Drugs Seized

On September 14, 1998, the U.S. Marshals Service conducted a seizure of veterinary drugs at the Mortar & Pestle Veterinary Pharmacy, Inc.,

Des Moines, IA. The seizure included all bulk drugs and finished pharmaceuticals at this firm. The Food and Drug Administration (FDA) issued a warning letter to Mortar & Pestle on June 13, 1997, advising the firm that its products were not in compliance with the Federal Food, Drug, and Cosmetic Act (the Act). When the firm did not make any significant corrections, its drug products were seized under the Act as unapproved new animal drugs and adulterated and misbranded drugs.

In 1996, FDA published a Compliance Policy Guide (CPG) that outlines criteria and boundaries for the compounding of animal drugs. This CPG states that FDA recognizes circumstances exist when it may be necessary for a veterinarian to compound, or direct a pharmacist to compound, an article that will result in an unapproved new animal drug. The agency will exercise regulatory discretion and ordinarily will not take regulatory action against violations of the Act resulting from the compounding of an unapproved new animal drug if the criteria described in the CPG are met. Among those criteria are: There must be a prescription from a licensed veterinarian, and dispensing must be done within the confines of a valid veterinarian-client-patient relationship; advertising, or other solicitation, for specific drug products or classes is not acceptable; products should be produced under good compounding practices using current pharmaceutical and pharmacological standards; and products should be labeled with an expiration date that is in line with the treatment period.

In taking this seizure action, FDA consulted frequently with the Iowa Board of Pharmacy. Federal and State authorities working together and independently developed information on violations of

their respective laws by Mortar & Pestle Veterinary Pharmacy, Inc. The Iowa Board of Pharmacy has been advised that the firm will surrender its pharmacy license, and is currently waiting to finalize its disciplinary action.

The Dairy Industry Announces Strategic Alliance with Government Agencies

The dairy industry announced an unprecedented alliance with nine state and federal regulatory agencies for environmental stewardship. During a formal signing, the dairy industry takes great strides in its continued efforts to protect public and animal health and safety. A key component of this newly formed alliance is environmental stewardship certification from the California Dairy Quality Assurance program (CDQA).

The dairy industry created the CDQA as a voluntary means to promote quality dairy products through improved on-farm practices. Its programs will concentrate on the three distinct areas of public health, animal health, and environmental stewardship. Dairy produc-

ers and industry leaders see the CDQA as an opportunity to distill critical management practices along with regulations that impact each area, set up protocol for procedures, as well as provide continuing education to all dairy farmers about the most efficient and cohesive manure management operations.

The first program to be adopted addresses the environmental stewardship component of dairy farm operations. In order for a dairy producer to earn CDQA certification, three requirements must be completed: an environmental stewardship short course, farm management plan, and on-site inspections.

The University of California Cooperative Extension, Davis is coordinating the development of the environmental stewardship education course with significant input from federal, state, and regional regulatory agency involved in environmental issues. The workshops and accompanying course notebooks cover water regulations, facility evaluation, manure management, and storm water pollution prevention plans. It is designed as education for dairy farmers to help them improve their manure management practices.

The second element of certification is the preparation of an environmental stewardship farm management plan prepared by each producer. The plan allows producers to evaluate their specific farm conditions to determine components of their facility that may put them at risk of incorrect manure handling. Risk assessments cover manure storage facilities, corral management, silage storage, and application of manure to land. Once high-risk components are identified, producers can prioritize management and facility modifications to further reduce possible risk of water contamination.

Finally, the producer will participate in an on-site evaluation by an independent party. A checklist, jointly developed by the CDQA, will serve as the evaluation tool. The evaluation will include a visual assessment of key dairy farm operations.

Once the full compliment of the CDQA has been established, the dairy industry will have a single source of guidelines, protocols, and certification in environmental stewardship, food safety, and animal health. In an industry already proud of its high standards and quality tradition, dairy farmers will have set a new path that many states are expected to follow.

University of California-San Francisco Researchers Report Test That Detects Prion Diseases

Reprinted from *Food Safety Network*, September 28, 1998

Researchers at the University of California-San Francisco report that they have developed a highly sensitive, rapid technique for detecting the infectious agents that cause prion diseases. They expect the assay will ultimately be useful for detecting prions causing BSE disease and Creutzfeldt-Jakob disease in humans. With automation, the tool could be applied to commercial testing of meat, biological, and pharmaceutical products.

But the significance of the UCSF study, reported in the October issue of *Nature Medicine*, extends beyond the hope for an effective screening tool. For the assay has revealed stunning insights into the nature of the novel, inscrutable pathogen that causes "mad cow" disease, Creutzfeldt-Jakob's disease in humans and a variety of other neurodegenerative diseases seen across species and known collectively as spongiform encephalopathies. The findings have been given the researchers new direction for exploring the way in which the pathogen, called prion, for proteinaceous infectious particle, functions.

The test tube immunoassay, which so far has been used to detect infection in hamsters, identifies extremely low levels of prion protein the only known component of the infectious prion and does so within a matter of eight hours. Researchers believe the design can be adapted for large-scale robotic processing.

By contrast, current detection models, called bioassays, involve inserting suspected infectious tissue into the brains of laboratory animals and observing them for development of the disease. The process takes between 60 to 180 days, and cannot be conducted on a large, commercial scale. The new technique, conducted in plastic plates, is also expected to prove effective for diagnosing new-variant Creutzfeldt-Jakob disease (CJD) in living patients. Scientists fear that some 25 people in Great Britain and France may have developed the disease by eating tainted meat in the 1980s. But the insights the test offers into the biology of the prion protein are consuming much of the researchers' attention. Previous research has revealed that all mammals examined contain normal, benign prion protein, and it is believed that they only become destructive when the prion protein changes shape, from a coiled structure to a flat sheet. The conversion in the infectious form of the disease (which can also be inherited or occur spontaneously) is believed to occur when already infectious prion protein, or PrPSc, clasps

onto the normal prion protein, or PrPC, twisting it down flat in a morbid, fateful dance.

The researchers developed an assay that detects a region of PrPSc protein that, while exposed in normal PrPC protein, becomes tucked, or folded, in the diseased PrPSc molecule. Fluorescently labeled antibody that reacts with the folded region of PrPSc only after the disease protein is unfolded, or denatured, is used in the assay.

The researchers first expose a tissue extract containing infectious prion protein in its natural state to the antibody and measure the reactivity. They then unfold the prion protein by chemical means so that the hidden region will be exposed. Predictably, the antibody's immunoreactivity to the denatured region, as measured by its degree of binding to the molecule, is much higher than it is to the diseased protein in its natural state. The ratio of denatured to native infectious prion protein indicates the amount of PrPSc.

The researchers used the model to test brain tissue taken from hamsters infected with eight different strains of prions. They plotted the results as a function of the concentration of PrPSc for each strain. And their findings were dramatic. Like seemingly insignificant holes cut in paper can create an image of a snowflake, the points on the graph revealed detail about the proteins' unique properties that the molecular biologists couldn't see on their own: specifically, that each of the eight different strains of infectious prions had unique shapes.

Researchers have known that prion diseases, even within species, vary in length of incubation, topology of prion accumulation and distribution of accumulated protein deposits in the brain. But while they have suspected that these variations, or strains, were represented by different protein shapes, they have never had direct evidence. Moreover, it has long been believed that a protein has only a single conformation, as determined by its amino acid sequence, and all eight strains did represent a single molecular sequence.

The assay also revealed that PrPSc protein contains a protease-sensitive fraction, which surprised the researchers. "We always thought PrPSc was strictly protease resistant," said Stanley B. Prusiner, MD, a professor of neurology, biochemistry and biophysics at UCSF, the winner of the 1997 Nobel Prize in Physiology or Medicine, and the other senior author of the study.

In an effort to tease out the component of prion protein that might actually confer the most crucial distinction in strains the time it takes for the disease to

develop the researchers plotted the protease-sensitive component of the PrPSc versus incubation time and were struck by what Safar called "a gorgeous straight line."

"Until now, we believed that once formed in the brain, prions could not be degraded. We now understand that it is the rate at which prions are degraded that explains the differences in the time that it takes a prion strain to cause disease," said Cohen. "Since the body can begin to clear the proteinaceous mess from the brain, treatments are being developed to assist this process."

"The only conclusion," Cohen said, "counter intuitive as it is, can be that the rate-limiting step in prion replication has little to do with PrPSc. Instead, Chen and Prusiner suggested, it must have to do with an earlier stage in the development of PrPSc, when normal PrPC protein binds to an as-yet-elusive "protein

X." Protein X is believed to act as a molecular chaperone, moving the normal protein out to the dance floor where it presumably is handed off to its deadly suitor.

Needless to say, the researchers are turning their attention to this earlier stage in the conversion cascade, before the protease-resistant fraction is formed.

"While we still can't visualize protein X, we need to see if we can figure out its role," said Safar. The researchers' challenge, which molecular biologists face every day in their explorations, will be developing still more clever techniques that will reveal to them what they can't actually see, in this case the machinations of a deadly protein.

The University of California has filed a patent on the full technology platform for the immunoassay. Centeon Inc. holds a license granting them exclusive rights to the immunoassay technology.

***Listeria* – Put It To The Test**

Have you counted the number of steps in your *Listeria* method? We have, and our findings may surprise you. It's no secret that every additional step in a lab test increases the risk of lab error. A superior *Listeria* method will deliver results faster and with fewer steps.

QA Life Sciences has a better answer. We've developed a brand new *Listeria* selective culture medium called LM-137. When combined with our ISO-GRID Membrane Filter, LM-137 produces results in less time with fewer steps and at lower cost than any other *Listeria* method.

***Listeria* Methods Compared**

	PCR	DNA	ELISA		ISO-GRID*
			DIPSLIDE	MICROWELL	
Enrichment steps	2	2	2	2	0
Washing steps	0	5	0	7	0
Other handling steps	10	13	3	7	3
Negative screen	2 DAYS	2 DAYS	2 DAYS	2 DAYS	ONE DAY
Confirmation time	2-3 DAYS	2-3 DAYS	2-3 DAYS	2-3 DAYS	ONE DAY
Cost per test	\$10.00	\$15.00	\$8.50	\$7.80	\$1.95

* New quantitative test using LM-137 Agar

QA Life Sciences, Inc., 6645 Nancy Ridge Drive, San Diego, CA 92121
Tel: (619) 622-0560; Fax: (619) 622-0564; E-mail: bugsy@qalife.com; Toll-Free (800) 788-4446

Reader Service No. 250

IndustryProducts



Osmonics

Lakewood Instruments™ Controller Allows Monitoring of Several Units

Osmonics announced the release of the Lakewood Instruments 2450 controller, which offers multiple monitoring and control capabilities in a single package.

Conductivity, pH, flow, machine recovery, and alarm conditions can all be monitored in one easy-to-use unit. In addition, alarms can be set for high and low conditions, triggering an emergency shutdown of the reverse osmosis (RO) system if necessary.

In addition to saving you money, space, and time, the Model 2450 also provides a convenient and reliable way to oversee your RO unit. This model allows data logging and graphing information via PC in a Windows®-based format plus the capability of remote two-way communication with a modem. With these two features, you will be able to monitor a single or multiple machines from your office computer or laptop.

Osmonics, Minnetonka, MN

Reader Service No. 351

A New Range of Aztec® Water Quality Monitors

Capital Controls Company Inc, introduces a new range of AZTEC® water quality monitors.

The new AZTEC® Series A1000, F1000 and N1000 monitors combine advanced microprocessor-based electronics with proven ion selective electrode measurement technology to provide the best instrument on the market for continuous, accurate, precise measurement of ammonia, fluoride or nitrate levels in drinking water, wastewater, and other process water applications.

The AZTEC® Series 1000 ISO monitors feature automatic two-point calibration for optimal accuracy and reproducibility and a lightweight, modular design for easy access and serviceability. Residual indication is provided on the 3" x 4" display in either a 1 inch digital format, or in a graphical format with up to 28 days of data at a glance. On-screen instructions, self-diagnostics, six adjustable relays and a 4-20 mAdc output signal are standard.

Each instrument includes a dry heating block to raise the sample temperature, which is continuously monitored to ensure the integrity of the residual measurement. Minimal reagent consumption and easy access to all components make the monitors the most cost-effective and easy to operate instruments

on the market. Universal power recognition is incorporated into the unit.

Capital Controls Company,
Colmar, PA

Reader Service No. 352

Devcon Offers High Performance Epoxy for Repair of Stainless Steel Equipment

Devcon introduces Stainless Steel Putty™, a stainless steel-filled epoxy putty for patching, repairing and rebuilding stainless steel equipment. Designed to make chemically safe, non-rusting repairs, Stainless Steel Putty is ideal for dairy, food processing and chemical plants. It is both USDA authorized for incidental food contact repairs, and NSF certified for potable water applications.

Devcon's Stainless Steel Putty is an easy-to-use, room temperature curing epoxy that bonds to ferrous and non-ferrous metals. It can be easily applied by plant maintenance personnel to repair cracks, dents, and breaks in stainless steel equipment, machinery, castings, or holding tanks. Additionally, Stainless Steel Putty provides excellent chemical resistance and can be machined, drilled, or painted.

Devcon, Danvers, MA

Reader Service No. 353

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New Improvements in Popular Cleantech® 2000S Handwash System

Meritech Incorporated has announced the introduction of their newest and most innovative Hand Wash system. The popular Clean-Tech® 2000S system has been redesigned by increased functionality, offering several important hygienic accessories. This system maintains the all-important standardized and effective handwashing cylinder technology.

Constructed of heavy-duty stainless steel, the CleanTech 2000S system has been designed housing a deeper, more splash-resistant hand inlet. Each fully-gasketed and water-resistant unit provides an integral compliance monitor so that handwashing can be easily verified for SSOP, HACCP and GMP programs. In addition, the CleanTech 2000S provides a solutions monitor to verify solutions flow along with an automatic 24-hour self-cleaning monitor to eliminate bacteria colonization during operation.

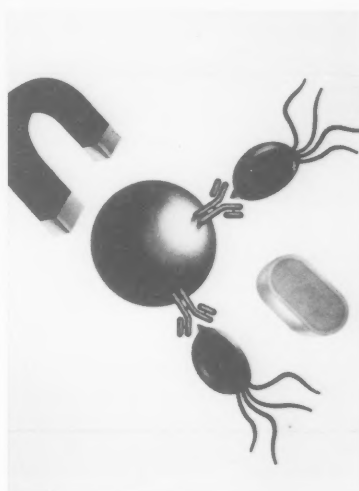
Designed to operate efficiently with standard electrical and plumbing connections, the CleanTech 2000S can be easily installed in wet, cold environments where sanitation is performed.

Meritech, Englewood, CO

Reader Service No. 354

Dynabeads® Immuno-Magnetic Separation (IMS) of Foodborne Pathogens

Dynabeads® anti-E coli O157, Dynabeads® anti-Salmonella, and Dynabeads® anti-Listeria are designed for rapid, immuno-magnetic selective enrichment of microorganisms directly from pre-enrichment broths. The rapid and simple protocol (less than 1 hour) saves 24 hours of valuable testing time compared to culture



Dynal, Inc.

methods using conventional selective enrichment media. Isolated colonies are achieved in 24 hours for *E. coli* O157 and 48 hours for *Salmonella* and *Listeria*. A method for EHEC isolation which utilizes Dynabeads® anti-E. coli O157 appears in the 8th edition of the Bacteriological Analytical Manual (BAM) and also is a Health Canada HPB Lab Procedure. Dynabeads® anti-Salmonella has achieved AOAC Performance Testing Status.

Dynabeads® are uniform, superparamagnetic microspheres (2.8 microns in diameter) with affinity purified antibodies on their surface. When incubated with a sample, Dynabeads® will bind their target bacterium forming a bacterium: magnetic bead complex. This complex is separated from the heterogeneous sample by performing the test in a magnetic test tube rack (Dynal MPC®-M). The isolated and concentrated bacterium: bead complex can then be cultured on any selective culture medium or used in other detection systems.

Dynabeads® IMS is a rapid culture technique – colony acquisition means rapid results with culture confirmation. This highly sensitive system will detect as few as 100 organisms/ml of pre-enriched sample. Improved bacterial

isolation with this method also makes it useful for the culture confirmation of other presumptive methods.

Dynal, Inc., Lake Success, NJ

Reader Service No. 355

UV Disinfection in Automated Filling and Packaging Machines

Filling and packaging machines are one area of the food industry where high levels of disinfection are essential. All packaging materials including cartons and preformed containers, closures, caps and foil seals need to be treated prior to filling, destroying any potential spoilage organisms. Conveyor belts, tracks and other surfaces within the machines also need to be disinfected, as does any incoming air. All of the above can be accomplished with UV, a quick, powerful treatment method with no moving parts, no chemical residue and little maintenance.

There are many applications for UV within filling and packing machines: disinfecting the interior of preformed containers prior to filling; disinfecting closures, caps and foil seals; disinfecting conveyor belts and tracks; treatment of incoming and circulated air; disinfecting other surfaces within the machine.

When containers are formed and ready for filling, they pass under a medium pressure UV unit with a UV dose calculated for the base of the container. Generally, an exposure time of less than a second is sufficient for a 99.99% (4 log) microbial reduction of most potential contaminants. Medium pressure units can also be used to treat closures, caps and foils prior to sealing.

Medium or low pressure units can be installed to treat conveyor belt tracks which can become

contaminated with product spillage. UV prevents any microbial growth in what is basically a rich source of nutrients. Other surfaces within the machine can be treated if considered at risk.

Low pressure systems may operate continuously throughout any line stop, while medium pressure systems incorporate shutters and optical sensors to protect containers from UV during line stops.

The air supply to the interior of a machine – necessary to maintain positive internal pressure – is a major potential source of infection. UV systems have now been developed to specifically treat the incoming air, protecting all internal surfaces from recontamination. Air treatment units can also be fitted at other critical points such as the product storage tank or the back of the filling system's product piston.

Aquionics UV treatment systems are easy to operate and maintain, with a control panel that is fully integrated with the controls of the filling machine. Maintenance requirements are minimal, the only routine task being the replacement of the UV lamps, an easy operation that can be carried out by on site maintenance staff.

Aquionics, Erlanger, KY

Reader Service No. 356

Handwash Training Now Easier with New View Box

The new view box handwash training kit is the easiest and most effective way to train large groups proper handwashing and cross-contamination. The new portable view box allows more than one person to see their handwashing results at once and the lights never have to be dimmed or curtains drawn during the training session.

The view box can be bought separately or as a kit with training

lotion, training powder (for cross-contamination training), a T-shirt and many other items to accompany the training session.

For proper handwashing techniques, the lotion is applied to trainee's hands while given basic instructions on proper handwashing. Then trainees are asked to go wash their hands as they normally would, return to the training session and view their hands in the view box. All of the spots missed will show up on their hands. This emphasizes all of the commonly missed areas in handwashing.

For cross-contamination training, the invisible powder is placed on a person's hand or other surface trainees would come into contact with during the training. After the trainer determines that everyone has come into contact with the powder in some way, the black light is used to show where the powder shows up. This demonstrates how quickly germs and disease are spread from one surface to another and one person to another.

All Quality Assurance Products, Gainesville, FL

Reader Service No. 357

New Wiper Assembly Breaks Lumps, Agglomerates

A new independently-driven Wiper Blade Assembly available on FLO-THRU screen separators breaks down lumps and agglomerates and prevents screen blinding more effectively than passive wiper blades driven by screen vibration.

The support arm of the assembly is mounted to the unsprung base plate of any FLO-THRU separator, allowing independent, secure adjustment of wiper blade height above the vibrating screen surface or at screen level. The action of an oscillating screen



Kason Corporation

surface beneath a fixed height blade, together with independent adjustment of blade rotation speed from 1 to 15 RPM, enable the user to achieve higher, more controlled delumping efficiency and screening capacity than possible using conventional wiper assemblies which are rotated by vibratory-induced friction.

Flexible rubber wiper blades or bristle brushes can be affixed to the agitator shaft arms to maximize delumping and anti-blinding results for individual materials.

Kason FLO-THRU screen separators are distinguished by their externally-mounted gyrotory motors, low profile shape, and straight-through material flow path.

Kason Corporation, Millburn, NJ

Reader Service No. 358

Remove Contaminants from Steam in Food Processing

Balston® Steam filters that permit direct steam contact with food are now available from Whatman, Inc.

Balston Steam Filters remove 98+% of 0.1 micron particles and 100% of all visible particles from steam. Liquid condensate is removed at the same efficiency as for solid particles. Models are available to handle flow rates of up to 3,000 lbs/hr.

Other benefits of Balston Steam filters include: Reduction in steam condensate mixing with the food

products when steam is used for agitating, mixing or cooking; significant reduction in carryover of boiler feedwater chemicals into the food product, causing taste and odor problems; greatly reduced maintenance requirements for valves, cookers, heat exchangers, and other equipment.

Balston Steam Filters are in full compliance with the requirements of the U.S. Food, Drug and Cosmetic Act. They meet the regulations for Indirect Food Additives used as Basic Components for Repeated Use Food Contact Surfaces as specified in 21 CFR Part 177, and Current Good Manufacturing Practices, 21 CFR Part 110. Balston Steam Filters have also been accepted by the USDA for use in federally inspected meat and poultry plants. They are also in full compliance with the 3A Accepted Practices (Number 609-00) for producing steam of culinary quality, and they are in full compliance with the requirements of the Health Protection Branch of Health and Welfare Canada.

Whatman Inc., Tewksbury, MA

Reader Service No. 359

New Line of Stainless Steel Funnels with Optional Fittings and Various Mesh Strainers Announced

An expanded line of stainless steel funnels, strainers, fittings and cones is being marketed by Terriss Consolidated Industries, Inc. Of special interest is the new, heavy duty funnel fabricated in 14 gauge, type 304 stainless steel. Offered in a seamless, 12" deep design with a 12" top diameter and large

2" bottom opening (spout), each funnel may be customized with one choice of seven spout fittings. Fittings range through tubular, half-coupling, NPT nipples or tri-clamp styles. A stainless steel strainer/sieve which can sit on the top of the funnel is also newly available. Strainer/sieves can be supplied in 6 stock mesh sizes with other mesh sizes manufactured on request.

Offered also are utility stainless steel funnels in various sizes and rated capacities. Presently they are supplied in top diameter sizes from 12" to 3" in type 304 stainless steel. Rated capacities range from 12 quarts to 5 ounces. Type 316 models are available in 12" and 10" top diameter sizes with rated capacities of 12 quarts and 10 quarts respectively. Bottom openings range from 1/2" to 3/4". 300 series stainless steel cones with welded rib joints, designed for placement between solid funnel sides and filtering medium (to speed-up process), are constructed as an 11-1/4" x 11-1/4" unit that can fit all funnels down to 7" diameter.

Terriss Consolidated Industries, Inc., Asbury Park, NJ

Reader Service No. 360

Self-Cleaning pH/ORP Flow System Has No Moving Parts

A novel self-cleaning pH/ORP flow system that has no moving parts and requires no power. This unique system utilizes Sensorex's flat measuring surface which allows the probe to become essentially self-cleaning when exposed to turbulent flow. This system solves many of the failure problems that can be attributed to solid or oily coatings, abrasive particles and viscous materials.

These rugged combination electrodes are available in both pH and ORP configurations. This flat surface electrode also employs a quick disconnect cartridge-type system which needs no tools and makes it possible to change an existing electrode in seconds. The result is improved precision of measurements, reduced maintenance, prolonged electrode life and the virtual elimination of breakage.

Specifications include use in temperatures up to 100°C and pressures as high as 100 PSIG. Electrodes are available in either CPVC or PVDF (Kynar) bodies and are compatible with most makes/models of pH/ORP transmitter or controller.

Sensorex, Stanton, CA

Reader Service No. 361

New Mixproof Valve Meets PMO Requirements

G&H Products Corp. has introduced the SMP-SC-PMO Mixproof Valve, a new single-bodied mixproof valve that complies with the Pasteurized Milk Ordinance – ideal for the dairy and dairy processing industries.

Some of the other features of this new mixproof valve include: Full port leak tube (vent); maximum protection against mixing of fluids, including product vs. CIP solution applications; authorized to carry the 3A symbol; simple valve disassembly/reassembly; compact size; total CIP hygienic environment; and fully pressure-balanced upper and lower valve.

G&H Products, Pleasant Prairie, WI

Reader Service No. 362

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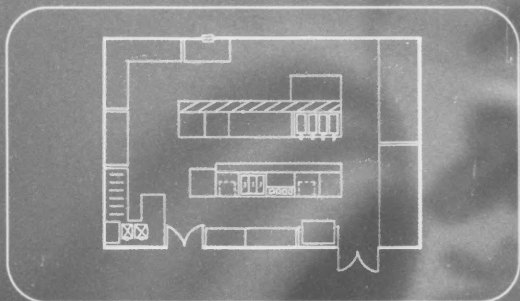
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Reader Service No. 213

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Revisions to 3-A Sanitary Standards for Sanitary Fittings for Milk and Milk Products Number 63-02

Formulated by
International Association of Milk, Food and Environmental Sanitarians
United States Public Health Service
The Dairy Industry Committee

It is the purpose of the IAMFES, USPHS, and DIC, in connection with the development of the 3-A Sanitary Standards Program to allow and encourage full freedom for inventive genius or new developments. Sanitary fittings specifications heretofore or hereafter developed which so differ in design, materials, and fabrication or otherwise as not to conform to the following standards but which, in the fabricator's opinion, are equivalent or better, may be submitted for the joint consideration of the IAMFES, USPHS, and DIC, at any time. The 3-A Sanitary Standards and 3-A Accepted Practices provide hygienic criteria applicable to equipment and systems used to produce, process, and package milk, milk products, and other perishable foods or comestible products.

A SCOPE

A1 These standards cover the sanitary aspects of fittings and gaskets for fittings used on processing equipment and on equipment and pipelines which hold or convey milk or milk products. These standards cover the product contact surfaces of disassemblable joints on sanitary fittings.

A1.1 These standards do not cover:

A1.1.1 Fittings, such as recessed ferrules, which are attached to a pipeline or equipment by means of soldering.

A1.1.2 Recessless or rolled on fittings.

A2 In order to conform to these 3-A Sanitary Standards for Fittings for Milk and Milk Products, fittings shall comply with the following design, material, and fabrication criteria, and the applicable documents referenced herein¹.

B DEFINITIONS

B1 *Product*: Shall mean milk and milk products.

B2 Surfaces

B2.1 *Product Contact Surfaces*: Shall mean all surfaces which are exposed to the product and surfaces from which liquid may drain, drop, diffuse, or be drawn into the product.

B2.2 *Nonproduct Contact Surfaces*: Shall mean all other exposed surfaces.

B3 Cleaning

B3.1 *Mechanical Cleaning or Mechanically Cleaned*: Shall mean soil removal by impingement, circulation, or flowing chemical detergent solutions and water rinses onto and over the surfaces to be cleaned by mechanical means in equipment or systems specifically designed for this purpose.

B3.1.1 *Cleaned In Place (CIP)*: Shall mean mechanical cleaning of equipment, the cleanability of which has been sufficiently established such that all product or solution contact surfaces do not have to be readily accessible for inspection, (i.e. pipelines that have welded joints).

B3.2 *Manual (COP) Cleaning*: Shall mean soil removal when the equipment is partially or totally disassembled. Soil removal is effected with chemical solutions and water rinses with the assistance of one or a combination of brushes, nonmetallic scouring pads and scrapers, high or low pressure hoses and tank(s) which may be fitted with recirculating pump(s), and with all cleaning aids manipulated by hand.

B4 Fitting Types

B4.1 *Butt Weld Fittings*: Shall mean fittings which have at least one plain end intended for welding to a pipeline or equipment.

- B4.2 *Mechanically Cleaned Fittings*: Shall mean a fitting which is cleaned while fully assembled. If such a fitting has a demountable joint, the joint is self-centering, employs a gasket, and the resulting gasketed joint forms a substantially flush interior surface. A fitting for attachment to glass or plastic which meets the preceding criteria may also be a mechanically cleaned fitting.
- B4.3 *Manually Cleaned Fittings*: Shall mean a fitting which has a disassemblable joint that is intended for dismantling for manual cleaning. An example of a manually cleaned fitting is the bevel-seat type.
- B5 *Substantially Flush*: Shall mean mating surfaces or other juxtaposed surfaces shall be within 1/32 in. (0.794 mm).
- B6 *Simple Hand Tools*: Shall mean implements normally used by operating and cleaning personnel such as a screwdriver, wrench, or mallet.
- B7 *Coatings*: Shall mean the results of a process where a different material is deposited to create a new surface. There is an appreciable, typically more than 1 µm, build-up of new material.

C MATERIALS

C1 Metals

- C1.1 Product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI) 300 Series² or corresponding Alloy Cast Institute (ACI) types³ (See Appendix, Section F), or metal which under conditions of intended use is at least as corrosion resistant as stainless steel of the foregoing types, and is nontoxic and nonabsorbent.

C2 Nonmetal

- C2.1 Rubber and rubber-like materials may be used for coatings for sealing surfaces, gaskets, O-rings, seals, and parts having the same functional purposes.
- C2.1.1 Rubber and rubber-like materials, when used for the above specified applications, shall conform to the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18.
- C2.2 Plastic materials may be used for coatings for sealing surfaces, fittings, gaskets, O-rings, seals, and parts having the same functional purposes.
- C2.2.1 Plastic materials, when used for the above specified applications, shall comply with the applicable provisions of the 3-A Sanitary

Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-

- C2.3 Rubber and rubber-like materials and plastic materials having product contact surfaces shall be of such composition as to retain their surface and conformational characteristics when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization.
- C2.4 Rubber and rubber-like materials and plastic materials having product contact surfaces that are a bonded coating or a covering shall be of such composition as to retain their surface and conformational characteristics when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization.
- C2.5 The final bond and residual adhesive, if used, on bonded rubber and rubber-like materials and bonded plastic materials shall be nontoxic⁴.
- C2.6 Glass may be used for fittings specified in the 3-A Accepted Practices for the Design, Fabrication, and Installation of Milking and Milk Handling Equipment, Number 606, and when used, shall be of a clear heat-resistant type.

C3 Sterilizability

- C3.1 In a processing system to be sterilized by heat and operated at a temperature of 250°F (121°C) or higher, all materials having product contact surface(s) used in the construction of fittings, gaskets, and nonmetallic component parts shall be such that they can be (1) sterilized by saturated steam or water under pressure (at least 15.3 psig or 106 kPa) at a temperature of at least 250°F (121°C) and (2) operated at the temperature required for processing.

C4 Nonproduct Contact Surfaces

- C4.1 All nonproduct contact surfaces shall be of corrosion-resistant material. All nonproduct contact surfaces shall be relatively nonabsorbent, durable, and cleanable.

D FABRICATION

D1 Surface Texture

- D1.1 All product contact surfaces shall have a finish at least as smooth as a No. 4 ground finish on stainless steel sheets and be free of imperfections such as pits, folds, and crevices in the final fabricated form. (See Appendix, Section G.)

D2 Permanent Joints

- D2.1 All permanent joints in metallic product contact surfaces of fittings shall be continuously welded. Welded areas on product contact surfaces shall be at least as smooth as a No. 4 ground finish on stainless steel sheets, and be free of imperfections such as pits, folds, and crevices.

D3 Cleaning and Inspectability

- D3.1 Fittings that are to be CIP or mechanically cleaned shall be so designed. If such fittings have demountable joints, the joints shall be gasketed and so designed as to cause self-centering of gaskets, and to result in substantially flush interior fit of gaskets when correctly assembled. Any demountable product contact parts shall be readily demountable by hand or using simple hand tools.
- D3.2 Manually cleaned fittings shall have demountable joints to allow easy access for cleaning and inspection. Use of gaskets in the joints is optional. Any demountable product contact parts shall be readily demountable by hand or using simple hand tools.

D4 Draining

- D4.1 All product contact surfaces shall be self-draining when properly installed.

D5 Threads

- D5.1 There shall be no threads on product contact surfaces.

D6 Dimensions and Tolerances

- D6.1 The inside diameter of the butt weld ends of plain end fittings shall be dimensioned to mate with the part to which it is to be welded and be substantially flush.
- D6.2 Mating faces of demountable joints on sanitary fittings shall have internal diameters meeting the dimension and tolerance specifications in Appendix H, Table 1 except:
- D6.2.1 Fittings for attachment to glass or plastic components which do not have the standard ID dimensions of metal tubing.
- D6.2.2 Fittings for special applications which require other than the standard ID dimensions of tubing.
- D6.3 Fittings excepted by Sections D6.2.1 and D6.2.2 shall be dimensioned to mate with the internal dimension of its counterpart tubing, pipe, glass tubing, plastic component, etc. (Dimension tolerances for these excepted fittings are not provided by these Sanitary Standards.)

D7 Gaskets and Gasket Retaining Grooves

- D7.1 Gaskets having a product contact surface shall be demountable or bonded.
- D7.2 Grooves in gaskets shall be no deeper than their width.
- D7.3 Gasket retaining grooves in product contact surfaces for demountable gaskets shall not exceed 1/4 in. (6.35 mm) in depth or be less than 1/4 in. (6.35 mm) wide except those for standard O-rings smaller than 1/4 in. (6.35 mm), and those for self-centering gaskets.

D8 Bonded Materials

- D8.1 Bonded rubber and rubber-like materials and bonded plastic materials having product contact surfaces shall be bonded in such a manner that the bond is continuous and mechanically sound, so that when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization, the rubber or rubber-like material or the plastic material does not separate from the base material to which it is bonded.

D9 Coatings

- D9.1 Coatings, if used, shall be free from surface delamination, pitting, flaking, spalling, blistering and distortion when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization.

D10 Radii

- D10.1 All internal angles of less than 135° on product contact surfaces shall have radii of not less than 1/8 in. (3.18 mm), except that:
- D10.1.1 Smaller radii may be used when they are required for essential functional reasons, such as those in gasket retaining grooves. In no case shall such radii be less than 1/64 in. (0.397 mm).
- D10.1.2 Radii in standard O-ring grooves shall be as specified in Appendix I.
- D10.1.3 Radii in nonstandard O-ring grooves shall be those radii closest to a standard O-ring as specified in Appendix I.

E STERILIZABLE FITTINGS

- E1 Fittings which have demountable joints and are to be used in a processing system to be sterilized by heat and operated at a temperature of 250° F (121°C) or higher shall comply with the following additional criteria:
- E1.1 The construction shall be such that all product contact surfaces can be (1) sterilized by saturated steam or water under pressure

(at least 15.3 psig or 106 kPa) at a temperature of at least 250°F (121°C) and (2) operated at the temperature required for processing.

E1.2 Fittings that have a product contact surface(s) to be used in such a processing system, not designed so that the system is automatically shut down if the product pressure in the system becomes less than that of the atmosphere and cannot be restarted until the system is resterilized, shall have a steam or other sterilizing medium chamber surrounding the fittings at the product contact surface if required to maintain sterility. The fittings shall be constructed so that the steam chamber or other sterilizing medium chamber may be exposed for inspection.

E1.3 Where steam or other sterilizing medium is used, the connection(s) on the sterilizable fittings shall be such that the steam lines or other sterilizing medium lines can be securely fastened to the sterilizable fittings. The sterilizable fittings shall be constructed so that the steam or other sterilizing medium chamber may be exposed for inspection.

E1.4 The seal(s) in sterilizable fittings designed to be used in a processing system to be sterilized by heat and operated at a temperature of 250°F (121°C) or higher shall be located between the product contact surface and the steam or other sterilizing chamber.

E2 Nonproduct contact surfaces shall have a smooth finish, free of pockets and crevices, and be readily cleanable.

APPENDIX

F STAINLESS STEEL MATERIALS

Stainless steel conforming to the applicable composition ranges established by AISI for wrought products, or by ACI for cast products, should be considered in compliance with the requirements of Section C1 herein. Where welding is involved, the carbon content of the stainless steel should not exceed 0.08%. The first reference cited in C1 sets forth the chemical ranges and limits of acceptable stainless steel of the 300 Series. Cast grades of stainless steel corresponding to types 303, 304, and 316 are designated CF-16F, CF-8, and CF-8M, respectively. The chemical compositions of these cast grades are covered by ASTM specifications⁵ A351/A351M, A743/A743M and A744/A744M.

G PRODUCT CONTACT SURFACE FINISH

Surface finish equivalent to 150 grit or better as obtained with silicon carbide, properly applied on stainless steel sheets, is considered in compliance with the requirements of Section D1 herein. A maximum R_a of 32 μin . (0.80 μm), when measured according to the recommendations in American National Standards Institute (ANSI)/American Society of Mechanical Engineers (ASME)⁶ B46.1 - *Surface Texture*, is considered to be equivalent to a No. 4 finish.

H DIMENSIONS AND TOLERANCES

Table 1 - Internal Diameter and Tolerance Specifications for Mating Faces of Demountable Joints (Unions) of all Sanitary Fittings in D6.2.1 and D6.2.2.

Nominal Diameter-in.	ID* in.	Tolerance-in.
1/4	0.152	±0.005
3/8	0.277	±0.005
1/2	0.370	±0.005
3/4	0.620	±0.005
1	0.870	±0.005
1 1/2	1.370	±0.005
2	1.870	±0.005
2 1/2	2.370	±0.005
3	2.870	±0.005
4	3.834	±0.005
6	5.782	±0.013
8	7.782	±0.016
10	9.732	±0.016
12	11.732	±0.016

I O-RING GROOVE RADII

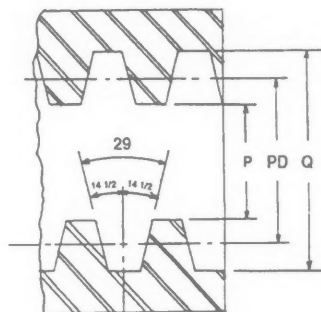
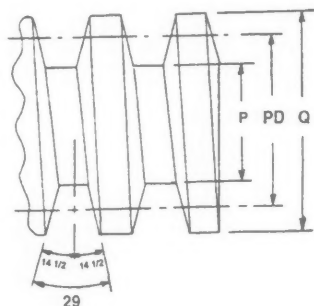
O-Ring Cross Section, Nominal (AS 568 ⁷)	O-Ring Cross Section, Actual (AS 568)	O-Ring Cross Section, Actual (ISO 3601-1 ⁸)	Minimum Groove Radius
1/16 in.	0.070 in.	1.80 mm	0.016 in. (0.406 mm)
3/32 in.	0.103 in.	2.65 mm	0.031 in. (0.787 mm)
1/8 in.	0.139 in.	3.55 mm	0.031 in. (0.787 mm)
3/16 in.	0.210 in.	5.30 mm	0.062 in. (1.575 mm)
1/4 in.	0.275 in.	7.00 mm	0.094 in. (2.388 mm)

DIAGRAMS

These diagrams are intended to promote interchangeability of threaded fittings for standard tubing by showing construction dimensions for Dairy ACME Threads. These threads are commonly utilized for threaded external fasteners, such as hexnuts

and spanner nuts, used to connect demountable joints. The 12 pages of drawings of bevel seat fittings formerly shown in this section have been deleted because, although complying with these standards, they are increasingly supplanted by welded pipeline joints and fittings using self-centering, flush-fitting gaskets, and clamp type unions.

3-A 63:02: Dairy ACME Threads



EXTERNAL THREAD DIMENSIONS

Size	Acme Threads per in.	P	Q	Pitch Dia.	Tolerance P,Q & P.D.
1	8	1.317	1.462	1.3995	+0.00 / -.018
1 1/2	8	1.849	1.994	1.9315	+0.00 / -.019
2	8	2.381	2.526	2.4635	+0.00 / -.020
2 1/2	8	2.913	3.058	2.9955	+0.00 / -.021
3	8	3.445	3.590	3.5275	+0.00 / -.022
4	6	4.509	4.695	4.6120	+0.00 / -.025

INTERNAL THREAD DIMENSIONS

Size	Acme Threads per in.	P	Q	Pitch Dia.	Tolerance P,Q & P.D.
1	8	1.352	1.497	1.4145	+0.018 / -.000
1 1/2	8	1.884	2.029	1.9465	+0.019 / -.000
2	8	2.416	2.561	2.4785	+0.020 / -.000
2 1/2	8	2.948	3.093	3.0105	+0.021 / -.000
3	8	3.480	3.625	3.5425	+0.022 / -.000
4	6	4.544	4.730	4.6270	+0.025 / -.000

These revised standards are effective November 25, 1998, at which time 3-A Sanitary Standards for Sanitary Fittings for Milk and Milk Products, Number 63-01 are rescinded and become null and void.

¹Use current revisions or editions of all referenced documents cited herein.

²The data for this series are contained in the *AISI Steel Products Manual, Stainless & Heat Resisting Steels*, November 1990, Table 2-1, pp. 17-20. Available from the American Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086; 412.776.1535.

³Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016; 708.299.9160.

⁴Adhesives shall comply with 21 CFR 175 - Indirect Food Additives: Adhesives and Components of Coatings. Document for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 202.512.1803.

⁵Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959; 610.832.9500.

⁶Available from the American Society of Mechanical Engineers, 345 East 47th Street, New York, NY 10017-2392 212.705.7722.

⁷The document establishing these standard dimensions is Aerospace Standard (AS) 568, published by SAE, 400 Commonwealth Drive, Warrendale, PA 15086; 412.776.4970.

⁸The document establishing these standard dimensions is ISO 3601-1: 1988 (E), published by the International Organization for Standardization (ISO), 1 Rue de Varembe, Case Postale 58, CH 1 1211, Geneva, Switzerland 41.22.734.1240.

3-A Accepted Practices for Spray Drying Systems for Milk and Milk Products, Number 607-04

Formulated by
International Association of Milk, Food and Environmental Sanitarians
United States Public Health Service
The Dairy Industry Committee

It is the purpose of the IAMFES, USPHS, and DIC in connection with the development of the 3-A Sanitary Standards Program to allow and encourage full freedom for inventive genius or new developments. Spray drying system specifications heretofore or hereafter developed which so differ in design, materials, and fabrication or otherwise as not to conform to the following standards but which, in the fabricator's opinion, are equivalent or better, may be submitted for the joint consideration of the IAMFES, USPHS, and DIC at any time. The 3-A Sanitary Standards and 3-A Accepted Practices provide hygienic criteria applicable to equipment and systems used to produce, process, and package milk, milk products, and other perishable foods or comestible products.

A SCOPE

A1 These 3-A Accepted Practices shall pertain to the sanitary aspects of equipment for spray drying milk and milk products, and include all equipment necessary for spray drying milk and milk products beginning with the discharge of the final pump which delivers the liquid product to the atomizers and terminates at the point the finished product leaves the system for conveying either to the packaging system or to bulk storage. The drying system may include but shall not be limited to the equipment used for moving and cleaning air, heating and/or cooling air, fluid product handling, fluid product heating, fluid product atomizing, gas injection into the product, atomized product dispersion into the heated air, dry ingredient introduction into the process air or product, product reintroduction, agglomeration, dry or partially dry product retention, additional product drying, separating dry product from the air, exhausting the air, dry product cooling and/or conveying, dry product sifting and classifying, dry product particle size reduction, metallic particle detection and separation, internal vibration, air locks, fire suppression appurtenances, pressure relief (explosion venting), product sampling, heat recovery, permanently installed mechanical cleaning

A2 Pneumatic and/or mechanical conveyors which are an integral part of a spray drying system are subject to the same material, fabrication, design, and processing air requirements of 3-A Sanitary Standards for Pneumatic Conveyors for Dry Milk and Dry Milk Products, Number 39 and 3-A Sanitary Standards for Mechanical Conveyors for Dry Milk and Dry Milk Products, Number 41- both of which apply to such conveyors that are not an integral part of a dryer system.

A3 In order to conform with these 3-A Accepted Practices, spray drying system components shall comply with the following criteria for design, material, fabrication, air supply and the applicable documents referenced herein².

B DEFINITIONS

B1 *Product*: Shall mean fluid milk or milk products, dry milk or dry milk products, and similar products.

B2 *Processing Air*: Shall mean air prepared by filtration which is intended to be used in contact with the product for such purposes as heating, cooling, drying, conveying, or similar purposes.

- B2.1 *Air to be Heated*: Shall mean processing air to be heated to at least 240°F (116°C).
- B2.2 *Air not to be Heated*: Shall mean processing air which either will not be heated or will be heated to a temperature less than 240°F (116°C).
- B3 *Pressurized Air*: Shall mean air which has been compressed by mechanical means (excluding fans and blowers) to exceed atmospheric pressure.
- B4 **Surfaces**
- B4.1 *Product Contact Surfaces*: Shall mean all surfaces which are exposed to the product and surfaces from which liquids and/or solids may drain, drop, diffuse or be drawn into the product.
- B4.2 **Air Contact Surfaces**
- B4.2.1 *Processing Air Contact Surfaces (for Air to be Heated or Air not to be Heated)*: Shall mean all surfaces in contact with filtered air prior to coming in contact with the product, commencing at the frame of the final inlet air filter(s) and ending at the first downstream product contact surface.
- B4.2.2 *Exhaust Air Contact Surfaces*: Shall mean the surfaces of the air ducts, plenum chamber(s) (if provided) and appurtenances from the final product contact surface through the exhaust system.
- B4.3 *Nonproduct Contact Surfaces*: Shall mean all other exposed surfaces.
- B5 **Cleaning**
- B5.1 *Mechanical Cleaning or Mechanically Cleaned*: Shall mean soil removal by impingement, circulation, or flowing chemical detergent solutions and water rinses onto and over the surfaces to be cleaned by mechanical means in equipment or systems specifically designed for this purpose.
- B5.1.1 *Cleaned In Place (CIP)*: Shall mean mechanical cleaning of equipment, the cleanability of which has been sufficiently established such that all product or solution contact surfaces do not have to be readily accessible for inspection (for example, silo-type tanks or welded pipelines).
- B5.2 *Manual (COP) Cleaning*: Shall mean soil removal when the equipment is partially or totally disassembled. Soil removal is effected with chemical solutions and water rinses with the assistance of one or a combination of brushes, nonmetallic scouring pads and scrapers, high or low pressure hoses and tank(s) which may be fitted with recirculating pump(s), and with all cleaning aids manipulated by hand.
- B6 **Sanitizing or Sanitization**
- B6.1 *Sanitizing or Sanitization*: Shall mean a process applied to a cleaned surface which is capable of reducing the numbers of the most resistant human pathogens by at least 5 log₁₀ reductions (99.999%) to 7 log₁₀ reductions (99.99999%) by applying accumulated hot water, hot air, or steam, or by applying an EPA-registered sanitizer according to label directions. Sanitizing may be effected by mechanical or manual methods.
- B7 **Component Equipment**
- B7.1 *Porous Belt Conveyors*: Shall mean flexible, porous, product-handling devices used to convey products through a spray drying system.
- B7.2 *Dry Product Sifters/Classifiers*: Shall mean equipment in which products are separated into different size fractions. This equipment includes, but is not limited to, vibratory and rotary sifters.
- B7.3 *Dry Product Particle Size Reducers*: Shall mean equipment in which product particle size is reduced by mechanical means. This equipment includes, but is not limited to, comminuter, hammer, and roller mills.
- B7.4 *Metal Detectors*: Shall mean equipment for detecting metallic particles in the product.
- B7.5 *Magnetic Separators*: Shall mean equipment in which metallic particles are removed from the product by magnetic attraction.
- B7.6 *Air Locks*: Shall mean equipment in which product is transferred between areas of differing pressure while maintaining the pressure differential. This equipment includes, but is not limited to, rotary and double flapper valves, and venturis.
- B7.7 *Fire Suppression*: Shall mean equipment which will suppress possible product fire by means of a suppressant material.
- B7.8 *Pressure Relief*: Shall mean equipment which will vent excessive pressures in the drying system so that structural and mechanical damage is avoided or minimized.
- B7.9 *Fluid Beds*: Shall mean equipment which suspends and moves product particles using processing air forced through a fluid bed screen.
- B7.10 *Fluid Bed Screens*: Shall mean thin metal sheets, which have perforations for the transmission of processing air for conveying, drying and/or cooling of product.

- B7.11 *Product Conveyors*: Shall mean equipment which mechanically or pneumatically conveys product.
- B7.12 *Product Diverter Valves*: Shall mean valves which divert flow between two or more destinations.
- B7.13 *Easily or Readily Removable*: Shall mean quickly separated from the equipment with the use of simple hand tools, if necessary.
- B7.14 *Easily or Readily Accessible*: Shall mean a location which can be safely reached by an employee from the floor, platform, or other permanent work area.
- B7.15 *Inspectable*: Shall mean all product contact surfaces can be made available for close visual observation.
- B7.16 *Simple Hand Tools*: Shall mean implements normally used by operating and cleaning personnel such as a screwdriver, wrench or mallet.
- B7.17 *Nontoxic Materials*: Shall mean those substances that under the conditions of their use are in compliance with applicable requirements of the Food, Drug, and Cosmetic Act of 1938, as amended.

C MATERIALS

C1 Product Contact Surfaces

- C1.1 The materials of product contact surfaces of equipment included in the spray drying system for which there are 3-A Sanitary Standards or 3-A Accepted Practices shall comply with the materials criteria of the applicable standards or accepted practices. (See Appendix, Section O.)
- C1.2 **Metals**
- C1.2.1 Product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI) 300 Series³ or corresponding Alloy Cast Institute (ACI) types⁴ (See Appendix, Section F), or metal which under conditions of intended use is at least as corrosion resistant as stainless steel of the foregoing types, and is nontoxic and nonabsorbent, except that:
- C1.2.1.1 Aluminum alloys conforming to the Aluminum Association⁵ designations 5052 and 6061 may be used as dry product contact surfaces for supporting or reinforcing members in lightweight moving parts of product removal (drag) systems, provided they are removable for cleaning.
- C1.3 **Nonmetals**
- C1.3.1 Rubber and rubber-like materials may be used for conveyor belts, short flexible connectors, hose assemblies, gaskets, scraper blades,

sealing applications, rollers, or as a coating on rollers, plugs for pressure relief and fire suppression devices and parts having the same functional purposes.

- C1.3.1.1 Rubber and rubber-like materials when used for the above specified application(s) shall conform with the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18.
- C1.3.2 Plastic materials may be used for spray cleaning devices, scraper blades, sight and/or light openings, bearings, bushings, short pieces of transparent tubing in dry product areas for observation purposes, short flexible connectors, sealing applications, diverter valve vanes, a coating for air lock parts, conveyor belts, a coating on the edges of conveyor belts, wear strips, pressure relief port membranes, coverings for pressure relief and fire suppression devices and parts having the same functional purposes.
- C1.3.2.1 Plastic materials when used for the above specified application(s) shall conform with the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20.
- C1.3.3 Rubber and rubber-like materials and plastic materials having product contact surfaces shall be of such composition as to retain their surface and conformational characteristics when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment.
- C1.3.4 The final bond and residual adhesive, if used, on bonded rubber and rubber-like materials and bonded plastic materials shall be nontoxic⁶. (Also see Sections C3.1.2 and D5.1.)
- C1.3.5 Cotton, wool, linen, silk, synthetic fibers, or expanded PTFE membrane laminates composed of these materials may be used for separation of product from exhaust air and for short flexible connectors used in contact with dry product. These materials shall be nontoxic, relatively insoluble in water, easily cleanable and shall not impart particulate material or a flavor to the product.
- C1.3.5.1 All plastic materials referenced in C1.3.5 shall be:
- C1.3.5.1.1 Constructed of materials meeting Title 21, Part 170-199 of the Code of Federal Regulations, or
- C1.3.5.1.2 Otherwise accepted by the Food and Drug Administration for food contact.

- C1.3.6 Plastic materials which meet Sections C1.3.5.1.1 and C1.3.5.1.2 may be used for flexible tubing, or for fittings for such tubing, used to distribute pressurized air for purging shaft seals and for sensing air pressure or flow as described in D15.
- C1.3.7 Rubber and rubber-like materials which meet applicable FDA regulations 21 CFR 177.2600 may be used for flexible tubing to distribute pressurized air for purging purposes described in Section C1.3.6. Fittings and connections for such tubing may be made of stainless steel or of plastic specified in Section C1.3.5.1.1 and C1.3.5.1.2.
- C1.3.8 Glass may be used in sight and/or light openings where required to evaluate burner operation and shall be of a clear, heat-resistant type.
- C2 Air Contact Surfaces**
- C2.1 Air contact surfaces, including air-to-air heat recovery systems, shall meet the materials requirements of a product contact surface, except for:
- C2.1.1 Flexible connectors in air to be heated and exhaust air contact surfaces.
- C2.1.2 **Burners**
- C2.1.3 Processing air heating devices for air to be heated only, such as steam coils or heat transfer fluid coils.
- C2.1.4 Exhaust fans and dampers in exhaust air contact surfaces.
- C3 Air Filters**
- C3.1 Air filter media used to filter processing air shall consist of one or more of the following materials:
- C3.1.1 Fiberglass with a downstream backing dense enough to prevent fiberglass break-off from passing through, cotton flannel, wool flannel, nonwoven fabric, absorbent cotton fiber, polyester fiber or other suitable materials which, under conditions of intended use, are nontoxic and nonshedding and which do not release toxic volatiles or other contaminants to the air, or volatiles which may impart any flavor or odor to the product.
- C3.1.2 Bonding materials contained in the air filter media shall be nontoxic, nonvolatile and insoluble under all conditions of use.
- C3.2 Filter element sealing gaskets, if affixed to the upstream face of the filter frame, or to the filters as supplied by the filter manufacturer, shall be of nonabsorbent material. Compliance of such gaskets with the 3-A Sanitary Standards for Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18- is not required.
- C3.3 Electronic air cleaners using electrostatic precipitation principles to collect particulate matter may be used in spray drying systems only as a prefilter.
- C4 Nonproduct Contact Surfaces**
- C4.1 All nonproduct contact surfaces shall be of corrosion-resistant material or material that is rendered corrosion resistant. If coated, the coating used shall adhere. All nonproduct contact surfaces shall be relatively non-absorbent, durable, and cleanable. Parts removable for cleaning having both product contact and nonproduct contact surfaces shall not be painted.
- D FABRICATION**
- D1 The fabrication criteria of equipment included in the spray drying system for which there are 3-A Sanitary Standards or 3-A Accepted Practices shall be those of the applicable standards or accepted practices. (See Appendix, Sections O and P.)
- D2 Surface Texture**
- D2.1 Product contact surfaces and processing air contact surfaces (for air not to be heated) shall have a finish at least as smooth as a No. 4 ground finish on stainless steel sheets and be free of imperfections such as pits, folds and crevices in the final fabricated form (see Appendix Section G) except that:
- D2.1.1 Product contact surfaces in high pressure pipelines need not be polished.
- D2.1.2 Welded joints made under the conditions outlined in D4.1.1 need not be polished.
- D2.1.3 Stainless steel sheets with a No. 2B finish may be used, provided they are free of imperfections such as pits, folds, and crevices in the final fabricated form. (See Appendix, Section G.)
- D3 Air Contact Surfaces**
- D3.1 Welds on air contact surfaces for air to be heated, and for exhaust air as described in Sections B4.2.1 and B4.2.2 respectively shall be continuous type. No minimum radius requirements apply for these welds, whether or not they are ground. For fabrication of square or rectangular ducts, corners shall be bent, when practical, so that joining welds can be made on flat surfaces instead of in corners.

D3.2 All air contact surfaces shall be accessible and cleanable. Where no other means of access are available, panels or doors shall be provided. Access to vertical exhaust air contact surfaces, such as stacks, can be provided externally by ladders or platforms.

D3.3 All air contact surfaces shall be designed to be mechanically cleaned or shall be accessible for cleaning and inspection, except as provided for in D3.2 for exhaust stacks.

D3.4 The construction of the spray drying system shall prevent the entrance of unfiltered air.

D3.5 Fans of the airfoil type shall be constructed with the blade cavities sealed by continuous welding.

D4 **Permanent Joints**

D4.1 All permanent joints in metallic product contact surfaces shall be continuously welded except as provided for in Section D4.1.2. Welded areas, press-fittings and shrink-fittings on product contact surfaces shall be at least as smooth as a No. 4 ground finish on stainless steel sheets, and be free of imperfections such as pits, folds and crevices, except that:

D4.1.1 When permanent welds of tubing and ductwork larger than 4 in. (101.6 mm) diameter but smaller than 24 in. (609.6 mm) diameter and not covered by ASTM A270-Standard Specification for Seamless and Welded Austenitic Stainless Steel Tubing⁸, are made by the tungsten inert gas (TIG) method with internal inert gas purging, the welds need not be ground and polished, but shall produce a finish at least as cleanable as a No. 4 finish on stainless steel sheets.

D4.1.2 In such cases where welding is permitted is practical, press-fitting or shrink-fitting may be employed where necessary for essential functional reasons such as bearings on air sweeps and purge air connections. (See Appendix, Section M.)

D4.2 Lapped joints in metallic product contact surfaces may be used for reasons of strength or fit provided that the finished joints are welded, ground and polished to meet the surface texture requirements of Section D2, and the radii requirements of Section D9, and are cleanable and free draining in the installed position.

D4.3 Welded joints in high pressure pipelines, except as provided by D10, shall be butt welded using tungsten inert gas (TIG) method with internal gas purging.

D5 **Bonded Materials**

D5.1 Bonded rubber and rubber-like materials and bonded plastic materials having product contact surfaces shall be bonded in a manner that the bond is continuous and mechanically sound so that when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment the rubber and rubber-like material or the plastic material does not separate from the base material to which it is bonded. The final bond and residual adhesive, if used, shall conform to the criteria in Section C1.3.4.

D6 **Coatings**

D6.1 Coatings, if used, shall be free from surface delamination, pitting, flaking, blistering and distortion when exposed to the conditions and environment of intended use and in cleaning and bactericidal treatment.

D6.2 Plastic materials, when used as a coating, shall be at least 0.0005 inches thick (0.0127 mm).

D7 **Cleaning, Inspectability and Draining**

D7.1 Spray dryer components that are to be mechanically cleaned shall be designed so that the product contact surfaces of the components and all nonremoved appurtenances thereto can be mechanically cleaned and are readily accessible and inspectable, except that:

D7.1.1 Permanently installed high-pressure pipelines need not be readily accessible and inspectable.

D7.1.2 Product contact surfaces of drying chambers and cyclone type collectors in excess of 10 ft. (3.05 m) inside height shall be accessible for inspection.

D7.2 Product contact surfaces not designed to be mechanically cleaned shall be readily accessible and inspectable when in an assembled position or when removed. Demountable parts shall be readily removable, except that:

D7.2.1 Parts such as fan wheels, nonrotary air lock valves, conveying mechanisms, and similar parts need only be readily accessible and inspectable, and that centrifugal atomizers and air disperser cones need only be removable for cleaning and inspection.

D7.3 Product contact surfaces intended for regular wet cleaning shall be self-draining or self-purging except for normal clingage. Where self-draining is not feasible, other drying methods, including air drying, may be used.

D8 Gaskets

- D8.1 Gaskets having a product contact surface shall be removable or bonded.
- D8.2 Foam rubber or hollow tubular gaskets shall not be used, except:
- D8.2.1 Hollow tubular gaskets may be used as inflatable seals using pressurized air.
- D8.2.1.1 A pressure sensing device shall be provided to detect rupture or air leakage from hollow tubular gaskets used as inflatable seals.
- D8.3 Grooves in gaskets shall be no deeper than their width, unless the gasket is readily removable and reversible for cleaning.
- D8.4 Gasket retaining grooves in product contact surfaces for removable gaskets shall not exceed 1/4 in. (6.35 mm) in depth or be less than 1/4 in. (6.35 mm) wide except:
- D8.4.1 Those for standard O-rings smaller than 1/4 in. (6.35 mm), and those provided for in Sections D14 and D15.
- D8.4.2 Radii in standard O-ring grooves shall be as specified in Appendix, Section H.
- D8.4.3 Retaining grooves for access door gaskets shall be no deeper than their width.

D9 Radii

- D9.1 All internal angles of less than 135° on product contact surfaces, shall have radii of not less than 1/4 in. (6.35 mm) except that:
- D9.1.1 Smaller radii may be used when they are required for essential functional reasons, such as those on filter frames, air lock blades, rotary airlock endplates, seal retainers, air distribution devices, chain drive sprockets and sanitary fittings provided for in Sections D14 and D15. In no case shall such radii be less than 1/32 in. (0.794 mm), except that:
- D9.1.1.1 Radii on atomizing devices may be less than 1/32 in. (0.794 mm). When the radius is less than 1/32 in. (0.794 mm), this internal angle must be readily accessible for cleaning and inspection.
- D9.1.1.2 Minimum radii are not applicable in perforations of fluid bed screens that are slot shaped, crescent-shaped, or that are round in shape and less than 1/16 in. (1.59 mm) diameter.
- D9.1.2 Radii for fillets of welds in product contact surfaces where the thickness of one or both parts joined is 3/16 in. (4.76 mm) or less shall be not less than 1/8 in. (3.18 mm).

D10 Threads and Crevices

- D10.1 There shall be no exposed threads or crevices on product contact surfaces except where required for functional and safety reasons

such as high pressure liquid product lines and valves including threaded, socket welded and compression fittings, high and low pressure atomizing devices, air distribution devices, and fan wheels.

D11 Fluid Bed Screen Perforations

- D11.1 Round perforations shall be not less than 0.012 in. (0.3048 mm) in diameter.
- D11.2 Slot-shaped perforations shall be at least 0.0060 in. (0.1524 mm) wide, and at least 0.020 in. (0.508 mm) long.
- D11.3 Crescent-shaped perforations shall be at least 0.004 in. (0.1016 mm) wide at the widest part of the opening and the perforations shall be at least 0.020 in. (0.508 mm) long. Internal angles of the perforations shall be well defined and free of crevices. One side of the screen may have indentations around the perforations. The other side may have projections around the perforations, together with shallow open grooves between the rows of perforations.
- D11.4 Fluid bed screens shall be designed and equipped for mechanical cleaning.
- D11.5 All perforations shall be free of burrs.
- D11.6 Fluid bed screens shall be accessible for cleaning and inspection.

D12 Springs

- D12.1 Any coil spring having product contact surfaces shall have at least 3/32 in. (2.38 mm) openings between coils, including the ends, when the spring is in the free position.

D13 Flexible Connections

- D13.1 Product contact surfaces of flexible connections shall have straight sides without corrugations except that:
- D13.1.1 Flexible connections less than 18 in. (457.2 mm) long which are used in a vertical position on vibratory sifters or fluid beds may have corrugations which have a radius of not less than 0.5 in. (12.7 mm) and are no deeper than their width.
- D13.2 If a flexible connection is a hose assembly it shall comply with applicable provisions of the 3-A Sanitary Standards for Hose Assemblies, Number 62.

D14 Fittings, Connections and Valves

- D14.1 All sanitary fittings, connections and valves, except those exempted in Section D10.1 and those larger than 6 in. (152.4 mm) which are used on dry product equipment, conveyors and process air, shall conform with the applicable design, material, and construction

provisions of the 3-A Sanitary Standards for Fittings for Milk and Milk Products, Number 63- and any applicable 3-A Sanitary Standards for Valves. See Appendix O and P.

D15 **Instrument Connections**

D15.1 All instrument connections having product contact surfaces shall conform with the applicable provisions of the 3-A Sanitary Standards for Sensors and Sensor Fittings and Connections for Milk and Milk Products Equipment, Number 09-, except those connections for instruments used to sense or measure air flow or pressure, which shall be of sanitary design and shall be removed and capped or isolated during cleaning operations.

D16 **Sanitary Tubing**

D16.1 All stainless steel tubing 4 in. (101.6 mm) diameter and smaller shall conform to the 3-A Sanitary Standards for Polished Metal Tubing for Dairy Products, Number 33-. Product contact surfaces of stainless steel tubing larger than 4 in. (101.6 mm) diameter shall meet the surface finish requirements of Section D2. (See Section D4.1.1 for welding requirements.)

D17 **Pressurized Air**

D17.1 Where air from a separate source is used for applications such as purging pipelines, nozzles, shaft seals, bearings, instruments and sight windows, and inflatable seals, the air supply shall comply with the applicable criteria contained in the 3-A Accepted Practices for Supplying Air Under Pressure in Contact with Milk, Milk Products and Product Contact Surfaces, Number 604-, except that:

D17.1.1 The filter and disposable media covered by Sections D6.4, D6.4.1, and D6.4.2 in 3-A Accepted Practices for Supplying Air Under Pressure in Contact with Milk, Milk Products, and Product Contact Surfaces 604- may be alternatively positioned as close as reasonably possible, in an easily accessible location, upstream of an air distribution manifold which supplies pressurized air to individual points of use.

D17.1.2 Any air distribution manifold located after a disposable filter as specified in Section D17.1.1 shall be made of stainless steel fabricated with no open seams and shall be readily accessible and inspectable.

D18 **Bearings**

D18.1 Bearings having a product contact surface shall be of a nonlubricated type.

D18.2 Lubricated bearings, including the permanently sealed type, shall be located outside the product contact surface with at least 1 in. (25.4 mm) clearance open for inspection between the bearing and any product contact surface.

D19 **Shafts**

D19.1 Where a shaft passes through a product contact surface, the portion of the opening surrounding the shaft shall be protected to prevent the entrance of contaminants.

D20 **Cyclone Collector Exhausts**

D20.1 When the exhausts of cyclone collectors are connected to the bottom of a plenum whose entire construction does not conform to the criteria for product contact surfaces, the top of the plenum shall be constructed so as to conform to product contact surfaces criteria and the collector exhaust connections shall extend upward into the plenum at least 6 in. (152.4 mm).

D21 **Porous Belt Conveyors**

D21.1 Product contact surfaces of porous belt conveyors shall be designed for mechanical cleaning and the following:

D21.1.1 If woven mesh belt construction is used, the necessary lapping contact area shall be minimized. Porous belt openings shall be designed so that product contact surfaces can be mechanically cleaned and are inspectable.

D21.1.2 Belts shall be continuous; however, a woven mesh belt is considered to meet this criterion if the ends of the belt are connected with loops and a pin made of stainless steel or plastic complying respectively with the criteria in Section C1.2.1 or C1.3.2.1. The loops and pin connection shall be designed to provide sufficient open construction to allow the flow of cleaning solutions.

D21.1.3 Belt washing and drying zones, if provided, shall be considered product contact areas and be constructed accordingly.

D21.1.4 Inspection access shall be provided to all belt surfaces, belt supports and belt washing, drying, tensioning, and tracking component areas.

D22 **Openings**

D22.1 Any opening in the top of a dryer for an atomizer that is removed for cleaning shall have a permanently installed flange or ring around the opening that extends upward at least 1/2 in. (12.70 mm) above the opening for the atomizer. A close fitting, overlapping

cover for this opening having a downward flange of at least 3/8 in. (9.52 mm) shall be provided when the atomizer(s) is removed.

D23 Nonproduct Contact Surfaces

D23.1 Nonproduct contact surfaces shall have a smooth finish, free of pockets and crevices, and be cleanable and those surfaces to be coated shall be effectively prepared for coating. Exposed threads shall be minimized. Exposed braided coverings of cable or hose shall not be used. No continuous or piano-type hinges shall be used on the equipment or its control cabinets. Electrical and utility connections shall be as remote as practical from the product areas. Riveted name plates or appendages shall not be used. Socket head cap screws shall not be used. Knurled surfaces shall not be used. Name plates shall be welded or effectively sealed to the equipment. External lap joints for sheathing over insulated areas shall be overlapped downward. Overlapped joints shall be sealed between the mating surfaces with a suitable sealant. (See Appendix, Section L.) Supporting structures, braces, catwalks, stairs, handrails and guards are not considered as nonproduct contact surfaces of the equipment and are considered as part of the building structure. Panels or doors shall be provided to allow easy access to the interior of the equipment. They shall be constructed in a manner that will prevent air entrance. Use of hinges, wing nuts, latches, and similar easy-opening fastening devices are recommended to allow easy access without special tools.

D23.2 The requirement to be free of pockets and crevices does not apply to exposed exterior surfaces of ancillary equipment such as sanitary fittings, service fittings, electric motors, drives, fans, mechanical linkages, drives for rotary atomizing devices and other similar equipment.

E PROCESSING AIR

E1 Intake Location

E1.1 The location and nature of adjacent structures and the variations of wind and weather shall be considered in selecting the location of the air supply intake opening. It shall be located so that it will reasonably insure that the quality of the intake air will be suitable for its intended use.

E2 Intake Opening

E2.1 Outside intake openings shall be suitably protected against the admission of foreign

objects. Openings shall be provided with louvers which can be closed when processing equipment is not in use and hoods shall be used over these openings to minimize the intake of rain, snow, dust, or other foreign material, except that louvers and/or hoods need not be provided if the nature and the location of the openings accomplish these purposes. Openings shall be equipped with sturdy screens having openings not larger than 3/4 in. (19 mm) mesh.

E3 Processing Air Fan Drives

E3.1 Motors, belt drives and bearings are not permitted in the air stream after the final air filters.

E4 Processing Air Supply Filtration

E4.1 The air supply system and/or ducting shall be such that all of the air is caused to pass through air filters properly installed in the final air filter frames. Filters shall meet or exceed the following specifications:

E4.1.1 Processing air to be heated shall pass through a properly installed and maintained filter(s), selected to have a minimum average efficiency of 90% when tested in accordance with the ASHRAE Synthetic Dust Arrestance Test⁹ when operated at its design face velocity.

E4.1.2 Processing air not to be heated shall pass through a properly installed and maintained filter(s), selected to have a minimum average efficiency of 85% when tested in accordance with the ASHRAE Atmospheric Dust Spot Method⁷ when operated at its design face velocity.

E4.1.3 Air filter media shall not be cleaned and reused.

E5 Exhaust Air

E5.1 Processing air exhausted from the processing equipment shall be through stacks or other openings located so as to prevent or minimize re-entry of exhausted air or product into air intakes for any use, and to minimize accumulation of product on surrounding structures. Except for relatively small air quantities, such as from bin or hopper vents, all air shall be exhausted to the outside atmosphere.

E5.2 Processing air may be preheated with exhaust air from the spray drying system by using one of the following methods:

E5.2.1 Indirect air-to-air heat exchanger equipment which completely separates the two air streams so there is no intermixing.

E5.2.2 Indirect air-liquid-air heat exchanger equipment which uses non-toxic intermediate fluid to transfer the heat.

E5.3 Exhaust air heat exchange surfaces shall be cleanable by either mechanical or manual means. The processing air heat exchange equipment may be located either before or after the final air filter. If located after the final air filter, processing air contact surface requirements apply for materials and fabrication.

E5.4 A self-closing or automatically-closing cover shall be installed at the terminal end of all ducts exhausting processing air to the atmosphere.

APPENDIX

F STAINLESS STEEL MATERIALS

Stainless steel conforming to the applicable composition ranges established by AISI for wrought products, or by ACI for cast products, should be considered in compliance with the requirements of Section C1 herein. Where welding is involved, the carbon content of the stainless steel should not exceed 0.08%. The first reference cited in C1 sets forth the chemical ranges and limits of acceptable stainless steel of the 300 Series. Cast grades of stainless steel corresponding to types 303, 304, and 316 are designated CF-16F, CF-8, and CF-8M, respectively. The chemical compositions of these cast grades are covered by ASTM specifications A351/A351M, A743/A743M and A744/A744M.

G PRODUCT CONTACT SURFACE FINISH

G1 Surface finish equivalent to 150 grit or better as obtained with silicon carbide, properly applied on stainless steel sheets, is considered in compliance with the requirements of Section D2.1 herein. A maximum R_a of 32 $\mu\text{in.}$ (0.80 μm), when measured according to the recommendations in American National Standards Institute (ANSI)/American Society of Mechanical Engineers (ASME)¹⁰ B46.1 - Surface Texture, is considered to be equivalent to a No. 4 finish.

G2 Sheets of 2B (cold rolled) stainless steel, inspected and selected to be free of pits, folds and crevices are generally found to be as smooth as or smoother than stainless steel sheets with a No. 4 finish and are acceptable for the fabrication of equipment used in spray drying systems.

H O-RING GROOVE RADII

TABLE 1
Groove Radii Dimensions for Standard O-Rings*

O-Ring Cross Section, Nominal (AS 568) ¹⁰	O-Ring Cross Section, Actual (AS 568)	O-Ring Cross Section, Actual (ISO 3601-1) ¹¹	Minimum Groove Radius
1/16 in.	0.070 in.	1.80 mm	0.016 in. (0.406 mm)
3/32 in.	0.103 in.	2.65 mm	0.031 in. (0.787 mm)
1/8 in.	0.139 in.	3.55 mm	0.031 in. (0.787 mm)
3/16 in.	0.210 in.	5.30 mm	0.062 in. (1.575 mm)
1/4 in.	0.275 in.	7.00 mm	0.094 in. (2.388 mm)

* Radii in nonstandard O-ring grooves should be those radii closest to a standard O-ring as specified in Table 1.

I CLEANING AND SANITIZING PROCEDURES

A cleaning and sanitizing regimen which is effective should be employed. A description of this regimen should be available at the drying plant.

II Wet Cleaning

II.1 Frequent wet cleaning and sanitizing should only be done on a spray dryer system designed for mechanical cleaning. The recommendations of the cleaning chemical supplier should be followed with regard to time, temperature and concentration of specific detergents, and sanitizers unless steam, hot water, or hot air sanitizing is used.

II.2 If some of the components of the dryer system are not to be wet cleaned, they should be completely segregated during the wet cleaning procedure. Examples of such segregation:

- Disconnecting a sifter and moving it away from an upstream wet cleaning operation.
- Loosening a duct flange, inserting a shut-off plate, then tightening the flange to wet clean one section of the duct.
- Disconnecting and capping off a sensor tube for an instrument that measures air pressure.
- Removal of a star valve and replacement with a spool piece for wet cleaning of an upstream cyclonic collector.
- Running an auxiliary fan or an inlet fan at slow speed to keep wet cleaning vapors out of the air handling system.

I2 Dry Cleaning

- I2.1 Equipment should be regularly inspected for cleanliness. Dry cleaning should be performed in accordance with need. Too frequent opening of equipment to dry clean may lead to increased contamination of product contact surfaces and should be avoided.
- I2.2 Cleaning methods employing pressurized air should be avoided.
- I2.3 While cleaning the spray dryer system, pressurized air complying with the requirements of Section D17.1 should be applied to all air pressurized seals.
- I2.4 Hand and vacuum cleaner brushes, scoops, scrapers, and any other tools used in the dry cleaning of product and process air contact surfaces should not be used on any other surfaces. Such tools should be made of materials that can be cleaned and sanitized and should not have wooden parts nor be of mild steel or other iron products that will rust. They should be maintained in a sanitary manner and stored in clean, separate, labeled lockers or cabinets.

J SANITARY ATTIRE AND CLEANING APPLIANCES

- J1 When it is necessary to enter the dryer for dry and/or manual cleaning:
 - J1.1 The cleaning crew should be furnished with freshly laundered multiple-use clothing, or new single service outer clothing and suitable footwear;
 - J1.2 A suitable place should be provided for the storage of clothing, footwear, and cleaning tools and appliances;
 - J1.3 A clean place should be provided adjacent to the point of entry to the dryer which provides:
 - J1.3.1 An area to which the laundered or new single service outer clothing and footwear can be carried;
 - J1.3.2 An area in which outer clothing can be removed and stored;
 - J1.3.3 An area in which the laundered or new single service outer clothing and footwear can be donned;
 - J1.3.4 A special sanitary platform, or a clean floor area covered with single-service plastic or clean paper to maintain the cleanliness of the footwear;
 - J1.4 Garments and boots worn for interior dryer cleaning should be worn only while cleaning the dryer and not while performing other

tasks. Boots that have been worn while walking outside the dryer should be replaced with other suitable boots before reentering the dryer.

- J2 Cleaning tools and appliances that are used in the dryer should be kept clean and used for no other purpose than cleaning the interior of the dryer.

K DIRECT FIRED GAS BURNER MAINTENANCE

- K1 It is essential that burners and their controls operate properly to achieve proper combustion of the gas and control of the processing air temperature. It is suggested that burners be cleaned as frequently as necessary. Burner controls and safety interlocks should be checked at least annually for proper operation.
- K2 If in doubt about the operation of the burner or its controls, the dryer manufacturer or a qualified service representative recommended by them should be consulted.

L NONPRODUCT CONTACT SURFACES

- L1 Room temperature vulcanizing silicone rubber may be used for formed-in-place gaskets on joints in nonproduct contact surfaces, such as coverings for insulation. This product should only be used where functionally necessary.

M PRESS FITS AND SHRINK FITS

Press-fits or shrink-fits may be used to produce crevice free permanent joints in metallic product contact surfaces when neither welding nor soldering is practical. Joints of these types may only be used to assemble parts having circular cross sections, free of shoulders or relieved areas. For example: they may be used to assemble round pins or round bushings into round holes. In both types of fits, the outside diameter of the part being inserted is greater than the inside diameter of the hole. In the case of the press-fit, the parts are forced together by applying pressure. The pressure required is primarily dependent upon the diameter of the parts, the amount of interference and the distance the inner member is forced in. In shrink-fits, the diameter of the inner member is reduced by chilling it to a low temperature. Dry ice is commonly used to shrink the inner member. Heat may also be applied to the outer member of the press-fit. Less assembly force is required for this type of fit.

The design of these fits depends on a variety of factors. The designer should follow recommended practices to assure that a crevice-free joint is produced. A recognized authoritative reference is Machinery's Handbook published by Industrial Press Inc., 200 Madison Avenue, New York, NY 10157.

N POROUS BELT CONVEYOR WASH WATER

N1 The water used for continuous washing of a porous belt conveyor should be monitored and maintained at a minimum temperature of 145°F (63°C) and should be changed at least every 4 hrs.

O PARTIAL LIST OF 3-A SANITARY STANDARDS AND 3-A ACCEPTED PRACTICES

- O1** 3-A Sanitary Standards for Centrifugal & Positive Rotary Pumps for Milk & Milk Products, Number 02.
- O2** 3-A Sanitary Standards for Homogenizers & Pumps of the Plunger Type, Number 04.
- O3** 3-A Sanitary Standards for Plate-Type Heat Exchangers for Milk & Milk Products, Number 11.
- O4** 3-A Sanitary Standards for Tubular Heat Exchangers for Milk & Milk Products, Number 12.
- O5** 3-A Sanitary Standards for Multiple-Use Rubber & Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18.
- O6** 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20.
- O7** 3-A Sanitary Standards for Sifters for Dry Milk & Dry Milk Products, Number 26.
- O8** 3-A Sanitary Standards for Polished Metal Tubing for Dairy Products, Number 33.
- O9** 3-A Sanitary Standards for Pneumatic Conveyors for Dry Milk & Dry Milk Products, Number 39.
- O10** 3-A Sanitary Standards for Bag Collectors for Dry Milk & Dry Milk Products, Number 40.
- O11** 3-A Sanitary Standards for Mechanical Conveyors for Dry Milk & Dry Milk Products, Number 41.
- O12** 3-A Sanitary Standards for Wet Collectors for Dry Milk & Dry Milk Products, Number 43.

- O13** 3-A Sanitary Standards for Air Driven Sonic Horns for Dry Milk & Dry Milk Products, Number 49.
- O14** 3-A Sanitary Standards for Level Sensing Devices for Dry Milk & Dry Milk Products, Number 50.
- O15** 3-A Sanitary Standards for Plug-Type Valves for Milk & Milk Products, Number 51.
- O16** 3-A Sanitary Standards for Thermoplastic Plug-Type Valves for Milk & Milk Products, Number 52.
- O17** 3-A Sanitary Standards for Compression-Type Valves for Milk & Milk Products, Number 53.
- O18** 3-A Sanitary Standards for Diaphragm-Type Valves for Milk & Milk Products, Number 54.
- O19** 3-A Sanitary Standards for Boot Seal-Type Valves for Milk & Milk Products, Number 55.
- O20** 3-A Sanitary Standards for Vacuum Breakers & Check Valves for Milk & Milk Products, Number 58.
- O21** 3-A Sanitary Standards for Rupture Discs for Milk & Milk Products, Number 60.
- O22** 3-A Sanitary Standards for Steam Injection Heaters for Milk & Milk Products, Number 61.
- O23** 3-A Sanitary Standards for Hose Assemblies for Milk & Milk Products Equipment, Number 62.
- O24** 3-A Sanitary Standards for Sanitary Fittings for Milk & Milk Products, Number 63.
- O25** 3-A Sanitary Standards for Sight and/or Light Windows & Sight Indicators in Contact with Milk & Milk Products, Number 65.
- O26** 3-A Accepted Practices for Supplying Air Under Pressure in Contact with Milk, Milk Products & Product Contact Surfaces, Number 604.
- O27** 3-A Accepted Practices for Permanently Installed Sanitary Product-Pipelines & Cleaning Systems Used in Milk & Milk Processing Plants, Number 605.
- O28** 3-A Accepted Practices for Instantizing Systems for Dry Milk & Dry Milk Products, Number 608.
- O29** 3-A Accepted Practices for a Method of Producing Steam of Culinary Quality, Number 609.

P SYSTEM INSTALLATION

Appropriate regulatory agencies should be contacted for guidance during system design and installation.

These revised practices are effective November 25, 1998 at which time the 3-A Accepted Practices for Spray Drying Systems for Milk and Milk Products, Number 607-03 are rescinded and become null and void. 3-A Accepted Practices for Spray Drying Systems for Milk and Milk Products, Number 607-04.

¹Use current revisions or editions of all referenced documents cited herein.

²The data for this series are contained in the *AISI Steel Products Manual, Stainless & Heat Resisting Steels*, November 1990, Table 2-1, pp. 17-20. Available from the Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086; 412.776.1535.

³Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016; 708.299.9160.

⁴Aluminum Association, 900 19th Street, Suite 300, NW, Washington, D.C. 20006; 202.862.5100.

⁵Adhesives shall comply with 21 CFR 175 - Indirect Food Additives: Adhesives and Components of Coatings. Document for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402; 202.512.1800.

⁶Glass of a borosilicate type with a coefficient of expansion, between 30°F and 300°F, of 3.0 to 3.5 ppm per degree.

⁷Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959; 610.832.9500.

⁸The method of making these tests will be found in ANSI/ASHRAE Standard 52.1-1992. Available from the American Society of Heating, Refrigerating and Air Conditioning Engineers, Inc., 1791 Tullie Circle, NE, Atlanta, GA 30329; 404.636.8400.

⁹Available from the American Society of Mechanical Engineers, 345 East 47th Street, New York, NY 10017-2392; 212.705.7722.

¹⁰The document establishing these standard dimensions is Aerospace Standard (AS) 568, published by SAE, 400 Commonwealth Drive, Warrendale, PA 15086; 412.776.4970.

¹¹The document establishing these standard dimensions is ISO 3601-1: 1988 (E), published by the International Organization for Standardization (ISO), 1 Rue de Varembe, Case Postale 58, CH 1 1211, Geneva, Switzerland (41.22.734.1240).

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**General Fund Statement of Activity
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Revenue:

Advertising	\$ 98,931
Membership & Administration	348,495
Communication	541,377
Annual Meeting	270,948
Workshops	23,920
Total revenue	<u>1,283,671</u>

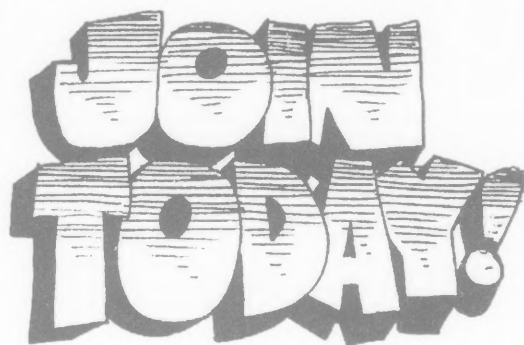
Expense:

Advertising	98,914
Membership & Administration	393,441
Communication	588,190
Annual Meeting	214,443
Workshops	11,283
Total expense	<u>1,306,271</u>

Change in General Fund \$ (22,600)

Net Assets as of 8/31/98:

General Fund	(70,526)
Foundation Fund	76,498
Restricted Fund	<u>49,643</u>
Total net assets	<u>\$ 55,615</u>



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Coming Events

JANUARY

• **28-29, HACCP Verification and Validation — An Advanced Workshop**, North Carolina State University, Raleigh, NC. This workshop is sponsored by The Food Processors Institute. The core of this program concentrates on the various verification activities included in the Sixth Principle of HACCP (National Advisory Committee on Microbiological Criteria for Foods, 1997). Any food safety professional in industry, government or academia interested in further developing their understanding and skills in HACCP should attend this workshop. For further information, contact FPI, (AHC) Dept. 134, Washington, D.C. 20055-0134, Phone: 202.639.5954; Fax: 202.637.8068.

FEBRUARY

• **3-4, 1999 Food Sanitation Workshop**, Doubletree Hotel, Modesto, CA. This two-day workshop is designed for all levels of personnel in the food industry directly or indirectly involved with sanitation. A supplier exhibit is included on the first day. Contact Dr. Linda Harris, Department of Food Science & Technology, University of California, Davis, CA 95616; 916.754.9485; E-mail: ljharris@ucdavis.edu.

• **5, Train the Trainer — Techniques for Educating Adults in Sanitation**, Doubletree Hotel, Modesto, CA (limited enrollment). This half-day workshop will cover the basics of adult education theory and will provide participants with the tools to deliver effective training sessions. Focus will be on sanitation training. Contact Dr. Linda Harris, Department of Food Science & Technology, University of California, Davis, CA 95616; 530.754.9485; E-mail: ljharris@ucdavis.edu.

• **6-8, United 99, United Fresh Fruit & Vegetable Association**

95th Convention & Exposition, San Diego Convention Center, San Diego, CA. For more information, call 703.836.3410; Fax: 703.836.7745.

• **16-18, Kentucky Assn. of Milk, Food & Environmental Sanitarians, Inc. Meeting**, for additional information, contact John Summers at 606.439.2361.

• **23-26, Better Process Control School**, University of California, Davis. Aimed toward high-acid food cannery employees, retort operators, seam closure operator, and food processing industry, this course examines microbiology of canning, still retorts, aseptic processing and packaging systems. For registration call 800.752.0881, Dept. 2406 or 530.757.8777. For program information, contact Diane Barrett at 530.752.4800; E-mail: dmbarrrett@ucdavis.edu.

MARCH

• **10, Dairy HACCP Workshop**, Madison, WI. This one-day workshop will cover design and implementation of HACCP plans in dairy plants. For additional information, contact the Program Coordinators or Dept. of Food Science, University of Wisconsin-Madison, Madison, WI 53706-1565; Phone: 608.262.3046; Fax: 608.262.6872.

• **10-12, Practical HACCP for Food Processors**, Sponsored by Silliker Laboratories Group, Inc. Waterfront Hilton, Huntington Beach, CA. For additional information, contact Silliker Laboratories, Education Services Dept., 900 Maple Road, Homewood, IL 60430; Phone: 800.829.7879; 708.957.7878; Fax: 708.957.8405.

• **22-24, Principles of Quality Assurance Seminar**, Manhattan, KS. This seminar provides basic instruction and examples for developing a quality assurance program. For more information or to enroll, contact AIB, 1213 Bakers Way, P.O. Box 3999, Manhattan, KS 66505-3999;

Phone: 785.537.4750; Fax: 785.537.1493; Web site: aibonline.org.

• **22-26, Laboratory Methods in Food Microbiology**, held at Silliker Laboratories' Corporate Research Center, Teaching Laboratory, South Holland, IL. For additional information, contact Silliker Laboratories, Education Services Dept., 900 Maple Road, Homewood, IL 60430; Phone: 800.829.7879; 708.957.7878; Fax: 708.957.8405.

• **29-1 April, IAFIS Annual Conference**, Westin Rio Mar Beach Resort and Country Club, Rio Grande, Puerto Rico. The Conference Committee has formulated a program that will incorporate the traditional Conference networking, Association business, and well-known speaker presentations with an in-depth look at the current business practices of member companies, and how they can be improved. For additional information, contact IAFIS, 1451 Dolley Madison Blvd., McLean, VA 22101-3850; 703.761.2600; Fax: 703.761.4334.

APRIL

• **7-8, Introduction to Microbiological Criteria and Sampling Plans**, Omni Netherland Plaza, Cincinnati, OH. Sponsored by Silliker Laboratories Group, Inc. For additional information, contact Silliker Laboratories, Education Services Dept., 900 Maple Road, Homewood, IL 60430; Phone: 800.829.7879; 708.957.7878; Fax: 708.957.8405.

• **8-10, Introduction to Statistical Methods for Sensory Evaluation of Foods**, University of California-Davis, Davis, CA. This course introduces statistical analysis to the beginning sensory scientist as well as being an excellent update on applying statistical procedures for the experienced professional. For additional information, contact Michael O'Mahoney at 530.752.6389; E-mail: maomhony@ucdavis.edu.

• **12-14, Sensory Evaluation: Overview and Update**, University of California-Davis, Davis, CA. Designed for both the beginner and experienced professional, this course will give an overview on why tests can be set up in some ways and not in others, enabling the professional to modify and custom-design techniques specific to the product being tested. For additional information, contact Michael O'Mahony at 530.752.6389; E-mail: maomhony@ucdavis.edu.

• **13-14, Microbiological Concerns in Food Plant Sanitation & Hygiene**, San Antonio, TX. Sponsored by Silliker Laboratories Group, Inc. For additional information, contact Silliker Laboratories, Education Services Dept., 900 Maple Road, Homewood, IL 60430; Phone: 800.829.7879; 708.957.7878; Fax: 708.957.8405.

• **19, International Dairy Federation Symposium**, Convention Centre, Ottawa, Canada. The symposium will deal with the subject of Laboratory Accreditation and Proficiency Testing. For additional information contact, International Dairy Federation, Secretariat, 41 Square Vergote, B-1030 Bruxelles, Belgium

or Fax: 32 2 733 04 13; E-mail: Info@fil-idf.org; Web site: www.fil-idf.org.

MAY

• **3-5, First NSF International Conference on Indoor Air Health: Impacts, Issues and Solutions**, Marriott Tech Center in Denver, CO. This new conference explores the contrasting and complementary viewpoints of medical, scientific, academic, laboratory, regulatory and industry forces focused on critical indoor air health issues. For additional information, contact Wendy Raeder by Phone: 734.769.8010 ext. 205; Fax: 734.769.0109; E-mail: raeder@nsf.org.

• **6-12, 15th International Trade Fair for Packaging Machinery, Packaging and Confectionery Machinery**, in Düsseldorf, Germany. For further information, contact Dusseldorf Trade Shows, Inc., 150 N. Michigan Ave., Suite 2920, Chicago, IL 60601 or Phone: 312.781.5180; Fax: 312.781.5188; Web Site: www.dtsusa.com/dts/.

• **12-14, "Food Irradiation 99 Conference—The Solution to the Food Safety Crisis?"**, Sheraton

National Hotel, Arlington, VA. This international conference will present an examination of the business and technical outlook for food irradiation as a solution to the growing global problem of food safety. For further information, contact Deborah Crommett, Conference Coordinator, Intertech Conferences, 411 US Route One, Portland, ME 04105 or Phone: 207.781.9800; Fax: 207.781.2150; E-mail: info@intertechusa.com or www.intertechusa.com.

• **24-26, 3rd International Symposium on Recombined Milk and Milk Products**, Penang, Malaysia. The symposium will seek to discuss and review issues facing the milk recombination industry, the need for the industry to keep pace with the challenges of the future, and product development opportunities presented by the introduction of new technologies and emerging markets. For further information, contact Alison Johnson, The Secretariat, 3rd International Symposium on Recombined Milk and Milk Products, Private Bag 16, Werribee, Victoria Australia, 3030 or Phone: 61 3 9742 0117; Fax: 61 3 9742 0201; E-mail: alison.johnson@foodscience.afisc.csiro.au.



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108	123	138	153	169	183	198	213	228	243	258	273	288	303	318	333	348	363	378	393
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112	127	142	157	173	187	202	217	232	247	262	277	292	307	322	337	352	367	382	397
113	128	143	158	174	188	203	218	233	248	263	278	293	308	323	338	353	368	383	398
114	129	144	160	175	189	204	219	234	249	264	279	294	309	324	339	354	369	384	399

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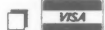
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