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FOOD PROTECTION TRENDS

SCIENCE AND NEWS FROM THE INTERNATIONAL ASSOCIATION FOR FOOD PROTECTION

OCTOBER 2003

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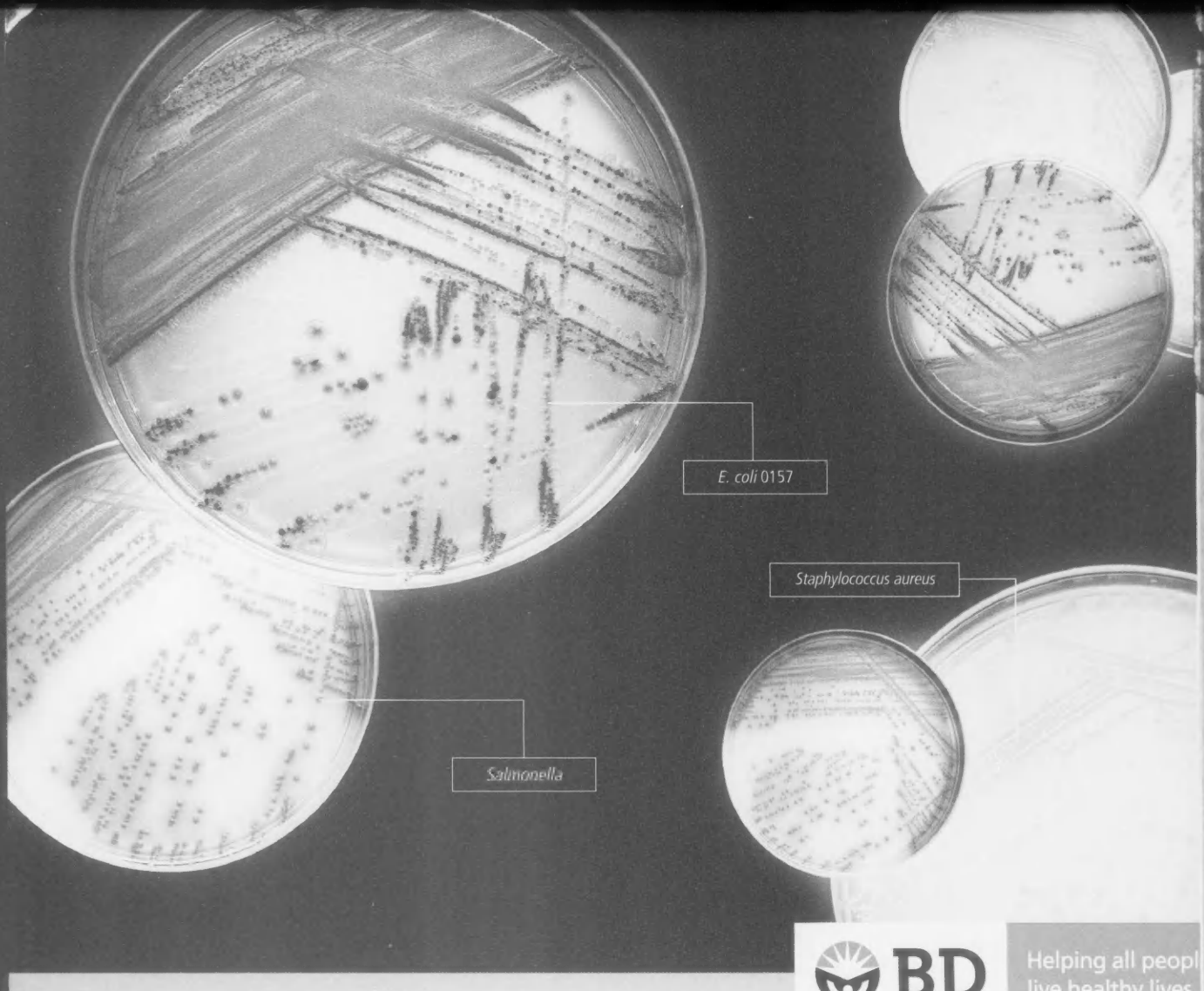

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International Association for Food Protection

FOOD PROTECTION TRENDS

VOLUME 23, NO. 10

ARTICLES

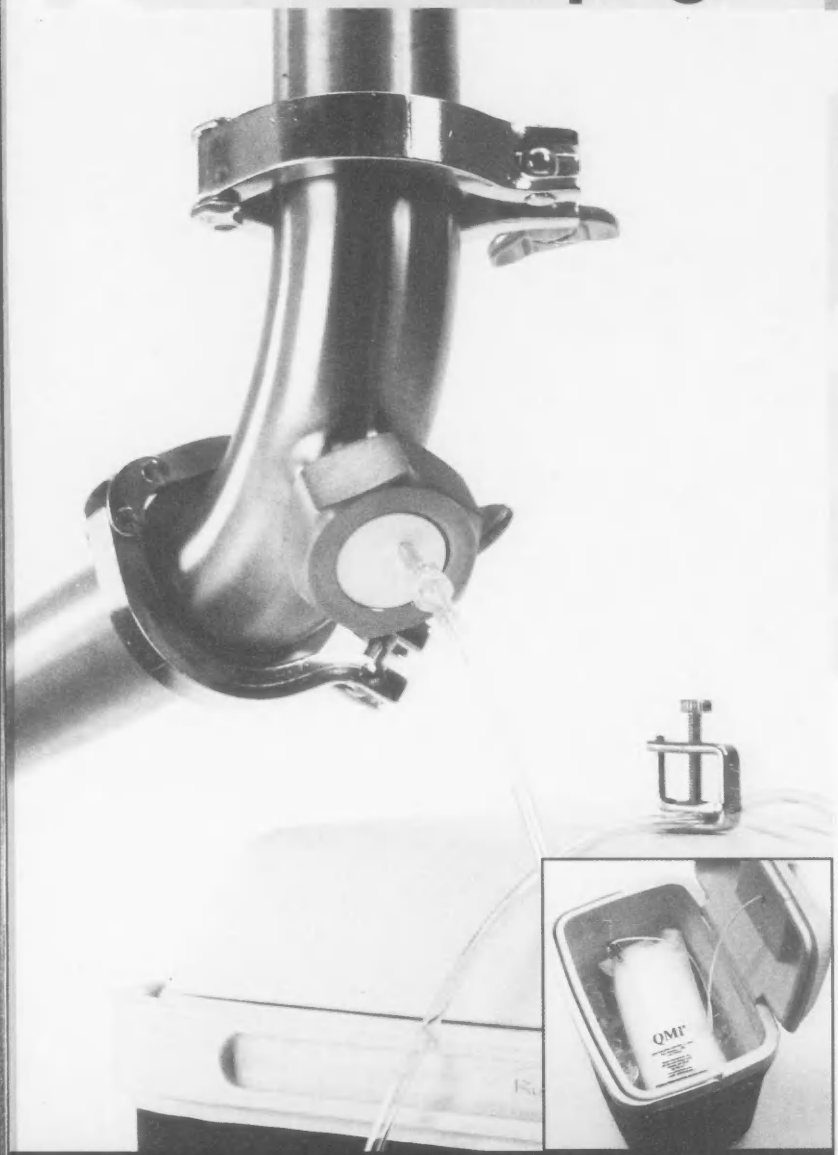
ASSOCIATION NEWS

DEPARTMENTS

EXTRAS

Today's Dairy Farmers Require Accurate Milk Sampling For Maximum Profits

Staphylococcus aureus



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SCIENCE AND NEWS FROM THE INTERNATIONAL ASSOCIATION FOR FOOD PROTECTION

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AUGUST 14-17

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Waterfront Hotel
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AUGUST 13-16

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"PRESIDENT'S" PERSPECTIVE

By PAUL HALL
PRESIDENT

"Making a dream come true!"

The great American lyricist Oscar Hammerstein II once said, "If you don't have a dream, how are you going to make a dream come true?" America's Poet Laureate and composer (in collaboration with Richard Rodgers) of such timeless works as *Show Boat*, *Oklahoma*, *South Pacific* and the *Sound of Music* had many dreams. Until his death in 1960, Hammerstein worked tirelessly to stamp out injustice and was keenly interested in the values that bind a community together. In my opinion, there are a number of values that bind our IAFP community together – making the world's food supply safer and healthier for all, educating food growers, manufacturers and consumers around the world in safe handling practices, helping developing nations improve their food supply and nurturing the next generation of food safety professionals – to name a few.

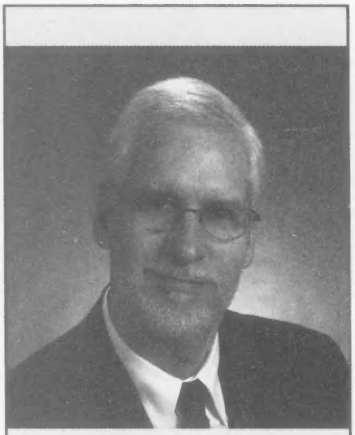
Your Association is successful because of you and only you can assure its continued success. We dedicated this year's Annual Meeting in New Orleans to one of our members who recently passed away. Harry Haverland had a dream for IAFP and worked exuberantly to make his dream come true. Harry served as the chairperson of the IAFP Foundation Fund Committee since its inception in the mid-80's until his death. His dream was to build the Foundation Fund to a level of $100,000 by the year 2000 — a dream that did come true. Another long-time friend and supporter of IAFP also shared his dream for the Foundation Fund at the awards banquet in New Orleans. Wilbur Feagan of the F&H Equipment Company, sponsor of the IAFP Black Pearl Award, announced his dream of building the IAFP Foundation Fund to a minimum level of $1,000,000. If these men and others like them did not dare to dream, then there could be no way for their dreams to come true. Hammerstein's point may seem obvious, but articulating our dreams and then taking steps to make them a reality takes courage, time and commitment. In benchmarking other professional association Foundations, I found that the Institute of Food Technologists Foundation in fiscal year 2002 took in $642,550 in contributions. They have surpassed that number already in 2003. While I admit IFT is a much larger association than IAFP, I submit that IAFP is the premier food safety association in the world. The IFT Foundation has funded over $7.1 million in support of IFT programs since 1985. Just imagine the impact our Association will have in improving the area of food safety if the IAFP Foundation had a similar level of funding. Student food safety scholarships and fellowships, travel grants for students and researchers from developing nations who otherwise

could not travel to our Annual Meeting, and expanded multilingual and educational materials are just a few examples of areas we dream to significantly impact in the future. For those of you working for industry, I urge you to exhort your company to make a contribution to the IAFP Foundation Fund via our Corporate Challenge Program. For all others, I encourage you to make a personal contribution — large or small — every year to the Foundation Fund. Let's help Harry and Wilbur realize their dreams for the Foundation Fund. The world will be a better place for it. I urge each of you to articulate your dreams and have the courage to make them come true. May all of your dreams come true! Please share your dreams about IAFP with me at phall@kraft.com. Until next month...

"COMMENTARY"
FROM THE EXECUTIVE DIRECTOR

Student involvement in IAFP continues to grow and we all benefit from this growth. If you attended IAFP 2003 in New Orleans, you most likely saw for yourself the active student participation. From the Student PDG booth in the registration foyer, to student session room monitors, to our student helpers at registration and those that assisted with our social events, to the students involved with the Developing Scientist Competition; student participation was everywhere!

We are fortunate to have an active student contingent and here is why. By having student involvement, we are training our Association's future. Students attend the Annual Meeting, give presentations, attend presentations and are actively involved in those areas discussed above. Through this involvement, students are learning the importance of the "IAFP way". That is the sharing of information between industry, government and education to help protect the world's food supply. I heard directly from a number of student participants at this year's Annual Meeting that IAFP 2003 energized them and that they can't wait to attend IAFP 2004! That is the best news we can hope for: young people, the future leaders of this Association, who want to return next year (and the year after that, too). This helps to ensure the longevity of IAFP.



"By having student involvement, we are training our Association's future!"

Our Student Members have always been an active component of IAFP but their growth has mushroomed over the past five or ten years. Five years ago, we had just 28 papers accepted for the Developing Scientists Competition. This year, we had 71! Five years ago, we had 51 student attendees at the 1998 Annual Meeting as compared to 158 this year. We have also seen an increase in Student Memberships. Back in 1997 we had 122 Student Members, 20 from outside of the USA. Now we have 279 Student Members including 61 from outside of the United States.

Just four years ago, the Student PDG was formed to provide the opportunity for students to gather at the Annual Meeting to meet one another and learn about each other's research interests. Each year since, a Student Luncheon has been held on Committee Day at the Annual Meeting. This year, close to 100 attended the luncheon and learned about corporate food safety from the featured speaker, Jeffery Rhodehamel from Cryovac / Sealed Air Corporation. We are proud of our student participation in the PDG and look for great things to come in the future.

One event that has been discussed is to hold a student social or a mixer of some type. This would allow interaction between students and food safety leaders in a relaxed social setting. We hope to be able to accomplish this at IAFP 2004, but will need support to enable this to happen. If your company has the ability to lend financial support for such an endeavor, please contact me at the IAFP office. We want to be able to keep the Student Membership in IAFP growing and prospering. After all, students are the future of the International Association for Food Protection!

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Is your organization in pursuit of "Advancing Food Safety Worldwide"? As a Sustaining Member of the International Association for Food Protection your organization can help to ensure the safety of the world's food supply.

Sustaining Membership

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International Association for Food Protection®

ARTICLES

Food Protection Trends, Vol. 23, No. 10, Pages 790-796

6200 Aurora Ave., Suite 200W, Des Moines, IA 50322-2864

International Association for Food Protection.

The Antibacterial Efficacy of Norwegian Hand Dishwashing Detergents

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SUMMARY

The antibacterial efficacy of the standard and antibacterial variants of *Zalo*®, the leading name brand hand dishwashing detergent in Norway, was investigated by a variety of techniques. Tests were chosen to simulate possible applications of the detergents that were expected to have relevance to kitchen hygiene. According to the manufacturer, the antibacterial detergent is designed for use as a bacterial inhibitor in cloths, sponges and brushes. This claim was investigated by inoculating commercially available kitchen sponges with test strains and detergent and then determining the number of cells surviving this treatment. The antibacterial formulation significantly reduced (> 4 log) numbers of both Gram negative bacteria and *Staphylococcus aureus*, whereas Gram negative bacteria increased by approximately equal numbers in control sponges (no detergent) and in sponges containing the standard version of the detergent. The standard detergent reduced the numbers of *Staphylococcus aureus* by > 2 log. The MIC of each formulation was determined by the pour plate technique, and growth curves (suspension tests) in broth containing detergents were generated for culture c23ollection strains and for a bacterial population present in dishwashing water. Both analyses showed that the antibacterial product was usually the most efficacious.

Pseudomonas aeruginosa was able to grow on a minimal agar medium including either detergent as a sole source of carbon and energy. *P. aeruginosa* was subcultured at least 10 times on minimal medium containing detergent over a period of about 2 months. In addition, *Salmonella* Typhimurium and *P. aeruginosa* were grown in tryptone soya broth containing the antibacterial detergent for 15 generations over a similar time period. Neither treatment had an effect on bacterial antibiotic resistance.

A peer-reviewed article

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INTRODUCTION

It has been claimed that the most frequent source of bacterial contamination resulting in food poisoning is the home setting *(11)*. One study identified kitchen sponges and dishcloths as the most contaminated environments in the home *(8)*. Antibacterial activity is not, however, necessarily an inherent property of liquid hand dishwashing compounds *(7)*, and perhaps as a consequence of this manufacturers have begun making antibacterial claims for some detergents. The most widely sold Norwegian antibacterial detergent, *Zalo® Antibakteriell* (Lilleborg AS, Oslo, Norway), now accounts for about 20% of the number of bottles of hand dishwashing detergent sold. Together with the standard formulation, *Zalo® Ultra*, these products dominate (80%) the Norwegian domestic market. The claim made for *Zalo® Antibakteriell* is the most common worldwide claim for such products *(7)*, namely that use of concentrated detergent on a kitchen brush, sponge or dishcloth will have the added effect (by comparison with the corresponding standard product) of inhibiting bacterial growth.

There is considerable variation in the composition of antibacterial soaps and dishwashing detergents. In the United States, triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether) is the most common antibacterial agent used in such products *(7)*. Resistance to triclosan has recently been connected with the development of bacterial antibiotic resistances through shared cellular targets and efflux mechanisms *(10)*. If this is correct, the widespread use of such products may have undesirable medical implications. The appearance on mobile genetic elements of resistance determinant(s) for antibacterial agents having a single or a small number of target molecules could, presumably, also facilitate the spread of antibiotic resistances. The possible significance of biocide usage on antimicrobial resistance in domiciliary environments has been recently reviewed *(2)*. The agent(s) underlying the antibacterial claim in *Zalo® Antibakteriell* is not specified in the product description, but it is probably not triclosan *(1)*. Nowithstanding, the use of any antibacterial products at non-biocidal concentrations may provide selective pressure for the increase and dissemination of naturally resistant strains. Both the antibacterial and standard detergents contain a number of component classes, particularly surface-active agents, likely to have a general biocidal activity. The properties of such compounds have been discussed previously *(9)*. The specific chemical names of the surface-active agents in the Norwegian dishwashing detergents are not specified by the manufacturer in the product information.

In this study, the manufacturer's claims for the antibacterial product as an inhibitor of bacterial growth in kitchen sponges were investigated. Furthermore, the ability of both standard and antibacterial *Zalo®* detergents to prevent the growth of bacteria in dishwashing water was examined.

MATERIALS AND METHODS

Bacterial strains

The following bacterial strains were used in this study: *Pseudomonas aeruginosa* (ATCC 27853); *Escherichia coli* (ATCC 25922); *Salmonella* Typhimurium (ATCC 14028); and *Staphylococcus aureus* (ATCC 25923). Bacteria were stored at -80°C as a thick cell paste in sterile tap water, and were grown prior to experiment on Tryptone Soya Agar (TSA; Oxoid, Hampshire, UK).

Liquid hand dishwashing detergents

The dishwashing detergents tested and relevant information taken from their product data sheets are given below in the author's translation:

Zalo® Ultra: chemical composition (%) — anionic surface-active agents (10–30), non-ionic surface-active agents (5–10), amphoteric surface-active agents (5–10), ethanol (1–5), perfume (% not declared), pH (concentrate) = ca 6.5.

Zalo® Antibakteriell: chemical composition (%) — anionic surface-active agents (10–20), non-ionic surface-active agents (1–5), amphoteric surface-active agents (5–10), ethanol (1–5), perfume (% not declared), pH (concentrate) = 3.7.

Determination of Minimum Inhibitory Concentration (MIC)

The MIC of detergents was determined by use of a non-standardized agar dilution (pour plate) procedure. Detergents were warmed to 42–43°C in a water bath, and aliquots were added to 10 ml TSA kept melted at the same temperature. The mixture was immediately vortexed and returned to the water bath. To each tube, 0.1 ml of a suitably dense stock challenge culture of a test organisms was added to give approximately 10^5 CFU/ml. Stock cell cultures were prepared from overnight TSA-plates. The mixture was vortexed and poured into empty 9 cm diameter plates. Plates were incubated at room temperature and examined for growth of colonies in the agar over a 2-week period. Plates lacking detergent and/or bacteria were included as controls. All tests were repeated at least once.

Growth curves (suspension tests)

The growth of test organisms in broth in the presence of various concentrations of detergents was deter-

TABLE 1. $MIC_{detergent}$ values for bacterial species

Bacterial species	$MIC_{detergent}$ (%)	
	Antibacterial	Standard
Staphylococcus aureus	0.1–0.2	0.1–0.2
Pseudomonas aeruginosa	17–23	> 33
Escherichia coli	13–17	> 33
Salmonella Typhimurium	13–17	> 33

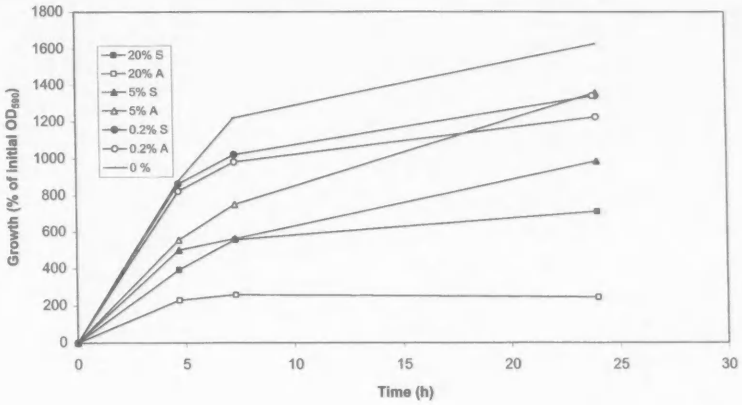
mined with a microtiter plate method as follows: bacterial inoculum (40 µl), prepared by suspending colonies from TSA-agar plates in Tryptone Soya Broth (TSB; Oxoid), was added to 160 µl TSB in wells in a microtiter plate to give about 10^6 CFU/ml. The optical density ($OD_{590\ nm}$) was immediately determined. Thereafter the plate was lidded and incubated at 32°C until an increase in $OD_{590\ nm}$ of about 0.05 was obtained. At this point, 50 µl of various dilutions of the detergents in TSB were added to the wells. Some wells, as controls, contained no detergent and others contained no cells. Cultures were allowed to develop at 32°C without shaking, and the $OD_{590\ nm}$ was measured at intervals using a BioRad 550 plate reader (BioRad, California, US). Growth curves were plotted using the diagram function of the EXCEL system (Windows 2000; Microsoft Corporation, US). All experiments were repeated at least twice.

In a related test, tap water used to rinse plates after a meal including raw vegetables and meat was allowed to stand at 4°C overnight to allow solids to settle; 175 µl of the liquid was then added to each well in a microtiter plate. Some wells were subcultured to determine the number and types of bacteria at the start of the experiment. Detergent (25 µl) was then added to each well as in the standard test and the growth of indigenous bacteria was monitored as described above. Bacteria present at the start and end of the test were compared based on colony morphology and appearance in the microscope.

Effect of liquid hand dishwashing detergents in sponges

It has been reported that commercially available sponges may contain small amounts of preservatives which can be easily removed by washing (*7*). Synthetic yellow sponges (9×6×3 cm) with green scouring pads (Rimco Sponges; NorgesGruppen as, Norway) were used in the present study. No mention is made of preservatives on the sponge packaging. However, as a precaution sponges were washed vigorously prior to testing. The preservative-stripping procedure included machine washing at 60°C with a standard soap powder containing 15–30% zeolites. Sponges were then soaked overnight in saturated NaCl, with the aim of breaking ion-ion bonds between any preservative present and the sponge material, and then rinsed 10 times with tap water and 2 times with distilled water, before being allowed to air dry. Sponges were divided through the middle into identical sections. One half of each sponge was placed in a sterile stomacher bag to which 100 ml of sterile 0.5% yeast extract (acumedia, Baltimore, Maryland, US) was added to simulate the organic load in dishwashing water. To each bag was added 0.1 ml of a bacterial inoculum containing about 1×10^8 cells of *S.* Typhimurium and *P. aeruginosa* in approximately equal numbers. In another test, a combined inoculum of *E. coli* and *S. aureus* was used. After addition of bacteria, the bagged sponges were massaged 20 times by hand to mix the inoculum evenly into the sponge. Subsequently the bag was inverted and squeezed once to remove excess liquid. Control sponges (to which no detergent would be added) were used to determine the bacterial load at the start of the experiment. In each experiment, 3 parallels (3 control bags, etc.) were used. Five times 0.1 ml aliquots were removed from the control bags in order to determine the bacterial numbers at the start of the experiment. The spread plate technique on TSA-agar, with incubation at 32°C, was employed. *P. aeruginosa* and *S.* Typhimurium colonies were distinguished on the basis of appearance and the oxidase test (positive for *P. aeruginosa*). *E. coli* and *S. aureus* were distinguished on the basis of appearance. To 2 bags each, 4 ml of detergent was added and the sponges were again squeezed 20 times to ensure thorough mixing of bacteria and detergent in the sponge. (The bottle label specifies only that the detergent should be squirted onto the cloth, brush, etc. The use of 4 ml in this test, although somewhat arbitrary, approximated a single squirt from the bottle). Bags were then allowed to stand open at room temperature overnight to allow the contaminated sponges to air dry in contact with detergent. The following day, sponges were rehydrated with sterile distilled water and massaged 20 times by hand to homogenize the

FIGURE 1. Effect of antibacterial (A) and standard (S) dishwashing detergents on the growth of *E. coli* in TSB



bacteria in the water. The number of surviving bacteria was determined at once, and again after standing for a further period of 24 h and of 6 days. The experiments were repeated on 2 separate occasions. Percentage reductions in bacterial numbers were calculated relative to the initial count in the untreated control. The test outlined above is basically similar to a previously described procedure *(7)*.

The effect on bacteria of prolonged cultivation in the presence of detergents

Pseudomonas aeruginosa and *S.* Typhimurium were grown by subculturing in TSB supplemented with a sublethal concentration (5%) of the antibacterial detergent for 15 generations over a period of about 2 months. The test was performed by aseptic serial transfer in the wells of a microtiter plate containing 150 µl detergent-amended TSB. Wells were covered with a sterile membrane (Nunc, Roskilde, Denmark) to prevent contamination. In another experiment, *P. aeruginosa* was grown as bacterial colonies with detergent as the sole source of carbon and energy (6% standard formulation; 4.5% antibacterial formulation). Detergent was dissolved in 10 times MSB-salts *(3)* and made solid by the addition of 15 g/l Bactoagar (Difco Laboratories, Detroit, MI, US) previously washed 5 times in distilled water. Control plates (containing no detergent) were included in the test. *P. aeruginosa* was subcultured onto fresh agar at least 10 times over a period of about 2 months. At the end of the experiments, bacteria were examined microscopically for signs of altered cell morphology. In addition, the antibiotic resistance profiles of detergent-exposed cultures were compared with those of non-exposed cultures by use of a standard disc-diffusion technique (User's Guide; Neosentitabs, 10th ed. 1998, Rosco, Denmark). The following antibiotics were tested: norfloxacin, gentamicin, ciprofloxacin, cefotaxime, amikacin, ticarcillin, tetracycline, trimethoprim+sulfa (for *P. aeruginosa*). Testing of *S.* Typhimurium included ampicillin and streptomycin in addition.

RESULTS

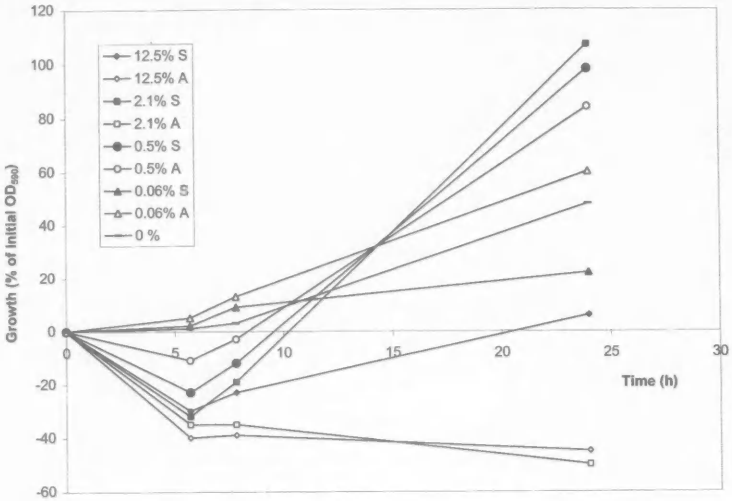
Determination of MIC

Both detergents showed greater activity against *S. aureus* than against the Gram negative species tested. The antibacterial product was the most effective against the Gram negative organisms, whereas at the range of dilutions tested both products fared equally well against *S. aureus*. *P. aeruginosa* was the most resistant organism. The results of testing are summarized in Table 1. The highest concentration of the standard detergent tested (33%) did not completely inhibit growth of any of the Gram negative bacteria. *S. aureus* was inhibited with about 0.1–0.2% of either detergent, but at even lower concentrations growth of colonies was severely retarded by comparison with control plates (no detergent).

Growth curves (suspension tests)

The antibacterial detergent generally inhibited bacterial growth the most. *P. aeruginosa* was shown to be least susceptible to the detergents, whereas *S. aureus* was the most sensitive species. The results were in general agreement with the MIC values. Some growth occurred in all Gram negative species at all concentrations of detergents tested. Figure 1 shows the growth curves of *E. coli* in the presence of various concentrations of both detergents. At the highest concentration investigated (20%), the antibacterial detergent had a greater inhibitory effect on bacterial growth than the standard version. This was also the observation for *S.* Typhimurium. *P. aeruginosa* grew equally well in the presence of 20% of either detergent (results not shown). It is of interest that, for *E. coli* and *S.* Typhimurium, in a lower concentration range (around 1–5% of both formulations), the standard detergent performed best in all test runs. Similarly, at around 4–10% detergent the same effect was observed for *P. aeruginosa*. In one experiment, no growth of *S. aureus* was registered in the presence of 9% of either detergent after 500 min. At the next concentration investigated (4.5%), growth occurred with both detergents. The antibacterial version gave greatest growth inhibition of *S. aureus* at 4.5% and at

FIGURE 2. Effect of antibacterial (A) and standard (S) dishwashing detergents on the growth of bacteria indigenous to dishwashing water (selection of available data)



all lower detergent concentrations. Similar tests were conducted by allowing bacteria in dishwashing water to propagate in the presence of detergents. Microscopic examination showed that the bacteria in the water at the start of the experiment were mainly (> 99%) two morphological types. These were a Gram positive/oxidase negative, nonmotile rod that formed yellow colonies on TSA, and a Gram positive/oxidase positive/motile rod forming cream colored colonies. Neither strain showed spores in wet mounts. All concentrations (0.03–12.5%) of the standard detergent tested allowed bacterial growth, whereas no viable bacteria were detected after incubation in wells containing 2% or more of the antibacterial detergent. Below about 8% of the standard detergent and 2% of the antibacterial variant, the growth curves obtained did not simply reflect the detergent concentration. At lower concentrations, either the inhibitory effect of the detergents either does not exist, or bacterial growth is affected in some more complex manner. A selection of the data obtained is shown (Fig. 2). An initial fall in OD_{590nm} seen after the addition of high detergent concentrations may suggest the lysis of indigenous bacteria and/or the dispersion of fat globules in the water. After incubation, several wells were investigated for bacterial types. Two new colony morphologies dominated in wells with viable bacteria. One of these (Gram positive/oxidase negative/non-spore-forming irregular rod) was present in small numbers at the start of the experiment. The results suggest that growth in the presence of detergent results in changes in the composition of the bacterial population.

Effect of liquid hand dishwashing detergents in sponges

The standard detergent produced no reduction in the numbers of contaminating Gram negative bacteria but had an effect on *S. aureus*. The numbers of viable Gram negative bacteria in the control and test samples with standard detergent increased approximately equally in the course of the first 24 h, suggesting that conditions were favorable for growth. The antibacterial detergent reduced the bacterial load of all test species by > 99.99% in the 3 experimental runs. The results are summarized in Table 2. Retesting of sponges 7 days after treatment with antibacterial detergent produced no colonies of any of the bacterial species investigated. The manufacturer's claim for the antibacterial product was thus borne out within the framework of the laboratory simulation.

The effect on bacteria of prolonged cultivation in the presence of detergents

Subculturing of bacteria in TSB in the presence of detergents (*P. aeruginosa*, *S.* Typhimurium) or on detergents as the sole source of carbon and energy (*P. aeruginosa*), produced no obvious changes in colony or cellular morphology, and no changes in the bacterial antibiotic resistance profiles. Under the conditions of the test, contact between bacteria and detergent resulted in no observable effect on the strains tested.

DISCUSSION

The most common worldwide claim for antibacterial hand dishwashing detergents, is that the concentrated form can inhibit growth of bacteria in dishwashing brushes, sponges and cloths (*7*). This is also the claim made for *Zalo® Antibakteriell*. Specifically, it is claimed that bacterial inhibition is a characteristic in addition to those of the standard detergent *Zalo® Ultra*. This claim was investigated for the two products, sales of which together account for about 80% of the Norwegian domestic market for hand dishwashing detergents. In addition, use of these detergents in other connections expected to have relevance for kitchen hygiene, such as in reducing bacterial growth in dishwashing water, were examined. The bacterial strains chosen for challenge tests are all important as transient microflora of the hands and include notable causative

TABLE 2. Effect on colony counts of 24-h incubation of bacteria in synthetic sponges treated with liquid hand dishwashing detergents and yeast extract

Bacterial species	Detergent	Change in log CFU/ml
Gram negative species[a]	Antibacterial	> - 4
	Standard	> + 2
	Control[b]	> + 2
Staphylococcus aureus	Antibacterial	> - 4
	Standard	> - 2
	Control[b]	> + 1

[a]Species tested: *P. aeruginosa*, *E. coli* and S. Typhimurium

[b]No detergent

agents of food poisoning *(5)*. The scientific community has expressed concern about possible links between use of antibacterial products and the development of bacterial antibiotic resistance; this aspect of detergent use was also investigated.

MIC

The antibacterial detergent, which was generally the most effective (Table 1), has a lower pH than the standard version. However, this alone cannot explain the biocidal effect achieved on contact of bacteria with the detergent or the results of MIC testing. It can, for example, be noted that 25% antibacterial detergent solution in TSB has a pH of about 6.0, which is favorable for growth of all the bacterial species investigated.

Gram negative organisms were more resistant than *S. aureus* to both detergents. This was also the observation in a previous, comparable study *(6)*. The greater resistance of Gram negative organisms is a common observation in the testing of many antibacterials, and is usually explained by the outer membrane in Gram negative species acting as a permeability barrier. Anionic surface-active agents present in both products at relatively high concentrations might contribute to the inactivation of Gram-positive bacteria, because these compounds, as typical targets, affect cytoplasmic membrane integrity and membrane-bound enzymes and cause cell leakage *(4, 6, 12)*. However, susceptibility testing of transient hand bacteria to para-chloro-meta-xylenol and triclosan, used in antimicrobial soaps, showed that the Gram-negative strains as a group were not less susceptible than the Gram-positive organisms *(5)*. This underlines the importance of screening new and existing antimicrobial products against a wide range of test strains. *P. aeruginosa* was more resistant to the antibacterial detergent than were the other Gram negative species tested. This is probably at least in part due to the low permeability of this species' outer membrane and cellular efflux mechanisms, which have been extensively discussed in the literature *(10)*. In a previous test of used sponges, identification of colonies isolated from plate count agar showed that the predominant microorganisms were *Pseudomonas* sensu stricto species *(6)*. Another factor that may be important was the demonstration in the present study, that *P. aeruginosa* is able to use both detergents as a sole source of carbon and energy.

The MIC analysis as employed, demonstrates the relative superiority of antibacterial *Zalo*® to the standard *Zalo*® formulation in the inhibition of bacterial growth. However, adoption of a standardized procedure would be required to compare the Norwegian detergent MICs with those of other detergents tested elsewhere.

Growth curves (suspension tests)

The growth curves are in general agreement with the MIC values and show that *S. aureus* and *P. aeruginosa* were the most and least sensitive species, respectively. Furthermore, the antibacterial detergent was, at most concentrations, more effective than the standard formulation in stopping or slowing bacterial growth. In a related study, the propagation of a natural population of dishwashing water bacteria in the presence of detergent was followed. If applicable, the results of this test indicate that, for example, around 2% of the antibacterial detergent would have been required to prevent the growth of "dishwashing water bacteria" (Fig. 2). This corresponds to about 400 ml (80% of a bottle) of antibacterial detergent in a sink with a 20 l volume. At 0.5% antibacterial detergent, almost no effect on bacterial growth would be registered.

Effect of liquid hand dishwashing detergents in sponges

The antibacterial detergent reduced the bacterial contamination of sponges by > 4 log (>99.99%), which is comparable to results reported for other similar products *(7)*. The sponge test thus provides some support for the manufacturer's claims for the antibacterial product. The presence of the standard version of the detergent in sponges did not prevent an increase in the numbers of Gram negative bacteria in the 24-h incubation period. However, the standard

detergent reduced the numbers of *S. aureus* by > 2 log. It is perhaps surprising that the standard detergent did not reduce the numbers of Gram negative bacteria, given its content of surface active agents and its application in the concentrated form. In a similar study of a wide range of detergents making antibacterial claims *(7)*, percentage bacterial reductions in synthetic sponges soiled with nonfat dry milk were 99.8% or better. However, in non-soiled sponges, one product making an antibacterial sponge claim produced a significant increase in bacterial numbers in the sponge, and two other products produced reductions of less than 50%. Unfortunately, the efficacy of these detergents in soiled sponges was not reported. The results of that investigation and of the present study suggest that antibacterial activity is not an inherent property of liquid hand dishwashing detergents even in the case of some products for which an antibacterial claim is made. In another study *(6)*, it was reported that an antibacterial dishwashing liquid was effective in the reduction of pathogens only in a suspension test, in which bacteria where incubated in saline in the presence of detergents. The coworkers report that in the soiled-sponge test, the numbers of *E. coli*, *S.* Enteritidis and *B. cereus* were hardly influenced. However, the detergent concentrations investigated were lower than those tested in comparable studies, including the present study *(7)*. The porous structure of sponges may provide microenvironments with no detergent where bacteria can proliferate on the organic load. The wetting ability of different detergent formulations when mixed with sponges moistened with, for example, aqueous yeast extract solution may be of relevance to the outcome of the tests.

The effect on bacteria of prolonged cultivation in the presence of detergents

Prolonged cultivation of *P. aeruginosa* and *S.* Typhimurium in the presence of the two detergent formulations did not appear to alter cellular or colony morphology. This may indicate little or no detergent-induced stress. Furthermore, the antibiotic resistance profiles of both species remained unchanged throughout the experiment. Although limited in scope, this study suggests that bacterial contact with these detergents at sublethal concentrations does not readily promote bacterial cell changes relevant to the cells' resistance to antibiotics.

It is concluded that the antibacterial detergent functions in kitchen sponges as claimed, if the product is used in accordance with the manufacturer's instructions. When used in other connections, e.g., as a dishwater disinfectant, the results were less satisfactory. The standard detergent, although showing some antibacterial activity, particularly against *S. aureus*, cannot be regarded as a true antibacterial detergent if its performance is compared with that of other such detergents tested here and elsewhere *(7)*. Neither detergent promoted the development of antibiotic resistance as measured in a simple assay under laboratory conditions.

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Hygiene in Warewashers Utilizing Blasting Granules That Foodservice Establishments Use

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SUMMARY

Four kitchens, each with a different work load, were used to evaluate the microbiological risk of utilizing blasting granules in a new type of warewash machine. The granules, plastic pellets 3.5 × 3.5 mm, are recirculated together with the dishwater in the machine, and when the dishwater is expelled, the granules remain in the machine until the next day.

Samples of soiled dishwater and tap water were collected on four occasions during a six-month period. In terms of CFU/ml, the APC in solutions of soiled dishwater was 2.6 ± 0.8 log, which is lower than that found in manual dishwashing (4.0 ± 1.6 log). The CFU/ml of *Bacillus cereus* was 2.8 ± 1.2 log and of *Enterobacteriaceae* was 0.2 ± 0.4 log. The microbiological levels found are representative of normal working conditions for warewash machines.

These levels were compared to results obtained in model experiments, in which granules were kept, moist but drained, for 16 hours and 40 hours, comparable to standstill periods overnight or longer. On the granules in contact with dishwater for 24 or 48 hours, the APC was not increased and the level of *B. cereus* was decreased. There was a slight increase in the number of *Enterobacteriaceae*, but the model experiments did not indicate any increased microbiological risk due to the use of the granules in warewash machines. Outside the machine, cross-contamination of the faucet was indicated by the numbers of microorganisms in tap water samples.

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INTRODUCTION

Cleaning of pots, pans and other utensils used for the preparing and serving hot and cold food in foodservice establishments is traditionally low-paid manual work in many countries. In service kitchens for restaurants, hospitals, schools and nursing homes, warewash machines can be used to replace this manual work and improve hygiene.

This paper deals with some hygienic aspects of a new type of warewash machine that utilizes water together with small plastic pellets, or granules, as a blasting medium, for more efficient cleaning of the wares and to shorten the wash cycle. The dishwater and granules are recycled in the machine during the day, and fresh hot water is used for the final rinse and to replace some of the recycled dishwater. The excess dishwater is expelled through an overflow valve. There is an expected increased microbiological risk, in this type of machine because the moist granules are kept in the machine for relatively long periods. To evaluate this risk, model experiments were designed, to represent the standing period of the machine. The model was tested for different standing periods and different workloads, representing four different kitchens.

The microbiological risk was evaluated by measuring the Aerobic Plate Count (APC) of mesophilic bacteria, *Bacillus cereus* and *Enterobacteriaceae*. The APC represents a measure of total hygiene and is a commonly employed method in investigations of the total microbiological quality of food *(7, 10, 12, 15)*. *B. cereus* is recognized as a pathogenic microorganism found in the dairy industry *(1)* and in connection with cooked rice *(6)*. Therefore, it is likely to be found in foodservice establishments where large quantities of dairy products or cooked rice are handled. Being a spore-forming microorganism, it can be expected to survive for long times in environments in which warewashers are used. *Enterobacteriaceae* were chosen to represent possible pathogenic microorganisms.

MATERIALS AND METHODS

The warewash machine studied, Granuldisk® GD 90, has one tank that contains the washing water and the granules, and another for the rinsing water *(5)*. The washing tank contains 200 l of water and 20 kg of granules. The granules are small plastic cylinders, about 3.5 mm in diameter and about 3.5 mm long, with a density of 1.4 kg/dm^3. They last about four to six months, depending on the workload. The wares are sprayed with a total flow of water and granules of 1600 l/minute. Wash water and granules are recycled in the machine throughout the day and the dishwater is drained from the tank before each standing period. The detergent level is kept constant by a conductivity-monitoring dosing system. The temperature of the wash water is regulated to 65°C and that of the rinse water to 85°C.

The specific warewasher cycle starts with four minutes of blasting with washing water containing detergent and granules, followed by one minute without blasting (Fig. 1). Thereafter, the wares (pots, pans and utensils) are rinsed with fresh hot water for 30 seconds. The total process achieves a sanitation level of more than 3600 HUE (Heat Unit Equivalence) which is in accordance with ANSI/NSF (American National Standard Institute/National Standard Foundation International) standard no. 3 *(2)*. An optional condensation period of one minute can be included in the warewasher cycle.

Selection of kitchens. A school kitchen (Kitchen 1) and a hospital kitchen (Kitchen 2) were chosen to represent kitchens with long-standing periods. The school kitchen serves 1,300 school lunches per day and has extremely long-standing periods on weekends and during school holidays. The hospital kitchen serves 4,500 meals per day. Both kitchens operate their warewashers for about eight to ten hours per day. Two restaurant kitchens (Kitchens 3 and 4) represented kitchens with short standing periods; each served 400 – 900 meals per day, depending on the season. The warewash machines in these kitchens are utilized fourteen to sixteen hours per day.

The operators of the machines in the school kitchen and the hospital were more skilled than the operators of the restaurant machines; therefore, the general maintenance instructions were more closely followed in the first two kitchens. All kitchens except the hospital kitchen used Solid Insure (Henkel Ecolab) as detergent. The hospital kitchen (Kitchen 2) used L20 Sumazon FL-M/75H from DiverseyLever.

Sampling and model experiments. Dishwater and tap water were collected on four occasions in each of the four different kitchens, after a complete day of washing. Samples were collected from the washing tank of the GD 90s and transported in sanitized plastic buckets. Tap water samples were collected in pre-sterilized bottles from the faucet at the sink, where pre-rinsing of the wares is performed. Samples of dishwater and tap water were kept at 7°C and analyzed within 24 hours. The collected samples from the four sampling occasions, of dishwater D_1, D_2, D_3, D_4, and tap water T_1, T_2, T_3, T_4, were also used for the model experiments.

Model experiments were designed to similate a situation in which granules are left overnight inside the machine or left for two nights in the machine. Both tap water and dishwater were used for model experiments (Table 1). The ratio of granules to water was the same as the ratio in the GD 90 machine. In Step 0, 93 ± 1 g unused granules were put in 1-l sterilized bottles and dishwater or tap water was added to the 1-l mark. The bottles were shaken and left at room temperature for 8 hours. The procedure is described in Table 2.

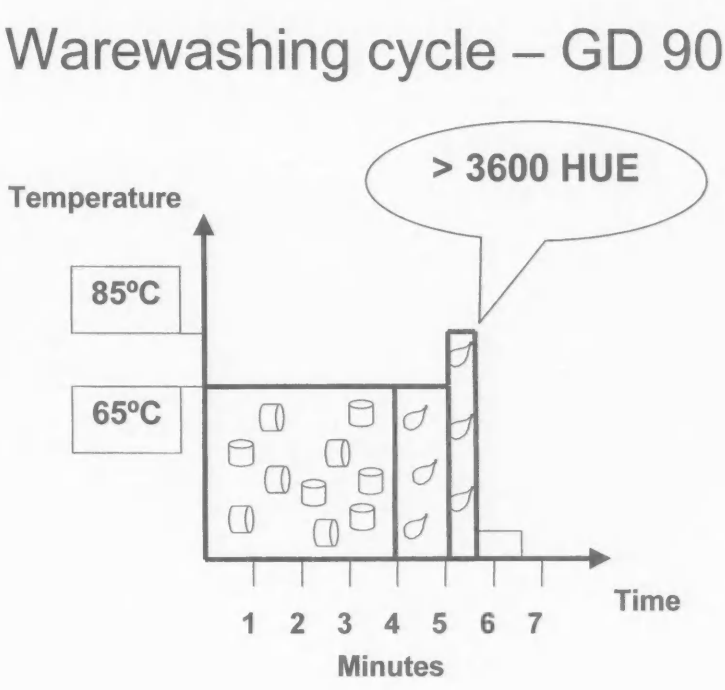
In Step 1, the mixture was strained, and moist granules were left in the bottles for another 16 hours at

TABLE 1. Samples used for model experiments on each of the four sampling occasions

Area	Kitchen 1				Kitchen 2				Kitchen 3				Kitchen 4			
Original samples	D_1		T_1		D_2		T_2		D_3		T_3		D_4		T_4	
Model samples	D_{11}	D_{12}	T_{11}	T_{12}	D_{21}	D_{22}	T_{21}	T_{22}	D_{31}	D_{32}	T_{31}	T_{32}	D_{41}	D_{42}	T_{41}	T_{42}
Dish water	x	x			x	x			x	x			x	x		
Tap water			x	x			x	x			x	x			x	x

D_{ij} and T_{ij} means dishwater and tap water, respectively, for Kitchen i and Step j

FIGURE 1. The washing cycle in the GD 90 warewasher



room temperature. Dishwater samples D_{11}, D_{21}, D_{31}, and D_{41} and tap water samples T_{11}, T_{21}, T_{31}, and T_{41} were analyzed by putting 30 ± 1 g of unused granules in 500 ml sterilized bottles using Stomacher™ bags, and 270 ml of sterile 0.5% peptone solution was added. The bottles were shaken and left for eight hours at room temperature. Samples were prepared in duplicate, resulting in sixteen samples. Microbiological analyses were then performed on the peptone solutions and on the granules. This procedure was repeated in Step 2, for dishwater samples D_{12}, D_{22}, D_{32} and D_{42} and for tap water samples T_{12}, T_{22}, T_{32} and T_{42}. D_{ij} and T_{ij} indicated dishwater and tap water samples, respectively, for Kitchen i and Step j.

This implies that for Step 1, granules were left drained but moist sixteen hours, comparable to the granules in a GD 90 in a service kitchen after one day of work. Step 2, corresponding to a situation in which granules are left drained for forty hours, represents a longer cessation of the continuous function of the machine.

Physical and chemical methods. The food particles in the dishwater solution were separated by filtration, using Munktell's Swedish Filter Paper, Class 2. One hundred ml was filtered and the retained substance was dried at 105°C for at least 12 hours and then weighed on a Mettler balance (± 0.0001 g). A Radiometer PHM210 pH meter with a pHC2015-8 electrode was used to measure the pH. The electrode was calibrated with IUPAC standards for pH 7 and pH 12.45. A CDC641T conductivity cell and a CDM210c conductivity meter from Radiometer were used to measure the conductivity. The cell was calibrated to the IUPAC standard 0.1 D KCl (12.85 mS/cm). Conductivity and pH were measured at 25°C and 65°C in dishwater and tap water samples. The workloads for each machine, expressed as number of warewash cycles, was continuously registered by an electrical counter.

Microbiological methods. The following analyses were performed on dishwater, tap water and peptone solutions. One ml of inoculum and 0.1 ml of inoculum, respectively, were transferred from the samples onto Petri dishes or spread on agar plates. The total number of mesophilic microorganisms was determined by APC on Tryptone-glucose-extract agar (TGEA) *(13)*. Samples were incubated at 30°C for three days. Chromocult Agar (CCA) was selected for determination of *Enterobacteriaceae (8)* by the pour plate technique and microfiltration. Samples were filtrated in a Micropore Filtration unit with a pore size of 0.45 µm and incubated

TABLE 2. Design of model experiments

Step 0	a) 93 g of unused granules are mixed with dishwater or tap water to a total mass of 1000 g in a 1l bottle.
	b) The samples are shaken for 2 minutes.
	c) The samples are left at room temperature for 8 hours.
	d) The granules in the samples are drained but left moist.
Step 1	a) The samples of moist granules are stored at room temperature for 16 hours.
	b) 30 g of granules are mixed with 270 ml of 0.5% sterile peptone solution, (SPS).
	c) The samples are shaken for 1 minute.
	d) The samples are stored at room temperature for 8 hours.
	e) Microbiological analysis are performed on the SPS and on the granules.
Step 2	a) Identical to Step 1, but the samples of moist granules are stored for a total of 40 hours.

TABLE 3. Microbiological methods and types of samples

Samples	Analysis	Agar	Temperature °C	Inoculum	Incubation Method	Incubation Time	Detection level Lower	Detection level Upper
Dishwater Tap water	APC, mesophilic microorganisms	TGEA	30	1.0 mL and 0.1 mL	Pour plate	3 days	> 1 CFU/ml	10^5CFU/ml
	Enterobacteriaceae	CCA	37	1.0 mL and 0.1 mL	Pour plate Filtration	24 hours 24 hours	> 1 CFU/ml > 50 CFU/ml	10^5CFU/ml 10^5CFU/ml
	Bacillus cereus	Selective agar SR49 SR99	37 and 21	1.0 mL and 0.1 mL	Surface inoculation	24 hours and 24 hours	> 1 CFU/ml	10^5CFU/ml
Peptone Solution	APC, mesophilic microorganisms	TGEA	30	1.0 mL and 0.1 mL	Pour plate	3 days	> 10 CFU/g granules	10^6 CFU/g granules
	Enterobacteriaceae	CCA	37	1.0 mL and 0.1 mL	Pour plate Filtration	24 hours 24 hours	> 10 CFU/g granules > 1 CFU/50 ml	10^4 CFU/g granules 300 CFU/0 ml
	Bacillus cereus	Selective agar SR49 SR99	37 and 21	1.0 mL and 0.1 mL	Surface inoculation	24 hours and 24 hours	> 10 CFU/g granules	10^6CFU/ g granules
Granules	APC, mesophilic microorganisms	TGEA	30	1 g of granules	Pour plate	3 days	> 1 CFU/g	300 CFU/g
	Enterobacteriaceae	CCA	37	1 g of granules	Pour plate	24 hours	> 1 CFU/g	300 CFU/g

TABLE 4. Statistics for four GD 90 machines at four different kitchens for a period of six months

Kitchen	Total number of washing cycles for the period studied	Mean number of washing cycles per day	Number of meals per washing cycle
1. School	651	8.6	151
2. Hospital	2757	19.4	116
3. Restaurant	3216	23.9	21– 38
4. Restaurant	2082	14.3	25

for 24 h at 37°C, after which the number of CFU (Colony Forming Units)/ 50 ml was determined. *B. cereus* was grown on selective agar (Oxoid CM 617X) containing egg yolk emulsion SR47 and *B. cereus* supplement SR99 *(14)*. Samples were surface inoculated and incubated at 37°C for 24 h after which they were incubated for 24 h at room temperature (21°C).The methods used are standard methods for determination of the microbiological status of food *(16)*.

The granules used in the model experiments were analyzed for mesophilic bacteria by means of tests for APC and *Enterobacteriaceae*. One gram of granules was placed in Petri dishes, TGEA or CCA was added and the dishes were incubated at 30°C for 3 days or 37°C for 1 day. The maximum detection level for microorganisms on granules was 300 CFU/g. Microbiological methods are summarized in Table 3.

RESULTS

The number of washing cycles per day and meals per washing cycle are given in Table 4. The highest number of meals per warewash cycle for the total measuring period was run through the school machine, followed by the hospital machine; the lowest number of total warewash cycles was run through the school machine. This reflects the differences in food preparation and working methods in the kitchens.

Chemical and physical parameters of dishwater. Figure 2 shows the conductivity of dishwater samples D_1, D_2, D_3 and D_4 at 65°C, from the four sampling occasions. Conductivity varies by a factor of 2 to 3 between the four kitchens. Figure 3 shows pH in the dishwater samples from the machines. The pH varied from 9.5 to 11 at 65°C. The pH, which is directly related to the logarithm of the hydroxyl ion concentration, varies for the four kitchens, but there is no mathematical correlation between conductivity and pH in the dishwater from the different kitchens. Conductivity is affected by the total ion concentration, not by only the hydroxyl ion concentration of the solution.

The dry matter content of the different dishwater samples was < 1% (w/w). The reason is that food residues are broken down mechanically by the pump and the granules. The high pH converts fat, proteins, and fibres into smaller molecules in the solution. Surfactants and the high pH of the dishwater keep in dissolved food residues in solution. The density of the dishwater was close to 1 kg/l (0.984 ± 0.004 kg/l).

Microbiological parameters of dishwater and tap water samples. In Table 5, the level of hygiene expressed as APC, *Bacillus cereus* and *Enterobacteriaceae*, is given for dishwater and tap water from the four sampling occasions. The concentration of microorganisms ranges from < 10 to < 10^4 CFU/ml in both dishwater and tap water samples, indicating that bacteria may arise from foodstuffs dissolved in the dishwater and from the tap water used to rinse the dishes. Bacteria can survive, even the high pH and temperature of the washing cycle employed by the GD 90 warewasher.

Bacillus cereus was mainly found in the dishwater. In Sweden, 10^3 CFU/ml is the limit for *B. cereus* in pasteurized milk and levels above this are thus regarded as a potential health risk *(15)*. Almost one-third (31%) of the dishwater samples exhibited levels above this. In tap water samples as expected, 75% contained less than 10 CFU/ml, but two samples (T_1,T_4) exhibited levels higher than 10^3 CFU/ml. The four samples with elevated levels of *B. cereus* (T_1, T_2, T_3, T_4) indicated cross-contamination in the tap water area (Table 5).

The *Enterobacteriaceae* count was low, < 1 CFU/ml in 81% of both dishwater and tap water samples. It is worth noting that the *Enterobacteriaceae* level was above this in three out of four samples from kitchen number four, (T_4), indicating cross-contamination of the tap water area.

Results of peptone solutions of model experiments, Step 1. After the granules had been in contact with dishwater or tap water for 8 hours at room temperature, then drained and left at room temperature for 16 hours, the range of APC in the peptone solutions was < 10 to < 10^4 CFU/g granules (Table 6). This is the same range as that found for the dishwater samples. In the peptone samples with granules that had been in contact with tap water, there seems to be a slight tendency towards higher levels, the range of APC being < 10 to < 10^5 CFU/g granules.

Over half of the samples that had been in contact with dishwater (63%) showed no detectable levels of

FIGURE 2. Measured conductivity in warewashing water samples at 65°C

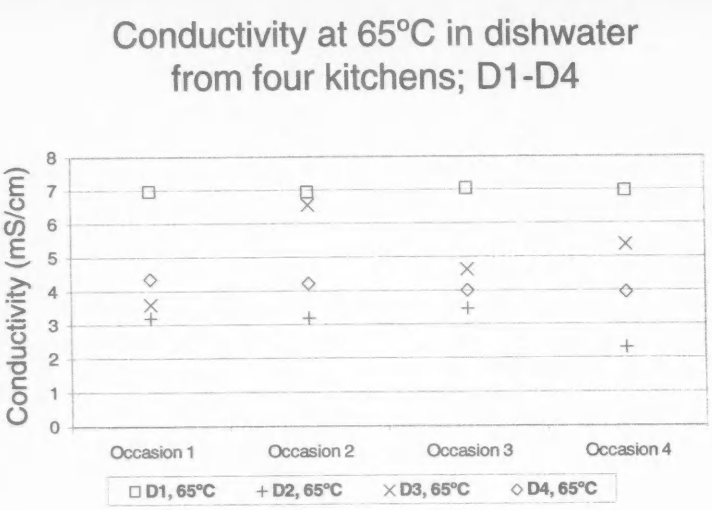
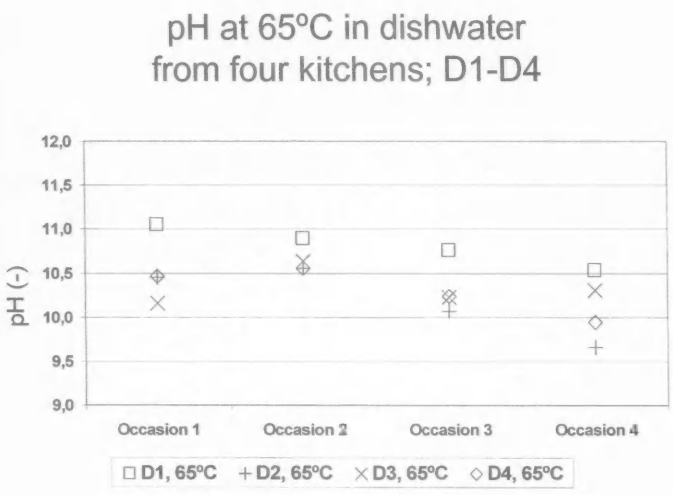


FIGURE 3. Measured pH in warewashing water samples at 65°C



B. cereus (< 10 CFU/g granules) and 19% of the samples showed levels of > 10^3 CFU/g granules. The pattern is similar for samples in which the granules had been in contact with tap water. Almost three quarters (72%) showed levels of < 10 CFU/g granules and 16% had levels > 10^3 CFU/g granules.

Most of the samples, 84% dishwater samples and 66% tap water samples, had undetectable amounts of *Enterobacteriaceae*. However, samples in which the granules had been in contact with tap water showed higher values of *Enterobacteriaceae* compared to tap water sample itself.

Results of peptone solutions from model experiments, Step 2. Compared with results from Step 1, there was an increased range (10 – 10^5 CFU/g granules) of APC in the samples with granules that had been in contact with dishwater. These moist granules had been stored at room temperature for a total of 40 hours. For granules exposed to tap water, the range was similar to that in Step 1, and in tap water samples themselves (T_1, T_3, T_4, T_5).

Over half (66%) of the samples, in which the granules had been in contact with dishwater had undetectable levels of *B. cereus* (< 10 CFU/g granules). One quarter of the samples contained levels of > 10^3 CFU/g granules. The pattern is similar for samples in which granules had been in contact with tap water. Over half (59%) showed levels of < 10 CFU/g granules and 19% contained levels of > 10^5 CFU/g granules.

As in Step 1, most of the dishwasher samples from Step 2 had undetectable levels of *Enterobacteriaceae*. *Enterobacteriaceae* were more frequent in tap water samples than in dishwater samples and the levels were generally higher. One-third of the samples that originated from tap water (34%) showed levels of > 10^5 CFU/g granules (Table 7).

Results for granule samples from model experiment, Steps 1 and 2. Dry, clean granules direct from the supplier were used in the experiments as unused granules, and no mesophilic microorganisms, *B. cereus* or *Enterobacteriaceae*, were detected on them before the experiments. Granules left in dishwater and tap water, however, showed varying amounts of microorganisms (Table 8). Half of the samples kept in dishwater (DG_{II}) showed a total overgrowth of mesophilic microorganisms analyzed for APC after Step 1, and three-fourths had levels > 100 CFU/g granules. For granules left in tap water (TG_{II}) there is an increase in microorganisms from Step 1 to Step 2, whereas for granules kept in dishwater the number of samples exceeding 300 CFU/g granules is less in Step 2 (18%) than in Step 1 (57%). The patterns are similar for the granules kept in peptone solutions for Step 1 and Step 2 (Tables 6 and 7).

No *Enterobacteriaceae* were detected among the granules after the first or the second day, which indi-

TABLE 5. Microbiological levels in dishwater samples, $D_i - D_4$, and tap water samples, $T_1 - T_4$, (CFU/ml). Total number of samples 16

Kitchen	Sample	APC*				*Bacillus cereus*				*Enterobacteriaceae*			
		$< 10^1$	$< 10^2$	$< 10^3$	$< 10^4$	$< 10^1$	$< 10^2$	$< 10^3$	$< 10^4$	< 1	$< 10^1$	$< 10^2$	$< 10^3$
1	D_1		1	2		2		2		4			
2	D_2		3	1		2			2	3	1		
3	D_3		1	2	1			2	2	2	2		
4	D_4	1		2	1	1		2	1	4			
	n	1	5	7	2	5	0	6	5	13	3	0	0
	(%)	(6)	(31)	(44)	(12)	(31)	(0)	(38)	(31)	(81)	(19)	(0)	(0)
1	T_1	2		1		3			1	4			
2	T_2	1	2	1		3		1		4			
3	T_3	1	2		1	3		1		4			
4	T_4		2	2		3			1	1		3	
	n	4	6	4	1	12	0	2	2	13	0	3	0
	(%)	(25)	(38)	(25)	(6)	(75)	(0)	(12)	(12)	(81)	(0)	(19)	(0)

*15 samples

D_i and T_i means dishwater and tap water, respectively, for Kitchen i

cates that *Enterobacteriaceae* found in the dishwater and the tap water prefer the liquid rather than the surface of the granules.

DISCUSSION

The four service kitchens differed in the type of food cooked and the way in which it is handled, and consequently in the flow of wares through the warewash machines. In spite of this, none of the kitchens deviated significantly regarding the microbiological results of the dishwater solution analyses. This indicates that the process in the machine, including elevated temperature, dosage of detergent and cleaning with blasting granules, is a safe procedure for warewashing.

Cross-contamination on the sink area faucet used for pre-rinsing of the wares was clearly indicated at one food service establishment (Kitchen 4) by the higher level of *Enterobacteriaceae*. The microbiological quality of drinking water is not determined by APC of mesophlic microorganisms, *Bacillus cereus* or *Enterobacteriaceae*, but specifically by the analysis for *Escherichia coli* and fecal coliforms < 1 CFU/100 ml and colifom bacteria <10 CFU/100 ml (*17*). With an elevated level of *Enterobacteriaceae*, seen in Kitchen 4 (T4), the probability of finding these specific microorganisms increases. Although bacterial contamination is found on almost all surfaces in foodservice kitchens, those with the highest level of contamination were water faucets, according to Chen et al. *(3)*. Contamination by *B. cereus* was more uniform at the four foodservice establishments. The presence of *B. cereus* indicated cross-contamination on the faucet in the pre-rinsing area in one of four samples from each establishment.

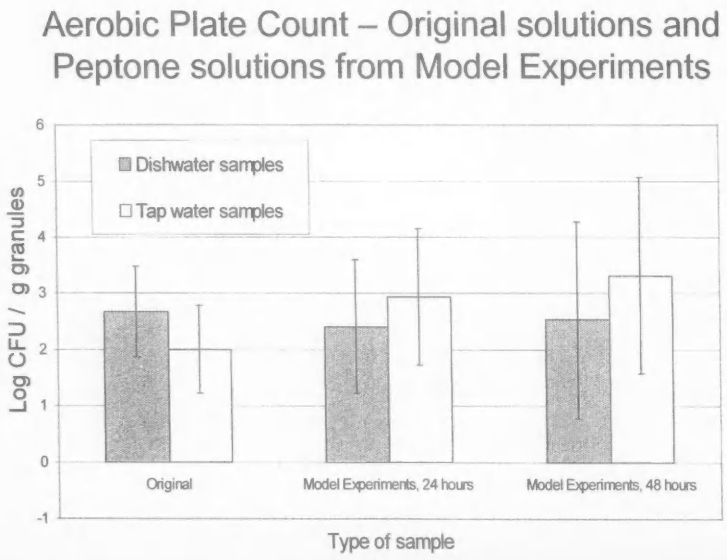
Conductivity is commonly used as a detergent dosing parameter in warewashers. The results of this study show that the conductivity varies from kitchen to kitchen and is dependent both on the type of detergent and the way it is set to control the dosage. Three kitchens used the same detergent. The conductivity values at each kitchen remained essentially constant over the four different sampling occasions, with no noticeable drop in either conductivity or pH that would

TABLE 6. Microbiological levels in peptone solutions from model experiments, Step 1, (CFU/g granules). Granules in contact with dishwater, D_{1i} – D_{4i}, and granules in contact with tap water, T_{1i} – T_{4i}. Total number of samples 32

Kitchen	Sample	APC					*Bacillus cereus*				*Enterobacteriaceae*			
		$< 10^1$	$< 10^2$	$< 10^3$	$< 10^4$	$< 10^5$	$< 10^1$	$< 10^2$	$< 10^3$	$< 10^4$	$< 10^1$	$< 10^2$	$< 10^3$	$< 10^4$
1	D_{1i}	2	1	2	3		4	1	1	2	6	1	1	
2	D_{2i}	1	5		2		4		2	2	7	1		
3	D_{3i}	2	2	2	2		5	1	1	1	7	1		
4	D_{4i}	4	3		1		7			1	7	1		
	n	9	11	4	8	0	20	2	4	6	27	4	1	0
	(%)	(6)	(31)	(44)	(12)	(0)	(63)	(6)	(13)	(19)	(84)	(12)	(3)	(0)
1	T_{1i}	1	1	2	3	1	3		2	3	4	3		1
2	T_{2i}	2	2	2		2	7	1			6	1	1	
3	T_{3i}	1	3	2	2		6	1		1	7			1
4	T_{4i}		3	1	4		7			1	5	1	2	
	n	4	9	7	9	3	23	2	2	4	22	5	3	2
	(%)	(13)	(28)	(22)	(28)	(9)	(72)	(6)	(6)	(16)	(69)	(19)	(9)	(6)

D_{ij} and T_{ij} means dishwater and tap water, respectively, for Kitchen i and Step j

FIGURE 4. APC found in dishwater and tap water, and in peptone solutions from model experiments, expressed as log CFU/g granules



have indicated a failure in the dosage system. In this respect, the microbiological levels found represent normal working conditions for the warewash machines.

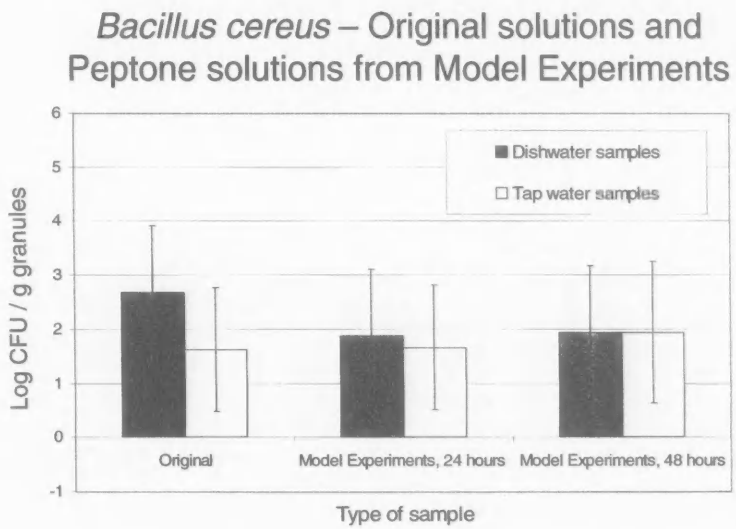
The mean logarithmic value of the APC for dishwater in this study was 2.6 ± 0.8 log/ml (n = 15). This level is significantly ($P < 0.05$) lower than that found by Mospuye and von Holy *(9)* of 4.0 ± 1.2 log/ml (n = 18). Their study was based on 200 food samples and 18 dishwater samples, and they concluded that the quality and safety of food samples from street vendors were acceptable. Furthermore, the range was narrower in the present study on warewash machines (1.0 – 4.0 log CFU/ml compared with 3.2 – 6.4 log CFU/ml). These levels can be compared to the APC limit for food samples, which in England is 10^6 CFU/g *(10)* and in Japan is 10^5

TABLE 7. Microbiological levels in peptone solutions from model experiments, Step 2 (CFU/g granules). Granules in contact with dishwater, $D_{12} - D_{42}$, and granules in contact with tap water, $T_{12} - T_{42}$. Total number of samples 32

Kitchen	Sample	APC					*Bacillus cereus*				*Enterobacteriaceae*			
		$< 10^1$	$< 10^2$	$< 10^3$	$< 10^4$	$< 10^5$	$< 10^1$	$< 10^2$	$< 10^3$	$< 10^4$	$< 10^1$	$< 10^2$	$< 10^3$	$< 10^4$
1	D_{12}	5			1	2	7		1		5	2	1	
2	D_{22}	1	3	1	2	1	3		1	4	6	1	1	
3	D_{32}	2	3	1	1	1	5			3	6	2		
4	D_{42}	3	3			2	6		1	1	6	1	1	
	n	11	9	2	4	6	21	0	3	8	23	6	3	0
	(%)	(34)	(28)	(6)	(13)	(19)	(66)	(0)	(9)	(25)	(72)	(19)	(9)	(0)
1	T_{12}	2		2	2	2	3	2	2	1	4	2		2
2	T_{22}	2	1		2	3	4		2	2	3	1		4
3	T_{32}	4			1	3	6			2		7	1	
4	T_{42}	2		1		5	6		1	1	2	1		5
	n	10	1	3	5	13	19	2	5	6	9	11	1	11
	(%)	(31)	(3)	(9)	(16)	(40)	(59)	(6)	(16)	(19)	(28)	(34)	(3)	(34)

D_{ij} and T_{ij} means dishwater and tap water, respectively, for Kitchen i and Step j

FIGURE 5. Concentration of *Bacillus cereus* found in dishwater and tap water, and in peptone solutions from model experiments, expressed as log CFU/g granules



CFU/g (*7*). Furthermore, according to Nichols et al. (*11*), the APC should not exceed 10^5 CFU/ml for ice used for retail purposes. The recommended limit for *Enterobacteriaceae* is 100 CFU/100 ml for ice used for cooling drinks (*11*).

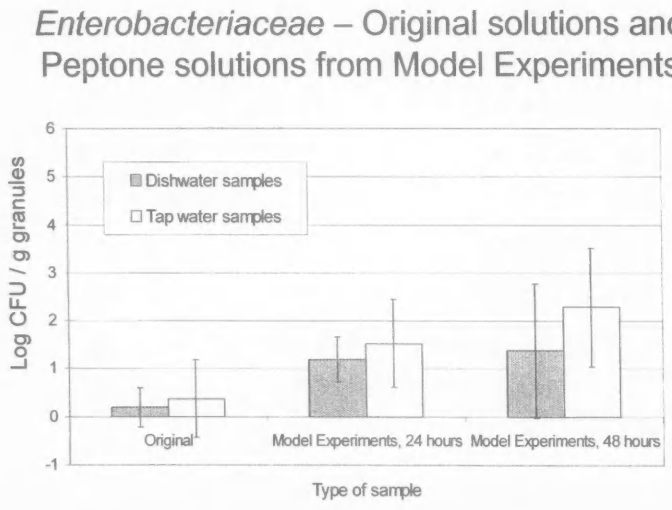
In the German industrial standard, DIN 10150:2001-4 for commercial multitank transport dishwashers, 500 CFU/ml ($\log_{10} = 2.7$) is stated as the critical value for the last dishwater, before the final rinse (*4*). This process is, however, different from that in a granular warewash machine in which all the water is recirculated and the inflow of fresh water is created by the final rinse cycle. The dishwater is continuously pumped forward in the multitank machine, so that the dirtiest water is found at the start of the washing cycle and the cleanest

TABLE 8. APC analysis of granules, Step 1 and Step 2 (CFU/g granules). Granules in contact with dishwater, DG_{12}–DG_{42}, and granules in contact with tap water, TG_{11}–TG_{42}. Total number of samples 16

Kitchen	Sample	APC Step 1				Sample	APC Step 2			
		$< 10^1$	$< 10^2$	< 300	> 300		$< 10^1$	$< 10^2$	< 300	> 300
1	DG_{11}	3			1	DG_{12}	2		2	
2	DG_{21}		1	3		DG_{22}	2	1	1	
3	DG_{31}				4	DG_{32}			1	3
4	DG_{41}			1	3	DG_{42}	1		2	
	n	3	1	4	9	n	5	1	6	3
	(%)	(18)	(5)	(25)	(55)	(%)	(31)	(5)	(37)	(18)
1	TG_{11}		2	2		TG_{12}	1	1	2	
2	TG_{21}	1		1	2	TG_{22}			2	2
3	TG_{31}	3			1	TG_{32}	2			2
4	TG_{41}		2	2		TG_{42}		1	1	2
	n	4	4	5	3	n	3	2	5	6
	(%)	(25)	(25)	(31)	(18)	(%)	(18)	(12)	(25)	(38)

DG_{ij} and TG_{ij} means granules immersed in dishwater and tap water, respectively, for Kitchen i and Step j

FIGURE 6. Concentration of *Enterobacteriaceae* found in dishwater and tap water, and in peptone solutions from model experiments, expressed as log CFU/g granules



at the end. The average concentration of microorganisms in a batchwise machine such as the GD 90 would be higher, as there is no counter-current water flow as in the multitank machine.

In Figure 4 it can be seen that the level of microorganisms was higher in dishwater than in tap water. The level of mesophilic microorganisms, as determined by APC, is constant with time in the dishwater, whereas in the tap water samples it increases with time from original samples to Step 1 samples and to Step 2 samples. This indicates the influence of pH in the dishwater, which has a retarding effect on the growth of microorganisms on the drained granules.

The presence of *B. cereus* is confirmed in the warewashing area by the dishwater and tap water samples. The levels found in the peptone solutions from granules that were left standing for one or two days at room temperature were not increased, according to the model experiments conducted for 24 hours and 48 hours, (Fig. 5).

The levels of *Enterobacteriaceae* are low in the dishwater and tap water samples. For the peptone samples with granules kept in tap water solutions, the level increases with time because of the lack of pH restriction, (Fig. 6). For the samples with granules kept in dishwater solutions, the level of *Enterobacteriaceae* is low but increasing with time, although not as fast as in the samples originated from tap water. Once again, this demonstrates the influence of pH, and the risk of contamination from *Enterobacteriaceae* on the drained granules is less likely in the warewashing area.

CONCLUSIONS

The results of this study clearly indicate that the washing procedure in a warewasher controls the microbiological level better than the most basic level of manual dishwashing, where access to clean running water may be a problem *(9)*. In addition, lower temperatures for both washing and rinsing are necessary in manual dishwashing, resulting in a temperature close to the optimum of 37° – 40°C for mesophilic bacteria, including *Enteorobacteriaceae* and several other pathogenic microorganisms. If the general level of microorganisms is kept low in the washing water, then the risk of contamination by harmful bacteria on the pots, pans and utensils, and thus the risk of transferring bacteria to people, will be reduced.

Furthermore, continuous use of the machine during the daytime and standing periods overnight, during which the drained granules are kept in the machine, together with routines for cleaning and maintenance, ensure that the washing and rinsing processes and the granules have a safe status. Even in the case in which general maintenance instructions were not followed (Kitchen 3 and 4), the normal operation with the times and temperatures chosen for washing and final rinsing and the continuous dosage of detergent maintained the wash water at a sufficiently safe microbiological level. The cross-contamination detected in the pre-rinsing area could be the result of poor routines and lack of maintenance routines in the area surrounding the warewash machine.

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Status of Prerequisite and HACCP Program Implementation in Iowa Restaurants

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SUMMARY

The safety of food served in restaurants should be a major concern to both restaurateurs and consumers. Hazard Analysis Critical Control Point (HACCP) programs are one means to assure the safety of food. The purpose of this research was to determine the extent to which prerequisite and HACCP programs were implemented in independent restaurants in Iowa and assess potential barriers to implementing food safety practices.

Approximately 8% of the restaurant managers indicated that they have a comprehensive HACCP plan in place. The majority of prerequisite programs were not implemented. Multiple linear regression analyses indicated having an employee with the responsibility for overseeing food safety was positively related to the number of food safety practices implemented. Female managers were more likely to implement food safety practices than their male counterparts. Additionally, there was a positive relationship between managers' education and the number of food safety practices implemented.

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INTRODUCTION

Restaurants are an integral part of today's society, with 40% of all adults eating in a restaurant on a typical day *(11)*. It is predicted that restaurant industry sales will reach $426 billion in 2003, a significant increase from $407 billion in 2002 *(10)*. While industry sales are increasing, consumer confidence in food safety in restaurants has decreased. In 1995, 50% of the people surveyed believed in the restaurant industry's ability to ensure the well being of customers, compared to 39% in 2000 *(1)*. In view of these statistics, it is imperative that restaurant managers be committed to food safety.

Significant emphasis has been placed on Hazard Analysis Critical Control Point (HACCP) programs for foodservice operations because "implementation of HACCP programs by the establishments will profoundly enhance their role in the protection of public health" *(5)*. However, HACCP programs represent a new, more detailed approach to food safety for restaurants compared to traditional visual inspections and microbiological testing.

Traditional visual foodservice inspections, which usually represent one point in time, are based on individual judgments of inspectors, and inspectors often rate operations differently than peers do *(3)*. In 1992, 300 people became infected with a gastrointestinal illness after dining in a restaurant that had passed one visual inspection two days before and another inspection immediately after the report of the outbreak *(12)*. Kassa, Harrington, Bisesi, and Khuder *(8)* found no correlation between the results of microbial testing and those of visual inspections. Limitations in traditional approaches support the need for and development of HACCP in foodservice.

Even though HACCP is valuable in assuring the safety of food served, there are barriers to implementation. Almanza and Ghiselli *(2)* found that managers in a grill-type restaurant are limited in the hours they can spend on any task, and implementing a HACCP plan requires a strong commitment and dedication. They found that once a HACCP system is established, it takes a manager approximately two hours a day to complete the necessary forms associated with HACCP, which would average about $6,700 per year of a manager's time. Managers must make choices that reflect their belief that the cost of a HACCP program is outweighed by considerations of what is in the best interest of public health *(2)*.

In the school foodservice segment, time to establish the HACCP program, time and labor costs to run the program on a daily basis, employee training, and union problems have been identified as barriers to HACCP implementation *(7, 13, 14, 15)*. Giampaoli, Sneed, Cluskey, and Koenig *(6)* found that employees' discomfort with change and inadequate time for training were barriers.

Many foodservice operations do not have appropriate prerequisite programs in place to implement HACCP. These programs are the foundation upon which HACCP is built and without which HACCP programs cannot be implemented *(9)*. Prerequisite programs, designed to protect food while it is in storage and production, include cleaning and sanitizing; chemical control; facilities; personal hygiene; pest control; production equipment; receiving, storage and shipping; specifications; supplier control; traceability and recall, and training *(9)*. In Youn and Sneed's *(16)* study of school foodservice directors, prerequisite programs most often lacking were written procedures for cleaning and sanitizing equipment, temperature logs, written procedures for cleaning the facility, standardized recipes, assurance or documentation from suppliers that they follow a HACCP program, and procedures to check the temperatures of refrigerated and frozen foods upon receiving.

Three significant factors have been found that lead managers to be more favorable toward HACCP: knowledge, training, and practice. Although it is believed that increased knowledge improves food safety practices, there is little research related to whether food safety certification programs and the way they are taught change food handling behaviors of foodservice workers and managers. Bryan *(3)* surmises that training courses are usually short in duration, and the information in them is used only to the degree that the foodservice worker understands it and is motivated to use it.

There is a paucity of research related to food safety, HACCP prerequisite programs, and HACCP implementation in restaurants. The overall goal in this study was to determine the extent to which prerequisite and HACCP programs are implemented in independent and small chain restaurants in Iowa. Specific objectives of this study are the following: (1) Determine if restaurants have prerequisite programs, necessary for HACCP implementation in place, (2) Analyze restaurant managers' perceptions of HACCP and their interest in implementing a HACCP program, and (3) Assess the HACCP components that are already in place in restaurants in Iowa.

METHODS

Sample

A total of 800 questionnaires were mailed to a sample of Iowa restaurant managers. Eighty-eight questionnaires were retuned because of wrong addresses and 22 were returned by respondents who stated that their restaurants were no longer in business. Disregarding these 110 reduced the sample size to 690. Of the 690 usable questionnaires, 131 were re-

TABLE 1. Characteristics of Iowa restaurant managers (N = 131)

Characteristic	n	%[a]
Age		
30 years or younger	7	5.3
31 – 50 years	89	67.4
51 – 65 years	28	21.2
Over 65 years	8	6.1
Gender		
Male	70	53
Female	62	47
Education		
High School	43	32.6
Some College	54	40.9
Bachelor's Degree	29	22.0
Graduate Degree	6	4.5
Years in foodservice		
5 years or less	19	14.4
6 – 15 years	50	37.9
16 – 25 years	40	30.3
26 years or more	21	15.9
Food safety certification		
No	77	58.3
Yes	54	40.9
ServSafe®	39	72.2
Serving It Safe	0	0
Other	14	25.9

[a] Percentages may not total 100% because of non-response to a question.

turned, for a response rate of 19%. The sample consisted only of restaurants that are independently owned and operated or small chains (less than 10 units). Large chain operations were excluded from the study because management in such operations may be more proactive to HACCP implementation because of greater resource availability and corporate support. Independent restaurant managers will have a greater need for external support from groups such as the Cooperative Extension Service, state restaurant associations, and the National Restaurant Association.

Survey instrument

The four-part questionnaire developed to collect data took approximately 15 minutes to complete. The Iowa State University Committee on the Use of Human Subjects in Research approved the research protocal and questionnaire.

Part one included 32 questions to determine practices related to prerequisite and HACCP programs that have been implemented. Responses to the questions were "yes", "no", "no, but have interest", and "don't know". Two open-ended questions asked about other food safety practices used and practices that managers planned to implement.

Part two, consisting of four questions, was used to determine restaurant managers' need for Cooperative Extension's assistance in training employees with regard to HACCP and food safety. Preference for methods of disseminating the information in these educational programs was also identified.

Part three determined restaurant managers' attitudes about HACCP and barriers to HACCP implementation in their operations. The 13 questions were answered on a 5-point scale: strongly disagree, disagree, neutral, agree, and strongly agree.

Part four consisted of demographic questions. Six questions requested demographic information about the restaurant and five questions requested information about the restaurant manager.

Two pilot tests were conducted, the first with graduate students in the Hotel, Restaurant, and Institution Management program at Iowa State University (n = 7), and the second with restaurant managers from two independent restaurants (n = 5). All suggestions from the participants were considered, and the questionnaire was revised based on the recommendations of the pilot test groups.

Data collection

The questionnaire, cover letter, and postage-paid return envelope were mailed to the study sample. An identification code number was assigned to each questionnaire for follow-up purposes, and respondents were ensured of confidentiality.

TABLE 2. Characteristics of Iowa restaurants (N = 131)

Characteristic	n	%[a]
Amount of food produced from scratch on-site		
90% or greater	27	20.5
51 – 89%	55	41.7
11 – 50%	27	20.5
10% or less	14	10.6
Average Check		
Breakfast		
Do not serve breakfast	60	45.5
$3.99 or less	34	25.8
$4.00 – $7.99	24	18.2
$8.00 – $11.99	5	3.8
$12.00 and up	0	0
Lunch		
Do not serve lunch	9	6.8
$5.99 or less	65	49.2
$6.00 – $11.99	47	35.6
$12.00 – $17.99	4	3.0
$18.00 and up	0	0
Dinner		
Do not serve dinner	18	13.6
$6.99 or less	38	28.8
$7.00 – $12.99	50	37.9
$13.00 – $18.99	10	7.6
$19.00 and up	6	4.5
Seating Capacity		
Up to 49	49	37.1
50 – 99	45	34.1
100 – 199	30	22.7
200 or more	5	3.8
Employee with primary responsibility for food safety		
No	68	51.5
Yes	58	43.9
Opportunity for employees to attend a food safety program within the last year		
No	95	72.0
Yes	31	23.5
Number of employees		
1 – 10	85	65.2
11 – 30	32	24.2
31 – 50	10	7.6
51 or more	2	1.5

[a] Percentages may not total 100% due to non-response to a question

The initial mailing was done in January 2002. Because January is typically a slower-than-normal time for the restaurant industry as a whole, it was chosen as the initial contact month to assure the highest possible response rate. A follow-up postcard was mailed two weeks after the initial mailing to those restaurant managers who had not yet replied. Those who did not reply after the postcard were sent a second questionnaire after an additional two weeks *(4)*.

SPSS version 10.0 was used to analyze data. Frequency distributions were computed for all variables in Parts I (food safety practices), II (food safety training needs), III (attitudes towards HACCP), and IV (demographics). Means and standard deviations were calculated for items in Part III. Principal component factor analysis with varimax rotation was done for all items included in Parts I and III. Based on a minimum eigenvalue of 1.0 and an examination of a screen plot to determine the point of discontinuity, the number of factors was selected. A Cronbach alpha reliability coefficient was calculated to determine the reliability for items in each factor identified. Multiple linear regression was used to determine the relationships between total scores and factor scores, and characteristics of restaurant managers and restaurants.

RESULTS

Characteristics of restaurant managers/restaurants

Characteristics of restaurant managers responding to the questionnaire are presented in Table 1. In a similar study in school foodservice *(15)*, the majority of managers also were between 31 and 50 years of age, with the 51 – 65 age range accounting for the second greatest number. About half (53%) of the respondents were

TABLE 3. Food safety practices indicating prerequisite programs and HACCP program implementation in Iowa restaurants (N= 131)

Food Safety Practices	Yes n (%)	No n (%)	No, but have interest n (%)	Don't know n (%)
Cleaning/Sanitizing				
All employees trained on cleaning and sanitation practices	120 (90.9)	8 (6.1)	2 (1.5)	1 (.8)
Written specifications for cleaning and sanitizing all equipment	63 (47.7)	57 (43.2)	11 (8.3)	0 (0)
Chemical Control				
Documented procedures for chemical storage	48 (36.4)	71 (53.8)	9 (6.8)	1 (.8)
Equipment				
Preventative maintenance schedules	80 (60.6)	41 (31.1)	6 (4.5)	2 (1.5)
Equipment certified by the National Sanitation Foundation (NSF)	80 (60.6)	18 (13.6)	7 (5.3)	24 (18.2)
Equipment temperature calibration schedules	33 (25.0)	77 (58.3)	12 (9.1)	7 (5.3)
Temperature logs for all cooling equipment	27 (20.5)	88 (66.7)	13 (9.8)	2 (1.5)
Temperature logs for all heating equipment	26 (19.7)	89 (67.4)	12 (9.1)	2 (1.5)
Facilities				
Written specifications for cleaning the facility	89 (67.4)	31 (23.5)	8 (6.1)	1 (.8)
A linear product and traffic flow that minimizes cross contamination	78 (59.1)	31 (23.5)	11 (8.3)	10 (7.6)
Food Production				
Procedures to check the final internal temperature of cooked foods	98 (74.2)	28 (21.2)	5 (3.8)	1 (.8)
Procedures for checking the internal temperature of foods while cooling	95 (72.0)	29 (22.0)	6 (4.5)	2 (1.5)
Standardized recipes with critical control points	75 (56.8)	42 (31.8)	7 (5.3)	4 (3.0)
Procedures to take and record the temperatures of all potentially hazardous foods as they flow through the restaurant	66 (50.0)	51 (38.6)	11 (8.3)	1 (.8)
Personal Hygiene				
A policy on the use of gloves	107 (81.1)	22 (16.7)	0 (0)	1 (.8)
A policy on the use of hair restraints	95 (72.0)	28 (21.2)	7 (5.3)	0 (0)
A policy on handwashing	94 (71.2)	32 (24.2)	4 (3.0)	0 (0)
Pest Control				
Routine spraying by pest control operator	107 (81.1)	22 (16.7)	0 (0)	1 (.8)
Receiving and Storage				
Thermometers in refrigerators	132 (100)	0 (0)	0 (0)	0 (0)
Thermometers in freezers	128 (97.0)	3 (2.3)	1 (.8)	0 (0)
Procedures to assure potentially hazardous foods are put under refrigeration quickly upon receiving	122 (92.4)	6 (4.5)	3 (2.3)	0 (0)
Thermometers in dry storage	74 (56.1)	50 (37.9)	6 (4.5)	0 (0)

TABLE 3. (Continued)

Food Safety Practices	Yes n (%)	No n (%)	No, but have interest n (%)	Don't know n (%)
Receiving and Storage				
Procedures to check temperatures when receiving food	53 (40.2)	60 (45.5)	17 (12.9)	1 (.8)
Specifications				
Written specifications for all ingredients and food products	54 (40.9)	66 (50.0)	8 (6.1)	2 (1.5)
Supplier Control				
Assurance from suppliers that they follow HACCP or good manufacturing practices	73 (55.3)	25 (18.9)	8 (6.1)	22 (16.7)
Procedures for checking the condition of the supplier's delivery trucks (i.e. sanitation, temperature)	36 (27.3)	69 (52.3)	17 (12.9)	9 (6.8)
Training				
All employees trained on safe food handling procedures	116 (87.9)	10 (7.6)	5 (3.8)	0 (0)
All employees trained on personal hygiene	115 (87.1)	11 (8.3)	4 (3.0)	1 (.8)
HACCP				
Food product flow charts	75 (56.8)	19 (14.4)	3 (2.3)	1 (.8)
HACCP team	21 (16.7)	97 (73.5)	15 (11.4)	10 (7.6)
Temperature logs to record end-point cooking temperatures	19 (14.4)	97 (73.5)	13 (9.8)	2 (1.5)
A comprehensive Hazard Analysis Critical Control Point plan (HACCP)	10 (7.6)	97 (73.5)	5 (11.4)	8 (6.1)

male. This contrasts with studies in school foodservice, in which about 90% of managers are women *(6, 7, 15)*. Characteristics of restaurants in this study are summarized in Table 2. In these restaurants, more than 60% of the food served is made from scratch. Less than half have an individual with primary responsibility for food safety.

Food safety practices related to prerequisite and HACCP program components

Prerequisite programs in 10 areas were explored: Chemical Control, Cleaning/Sanitizing, Equipment, Facilities, Food Production, Specifications, Supplier Control, Pest Control, Receiving and Storage, and Training. Practices that indicate implementation of these prerequisite programs and HACCP components in Iowa restaurants are presented in Table 3.

When responding to the open-ended question about the practices currently being used in the restaurant, the majority of restaurant managers stated that they use gloves, labeling and dating, and common sense. Other practices that were cited were first-in first-out (FIFO) rotation, continuous training, and use of sanitizer on tabletops. Two managers stated they have handwashing schedules for employees. When responding to the second open-ended question concerning what they planned to implement, responses included written procedures for cleaning and maintaining equipment and continuous training.

Principal components factor analysis was done on the 32 questions related to prerequisite and HACCP programs. SPSS was not able to factor the variables because of the lack of variance in responses.

Multiple Linear Regression was used to examine the relationships between the total practices score (dependent variable) and restaurant managers' characteristics (age, gender, education, certification, and years of experience in foodservice) and restaurant characteristics (amount of on-site food production, seating capacity, whether employee(s) has primary responsibility for food safety, whether a certification course was offered within the last year, and the number of employees) as independent variables. The relationship be-

tween the total practices score and restaurant managers' characteristics was not significant. However, the relationship between the total practices score and restaurant characteristics was significant ($F = 4.511$, $P < 0.001$). The significant independent variable in the model was restaurants having an employee with primary responsibility for implementing and monitoring food safety practices (ß = 0.357, $P < 0.001$). Youn and Sneed *(15)* also found that having an employee responsible for implementing and monitoring food safety practices was related to the number of food safety practices implemented in school foodservice.

Barriers to following food safety practices

Restaurant managers' perceptions of barriers to following food safety practices are shown in Table 4. Principal components factor analysis with varimax rotation was used for the 15 barriers to determine if there were fewer underlying factors. Two factors were extracted.

The first factor, which was named HACCP, consisted of nine barriers to following food safety practices. The second factor, named resources, consisted of six items. Both factors are shown in Table 4. To determine the reliability of each item in the factor, a Cronbach alpha was calculated. The Cronbach alphas for the factors (HACCP and Resources) were .88 and .78, respectively. For both factors, the item-total statistics showed that deleting any item would decrease the alpha. Therefore, all items were retained.

A Cronbach alpha calculated for all 15 items was .89. The item-total statistic for this model also showed that deleting any item would decrease the alpha. Therefore, because the alpha was high for all items, analysis used one total barrier score.

Six Multiple Linear Regression models were produced, using the total barriers score, HACCP factor score, and resources factor score as the dependent variable, and restaurant managers' characteristics (age, gender, education, certification, and years of experience in foodservice) and the restaurant characteristics (amount of on-site food production, seating capacity, whether an employee(s) has primary responsibility for food safety, whether a certification course had been offered within the last year, and the number of employees) as independent variables. For the first model, the relationship of the total barriers score and the characteristics of the restaurant was not statistically significant. However, when the model was used for testing the relationship between the total barriers score and the characteristics of the managers, the relationship was significant ($F = 3.478$, $P = 0.006$). Gender (ß = -0.218, $P = 0.016$) and educational level (ß = 0.194, $P = 0.028$) were significant independent variables. For gender, the results showed that males rate food safety barriers higher than do their female counterparts. As the educational level of restaurant managers increased, their rating of barriers decreased.

The model testing the relationship between the HACCP factor score and demographic characteristics of the restaurant was not significant. However, the model testing the relationship between the characteristics of the managers and HACCP was significant ($F = 3.663$, $P = 0.004$), and educational attainment of the manager (ß = 0.251, $P = 0.004$) was the significant individual characteristic. The models testing the relationship of the resources factor total was not significant for either the characteristics of the manager or characteristics of the restaurant.

DISCUSSION

These results indicate that there are important food safety practices that restaurateurs have not implemented. Many of these practices represent prerequisite programs that must be in place before HACCP can be implemented. Restaurant managers could use these survey questions as a self-assessment tool to evaluate current practices and identify areas where improvement is needed.

This research suggests that assigning responsibility for food safety to specific employees increases the number of food safety practices implemented in restaurants. Also, educational level should be considered in the hiring process, as managers with higher educational attainment are more likely to implement food safety practices. Further, less than half of all managers indicated that they had been certified in food safety, which means that marketing these programs by state restaurant associations, cooperative extension, and other entities should be emphasized. More opportunities are needed for basic food safety training of employees at the restaurant level.

Resources were identified as a barrier to HACCP implementation. With most restaurants operating on a low profit margin, food safety training programs must be cost effective. Extension or state restaurant associations could develop a model HACCP program that would aid restaurant owners and managers in implementing such programs. However, some practices related to food safety can be implemented with little or no cost to the operation. Checking temperatures of food as it arrives, developing a policy on handwashing, placing thermometers in dry storage, and recording end-point cooking temperatures are all steps that a manager can take, with little time and minimal effect on the bottom line, to help ensure the safety of food.

Results from this study indicate that many restaurants do not have written policies and procedures. These need to be developed to pro-

TABLE 4. Restaurant managers perceptions' of barriers to following food safety practices (N= 131)

Potential Barriers[a]	Mean ± sd[b]	Frequency of Responses[c] (%)				
		SD	D	N	A	SA
HACCP (α=.88)						
Employees had more opportunities for training at the restaurant conducted by a manager	3.8 ± 1.0	3 (2.3)	10 (7.6)	32 (24.2)	47 (35.6)	33 (25.0)
Employees had more training outside of operation	3.3 ± 1.0	6 (4.5)	15 (11.4)	50 (37.9)	34 (25.8)	18 (13.6)
We could implement a HACCP program	3.3 ± 1.0	8 (6.1)	11 (8.3)	49 (37.1)	43 (32.6)	8 (6.1)
We documented food flow and temperatures	3.3 ± 1.0	6 (4.5)	14 (10.6)	34 (25.8)	40 (30.3)	27 (20.5)
We had a model HACCP plan to follow	3.2 ± 1.1	10 (7.6)	16 (12.1)	41 (31.1)	43 (32.6)	11 (8.3)
I would be interested in implementing a HACCP program in my restaurant	3.2 ± 1.1	9 (6.8)	25 (18.9)	42 (31.8)	36 (27.3)	9 (6.8)
HACCP would be very beneficial to helping us achieve our business goals	3.1 ± 1.0	7 (5.3)	24 (18.2)	46 (34.8)	36 (27.3)	8 (6.1)
HACCP is critical to the long-term success of my restaurant	3.0 ± 1.0	10 (7.6)	27 (20.5)	48 (36.4)	26 (19.7)	9 (6.8)
We could hire a food safety consultant	2.5 ± 1.1	25 (18.9)	39 (29.5)	34 (25.8)	19 (14.4)	4 (3.0)
Resources (α=.78)						
Employees were more motivated to implement food safety procedures	3.7 ± 1.0	5 (3.8)	10 (7.6)	29(22.0)	51(38.6)	29 (22.0)
Managers had more time to implement food safety procedures	3.6 ± 1.0	6(4.5)	5(3.8)	37 (28.0)	57 (43.2)	19 (14.4)
We had more money to devote to food safety	3.5 ± 1.1	7 (5.3)	14 (10.6)	34 (25.8)	40 (30.3)	27 (20.5)
We did not have high levels of turnover	3.5 ± 1.1	9 (6.8)	11 (8.3)	40 (30.3)	36 (27.3)	25 (18.9)
Employees had more time to implement food safety procedures	3.5 ± 1.0	5 (3.8)	9 (6.8)	45 (34.1)	55 (41.7)	22 (8.3)
Our facilities were designed differently	3.0 ± 1.0	8 (6.1)	28 (21.2)	42 (31.8)	34 (25.8)	8 (6.1)[a]

[a]The stem "Food safety in my restaurant would improve if" was used for all questions

[b]Mean ± Standard Deviation

[c]A five-point scale was used for responses. Strongly disagree (SD) was coded as 5; disagree (D) as 2; neutral (N) as 3; agree (A) as 4; and strongly agree (SA) as 5.

vide the basis for training and HACCP implementation. Model standard operating procedures for restaurants could be developed similar to those developed for school foodservice, to save time for operators, (these are posted at www.iowahaccp.iastate.edu).

Restaurateurs also should consider giving one or two employees primary responsibility for food safety, as it was shown that this affects the number of food safety practices implemented. This relationship has been found in both school foodservice and restaurants, so it may be a key to successful implementation of food safety and HACCP programs.

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International Association for Food Protection®

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Send letters of nomination along with a biographical sketch to the Nominations Chairperson:

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- Persons nominated for individual awards must be current IAFP Members. Black Pearl Award nominees must be companies employing current IAFP Members. NFPA Food Safety Award nominees do not have to be IAFP Members.
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Harold Barnum Industry Award — Plaque and $1,000 Honorarium

Presented to an individual for outstanding service to the public, IAFP and the food industry.

Sponsored by NASCO International, Inc.

Educator Award — Plaque and $1,000 Honorarium

Presented to an individual for outstanding service to the public, IAFP and the arena of education in food safety and food protection.

Sponsored by Nelson-Jameson, Inc.

Sanitarian Award — Plaque and $1,000 Honorarium

Presented to an individual for outstanding service to the public, IAFP and the profession of the Sanitarian.

Sponsored by Ecolab, Inc., Food and Beverage Division

Maurice Weber Laboratorian Award — Plaque and $1,000 Honorarium

Presented to an individual for outstanding contributions in the laboratory, recognizing a commitment to the development of innovative and practical analytical approches in support of food safety.

Sponsored by Weber Scientific

International Leadership Award — Plaque, $1,000 Honorarium and Reimbursement to attend IAFP 2004

Presented to an individual for dedication to the high ideals and objectives of IAFP and for promotion of the mission of the Association in countries outside of the United States and Canada.

Sponsored by Unilever

NFPA Food Safety Award — Plaque and $3,000 Honorarium

This Award alternates between individuals and groups or organizations. In 2004, the award will be presented to a group or organization in recognition of a long history of outstanding contributions to food safety research and education.

Sponsored by National Food Processors Association

Call for Abstracts

IAFP 2004

The Association's 91st Annual Meeting

August 8–11, 2004

Phoenix, Arizona

General Information

1. Complete the Abstract Submission Form.
2. All presenters must register for the Annual Meeting and assume responsibility for their own transportation, lodging, and registration fees.
3. There is no limit on the number of abstracts registrants may submit. However, presenters must present their presentations.
4. Accepted abstracts will be published in the Program and Abstract Book. Editorial changes will be made to accepted abstracts at the discretion of the Program Committee.
5. Photocopies of the abstract form may be used.
6. Membership in the Association is not required for presenting a paper at IAFP 2004.

Presentation Format

1. Technical — Oral presentations will be scheduled with a maximum of 15 minutes, including a two to four minute discussion. LCD projectors will be available.
2. Poster — Freestanding boards will be provided for presenting posters. Poster presentation surface area is 4′ high by 8′ wide. Handouts may be used, but audiovisual equipment will not be available. The presenter will be responsible for bringing pins and velcro.

Note: The Program Committee will make the final decision on presentation format.

Instructions for Preparing Abstracts

1. Title — The title should be short but descriptive. The first letter in each word in the title and proper nouns should be capitalized.
2. Authors — List all authors using the following style: first name followed by the surname.
3. Presenter Name & Title — List the full name and title of the person who will present the paper.
4. Presenter Address — List the name of the department, institution and full postal address (including zip/postal code and country).
5. Phone Number — List the phone number, including area, country, and city codes of the presenter.
6. Fax Number — List the fax number, including area, country, and city codes of the presenter.
7. E-mail — List the E-mail address for the presenter.
8. Format preferred — Check the box to indicate oral or poster format. The Program Committee makes the final decision on the format of the abstract.
9. Category — Check the box to indicate which category best fits the subject of the abstract.
10. Developing Scientist Awards Competitions — Check the box to indicate if the paper is to be presented by a student in this competition. A signature and date is required from the major professor or department head. See "Call for Entrants in the Developing Scientist Awards Competitions."
11. Abstract — Type abstract, double-spaced, in the space provided or on a separate sheet of paper, using a 12-point font size. Use no more than 250 words.

Abstract Submission

Abstracts submitted for IAFP 2004 will be evaluated for acceptance by the Program Committee. Please be sure to follow the format instructions above carefully; failure to do so may result in rejection. Information in the abstract data must not have been previously published in a copyrighted journal.

Abstracts must be received no later than January 5, 2004. Return the completed abstract form through one of the following methods:

1. Online: Use the online abstract submission form located at www.foodprotection.org. You will receive an E-mail confirming receipt of your submission.
2. E-mail: Submit via E-mail as an attached text or MS Word™ document to abstracts@foodprotection.org.

Selection Criteria

1. Abstracts must accurately and briefly describe:
   (a) the problem studied and/or objectives;
   (b) methodology;
   (c) essential results; and
   (d) conclusions and/or significant implications.
2. Abstracts must report the results of original research pertinent to the subject matter. Papers should report the results of applied research on: food, dairy and environmental sanitation; foodborne pathogens; food and dairy microbiology; food and dairy engineering; food and dairy chemistry; food additives and residues; food and dairy technology; food service and food administration; quality assurance/control; mastitis; environmental health; waste management and water quality. Papers may also report subject matter of an educational and/or nontechnical nature.
3. Research must be based on accepted scientific practices.
4. Research should not have been previously presented nor intended for presentation at another scientific meeting. Papers should not appear in print prior to the Annual Meeting.
5. Results should be summarized. Do not use tables or graphs.

Rejection Reasons

1. Abstract was not prepared according to the "Instructions for Preparing Abstracts."
2. Abstract does not contain essential elements as described in "Selection Criteria."
3. Abstract reports inappropriate or unacceptable subject matter or is not based on accepted scientific practices, or the quality of the research or scientific approach is inadequate.
4. Work reported appears to be incomplete and/or data are not presented. Indication that data will be presented is not acceptable.
5. Abstract was poorly written or prepared. This includes spelling and grammatical errors.
6. Results have been presented/published previously.
7. Abstract was received after the deadline for submission.
8. Abstract contains information that is in violation of the International Association for Food Protection Policy on Commercialism.

Projected Deadlines/Notification

Abstract Submission Deadline: January 5, 2004. Submission Confirmations: On or before January 6, 2004. Acceptance/Rejection Notification: February 13, 2004.

Contact Information

Questions regarding abstract submission can be directed to Bev Brannen, 515.276.3344 or 800.369.6337; E-mail: bbrannen@foodprotection.org.

Program Chairperson

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Abstract Form

DEADLINE: Must be Received by January 5, 2004

(1) Title of Paper _____

_____

(2) Authors _____

_____

(3) Full Name and Title of Presenter _____

_____

(4) Institution and Address of Presenter _____

_____

(5) Phone Number _____

(6) Fax Number _____

(7) E-mail _____

(8) Format preferred: ☐ Oral ☐ Poster ☐ No Preference

The Program Committee will make the final decision on presentation format.

(9) Category: ☐ Produce ☐ Foods of Animal Origin ☐ Seafood ☐ Other Food Commodities

☐ Risk Assessment ☐ Education ☐ General Microbiology and Sanitation

☐ Antimicrobials ☐ Pathogens

(10) Developing Scientist Awards Competition ☐ Yes Graduation date _____

Major Professor/Department Head approval (signature and date) _____

(11) TYPE abstract, DOUBLE-SPACED, in the space provided or on a separate sheet of paper, using a 12-point font size. Use no more than 250 words.

Call for Entrants in the Developing Scientist Awards Competitions

Supported by the International Association for Food Protection Foundation

The International Association for Food Protection is pleased to announce the continuation of its program to encourage and recognize the work of students and recent graduates in the field of food safety research. Qualified individuals may enter either the oral or poster competition.

Purpose

1. To encourage students and recent graduates to present their original research at the Annual Meeting.
2. To foster professionalism in students and recent graduates through contact with peers and professional Members of the Association.
3. To encourage participation by students and recent graduates in the Association and the Annual Meeting.

Presentation Format

Oral Competition – The Developing Scientist Oral Awards Competition is open to graduate students (enrolled or recent graduates) from M.S. or Ph.D. programs or undergraduate students at accredited univesities or colleges. Presentations are limited to 15 minutes, which includes two to four minutes for discussion.

Poster Competition – The Developing Scientist Poster Awards Competition is open to students (enrolled or recent graduates) from undergraduate or graduate programs at accredited universities or colleges. The presenter must be present to answer questions for a specified time (approximately two hours) during the assigned session. Specific requirements for presentations will be provided at a later date.

General Information

1. Competition entrants cannot have graduated more than a year prior to the deadline for submitting abstracts.
2. Accredited universities or colleges must deal with environmental, food or dairy sanitation, protection or safety research.
3. The work must represent original research completed and presented by the entrant.
4. Entrants may enter only one paper in either the oral or poster competition.
5. All entrants must register for the Annual Meeting and assume responsibility for their own transportation, lodging, and registration fees.
6. Acceptance of your abstract for presentation is independent of acceptance as a competition finalist. Competition entrants who are chosen as finalists will be notified of their status by the chairperson by May 28, 2004.
7. All entrants with accepted abstracts will receive a complimentary, one-year Student Membership. This membership will entitle you to receive *JFP* Online.
8. In addition to adhering to the instruction in the "Call for Abstracts," competition entrants must check the box to indicate if the paper is to be presented by a student in this competition. A signature and date is required from the major professor or department head.

Judging Criteria

A panel of judges will evaluate abstracts and presentations. Selection of up to five finalists for each competition will be based on evaluations of the abstracts and the scientific quality of the work. All entrants will be advised of the results by May 28, 2004. Only competition finalists will be judged at the Annual Meeting and will be eligible for the awards.

All other entrants with accepted abstracts will be expected to be present as part of the regular Annual Meeting. Their presentations will not be judged and they will not be eligible for the awards.

Judging criteria will be based on the following:

1. Abstract – clarity, comprehensiveness and conciseness.
2. Scientific Quality – Adequacy of experimental design (methodology, replication, controls), extent to which objectives were met, difficulty and thoroughness of research, validity of conclusions based upon data, technical merit and contribution to science.
3. Presentation – Organization (clarity of introduction, objectives, methods, results and conclusions), quality of visuals, quality and poise of presentation, answering questions, and knowledge of subject.

Finalists

Awards will be presented at the International Association for Food Protection Annual Meeting Awards Banquet to the top three presenters (first, second and third places) in both the oral and poster competitions. All finalists are expected to be present at the banquet where the awards winners will be announced and recognized.

Awards

First Place – $500 and an engraved plaque
Second Place – $ 300 and a framed certificate
Third Place – $100 and a framed certificate

Award winners will receive a complimentary, one-year Student Membership including *Food Protection Trends, Journal of Food Protection,* and *JFP* Online.

Journal of Food Protection

Now Accepting Manuscripts Online

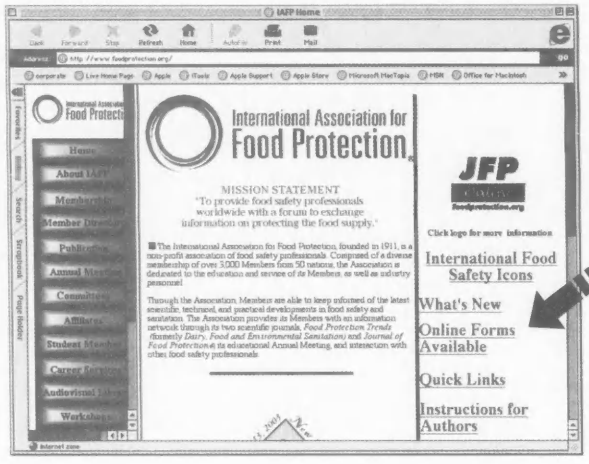
The International Association for Food Protection and the *Journal of Food Protection* recently launched an Online Manuscript Submission system.

It's as easy as 1, 2, 3...

Step 1 – Complete Submission Form

Step 2 – Upload Documents

Step 3 – Complete and Mail Assignment of Copyright



The *Journal of Food Protection* welcomes online submission of new manuscripts at www.foodprotection.org using PDF, Word or Word Perfect files. Electronic submission will speed the handling of manuscripts through the submission and review process. The Online Manuscript Submission System can be used from any computer, any operating system, anywhere in the world with an Internet connection. There are no programs to download.

Visit www.foodprotection.org for more information

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UPDATES

Robert Colvin Promoted to Vice President of Operations, Division I at Silliker

Robert Colvin joined Silliker in 1997 as general manager of the East Region. Responsible for overseeing six food testing labs located in the Midwest and Northeast, Mr. Colvin oversees a staff of 180.

During the last year, Mr. Colvin has managed the design and development process for the newest Silliker facility in Allentown, PA.

Mr. Colvin has been published professionally and is a member of the International Association for Food Protection, the American Society of Microbiology, the Institute of Food Technologists and the American Society of Clinical Pathologists. He earned a Master of Business Administration from Long Island University, a Medical Technologists Certification from Lenox Hospital School of Medical Technology, and a Bachelor of Science in microbiology/chemistry from Hunter College.

Mark Westover Joins Bell Laboratories as Sales Manager for United States and Canada

Mark Westover has joined Bell Laboratories as sales manager of its sales and marketing division for North America which includes the United States and Canada.

As sales manager, Mr. Westover positions Bell's complete line of rodent control products in the professional pest control market. He also manages Bell's sales and marketing team, providing training and support in business development.

Before joining Bell, Mr. Westover worked as corporate sales manager for Industrial Towel and Uniform, Inc. of New Berlin, WI and as national sales manager for Menasha Corporation of Oconomowoc, WI.

Mr. Westover holds a bachelor of business administration from the University of Wisconsin-Oshkosh.

Joseph O'Donnell Assumes Post as President of American Dairy Science Association Board of Directors

Dr. Joseph O'Donnell, executive director of the California Dairy Research Foundation (CDRF), took the helm as president of the American Dairy Science Association (ADSA) Board of Directors in July 2003.

Dr. O'Donnell will serve as president for the 2003-2004 term, part of a five-year commitment to ADSA that began in 2002 as vice president of the organization and includes three years as an officer and two years on the Federation of Animal Science Societies (FASS) board. He will work with the ADSA executive team, Vice President Mike Hutjens of the University of Illinois and Past President Dave Beede of Michigan State University to achieve the goals of the Association.

Dr. O'Donnell holds a B.S. degree in biochemistry from Benedictine University, a master's degree in biochemistry from Boston University, and a doctorate in nutrition from the University of California at Davis.

In addition to his CDRF duties, Dr. O'Donnell has authored numerous articles and abstracts, is a regular contributing writer to dairy industry publications, and travels extensively coordinating research and fostering communications within the global dairy industry. In addition to the ADSA, he is active in such professional organizations as the American Society for Nutritional Sciences, International Dairy Federation (IDF), and Institute of Food Technologists and serves as chair of the IDF Standing Committee on Nutrition and Health and the Editorial Advisory Board of *Dairy Foods* magazine.

International Association for Food Protection® NEWS

3-A Sanitary Standards Sets New Test Dates in United States and Europe for Conformance

Applications are now available from 3-A Sanitary Standards Inc. (3-A SSI) for candidates interested in obtaining certification as a 3-A Certified Conformance Evaluator (CCE). Qualified candidates may take the accreditation exam in Chicago on October 30, 2003 or in Brussels, Belgium on October 15 or November 25, 2003.

Please see the link to the 3-A SSI Web site (http://www.3-a.org/news_events/8-21-03_cce.htm) for a complete copy of the announcement and a link to the exam details and the complete application form. Copies of the actual release and the application are also attached.

USDA Creates Regional Training Centers for Meat Inspectors: Names Coordinator for Training and Education Initiative

The US Department of Agriculture has announced new regional training centers designed to bring comprehensive workforce training programs to the Food Safety and Inspection Service's (FSIS) field employees throughout the country.

On July 20, FSIS released a vision document to guide continuing food safety initiatives, including revamping its education and training programs to better prepare field employees to implement and enforce new food safety regulations. FSIS is focused on strengthening its public health emphasis by recruiting scientifically trained employees and training its current employees in scientific and technical principles.

"This Administration remains committed to improving our meat inspection systems," said Agriculture Secretary Ann M. Veneman. "Training for inspectors is an important part of our efforts to ensure that all our systems effectively protect the public health."

FSIS is establishing regional training centers in the five following field locations: Atlanta, Dallas, Philadelphia, Des Moines and Boulder. In addition, FSIS will be conducting interactive and on-site training sessions that will be easily accessible to its field employees.

"We are committed to aggressively addressing the training and education of the men and women who work every day to keep America's meat, poultry, and egg products safe," said FSIS Administrator Dr. Garry L. McKee, while addressing employees and inspectors during a tour at the Des Moines Cold Storage facility. "The most effective way to provide comprehensive training to our field employees is to bring that training to them."

In addition to establishing the new training centers, FSIS has designated a position inside the agency's highest office to oversee the comprehensive workforce training program. Commander Lynn Hodges, of the US Public Health Service, will coordinate this program as senior advisor for workforce training and education. "Commander Hodges is a welcome addition to the FSIS scientific team and will ensure that training and education remains a key focus for the agency," said McKee.

Regional, interactive and on-site training that is coordinated from agency headquarters will allow FSIS to train more inspectors each year in various skills to enhance their technical and regulatory abilities. During fiscal year 2004, which begins October 1, FSIS will train all new entry-level slaughter establishment inspectors and veterinary medical officers in technical, regulatory and public health methods. The types of training offered will be expanded in the future.

Lactoferrin Considered Safe to Fight *E. coli*

FDA has announced that aLF Ventures, Salt Lake City, UT, has consulted with the agency about aLF Ventures' plans to market lactoferrin, a component of an antimicrobial spray. This spray can be applied to uncooked beef carcasses to fight *E. coli* O157:H7, an organism that can cause severe gastrointestinal disease in humans. FDA informed aLf Ventures that it does not question their decision to market lactoferrin, an antimicrobial protein found in cow's milk and beef.

Although aLF Ventures was not required to seek approval from FDA before it marketed lactoferrin, aLF Ventures provided FDA scientific data supporting the firm's conclusion that lactoferrin is "generally recognized as safe" (GRAS) and safe for the general population as well as for individuals who are allergic to milk.

"Innovative technology is a critical building block in preserving the strong foundation of the US food supply," said Dr. Lester Crawford, Deputy Commissioner of the Food and Drug Administration. "We must continue to encourage scientific research and new technol-

ogy to maintain this nation's safe food supply." A substance used in food can be GRAS if its safety has been established by generally available scientific data and information that lead qualified experts to conclude that the use of the ingredient is safe for its proposed use.

In its notice submitted to FDA, aLF Ventures noted that the amount of added lactoferrin that remains on the beef after spraying is comparable to the amount of lactoferrin that is naturally occurring in the beef. aLF Ventures also submitted data to the US Department of Agriculture (USDA) regarding the effectiveness of lactoferrin against *E. coli* O157:H7. USDA is the agency responsible for addressing labeling issues with lactoferrin-treated beef.

Guidance on Food Assurance Schemes

The Food Standards Agency has published best-practice guidance for food assurance schemes, with the aim of ensuring that schemes are run in an open and transparent way and provide consumers with clear information.

Food assurance schemes are voluntary arrangements adopted by producers who aim to work to specific production standards. The Agency believes that the schemes can assist in increasing consumer choice and, potentially, raise production standards.

However, the Agency feels that consumers must have confidence that schemes deliver what they claim, and that consumers should also have access to further information about the scheme standards and how they are implemented. The Agency has issued its guidance in a booklet, "Advice for Assurance Schemes."

The booklet was produced in consultation with a wide range of stakeholders, following an Agency-funded independent consumer review of assurance schemes, which was published in July 2002.

The main recommendation of the review was that consumers should be more involved in the setting up and running of schemes. It also suggested that schemes should be more transparent, for example by giving consumers access to clear information about what they aimed to deliver.

The Agency intends to follow up the publication of Advice for Assurance Schemes with a survey, probably in 2005, to look at the extent to which schemes are following its guidance.

New Fish Labeling Regulations to Benefit Consumers

The Food Safety Authority of Ireland (FSAI) confirmed that new EU Regulations on the labeling of fish and seafoods on the Irish market are now in effect and aim to give consumers better information on these products. Retailers for the first time in Ireland are now legally obliged to include specific information on labeling. This includes the country of origin, stating if fish are farmed, the catch area and the common names for the species. The FSAI suggests this is a major positive initiative to provide greater transparency for consumers on the traceability of all fish.

The Regulations require that fish are labeled with details of the common or commercial name and provides an option for including the scientific name of the species. Where Irish processors are exporting fish, these must be labeled with the common name of the fish in that country. These Regulations apply to both marine and farmed fish sold through retailers to consumers.

According to Alan Reilly, Deputy Chief Executive, FSAI, the Regulations for the first time make it a legal requirement in Ireland to label fish stating if it was farmed or caught in the wild and the country of origin. This should provide clarity and end misleading and dubious labeling. "There was some misleading labeling in relation to portraying whether a product was farmed or caught in the wild and indeed if it was Irish or not. The terms "Irish Smoked Salmon" and "Smoked Irish Salmon" caused some confusion as to which product was actually an Irish salmon and which was an imported salmon that was smoked in Ireland. This Regulation will assist clarification of this for consumers. Consumers should be aware that the new labeling information must be provided on fish available in all retail premises. Declarations such as "caught at sea", "cultivated" or "farmed" are now necessary under these new Regulations. It will also be necessary to include the name of the geographical area where the fish was caught, such as the "Northeast Atlantic" or "Mediterranean Sea"," Mr. Reilly confirmed.

The Regulations apply to live fish, fresh, chilled or frozen fish, fillets of fish, smoked fish, salted and dried products, raw or cooked whole prawns and shrimps, and live or raw shellfish, such as oysters or mussels. Processed products such as breaded fillets, crab sticks or ready-to-eat dishes are not included by the new Regulations. However, it will be possible for consumers to purchase fish directly from a fisherman or fish farmer in small quantities, up to a value of EUR20 without the need for labeling.

To assist the trade in complying with the new requirements, the FSAI has joined forces with Bord Iascaigh Mhara and the Department of Communications, Marine and Natural Resource in issuing a comprehensive guide to ensure consumers are provided with the necessary information so they can make an informed choice when purchasing seafood. This guide explains the details of the new Regulations on the labeling of fishery and aquaculture products and the labeling and packaging requirements

that must be complied with to facilitate consumer understanding.

"This guide will ensure that the seafood industry has no excuse in misleading the consumer through mischievous, misleading or illegal labeling as they cannot claim ignorance of the legal requirements," continued Alan Reilly. "Ultimately, industry must provide more accurate, specific information for consumers and this will assist consumers to make informed purchasing choices based on a wider range of product information."

The policing of labeling requirements to ensure compliance is being carried out by enforcement officers throughout the country, working under service contract to the FSAI. Consumers who have concerns and wish to report apparently incorrect labeling of fish and seafoods are encouraged to contact the FSAI who will liaise with the appropriate agency.

Along with all EU Member States, Ireland has drawn up and published a list of fish species sold in the EU territories. The list complied by the Department of the Communications, Marine and Natural Resources contains almost 450 different fish and shellfish that can be sold in Ireland. This list and the guide for industry can be viewed on the FSAI website at www.fsai.ie.

USDA Creates Food Safety Risk Assessment Committee

The US Department of Agriculture's Under Secretary for Food Safety Dr. Elsa A. Murano has announced the establishment of a Food Safety Risk Assessment Committee to enhance coordination and communication among various USDA agencies in planning and conducting activities related to risk assessments.

On July 10, 2003, Under Secretary Murano released a vision document to guide continuing food safety initiatives, including strengthening the use of risk assessments to support and guide response to emerging public health threats.

The new risk assessment committee will combine the expertise of several USDA agencies to build a solid scientific basis on which to base regulatory and policy decisions. "The use of risk assessment has allowed USDA to focus its resources on those hazards along the farm-to-table continuum that pose the greatest risk to public health," said Murano, during remarks to the Southwest Meat Association. "Each agency involved in this new committee brings a specific expertise to ensure that our research, regulatory and public outreach resources achieve greater public health benefits."

The committee will prioritize risk assessments, identify research needs and identify needs for modeling techniques, methods or data; provide guidance related to carrying out risk assessments, including addressing issues such as data quality and peer review; and identify outside experts and/or universities to assist in the development of risk assessments.

The committee will be comprised of representatives from the following USDA agencies: Food Safety and Inspection Service; Agricultural Marketing Service; Agricultural Research Service; Animal and Plant Health Inspection Service; Cooperative State Research, Education and Extension Service; Economic Research Service; Food and Nutrition Service; and the Office of Risk Assessment and Cost Benefit Analysis.

New Vaccine Fights *Salmonella* in Poultry

Hens inoculated with a new, ARS-developed vaccine are less likely to transmit *Salmonella* Enteritidis into their eggs. This reduces the chance that people who eat raw or undercooked eggs would contract salmonellosis, typified by nausea, vomiting and severe diarrhea. Raw cookie dough or homemade mayonnaise or hollandaise sauce can contain raw eggs.

ARS scientists also found that inoculated hens shed 10 to 40 percent less *S.* Enteritidis in their feces. Less shedding helps reduce the spread of the infection through flocks. For these tests, researchers at the ARS Southeast Poultry Research Laboratory twice-inoculated hens with the experimental vaccine and then exposed the animals to the disease organism. ARS is seeking a patent for the experimental vaccine. The invention is more effective than current commercial vaccines because it boosts levels of antibodies that hens produce, in their intestines, to fight infection. Approximately 25 million doses of *S.* Enteritidis vaccine are used each year by US poultry producers

Bacteriophage Poultry Virus *Salmonella* Food Safety

It's an idea that might alarm people who are conditioned to believe that viruses have no redeeming qualities. But Billy Hargis and his Food Safety Consortium research team at the University of Arkansas would remind them that these particular viruses can make poultry a safer commodity for consumers.

The credit goes to bacteriophages, a specific kingdom of viruses that only infects bacteria and that cannot infect plants, animals or humans. "If you lick your lips, you're probably eating several hundred bacteriophages that are on your skin right now. They're pretty ubiquitous," said Hargis, director of the UA Poultry Health Research Laboratory.

Bacteriophages, which are obtained from natural sources and cloned for use against bacteria, have been used in experiments to kill *Salmonella* bacteria in poultry. Hargis' team used a couple of approaches. One was to rinse broiler and turkey carcasses with bacteriophage isolates. Two bacteriophage isolates were found to destroy eight *Salmonella* isolates on poultry.

Hargis' group also developed another method. They administered bacteriophages orally to poults to use the poults as a biological filter. They recovered the bacteriophages from the poults' feces, then the recovered bacteriophages were administered to a second group of poults, a procedure which reduced the levels of *Salmonella* that the poults were carrying. "We found in our early experiments that most of the bacteriophages, when we administered them to baby poultry, died or disappeared as they passed through the part of the gastrointestinal tract that's similar to the human stomach — it's called the proventriculus," Hargis said. Its low acidity was killing most of the bacteriophages.

But some bacteriophages were surviving, so the answer seemed to be in overwhelming the gastrointestinal tract with numbers. Hargis' group took the bacteriophage populations, grew their numbers and administered them to baby poultry to see what would survive. The plan worked. The large numbers of bacteriophage were passed through the poultry, separated and re-amplified to pass through them again. The mutations of bacteriophage managed to survive conditions in the poultry's guts well enough to be effective in reducing *Salmonella* by significant numbers.

"As the bacteriophage travels down the gut, when it gets to an appropriate point in the gut where that organism can grow, it actually amplifies the phage," Hargis explained. "And then you can achieve incredibly high numbers of bacteriophage in the lower part of the gut. Once you've got the phage there you just feed them the bacteria so that the bacteriophage population is constantly being fed new hosts. Any bad guys that happen to be in the environment are in trouble."

Pending further development of the patent pending technology jointly owned by the university and the US Department of Agriculture, the research has positive implications for a poultry industry in search of reliable ways of fighting *Salmonella* contamination. Poultry producers have long used antibiotics against pathogens, but many bacteria have developed resistance to antibiotics. The use of naturally occurring bacteriophages could be a more potent and reliable weapon for producers seeking to maintain healthy birds.

FSIS Announces New Food Safety and Security Guidelines to Assist Transporters and Distributors of Meat, Poultry and Egg Products

The Food Safety and Inspection Service (FSIS) has announced the availability of new food safety and security guidance for transporters and distributors of meat, poultry and egg products as part of its continuing effort to help protect America's food supply from intentional and unintentional contamination. In May 2002, FSIS issued security guidelines for food processors.

FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry and Egg Products is designed to help facilities and shippers that handle meat, poultry and egg products strengthen their food safety and security plans. The guidelines provide recommendations to ensure the security of food products through all phases of distribution.

"Protecting food during transportation and storage is a critical component in our defense against all types of foodborne contaminants," said FSIS Administrator Dr. Garry L. McKee. "These guidelines will further enhance the safety and security of meat, poultry and egg products throughout the food distribution chain."

Meat, poultry and egg products are frequently transported multiple times on their way to the consumer and may be exposed to hazards at each step. The guidelines address points in the transportation and distribution process where potential contaminants could be introduced, including loading and unloading, and in-transit storage. FSIS encourages shippers, transporters, distributors and receivers to develop and implement controls to prevent contamination of products through all phases of distribution and to have plans in place in the event of accidental or deliberate contamination.

FSIS is requesting public comments in response to a series of questions contained in the Federal Register notice announcing the guidelines. The agency is interested in comments that address any shortcomings or suggest possible improvements in the published guidelines and any challenges the guidelines may pose, particularly for smaller transportation, distribution and storage companies.

FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry and Egg Products is now available on the FSIS website at www.fsis.usda.gov/oa/topics/biosecurity.htm.

INDUSTRY PRODUCTS

Aeromix Systems, Inc.

ZEPHYR Induced Air Flotation System from Aeromix

The "Dial-a-Bubble," the latest improvement to the ZEPHYR, improves equipment performance by allowing the user to adjust the size and volume of air bubbles produced. A separate "flow stopper" chamber reduces mixing to allow the unit to be used in the same tank as the skimmer.

The new ZEPHYR from Aeromix Systems, Inc. is a high-efficiency induced air flotation system. The system creates micro-fine bubbles that adhere to various solids, lifting them to the surface for eventual skimming or disposal. It precisely separates liquid phases, making it ideally suited for oil and grease removal. The ZEPHYR has proven ideal for the removal of fine particulates from liquids such as oil, fat, or water and has a multitude of applications in the chemical, petroleum and food processing industries. In addition to flotation, the ultra fine bubbles created by the ZEPHYR are an ideal method for gas injection.

Aeromix Systems, Inc., Minneapolis, MN

READER SERVICE NO. 303

Biometrics USA to Offer a New Line of Secure Biometric Fingerprint Door Locks

Biometrics USA, a distributor of Biometric Fingerprint Solutions is proud to offer a new line of Fingerprint Door Locks from BioCert. This line of door locks combines the highest level of security with sophisticated sensor technology, making it an affordable and secure alternative to conventional door locks for homes and businesses.

Our signature biometric product, the FS-100 and fingerprint scanning are part of an up-and-coming technology known as "biometrics." Biometrics applies precise mathematical measurements to distinct physical attributes, such as fingerprints.

Other biometric applications include retinal scanning, which detects the unique pattern of blood vessels within the eye, and facial recognition systems, which measure structural features (distance between eyes, etc.) to tell one face from another.

The FS-100 fingerprint dead bolt has only been on the market for a few weeks, and has already started to make an impact as it is now compatible with most doors in North America and other parts of the globe. The FS-100 resembles a large, high-end door handle and lock, with a small opening at the very top. The opening holds the unit's fingertip scanner. A front panel covers a numeric key pad for programming the unit.

The unit is powered by five AA batteries. In the event they die while you're out, a 9-volt battery can be inserted into the front panel to provide enough power to enter. It also comes with emergency keys just in case. To operate the lock, an authorized user simply places a finger over the scanner and within a second or two, the print is recognized and the door unlocks. "It is very convenient in the case where you have guests, short term occupants, or renters. You can provide them with access as they require it, and then easily remove their prints from the system when they depart. It is much more secure, as you will have the peace of mind knowing that they can't lose or copy your key," said Ryan Mahabir, founder of Biometrics USA.

Biometrics, Mississauga, Ontario, Canada

READER SERVICE NO. 304

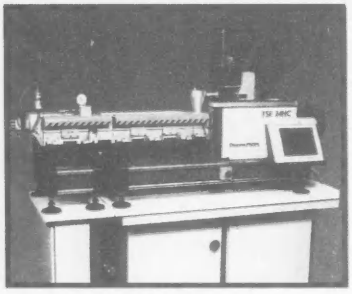
An Expanded Line of UVC Emitters™ from Steril-Aire, Inc.

The UVC Emitters from Steril-Aire offer exhanced food safety through airborne and surface control of mold, bacteria and viruses. The expanded line includes double- and single-ended UVC light fixtures and special shatter-resistant plastic tubes in a variety of sizes and configurations to fit virtually any application, including conveying lines, packaging containers, filling stations, cooling and drying areas, HVAC and refrigeration systems and storage rooms. The company's multi-patented UVC technology provides continuous, non-chemical de-

contamination of food surfaces and the surrounding environment. The UVC energy emitted by the high- output tubes delivers 99.9+ percent surface "kill" rates on pathogens such as *E. coli*, *Salmonella* and *Listeria*, without producing ozone or any secondary emissions.

Steril-Aire, Inc., Cerritos, CA

READER SERVICE NO. 305



Thermo Electron Corp.

PRISM Provides Precision and Convenience in One High Quality Product

Thermo Electron Corp. lab engineers who create and test multiple compounds that require a variety of compounding machine configurations now have a more convenient option — the PRISM line from Thermo Electron Corporation. Coming in a range of sizes and utilizing a twin-screw extruder, PRISM compounding systems provide the perfect solution for virtually all compounding and sample preparation needs.

PRISM's complete line of 16, 24 and 36 mm compounding systems meet the most demanding requirements with such convenient features as quick-release screws for easy configuration changes and a complete range of ancillaries, including all feeder types, liquid injections, strand dies, sheet dies, blown film units and more. Segmented barrels and screws for variable L/D provide essential versatility in an easy-to-clean clamshell design. Optional stainless steel construction that conforms to GMP standards for pharmaceutical uses is also available.

Thermo Electron Corp., Waltham, MA

READER SERVICE NO. 306

Pioneering Wedge – Wire Deck Replaces Drilled Hole Deck to Prevent Product Blockages and Ease Cleaning in Fluid Bed Drying from Witte

Fluid bed dryers and coolers from processing machinery and drying equipment manufacturer, The Witte Company, Washington, NJ, feature wedge-wire decks that significantly increase drying efficiency vs. outdated drilled hole decks. Permitting intimate product contact with the drying air, the Witte Wedge-Wire Decks replace the 1/8" hole on one-inch center drilled hole decks that trap product and block flow with tapered slots measuring 1/100" on 1/8" centers. This wedge, or triangular wire construction, establishes immediate openings for airflow that prevent blinding and ease cleaning. In addition, the Witte Wedge-Wire Decks allow a more gentle airflow that prevents product degradation, promotes product advance and ensures plug flow.

While old-fashioned drilled hole decks require frequent, hole-by-hole cleaning to remove trapped product, the smooth, Witte Wedge-Wire Decks may be cleaned quickly and easily by a single operator with no tools and at less frequent intervals. Line downtime and manual labor are reduced, product quality is assured and product waste is minimized.

The Witte Wedge-Wire Decks are manufactured from FDA-approved stainless steel and are ideal for drying and cooling foods, beverages dairy products, chemicals, pharmaceuticals, minerals, metals, plastic pellets and other products.

The Witte Company, Inc., Washington, NJ

READER SERVICE NO. 307

Conveyor Ideal for Fragile Product from Eriez Magnetics

Eriez' variable speed E-Z Slide Conveyor moves fragile products with a gentle sliding motion. The new HMC-18 model uses a counter rotating weight drive system so the product remains stationary as it is carried forward, then instantly slides along the tray surface as the drive quickly reverses its action. This mid-drive conveyor has its quiet 1 HP drive mounted below the center of the tray eliminating infeed and discharge obstruction with up to 48 inches of clear overhang.

The conveyor's sliding motion reduces product damage and oily particle build up from coatings being shaken off, providing wide application in the food processing industry. The E-Z Slide is capable of moving product 40 feet per minute, comes standard with a sanitary stainless steel tray ranging up to 24 inches wide and 10 feet long and can be suspended overhead.

The quiet, non-vibratory operation of the E-Z Slide also improves handling of small castings and powdered metal parts in foundry and metalworking environments.

Eriez Magnetics, Erie, PA

READER SERVICE NO. 308

E-Beam Process Effectively Treats Flour, Cereal, and Grain Extending Freshness by Reducing Microbial Content

Fast, effective electron-beam processing of flour, cereal, rice and

mixed grain products is provided by E-BEAM Services, Inc. to increase product shelf life and reduce contamination caused by microorganisms without using chemical fumigants.

Listeria, *Salmonella*, *E. coli*, grain beetles (*Oryzaephilus* spp.), lesser grain borers (*Rhizopertha dominica*), flour beetles (*Tribolium castaneum*), Indian meal moth (*Plodia interpunctella*), Angoumois grain moth (*Sitotroga cerealella*), Flat grain beetle (*Cryptolestes pulillus*), Saw-toothed grain beetle, (*Oryzaephilus surinamensis*), Bean weevil (*Acanthoscellides obtectus*), and other insects, rodents and pests can carry bacterial content that blossoms during grain or cereal processing, storage, or shipping. Foods that contain bacteria have the potential to cause illness, diarrheal disease, or death, and can result in financial loss and brand erosion for the food processor and/or distributor.

In a process similar to the sterilization of medical devices, E-BEAM Services irradiates flour and grain products with a low power electron-beam system that treats bulk or packaged products by rapidly penetrating the packaging without disturbing the product.

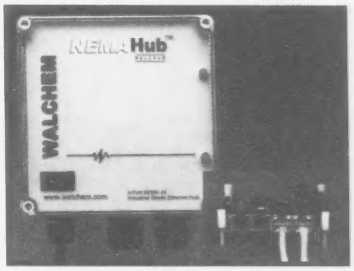
E-BEAM irradiation of flour, cereal and grain is an effective bio-reduction process that does not add any additional ingredient or change formulation requirements and leaves no chemical residue or after-taste. An additional advantage is that treated flour and grain products are prevented from sprouting.

E-BEAM Services, Inc., Cranbury, NJ

READER SERVICE NO. 309

Walchem Introduces the NEMAHub

Walchem, a provider of on-line analytical instruments and electronic metering pumps, has introduced NEMAHub, a waterproof



Walchem Corporation

Ethernet hub used to network Ethernet devices in an industrial environment. Priced at $599, NEMAHub is the first waterproof 10/100 Base T hub that uses standard Cat 5 Ethernet cables — a significant achievement since competing solutions typically entail expensive cable modifications and cost upward of $1,000.

"The NEMAHub is perfectly suited to industrial or outdoor local area networks where water and humidity, or high ambient temperature, are present," said Scott Koller, vice president of sales and marketing for Walchem. "There is no comparable product on the market right now. When our engineers tried to purchase a high-quality, waterproof hub for Walchem clients' LANs, they found nothing that fit customer needs, only a patchwork of hardware solutions that were both inconvenient and expensive."

The hub meets NEMA 4X standards for water tightness, with properly installed Cat 5 Ethernet cables. Its operating temperature range is 0 to 70 degrees centigrade (32 to 158 degrees Fahrenheit). The NEMAHub is supplied with four 10/100 Base T Ethernet ports with RJ45 connectors, and a built-in power supply allows for connection to any standard AC power source (120/246 VAC). 10BaseT compliance is IEEE 802.3; 100 BaseT compliance is IEEE 802.3u.

Walchem Corporation, Holliston, MA

READER SERVICE NO. 310

Malcom Hot Air Systems' Heat Guns Eliminate Need for Shrink Tunnels

A full line of heat guns and nozzles that eliminate the need for shrink tunnels in typical low volume shrinking applications is available from Malcom Hot Air Systems.

Malcom's Leister® Hand-Held Heat Guns feature temperatures up to 1,300°F with adjustable air flows to 30 CFM and are available with a wide variety of nozzles for shrink wrapping all types of products. Suitable for hand shrinking or for use in conveyor systems, these heat guns are capable of eliminating the need for shrink tunnels in low volume applications.

Effectively replacing heat lamps, quartz- and infrared heaters, and other passive heat sources, Malcom's Leister® Hand-Held Heat Guns can be equipped with different nozzles to concentrate or spread the heat, in a controlled manner, as required. Incorporating built-in electronics which provide over-load protection, they can also be used for curing, laminating, and drying.

Malcom Hot Air Systems, Portsmouth, RI

READER SERVICE NO. 311

Praxair Develops Non-Thermal Process for Low Acid Juices and Beverages

Praxair, Inc. has announced new applications for its Better Than Fresh™ beverage processing system. The new applications are for low acid juices, including carrot, and dairy-based beverages both of which are major pillars in the functional food segment. The Praxair® Better Than Fresh™ technology utilizes carbon dioxide as a processing aid, in lieu of heat, to significantly extend the shelf life of low acid beverages while retaining the

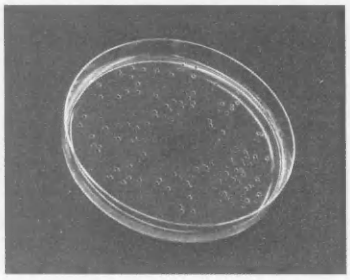
nutritional and sensory characteristics of fresh product. The Better Than Fresh™ process has previously been commercialized for the orange juice industry as an alternative to thermal pasteurization.

"This is a new product category that holds great potential," commented Sam Johnston, Praxair business development manager. "Our success with orange juice has created an opportunity to apply the technology to less acidic fruit and vegetable juices. In addition, we see a growing trend in dairy-based foods which will also benefit from Better Than Fresh™ processing." Carbon dioxide has been used for years to extend the shelf life of dairy products such as cottage cheese when trace amounts are sparged into product. Praxair's recent testing with its dense-phase CO_2 system is producing consistent results including the finding that with the dense-phase CO_2 process, the number of spoilage microorganisms is greatly reduced allowing for extended shelf life without subjecting product to detrimental levels of heat in thermal pasteurization.

Praxair conducts tests on scaled-down commercial equipment in its Food Technology Laboratory near Chicago. The lab evaluates product produced at a rate of 0.5 gallons/minute to simulate actual production conditions. In product evaluation, Praxair looks at sensory attributes, nutritional components, microbial control and shelf-life testing. As an option for customers, the demonstration units are skidded for transport and easily installed to allow testing at their facilities.

Praxair, Chicago, IL

READER SERVICE NO. 312



Oxoid GmbH

Oxoid GmbH Chooses ProtoCOL to Improve Its Quality Control Process

Synbiosis, a manufacturer of automated colony counters, is pleased to announce that Oxoid GmbH in Germany, a major supplier of microbial growth media, is using a ProtoCOL system in its quality control laboratories to produce more accurate results with a wide range of its media.

The fully GLP compliant ProtoCOL, with its integrated CCD camera and software, is being used at Oxoid to quality assure around 200 types of media with 60 different microorganisms plated out on them. The system is so efficient it can capture a plate image, while its software automatically compensates for different colored media and agar thickness, to produce a count in seconds.

Dr. Conny Mallach, head of microbiology at Oxoid GmbH said, "We use the ProtoCOL to test over 100 plates per day for microbial recovery rates. We do this by plating out a defined number of microorganisms onto spiral or spread plates and then counting how many actually grow. This way we can see how well each batch of media performs."

"We have had the ProtoCOL since January and have been able to do some very good work with it. In fact, we have not yet detected any kind of colony or plate type it cannot cope with. Prior to this, we used a manual counter but found that although the ProtoCOL does save time, its main benefit for us has been improving the accuracy of our results with highly reproducible counts," added Dr. Mallach.

Simon Johns, international product manager for Synbiosis stated, "this is the second major Oxoid site to choose a ProtoCOL for its quality control. The other is the main manufacturing unit in the UK, where they have been using the system for over two years. Therefore, we view this latest installation as a great independent endorsement and believe it will reassure microbiologists using Oxoid media that a ProtoCOL will benefit them with precise counts of virtually all colony types on any plate."

Oxoid GmbH, Wesel, Germany

READER SERVICE NO. 313

3-A Sanitary Standards for Blending Equipment, Number 35-01

Standards Developing Organizations
3-A Sanitary Standards, Inc. (3-A SSI)
in collaboration with
United States Public Health Service (USPHS)
United States Department of Agriculture (USDA)
European Hygienic Engineering & Design Group (EHEDG)

35-01

Disclaimers

3-A Sanitary Standards, Inc. (3-A SSI) and collaborating organizations do not assume or undertake to discharge all or any responsibilities of manufacturers or any other user of 3-A Accepted Practices. 3-A SSI is not responsible to any individual, organization or entity for the use of 3-A Standards and 3-A Accepted Practices. It is the science based opinions, professional findings of volunteer experts and consensus that provides the sanitary (hygienic) criteria included in 3-A documents.

3-A Standards and 3-A Practices do not include provisions for mechanical and electrical safety. Mechanical and electrical safety criteria are established by government regulations and other standards development organizations (SDOs). Other SDO standards may be referenced.

3-A Sanitary Standards, Inc., its employees and its volunteer committees shall not incur any obligation or liability for damages, including consequential damages, arising out of or in connection with the development, use, interpretation of, and reliance upon this 3-A Standard.

Drawings and illustrations contained herein are to assist in understanding the criteria in this 3-A Standard. Drawings and illustrations are not intended to show all variations of the equipment or system nor are they (it) to exclude alternate methods meeting this standard. Drawings and illustrations are non-normative.

Foreword

This 3-A Standard is to establish minimum sanitary (hygienic) requirements for Blending Equipment. Standard English is the official language of 3-A Sanitary Standards and 3-A Accepted Practices.

This 3-A Standard is for voluntary use by directly and materially affected organizations such as equipment and machinery fabricators, processors, regulatory agencies and by 3-A Sanitary Standards, Inc. to assure adequate public health protection exist for the devices and covered products. 3-A Sanitary Standards, Inc. use these documents as the source for sanitary criteria as part of 3-A Symbol authorization.

This 3-A Standard was developed jointly by 3-A Sanitary Standards, Inc. (3-A SSI), the United States Public Health Service (USPHS), the United States Department of Agriculture – Dairy Programs (USDA), and the European Hygienic Engineering & Design Group (EHEDG).

It is our purpose to encourage inventive genius and provide a forum to discuss new developments. Suggestions for improvement and new technology are welcome any time for consideration by the 3-A Sanitary Standards Committees. Please forward comments to the 3-A SSI, 1451 Dolley Madison Boulevard, Suite 210, McLean, VA 22101-3850, USA. By fax: 703-761-4334. By e-mail to: trug@3-a.org.

35-01

A SCOPE

A1 These standards cover the sanitary aspects of blending equipment used for combining and/or mixing either wet or dry products and includes any component equipment which shall conform to their respective 3-A Sanitary Standards.

A1.1 The blending equipment begins at the entrance to the hopper or infeed pipe connection(s) and ends at the exit pipe fitting and includes all equipment in between.

A2 In order to conform to these 3-A Sanitary Standards, blending equipment shall conform to the following design, material and fabrication criteria.[1]

A3 **Normative References:**
3-A Sanitary Standards for:
02- Centrifugal and Positive Rotary Pumps
18- Multiple-Use Rubber and Rubber-Like Materials
20- Multiple-Use Plastic Materials
32- Unmsulated Tanks
33- Polished Metal Tubing
36- In-Line Rotor-Stator Mixers
51- Plug-Type Valves
52- Plastic Plug-Type Valves
53- Compression-Type Valves
54- Diaphragm-Type Valves
55- Hoist Seal-Type Valves
57- Tank Outlet Valves
58- Vacuum Breakers and Check Valves
62- Hose Assemblies
63- Sanitary Fittings
65- Sight and/or Light Windows and Sight Indicators
73- Shear Mixers, Mixers, and Agitators
74- Sensors and Sensor Fittings and Connections Used on Equipment
78- Spray Devices to Remain in Place
81- Auger-Type Feeders

3-A Accepted Practices for:
605- Permanently Installed Product and Solution Pipelines and Cleaning Systems

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

B DEFINITIONS

B1 *Product:* Shall mean milk, milk products and other consumables.

B2 *Solutions:* Shall mean water and/or those homogeneous mixtures of cleaning agents and/or sanitizers and water used for flushing, cleaning, rinsing, and sanitizing.

B3 **Surfaces**

B3.1 *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.

B3.2 *Nonproduct Contact Surfaces:* Shall mean all other exposed surfaces.

B3.2.1 *Splash Contact Surfaces:* Shall mean nonproduct contact surfaces that during normal use are subject to accumulation of soil and which require routine cleaning.

B4 **Cleaning**

B4.1 *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 or equipment specifically designed for this purpose.

B4.2 *Manual (CIP) 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.

B5 **Surface Modification**

B5.1 *Surface Treatments:* Shall mean a process whereby chemical compositions or mechanical properties of the existing surface are altered. There is no appreciable, typically less than 1 µm, build-up of new material, or removal of existing material.

35-01

B5.1.1 Surface treatments include:

1. Mechanical (shot peening[2], polishing)
2. Thermal (surface hardening laser, electron beam)
3. Diffusion (carburizing, nitriding)
4. Chemical (etching, oxidation)
5. Ion Implantation
6. Electropolishing

B5.2 *Coatings:* Shall mean the results of a process where a different material is deposited to create a new surface. There is appreciable, typically more than 1 µm, build-up of new material. The existing material does not alter the physical properties of the substrate.

B5.2.1 Coating processes include:

1. Chemical (conversion coatings)
2. Engineering Plating, (e.g., Electrodeposition[3])
3. Thermal spraying (e.g., flame, plasma, arc spray)
4. Physical Vapor Deposition
5. Chemical Vapor Deposition
6. Overlays and Encapsulation

B6 *Bond:* Shall mean the adhesive or cohesive forces holding materials together. This definition excludes press and shrink fits.

B7 *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.

B8 *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.

B9 *Easily or Readily Accessible:* Shall mean a location which can be safely reached by personnel from a floor, other permanent work area, or stable platform (permanent or moveable).

B10 *Easily or Readily Removable:* Shall mean separated from the equipment with the use of simple hand tools if necessary.

B11 *Inspectable:* Shall mean all product contact surfaces can be made available for close visual observation.

B12 *Nontoxic Material:* Shall mean those substances which under the conditions of their use are in compliance with applicable requirements of the Food and Drug Administration.

B13 *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 $\log_{10}$ reductions (99.999%) to 7 $\log_{10}$ 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.

B14 *Simple Hand Tools:* Shall mean implements such as a screwdriver, a wrench, or mallet normally used by operating and cleaning personnel.

B15 *Soil:* Shall mean the presence of unwanted organic residue or inorganic matter.

C MATERIALS

C1 Metals

C1.1 The materials of product contact surfaces of components included in the blending equipment for which there are 3-A Sanitary Standards or 3-A Accepted Practices shall conform to the materials criteria of the applicable standards or accepted practices. (See Section A3.)

[2] AMS-S-13165, Shot Peening of Metal Parts. Available from Society of Automotive Engineers, Inc. (SAE), 400 Commonwealth Drive, Warrendale, PA 15096-0001.

[3] SAE-AMS-QQ-C-320 Chromium Plating (Electrodeposited); SAE-AMS-QQ-N-290, Nickel Plating (Electrodeposited). Society of Automotive Engineers, 400 Commonwealth Dr., Warrendale, PA 15096-0001.

35-01

C1.2 Product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI) 300 Series[4] (except 301 and 302) or corresponding Alloy Cast Institute (ACI) types[5], 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. (See Appendix, Section F.)

C1.3 Product contact surfaces made of the materials provided for in C1.1 may have their surfaces modified by coatings(s).

C2 Nonmetals

C2.1 Rubber and rubber-like materials may be used as a coating or covering on rotors and may be used for gaskets, seals, scrapers and flexible connection, and parts having the same functional purposes.

C2.1.1 Rubber and rubber-like materials, when used for the above-specified application(s), shall conform to the applicable provisions of the 3-A Sanitary Standards, Number 18-.

C2.2 Plastic materials may be used as a coating or covering on rotors and may be used for gaskets, seals, scrapers, flexible connections, bearings, augers, inspection port covers, and parts having the same functional purposes.

C2.2.1 Plastic materials when used for the above-specified applications shall conform to the applicable provisions of the 3-A Sanitary Standards, Number 20-.

C2.2.2 Plastic may be used in sight and or light openings and as direct reading gauge tubes, and when used shall be of a clear, heat resistant type.

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 conformation characteristics when exposed to the conditions encountered in the environment of intended use and in cleaning and sanitization.

C2.4 The adhesive, if used on bonded rubber and rubber-like materials and bonded plastic materials shall be nontoxic.[6]

C2.5 Where materials having certain inherent functional properties are required for specific applications, such as seals, gasket and or ceramic materials may be used. Carbon and ceramic materials shall be inert, nonporous, nontoxic, nonabsorbent, insoluble, resistant to scratching, scoring, and distortion when exposed to the conditions encountered in the environment of intended use and in cleaning and sanitization.

C2.6 Glass may be used in sight and or light openings and as direct reading gauge tubes, and when used, shall be of a clear, heat-resistant type.

C3 Nonproduct Contact Surfaces

C3.1 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 nonabsorbent, 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 components included in the blending equipment for which there are 3-A Sanitary Standards or 3-A Accepted Practices shall be those of the applicable standards or accepted practices. (See Section A3.)

D2 Surface Texture

D2.1 All product contact surfaces shall have a texture at least as smooth as 32 µin. or 0.8 µm R$_a$ finish on stainless steel sheets and be free of imperfections such as pits, folds, and crevices in the final fabricated form. (See Appendix, Section F.)

[4] The data for this surface are contained in the AISI Steel Products Manual: Stainless & Heat Resisting Steels, Table 5-D. Available from the American Iron and Steel Society, 4101 Commonwealth Drive, Warrendale, PA 15086.

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

[6] Adhesives 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, DC 20402.

D3 **Permanent Joints**

D3.1 All permanent joints in metallic product contact surfaces shall be continuously welded[1], except that:

D3.1.1 In such cases where welding is impractical, press-fitting or shrink-fitting may be employed for bushings, pins, and bearings. (See Appendix, Section G)

D3.1.2 Welding, press-fitting, or shrink-fitting shall produce product contact surfaces which are at least as smooth as a 32 µin. (0.8 µm) R_a on stainless steel sheets and which are free of imperfections such as pits, folds, and crevices. See Appendix, Section G for press-fitting and shrink-fitting restrictions and limitations.

D3.1.3 Equipment employing press-fits and shrink fits shall be designed for mechanical cleaning.

D4 **Bonded Materials**

D4.1 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 sanitizing treatment, the rubber and rubber-like material or the plastic material does not separate from the base material to which it is bonded.

D5 **Coatings**

D5.1 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 sanitizing treatment.

D5.2 The minimum thickness of electrodeposited coatings shall not be less than 0.0002 in. (0.005 mm) for all product contact surfaces.

D5.3 Thermospray materials used as coatings shall be at least 0.003 in. (0.08 mm) thick.

D5.4 Plastic or rubber and rubber-like materials, when used as a coating, shall be at least 0.001 in. (0.025 mm) thick.

D6 **Cleaning and Inspectability**

D6.1 Blending equipment that is to be mechanically cleaned shall be designed so that all product contact surfaces of the blending equipment and all nonremoved appurtenances thereto can be mechanically cleaned and are easily accessible, readily removable and inspectable.

D6.2 Product contact surfaces not designed to be mechanically cleaned shall be easily accessible for cleaning and inspection either when in an assembled position or when removed. Demountable parts shall be readily removable.

D6.3 Appurtenances having product contact surfaces shall be readily removable, or they shall be readily cleanable when assembled or installed, and shall be easily accessible for inspection.

D7 **Draining**

D7.1 Product contact surfaces of nonremovable parts shall be self-draining except for normal adherence.

D7.2 If the product contact surfaces are not self-draining, the blending equipment shall have sufficient slope to suitable drain points so the blending equipment can be drained.

D8 **Fittings and Valves**

D8.1 All sanitary fittings and connections having product contact surfaces that are furnished by the blending equipment manufacturer shall conform to the applicable provisions of the 3-A Sanitary Standards, Number 63-.

D8.2 Valves shall conform to the provisions of the applicable 3-A Sanitary Standards (see Section A3).

D9 **Instrument Connections**

D9.1 All instrument connections having product contact surfaces, when provided, shall conform to the applicable provisions of the 3-A Sanitary Standards, Number 74-.

[1] Criteria for hygienic welds may be found in AWS/ANSI D18.1 *Specification for Welding of Austenitic Stainless Steel Tube and Pipe Systems in Sanitary (Hygienic) Applications*. Available from the American Welding Society, 550 N.W. LeJeune Rd., Miami, FL 33126; and EHEDG Doc. 9 – Welding Stainless Steel to Meet Hygienic Requirements. Available from the European Hygienic Equipment Design Group, 1 Ilen Mains, Avenue Grand Champ 148, 1150 Brussels, Belgium.

D10 **Hose Assemblies**

D10.1 Hose assemblies having product contact surfaces, if provided, shall conform to the applicable provisions of the 3-A Sanitary Standards, Number 62-.

D11 **Sight and Light Openings**

D11.1 Sight and light openings provided shall conform to the applicable provisions of the 3-A Sanitary Standards, Number 65-.

D12 **Spray Devices**

D12.1 Spray devices having product contact surfaces, if provided, shall conform to the applicable provisions of the 3-A Sanitary Standards, Number 78-.

D13 **Sanitary Tubing**

D13.1 Metal tubing shall conform to the applicable provisions for welding sanitary product pipelines found in Section G of the 3-A Accepted Practices, Number 605- and with the 3-A Sanitary Standards, Number 33-.

D14 **Gaskets**

D14.1 Gaskets having a product contact surface shall be removable or bonded.

D14.2 Grooves in gaskets shall be no deeper than their width.

D14.3 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 those for standard O-rings smaller than 1/4 in. (6.35 mm), and those provided for in Sections D8 and D9.

D15 **Radii**

D15.1 All internal angles of less than 135° or less on product contact surfaces shall have radii of not less than 1/4 in. (6.35 mm), except that:

D15.1.1 Smaller radii may be used in sealing ring grooves but in no case shall the radii be less than 1/32 in (0.794 mm). The product contact surface of the internal angle shall be readily accessible for cleaning and inspection.

D15.1.2 The radii in grooves in gaskets or gasket retaining grooves shall be not less than 1/16 in. (1.59 mm); except for those for standard 1/4 in. (6.35 mm) and smaller O-rings, and those provided for in Section D8 and D9.

D15.1.3 Radii in standard O-ring grooves shall be as specified in Appendix, Section H.

D15.1.4 Radii in nonstandard O-ring grooves shall be those radii closest to a standard O-ring as specified in Appendix, Section H.

D15.1.5 When the thickness of one or both parts joined is less than 3/16 in. (4.76 mm), the minimum radii for fillets of welds on product contact surfaces shall be not less than 1/8 in. (3.18 mm).

D16 **Threads**

D16.1 There shall be no threads on product contact surfaces, except that:

D16.1.1 Where necessary for attaching a rotor to a shaft, the threads shall be ACME type as specified in the 3-A Sanitary Standard, Number 63- or the American Standard Stub Acme Thread (see Appendix, Section I). These threads shall conform to the drawing, Fig. (1), the "American Stub Acme Thread" (see Appendix, Section I). The threaded angles shall be not less than 60° and with not more than 8 threads to the inch (25.4 mm), nor less than 5/8 in. (15.9 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 components with exposed threads as described above shall be designed for manual cleaning, or,

D16.1.2 Where necessary for attaching a rotor to a shaft, non-sanitary threads may be enclosed in acorn-type nuts or the body of the impeller. In this case, there shall be an O-ring or gasket with similar function between the product and the non-sanitary threads. Equipment components utilizing these enclosed threads shall be designed for mechanical cleaning. Recessed threaded areas, with the exception of acorn nuts or impeller, are unacceptable. (See Appendix I.)

D17 **Perforated Product Contact Surfaces**

D17.1 Perforations in product contact surfaces of blending equipment may be any shape. If round, the holes shall be a minimum of 1/32 in. (0.794 mm) in diameter. If other than round, the least dimension shall be no less than 0.020 in. (0.51 mm) with corner radii of no less than 0.0050 in. (0.13 mm). All perforations shall be free of burrs.

D18 **Springs**

D18.1 Coil springs shall be made of round cross-section stock. Coil springs 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. End coils shall not be modified to produce a flat mounting surface.

D19 **Shafts and Bearings**

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.

D19.2 Bearings having a product contact surface shall be of a nonlubricated type.

D19.3 Lubricated bearings, including the permanently sealed type, shall be located outside the product contact surface with at least 1.00 in. (25.4 mm) clearance open for inspection between the bearing and any product contact surface.

D19.4 Shafts (Other than those covered by 3-A Sanitary Standard 73-) of blending equipment shall have a seal that is of a packless type and is sanitary in design, and shall be readily accessible and inspectable.

D20 **Openings and Covers**

D20.1 Openings through either hinged or removable covers, to which connections are not permanently attached, shall be flanged upward at least 3/8 in. (9.52 mm). All sanitary pipelines and other appurtenances entering through the cover shall be fitted with a sanitary umbrella deflector that overlaps the edges of the opening. Other openings, with the exception of agitator openings, shall have a removable cover, which shall be downwardly flanged to make close contact with the upper edges of the upwardly flanged opening in the cover surface. When the removable cover is located in the main cover, it shall remain in position when the main cover is raised.

D20.2 Covers and bridges shall slope to an outside edge(s).

D20.2.1 Permanent covers and bridges shall be integral with or continuously welded to the lining.

D21 **Agitators**

D21.1 Agitators shall conform to the applicable provisions of 3-A Sanitary Standard, Number 73-, except that:

D21.1.1 Agitators, including the complete seal, shall be readily accessible and removable for cleaning. Nonremovable parts having product surfaces shall be designed so that the product contact surfaces are readily cleanable and inspectable.

D22 **Hoppers**

D22.1 If hoppers are included with or accessory to the blending equipment, they shall conform to the applicable material and fabrication requirements herein and to the applicable provisions of the 3-A Sanitary Standards, Number 32-.

D23 **Nonproduct Contact Surfaces**

D23.1 Nonproduct contact surfaces shall have a relatively smooth finish, be cleanable and relatively free of pockets and crevices. Those surfaces to be coated shall be effectively prepared for coating.

D23.2
- Exposed threads shall be minimized.
- 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.
- Name and information plates shall be welded or effectively sealed to the equipment.
- Riveted nameplates or appendages shall not be used.
- Socket head cap screws shall not be used.
- Knurled surfaces shall not be used.

D23.3 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, mechanical linkages, and other similar equipment.

D23.4 **Supports**

D23.4.1 *Supports:* The means of supporting blending equipment shall be one of the following:

D23.4.1.1 If legs are used, they shall be smooth with rounded ends or with a flat, load-bearing foot suitable for sealing to the floor, and have no exposed threads. Legs made of hollow stock shall be sealed. Legs shall provide a minimum clearance between the lowest part of the base and the floor of not less than 4.0 in. (100 mm) when the blending equipment outlines an area in which no point is more than 12.5 in. (305 mm) from the nearest edge of the base or a clearance of at least 6.0 in. (152 mm) when any point is more than 12.5 in. (305 mm) from the nearest edge of the base.

D23.4.1.2 If casters are used, they shall be of sufficient size to provide a clearance between the lowest part of the base and the floor of not less than 4.0 in. (101 mm). Casters, if provided, shall be easily cleanable, durable and of a size that will permit easy movement of the blending equipment.

D24 **Guards and Other Safety Devices**

D24.1 Guards required by a personnel safety standard that will not permit accessibility for cleaning and inspection shall be designed so that they can be removed with the use of simple hand tools.

APPENDIX

E STAINLESS STEEL MATERIALS

E1 Stainless steel conforming to the applicable chemical composition ranges established by AISI[2] for wrought products, or by ACI[3] for cast products, should be considered in conformance to the requirements of Section C1 herein. Where welding is involved, the carbon content of the stainless steel should not exceed 0.080%.

E2 **Table 1**

WROUGHT PRODUCTS TYPICALLY USED			
UNS#	ASTM[4]	AISI/ SAE[2]	Common Names
S30300	A-582	303	Free-Machining S.S.; Austenitic
S30400	A-276 A-666	304	Austenitic S.S.
S30403	A-276 A-666	304L	Low Carbon Austenitic S.S.
S31600	A-276 A-666	316	Austenitic S.S. plus Mo*
S31603	A-276 A 666	316L	Low Carbon Austenitic S.S plus Mo*

*Molybdenum

Table 2

CAST PRODUCTS			
UNS #	ASTM[4]	ACI[3]	Common Names
J92500	A-351 A-743 A-744	CF-3	Cast 304L
J92800	A-351 A-743 A-744	CF-3M	Cast 316L
J92600	A-351 A-743 A-744	CF-8	Cast 304
J92900	A-351 A-743 A-744	CF-8M	Cast 316
J92180	A-747	CB7 Cu – 1	Cast 17-4 PH
J92110	A-747	CB7 Cu -2	Cast 15-5 PH
N26055	A-494	CY55n BiM	Alloy 88
J92701	A-743	CE-16n	Free Machining Austenitic S.S.

[2] Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959.

TABLE 3 OPTIONAL METAL ALLOYS

Optional metal alloys having the following compositions are examples considered in conformance to Section C (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 R5004
	ASTM A743 Grade CN-3MN	ASTM A743 Grade CF-10 SMnN		ASTM A494 Grade CY5SnBiM	ASTM A494 Grade CW-2M	ASTM A747 Grade CB7Cu-1	ASTM A747 Gradb CB7Cu-2		ASTM A560 Grade 50Cr-50Ni	ASTI B67 Grad 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	0.50	
Si	1.00	3.50-4.50	1.00-3.00	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	15.50-17.5	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	3.50-5.50	2.50-5.00	Balance	
Mn	0.6-5.0			2.0-5.5	15.0-17.5			1.00-2.00		
Cb						0.15-0.35	0.15-0.45			
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		0.90	
Fe	Balance	Balance	Balance	2.00	2.00	Balance	Balance	Balance	1.00	0.50
Sn				3.0-5.0						
Bi				3.0-5.0						
W					1.0					
Ti									0.50	Balan
Al									0.25	
Other										If = 0.01 N = 0.01 Ti = 0.25

L3 Metal alloys or metals other than the above may be as corrosion resistant as 300 Series Stainless steel. Thi shown when metal alloys or metals are tested in accordance with ASTM G31 Laboratory Immersion Corrosion of Metals[8] and have a corrosion rate of less than 10 mil per year. The test parameters such as the type of che their concentration(s), and temperature(s) should be representative of cleaning and sanitizing conditions use equipment. Alloys containing lead, leachable copper, or other toxic metals should not be used.

F **PRODUCT CONTACT SURFACE FINISH**

F1 Surface finish equivalent to 150 grit or better, as obtained with silicon carbide properly applied on stainless steel sheets, is considered in conformance to the requirements of Section D2.1 herein. A maximum R_a of 32 µin. (0.8 µm), when measured according to the recommendations in American National Standards Institute (ANSI)/American Society of Mechanical Engineers (ASME)[9] B46.1 - *Surface Texture Waviness and Lay* is considered to be equivalent to a No. 4 finish.

F2 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 ($R_a \leq 32$ µin. or ≤ 0.8 µm) finish and are acceptable for the fabrication of equipment if free of imperfections.

G **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.

O-RING GROOVE RADII

TABLE 4 - 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	0.0160 in. (0.406 mm)
3/32 in.	0.103 in.	2.65 mm	0.0310 in. (0.787 mm)
1/8 in.	0.139 in.	3.55 mm	0.031(0 in. (0.787 mm)
3/16 in.	0.210 in.	5.30 mm	0.0620 in. (1.575 mm)
1/4 in.	0.275 in.	7.00 mm	0.0940 in. (2.39 mm)

[8] ble from the American Society of Mechanical Engineers, ard 47th Street, New York, NY 10017-2392.

[10] The document establishing these standard dimensions is Aerospace standard (AS) 568 published by SAE, 400 Commonwealth Drive, Warrendale, PA 15096.

[11] The document establishing these standard dimensions is ISO 3601-1 published by the International Organization for Standardization (ISO), 1, Rue de Varembe, Case Postale 56, CH-1211, Geneva, Switzerland.

I **THREADS**

I1 American Standard Stub Acme Thread

P = PITCH
S.D. = SINGLE DEPTH
T.F. = TOP FLAT
B.F. = BOTTOM FLAT
T.P.I. = THREADS PER INCH

P = 1/T.P.I.
S.D. = 0.433 x P
T.F. = 0.258 x P
B.F. = 0.227 x P

I2 **Enclosed Threads**

I2.1 Blind threaded holes are not cleanable.

I2.1.1 Acorn-type nuts or other enclosed threaded pieces that become soiled after failure of an "O" ring (or gasket having similar function) should be discarded when soiled.

J **ENGINEERING DESIGN AND TECHNICAL CONSTRUCTION FILE**

The following is an example of an engineering design and technical construction file (EDTCF) to be maintained by the fabricator as evidence of conforming to 3-A Sanitary Standards or 3-A Accepted Practices. (The file may contain more or less information as applicable to the equipment or system.)

J1 **Purpose**

J1.1 To establish and document the material, fabrication, and installation (where appropriate) requirements for the engineering design and technical construction files for all products, assemblies, and sub-assemblies supplied by the manufacturer thereof to be in conformance to the sanitary criteria found in 3-A Sanitary Standards or 3-A Accepted Practices. It is recommended that the engineering and construction file or files be submitted with applications for 3-A Symbol use authorization.

J2 **Scope**

J2.1 This EDTCF applies to equipment specified by

J2.1.1 3-A Sanitary Standards for Blending Equipment, Number 35-01.

J2.2.2 List all applicable 3-A Sanitary Standards and 3-A Accepted Practices.

J3. **Responsibilities**

J3.1 This EDTCF is maintained by The Engineering Manager (or other company official) **[name and title of responsible official]** is responsible for maintaining, publishing, and distributing this EDTCF.

J3.2 Implementation. All divisions, specifically development engineering, standards engineering, sales engineering, and product departments are responsible for implementing this EDTCF.

J4. **Applicability**

J4.1 The 3-A Sanitary Standards and 3-A Accepted Practices are voluntarily applied as suitable sanitary criteria for dairy and food processing equipment. 3-A Sanitary Standards are referenced in the Grade A Pasteurized Milk Ordinance. "Equipment manufactured in conformity to 3-A Sanitary Standards conforms to the sanitary design and construction standards of this Ordinance."

J5 **References**

J5.1 List any additional regulations that apply to the equipment or system covered by this EDTCF.

J5.2 Date of conformity or 3-A Symbol Authorization and certificate number, if authorized.

J6 **Design and Technical Construction File**

J6.1 The Engineering Design and Technical Construction File may consist of the following:

a. an overall drawing of the subject equipment;
b. full detailed drawings, accompanied by any calculations, notes, test results, etc. required to check the conformity of the equipment with the 3-A Standards or 3-A Practices;
c. a list of:
(1) the essential requirements of the standards or practices;
(2) other technical specifications, which were used when the equipment was designed;
d. a description of methods adopted;
e. if essential, any technical report or certificate obtained from a competent testing body or laboratory;
f. any technical report giving the results of tests carried out internally by Engineering or others;
g. documentation and test reports on any research or tests on components, assemblies and or the complete product to determine and demonstrate that by its design and construction the product is capable of being installed, put into service, and operated in a sanitary manner (optional);
h. a determination of the foreseeable lifetime of the product (optional);
i. a copy of the instructions for the product (Instruction Manuals Instruction Books);
j. for serial manufacturing, the internal measures that will be implemented to ensure that the equipment will continue to be manufactured in conformity to the provisions of the 3-A Sanitary Standards or 3-A Accepted Practices;
k. engineering reports;
l. laboratory reports;
m. bills of material;
n. wiring diagrams, if applicable;
o. sales order engineering files;
p. hazard evaluation committee reports, if executed;
q. change records;
r. customer specifications;
s. any notified body technical reports and certification tests;
t. copy of the 3-A Symbol authorization, if applicable.

J6.2 The file does not have to include detailed plans or any other specific information regarding the sub-assemblies, tooling, or fixtures used for the manufacture of the product unless a knowledge of them is essential for verification of conformity to the basic sanitary requirements found in 3-A documents.

J6.3 The documentation referred to in J6.1 above need not permanently exist in a material manner in the EDTCF, but it must be possible to assemble them and make them available within a period of time commensurate with its importance (one week is considered reasonable time). As a minimum, each product EDTCF must physically contain an index of the applicable document of J6.1 above.

J6.4 The EDTCF may be in hard copy or software form.

J7 **Confidentiality**

J7.1 The EDTCF is the property of the manufacturer and is shown at their discretion, except that all or part of this file will be available to 3-A SSI or a regulatory agency for cause and upon request.

J8 **File Location**

J8.1 The EDTCF shall be maintained at **[location]**.

J9 **File Retention**

J9.1 The EDTCF (including all documentation referred to in J6.1) shall be retained and kept available for 12 years following the date of placing the product in use or from the last unit produced in the case of series manufacture.

3-A® Sanitary Standards for Inline Rotor-Stator Mixers Number 36-01

Standards Developing Organizations
3-A Sanitary Standards, Inc. (3-A SSI)
in collaboration with
United States Public Health Service (USPHS)
United States Department of Agriculture (USDA)
European Hygienic Engineering & Design Group (EHEDG)

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3-A Standards and 3-A Practices do not include provisions for mechanical and electrical safety. Mechanical and electrical safety criteria are established by government regulations and other standards development organizations (SDOs). Other SDO standards may be referenced.

3-A Sanitary Standards, Inc., its employees and its volunteer committees shall not incur any obligation or liability for damages, including consequential damages, arising out of or in connection with the development, use, interpretation of, and reliance upon this 3-A Standard.

Drawings and illustrations contained herein are to assist in understanding the criteria in this 3-A Standard. Drawings and illustrations are not intended to show all variations of the equipment or system nor are they (it) to exclude alternate methods meeting this standard. Drawings and illustrations are non-normative.

Foreword

This 3-A Standard is to establish minimum sanitary (hygienic) requirements for Inline Rotor-Stator Mixers. Standard English is the official language of 3-A Sanitary Standards and 3-A Accepted Practices.

This 3-A Standard is for voluntary use by directly and materially affected organizations such as equipment and machinery fabricators, processors, regulatory agencies and by 3-A Sanitary Standards, Inc. to assure adequate public health protection exist for the devices and covered products. 3-A Sanitary Standards, Inc. use these documents as the source for sanitary criteria as part of 3-A Symbol authorization.

This 3-A Standard was developed jointly by 3-A Sanitary Standards, Inc. (3-A SSI), the United States Public Health Service (USPHS), the United States Department of Agriculture - Dairy Programs (USDA), and the European Hygienic Engineering & Design Group (EHEDG).

It is our purpose to encourage inventive genius and provide a forum to discuss new developments. Suggestions for improvement and new technology are welcome any time for consideration by the 3-A Sanitary Standards Committees. Please forward comments to the 3-A SSI, 1451 Dolley Madison Boulevard, Suite 210, McLean, VA 22101-3850, USA. By fax: 703-761-4334. By e-mail to: tng@3-a.org

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A SCOPE

A1 These standards cover the sanitary aspects of inline devices which use a combination of a rotor and a stator to effect mixing and size reductions for liquids, slurries, and liquid-gas mixtures.

A1.1 The rotor-stator mixer begins at the infeed pipe connection(s) and ends at the exit pipe fitting and includes all equipment in between.

A2 In order to conform to the 3-A Sanitary Standards, rotor-stator inline mixers, (Referred hereinafter as "inline mixers") shall conform to the following design, material and fabrication criteria and the applicable documents referenced herein.[1]

A3 **Normative References**
3-A Sanitary Standard for:
18- Multiple-Use Rubber and Rubber-Like Materials
20- Multiple-Use Plastic Materials
63- Sanitary Fittings
74- Sensors and Sensor Fittings and Connections Used on Equipment

B DEFINITIONS

B1 *Product:* Shall mean milk and milk products or other comestibles.

B2 *Inline mixers:* As defined in A Scope, describes equipment commonly known as colloid mills, shear pumps, inline mixers and shear blenders, used for producing suspensions, emulsions, dispersions, particle reduction, or intimate mixtures.

B3 **Surfaces**

B3.1 *Product Contact Surfaces.* Shall mean all surfaces that are exposed to the product and surfaces from which liquids and/or solids may drain, drop, diffuse, or be drawn into the product.

B3.2 *Nonproduct Contact Surfaces.* Shall mean all other exposed surfaces.

B4 **Cleaning**

B4.1 *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.

B4.2 *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.

B5 **Surface Modification**[2]

B5.1 *Surface Treatments.* Shall mean a process whereby chemical compositions or mechanical properties of the existing surface are altered. There is no appreciable, typically less than 1 µm, build-up of new material; or removal of existing material.

B5.1.1 Surface treatments include:

1. Mechanical (shot peening[3], polishing)
2. Electropolishing

B5.2 *Coatings:* Shall mean the results of a process where a different material is deposited to create a new surface. There is appreciable, typically more than 1 µm, build-up of new material. The coating material does not alter the physical properties of the substrate.

B5.2.1 Coating processes include:

1. Chemical (conversion coatings)
2. Engineering Plating,[4]
3. Thermal spraying, when appropriately sealed, (e.g., flame, plasma, arc spray).
4. Physical Vapor Deposition
5. Chemical Vapor Deposition
6. Overlays and Encapsulation

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

[2] Additional information on surface modification is contained in *Advanced Materials and Processes*, Volume 137(1), "Coatings and Coating Practices" by H. Herman; "Surface Modification" by F. A. Smidt. ASM International, Materials Park, OH 44073.

[3] AMS S-13165, *Shot Peening of Metal Parts*. Available from Society of Automotive Engineers, Inc. (SAE), 400 Commonwealth Drive, Warrendale, PA.

[4] SAE AMS QQ-C 320, "Chromium Plating (Electrodeposited)" and SAE AMS-QQ-N-290, "Nickel Plating (Electrodeposited)." Available from Society of Automotive Engineers, Inc (SAE), 400 Commonwealth Drive, Warrendale, PA.

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B6 *Soil:* Shall mean the presence of unwanted organic residue or inorganic matter, with or without microorganisms, including food residue, in or on the equipment.

B7 *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 $\log_{10}$ reductions (99.999%) to 7 $\log_{10}$ 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.

B8 *Sterilization:* Shall mean a process effected by heat, chemicals, or other mechanical means that destroys all vegetative bacteria and inactivates relevant bacterial spores.

B9 *Easily or Readily Removable:* Shall mean quickly separated from the equipment with the use of simple hand tools if necessary.

B10 *Easily or Readily Accessible:* Shall mean a location which can be safely reached by personnel from the floor, platform, or other permanent work area.

B11 *Inspectable:* Shall mean all product contact surfaces can be made available for close visual observation.

B12 *Simple Hand Tools:* Shall mean implements normally used by operating and cleaning personnel such as a screwdriver, wrench, or mallet.

B13 *Nontoxic Materials:* Shall mean those substances which under the conditions of their use are in compliance with applicable requirements of the Food and Drug Administration.

B14 *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 treatment, or sterilization compounds or solutions.

C MATERIALS

C1 **For Product Contact Surfaces**

C1.1 **Metals**

C1.1.1 Product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI) 300 Series[5], (except 301 and 302) or corresponding Alloy Cast Institute (ACI) types[6] 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. (See Appendix, Section E.)

C1.1.2 Product contact surfaces made of the materials provided for in C1.1.1 may have their surfaces coated.

C1.2 Solder, when used, shall be gold or silver containing solder and shall be corrosion resistant, free of cadmium, lead and antimony, nonabsorbent, and shall not impart any toxic substance to the product when exposed to the conditions encountered in the environment of intended use and in cleaning/sanitizing treatment or sterilization.

C1.3 **Nonmetals**

C1.3.1 Rubber and rubber-like materials may be used for gaskets, seals, and parts having the same functional purposes.

C1.3.1.1 Rubber and rubber-like materials when used for the above-specified applications shall conform to the applicable provisions of the 3-A Sanitary Standards Number 18-.

C1.3.2 Plastic materials may be used for gaskets, seals, and parts having the same functional purposes.

C1.3.2.1 Plastic materials when used for the above-specified applications shall conform to the applicable provisions of the 3-A Sanitary Standards, Number 20-.

[5] The data for this series are contained in the *AISI Steel Products Manual: Stainless & Heat Resisting Steel Table 2-1*. Available from the American Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086.

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

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C1.3.3 Rubber and rubber-like materials or 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 sanitizing treatment or sterilization.

C1.3.4 Where materials having certain inherent functional properties are required for specific applications, such as seals, carbon and/or ceramic materials may be used. Carbon and/or ceramic materials shall be inert, nonporous, nontoxic, nonabsorbent, insoluble, resistant to scratching, scoring, and distortion when exposed to the conditions encountered in the environment of intended use and in cleaning and sanitizing treatment or sterilization.

C2 **High Temperature Materials**

C2.1 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 in-line mixers 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.

C3 **Nonproduct Contact Surfaces**

C3.1 Nonproduct contact surfaces shall be of corrosion-resistant material or material that is rendered corrosion resistant. If coated, the coating used shall adhere. Nonproduct contact surfaces shall be relatively nonabsorbent, durable and cleanable. Parts removable for cleaning having both product contact and nonproduct contact surfaces shall not be painted.

D FABRICATION

D1 **Surface Texture**

D1.1 All product contact surfaces shall be at least as smooth as an *R*$_a$ 32 µin. (0.8 µm) finish on stainless steel sheets and be free of imperfections such as pits, folds and crevices in the final fabricated form. (See Appendix, Section F.)

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D2 **Permanent Joints**

D2.1 All permanent joints in product contact surfaces shall be continuously welded[7] and conform to Section D1.1, except that:

D2.1.1 In such cases where welding is impractical, press-fitting, or shrink-fitting may be used for pins, bushings, and sleeves (See Appendix, Section G.)

D2.1.1.1 Equipment employing press-fit and shrink fit shall be designed for mechanical cleaning.

D2.1.2 In such cases where welding is impractical, soldering may be used for connecting stator components.

D2.1.3 Press-fitting, shrink-fitting, or soldering shall produce product contact surfaces equivalent to D1.1. See Appendix G) for press-fitting and shrink-fitting restrictions and limitations.

D3 **Coatings**

D3.1 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.

D3.2 The minimum thickness of electrodeposited coatings shall not be less than 0.00020 in. (0.0050 mm) for all product contact surfaces.

D3.3 Thermospray materials used as coatings shall be at least 0.0030 in. (0.080 mm) thick.

D4 **Cleaning and Inspectability**

D4.1 Inline mixers intended to be mechanically cleaned shall be designed so that all product contact surfaces of the inline mixer and all non-removed appurtenances thereto can be mechanically cleaned and are inspectable.

D4.1.1 Rotors and stators shall be readily removable.

[7] Criteria for hygienic welds may be found in AWS/ASSI D18.1 *Specification for Welding of Austenitic Stainless Steel Tube and Pipe Systems in Sanitary (Hygienic) Applications*. Available from the American Welding Society, 550 N.W. LeJeune Rd., Miami, FL 33126, and EHEDG Doc. 9 - Welding Stainless Steel to Meet Hygienic Requirements. Available from the European Hygienic Equipment Design Group, Eliott Morris, Avenue Grand Champ 148, 1150 Brussels, Belgium.

D4.2 Product contact surfaces not designed to be mechanically cleaned shall be easily accessible for cleaning and inspection either when in an assembled position or when removed. Demountable parts shall be readily removable.

D5 **Draining**

D5.1 All product contact surfaces shall be self-draining or shall drain when the inline mixer is disassembled except for normal adherence.

D6 **Fittings**

D6.1 All sanitary fittings and connections shall conform to the applicable provisions of the 3-A Sanitary Standards, Number 63-.

D7 **Instrument Connections**

D7.1 All instrument connections having product contact surfaces shall conform to the applicable provisions of the 3-A Sanitary Standards, Number 74-.

D8 **Gaskets**

D8.1 Gaskets having a product contact surface shall be removable.

D8.2 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 those for standard O-rings smaller than 1/4 in. (6.35 mm), and those provided for in Section D6.1 and D7.1.

D8.3 Grooves in gaskets shall be no deeper than their width.

D9 **Radii**

D9.1 Internal angles of less than 135° on product contact surfaces shall have radii of not less than 1/4 in. (6.35mm) except:

D9.1.1 Smaller radii may be used in stator and rotor openings, rotor blades, and seal components. In no case shall the radii be less than 1/32 in (0.794 mm). The product contact surface of the internal angle shall be readily accessible, easily removable, and inspectable.

D9.1.1.1 Smaller radii may be used for rotor/stator serrations. These shall be readily accessible, easily removable, and inspectable.

D9.1.2 The radii in grooves in gaskets or gasket retaining grooves shall be not less than 1/8 in. (3.18 mm) except for those for standard 1/4 in. (6.35 mm) and smaller O-rings, and those provided for in Section D6.1 and D7.1.

D9.1.3 Radii in standard O-ring grooves shall be as specified in Appendix, Section H.

D9.1.4 Radii in nonstandard O-ring grooves shall be those radii closest to a standard O-ring as specified in Appendix, Section H.

D10 **Threads**

D10.1 There shall be no threads on product contact surfaces, except that:

D10.1.1 Where necessary for attaching a rotor to a shaft, the threads shall be ACME type as specified in the 3-A Sanitary Standard, Number 63- or the American Standard Stub Acme Thread (see Appendix, Section I). These threads shall conform to the drawing, Fig. (1), the "American Stub Acme Thread" (see Appendix, Section F). The threaded angles shall be not less than 60° and with not more than 8 threads to the inch (25.4 mm), nor less than 5/8 in. (15.9 mm) major base 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 components with exposed threads as described above shall be designed for manual cleaning. Or,

D10.1.2 Where necessary for attaching a rotor to a shaft, non-sanitary threads may be enclosed in acorn-type nuts or the body of the impeller. In this case, there shall be an "O"ring or gasket with similar function between the product and the non-sanitary threads. Equipment components utilizing these enclosed threads shall be designed for mechanical cleaning. Recessed threaded areas, with the exception of acorn nuts or impeller are unacceptable. (See Appendix I.)

D11 **Seals**

D11.1 Seals on the shafts in inline mixers shall be of a packless type.

D11.2 Seals shall be sanitary in design, and shall be readily accessible and inspectable. (See Section D12.)

D12 **Inspectability**

D12.1 An inline mixer shall be designed so that the open area between the exterior of the driver or gear case housing to the exterior of the product chamber shall be ½ in. (12.0 mm) minimum width and of sufficient area to allow unrestricted viewing of the pump shaft(s) or seal components at the potential leak site. This area shall be self-draining. (See Appendix, Section J.)

D12.2 At least ¼ in. (6.00 mm) of the shaft(s) exclusive of the seal components shall be visible.

D13 **High Temperature Systems**

D13.1 Inline mixers used in a processing system to be sterilized by heat and operated at a temperature of 250°F (121°C) or higher shall conform to the following additional criteria:

D13.2 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.

D13.3 Where steam or other sterilizing medium is used, the connection(s) on the inline mixers shall be such that the steam lines or other sterilizing medium lines can be securely fastened to the inline mixers. The Inline mixers shall be constructed so that the steam or other sterilizing medium chamber may be exposed for inspection.

D13.4 The seal(s) in an inline mixer(s) 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 between the product contact surface and the steam or other sterilizing chamber.

D14 **Nonproduct Contact Surfaces**

D14.1 Nonproduct contact surfaces shall have a relatively smooth finish, be relatively 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. Electrical and utility connections shall be as remote as practical from the product areas. Riveted nameplates or appendages shall not be used. Socket head cap screws shall not be used. Knurled surfaces shall not be used. Nameplates shall be welded or effectively sealed to the equipment.

D14.2 The requirement to be relatively free of pockets and crevices does not apply to exposed exterior surfaces of ancillary equipment such as sanitary fittings, service fittings, electric motors, drives, mechanical linkages, and other similar equipment.

D15 **Supports**

D15.1 The means of supporting an inline mixer shall be one of the following:

D15.1.1 If legs are used they shall be smooth with rounded ends or with a flat, load-bearing foot suitable for sealing to the floor, and have no exposed threads. Legs made of hollow stock shall be sealed. Legs shall provide a minimum clearance between the lowest part of the base and the floor of not less than 4.00 in. (102 mm) when the inline mixer outlines an area in which no point is more than 12 ½ in. (305 mm) from the nearest edge of the base or a clearance of at least 6.00 in. (152 mm) when any point is more than 12 ½ in. (305 mm) from the nearest edge of the base, except that:

D15.1.1.1 Legs shall be of sufficient length to provide a minimum clearance of 2.00 in. (50.0 mm) on inline mixers having a horizontal base area of 1.00 ft^2 (0.0950 m^2) or less and not designed to be fixed to the floor.

D15.1.2 If casters are used they shall be of sufficient size to provide a clearance between the lowest part of the base and the floor of not less than 4.00 in. (102 mm). Casters, if provided, shall be easily cleanable, durable and of a size that will permit easy movement of the inline mixer.

D16 **Guards and Other Safety Devices**

D16.1 Guards required by a personnel safety standard shall be removable for cleaning and inspection of the equipment. When guards are removed, OSHA lockout/tagout regulations[2] shall be followed.

APPENDIX

E **STAINLESS STEEL MATERIALS**

E1 Stainless steel conforming to the applicable chemical composition ranges established by AISI[3] for wrought products, or by ACI[4] for cast products, should be considered in conformance to 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[5] A351/A351M, A743/A743M and A744/A744M.

E2 Table 1

WROUGHT PRODUCTS TYPICALLY USED			
UNS#	ASTM[5]	AISI/ SAE[3]	Common Names
S30300	A-582	303	Free Machining S.S.; Austenitic
S30400	A-276 A-666	304	Austenitic S.S.
S30403	A-276 A-666	304L	Low Carbon Austenitic S.S.
S31600	A-276 A-666	316	Austenitic S.S. plus Mo*
S31603	A-276 A-666	316L	Low Carbon Austenitic S.S. plus Mo*

*Molybdenum

Table 2

CAST PRODUCTS			
UNS #	ASTM[5]	ACI[4]	Common Names
J92500	A-351 A-743 A-744	CF-3	Cast 304L
J92800	A-351 A-743 A-744	CF-3M	Cast 316L
J92600	A-351 A-743 A-744	CF-8	Cast 304
J92900	A-351 A-743 A-744	CF-8M	Cast 316
J92180	A-747	CB7 Cu - 1	Cast 17-4 PH
J92110	A-747	CB7 Cu--2	Cast 15-5 PH
N26055	A-494	CY5Sn BiM	Alloy 88
J92701	A-743	CF-16F	Free Machining Austenitic S.S.

TABLE 3 - OPTIONAL METAL ALLOYS

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

	UNS N08367	UNS S21800	UNS S20161	UNS N26055	UNS N26455	UNS S37400	UNS S15500	UNS S32906	UNS R20500	UNS R30400
	ASTM A743 Grade CN-3MN	ASTM A743 Grade CF-10 SMnN		ASTM A494 Grade CY5SnBiM	ASTM A494 Grade CW-2M	ASTM A747 Grade CB7Cu-1	ASTM A747 Grade CB7Cu-2		ASTM A560 Grade 50Cr-50Ni	ASTM 907 Grade C-2
C	0.03	0.10	0.15	0.05	0.02	0.07	0.07	0.20	0.04	0.10
Mn	2.00	7.00-9.00	4.00-6.00	1.5	1.00	0.70	0.70	1.00	0.50	
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	0.01	0.03	0.03	0.03	0.030	0.02	
Cr	20.0-22.0	16.00-19.00	15.0-18.0	17.0-18.0	15.0-17.5	15.50-17.7	14.0-15.50	24.0-28.0	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	1.5-2.5			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		0.50	
Fe	Balance	Balance	Balance	2.00	2.00	Balance	Balance	Balance	1.00	0.30
Se				0.5-3.0						
Bi				0.5-3.0						
W					1.0					
Ti									0.50	Balance
Al									0.25	
Other										Ti 0.015 N 0.01 O 0.25

E3 Metal alloys or metals other than the above may be as corrosion resistant as 300 Series Stainless steel (except 301 and 302). This may be shown when metal alloys or metals are tested in accordance with ASTM[6] 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.

[2] 29 CFR 1910.147 The Control of Hazardous Energy. Document for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

[3] Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959.

F PRODUCT CONTACT SURFACE FINISH

F1 Surface finish equivalent to 150 grit or better as obtained with silicon carbide, properly applied on stainless steel sheets, is considered in conformance to the requirements of Section D1 hereon. A maximum R_a of 32 µin. (0.8 µm), when measured according to the recommendations in American National Standards Institute (ANSI)/American Society of Mechanical Engineers (ASME)[10] B46.1 - *Surface Texture Wirviness and Lay* is considered to be equivalent to a No. 4 finish.

F2 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 ($R_a \leq 32$ µin. or ≤ 0.8 µm) finish and are acceptable for the fabrication of equipment if free of imperfections.

G PRESS-FITS AND SHRINK-FITS

G1 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 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.

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

H O-RING GROOVE RADII

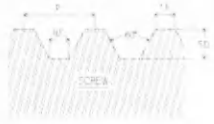
TABLE 4 - Groove Radii Dimensions for Standard O-Rings

O-Ring Cross Section, Nominal (AS 568[11])	O-Ring Cross Section, Actual (AS 568)	O-Ring Cross Section, Actual (ISO 3601-1[12])	Maximum 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)

I THREADS

I1 American Standard Stub Acme Thread

P = PITCH P = 1/T P1



S.D = SINGLE DEPTH
T.F. = TOP FLAT
B.F. = BOTTOM FLAT
T.P.I. = THREADS PER INCH

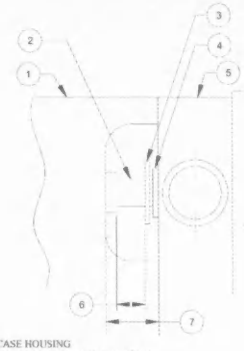
S.D. = 0.433 x P
T.F. = 0.250 x P
B.F. = 0.227 x P

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

[12] The document establishing these standard dimensions is ISO 3601-1: 1988 (F), published by the International Organization for Standardization (ISO), 1 Rue de Varembe, Case Postale 56, CN 1 1211, Geneva, Switzerland.

J Diagrams

This diagram is intended to demonstrate general principles only, and is not intended to limit individual ingenuity. The design should conform to the sanitary requirements set forth in these 3-A Sanitary Standards.



1. DRIVER OR GEARCASE HOUSING
2. DRIVE SHAFT WITH OR WITHOUT SHAFT SLEEVE
3. SLINGER (OPTIONAL)
4. SANITARY SEAL
5. INLINE MIXER BODY
6. ¼" MIN.
7. ½" MIN.

K ENGINEERING DESIGN AND TECHNICAL CONSTRUCTION FILE

The following is an example of an engineering design and technical construction file (EDTCF) to be maintained by the fabricator as evidence of complying with 3-A Sanitary Standards or 3-A Accepted Practices. (The file may contain more or less information as applicable to the equipment or system.)

K1 Purpose

K1.1 To establish and document the material, fabrication, and installation (where appropriate) requirements for the engineering design and technical construction files for all products, assemblies, and sub-assemblies supplied by the manufacturer thereof to be in conformance to the sanitary criteria found in 3-A Sanitary Standards or 3-A Accepted Practices. It is recommended that the engineering and construction file or files be submitted with applications for 3-A Symbol use authorization.

K2 Scope

K2.1 This EDTCF applies to equipment specified by:

K2.1.1 3-A Sanitary Standards for Inline Rotor-Stator Mixers, Number 36-01.

K2.1.2 List all applicable 3-A Sanitary Standards and 3-A Accepted Practices.

K3 Responsibilities

K3.1 This EDTCF is maintained by: The Engineering Manager (or other company official) **[name and title of responsible official]** is responsible for maintaining, publishing, and distributing this EDTCF.

K3.2 Implementation: All divisions, specifically development engineering, standards engineering, sales engineering, and product departments are responsible for implementing this EDTCF.

K4 Applicability

K4.1 The 3-A Sanitary Standards and 3-A Accepted Practices are voluntarily applied as suitable sanitary criteria for dairy and food processing equipment. 3-A Sanitary Standards are referenced in the Grade A Pasteurized Milk Ordinance: "Equipment manufactured in conformity to 3-A Sanitary Standards conforms to the sanitary design and construction standards of this Ordinance."

K5 References

K5.1 List any additional regulations that apply to the equipment or system covered by this EDTCF.

K5.2 Date of conformity or 3-A Symbol Authorization and certificate number, if authorized.

K6 Design and Technical Construction File

K6.1 The Engineering Design and Technical Construction File may consist of the following:

a. an overall drawing of the subject equipment;
b. full detailed drawings, accompanied by any calculations, notes, test results, etc. required to check the conformity of the equipment with the 3-A Standards or 3-A Practices;
c. a list of:
   (1) the essential requirements of the standards or practices;
   (2) other technical specifications, which were used when the equipment was designed;
d. a description of methods adopted;
e. if essential, any technical report or certificate obtained from a competent testing body or laboratory;
f. any technical report giving the results of tests carried out internally by Engineering or others;
g. documentation and test reports on any research or tests on components, assemblies and/or the complete product to determine and demonstrate that by its design and construction the product is capable of being installed, put into service, and operated in a sanitary manner (optional);
h. a determination of the foreseeable lifetime of the product (optional);
i. a copy of the instructions for the product (Instruction Manuals/Instruction Books);
j. for serial manufacturing, the internal measures that will be implemented to ensure that the equipment will continue to be manufactured in conformity to the provisions of the 3-A Sanitary Standards or 3-A Accepted Practices;
k. engineering reports;
l. laboratory reports;
m. bills of material;

n. wiring diagrams, if applicable;
o. sales order engineering files;
p. hazard evaluation committee reports, if executed;
q. change records;
r. customer specifications;
s. any notified body technical reports and certification tests;
t. copy of the 3-A Symbol authorization, if applicable.

K6.2 The file does not have to include detailed plans or any other specific information regarding the sub-assemblies, tooling, or fixtures used for the manufacture of the product unless a knowledge of them is essential for verification of conformity to the basic sanitary requirements found in 3-A documents.

K6.3 The documentation referred to in K6.1 above need not permanently exist in a material manner in the EDTCF, but it must be possible to assemble them and make them available within a period of time commensurate with its importance (one week is considered reasonable time). As a minimum, each product EDTCF must physically contain an index of the applicable document of K6.1 above.

K6.4 The EDTCF may be in hard copy or software form.

K7 Confidentiality

K7.1 The EDTCF is the property of the manufacturer and is shown at their discretion, except that all or part of this file will be available to 3-A SSI or a regulatory agency for cause and upon request.

K8 File Location

K8.1 The EDTCF shall be maintained at **{location}**.

K9 File Retention

K9.1 The EDTCF (including all documentation referred to in K6.1) shall be retained and kept available for 12 years following the date of placing the product in use or from the last unit produced in the case of series manufacture.

3-A Sanitary Standards for Crossflow Membrane Modules, Number 45-02

Standards Developing Organizations
3-A Sanitary Standards, Inc. (3-A SSI)
in collaboration with
United States Public Health Service (USPHS)
United States Department of Agriculture (USDA)
European Hygienic Engineering & Design Group (EHEDG)

Adopted November 16, 2003

[illegible] Statement

3-A Sanitary Standards, Inc. (3-A SSI) and collaborating organizations do not assume or undertake to discharge all or any responsibilities of manufacturers or any other user of 3-A Sanitary Standards or 3-A Accepted Practices. 3-A SSI is not responsible to any individual, organization or entity for the use of 3-A Standards and 3-A Accepted Practices. It is the science-based opinions, professional findings of volunteer experts and consensus that provides the sanitary (hygienic) criteria included in 3-A documents.

3-A Standards and 3-A Practices do not include provisions for mechanical and electrical safety. Mechanical and electrical safety criteria are established by government regulations and other standards development organizations (SDOs). Other SDO standards may be referenced.

3-A Sanitary Standards, Inc., its employees and its volunteer committees shall not incur any obligation or liability for damages, including consequential damages, arising out of or in connection with the development, use, interpretation of, and reliance upon this 3-A Standards.

Drawings and illustrations contained herein are to assist in understanding the criteria in this 3-A Standard. Drawings and illustrations are not intended to show all variations of the equipment or system nor are they (1) to exclude alternate methods meeting this standard. Drawings and illustrations are non-normative.

Foreword

This 3-A Standard is to establish minimum sanitary (hygienic) requirements for Crossflow Membrane Modules. Standard English is the official language of 3-A Sanitary Standards and 3-A Accepted Practices.

This 3-A Standard is for voluntary use by directly and materially affected organizations such as equipment and machinery fabricators, processors, regulatory agencies and by 3-A Sanitary Standards, Inc. to assure adequate public health protection exist for the devices and covered products. 3-A Sanitary Standards, Inc. use these documents as the source for sanitary criteria as part of 3-A Symbol authorization.

This 3-A Standard was developed jointly by 3-A Sanitary Standards, Inc. (3-A SSI), the United States Public Health Service (USPHS), the United States Department of Agriculture – Dairy Programs (USDA), and the European Hygienic Engineering & Design Group (EHEDG).

It is our purpose to encourage inventive genius and provide a forum to discuss new developments. Suggestions for improvement and new technology are welcome any time for consideration by the 3-A Sanitary Standards Committees. Please forward comments to the 3-A SSI, 1451 Dolley Madison Boulevard, Suite 210, McLean, VA 22101-3850, USA. By fax: 703-761-4334. By e-mail to: mail@3-a.org.

A **SCOPE**

A1 These standards cover the sanitary aspects of crossflow membrane modules for use with ultrafiltration, diafiltration, microfiltration and reverse osmosis systems for processing milk and milk products.

A2 In order to conform to these 3-A Sanitary Standards, membrane modules shall conform to the following design, material, and fabrication criteria.[1]

B **DEFINITIONS**

B1 **General**

B1.1 *Product:* Shall mean milk, milk products or their fractions which are fractionated, concentrated or otherwise processed in this equipment and are to be used for human food. Either or both permeate or retentate are products.

B1.2 *Feed:* Shall mean that portion of the product that is about to enter the element. It may include recycled permeate, concentrate or retentate.

B1.3 *Permeate:* Shall mean that portion of the product which has passed through the membrane during processing.

B1.4 *Retentate:* Shall mean that portion of the product which does not pass through the membrane during processing.

B1.5 *Concentrate:* Shall mean that portion of the retentate that has left the system for disposition as final product or for recycling.

B1.6 *Membrane:* Shall mean a selectively permeable barrier which can separate a multi-component stream into fractions. This membrane may be polymeric, organic, inorganic or mineral.

B1.6.1 *Asymmetric Membrane:* Shall mean a membrane with an integral graded structure having a relatively consolidated surface skin underlain by a progressively more open spongy base.

B1.6.2 *Composite Membrane:* Shall mean a membrane which consists of several superimposed chemically or physically different layers. (Usually a composite membrane has a thin active surface membrane of one material affixed to an asymmetric supporting membrane of another material.)

B1.7 *Membrane Support Material:* Shall mean porous material used for supporting the membrane.

B1.8 *Feed Channel Spacer:* Shall mean the open mesh screen used to maintain spacing between the membranes in elements and to define the channels through which retentate flows.

B1.9 *Permeate Carrier:* Shall mean the porous material used for conducting permeate away from the membrane to a collection point in the membrane element. The permeate carrier may be identical with the membrane support material.

B1.10 *Bypass Flow Restrictor:* Shall mean a device to direct feed material through the membrane elements' retentate flow channels while allowing a controlled amount to bypass these channels.

B1.11 *Module:* Shall mean that part of the membrane equipment that contains the membrane elements, element connectors, and external shrouds or housing. The module interfaces with the system pipelines carrying products to and from it.

B1.11.1 *Boundaries:* The boundaries of the membrane module are defined as the connections between:
a. The feed manifold and the feed line(s) to the module.
b. The retentate collection manifold and the retentate line(s) from the membrane module.
c. The permeate collection manifold and the permeate line(s) from the membrane module.

B1.12 *Membrane Element:* Shall mean that part of the module which contains the membrane and is replaceable. (The element may be identical with the module and may contain the membrane support material and the permeate carrier.) There are six configurations of elements. These are:
a. Tubular
b. Spiral wound
c. Plate and frame
d. Parallel leaf
e. Hollow fiber
f. Monolithic ceramic
In these different configurations, the membrane support material may be part of the replaceable element or part of the module structure.

B1.13 *External Shroud:* Shall mean the impermeable shell which forms the exterior structure of the

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

module. It may provide mechanical strength to resist internal operating pressure and may serve as a permeate collection vessel except for spiral modules where it serves as a feed conduit.

B1.14 *Membrane Element Seal(s):* Shall mean that part of the module which is designed to prevent flow between the feed and retentate channel spaces and the permeate space.

B1.15 *Feed Channel Space:* Shall mean that flow channel within the module where product is introduced to the membrane element(s) for the purpose of concentration, fractionation or otherwise processed.

B1.16 *Retentate Channel Space:* Shall mean that flow channel within the module where products that do not flow through the membrane are discharged from the membrane element(s).

B1.17 *Permeate Channel Space:* Shall mean that part of the module where the permeate is collected as it flows from the membrane element(s).

B1.18 *Permeate Connector:* Shall mean that part of the module used for making a sanitary connection to the permeate collection line or manifold at the boundary of the module.

B1.19 *Feed Connector:* Shall mean that part of the module used for making a sanitary connection to the feed line(s) or manifold at the boundary of the module.

B1.20 *Retentate Connector:* Shall mean that part of the module used for making a sanitary connection to the retentate line(s) or manifold at the boundary of the module.

B1.21 *Cross Flow:* Shall mean the retentate flows in a direction parallel to the membrane surface.

B1.22 *Through Flow:* Shall mean entrance of fluid at one end of a passage and its removal at the opposite end so that the flowing fluid passes without dead areas through the intervening space.

B1.23 *System:* Shall mean all mechanical hardware, pumps, pipelines, instrumentation and the membrane module(s).

B1.24 *Membrane Process Equipment:* Shall mean equipment in which products are fractionated, concentrated or otherwise processed by a membrane.

B1.25 *Manifold:* Shall mean that part of the system to which connections are made to bring product, permeate, or cleaning solution to and from the module.

B2 **SURFACES**

B2.1 *Product Contact Surface:* Shall mean all surfaces that are exposed to the product or any of its fractions (whether feed, concentrate, retentate, or permeate) and surfaces from which liquid may drain, drop, or be drawn into the products.

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

B3 **CLEANING**

B3.1 *Mechanical Cleaning or Mechanically Cleaned:* Shall denote cleaning, solely by circulation and/or flowing chemical and/or enzyme cleaning solutions and water rinses onto, over, and/or through the surfaces to be cleaned, by mechanical means.

B4 **TUBULAR MODULE**

B4.1 *Tubular Module:* Shall mean a module whose membrane elements carry retentate in individual, separated, rigid tubes of about 0.2 inch or larger inside diameter. These tubes may be single or multiple elements within an external shroud. (See Appendix F1).

B4.2 *"U" Bend:* Shall mean that device attached to the end of a tubular element used to reverse the direction of retentate flow and direct it into another tubular element.

B4.3 *Ferrule:* Shall mean the fitting(s) attached to the end of a tubular element used for making sanitary connection to a "U" Bend or manifold.

B4.4 *Membrane Array:* Shall mean a parallel array of one or more hollow single tubular or multi-channel tubular membrane elements contained within the module's external shroud.

B4.5 *Header:* Shall mean the device at the end of a multitubular element that holds the tubes in fixed array and into which they are sealed. Headers may be potted or cast in place, molded, or machined.

B4.6 *Grommet:* Shall mean the elastomeric part used to seal tubes into headers. It acts as a membrane element seal.

B4.7 *Expander:* Shall mean that device which when inserted into the end of the tube expands it against the grommet and the grommet against the tube sheet to effect a seal.

B4.8 *Membrane Element Support Tube:* Shall mean that part of the module which closely supports the membrane element. This tube may be made of a porous composite or stainless steel.

B4.9 *Module End Plate:* Shall mean part of a multi-tube into which the membrane element support tubes are fitted. (Single tube elements may have an individual connector like a ferrule.)

B4.10 *Header Cap:* Shall mean that device fitted to the end of a module, used to direct the flow-path of the feed and retentate through the tubular membrane elements in the module. The header cap may:

a. Direct the flow-path through all the tubular elements in parallel; or
b. Connect all the tubular elements in series by means of internally-molded U-bends; or
c. Separate the flow into two or more parallel paths each consisting of two or more tubular elements connected in series by means of internally-molded U-bends.

B4.11 *Supported Metallic Oxide Membrane Module:* Shall mean a tubular module whose elements are formed from a rigid porous support on which has been deposited a metallic oxide coating to form the membrane. (See Appendix F1.3)

B4.11.1 *End Tubular Plate:* Shall mean the drilled plate which holds the membrane elements in position and provides the surface to support and seal the membrane element gasket and counter plate.

B4.11.2 *Counter Plate:* Shall mean the bored plate used to compress the membrane element gasket and to conduct retentate flows to the inlet of membrane elements.

B4.11.3 *Inner Spacer:* Shall mean the device used to hold the membrane elements in the correct position in the interior of the module.

B5 **Spiral Wound Module**

B5.1 *Spiral Wound Module:* Shall mean a module whose element is formed of leaves of membrane, membrane support, feed channel spacer, and permeate carrier wound in spiral fashion around a central permeate collection tube. (See Appendix F2)

B5.2 *Anti-Telescope Device (ATD):* Shall mean a support for spiral type elements to prevent their layers from sliding past each other when the element is in operation.

B5.3 *Element Connector or Interconnector:* Shall mean the device used within modules to connect together membrane elements. In some embodiments, the element connector may be incorporated into the anti-telescoping device.

B5.4 *Permeate Collection Tube:* Shall mean a perforated tube usually centrally located in a spiral membrane element into which permeate is conducted from the permeate carrier. The permeate collection tube conducts permeate out of the element.

B5.5 *Connector/Interconnector Seals:* Shall mean the device for forming a seal between the module connector and the permeate collection tube.

B5.6 *End Cap:* Shall mean the cover at the end of the external shroud which connects with the permeate collection tube.

B5.7 *Glue Seams:* Shall mean the areas at each edge of a leaf to which adhesive is applied to bind the materials together and form a seal.
(Note that each leaf generally has two end glue seams and one axial glue seam so named because of their relative locations in the finished element.)

B5.8 *Leaf:* Shall mean the sandwich of membrane, membrane support material, permeate carrier and feed channel spacer that are multiply laid up and wound around the permeate collection tube to form a spiral element.

B5.9 *Fold Line:* Shall mean the location adjacent to the permeate tube at which the membrane is bent 180° back upon itself for insertion into the spiral wound membrane element.

B5.10 *Crease Protection Materials:* Shall mean materials applied to the fold area, on either side of the membrane to prevent leakage of feed into the

permeate in the event of damage to the membrane.

B5.11 *Stitching Material:* Shall mean thread used to sew and attach adjacent leaves of the permeate carrier material to maintain leaf spacing during fabrication.

B6 **Plate and Frame Module**

B6.1 *Plate and Frame Module:* Shall mean a module formed of multiple sandwiches of flat membrane elements held together by an external supporting frame. (See Appendix F3)

B6.2 *Module of Plate and Frame Design:* Shall mean that part of the membrane processing system that contains the membrane elements of plate and frame design. The module consists of:
a. Membrane elements.
b. Supporting frame.
c. Permeate collection manifold.
The module interfaces with the system pipelines carrying product to and from it.

B6.3 *Membrane Support Plate:* Shall mean that part of the membrane element which provides mechanical support for the membrane. The membrane support plate receives the permeate from the membranes and delivers it to the permeate collection manifold.

B6.4 *Lock Rings:* Shall mean that part of the membrane element which can hold the membrane support plate and the two attached membranes together and form a barrier between the permeate and the retentate.

B6.5 *Spacer Plate:* Shall mean that part of the membrane element which provides the necessary space to create the circulation channels across the membrane. The spacer plate separates two adjacent membrane support plates with membranes and lock rings.

B6.6 *Section Plate:* Shall mean that part of the membrane element that makes it possible to divide the module into sections.

B6.7 *Supporting Frames:* Shall mean that part of the module which internally or externally holds all the membrane elements within the module pressed together and provides the necessary support. The supporting frame consists of:
a. End flanges.
b. Connecting bolt(s).
c. Supporting legs.

B6.7.1 *End Flanges:* Shall mean those parts of the supporting frame which hold together all the membrane elements within the module and provide the inlet connection from the feed line(s) to the module and the outlet connection from the module to the retentate line(s). The end flanges may include a flow distributing ring.

B6.7.2 *Connecting Bolt(s):* Shall mean that part(s) of the supporting frame which connects the end flanges and holds together the stack of membrane elements.

B6.7.3 *Supporting Legs:* Shall mean that part of the supporting frame which provides means for support of the whole module.

B6.8 *Permeate Collection Manifold:* Shall mean that part of the membrane module that receives the permeate from the membrane element. The manifold can be an integral part of the membrane element or be connected to this by flexible hose.

B7 **Parallel Leaf Module**

B7.1 *Parallel Leaf Module:* Shall mean a module formed of multiple membrane elements whose membrane has been permanently bonded to a rigid support plate. (See Appendix F.4)

B7.2 *Membrane Cartridge:* Shall mean a multiple of membrane elements joined to form a unit to be inserted into a membrane housing.

B7.3 *Permeate Fitting:* Shall mean a device for communicating permeate from the membrane cartridge to the permeate tubing. It may hold and seal the membrane cartridge in situ.

B7.4 *Membrane Element Retaining Clamp:* Shall mean a device for holding together a multiple of membrane elements (membrane element stack). The retaining clamp consists of two rigid nonporous plates, one on each side of the membrane element stack, and a tie rod that holds the two rigid plates together.

B8 **Hollow Fiber Module**

B8.1 *Hollow Fiber Module:* Shall mean a module whose membrane elements are formed of a multiplicity of flexible tubules generally less than 0.2 inches (5.1 mm) in inside diameter and potted

or otherwise bound together into a common header. (See Appendix, F5)

B8.2 A module of hollow fiber design shall consist of the following components:
a. Membrane cartridge.
b. Process manifold adapter assembly.
c. Permeate adapter assembly.

B8.3 *Membrane Cartridge:* Shall mean a parallel array of hollow fiber membrane elements which are housed in a plastic or metallic cartridge assembly and fixed at both ends via an adhesive tubesheet. The hollow fiber membrane element is a self-supporting structure. Therefore, in this configuration, the membrane element and support are an integral part of the membrane cartridge.

B8.4 *Process Manifold Adapter Assembly:* Shall mean that part of the membrane module that connects the membrane cartridge to the system pipelines that carry product to and from the cartridge. This assembly consists of a manifold adapter, V-band clamp and a gasket.

B8.5 *Permeate Adapter Assembly:* Shall mean that part of the membrane module that connects the permeate outlets of each membrane cartridge to the permeate collection manifold. This assembly consists of a permeate adapter, V-band clamp and gasket.

B8.6 *Membrane Sheath:* Shall mean that part of the membrane cartridge which provides mechanical support to the hollow fiber membrane elements.

B8.7 *Tube Sheet:* Shall mean the thermoset adhesive compound that is used to seal the hollow fiber membrane elements into the membrane housing.

B9 **Monolithic Ceramic Modules**

B9.1 *Monolithic Ceramic Module:* Shall mean a module that contains membrane elements wherein the membrane and the support are ceramic bonded structures which are in turn joined by ceramic bonds such that the joined membrane and support are monolithic in nature. (See Appendix F5)

B9.2 *Ceramic Bond:* Shall mean the joining of ceramic materials by heat to produce fusion or sintering between particles.

B9.3 *Ceramic Membrane Support:* Shall mean a ceramic porous base structure used to support a thinner and finer more uniformly graded porous structure. A membrane element may contain one or more supports all joined by ceramic bonds.

B9.4 *Membrane Element Retainer:* Shall mean that part of the module which is designed to retain in place the membrane element seals and membrane element(s).

B9.5 *Membrane Element Fixed Retainer:* Shall mean a retainer which is a part of the shroud.

B9.6 *Membrane Element Removable Retainer:* Shall mean a retainer which is secured to the external shroud by mechanical means and may be removed for membrane element seal or membrane element cleaning or replacement.

B9.7 *Membrane Element Array:* Shall mean a parallel array of one or more single tubes or multichannel membrane elements contained within the module shroud.

B9.8 *Uniform Transmembrane Pressure System:* Shall mean process equipment including pumps, valves, flow meters, and pressure sensors used to monitor feed-to-retentate pressure drop and adjust permeate recirculation flow to create a corresponding permeate pressure drop, thereby maintaining a uniform pressure differential from feed side to permeate side of the membrane along the length of the module.

C **MATERIALS**

C1 Membrane product contact surfaces, membrane support material, permeate carrier material, stitching and crease protection materials, shall be constructed of materials meeting one of the following:
a. Title 21, Part 177 of the Code of Federal Regulations, or
b. Generally recognized as safe (GRAS Title 21, Part 182 of the Code of Federal Regulations) or affirmed (GRAS Title 21 Part 186 of the Code of Federal Regulations), or
c. Otherwise be approved by the Food and Drug Administration for food contact.
Users may rely on vendor certification that proprietary materials meet these requirements.

C2 All product contact surfaces except those listed in C1 shall be:

C2.1 Plastic or plastic-like materials conforming to applicable provisions of 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-, or

C2.2 Stainless steel of the American Iron and Steel Institute (AISI) 300 series[2] or the corresponding Alloy Cast Institute (ACI)[3] types. (See Appendix G.) or types which under conditions of intended use are at least as corrosion-resistant as stainless steel of the foregoing types and are non-toxic and non-absorbent, except that:

C2.2.1 Rubber and rubber-like materials may be used for gaskets, seals, flexible product connectors, and O-rings.

C2.2.2 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-.

C2.2.3 Bonded rubber and rubber-like materials and bonded plastic materials having product contact surfaces shall be of such composition as to retain their surface and conformational characteristics when exposed to conditions encountered in the environment of intended use in cleaning and bactericidal treatment.

C2.2.4 Fiberglass reinforced composites may be used where required for strength such as for membrane element support tubes.

C2.2.5 Adhesive and potting materials in product contact surfaces including edge contact shall meet the requirements of Title 21, Part 175.105 or part 175.300 of the Code of Federal Regulations and be inert under conditions of operation, cleaning and sanitizing.

C2.2.6 Composite methods of construction may be used to produce elements with ceramic materials for supports different than the materials used for the membrane. Such composites shall retain the ceramic bond properties between multiple supporting layers.

C2.2.6.1 Ceramic materials selected shall be such that the membrane ceramic bonds attach the membrane to the support with sufficient mechanical integrity that it does not peel, chip or spall under processing or cleaning and sanitizing conditions.

C3 All materials used shall be inert, nontoxic, insoluble in the product and in cleaning and sanitizing solutions. They shall be resistant to scratching, scoring, and distortion when exposed to the conditions of intended use and of cleaning and sanitizing.

C4 Nonproduct surfaces shall be of corrosion-resistant material or material that is rendered corrosion resistant. If coated, the coating used shall adhere. Nonproduct surfaces shall be relatively nonabsorbent, durable, and cleanable. Parts removable for cleaning having both product and nonproduct contact surfaces shall not be painted.

D **FABRICATION**

D1 **General**

D1.1 The module shall be constructed such that the element can be mechanically cleaned on both retentate and permeate sides.

D1.2 Membrane elements designed and constructed to fit into a shroud shall fit without dead spaces so that they and it can be mechanically cleaned by a through flow of cleaning and sanitizing solutions.

D1.3 The design and fabrication of the membrane element seals and retainers shall take into consideration the combined effects of differential thermal expansions, between the shroud, if any, and the elements, hydraulic shock and thermal shock such that the membrane elements are free of excessive compressive or tensile forces. The membrane element seals or supports, as the case may be, shall be designed in such a manner as to firmly support the membrane elements but allow for elastic axial and lateral movements to prevent undue stress and strains which could lead to failure of the membrane.

D1.4 The membrane shall be firmly attached to its support material or have sufficient mechanical integrity that it does not peel, spall or chip.

[2] The data for this series are contained in the AISI Steel Products Manual, Stainless & Heat Resisting Steels, Table 2-1. Available from the American Iron and Steel Society, 186 Thorn Hill Road, Warrendale, PA 15086.

[3] Steel Founders' Society of America, Cast Metals Federation Bldg., 455 State St., Des Plaines, IL 60016.

D1.5 Grommets or seals against the membrane surface must be made against impermeable support materials or alternatively against porous materials that can be mechanically cleaned or demonstrated to be effectively sealed.

D1.6 **Surfaces**

D1.6.1 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 except those in the membrane element. (See Appendix H.)

D1.6.2 Permanent metallic joints in product contact surfaces shall be continuously welded, except that tubes may be expanded and rolled into tube sheets. Welded seams on product contact surfaces shall be at least as smooth as a No. 4 ground finish on stainless steel sheets free of imperfections such as pits, folds, and crevices. When tubes are expanded and rolled into tube sheets, the resulting joint shall be completely rigid and, without pockets or crevices. Alternatively metallic joints, if used, shall be in accord with the 3-A Accepted Practices for Permanently Installed Product and Solution Pipelines and Cleaning Systems Used in Milk and Milk Product Processing Plants, Number 605-.

D1.6.3 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 plastic material does not separate from the base material to which it is bonded.

D1.6.4 Appurtenances having product contact surfaces shall be easily removable for cleaning and inspection, or shall be mechanically cleanable.

D1.6.5 Membrane modules shall be designed for chemical and mechanical cleaning and sanitizing of all product contact surfaces.

D1.6.6 There shall be no exposed threads on product contact surfaces.

D1.6.7 Nonproduct contact surfaces shall be smooth, free of pockets and crevices and be readily cleanable and those to be coated shall be properly prepared for coating.

D1.6.8 When used, fiberglass shall be completely encapsulated with no exposed fibers with a polymeric coating meeting the requirements of Title 21, Section 175 or 177 of the Code of Federal Regulations.

D1.7 **Connections**

D1.7.1 Product connections to manifolds shall meet 3-A Sanitary Standards for Sanitary Fittings for Milk and Milk Products, Number 63- except that these connections shall be made in a sanitary manner with rigid and or flexible connectors provided the materials conform to the applicable provisions of 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-.

D1.7.2 Flexible permeate tubes are permitted and shall have connections that are crevice free. Internal diameter may be selected to suit mechanical requirements.

D1.7.3 Hose clamps shall be easily disassembled and assembled.

D1.8 **Gaskets and Seals**

D1.8.1 Gaskets having a product contact surface shall be removable or permanently bonded to the surface. Any gasket groove or gasket retaining groove except in the bonded area shall be no deeper than its width and shall not exceed 1/4 inch (6.35 mm) in depth or be less than 1/4 inch (6.35 mm) wide except those for standard O-Rings smaller than 1/4 inch (6.35 mm).

D1.8.2 Grooves in gaskets shall be no deeper than their width and the minimum radius of any internal angle shall not be less than 1/8 inch (3.18 mm) unless the gasket is readily removable and reversible for cleaning.

D1.8.3 Gasket grooves or gasket retaining grooves in product contact surfaces for removable gaskets shall not exceed 1/4 inch (6.35 mm) in depth and, except those for standard O-rings smaller than 1/4 inch (6.35 mm), shall be at least 1/4 inch (6.35 mm) wide.

D1.8.4 Element seals that are potted, poured, or otherwise cast in place shall have joints that are

fully filled such that there are no voids pits or cavities.

D1.8.5 Element seals of the grommet type shall be one piece construction and shall firmly fit the mating surfaces such that there are no crevices or voids.

D1.9 **Radii**

D1.9.1 Internal angles on product contact surfaces shall have minimum radii of 1/16 inch (1.59 mm), except:

D1.9.1.1 Gasket recesses and grooves in which all sharp corners shall be avoided.

D1.9.1.2 The minimum radii in gasket grooves or gasket retaining grooves other than those for bonded gaskets or for standard 1-4 inch (6.35 mm) and smaller O-rings shall be not less than 1/8 inch (3.18 mm).

D1.9.1.3 The minimum radii in grooves for standard 1-4 inch (6.35 mm) O-rings shall be not less than 3/32 inch (2.38 mm) and for standard 1-8 inch (3.18 mm) O-rings shall be not less than 1/32 inch (0.794 mm). In either case the internal product contact surface must be readily available for cleaning and inspection.

D1.9.1.4 For essential functional reasons, smaller internal angles or radii may be used provided the product contact surfaces are demonstrated to be mechanically cleanable.

D2 **Tubular Modules**

D2.1 The element shall fit into its shroud without dead spaces so that it can be completely mechanically cleaned by through flow of cleaning solutions or placed in the shroud so that the exterior can be flooded or sprayed with cleaning solution to achieve effective cleaning.

D2.2 Ferrules that are potted, swaged or otherwise attached to tubes must have joints fully filled so that there are no voids.

D3 **Spiral Wound Modules**

D3.1 Glue seams in spiral elements shall be free of indentations or protrusions that may interfere with cleaning and shall be of sufficiently uniform width not to impede permeate flow.

D3.2 The cut surfaces of the element shall be completely within the glue area.

D3.3 Elements shall be tightly wound and have interflow channels that are uniform in height.

D3.4 Elements shall be equipped with a bypassing flo restrictor to allow a portion of the feed stream flow through the annulus between the eleme and its external shroud to eliminate an annul dead-end condition and to keep that area clean.

D3.5 The membrane support material and the permea carrier material are porous. Visual inspection an element from time to time after cleaning sh be necessary to confirm that cleaning a sanitation are effective.

D3.5.1 Permeate carrier material may be fixed in positi with porous materials by stitching, intermitte ultrasonic attachment, or other methods, provid that the areas are open to the flow and penetrati of cleaning solutions.

D3.6 Shrouds for spiral elements shall be fabricated stainless steel or plastic. All joints shall be fr from flaws and voids and flush with adjoinin surfaces.

D3.7 The anti-telescope device and module inte connectors shall be designed in such a way th element surfaces can be mechanically cleaned a no dead-end areas are created.

D3.8 Inter-connector seals shall be tight with no ope crevices and shall be made against impervio surfaces.

D3.9 Crease protection materials conforming Sections C.1 or C.2.2.5 such as tape may b present at the fold lines.

D3.10 Feed channel spacer material shall be located close as practical to the fold line to promote flo through the fold line area.

D4 **Plate and Frame Modules**

D4.1 Membrane surface shall be smooth, flat a devoid of wrinkles.

D4.2 The membrane, support plates, and spacer plat shall be tightly stacked and have a uniform flo in the retentate flow channels.

D4.3 Elastomeric seals, locking rings and gaskets shall be a sanitary design with no open crevices and made against impervious surfaces or demonstrated to be effectively sealed.

D4.4 End-flange(s), spacer, section, and support plates, permeate manifolds, and lock rings shall be fabricated of stainless steel or plastic.

D4.5 The membrane support plates may be porous. Visual inspection of the plates from time to time, after cleaning, shall be necessary to ensure cleaning and sanitation procedures are effective.

D4.6 The permeate outlet shall be positioned in such a way that when assembled, air is not entrapped in the plate.

D5 **Parallel Leaf**

D5.1 The membrane (of the membrane element) shall be firmly attached to the membrane support plate with even and continuous leak-proof bonds of sufficient mechanical integrity to remain free of voids, peel backs or delaminations. The transition from protruding support plate surface to membrane surface shall be smooth.

D5.2 Membrane surface shall be smooth, flat and devoid of wrinkles.

D5.3 Membrane cartridges shall be tightly stacked and have uniform retentate flow channels.

D5.4 When bypassing flow restrictors are employed, they shall allow a portion of the feed stream to flow through the annulus between the membrane cartridge and the membrane housing to keep that area clean.

D5.5 Elastomeric seals and gaskets should be of sanitary design with no open crevices, and made against impervious surfaces, or alternatively, against porous materials that can be mechanically cleaned or demonstrated to be effectively sealed.

D5.6 Housings and membrane element retaining clamps shall be fabricated of stainless steel or plastic.

D5.7 The membrane support material and the membrane element permeate carrier material are porous. Visual inspection of an element from time to time, after cleaning, shall be necessary to assure cleaning and sanitation procedures are effective.

D6 **Hollow Fiber Modules**

D6.1 The manifold adapter assembly shall utilize sanitary type gasket designs and stainless steel clamps at both the membrane cartridge and system feedline interface connections.

D6.2 The permeate adapter assembly shall utilize sanitary type gasket designs and stainless steel clamps at both the cartridge permeate outlet and permeate collection manifold interface connections.

D6.3 The surface of the epoxy or thermoset adhesive tube sheet shall be smooth and free of pits, voids or crevices.

D6.4 Membrane cartridge housings shall be fabricated of plastic or stainless steel.

D7 **Monolithic Ceramic Modules**

D7.1 Ceramic membrane elements shall be a monolithic construction incorporating both the support and the membrane into a one-piece element resistant to delamination, peeling, chipping or spalling of the membrane.

D7.2 Plastic balls may be used to fill the permeate space when the module is used with a uniform transmembrane pressure system; provided that:

D7.2.1 The permeate space shall have inlet and outlet ports positioned adjacent to the feed and retentate ends of the module, respectively, to allow recirculation of permeate fluid through the space by means of a uniform transmembrane pressure system.

D7.2.2 Plastic balls shall be relatively free of geometrical imperfections, be of relatively uniform diameter, and be equal to or greater than 0.140 in. (3.50 mm).

D7.2.3 Plastic balls shall be readily removable for inspection.

E **INSTALLATION, OPERATION AND CLEANING**

E1 Membrane modules shall be installed, operated and mechanically cleaned in a membrane processing system meeting the requirements of the 3-A Accepted Practice for the Sanitary Construction, Installation, and Cleaning of Membrane Processing Systems for Milk and Milk Products, Number 610-.

APPENDIX

F **MODULE DESCRIPTION**

F1 **Tubular Modules**

Tubular modules may be made of single tubes, multiple tubes and/or arrays of tubes. In general, tubular modules are cylindrical with the tubes sealed at each end into an external shroud. The feed product usually flows inside the tubes with the external shroud acting as a permeate collection vessel. In some elements headers are used to join together multiple tubes in parallel as on a shell and tube heat exchange. U-bends are used to join modules together in series.

F1.1 **Large Diameter Tubes**

These tubes are usually one inch (25.4 mm) in diameter and approximately ten feet (305 cm) long. A stainless steel ferrule at each end of the tube connects to a U-bend to join a number of tubes in series. These tubes are placed in a cabinet which contains inlet and outlet manifolds for the product to be processed. Permeate drips from the tubes and collects in the bottom of the cabinet which serves as an external shroud. Permeate is collected and pumped away for disposal or use. Cabinets are often equipped with spray nozzles to help clean and sanitize the exterior of tubes. Figure F1.1 illustrates a large diameter tube and cabinet. The tube itself is formed from a membrane placed on a porous composite membrane support material.

F1.2 **Small Diameter Tubes**

These tubes are usually about one-half inch in diameter and are formed together into elements of multiple tubes by gluing or potting the ends together. There are several configurations.

a. Exposed Outer Surface - This design is similar to concept to the one inch tube. There is no closely fitted external shroud. The tubes are glued in stainless steel manifolds in cabinets. A composite material is used for membrane support. See Figure F1.2.

b. Closely Supported - In this configuration the membrane tubes are placed into closely fitting stainless steel support tubes which may in some cases also serve the function of external shroud and permeate collection vessel. Stainless steel headers are customarily used at each end to bring product to and from the tubes. In some configurations the headers also have internal flow channels that collect permeate from the annular space between the membrane tube and its supporting stainless steel tube. In others the supporting stainless tube is perforated so that permeate collects within a separate external shroud. See Figure F1.3.

c. Potted - Here a bundle of tubes are potted together and sealed into an external shroud that has inlet and outlet fittings for the product. The tubes are self-supporting with the shroud serving as the permeate collection vessel. See Figure F1.5.

F1.3 **Supported Metallic Oxide**

F1.3.1 The supported metallic oxide module consists of a multitude of tubular membrane elements. Membrane elements are assembled in parallel bundle tubes in a pressure shroud. An end tubular plate at both ends of the shroud holds each membrane element. A membrane element gasket at each end of the module provide sealing of all ends of membrane elements and between retentate and permeate side. Counter plates are used to press gaskets and for conducting retentate flow to the membrane elements. One inner spacer holds membrane elements spaced. The shroud is equipped with connection as two retentate inlet or outlet and two permeate outlets.

F1.3.2 The fluid to be processed enters the module through the retentate inlet. It flows as cross flow through the tubular membrane element. Permeate is conducted away from the membranes by supports to permeate vessel, then to the outlet.

F1.3.3 Figure F1.6 shows assembly of membrane elements in the shroud and associated parts.

F2 **Spiral Wound Modules**

F2.1 Spiral wound elements have multiple leaves of alternating membrane, feed carrier and permeate carrier wound around perforated central permeate collection tube. Figure F2.1 is a schematic illustration of the assembly. The fluid being processed flows axially parallel to the permeate tube in between sheets of membrane held apart by the feed channel spacer. Permeate collects in the permeate carrier and flows in that carrier in a spiral fashion inwardly to the permeate collection tube.

F2.2 Spiral elements are usually connected together in groups of two or three at the permeate tube. These elements fit into an external shroud that contains all necessary inlet and outlet ports.

F2.3 An anti-telescoping device (ATD) helps each element to resist the flow forces during operation. These anti-telescope devices (ATDs) may also be connectors for the modules.

F2.4 Figure F2.2 shows how elements fit into the external shroud and its associated hardware. This assembly of elements, connectors, anti-telescope devices, shroud and associated hardware forms the membrane module.

F3 **Plate and Frame Modules**

F3.1 The plate and frame module consists of a multitude of membrane elements assembled (stacked) and held together by means of the supporting frame. (Figures F3.1.1, F3.1.2, F3.1.3, F3.1.4 and F3.1.5.)

F3.2 The geometry of the membrane support plate is such as to form retentate flow channels between the membranes. A variant is to have the retentate flow channels formed in a spacer plate inserted between the support plates with membranes.

F3.3 The sealing between the elements or to the end flanges can be made either with an elastomeric ring or with a seal lip formed at the perimeter of the support plate or spacer plate.

F3.4 The module can be divided into sections of membrane elements by means of sections plates (Figures F3.1.2 and F3.1.4).

F3.5 Each membrane support plate has a permeate outlet which is connected to the permeate manifold. The permeate manifold can be an integral part of the membrane element or be connected by flexible hoses. (Figure F3.1.1.)

F4 **Parallel Leaf Modules**

F4.1 The parallel leaf membrane element consists of a membrane permanently joined to a rigid flat support plate that provides integrity of geometry and facilitates permeate transport to a collection port (Figure F4.1). A multitude of membrane elements are assembled (stacked) and sealed to each other with an elastomeric ring at the permeate collection port so as to conduct permeate from each membrane element. The membrane element stack is held together with a retaining clamp consisting of two rigid non-porous plates, one on each side of the membrane element stack, and a tie-rod that holds the two rigid plates together at their center, and protruding through the permeate collection ports so as to provide a common permeate collection port for the membrane element stack (Figure F4.2). The geometry of the membrane elements is such as to form retentate flow channels in between the membrane elements. A variant is to have retentate flow channels formed with the insertion of a channel spacer, such as a monofilament mesh of a size selected to maintain the desired flow channel height.

F4.2 Several of these assemblies, or "membrane cartridges", (each consisting of a multitude of membrane elements, inter-element elastomeric seals, and retaining clamp) are inserted, end to end, in a close fitting pressure vessel (shroud) equipped with a feed connection, a retentate connection, and permeate connections for each membrane cartridge. Each cartridge is mechanically held and sealed in place with a permeate fitting. Frequently a bypassing flow restrictor is inserted upstream of each membrane cartridge for the purpose of increasing/directing feed flow through the cartridge flow channels. A permeate manifolding system, including anti-flow-reversal valves for each cartridge, collects permeate from each cartridge containing pressure vessel with feed and retentate connections, together with the permeate manifold system, constitute the membrane module (Figure F4.3).

F4.3 Pressurized feed enters the membrane module through the feed connection, flows through the membrane element retentate flow channels (over the membranes), and exits through the retentate connection. Permeate is forced through the permeate fittings into the permeate manifold.

F5 **Hollow Fiber Modules**

F5.1 Hollow Fiber Membrane Elements are self-supporting membrane tube structures that do not require porous support material for mechanical strength. The perm-selective membrane skin on the inside of the fiber and the porous fiber wall are a homogeneous polymer matrix and therefore, act as the pressure vessel. As such, the hollow fiber membrane is cleaned by back-flushing the membrane with cleaning solutions that are recommended by the manufacturer. See 3-A Accepted Practice for the Sanitary Construction, Installation, and Cleaning of Membrane Processing Systems for Milk and Milk Products, 610-. Figure F5.1 is a schematic illustration of a hollow fiber membrane module.

F5.2 A bundle of parallel hollow fiber membrane elements is inserted into a protective membrane sheath which is then sealed into a hydraulically symmetrical shell and tube cartridge by bonding the ends of the fibers in an epoxy resin tube sheet.

F5.3 The fluid being processed flows through the cartridge manifold adapter assembly and enters the lumen or center of the fiber and flows longitudinally down the fiber with the permeate passing radially through the fiber wall and collecting in the "low pressure" or shell side chamber of the membrane cartridge. The retentate exits the other end of the cartridge and is directed to the system retentate/feed lines while the permeate flows out of the permeate outlets of the cartridge through the permeate adapter assembly into the permeate collection manifold. This membrane cartridge, process manifold and permeate adapter assemblies form the membrane module.

F6 **Monolithic Ceramic Membrane Modules**

F6.1 The monolithic ceramic membrane modules consist of a membrane array of one or more parallel single tubular elements or multi-channel tubular elements or tubular elements in a bundled arrangement in the shroud. The shroud is used to protect the membrane elements and divide the module into feed, retentate and permeate channels and spaces.

F6.2 The membrane elements are self-supporting structures with the membranes on the inside of the flow channels. The outside of the element is the porous support for the membrane and provides mechanical integrity and protection for the membranes. The ends of the membrane elements are generally sealed with a very fine ceramic bonded layer of the same material as used for the membrane but of a greater thickness and a finer pore structure. In alternate designs a self-curing or catalyzed sealant may be used to fill the support structures and seal the membranes to the feed and retentate channel spaces and the permeate spaces.

F6.3 Membrane elements are supported within the shroud by either single element grommets or seals, which may be either O-rings or gaskets, or monolithic precast or cast-in-place rubber-like, plastic-like or epoxy material to form a membrane bundle or a membrane array within the shroud. Fixed retainers may be used to secure the bundle or array firmly to the shroud and removable retainers may be used to secure the element seals, bundle seals, or array seals, as the case may be, to the elements.

F6.4 The geometry of the module is such as to form a channel space to feed products to the membrane elements, a channel space at the discharge of the membrane elements to collect the retentate and provide a flow path to connect to boundary retentate lines, and a permeate space surrounding the outside of the membrane elements to collect the permeate and channel it to one or more permeate connectors at the module boundary lines.

F6.5 Figure F6.1 shows the arrangement of a monolithic ceramic assembly of several multichannel elements. Figure F6.2 shows an alternate design of a monolithic ceramic module element fixturing for one or more multichannel elements. Figure F6.3 shows the principal of the multichannel element. The details of this assembly may vary depending on the design of the elements as single tubular or multichannel and the type of membrane element seals required to support a cast-in-place or pre-cast bundle, or the membrane array-type designs with grommet seals.

G **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 conformance to the requirements of Section C.1 herein. Where welding is involved the carbon content of the stainless steel should not exceed 0.08 %. The first reference cited in C.1 sets forth the chemical ranges and limits of acceptable stainless steels 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[5] A351/A351M, A743/A743M and A744/A744M.

H **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 conformance to the requirements of Section D1.6.1 herein.

_____ Drawings remain unchanged from 45-01.

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

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- **5, HACCP: A Management Summary,** Guelph, Ontario, Canada. For more information, call Guelph Food Technology Centre at 519.821.1246; E-mail: gftc@gftc.ca.
- **6-7, Advanced HACCP,** Davis, CA. For more information, call Food Processors Institute at 202.393.0890; E-mail: jepstein@nfpa-food.org.
- **9-13, 6th OIE Seminar on Biotechnology and 11th International Symposium of the World Association of Veterinary Laboratory Diagnosticians,** Bangkok, Thailand. For more information, call OIE at 33.1. 44.15.18.88.
- **10-11, American Dairy Product Institute Lactose Utilization Seminar,** in conjunction with Germany's Institute for Dairy Innovation and Marketing, Atlanta, GA. For more information, call 630.530.8700; E-mail: info@adpi.org.
- **11-12, Food Plant Sanitation,** Guelph, Ontario, Canada. For more information, call Guelph Food Technology Centre at 519.821.1246; E-mail: gftc@gftc.ca.
- **14-15, Mexico Association for Food Protection Annual Fall Meeting,** Mission Carlton Hotel, Guadalajara, Jal., Mexico. For more information, contact Alex Castillo at 979.845.3565.
- **17-21, Brazil Association for Food Protection Annual Meeting,** Centro-Sul Convention Center, Florianopolis, Santa Catarina State, Brazil. For more information, contact Maria Teresa Destro at 55.11.3091. 2199.
- **19, Alabama Association for Food Protection Annual Fall Meeting,** Holiday Inn, Homewood, AL. For more information, contact G. M. Gallaspy at 334.206.5375.
- **20, Ontario Food Protection Association Annual Fall Meeting,** Mississauga Convention Centre, Mississauga, Ontario, Canada. For more information, contact Glenna Haller at 519.823.8015.
- **27-28, SQF 1000/2000^{CM} Systems Training,** GFTC, Guelph, Ontario, Canada. For more information, call 519.821.1246; E-mail: gftc@gftc.ca.
- **30, Southern California Association for Food Protection Fall Luncheon,** Radisson Resort, Knott's Berry Farm, Buena Park, CA. For more information, contact Jennylynd James at 818.874.4710.

DECEMBER

- **3-5, Basic HACCP,** Ithaca, NY. For more information, call Food Processors Institute at 202.393.0890; E-mail: jepstein@nfpa-food.org.
- **9-12, Refrigeration and Deep-Freeze,** Triumph Pavilion, Rosstroy Expo in Moscow. For more information, contact Ken Cardelle at 203. 357.1400; E-mail: KCardelle@iegexpo. com.

JANUARY

- **28-30, International Poultry Exposition,** Georgia World Congress Center, Atlanta, GA. For more information, contact Jackie Stewart at 770.493.9401; E-mail: jstewart@ poultryegg.org

FEBRUARY

- **17-19, Kentucky Association of Milk, Food and Environmental Sanitarians,** Hurstbourne Hotel, Louisville, KY. For more information, contact Sue Jewell at 859.371.2278.

Audiovisual Library Resouce

The Foodborne Illness Education Information Center of the National Agricultural Library (NAL) is a valuable database maintained by the USDA/FDA offering a large selection of food safety videos to loan. Contact the following link to access the NAL database: http:// peaches.nal.usda.gov/foodborne/fbidb/videos.asp

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100	115	130	145	161	175	190	205	220	235	250	265	280	295	310	325	340	355
101	116	131	146	162	176	191	206	221	236	251	266	281	296	311	326	341	356
102	117	132	147	163	177	192	207	222	237	252	267	282	297	312	327	342	357
103	118	133	148	164	178	193	208	223	238	253	268	283	298	313	328	343	358
104	119	134	149	165	179	194	209	224	239	254	269	284	299	314	329	344	359
105	120	135	150	166	180	195	210	225	240	255	270	285	300	315	330	345	360
106	121	136	151	167	181	196	211	226	241	256	271	286	301	316	331	346	361
107	122	137	152	168	182	197	212	227	242	257	272	287	302	317	332	347	362
108	123	138	153	169	183	198	213	228	243	258	273	288	303	318	333	348	363
109	124	139	154	170	184	199	214	229	244	259	274	289	304	319	334	349	364
110	125	140	155	171	185	200	215	230	245	260	275	290	305	320	335	350	365
111	126	141	156	172	186	201	216	231	246	261	276	291	306	321	336	351	366
112	127	142	157	172	187	202	217	232	247	262	277	292	307	322	337	352	367
113	128	143	158	173	188	203	218	233	248	263	278	293	308	323	338	353	368
114	129	144	160	174	189	204	219	234	249	264	279	294	309	324	339	354	

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Articles

Research Notes

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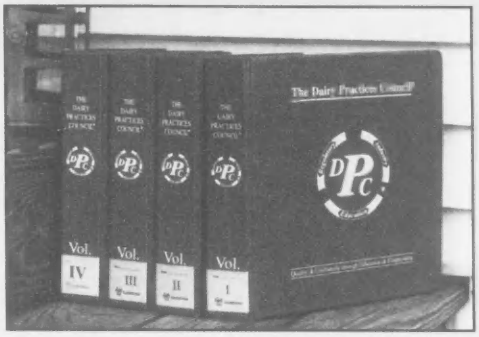
Review



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12 Tunnel Ventilation for Dairy Tie Stall Barns
13 Environmental Air Control and Quality for Dairy Food Plants
14 Clean Room Technology
15 Milking Center Wastewater
16 Handling Dairy Products from Processing to Consumption
17 Prevention of & Testing for Added Water in Milk
18 Fieldperson's Guide to High Somatic Cell Counts
21 Raw Milk Quality Tests
22 Control of Antibacterial Drugs & Growth Inhibitors in Milk and Milk Products
23 Preventing Rancid Flavors in Milk
24 Troubleshooting High Bacteria Counts of Raw Milk
25 Cleaning & Sanitation Responsibilities for Bulk Pickup & Transport Tankers
27 Dairy Manure Management From Barn to Storage
28 Troubleshooting Residual Films on Dairy Farm Milk Handling Equipment
29 Cleaning & Sanitizing in Fluid Milk Processing Plants
30 Potable Water on Dairy Farms
31 Composition & Nutritive Value of Dairy Products
32 Fat Test Variations in Raw Milk
33 Brucellosis & Some Other Milkborne Diseases
34 Butterfat Determinations of Various Dairy Products
35 Dairy Plant Waste Management
36 Dairy Farm Inspection
37 Planning Dairy Stall Barns
38 Preventing Off-Flavors in Milk
39 Grade A Fluid Milk Plant Inspection
40 Controlling Fluid Milk Volume and Fat Losses
41 Milkrooms and Bulk Tank Installations
42 Stray Voltage on Dairy Farms
43 Farm Tank Calibrating and Checking
45 Gravity Flow Gutters for Manure Removal in Milking Barns
46 Dairy Odor Management
48 Cooling Milk on the Farm
49 Pre- & Postmilking Teat Disinfectants
50 Farm Bulk Milk Collection Procedures
51 Controlling the Accuracy of Electronic Testing Instruments for Milk Components
53 Vitamin Fortification of Fluid Milk Products
54 Selection of Elevated Milking Parlors
54S Construction Materials for Milking Parlors
56 Dairy Product Safety (Pathogenic Bacteria) for Fluid Milk and Frozen Dessert Plants
57 Dairy Plant Sanitation
58 Sizing Dairy Farm Water Heater Systems
59 Production and Regulation of Quality Dairy Goat Milk
60 Trouble Shooting Microbial Defects: Product Line Sampling & Hygiene Monitoring
61 Frozen Dessert Processing
62 Resources For Dairy Equipment Construction Evaluation
63 Controlling The Quality And Use Of Dairy Product Rework
64 Control Points for Good Management Practices on Dairy Farms
65 Installing & Operating Milk Precoolers Properly on Dairy Farms
66 Planning A Dairy Complex - "100+ Questions To Ask"
69 Abnormal Milk - Risk Reduction and HACCP
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IAFP has agreed with The Dairy Practices Council to distribute their guidelines. DPC is a non-profit organization of education, industry and regulatory personnel concerned with milk quality and sanitation throughout the United States. In addition, its membership roster lists individuals and organizations throughout the world.

For the past 34 years, DPC's primary mission has been the development and distribution of educational guidelines directed to proper and improved sanitation practices in the production, processing, and distribution of high quality milk and milk products.

The DPC Guidelines are written by professionals who comprise six permanent task forces. Prior to distribution, every guideline is submitted for approval to the state regulatory agencies in each member state. Should any official have an exception to a section of a proposed guideline, that exception is noted in the final document.

The guidelines are renown for their common sense and useful approach to proper and improved sanitation practices. We think they will be a valuable addition to your professional reference library.

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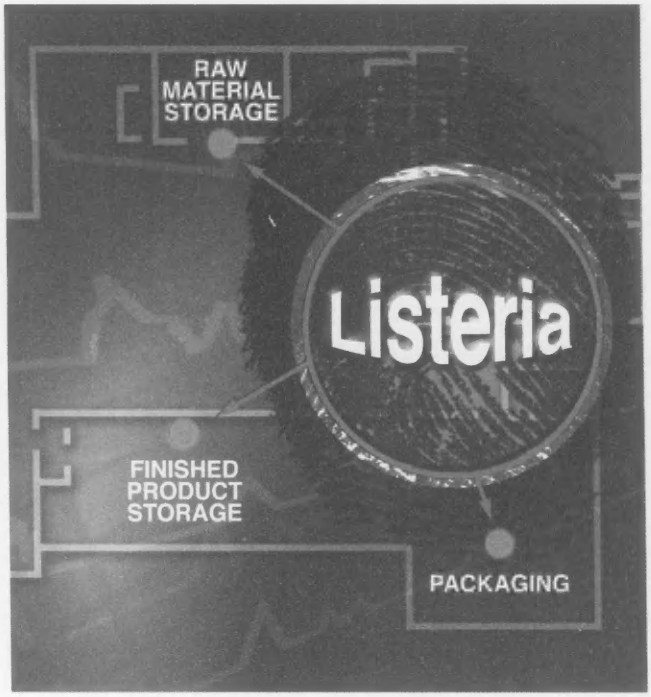

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