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## OFF THE TOP

#### **FROM THE PRESIDENT**



By MICHAEL H. BRODSKY, IAMFES President

"Ask not what my organization can do for me, ask what I can do for my organization"

#### Why IAMFES?...

Analysis of membership data indicates that, on average, members remain in IAMFES for only 3-5 years. Why? With all of the professional societies vying for your membership, why did you join IAMFES? What would you tell your colleagues to convince them that they should also join IAMFES? How can you derive the most benefit out of your membership and how can IAMFES derive the most benefit from you?

In 1973, as a newly appointed environmental research microbiologist in the Central Public Health Laboratory in Ontario, I was looking for a professional affiliation that had a strong association with the microbiological safety of food, water and environmental sanitation. My initial contact was with a local organization called the Ontario Association of Milk, Food and Environmental Sanitarians (OAMFES), which later became the Ontario Food Protection Association (OFPA). I joined this organization in 1975 and subsequently began to receive the Journal of Milk and Food Technology from some organization called the International Association of Milk, Food and Environmental Sanitarians, or IAMFES, out of Ames, Iowa. I initially only attended the OAMFES annual meetings. Then, out of curiosity, I began to attend the monthly meetings of the Board of Directors. It was through the BOD that I really began to meet and get involved with other members in planning and organizing meetings. I was subsequently nominated and elected to the Board of Directors of the OFPA in 1982. It was at this point that I started to take a greater interest in IAMFES, which I now realized was the parent organization of the local affiliate.

My involvement in the OFPA and subsequently my activities in IAMFES, stemmed from a desire: to travel; to share research data; and to meet international colleagues and discuss microbiological concerns of mutual interest. I guess my initial interest was somewhat selfserving; but, the more active I became, the more enjoyment I received from my membership in the OFPA/IAMFES. At first, I presented research papers only at the OFPA's annual meetings; but, in 1985, I made my first presentation at the IAMFES Annual Meeting in Tampa, Florida, I became aware that government support for my attendance at, and travel to international meetings was dependent upon my playing an active role in terms of presenting data, organizing symposia or presenting workshops. In addition, I had to show the benefit of my role in IAMFES to my employer, the Ministry of Health in Ontario. Perhaps the greatest benefit that I derived from my involvement with the OFPA/IAMFES were the many professional contacts I made and the many special friendships that evolved.

As you reflect on your membership, either with your local affiliate, or with the International Association, ask yourself if you are getting the most benefits from your membership. If you are not getting out of your membership all that you expected, look at how much you are putting in. By increasing your input, I guarantee that the output to you will increase dramatically. With due respect for the originator of this thought and using literary licence, "Ask not what my organization can do for me, ask what I can do for my organization." The rewards will be well worth the effort. I can personally vouch for it.

## We don't care how you get it here...











## but we do care *if* we get it!

Affiliates are an important part of IAMFES, and that's why we need you, our Affiliate Associations and Affiliate Members, to let us know what is going on in your organizations. Keep us abreast of meetings, activities, seminars and other events by sending us minutes, announcements or just a quick update. In return, we'll publish it in our next issue of *Dairy, Food and Environmental Sanitation*. All we ask is that you please send information regarding upcoming events at least two months in advance.

Please address to: Managing Editor, *Dairy, Food and Environmental Sanitation*, 6200 Aurora Avenue, Suite 200W, Des Moines, Iowa 50322-2863, Telephone: (515) 276-3344 or Fax: (515) 276-8655; e-mail: iamfescm@dwx.com

## **Our Affiliates Count!**

## PERSPECTIVES...

#### From the Executive Director



By DAVID M. MERRIFIELD, IAMFES Executive Director

### "How do you become involved"

I'm jealous! One article in *DFES* by our new president, Michael Brodsky, and he gets several responses. And, like any good president, he passes them on to me to follow-up. Secretly, I'm glad he did, because one member suggested we write an article about our committees and how to get involved. What an opening...an opportunity to present a primer on IAMFES involvement! So, in the words of an old TV show, "You Asked For It!"

In addition to the Executive Board and staff, IAMFES is made up of committees, professional development groups, task forces, and support groups. Some are defined in our Constitution and Bylaws, while most were formed out of a recognized need to develop and promote technical standards and to exchange information. Each has different purposes, functions, requirements and commitments. A complete listing was printed in the "mini-directory" distributed in March, however, many of the leaders and members have since changed. A current listing will be published in this Fall's membership directory.

Committees established in the Bylaws are of two types; standing and special. They are led by a chairperson appointed by the President-Elect with Executive Board approval for a oneyear, renewable term. Committee members, unless otherwise defined in the Bylaws, are appointed by the chairperson with Executive Board approval.

**IAMFES Standing Committees** include: the DFES and JFP Management Committees; the Nominating Committee; the Teller Committee; and the Past Presidents' Advisory Committee. The journal management committees are tasked with the oversight of the two IAMFES monthly journals. Among its members are the scientific editors and the IAMFES managing editor. The Nominating and Teller Committees have responsibility for the nomination and election process for a new secretary each year. The Past Presidents' Advisory Committee serves in an advisory capacity to the Executive Board.

Special Committees include: Communicable Diseases Affecting Man with primary responsibility for producing the various IAMFES procedure booklets such as *Procedures to Investigate Waterborne Illness*; the Program Advisory Committee, responsible for developing the program for the Annual Meeting; and the Sanitary Procedures Committee, IAMFES' representatives for the 3-A Sanitary Standards Program.

Professional Development Groups (PDGs) are led by a group leader who serves a two-year, renewable term at the direction of the President. The PDGs accomplish projects and other work of a continuous nature, primarily where a need is recognized. Members, invited to serve by the group leader, complete work of a scientific and technical nature. The PDGs include all of the Safety and Quality groups (dairy, meat, poultry and seafood), as well as the Food Safety Network, Food Sanitation, Applied Laboratory Methods, Audio Visual Library and Viral Foodborne Disease. Recently, a new PDG was formed on Microbial Risk Assessment.

Task Forces (TFs) are led by an Executive Board appointed task leader, normally for the duration of the task assigned. The Executive Board also appoints all TF members. Active IAMFES TFs include Awards, Constitution and Bylaws, Developing Scientist Awards, Education, and Finance.

Lastly, there are two IAMFES Support Groups; the Foundation Fund, which sponsors Annual Meeting speakers and the Audio Visual Library, and the Affiliate Council, made up of delegates of all of the IAMFES local affiliates. The chairperson of the Affiliate Council is elected annually by the delegates and serves as a voting member of the Executive Board.

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Dairy, Food and Environmental Sanitation, Vol. 16, No. 9, Pages 546-548 Cepyright© IAMFES, 6200 Aurora Ave., Suite 200W, Des Moines, IA 50322

## **Redox Potential in Deli Foods: Botulism Risk?**

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#### SUMMARY

The oxidation-reduction potential  $(E_h)$  of packages of four delicatessen food items (lasagna, deluxe chicken salad, dressy chicken, and chicken à la king) was measured. The  $E_h$ of these four foods ranged from -198 to -23 mV. This range is more than sufficient to allow the growth of *Clostridium botulinum* in food. Supermarket delicatessens and restaurant operations do not purposely add preservatives to prevent the growth of *C. botulinum* in food. Therefore, it must be assumed that keeping food temperatures below 50°F (10°) has been adequate to prevent the hazards from both proteolytic and nonproteolytic strains of *C. botulinum*, since there has been no record of botulism from deli food in retail food operations.

#### INTRODUCTION

Today in the retail food industry there is essentially a ban on vacuum packaging of potentially hazardous food, because the U.S. Food and Drug Administration (FDA) insists on multiple barriers in addition to cold temperature (2). The apparent concern of the FDA is that vacuum packaging represents an unusually risky foodpackaging method that will imminently lead to a greater occurrence of the outgrowth of the common food contaminant, proteolytic Clostridium botulinum, or the uncommon contaminant, nonproteolytic C. botulinum, with the resulting production of toxin and the death of people consuming the food.

In contrast, the U.S. Department of Agriculture (USDA) has no special concern. It simply requires that when processors request a label for a food product, detailed processing procedures (description of product formulation, preparation, cooking and cooling temperatures, type of container, and cooking and handling instructions) be included with adequate consumer labeling information. This is called a partial quality control program (6). Through the partial quality control program, it is determined if processors have taken adequate precautions so that there is an acceptable risk of consumer illness or death from *C. botulinum*. There is no mandatory set of additional microbiological hurdles in finished products other than temperature.

A principal category of chilled food that has been produced for more than 25 years in USDA approved facilities is that of chilled deli meats, specifically, turkey, beef, chicken, and ham loaves, which are either dry roasted or slowly cooked in water baths to maintain maximum yield. These products come in large-sized packages in the range of 5- to 10-lb loaves. They are vacuum-packed, anaerobic products that have the potential for C. botulinum outgrowth and represent the risk about which the FDA Retail Food Protection Branch is apparently concerned.

In many states such as Minnesota, where retail food markets are under the jurisdiction of the state's Department of Agriculture, state inspectors follow the USDA guidelines for vacuum packaging sliced meats. They allow food markets to slice processed meat and poultry products in house, and repackage them in vacuumpacked bags to sell in the stores' delicatessens. There is no further microbiological control other than temperature. This practice has continued for many years with no epidemiological indication of any hazard.

Actually, food does not need to be in a vacuum bag in order to have a sufficiently low oxidation-reduction

Food item	Temperature °F (°C)	рН	E <sub>h</sub> (mV)
Lasagna	136 (57.8)	4.7	-26
Deluxe chicken salad	57 (13.9)	5.5	-23
Dressy chicken	125 (51.7)	5.7	-125
Chicken à la king	134 (56.7)	6.1	-198

#### Figure 1. Lasagna



#### Figure 2. Deluxe chicken salad







potential ( $E_h$ ) to grow *C. botulinum*. Most food, 2 in. (5.08 cm) deep in a pan, provides an environment that is conducive for the growth of *C. botulinum*. In order to ascertain if this condition does in fact exist, the following experiment was performed on four foods purchased at a local food market delicatessen. The ( $E_h$ ) of the foods was measured to show the potential of these typical foods to grow *C. botulinum* if they are sufficiently temperature abused.

#### **MATERIALS AND METHODS**

Eight-ounce portions of four food items, lasagna, deluxe chicken salad, dressy chicken, and chicken à la king, were purchased from a local food market delicatessen. Each of these food items was placed in a small plastic take-home container, with dimensions of approximately 1.25-in. depth and 5-in. diameter. The packaged food items were transported to the laboratory, where the (E) was measured using a platinum redox electrode Model 96-78 (Orion, Cambridge, MA). The electrode was standardized with quinhydrone saturated buffer at pH 4 and pH 7. The pH of the food items was measured with an Accumet Basic pH meter with an Accumet pH electrode Model 13-620-758 (Fisher Scientific, Pittsburgh, PA). Food temperature was measured using a thermocouple meter Model 115 (Barnant Company, Barrington, IL).

#### RESULTS

The positioning of the  $(E_p)$  electrode in the food items is shown in Figures 1 to 4. The data are presented in Table 1.

#### DISCUSSION

The upper  $E_h$  level that will allow initiation of growth from spores of both proteolytic and nonproteolytic *C. botulinum* strains is on the order of +200 mV (1, 4). Stress factors such as salt concentration and decreased acidity will lower the critical level for spore growth (5). Once growth is initiated, the  $E_h$  of the *C. botulinum* culture declines rapidly to -200 mV. It is apparent from the data in this study



that the E<sub>b</sub> of typical foods sold in delicatessens, which will also be found in restaurant kitchens, is more than sufficiently reduced, and will allow the growth of C. botulinum, given the opportunity. The spores of C. botulinum are extremely resistant to pasteurization temperatures. It takes 3 min at 250°F to achieve sufficient destruction of 10<sup>-12</sup> C. botulinum spores, according to canning standards. Typical retail food cooking temperatures of 180 to 212°F (82.2 to 100°C) are merely activation temperatures for the spores. In these four food items, the pH was sufficient to allow growth and toxin production from proteolytic strains of C. botulinum, which begin to produce a toxin at 50°F (10°C) (3), and of nonproteolytic strains of C. botulinum, which begin to grow and produce toxin at 38°F (3.3°C) (3).

#### CONCLUSIONS

It is apparent from this simple study that foods processed in typical retail food operations may have an oxidation-reduction potential low enough to allow the growth of *C. botulinum* and consequently, production of toxin, if temperature is not controlled. No additives are specifically added to typical recipes in the retail food industry to prevent the growth of *C. botulinum*. If the 1995 FDA Food Code (3-502.12 *Reduced Oxygen Packaging, Criteria*) (2) is to be followed, essentially all foods in the retail food industry must be formulated with hurdles in order to meet these criteria, because even food in a pan 2 in. deep will have an  $E_h$  low enough to be hazardous.

While the word, "packaging," may be interpreted as a container for sales, it is equally appropriate to consider packaging as a hot-packed pan, or as wrapped with plastic wrap and then refrigerated. These forms of packaging are more than adequate to prevent the transmission of oxygen and promote the development of a sufficiently low E, in the center of the food product to allow the outgrowth of C. botulinum. Clostridium botulinum will normally be present in most retail foods because this pathogen is found on most vegetables and spices, which are specified in the recipes formulated in retail food operations.

It is evident that over the many years of commercial food-service operation, there have been no reported outbreaks of C. botulinum intoxication when hot foods or cold foods under temperature control are sold. Problems have arisen when cooked food was allowed to remain at room temperature for 24 to 48 h. When vegetables, especially, come out of the ground, they contain low levels of C. botulinum. Clostridium botulinum will be found in almost all food items prepared in the retail food environment. All people consume this organism throughout their lives. This information clearly indicates that temperature and time management alone, such as keeping food below 50°F (10°C) and eating it soon after purchase is sufficient to prevent the hazardous growth and toxin production of *C. botulinum*.

#### REVIEW

There will be no new hazard created by placing food in a plastic bag versus current methods of packaging hot and cold food in rigid containers for take-out or use in retail food operations. Vacuum packaging should be allowed in the same way that all packaging is allowed in the retail food industry. However, people who want to vacuum pack food items for retail sale should complete a USDA Partial **Ouality Control Program**, because if food abuse is sufficient, a hazard can be created. People who want to use vacuum packaging only in their food operating systems should write a HACCP internal procedure scheme, and should not be required to add chemicals to provide multiple barriers.

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## Implementation of a HACCP Program in a Commercial Fresh-Market Tomato Packinghouse: A Model for the Industry

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#### SUMMARY

Epidemiologic studies linked outbreaks of salmonellosis in 1991 and 1993 to raw tomatoes. Subsequent research funded by the tomato industry confirmed that Salmonella montevideo can grow on raw tomatoes at temperatures commonly found in food handling systems. In response to this situation, a model hazard analysis critical control points (HACCP) program was designed, implemented, and monitored in a commercial tomato packinghouse in South Carolina in 1994 and 1995. Three control points were identified. The key point was water quality maintenence, i.e., control of chlorine, pH, and temperature in the water bath. Other points were cleaning and inspection of field bins and monitoring of the hand-sorting procedures on the packingline. Testing of tomatoes in 1994 and 1995 for the presence of Salmonella spp. verified that the HACCP program was effective in controlling the risk of contamination in the packinghouse. This model HACCP program, especially monitoring of water quality, could be applicable to other fresh fruit and vegetable handling systems.

#### BACKGROUND

Salmonella contamination is the most frequently reported cause of foodborne outbreaks of gastroenteritis in the United States, with an estimated 2 to 6 million cases each year (8, 17). Foods of animal origin, including poultry and other meats, eggs, and dairy products, are the most commonly implicated sources of salmonellosis (17). In recent years, however, several multistate outbreaks of salmonellosis have been associated with eating fresh fruits and vegetables (7, 10, 12). Two of these outbreaks were thought to have resulted from eating fresh uncooked tomatoes contaminated with Salmonella spp.; S. javiana in 1991 (19) and S. montevideo in 1993 (2). In both of these outbreaks, Salmonella was not isolated from tomatoes, but epidemiologic evidence indicated that the cause of both outbreaks may have originated from the same tomato packinghouse in South Carolina (2, 11). Therefore, we

designed and implemented a hazard analysis critical control points (HACCP) program in a commercial tomato packinghouse in South Carolina with the goal of preventing *Salmonella* contamination of tomatoes.

#### HACCP PROGRAM

#### **Hazard** analysis

The possibility that uncooked tomatoes might be a vehicle for salmonellosis was demonstrated in recent laboratory studies which revealed that Salmonella spp. could survive on or in tomatoes subjected to handling practices currently used for their movement from packinghouses to retail outlets (20). Chopped, ripe, uncooked tomatoes supported Salmonella growth, and small populations that infiltrated into the stem scar of whole tomatoes multiplied inside the fruit when temperatures were favorable for microbial growth (20). This finding was in agreement with those of earlier studies on tomato infiltration by decay-causing bacteria, in which infiltration was significantly increased when the temperature of the water bath was 5°C cooler than the pulp temperature of the tomato (4, 16). Since Salmonella spp. can survive and multiply on tomatoes, these results suggest that even a small amount of bacterial inoculum on tomatoes may ultimately lead to human infections if the fruit is not handled properly (3, 20).

Because eating uncooked tomatoes had been associated with human illness, and because of the observation that fresh tomatoes can support Salmonella growth, we sought to explore methods of ensuring the absence of Salmonella spp. in tomatoes. In South Carolina, tomatoes are grown on plastic mulch, staked and tied to further restrict contact with the soil, fertilized through drip-irrigation tubes under the plastic mulch, and hand-picked (9), practices that seemed unlikely to result in widespread Salmonella contamination.

Contamination seemed more likely to occur at the packinghouse, where tomatoes are dumped into a water bath and transported across conveyors for hand sorting and other procedures before being machine packed into cartons.

#### **Process flow description**

Before the 1994 harvest, the harvesting, handling, and packing procedures were inspected on farms and in a packinghouse in South Carolina to identify critical control points. Mature green tomatoes are transported from the field to the packinghouse in 40-ft<sup>3</sup> (1.32 m<sup>3</sup>) wooden bins that have a capacity of approximately 1,000 lb (ca. 453.6 kg) of fruit. At the packinghouse, tomatoes are dumped into a water bath, also called a dump tank, which minimizes physical injury to the fruit as it is emptied from the bins. The dump tank contains approximately 4,000 gal (ca. 15,140 liters) of water, which is circulated with pumps in a closed system. Water is added to this system during operation only if there is substantial loss of volume due to spillage or drainage for repairs; normally, the tank is emptied and washed each night and refilled with clean water for the following day's operation. Fruit leaves the dump tank via a roller conveyor. Transit time for fruit in the water is 5 to 10 s.

The packing-line conveyors pass the fruit through a light application of vegetable oil-based wax and automatically separate the fruit into several size categories. The fruit is then hand sorted (by workers without gloves) into quality categories and transported to automated carton-filling machines, which place 25 lb (ca. 11.25 kg) of fruit per box. Boxes are labeled with a code that identifies the grower and the date the fruit was packed. An additional label indicates the type of wax that was applied. The total lapsed time from bin dumping to carton filling is approximately 3 min. Filled boxes are placed on pallets by hand and the pallets are then moved to storage rooms and held at 12°C with approximately 90% relative humidity. Ripening is initiated by metering ethylene gas into the storeroom to a concentration of approximately 100 ppm. The timing and duration of ethylene treatment varies according to the requirements of the buyer, who may request that the fruit be at a particular stage of development (e.g., mature-green, pink, or fullripe) upon arrival at the destination. As sales are confirmed and appropriate ethylene treatments completed, pallets are transferred from holding rooms to refrigerated trucks for shipment.

#### **Critical control points**

Three critical control points in the tomato handling system were identified: (i) cleaning and inspection of the wooden bins used for transporting fruit from the field to the packinghouse, (ii) water quality maintenance in the packinghouse dump tank, and (iii) hand sorting of individual tomatoes on the packing line. In addition to these specific control points, general sanitation procedures throughout the facility were inspected and potential problems identified.

#### Implementation and monitoring

The HACCP program was implemented in the 1994 season and monitoring was continued through the 1995 season. In the week preceding the harvest, each wooden bin was sprayed thoroughly with a solution of 10% sodium hypochlorite and pressure cleaned with hot water. Harvest managers then visually inspected the cleanliness of the bins in the field before filling them with freshly harvested fruit.

The dump tank had previously been equipped with a chlorine gas injection system (Decco, Inc., Monrovia, CA). To monitor the operation of the injection system, a free-chlorine monitor and control-

ler (both from Decco, Inc.) were installed before the 1994 harvest. The monitor used electronic oxidation-reduction potential sensors to sense free-chlorine content. Solenoid valves regulated the input of chlorine gas into the dump tank water upon demand. The chlorinated water passed through a bed of calcium carbonate to neutralize the pH before injection into the dump tank. The unit was equipped with a recorder, which provided a continuous record of free chlorine level as a function of oxidation-reduction potential, and an alarm, which alerted packinghouse workers when free-chlorine concentration fell below the desired level. The temperature of the dump-tank water was maintained with a thermostatically controlled gas heater. The thermostat set point was 40°C.

To further ensure that the automated system was functioning properly, total chlorine, pH, and water temperature were checked manually at approximately 2-h intervals. Total chlorine was checked with paper test strips (Diversey Wyandotte, Inc., Wyandotte, MI) and a liquid chemical kit (Hach, Inc., Loveland, CO). An electrode type pH meter was used for pH measurement and an electronic thermometer was used for monitoring water temperature (Cole-Parmer, Inc., Nile, IL). Measurements of water quality parameters, i.e., pH, chlorine content, and temperature, were recorded manually and the handwritten records were made available to University personnel who visited the site.

Recommendations for tomato dump-tank water conditions are usually in the range of 100 to 200 ppm free chlorine, pH between 6.5 and 7.5, and temperature at least  $5^{\circ}$ C above the pulp temperature of the fruit (6, 13, 14, 15). The mechanisms for chlorine injection, pH control, and water heating were adjustable. When manual testing revealed that any quality parameter was outside the recommended range, or when the alarm indicated that chlorine concentration was reduced to 10 ppm, adjustments were made in the equipment to compensate for the deficiency in water quality.

Workers who had to touch the fruit on the packing line were issued rubber gloves and instructed to disinfect the gloves at the beginning of the work day and following breaks or visits to the restroom. A continuous supply of rubber gloves was available. Wearing gloves was mandatory; the supervisor monitored glove use and instructed workers who had removed the gloves to put them back on. No records are available for the number of workers who violated this rule. Soap and disinfectant were provided in all restrooms, and instructions for workers to wash their hands before returning to work were posted in prominent locations. The signs were written in **English and Spanish. Restrooms** were thoroughly cleaned each evening and periodically inspected throughout the day.

General sanitation throughout the packing facility was improved over past practices. All of the packing-line equipment was cleaned with a pressure cleaner and industrial disinfectant at the start of the season as described for the wooden bins. Special attention was given to areas that could retain small amounts of water and potentially support the survival of bacteria. This included all drain pans underneath the machinery and water troughs recessed in the concrete floor. Each evening floors were swept and washed with disinfectant, soap, and water. Special care was taken to remove all fruit, leaves, or other debris from floors and beneath equipment. In the ripening rooms, refrigeration coils, condensate drainage pans, walls, and floors were pressure cleaned with disinfectant as described for bins and packing lines.

#### Verification

During the 1994 and 1995 seasons, samples of fruit were collected at the packinghouse and analyzed for Salmonella spp. to verify the success of the HACCP program. Tomato fruit samples (20 fruits per sample) were collected from the distal end of the packing line approximately every 2 h on 2, June 1994, the first day of packing. These samples were immediately placed in cold storage (1°C) in darkness to await analysis. The packinghouse did not run more fruit for 3 days, but when packing resumed, water samples (100 ml) were collected from the dump tank and additional fruit samples (5 fruits per sample) were collected every 2 h on 6 and 7 June. These samples were transported in an ice chest to the Centers for Disease Control and Prevention (CDC) and to the University of Georgia for analysis.

Water samples were tested at the Centers for Disease Control and Prevention by using standard membrane-filtration techniques (1). No coliforms were detected in water samples. At the University of Georgia, tomatoes were individually placed in plastic bags with 20 ml of sterile aqueous solution of 0.1% peptone. The bag was sealed and the surface of the tomato was gently rubbed by hand for 1 min. The wash fluid from the tomato surface was serially diluted (1:10) in 0.1% peptone, surface plated (0.1 ml) in duplicate on bismuth sulfite agar and brilliant green agar (Difco Laboratories, Detroit, MI) and incubated for 24 h at 37°C. No Salmonella spp. were detected on the 45 tomatoes analyzed, but coliforms were detected on the surface of 2 of the 45 fruits: the coliforms were identified as Leclercia adecarboxylata and Enterobacter cloacae.

Beginning 6, June 1994, and continuing through the 1995 season, tomatoes were also analyzed for *Salmonella* spp. in a private laboratory (ABC Research, Gainesville, FL). In 1994, samples of 5 fruits each were collected

approximately every 2 h on every day of packinghouse operation. In 1995, sampling was done at approximately 4-h intervals. Each evening, samples were transported by car at ambient temperature to the laboratory. A radial slice, approximately 2 cm thick, was removed from the stem end of each tomato. Slices were placed in 225 ml of lactose enrichment broth at 35°C for 24 h, and then 1-ml aliquots were removed and plated as described above. In 1994 and 1995, respectively, 158 and 77 samples were collected and analyzed. All samples were negative for the presence of Salmonella spp.

Numerous unannounced visits were made to the packinghouse by **Clemson University Extension** personnel in 1994 and 1995 to verify that management was implementing the HACCP program appropriately. Random checks of the water bath revealed that the water pH varied from 6.8 to 7.2 and that the water temperature was between 35 and 39°C. The water temperature never reached the setpoint temperature of 40°C, which is normal because of the cooling effect of constantly running fruit. The total chlorine content exceeded 250 ppm in all tests and free chlorine varied from 40 to 100 ppm, except once, when the chlorine content of the water had been depleted to about 10 ppm free chlorine and the low-chlorine alarm sounded. In this case, none of the tomatoes packed during this time was sold until test results from the private laboratory were received to confirm that no Salmonella spp. were present.

#### DISCUSSION

A HACCP program has not previously been reported for a tomato-handling system. Tomatoes are an appropriate commodity for the testing of a HACCP program because they are consumed raw in most households, they usually are not refrigerated below 12°C, they may be stored as long as 3 weeks from harvest to consumption, and they support Salmonella growth. In our study, the risk to tomato consumers was previously identified, the CDC and Clemson University personnel visited the fields and packinghouse, hazards were analyzed, critical control points were defined, and the HACCP program was implemented. The advantage of a HACCP program is that it is a comprehensive preventive strategy which appropriately places responsibility for food safety on handlers, manufacturers, or distributors (18). This preventive proactive role of industry is a greater safeguard for the health and safety of consumers than the reactive measures that regulatory agencies are forced to take after problems arise.

Water is the most likely source of widespread low-level microbial contamination in food-handling systems in general. Virtually all fruit and vegetable packing and processing facilities include operations that require water. Chlorination is effective in reducing the proliferation of microbes in water, but its efficacy is dependent on the amount of free chlorine present (5). As the water becomes contaminated with soil and organic debris, free chlorine may decrease dramatically. For this reason, the freechlorine content needs to be automatically monitored, and all fruit packers should consider installing a monitoring system. As an additional measure, tomato dump-tank water should be heated at least 5°C above the pulp temperature of the fruit to prevent infiltration of contaminated water through the stem scar due to the suction effect created by cooling and contraction of intercellular spaces (16). The importance of water quality maintenance in postharvest operations has long been recognized and university extension services in several states have published information specifically directed to fresh-produce handlers (6, 13, 14, 15).

Implementation and testing of a HACCP program requires cooperation and open communication between all parties involved (18). In this study, risk was identified by the CDC, funding was provided by the tomato industry for University researchers to further define the risk, the packer fully cooperated in implementation of the HACCP program, the university extension service had unrestricted access to the packing facilities and to the results of private testing, there was oversight and participation by CDC, and there were numerous follow-up visits to the site by university personnel. All these factors allowed us to successfully meet our objective of implementing and testing a HACCP program for fresh-tomato packing operations, and we commend the leaders of the tomato industry for their support. Future effort by university extension personnel will emphasize the need for packinghouse operators to improve record-keeping procedures so that regulatory agencies will have a basis for evaluation of the HACCP program implementation and monitoring.

We propose that this HACCP program for fresh-market tomato packinghouses and the manner in which it was implemented and monitored can serve as a general model for the fresh-produce industry.

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## HACCP and HAZOP for a Pulsed Electric Field Processing Operation

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#### SUMMARY

The hazard analysis critical control point (HACCP) and hazard and operability study (HAZOP) concepts have been considered in the design of a pulsed electric field (PEF) food-processing operation. These concepts are currently used for the improvement of industrial operations as total quality management tools. The HACCP program leads to the processing and production of safe foods in analyzing health hazards associated with processing, distribution, and consumption of food, while the HAZOP analysis is used to identify hazardous working conditions in a specific step of a processing operation.

The design of a PEF facility based upon the HACCP and HAZOP concepts is a preliminary step toward approval by regulatory agencies such as the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). The HACCP concept was used to define the following critical control points in a PEF facility: (i) the raw material receiving area, (ii) the treatment chamber, and (iii) the packaging machine. Process parameters and process conditions, such as product temperature, electric field intensity, number of pulses, pulse shape, and cleanliness are fundamental in the inactivation of microorganisms and enzymes. Product characteristics such as conductivity, pH, ionic strength, and composition must be considered in designing the process. In addition, treatment chamber geometry, and electrical components and connections are key engineering aspects at the design and construction phases of both the pulser and treatment chambers to avoid safety hazards concerning both equipment operation and product integrity.

#### INTRODUCTION

The hazard analysis critical control point (HACCP) and the hazard and operability study (HAZOP) concepts are used as total quality management tools. The HACCP concept was advanced in the 1970s at the Pillsbury Company (Minneapolis, MN) in collaboration with the National Aeronautics and Space Administration (NASA) and the U.S. Army Research Laboratories (9). The HACCP concept leads to the production of safe foods by the analysis of health hazards associated with the production, distribution, and consumption of food. The system places emphasis on the microbiological safety of ingredients and process specifications on the premise that safe products will result from the use of high-quality raw materials and proper operation of the equipment to accomplish process specifications (5, 8). The U.S. National Advisory Committee on the Microbiological Criteria for Foods (NACMCF) and the International **Commission on Microbiological** Specifications for Foods (ICMSF) view HACCP use as a systematic approach to food safety consisting of the seven principles listed in Table 1 (9).

#### TABLE 1. HACCP principles (5, 9)

- Assess the hozords and risks ossociated with the growing, horvesting, processing, manufacturing, distribution, marketing, preparation, and consumption of the food.
- 2. Determine the CCP(s)<sup>a</sup> required to control the identified hozord.
- 3. Establish the critical limits that must be met at each identified CCP.
- 4. Establish procedures to monitor the CCP(s).
- 5. Establish corrective actions when there is a deviation in a CCP.
- 6. Establish effective record-keeping systems.
- Establish procedures for verification that the HACCP system is working properly.

°CCP: criticol control point.

#### TABLE 2. HAZOP principles (6)

- 1. Identify the hazordous condition ossocioted with on operation.
- 2. Establish corrective actions to prevent the hazardous condition(s).
- Implement corrective actions by modifying the procedures used in the operation.
- Establish monitoring procedures to verify the effectiveness of the corrective actions.
- 5. Establish personnel troining programs.
- 6. Establish effective record-keeping systems.
- Establish procedures for verification of the effectiveness of the corrective octions.
- 8. Update plant layout scheme with the corrective actions.

The design and construction of processing equipment and facilities is regulated by the Occupational Safety and Health Administration in the U.S. HAZOP analysis is used to identify hazardous conditions in manufacturing and packaging operations that jeopardize the safety of employees (6). Table 2 summarizes the steps considered while developing and implementing a HAZOP analysis.

Both HACCP and HAZOP concepts may be used in the design, construction, and troubleshooting of a pulsed electric field (PEF) processing facility. The HACCP component will focus on the process design in terms of process-product compatibility, product safety, process capability, and consumer preferences. The HAZOP component will focus on the equipment design, process requirements, personnel protection, and equipment safeguards.

The development of pulsed electric field technology started in the 1920s with the so-called Electropure Process for milk (13). The Electropure Process consisted of passing an electric current through carbon electrodes to heat the milk to 70°C. Beattie and Lewis (1) demonstrated the lethal effect of electrical discharges on microorganisms, in addition to the thermal effects, when the voltage applied to inactivate the microorganisms was increased to 3,000 to 4,000 volts. The electrohydraulic treatment to inactivate microorganisms suspended in liquid foods was introduced in the 1950s, using capacitor discharges and arcs. The inactivation of microorganisms was attributed to the shock wave generated by the arc and the formation of highly reactive free radicals from chemical species contained in the food by the spark (13). Gilliland and Speck (2) applied the concept of pulsed electric discharges at different energy levels in the inactivation of Escherichia coli, Streptococcus faecalis, Bacillus subtilis, Streptococcus cremoris, and Micrococcus radiodurans suspended in sterile distilled water and observed the effect of the electric-shock treatment on trypsin and a protease from Bacillus subtilis.

Sale and Hamilton (11) demonstrated the nonthermal lethal effect of homogeneous electric fields on bacteria such as Escherichia coli, Staphylococcus aureus, Micrococcus lysodeikticus, Sarcina lutea, Bacillus subtilis, Bacillus cereus, Bacillus megaterium, Clostridium welchii and yeasts such as Saccharomyces cerevisiae and Candida utilis. In general, an increase in the electric field intensity and the number of pulses leads to an increase in the inactivation of microorganisms (3, 4, 7, 10, 12, 15, 16). Other factors that affect microbial inactivation are the treatment temperature, pH, ionic strength, and conductivity of the medium containing the microorganisms (10, 14).

The main objective of this paper was to develop the HACCP and HAZOP concepts in a PEF facility as a preliminary step toward the approval of this novel process by regulatory agencies such as the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). Figure 1. Pulsed electric field unit operations layaut.



#### TABLE 3. General microbial hazard characteristics (9)

- Hazard A: A special class that applies to nonsterile products designated and intended for cansumption by at-risk populatians.
- Hazard B: The praduct cantains sensitive ingredients in terms of microbiological hazards.
- Hazard C: The pracess does nat cantain a cantralled pracessing step that effectively destrays harmful micraarganisms.
- Hazard D: The product is subject to recontamination after processing before packaging.
- Hazard E: There is a substantial patential far abusive handling in distribution ar in cansumer handling that cauld render the praduct harmful when consumed.
- Hazard F: There is na terminal heat process after packaging ar when cooked in the home.

#### TABLE 4. Risk categories for food products and raw materials (9)

Risk	Definition
0	No hazard.
I	Food praducts subject ta ane af the general hazard characteristics.
11	Food products subject to twa of the general hazard characteristics.
111	Food products subject to three of the general hazard characteristics.
IV	Faod praduct subject to any faur general hazard characteristics.
V	Food products subject ta all five general hazard characteristics.
VI	Special category that applies to nonsterile products.

#### HACCP PRINCIPLES AND PEF TECHNOLOGY

The PEF process is summarized in Figure 1, where key operations are the receiving of raw materials, PEF treatment, aseptic packaging operation, and finished product storage and distribution. The seven principles described in Table 1, when applied to the PEF process, lead to the following analysis.

#### 1. Hazard assessment

Microbial hazards are the main concern throughout the PEF operation. Raw materials contain pathogens and spoilage microbes that may spoil the ingredient or raw material and may be harmful to the consumer. In addition, the storage facilities for raw materials may increase the risk of microbial contamination from soil and water deposits and airborne microorganisms. The cleanliness of processing equipment plays a key role in preventing microbial contamination, because multiple-assembly parts that are not properly sanitized can be a source of microorganisms. Finally, the aseptic packaging operation and storage conditions of the processed product may result in microbial contamination if improper handling of the product occurs.

The chemical hazards to consider are the presence of antibiotic and pesticide residues on raw materials, electrically induced chemical reactions, and excessive detergent-sanitizer residues from processing and packaging equipment.

The physical hazards include foreign matter in raw materials (e.g., stones, rubber, plastic, metals, egg shells), metal particles from the treatment chamber after a spark, and plastic or rubber pieces from seals.

The final risk classification may be defined in terms of the products (e.g., milk, apple juice, eggs, soups, etc.). Six microbiological hazard characteristics, listed in Table 3, as

Figure 2. Schematic diagram af a PEF equipment canfiguratian.



Control Room

TABLE 5. CCP deviations and possible corrective actions in a PEF operation				
ССР	Contral parameter	Deviation	Action	
Raw material				
Receiving & starage	Spailage/particulate	Detected	Reject	
	Starage time	Exceeded	Reject	
	Starage temperature	Above specifi- catians	Adjust temperature Reject	
PEF processing unit	Electric field intensity	Below specifi- cations	Adjust electric field	
			Reprocess product Laboratory analysis	
	Pulsing rate	Belaw specifi- catians	Adjust pulsing rate	
			Reprocess product	
	Flow rate	Above specifi- catians	Adjust flow	
			Reprocess praduct	
	Arcs ar sparks	Detected	Reject	
Finished praduct				
Packaging/storage	Package seal	Leaks	Adjust packaging machine	
			Reprocess/reject	
	Starage temperature	Above specifi- cations	Adjust temperature	
			Laboratary analysis	
			/reject	
	Starage time	Exceeded	Reject	
	Spoilage/particulate	Detected	Reject	

well as chemical and physical hazard characteristics are defined by the National Advisory Committee on the Microbiological Criteria for Foods (NACMCF) and will be used to classify the PEF products. In general, the final hazard classification should range between risk categories IV and VI as defined by the NACMCF. Table 4 illustrates the seven risk categories identified by the NACMCF (5, 9).

#### 2. Critical control points (CCPs) — determination, limits, procedures, and corrective actions

The following CCPs should be selected to ensure the safety of PEF products:

- Receiving and storage section
- PEF treatment section
- Aseptic packaging section

The main factors considered and monitored for each CCP are the handling and processing time, temperature of material, and cleanliness of equipment and utensils. The treatment conditions (electric field intensity, pulsing rate, input voltage, input current, and chamber temperature) should be monitored and recorded on a continuous basis. A uniform PEF treatment requires the design and construction of a pulser that produces variable pulsing rates, charging rates, voltage settings, pulse widths, and pulse shapes. Pulser components such as the power source, computerized controls, triggering mechanism, overloads, dummy loads, and treatment chamber should comply with defined specifications and characteristics such as maximum operating temperature, maximum voltage and current outputs, and reliability (i.e., mean time between failures, yields, etc.). The reliability of the pulser may be measured in terms of number of pulses with correct energy level per unit of time as well as total pulses per unit of time. Monitoring devices may include oscilloscopes for voltage and current measures and pulse counters.

Product: Batch ID:	
A. Row Materials	
Item Description ID Number Amount	
By: Time:	
B. Equipment and Utensils	
Treotment chomber:	
Sterile utensils [] Yes [] No By: Time:	
Totolly disassembled [] Yes [] No By: Time:	Cleoned
with detergent [] Yes [] No By: Time:	Sonifized
with chlorine-200 ppm [] Yes [] No By: lime:	
Kinsed with sterile woter [] Yes [] No by: lime:	
Autocloved - 121°C/15 min [] 165 [] No	
Cleaned with detergant	Sonitized
with delergent [] is [] No By Time_	001111260
Wini children 200 ppin [] les [] No by nine	
Autocloved -121°C/15 min []Yes []No By: Time:	
Aseptic Package	
Number of bogs: Time:	
UV light exposed [] Yes [] No By: Time:	Sonifized
with H <sub>2</sub> O <sub>2</sub> % [] Yes [] No By: Time:	
Rinsed with sterile woter [] Yes [] No By: Time:	
Work Bench	
UV light exposed [] Yes [] No By: Time:	Sonitized
with chlorine - 200 ppm     [] Yes     [] No     By:	
Rinsed with sterile woter [] Yes [] No By: Time:	
Dry ond cleon [] Yes [] No By: Time:	
C. Prepulsing Procedures	
Pulser Setup	
Sofeguords in ploce [] Yes [] No By: lime:	
Compressor "ON" [] Yes [] No By: Ime:	
Setup voltoge:	Operation
Setup requency for pulsing: nz by: file	
Broduct Circulation	
Removed of or bubbles [] Yes [] No By Time:	
Flow role: 1/min By: Time:	Number
of steps: By: Time:	
D. Process Conditions	
Process Parameters:	
Step $1 2 3 4 5 0 7 8 9$	
Peok field ////////////////////////////////////	
Peok current	
In - treotment chomber:	
Out - treotment chomber:	
Holding section length:	
In - cooling coil://////°C	
Out - cooling coil://////°C	
Length of cooling coil/////// m	
Operotor////////	
Packaging	
Aseptic tonk - intermediote [] Yes [] No By: Time:	
Aseptic monuol pockoging [] Yes [] No By: Time:	
Lominor flow hood pock [] Yes [] No By: Time:	
Automatic packoging [] Yes [] No By: Time:	

Standard operating procedures (SOPs) should be in place to define aspects such as receiving, storing, and preparation of raw materials to ensure proper handling and reduce the risk of contamination. The pulsing and packaging units must have procedures to specify the assembly and disassembly of the machinery. Cleaning specifications such as frequency and type of detergents and sanitizers should be established to prevent any type of contamination between products. The operational parameters for PEF treatments must be specified for each product based upon microbial, physical, and chemical characteristics (e.g., initial microbial counts, pH, ionic strength, and composition) as well as the maximum time needed to complete the processing of each food (i.e., time from initial discharge of raw materials to the end of the packaging operation). Alternative procedures must define the corrective actions for deviations from process specifications or CCP limits. Quality assurance procedures must be developed for the approval or rejection of PEF treated products based on the CCP limits and corrective actions (Table 5).

#### 3. Record keeping

Record keeping is a key aspect not only in a PEF operation but in any successful manufacturing operation. The status of raw materials, process and packaging sequence, and storage and shipping procedures must be reflected in the batch or lot documents. Proper design of the documents is an important and difficult task because they must provide enough space for critical measurements without confusing the operator. Table 6 is an example of a batch record intended for a PEF operation, combining the setup and CCP monitoring procedures into a single document.

#### HAZOP PRINCIPLES AND PEF TECHNOLOGY

The main concern of the individuals working in a PEF facility is the voltage intensity, which reaches the kilovolt range. A typical pulser configuration is presented in Figure 2. A high-voltage power supply is selected to charge the capacitors and a discharge switch releases the stored electric energy from the capacitor(s) through the product in the form of an electric field. The power supply, capacitors, and treatment chamber must be confined in a restricted access area with interlocked gates. Opening the gates will turn off the pulser while the power supply is on. Emergency switches must be accessible in case of a process failure. Also, discharging bars must be provided to discharge the elements in the circuit before maintenance or inspection of the unit occurs. To prevent the leakage of high voltage through any fluid (food or refrigerant) in contact with the treatment chamber, all connections to the chamber are isolated and the pipes carrying materials to or from the chamber connected to ground.

Electrical and mechanical devices such as pumps, computers, and packaging machines must be protected using safeguards. Proper warning signs must be in place regarding safety hazards (high voltage, high-intensity electric field) in the processing area. The information related to the operation and maintenance procedures must be contained in standard operating procedures (SOPs). The personnel involved in the PEF operation must be properly trained and instructed in those SOPs.

The selection of appropriate detergents and sanitizers must comply with FDA and USDA/FSIS regulations. Proper protection devices such as face masks or goggles, aprons, boots, and gloves must be used by employees while applying and removing the cleaning solutions. A complete procedure must be in place to define how, when, what, and where to use the cleaning and sanitizing solutions. Proper record keeping is required to avoid contamination of the products with the detergent or sanitizer solutions.

A complete layout of the facility including details about location of utilities, location of equipment, and emergency exits must be available. Changes in the configuration of the facility must be reflected in the layout.

#### **FINAL REMARKS**

The design and construction of a PEF facility for food processing requires both state-of-the-art equipment and common sense. The HACCP principles are key elements to the preparation of a strategy for manufacturing a PEF product, with special attention given to product handling, treatment parameters and equipment cleanliness. Appropriate batch records and procedures must be implemented to ensure the production of a safe product.

Safety to the personnel working in a PEF facility is another key issue in the design and construction of the PEF facility. Proper safeguards must be in place to prevent anyone working with the pulser from an electro-shock as well as to protect the pulser itself.

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## Book Review



#### "Poultry Products Technology"

George J. Mountney, Ph.D. Carmen R. Parkhurst, Ph.D.

he Third Edition of "Poultry Products Technology" is one of the few texts that covers both poultry meat and eggs. The entire spectrum of poultry products is presented, from the live bird through processing, preserving, value-added products, and much more. Likewise, eggs receive complete coverage as well. A real bonus in this book is the chapter on methods of analyses, making the text very useful for us in academics (faculty and students), and also for the egg industry.

This text will be used in many classrooms, especially for those courses that address poultry and egg processing products. Information in this book will also be helpful to consumers via university and industry education and outreach programs. The poultry industry will benefit from chapters that relate to their particular processes and products. For example, the information and formulas on value-added products will help companies get started on new items or allow processors to expand and improve existing product lines. Internationally, many entrepreneurs will be able to obtain a good overview of the entire poultry products industry as they consider initiating new business ventures in poultry marketing.

Although this Third Edition is a complete text on poultry meat and eggs, there are some topics that could be added in a future revision to make it even more comprehensive. For example, advancements in electrical and  $CO_2$  stunning prior to poultry slaughter is an important area. Likewise, some of the recent research findings could be integrated more fully into a next edition. Nevertheless, the Third Edition of "Poultry Products Technology" provides a wealth of information for poultry processors, food scientists, dietitians, consumers and anyone else who wishes to learn about poultry.

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Please TYPE abstract, DOUBLE-SPACED, in the space provided here.

### Call for Entrants in the Developing Scientist Awards Competitions (Supported by Sustaining Members)

IAMFES is pleased to announce 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 Developing Scientist Oral Competition **or** the Developing Scientist Poster Competition.

#### **Purpose:**

- To encourage students and recent graduates to present their original research at the IAMFES Annual Meeting.
- To foster professionalism in students and recent graduates through contact with peers and professional members of IAMFES.
- To encourage participation by students and recent graduates in IAMFES and its Annual Meeting.

#### **Developing Scientist Oral Awards Competition:**

The Developing Scientist Oral Awards Competition is open only to graduate students enrolled in M.S. or Ph.D. programs or recent M.S. or Ph.D. graduates in programs at accredited universities or colleges where research deals with environmental, food or dairy sanitation, protection or safety. Competition entrants cannot have graduated more than one year prior to the deadline for submitting abstracts.

Prior to the Annual Meeting, up to ten finalists will be selected for Competition and awards will be presented at the Annual Meeting to the top three presenters (first, second and third places). Presentations are limited to fifteen minutes which should include two to four minutes for discussion.

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 also receive a complimentary, one-year IAMFES membership including both *Dairy, Food and Environmental Sanitation* and *Journal of Food Protection*.

#### **Developing Scientist Poster Awards Competition:**

The Developing Scientist Poster Awards Competition is open to enrolled undergraduate and graduate students or recent graduates from undergraduate or graduate programs at accredited universities or colleges where research deals with environmental, food or dairy sanitation, protection or safety. **Competition entrants cannot have graduated more than one year prior to the deadline for submitting abstracts**.

Prior to the Annual Meeting, up to ten finalists will be selected for Competition and awards will be presented at the Annual Meeting to the top three presenters (first, second and third places). The presentation must be mounted on an eight feet by four feet  $(8' \times 4')$  display board provided at the Annual Meeting for the duration of the assigned Poster Session. The presenter must be present at his or her poster for the specified time (approximately two hours) during the assigned session.

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 also receive a complimentary, one-year IAMFES membership including both *Dairy, Food and Environmental Sanitation* and *Journal of Food Protection*.

Instructions to Developing Scientist Awards Oral and Poster Competitions Entrants:

- 1. Abstracts must be received by the IAMFES office no later than December 16, 1996.
- In addition to adhering to the general procedures for abstract preparation and submission required of all individuals submitting abstracts, Competition entrants must submit one additional copy of their abstract (i.e., a total of three (3) copies must be submitted). Competition entrants must also mark the appropriate box on the abstract form to indicate their intention to participate in the Developing Scientist Awards Competition and to designate whether it is "oral" or "poster."
- 3. Both the Competition entrant and his or her presentation must be recommended and approved for the Competition by his or her major professor or department head, who must sign the abstract.
- The work must represent original research done by the Competition entrant and must be presented by the Competition entrant.
- 5. Competition entrants may enter only one paper in either the Oral or the Poster Competition.

#### Additional Information:

- Acceptance of papers by IAMFES for presentation at the Annual Meeting is independent of acceptance as a Competition finalist. Competition entrants who are chosen as finalists will be notified of their status by the Competition Chair by May 1, 1997.
- 2. All Competition entrants (not just Competition finalists) with abstracts accepted by IAMFES will receive a complimentary, one-year IAMFES membership which includes their choice of *Dairy, Food and Environmental Sanitation* or *Journal of Food Protection*.
- All Competition finalists will receive a complimentary Awards Banquet ticket and are expected to be present at the banquet where the award winners will be announced and recognized.
- 4. All Competition entrants are required to pay the registration fee (i.e., student member rate, member rate, or nonmember rate). Nonmembers may join IAMFES and receive the member rate.

#### Judging the Developing Scientist Awards Competitions:

Abstracts and presentations will be evaluated by an independent panel of judges. Selection of up to ten finalists for the Developing Scientist Oral and Poster Awards Competitions will be based on evaluations of the abstracts and the scientific quality of the work (see judging criteria). All Competition entrants will be advised of the judges' decisions by May 1, 1997.

Only the Competition finalists will be judged at the Annual Meeting and will be eligible for the awards. All other Competition entrants with abstracts accepted by the IAMFES Program Advisory Committee will be expected to present their papers/posters as part of the regular Annual Meeting program, but their presentations will not be judged and they will not be eligible for the awards.

Judging Criteria for the Developing Scientist Awards Competitions:

#### **ABSTRACT:**

Clarity; comprehensiveness; conciseness.

#### SCIENTIFIC QUALITY:

Adequacy of experimental design; extent to which objectives were met; difficulty and thoroughness of research; validity of conclusions based upon data; technical merit; contribution to science.

#### **ORAL PRESENTATION OR POSTER PRESENTATION:**

Organization (clarity of introduction, objectives, methods, results and conclusions); quality of visuals; quality and poise of presentation and in answering questions.

\*NOTE: Your abstract must be received by the IAMFES office no later than December 16, 1996. Photocopies of the abstract form may be used.

### **IAMFES Policy on Commercialism**

#### 1. INTRODUCTION

No printed media, technical sessions, symposia, posters, seminars, short courses, and/or all related type forums and discussions offered under the auspices of IAMFES (hereafter referred to as IAMFES forums) are to be used as platforms for commercial sales or presentations by authors and/or presenters (hereafter referred to as authors) without the expressed permission of the IAMFES staff or Executive Board. IAMFES enforces this policy in order to restrict commercialism in technical manuscripts, graphics, oral presentations, poster presentations, panel discussions, symposia papers, and all other type submissions and presentations), so that scientific merit is not diluted by proprietary secrecy.

Excessive use of brand names, product names or logos, failure to substantiate performance claims, and failure to objectively discuss alternative methods, processes, and equipment are indicators of sales pitches. Restricting commercialism benefits both the authors and recipients of submissions and presentations.

This policy has been written to serve as the basis for identifying commercialism in submissions and presentations prepared for IAMFES forums.

#### 2. TECHNICAL CONTENT OF SUBMIS-SIONS AND PRESENTATIONS

#### 2.1 Original Work

The presentation of new technical information is to be encouraged. In addition to the commercialism evaluation, all submissions and presentations will be individually evaluated by the Program Advisory Committee (PAC) chair, technical reviewers selected by the PAC chair, session convenor, and/or IAMFES staff on the basis of originality before inclusion in the program.

#### 2.2 Substantiating Data

Submissions and presentations should present technical conclusions derived from technical data. If products or services are described, all reported capabilities, features or benefits, and performance parameters must be substantiated by data or by an acceptable explanation as to why the data are unavailable (e.g., incomplete, not collected, etc.) and, if it will become available, when. The explanation for unavailable data will be considered by the PAC chair and/or technical reviewers selected by the PAC chair in order to ascertain if the presentation is acceptable without the data. Serious consideration should be given to withholding submissions and presentations until the data are available as only those conclusions that might be reasonably drawn from the data may be presented. Claims of benefit and/or technical conclusions not supported by the presented data are prohibited.

#### 2.3 Trade Names

Excessive use of brand names, product names, trade names, and/or trademarks is forbidden. A general guideline is to use proprietary names once and thereafter to use generic descriptors or neutral designations. Where this would make the submission or presentation significantly more difficult to understand, the PAC chair, technical reviewers selected by the PAC chair, session convenor, and/or IAMFES staff will judge whether the use of trade names, etc., is necessary and acceptable.

#### 2.4 "Industry Practice" Statements

It may be useful to report the extent of application of technologies, products, or services, however, such statements should review the extent of application of all generically similar technologies, products, or services in the field. Specific commercial installations may be cited to the extent that their data are discussed in the submission or presentation.

#### 2.5 Ranking

Although general comparisons of products and services are prohibited, specific generic comparisons that are substantiated by the reported data are allowed.

#### 2.6 Proprietary Information (See also 2.2.)

Some information about products or services may be proprietary to the author's agency or company, or to the user and may not be publishable. However, their scientific principles and validation of performance parameters must be described. Conclusions and/or comparisons may only be made on the basis of reported data.

#### 2.7 Capabilities

Discussion of corporate capabilities or experiences are prohibited unless they pertain to the specific presented data.

#### **3. GRAPHICS**

#### 3.1 Purpose

Slides, photographs, videos, illustrations, art work, and any other type visual aids appearing with the printed text in submissions or used in presentations (hereafter referred to as graphics) should be included only to clarify technical points. Graphics which primarily promote a product or service will not be allowed. (See also 4.6.)

#### 3.2 Source

Graphics should relate specifically to the technical presentation. General graphics regularly shown in, or intended for, sales presentations cannot be used.
#### 3.3 Company Identification

Names or logos of agencies or companies supplying the goods or services must not appear on the graphics, except on the first slide of the presentation. Slides showing products may not include predominant nameplates. Graphics with commercial names or logos added as background borders or corners are specifically forbidden.

#### 3.4 Copies

Graphics that are not included in the preprint may be shown during the presentation only if they have been reviewed in advance by the PAC chair, session convenor, and/or IAMFES staff, and have been determined to comply with this policy. Copies of these additional graphics must be available from the author on request by individual attendees. It is the responsibility of the session convenor to verify that all graphics to be shown have been cleared by PAC chair, session convenor, IAMFES staff, or other reviewers designated by the PAC chair.

## 4. INTERPRETATION AND ENFORCEMENT

#### 4.1 Distribution

This policy will be sent to all authors of submissions and presentations in IAMFES forums.

#### 4.2 Assessment Process

Reviewers of submissions and presentations will accept only those that comply with this policy. Drafts of submissions and presentations will be reviewed for commercialism concurrently by both IAMFES staff and technical reviewers selected by the PAC chair. All reviewer comments shall be sent to and coordinated by either the PAC chair or the designated IAMFES staff. If any submissions are found to violate this policy, authors will be informed and invited to resubmit their materials in revised form before the designated deadline.

#### 4.3 Author Awareness

In addition to receiveing a printed copy of this policy, all authors presenting in an IAMFES forum will be reminded of this policy by the PAC chair, their session convenor, or the IAMFES staff, whichever is appropriate.

### 4.4 Monitoring

Session convenors are responsible for ensuring that presentations comply with this policy. If it is determined by the session convenor that a violation or violations have occurred or are occurring, he or she will publicly request that the author immediately discontinue any and all presentations (oral, visual, audio, etc.), and will notify the PAC chair and IAMFES staff of the action taken.

#### 4.5 Enforcement

While both technical reviewers, session convenors, and/or IAMFES staff may check submissions and presentations for commercialism, ultimately it is the responsibility of the PAC chair to enforce this policy through the session convenors and IAMFES staff.

#### 4.6 Penalties

If the author of a submission or presentation violates this policy, the PAC chair will notify the author and the author's agency or company of the violation in writing. If an additional violation or violations occur after a written warning has been issued to an author and his agency or company, IAMFES reserves the right to ban the author and the author's agency or company from making presentations in IAMFES forums for a period of up to two (2) years following the violation or violations.

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**Tim Carr** Mississippi State Dept. of Health Magnolia

Edward M. Course, Jr. Delta Hills Public Health District III Greenwood



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Just a

reminder...

It's time to start planning for the 1997 IAMFES Annual Meeting in Orlando, FL at the Hyatt Regency Grand Cypress Hotel.

July 6-9, 1997



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(307)266-1203

## Pete Herb Promoted at Fristam Pumps

Pete Herb has been promoted to Director of Engineering and Research & Development at Fristam Pumps, Inc., Middleton, WI. Pete has been with Fristam for nearly 8 years. He is responsible for the design, development and improvement of Fristam's product lines, as well as providing technical support for the company and its customers. He holds a BS in Mechanical Engineering from the University of Wisconsin-Madison and a Masters of **Business Administration (Market**ing) from the University of Wisconsin-Whitewater. Fristam congratulates Pete on his new position.

## Sandra T. Larson Joins NAMA as Western Manager and Counsei

S andra T. Larson of Sunland, CA has joined the staff of the National Automatic Merchandising Association (NAMA), as western manager and counsel. Her office will be in the association's western office in Encino, CA.

She replaces Joan Bentler who left NAMA to attend graduate school full-time.

A native of Glendale, CA, Larson attended school in Burbank, CA, graduated from the University of California at Los Angeles and received a law degree from Southwestern University School of Law in Los Angeles. Before joining NAMA, Larson was deputy trial counsel for the State Bar of California in Los Angeles. Previously she was an attorney with the law firm of Clark, White, Hutton, Holmes & Simpson in Glendale and did fund-raising activities for the Boy's Club of Pasadena, CA and United Way of Los Angeles County.

NAMA is the national trade association of the merchandise vending and contract foodservice management business. Its headquarters are in Chicago, with field offices in Reston, VA and Marietta, GA in addition to the office in Encino.

## Tri-Clover Names Regional Manager for Food and Dairy Division

Tri-Clover Inc. has announced the appointment of Owen Skelly as district manager for its Food & Dairy Division.

Skelly will be based in Chicago, IL, and will serve customers and distributors throughout Illinois and Indiana as part of the company's Tri-Clover Team 2000 organization. Skelly joins Tri-Clover from APV Fluid Handling where he served as a regional sales manager based in Corpus Christi, TX.

Tri-Clover is a manufacturer of sanitary stainless steel valves, pumps and fittings, as well as automated flow control and Clean-In-Place systems. Founded in 1919, Tri-Clover Inc., is an Alfa Laval company.

## AFFI Promotes Bishop to Vice President of Industry and Government Affairs

McNair Bishop has been promoted to the position of vice president of industry and government affairs at the American Frozen Food Institute (AFFI). In that

# **UpDates**

role, Bishop will have primary staff responsibility for AFFI's Meat and Poultry Committee, Distribution and Logistics Council, Transportation Committee, and the Superfund Task Force, among other issues. Bishop joined AFFI in January 1995 as director of government affairs.

From 1989 to 1994, Bishop was a lobbyist for the Association of National Advertisers, Inc. (ANA), a trade organization that represents national and regional advertisers. Among her achievements at ANA. Bishop was instrumental in assisting the membership in implementing the Nutrition Labeling and Education Act, and evaluating the impact of the labeling law on advertising. Bishop also organized a coalition that orchestrated a three-year campaign to maintain limits on the authority of the Federal Trade Commission to restrict "unfair" advertising.

Bishop received her bachelor's degree from Davidson College in Davidson, NC.

## Theodore Wiseman Receives Sait Institute's 1996 Tony J. Cunha Award

Theodore Wiseman, a graduate student at Ohio State University in Columbus, Ohio has received the Salt Institute's 1996 Tony J. Cunha Award.

Eight years ago, the Salt Institute initiated this \$1,500 research support award to commemorate Dr. Tony J. Cunha's contributions in promoting the understanding of the role of salt in animal nutrition and to recognize

#### JpDates, contin

the need for research in this important area. The 1996 Award was presented to the graduate student whose proposed research showed the greatest promise of furthering our understanding of the role of salt in animal diets or the benefits of salt as a carrier for trace minerals. Mr. Wiseman hypothesizes that because both Na and Cl are essential for the digestion of protein and the maintenance of homeostasis in the intestinal tract of the pig, an inadequate level of either element will contribute toward poor postweaning performance. Therefore, he hopes to determine the dietary level of NaCl (salt) needed for the 14 day old

weaning pig. The results will help define the mechanism of action of both nutrients for the initial weeks postweaning.

The 1997 Tony J. Cunha Award will be announced in July, 1997. Persons interested in being considered for this prestigious recognition should contact the Salt Institute at 700 North Fairfax, #600, Alexandria, VA 22314, or call (703) 549-4648, or e-mail the Salt Institute at bert@saltinstitute.org. As a nonprofit association representing North American and international salt producers, the Salt Institute was founded in 1914, dedicated to promoting better understanding of all aspects of salt production and use.

## Tom Holdorf Appointed General Manager at Fristam Pumps

Tom Holdorf has been named Senior Vice President and General Manager of Fristam Pumps, Inc., Middleton, WI. Tom has been with Fristam for 10 years. He holds a BS in Industrial Technology from the University of Wisconsin-Stout. We congratulate Tom on his appointment.

Fristam Pumps, Inc. is a leading manufacturer of sanitary centrifugal and positive displacement pumps sold to the food, dairy, beverage, and pharmaceutical/biotech industries.



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**Reader Service No. 108** 

## UGA Breaks Ground on \$7.5 Million Expansion to Center for Food Safety & Quality Enhancement

he University of Georgia College of Agricultural and Environmental Sciences broke ground June 5 for a \$7.5 million expansion to the College's Center for Food Safety and Quality Enhancement (CFSQE).

Located on the campus of the Georgia Experiment Station in Griffin, GA, the Center's principal focus is microbial safety of foods and enhancement of food quality through a research team approach. These teams consist of biochemists, engineers, microbiologists, sensory specialists and food scientists. The CFSQE is home to one of the leading food microbiology teams in the country as well as one of the leading sensory programs in academia.

"Food safety and quality research is at the forefront of the food industry's needs and the addition will enable us to conduct the necessary research," said Dr. Michael Doyle, Director of the Center. "The extramural support we are receiving from the food industry for research is stressing our existing facility and without this addition, we would never be able to meet the growing needs of this industry."

Georgia's Lieutenant Governor Pierre Howard, also present at the ground breaking, saluted the work conducted by the food scientists at the CFSQE. "The scientists here at the Center are fighting to prevent outbreaks of foodborne illnesses such as the deadly *E. coli* which caused the Jack-in-the-Box tragedy," said Howard. "These scientists are fighting to prevent that kind of tragedy from happening to another family again."

Also present at the ground breaking were several food industry representatives including Paul Hall, Director of Microbiology and Food Safety for Kraft Foods, Inc. of



Glenview, IL. Hall described the Center as an investment for the entire food industry, not only in the United States, but worldwide.

James L. Ayres, Director of Research and Development/Quality Assurance for GoldKist Inc. of Atlanta, GA, said the Center serves as a source of "impartial advice and research information" for his corporation.

The 28,000 square feet of expansion to the Center is expected to take 18 months to complete with a tentative completion date set for December 1997.

## Ecolab Completes Monarch Acquisition

colab Inc., the global leader in cleaning and sanitizing products and services for the hospitality, institutional and industrial markets, stated it has completed the previously announced purchase of the Monarch division of H.B. Fuller Company, of St. Paul, MN. Monarch is a provider of cleaning and sanitizing products and services to the food processing and farm markets in the U.S., Canada and Australia.

Details of the transaction were not disclosed.

Ecolab news releases and other investor information are available

on the Internet at http://www. shareholder.com/ecolab/; and by telephone at 1-800-FACT-ECL.

## Dairy Industry Innovator Celebrates 100th Anniversary

n these days of rapidly advancing technology and sophisticated business practices, it's rare to be able to trace the beginnings of a family-run business back to the days of horse and wagon. However, Axelrod, a company founded in the eighteenth century in Brooklyn, NY, can do just that. This year it is celebrating its 100th year in business.

Wolf Axelrod founded the now successful dairy company in 1896. establishing a retail store and wholesale distribution center on Madison Street on the lower east side of New York City. In the company's early days, sour cream, sweet cream, pot cheese (cottage cheese), and farmers cheese were its specialties. The dairy products were manufactured in small cheese factories located in upstate New York, and along the Canadian side of the St. Lawrence River. The business thrived, and in 1920, 24 years after he founded the company, Wolf Axelrod retired.

Abraham Axelrod, the youngest of Mr. Axelrod's five sons, assumed control of the company, concentrating on the distribution of "soft" cultured cheeses, such as cottage cheese and sour cream. Brooklyn continued as the business' headquarters and in 1930 an Axelrod branch was established in Freeport, NY.

Two years later the business was sold to a subsidiary of the National Dairy Products Corporation, now known as Kraft, Inc. Abraham Axelrod spent the next six years with National Dairy Products as general manager of distribution and sales facilities in New York, New Jersey, Philadelphia, and Boston.

#### News, continued

In 1938 Abraham re-established his own dairy products company and named it Axelrod Dairy, keeping the long family tradition intact. He bought products for resale from creameries in New York, Pennsylvania, and Vermont. Along the way, he established strict quality standards for his suppliers, forging a solid reputation for quality and reliability.

In 1949, Axelrod introduced its first packaged product for the consumer – a pint container of yogurt. It was an immediate success, and soon after, cottage cheese and sour cream followed in its packaging footsteps.

On November 27, 1961, Axelrod was sold to Crowley Foods, Inc. Abraham retired that year. His son, Herbert, succeeded Abraham as president and chief operating officer. During Herbert's tenure, the company expanded geographically, opening branches in Paterson, NJ; East Windsor, CT; and Baltimore, MD. Axelrod's headquarters is in Paterson, NJ.

Herbert Axelrod retired in 1988. Today Steve Harper is the chief operating officer. The company enjoys substantial market share in its major areas of distribution (New York City and New Jersey). The company also distributes its products in Baltimore and parts of New England and southern Florida. In most marketing areas, Axelrod-labeled products appear on the dairy shelves of every major retail store. Axelrod is proud to celebrate its 100th year in business.

## Peter Barton Hutt Gives Frazier Memorial Lecture

eter Barton Hutt, formerly with the Food and Drug Administration and now a partner in the law firm of Covington and Burling in Washington, D.C., gave the fifth annual Frazier Memorial Lecture. The lecture was given on May 29, 1996 in conjunction with the annual meeting of the Food Research Institute at the University of Wisconsin.

Hutt spoke on "Reform of FDA Food Regulations." In his remarks, he opined that priorities within the FDA do not reflect the real concerns in food safety. According to Hutt, most FDA commissioners since the 1970s have identified foodborne pathogens as the greatest food safety problem but then failed to properly direct resources. Hutt went on to say we should declare war on food pathogens and demand that the needed resources be devoted to this effort.

The Frazier Memorial Lecture commemorates the life and career of the late Dr. William C. Frazier, a pioneering professor of food and dairy microbiology at the University of Wisconsin-Madison. Earlier Frazier Memorial lecturers include Drs. Douglas Archer, Richard Gilbert, Mitchel Cohen, and Robert Buchanan. The lectureship is administered jointly by the Departments of Food Science, Bacteriology, and Food Microbiology and Toxicology.

## NSF International Prepared to Help Meat and Poultry Companies Comply with New Federal Rules

SF International, a not-forprofit organization based in Michigan, announced that they are ready to assist the meat and poultry industry by offering a food safety and quality registration program, known as the HACCP-9000sM Program, to processing plants throughout the country.

On Saturday, July 6th, President Clinton announced the biggest changes in ninety years, in the rules governing meat and poultry safety, adding science to the tools federal inspectors will use to guard Americans against deadly bacteria. Clinton said the system will be revamped with a scientificallybased food system combined with mandatory microbiological tests to uncover the presence of *E. coli* and *Salmonella* bacteria.

NSF International currently offers the HACCP-9000sm Program as a food safety and quality management system that will greatly assist the meat and poultry industry in following these new rules. NSF's program integrates the food safety principles of HACCP (Hazard Analysis and Critical Control Points), with sanitation requirements as embodied by USDA regulations, with the quality management system of the internationally recognized ISO 9000 standards.

NSF has a network of qualified food safety experts that conduct on-site reviews of a company's food safety (HACCP) plan to ensure that the plan has been satisfactory validated. NSF conducts a full food safety and sanitation audit to verify that the food safety system (HACCP Plan) has been effectively implemented. NSF food safety experts and auditors are supported by NSF laboratories that can conduct microbiological and chemical testing to verify the safety of the food processes.

An NSF registration mark is used to communicate conformance to all stakeholders, government officials, suppliers, and customers. This service also includes a monitoring process with periodic surveillance audits to verify continued conformance.

For more information contact Hoz Vischer, HACCP-9000sM Program, NSF International. (Phone (313) 669-0098 or Fax (313) 669-0196).

## Food Safety Experts Say Temperature Monitoring is Number One Defense for Food Safety and Quality

s President Clinton announced tough new food safety regulations, the meat and poultry industries are turning to new technologies to make food more safe and address a critical issue: temperature monitoring. According to Dr. Steve Otwell, Professor of Food Science at the University of Florida, "Temperature monitoring is the number one defense against quality and safety problems; temperature monitoring needs to be involved in every facet of food production, including handling and packaging."

Already major meat/poultry processors, fast food chains and supermarkets are adopting new technologies to monitor plant, storage and in-transit temperatures. Said Dr. Otwell: "There are a lot of related food safety issues, but temperature is by far the most important. Temperature controls that can influence food safety involve cooling, cooking, heating, reheating and storage. Temperature abuse enhances cross-contamination, chemical and microbiological contaminant problems. The FDA and the USDA have highlighted the issue by making it mandatory that companies monitor critical control points in processing and handling."

## FDA Panel Backs Monsanto on BST Question, but Wants Further Information

n advisory committee to the Food and Drug Administration met last week and concluded that the Monsanto Co. drug BST was not causing additional health problems for dairy cows, but wants further information. The committee also recommended a change in label directions on use of the drug, and that more information should be given farmers on dietary management for cows using BST. The FDA will decide later whether to adopt the recommendations. The recommended label change would warn farmers of increased risk of udder swelling if BST use is not initiated at the recommended ninth week of lactation. About 15 percent of U.S. Dairy cows are treated with BST, which is sold under the brand name Posilac. Monsanto researchers and FDA staff said date indicated no change in the tiny amount of milk rejected for human use because of antibiotic residues. A Michigan State University study, presented to the panel, indicated no difference in mastitis rates between cows using BST and those that did not. Committee members expressed pleasure at the information, but said they wanted to see the results of a study of disease rates in 28 herds using BST on a commercial basis. The panel delayed until November a discussion of whether to require Monsanto to carry out a comparison of milk discard rates between BST and non-BST herds. Monsanto agreed two years ago to conduct the study but indicated that some processors were balking at providing the information.

## FDA Publishes Compounding Guide

n the July 3, 1996, Federal Register, FDA announced the availability of a new Compliance Policy Guide (CPG) entitled, "Compounding of Drugs for Use in Animals." The text of the CPG is included in the Federal Register announcement.

The CPG defines compounding as "any manipulation to produce a dosage form drug other than that manipulation that is provided for in the directions for use on the labeling of the approved drug product, for example, the reconstitution of a sterile powder with sterile water for injection."

The Federal Food, Drug, and Cosmetic Act (the Act) does not distinguish compounding from manufacturing or other processing of drugs for use in animals. Under the Act, compounding is limited to the preparation of drug products which do not meet the definition of new animal drugs. This restriction severely limits the compounding of animal drugs. In the absence of an approved new animal drug application (NADA), the compounding of a new animal drug from any article, including an approved or unapproved finished human or animal drug, or a bulk drug, is a violation of the Act. FDA's Center for Veterinary Medicine recognizes the medical need for compounded animal drugs extending beyond the statutory limitations. This CPG outlines criteria and boundaries for regulatory discretion in respect to the compounding of animal drugs.

When the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) goes into effect, it will allow the "extra-label" use of *approved* animal and human drugs. Under AMDUCA "extra-label" use, which includes compounding, will be subject to conditions specified by regulation. AMDUCA becomes effective after the promulgation of the regulations.

The new Compounding CPG states that FDA recognizes that circumstances exist when it may be necessary for a veterinarian to compound, or direct a pharmacist to compound, an article that will result in an unapproved new animal drug. There is occasionally a need to utilize drugs labeled for human use, and much less commonly, bulk drug substances, for compounding into an appropriate dosage form. The Agency will exercise regulatory discretion and ordinarily will not take regulatory action against if the criteria described in the CPG are met, within the confines of a legitimate practice. The following general criteria apply:

## News, cont

• A legitimate medical need is identified (the health of animals is threatened and suffering or death would result from failure to treat the affected animals),

• There is a need for an appropriate dosage regimen for the species, age, size, or medical condition of the patient, and

· There is no marketed approved animal drug which, when used as labeled or in an extra-label manner in conformity with criteria listed in CPG 615.100 ("Extralabel Use of New Animal Drugs in Food-Producing Animals"), or humanlabeled drug when used in conformity with criteria listed in CPG 608.100 ("Human Labeled Drugs Distributed and Used in Animal Medicine"), may treat the condition diagnosed in the available dosage form, or there is some other rare extenuating circumstance. For example, the approved drug cannot be obtained in time to treat the animal(s) in a timely manner, or there is a medical need for different excipients.

The CPG lists additional specific criteria that should be met and precautions that should be observed if the above conditions are met. Among those criteria are that dispensing should be done by a licensed veterinarian or by receipt of a prescription from a licensed veterinarian by a pharmacist. Dispensing should be within the confines of a valid veterinarianclient-patient relationship. In addition, veterinarians need to take measures to ensure that when used in food-producing animals no illegal residues occur, sufficient time is assigned for drug withdrawal, and

steps are taken to assure that the assigned time frames are observed. In addition, procedures should be instituted to assure that appropriate patient records for the treated animals are maintained. All drugs dispensed to the animal owner by the veterinarian or a pharmacist must bear adequate labeling information. The CPG lists a number of other criteria for the exercise of enforcement discretion.

Copies of the Compliance Policy Guide are available from CVM's Communications and Education Branch at the following address: FDA/Center for Veterinary Medicine Communications and Education Branch, HFV-12, 7500 Standish Place, Rockville, MD 20855.

## Lipton Foodservice Joins Food Safety Sponsors

he Educational Foundation of the National Restaurant Association announces that Lipton Foodservice has become a program sponsor of the Industry Council on Food Safety, as well as the SERVSAFE<sup>©</sup> Serving Safe Food training program.

Lipton's sponsorship will help support a national food safety awareness campaign by the Industry Council on Food Safety, a coalition of foodservice operators, manufacturers, suppliers and associations who are concerned and proactive about food safety. In addition to encouraging industrywide food safety training, this campaign informs the public of the foodservice industry's training commitment and educates consumers about the importance of following food safety procedures.

Lipton is the world's largest tea buying organization, with 100 years of indepth knowledge concerning all aspects of tea and some of the most experienced tea tasters and blenders in North America. As the industry leader, Lipton takes the responsibility seriously when it comes to protecting the integrity of tea and meeting the high quality customers demand.

To participate in the Industry Council, which was formed by The Educational Foundation in 1993, a foodservice operation must verify that at least one manager or professional is trained and certified in the SERVSAFE program. Developed by The Educational Foundation, SERVSAFE has been the industry's leading food safety and sanitation training program for more than 20 years.

As part of the food safety campaign, supported by Lipton, The Educational Foundation has designated September 1996 as the second annual National Food Safety Education Month. The objectives of National Food Safety Education Month are to make food safety training accessible to as many people as possible, and to build public awareness and understanding of the foodservice industry's commitment to serving safe food. All segments of the foodservice industry take part in the National Food Safety Education Month in a variety of ways, including providing or promoting food safety training or participating in the Industry Council on Food Safety.

# Industry **Products**



G & H Products Corporation

## Advanced Control System Reduces Cabling by 95%

The LKM LINK universal remote control system from G&H Products Corp. can control up to 120 valves or pumps within a single loop with only one air line and one cable, reducing cabling and air lines up to 95%.

The LKM LINK system can automate existing components as an economical, universal remote control for processing components in flow systems. As a comprehensive component link, it provides valves and pump motors with data communication facilities and local interface units for remote control.

The system is comprised of an operator's panel, local interface units, and power supply cables. The operator's panel communicates with local interface units, providing communications interface with the host control system. Local interface units receive communication and perform control and monitoring operations, and the cable installation provides data communication and power supply to the electrical units.

The LKM LINK system has low maintenance requirements. The same system is used for all valves. and local control units can be replaced, adjusted, or added independently without taking the system off-line. High operational security is achieved with sensors at each control point, alarms and password protection, a manual mode for system override, and reliable, high speed field bus communication. In addition, the system also offers a high degree of protection against vibration, noise, and harsh processing environments.

G&H Products Corp., Kenosha, WI

Reader Service No. 375

## 6MM Flexible Borescope Provides High Resolution for Inspecting Wide Range of Industrial Equipment

A new high-resolution smalldiameter (6mm) flexible borescope which reaches, magnifies, illuminates and inspects otherwise inaccessible locations of industrial equipment is available from Lenox Instrument Co., Inc. in Trevose.

The flexible fiberoptic scope provides a resolution of .001" – comparable to that of rigid models. Priced thousands of dollars lower than competitive products, it can be snaked through narrow curved sections and obstructions of diesel engines, heat exchangers and many other types of equipment, viewing locations from closeup.

The scope's 6mm flexible probe is available in a variety of lengths, including 40", 60", 80", and 120". It provides direct and right angle viewing through a movable two-way (left or right) articulated tip which the user can easily move in different directions, and lock in place as required.

Two bundles of glass fiber carry light to the inspection area, and convey bright self-illuminated images back to the eyepiece with exceptional coherence for maximum resolution.

A flexible stainless steel jacket protecting the bundles easily slides in and out of the part being inspected and can be maneuvered around sharp corners or elbows without sacrificing brightness or image quality.

The flexible scope incorporates quality features which Lenox developed to meet exacting durability requirements of borescopes which inspect jet engines on military aircraft. These features include being waterproof and submersible.

The scope can be easily fitted with a battery-operated Camcorder to record findings on color videotape, displaying these results on a 3" Liquid Crystal Display (LCD) screen.

Lenox Instrument Co., Inc., Trevose, PA

Reader Service No. 376

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Industry Products, co

## Food Analysis Made Faster & Easier

A dvanced ion selective electrode design expands capabilities. Orion's new *ionplus*<sup>™</sup> Combination Ion Selective Electrodes help you meet your quality control testing requirements. Quickly and accurately measure levels of chloride, nitrate, nitrite, fluoride, iodide, and calcium in a variety of foods and beverages.

These rugged epoxy bodied electrodes feature the exclusive Sure-Flow® reference system, guaranteed never to clog. Cleaning is trouble free with this flushable reference junction.

Eliminate testing problems caused by varying sample temperature and background matrix with the specialized Optimum Results<sup>™</sup> electrode filling solutions. In addition, the methods avoid hazardous chemicals, such as silver nitrate, and are so fast and simple you can test product right at the production line.

Orion Research, Inc., Boston, MA

Reader Service No. 377

## New Image Analysis Software for Power Macintosh™

The newest addition to the Zeiss Image<sup>™</sup> series of image analysis software packages is specifically designed for use with Power Macintosh computers.

The software covers the full range of counting, measurement, image, image enhancement and image archiving applications. Users can employ gray scale or color acquisition, processing and analysis. Zeiss Image For Power Macintosh works scamlessly with other Macintosh-based applications such as Microsoft Excel and Word. It is suitable for both biological and industrial research applications. Carl Zeiss, Inc., Thornwood, NY

Reader Service No. 378



Solatron, Inc.

## Advanced Liquid Density Transducer with Built-in Signal Conversion Simplifies Process Plant Design

Solartron, Inc. has significantly simplified the integration of liquid density transducers into DCS and SCADA systems with the introduction of its range of intrinsically-safe advanced densitometers. Built-in processing in the densitometer head eliminates the need for separate flow computers or signal converters, allowing stand-alone operation, and offering significant savings to process engineers. Industry-standard Modbus and analog outputs facilitate direct connection into control systems. This highly cost-effective range includes densitometers suitable for fiscal metering and processes involving aggressive fluids or demanding hygiene standards.

Solartron's densitometers use the 'vibrating element' principle, a technique thoroughly proven in thousands of installations worldwide. By monitoring the resonant frequency of a known vibrating mass immersed in a liquid, the liquid's line density can be calculated continuously. The technique allows the company's advanced densitometers to offer an accuracy of 0.000lg/cc.

Measured and calculated values are output from the densitometer via two standard 4-20mA analog links; a separate pulse output monitors resonant frequency and provides an alarm status line. The microcontroller contains all necessary calibration data for the densitometer, significantly reducing the on-line programming task for the process engineer. An optional mezzanine board on the microcontroller adds digital HART communications, simplifying programming and data acquisition by a control system. This modular approach allows support for fieldbus protocols to be added as standards evolve.

A simple hand-held or wallmounted terminal is available for insitu monitoring. This intrinsically safe unit communicates with up to 24 densitometers using Modbus protocol over the meter's standard RS485 digital link – enabling it to be located remotely – and provides a convenient means of displaying calculated values or analyzing a system set-up using the densitometer's built-in diagnostic facilities.

Solartron, Inc., Houston, TX

Reader Service No. 379

## X-Ray Inspection Matches Production Line Feeds and Speeds

**Fine Tuned Inspection** – Unobtrusive, compact and portable X-ray based inspection systems represent a major breakthrough for many industries. "X-ray systems can be fine tuned to inspect for a total range of nonconformity and contamination. They can detect foreign bodies in either single or bulk products, in almost any production flow process."

In food processing, the systems detect bone, cartilage or shell fragments in meat, poultry and seafood; or detect glass and metal fillings in canned foods, glass or plastic containers. Also, the systems detect metal slivers, rubber and other foreign bodies in tobacco products. X-rays inspect beverages packaged in metal glass or plastic containers; and pre-packaged candy, cereal, frozen foods, dairy products, for both contamination and correct quantity.

Digitial X-Ray Technology – Digital X-ray screening uses a narrow focus fan beam, which scans objects in defined "slices." An array of photodiodes senses the varying intensities of the beam within the narrow slice. Information gathered is stored in digital form before an image is displayed on a monitor. The travel speed of the object being inspected precisely matches the clock span speed of the diodes so that the data presents a clear picture.

NIS real-time systems view objects while they are in motion, then present a three-dimensional image to an operator. The systems focuses the X-ray beam on a fluorescent screen, while at the same time, a CCD camera views the image on a monitor. An image intensifier makes the video image clearer and brighter. The picture is presented in a clear concise manner that distinguishes small objects present in a diffused background. Computer enhancement further clarifies the pictures.

X-Ray In Action – NIS's FBD X-ray system operates as follows. A flat conveyor belt carries products through a low energy, X-ray beam and detector. Every image captured by the camera(s) contain information in the form of light intensity levels; or levels of gray, varying in value from 0 (black) to 255 (white). Typically, the image being examined has a very low contrast; a foreign object will show up as darker gray against a lighter gray background.

NIS's FBD X-ray system's computer continuously monitors the data of changing densities and once a variation is found, the package or product is tracked until it reaches a reject device, where it is automatically removed. The FBD system can interface with either a conveyor or a pipeline inspection point. It can run automatically without an operator.

Nationwide Inspection Systems, Inc., Largo, FL





Ryan Instruments, Inc.

## Introducing the NEW Handheid Printer for Use with RL100 and PRO Temperature Monitors

Ryan Instruments has announced the introduction of its new handheld printer for the RL100 and PRO temperature monitors. This printer allows those users who do not have immediate access to a PC to download data from either the RL100 or PRO temperature recorders. Users will be able to retrieve data in the form of graphs, header information and summary reports. The data still is stored in the recorder and if at a later date the user wants to download the data to their PC they may. Ryan has made this printer easy to use. It comes complete, ready for use, with cable, connector and paper. All one has to do is plug in and press the print button - quick, easy and convenient.

Take the printer to remote locations, or use when a PC is not available. The printer adds another new dimension to using the Ryan RL100 and Ryan PRO recorders. When more printer supplies are needed, such as printer ribbon and paper, they are easily purchased at most office supply stores. This easyto-use printer runs on either battery or 120 VAC power. The battery can be recharged overnight.

Ryan Instruments, Redmond, WA

Reader Service No. 381

## 3M Introduces Convenient Redigel Pectin Gel Testing Products

3 M has introduced convenient 3 M Redigel tests –sample ready testing products–for the food and beverage industry.

Because the media is already prepared, Redigel testing methods are quick and easy. There is no need for sterilization, beakers, test tubes and other media preparation apparatus. The broad product line provides testing for acidophilic microbes, yeast and molds, aerobic bacteria, coliforms and other bacteria.

Redigel tests, used for monitoring a facility's environment or testing for food quality, are an alternative to conventional pour plate testing methods. Now they are backed by technical support and service from 3M Microbiology.

3M Redigel Products, St. Paul, MN

Reader Service No. 382

## Cutting Boards Certified To Meet FDA Requirements! **REQUIRE HACCP** SAFE CUTTING BOARDS WITH NSF LOGO EMBOSS!

New Technology Makes **NSF-Certified Boards** Easy To Spot!

Most plastic cutting boards are not safe for direct food contact! While any cutting board supplier can claim their boards meet FDA requirements, very few plastic cutting boards sold for use in commercial foodservice actually do meet those federal requirements or your state health code.

The problem has always been health inspectors have had no way of evaluating safe cutting boards from non-durable, absorbent, non-sanitizable, unsafe boards. Until now! Now, the technology exists to help you distinguish boards which meet FDA requirements and are NSF-certified to prove it. And when you consider that almost every food which passes through a commercial kitchen touches a cutting board, the ability to tell safe from unsafe boards is critical.

All Kolor-Cut Cutting Boards from KatchAll are NSF-certified for direct food contact -- and it clearly shows that fact right on the board! There can be no mistakes or uncertainty when you require foodservice operators to use cutting boards with the NSF logo embossed into the material from which the board is made.

## Kolor-Cut Features

- Meets Board of Health (FDA) requirements for food contact
- NSF emboss for "no-mistake" safety
- Protects against cross-contamination
- Solid color for easy identification from any distance
- Dishwasher, pot sink & sanitizer safe
- Non-porous, non-absorbent
- No special care requirements

KOLOR-CUT WITH NSF LOGO ID -- Another Quality Product in the KatchAll HACCP System!

atchAll Industries International. Inc. 5800 Creek Road Cincinnati, Ohio 45242

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## Volunteers Needed to Set Industry Standards

The Steering Committee of the 3-A Sanitary Standards Program has approved requests to organize two new Task Committees to develop new 3-A Sanitary Standards. In addition a preexisting Task Committee will be reactivated to develop new standards and two holdover projects are moving ahead.

A Task Committee is being formed to develop new 3-A Sanitary Standards for hygienic mechanical seals. A second Task Committee is required for the development of standards for spray balls, other mechanical cleaning devices and product spray devices. Both groups will meet toward the end of the 1996 calendar year.

The Ingredient Feeders Task Committee will be reactivated to develop new 3-A standards for liquid (screw-type) ingredient feeders. The 3-A Steering Committee recommended that a proposal be presented to the User Group during the May 1997 Annual 3-A Committees Meeting. This group is also expected to meet late in 1996. Two holdover projects on 3-A accepted practices 603-06 for HTST (High Temperature, Short Time) to provide pressure differential in cooling sections and new standards for clarifiers/separators will be scheduled in early 1997.

Parties interested in any of the above activities are asked to contact 3-A Secretary Dr. Thomas Gilmore, at DFISA, phone 703-761-2600, fax 703-761-4334, or write to: 1451 Dolley Madison Blvd., McLean, VA 22101.

The 3-A Sanitary Standards Committees were founded by the Milk Industry Foundation (MIF), the International Association of Milk, Food and Environmental Sanitarians (IAMFES) and the Dairy & Food Industries Supply Association in the 1920s. The objective of the group is to formulate standards and accepted practices for the equipment and systems used to process milk and milk products and other perishable foods. These standards are developed through the cooperative efforts of local, state and federal sanitarians, equipment manufacturers and equipment users, so that they are acceptable to those involved in the sanitary aspects of the dairy and related food industries.

# **3-A Sanitary Standards Actions** May 1996

Twenty-one documents were passed during the Annual Meeting of the 3-A Sanitary Standards Committees held this past May. These documents include four new standards, five revisions to standards or practices, and twelve amendments to standards or practices. Two 3-A Sanitary Standards were rescinded and combined to form a new standard, and two E-3-A Sanitary Standards were rescinded.

## The new standards are:

- 3-A Sanitary Standards for Centrifugal and Positive Rotary Pumps for Pumping, Cleaning, and Sanitizing Solutions, Number 47-00, effective November 24, 1996.
- 3-A Sanitary Standards for Ball Valves for Milk and Milk Products, Number 68-00, effective November 23, 1996.
- 3. 3-A Sanitary Standards for Shear Mixers and Agitators, Number 73-00, effective November 24, 1996.
- 3-A Sanitary Standards for Belt-Type Ingredient Feeders, Number 75-00, effective November 24, 1996.

## The revised standards and practices are:

- 3-A Sanitary Standards for Centrifugal and Positive Rotary Pumps for Milk and Milk Products, Number 02-09, effective November 24, 1996.
- 3-A Sanitary Standards for Homogenizer and Reciprocating Pumps, Number 04-50, effective November 24, 1996.
- 3. 3-A Sanitary Standards for Formers, Fillers, and Sealers of Containers for Fluid Milk and Fluid Milk Products, Number 17-08, effective November 23, 1996.
- 3-A Sanitary Standards for Thermoplastic Plug-Type Valves for Milk and Milk Products, Number 52-02, effective November 23, 1996.
- 3-A Accepted Practices for Design, Fabrication, and Installation of Milking and Milk Handling Equipment, Number 606-04.

## The twelve amendments are:

- Amendments to 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-18, effective August 23, 1996.
- Amendment 1 to 3-A Sanitary Standards for Silo-Type Storage Tanks for Milk and Milk Products, Number 22-06, effective November 23, 1996.

- 3. Amendment 1 to 3-A Sanitary Standards for Equipment Packaging Dry Milk and Dry Milk Products, Number 27-02.
- Amendment 1 to 3-A Sanitary Standards for Mechanical Conveyors for Dry Milk and Dry Milk Products, Number 41-00.
- Amendment 1 to 3-A Sanitary Standards for Air or Hydraulically Driven Diaphragm Pumps for Milk and Milk Products, Number 44-01, effective November 24, 1996.
- Amendment 3 to 3-A Sanitary Standards for Diaphragm-Type Valves for Milk and Milk Products, Number 54-00, effective November 23, 1996.
- Amendment 1 to 3-A Sanitary Standards for Boot Seal-Type Valves for Milk and Milk Products, Number 55-00, effective November 23, 1996.
- Amendment 1 to 3-A Sanitary Standards for Tank Outlet Valves for Milk and Milk Products, Number 57-00, effective November 23, 1996.
- 9/10. Amendments 1 and 2 to 3-A Sanitary Standards for Hose Assemblies for Milk and Milk Products, Number 62-00, effective November 23, 1996.
  - Amendment 1 to 3-A Sanitary Standards for Sanitary Fittings for Milk and Milk Products, Number 63-00, effective November 23, 1996.
  - Amendment 1 to 3-A Accepted Practices for Method of Producing Steam of Culinary Quality, Number 609-01, effective November 23, 1996.

The 3-A Sanitary Standards for Instrument Sensors and Sensor Fittings and Connections Used on Milk and Milk Products Equipment, Number 09-09 and 3-A Sanitary Standards for Pressure & Level Sensing Devices, Number 37-01 were rescinded, effective November 24, 1996. These two documents were combined to form a new standard, 3-A Sanitary Standards for Sensor and Sensor Fittings and Connections Used on Milk and Milk Products Equipment, Number 74-00, effective November 24, 1996.

The two documents that were rescinded were E-3-A Sanitary Standards for Liquid Egg Products Cooling and Holding Tanks, Number E-1300 and E-3-A Sanitary Standards for Fillers and Sealers of Single-Service Containers for Liquid Egg Products, Number E-1700, effective May 20, 1996.

For more information on the 3-A Sanitary Standards Program, contact Dr. Thomas Gilmore, 3-A Secretary, 1451 Dolley Madison Boulevard, McLean, VA 22101, Phone (703-761-2600), Fax (703-761-4334). Datry, Food and Environmental Sanitation, Vol. 16, No. 9, Pages 585-593 Copyright© IAMFES, 6200 Aurore Ave., Suite 200W, Des Moines, IA 50322

## 3-A Sanitary Standards for Formers, Fillers, and Sealers of Containers for Fluid Milk and Fluid Milk Products, Number 17-08

Formulated by

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

It is the purpose of the IAMFES, USPHS, and DIC in connection with the development of the 3-A Sanitary Standards program to allow and encourage full freedom for inventive genius or new development. Specifications for formers, fillers, and sealers of containers for fluid milk and fluid milk products heretofore and hereafter developed which so differ in design, material, fabrication, or otherwise as not to conform with the following standards, but which, in the fabricator's opinion, are equivalent or better, may be submitted for the joint consideration of the IAMFES, USPHS, and DIC at any time. **NOTE:** Use current revisions or editions of all referenced documents cited herein.

## A SCOPE

- A1 These standards cover the sanitary aspects of unitized equipment for forming, filling, and sealing containers for fluid milk and fluid milk products. The equipment shall perform one or more of the following functions: 1) forming the container, 2) applying and sealing a supplementary fitment or device, 3) filling the container and 4) sealing, including capping if part of the unitized equipment, the container. The equipment shall start at the points where the product, utilities (air, water, steam, cleaning chemicals, etc.), container, container blank, or container material first enters the unitized equipment. The equipment shall end where the formed, filled, and/or sealed container exits the equipment.
- A2 These standards do not pertain to the container, to free-standing container forming equipment or to other equipment such as labelers, printers, daters, cappers, applicators of supplementary fitments or devices or wrappers not furnished as part of the unitized equipment, nor shall it apply to fillers of viscous products, such as frozen desserts, cottage cheese, cultured yogurt, sour cream, whipped butter, cream cheese, and other similar viscous dairy products.
- A3 In order to conform with these 3-A Sanitary Standards, formers, fillers, and sealers of containers shall comply with the following design, material, and fabrication criteria.

## **B DEFINITIONS**

- B1 *Product:* Shall mean fluid milk or fluid milk products, such as whole milk, low-fat milk, skim milk, half and half, creams, cultured buttermilk, frozen dessert mixes, and similar fluid milk products.
- B2 *Container:* Shall mean a package or material being formed into the package, or a packaging construction including one or more of a package body, cap, closure, cover, supplementary device (such as a dispensing fitment), or other structure capable of holding the product.
- B3 *Mechanical Forming Equipment*: Shall mean the equipment for performing all or part of the following integral functions without manual contact with any product contact surface of the container: feeding, opening, seaming, forming, or sealing, and all parts which are essential to those functions that are furnished as a unit by the manufacturer.
- B4 *Mechanical Filling Equipment:* Shall mean the equipment for filling the container with the product without manual contact with any product contact surface of the container.
- B5 *Mechanical Opening Equipment:* Shall mean the equipment for opening a container without manual contact with any product contact surface of the container.
- B6 *Mechanical Sealing Equipment*: Shall mean the equipment for closing and/or sealing the filled container without manual contact with any product contact surface of the container.

#### B7 Surfaces

- B7.1 *Product Contact Surfaces:* Shall mean all surfaces which are exposed to the product during normal equipment operation, surfaces from which liquids may drain, drop, diffuse, or be drawn into the product or into the container, and surfaces that touch product contact surfaces of the container.
- B7.2 Solution Contact Surfaces: Shall mean the interior surfaces of the equipment or system which are used exclusively for supply and recirculation of cleaning and/or sanitizing solutions, except those used to supply concentrated cleaning and/or sanitizing materials to the point of use.
- B7.3 Nonproduct Contact Surfaces: Shall mean all other exposed surfaces except Sterilant Contact Surfaces and Splash Contact Surfaces.
- B7.3.1 Splash Contact Surfaces: Shall mean other nonproduct contact surfaces that during normal use are subject to accumulation of soil and which require routine cleaning.
- B7.4 Sterilant Contact Surfaces: Shall mean the interior surfaces of the equipment or system which are used exclusively for the supply and recirculation of sterilizing solutions.
- B8 Cleaning
- B8.1 Mechanical Cleaning or Mechanically Cleaned: Shall mean soil removal by impingement, circulation, flowing chemical detergent solutions, and water rinses onto and over the surfaces to be cleaned, by mechanical means in equipment specifically designed for this purpose.
- B8.2 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.
- B9 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 cycles (99.999%) to 7 log cycles (99.99999%) by applying accumulated hot water or steam or by applying an EPA registered sanitizer according to label directions. Sanitizing may be effected by mechanical or manual methods.
- B10 *Sterilization:* Shall mean a process effected by heat, chemicals, or other mechanical means that destroys all vegetative bacteria and inactivates relevant bacterial spores.

- B11 Surface Modification<sup>1</sup>
- B11.1 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.
- B11.1.1 Surface treatments may include:
  - Mechanical (shot peening<sup>2</sup>, glass beading, polishing)
  - 2) Thermal (surface hardening by laser, electron beam)
  - 3) Diffusion (carburizing, nitriding)
  - 4) Chemical (etching, oxidation)
  - 5) Ion Implantation
  - 6) Electropolishing
- B11.2 *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.
- B11.2.1 Coating processes may include:
  - 1) Chemical (conversion coatings)
  - 2) Electrodeposition<sup>3</sup>
  - Spraying (pneumatic, flame, plasma, arc spray)
  - 4) Physical Vapor Deposition
  - 5) Chemical Vapor Deposition
  - 6) Centrifugal Casting
- B12 Arithmetical Mean  $(R_a)$ : Shall be the arithmetical mean of the absolute values of the profile departure within a sampling length.<sup>4</sup>
- B13 Supplementary Fitment or Device: Shall mean any component or assembly which is attached to the container. Examples include but are not limited to pour spouts, closures, handles, and tamper evident scals.
- B14 *Readily or Easily Removable:* Shall mean quickly separated from the equipment with the use of simple hand tools if necessary.
- B15 *Easily or Readily Accessible:* Shall mean a location which can be safely reached by an employee from the floor, platform, or other permanent work area.
- B16 Simple Hand Tools: Shall mean implements normally used by operating and cleaning personnel such as a screwdriver, wrench, or hammer.
- C MATERIALS

C1 Metals

C1.1 All product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI) 300 Series<sup>5</sup> or corresponding Alloy Cast Institute (ACI)<sup>6</sup> types (See Appendix, Section E.), or metal which under conditions of intended use is at least as corrosion resistant as stainless steel of the foregoing types and is nontoxic and nonabsorbent, except that:

C1.1.1 Those surfaces of container forming, closing, and sealing devices which are product contact surfaces may be made of a nontoxic, nonabsorbent metal which can be adequately manually cleaned and that is corrosion resistant under conditions of intended use; or may be made of metal made corrosion resistant and wear resistant by a covering of an electrodeposited coating of chromium and/or nickel, electroless nickel,<sup>7</sup> or an equally corrosion and wear-resistant nontoxic metal. (See Appendix, Section F.)

## C2 Nonmetals

C2.1 Where materials having certain inherent functional purposes are required for specific applications, such as rotary seals, carbon and/or ceramic materials may be used. Carbon and/or ceramic materials shall be inert, nonporous, nontoxic, nonabsorbent, insoluble, and resistant to scratching, scoring, and distortion when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization.

C2.2 Rubber or rubber-like materials may be used for filling nozzles, plungers, gaskets, diaphragms, scaling rings, O-rings, rollers, belts, or conveyors, drip shields, protective caps for sanitary connections, container forming and closing parts, filling valve parts, seals, flexible tubing, hoses, and parts having the same functional purpose.

C2.2.1 Rubber and rubber-like materials, when used for specific applications, shall comply with the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-.

C2.3 Plastic materials may be used for filling nozzles, plungers, gaskets, diaphragms, sealing rings, O-rings, rollers, belts, or conveyors, drip shields, protective caps for sanitary connections, container forming and closing parts, filling valve parts, seals, flexible tubing, hoses, and parts having the same functional purpose.

C2.3.1 Plastic materials, when used for specified applications, shall comply with the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Plastic Materials Used on Product Contact Surfaces for Dairy Equipment, Number 20-. C2.4 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.

- C2.5 Rubber and rubber-like materials and plastic materials having product contact surfaces shall be of such composition as to retain their surface and conformational characteristics when exposed to conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization.
- C2.6 The final bond and residual adhesive, if used, of bonded rubber and rubber-like materials and bonded plastic shall be nontoxic.<sup>8</sup>

C2.7 Single service gaskets of a sanitary type may be used on parts which must be disassembled for daily cleaning.

C3 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 packaging equipment and nonmetallic component parts shall be such that they can be (1) sterilized by saturated steam or water under pressure (at least 15.3 psig or 106 kPa) at a temperature of at least 250°F (121°C) and (2) operated at the temperature required for processing.

## C4 Nonproduct Contact Surfaces

C4.1 All nonproduct contact surfaces shall be of corrosion-resistant material 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 General Fabrication Requirements
- D1.1 Surface Texture
- D1.1.1 All product contact and solution contact surfaces shall have a finish at least as smooth as an  $R_a$  of 32 µin. (0.80 µm) (No. 4 Finish) and be free of imperfections such as pits, folds, and crevices in the final fabricated form (See Appendix, Section G), except that:
- D1.1.1.1 Rollers used to apply sterilizing chemicals by contact to the product contact surfaces of the package material may have a surface finish at least as smooth as an R<sub>a</sub> finish of 125 μin. (3.18 μm).

### D1.2 Permanent Joints

D1.2.1 All permanent joints in metallic product contact surfaces shall be continuously welded. Welded areas on product contact surfaces shall be at least as smooth as an R<sub>a</sub> of 32 μin. (0.80 μm) (No. 4 finish) and be free of imperfections such as pits, folds, and crevices.

## D1.3 Bonded Materials

D1.3.1 Bonded rubber and rubber-like materials and bonded plastic materials having product contact surfaces shall be bonded in a manner that the bond is continuous and mechanically sound, so that when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization the rubber and rubber-like material or the plastic material does not separate from the base material to which it is bonded. Excess bonding adhesive shall be removed.

## D1.4 Hoses and Flexible Tubing

D1.4.1 Hoses and flexible tubing, with attached sanitary fittings used for flexible connections shall meet the requirements of 3-A Sanitary Standards for Hose Assemblies for Milk and Milk Products, Number 62-.

## D1.5 Coatings

- D1.5.1 The thickness of electrodeposited coatings on product contact surfaces shall not be less than 0.0002 in. (0.005 mm), except that when these surfaces are other than stainless steel, the thickness of electrodeposited coatings shall not be less than 0.002 in. (0.05 mm).
- D1.5.2 Coatings of electroless nickel alloy, as specified in C1.1.1, shall conform to the applicable provisions of MIL-C-26074E NOT 2, as amended.
- D1.5.3 The minimum thickness of coating of electroless nickel alloy, as specified in C1.1.1, shall be 0.002 in. (0.05 mm).

## D1.6 Cleaning and Inspectibility

- D1.6.1 Equipment that is to be mechanically cleaned shall be designed so that the product contact surfaces of the equipment and all nonremovable components of the equipment can be mechanically cleaned and are easily accessible and readily removable for inspection employing simple hand tools.
- D1.6.2 Product contact surfaces not designed to be mechanically cleaned shall be easily accessible for cleaning and inspection either when in an installed position or when removed. Demountable parts shall be readily removable.

## D1.7 Draining

- D1.7.1 All product contact surfaces shall be selfdraining or self-purging except for normal clingage.
- D1.7.2 If filler bowl product contact surfaces are not self-draining, the filler bowl shall have sufficient pitch to suitable drain points so the filler bowl can be drained.

## D1.8 Filler Bowls

- D1.8.1 All filler bowls shall be effectively enclosed or covered and covers shall be self-draining.
- D1.8.1.1 Filler bowls or tanks not designed for mechanical cleaning or sterilization with pressurized steam shall be equipped with covers which (1) shall be sufficiently rigid to prevent buckling, (2) if provided with handles, the handles shall be adequate, durable, conveniently located and of sanitary design, welded in place or formed into the cover materials, and, (3) unless gasketed and clamped, shall have downward flanges not less than 3/8 in. (10 mm) along all edges. The edges of all cover openings shall extend upward at least 3/8 in. (10 mm) or be fitted with a permanently attached sanitary pipeline connection conforming to D1.17 or D1.18.
- D1.8.1.2 Openings in the bowl cover, except those fitted with a permanently installed sanitary instrument connection, shall be provided with covers having a downward flange of not less than 1/4 in. (6 mm) so designed as to prevent liquid from entering the filler tank.
- D1.8.1.3 Systems in which the filler bowls are subjected to vacuum shall be designed to prevent the movement of gasketing materials or the ingress of contamination while under expected levels of negative pressure.
- D1.8.1.4 The bottom of the filler tank(s) shall have a minimum pitch of 1/8 in. per ft. (10 mm per m) toward the outlet(s).
- D1.8.2 The filling equipment shall be so designed that adjustments necessary during the operation may be made without raising or removing the filler bowl cover(s).

## D1.9 Gaskets

- D1.9.1 Gaskets having a product contact surface shall be removable or bonded.
- D1.9.2 Grooves in gaskets shall be no deeper than their width, unless the gasket is readily removable and reversible for cleaning.
- D1.9.3 Gasket retaining grooves in product contact surfaces for removable gaskets shall not exceed 1/4 in. (6 mm) in depth or be less than 1/4 in. (6 mm) wide except those for standard O-rings smaller than 1/4 in. (6 mm) and those provided for in Section D1.17.

- D1.10 Radii
- D1.10.1 All internal angles of less than 135° on product contact surfaces shall have radii of not less than 1/4 in. (6 mm), except that:
- D1.10.1.1 Radii of 1/32 in. (1 mm) may be used when they are required for essential functional reasons, such as those in filler nozzles.
- D1.10.1.2 The radii in grooves in gaskets or gasket retaining grooves shall not be less than 3/32 in. (2 mm), except for those for standard 1/4 in. (6 mm) and smaller O-rings and those provided for in Sections D1.17 and D1.18.
- D1.10.1.3 Radii in standard O-ring grooves for standard 1/4 in. (6 mm) O-rings shall not be less than 3/32 in. (2 mm) and for standard 1/8 in. (3 mm) O-rings shall be not less than 1/32 in. (1 mm).
- D1.10.1.4 The minimum radii for fillets of welds in product contact surfaces shall be not less than 1/4 in. (6 mm) except that the minimum radii for such welds may be 1/8 in. (3 mm) when the thickness of one or both parts joined is less than 3/16 in. (5 mm).
- D1.11 Shields and Guards
- D1.11.1 Shields or guards shall be provided as necessary and shall be so designed to be selfdraining and located to prevent liquid or other contaminants from draining or dropping into the container or product, or onto the product contact surfaces, except that:
- D1.11.1.1 Shields and guards may not be required in equipment designed to provide a controlled environment such as an enclosure pressurized with sterile air or inert gas, or an environment controlled by flowing air rendered sterile by incineration, filtration, irradiation, or other means to adequately prevent contamination.
- D1.11.2 Shields shall be easily cleaned.
- D1.11.3 When packaging material rolls are used, the packaging material product contact surface shall be protected from contamination when installed on the machine.
- D1.11.4 Each fill valve or valve block shall have a deflector shield installed at the lowest practical location in such a manner that it will collect the maximum amount of condensate draining from the exterior of the valve or valve block and discharge it to waste away from the open container, except that:
- D1.11.4.1 Deflector shields may not be required in a system designed to prevent the formation of condensate in critical areas. The formation of condensate may be prevented by:
  - 1. Maintaining a valve block temperature higher than the dew point of its operating environment. Methods include but

are not limited to: preventing heat transfer from the product to the exterior of the valve block, warming the valve block, or chilling the ambient air.

- 2. Dehumidifying the ambient air.
- Maintaining a flow of unsaturated air, across the valve block, of sufficient volume and velocity to prevent the formation of condensate.
- D1.11.4.2 Deflector shields may be required if the exterior of the fill valve is subject to chemical sprays.
- D1.11.5 When an enclosure is provided around the filling system, shields which are outside of such an enclosure shall not drain into the filling enclosure.
- D1.11.6 Shields which are made up of several independent parts shall overlap in such a manner as to prevent condensate from draining between the individual parts.
- D1.11.7 Any guard(s) required by a safety standard shall permit accessibility for cleaning and inspection.
- D1.12 Threads
- D1.12.1 There shall be no exposed threads on product contact surfaces except as provided in D1.16.
- D1.13 Threads on Splash Contact Surfaces
- D1.13.1 There shall be no exposed threads on splash contact surfaces, except that:
- D1.13.1.1 Exposed threads are permitted on removable clamps or other components which can be easily removed for cleaning.
- D1.13.1.2 Exposed threads are permitted when required for essential functional reasons. Such exposed threads shall be easily accessible for cleaning.

## D1.14 Metal Tubing

- D1.14.1 All metal tubing shall comply with the applicable provisions of the 3-A Sanitary Standards for Polished Metal Tubing, Number 33-.
- D1.15 Flow Meters
- D1.15.1 Product flow meters, if used, shall conform with the applicable provisions of 3-A Sanitary Standards for Flow Meters for Milk and Liquid Milk Products, Number 28-.

## D1.16 Product Pumps

D1.16.1 Product pumps, if used, shall conform with the applicable provisions of 3-A Sanitary Standards for Centrifugal and Positive Rotary Pumps for Milk and Milk Products, Number 02-, 3-A Sanitary Standards for Homogenizers and Pumps of the Plunger Type, Number 04-, or 3-A Sanitary Standards for Air Driven Diaphragm Pumps for Milk and Milk Products, Number 44-.

#### D1.17 Fittings and Connections

D1.17.1 All sanitary fittings and connections shall conform with the applicable provisions of the 3-A Sanitary Standards for Fittings, including Numbers 59- (Automatic Positive Samplers), 60- (Rupture Discs), 62- (Hose Assemblies), 63- (Sanitary Fittings), and 65- (Sight and/or Light Windows and Sight Indicators) for Milk and Milk Products.

## D1.18 Instrument Connections

D1.18.1 All instrument connections having product contact surfaces shall conform to the 3-A Sanitary Standards for Sensor and Sensor Fittings and Connections Used on Milk and Milk Products Equipment, Number 74-.

#### D1.19 Sanitary Valves

- D1.19.1 All sanitary valves shall conform with those applicable provisions of 3-A Sanitary Standards for Valves, including Numbers 51- (Plug-Type Valves), 52- (Thermoplastic Plug-Type Valves), 53- (Compression-Type Valves), 54- (Diaphragm-Type Valves), 55- (Vacuum Breakers and Check Valves), and 64- (Pressure Reducing and Back Pressure Regulating Valves) for Milk and Milk Products.
- D1.20 Springs
- D1.20.1 Coil springs having product contact surfaces shall have at least 3/32 in. (2 mm) openings between coils including the ends when the spring is in a free position. Coil springs shall be readily accessible for cleaning and inspection.

## D1.21 Sight and Light Openings

D1.21.1 Sight and light openings into product contact surfaces, when provided, shall be of such design and construction that the inner surfaces drain inwardly; if the equipment is designed for mechanical cleaning, the inner surface of the glass shall be relatively flush with the inner surface of the product contact surface. The exterior flare shall be pitched so that liquids cannot accumulate. The glass shall be readily removable. The inside diameter or smallest dimension of the opening shall be at least 3 3/4 in. (95.25 mm).

## D1.22 Supports

D1.22.1 The equipment shall be mounted on legs or casters that will provide a clearance between the lowest fixed point on the equipment and the floor of at least 4 in. (100 mm) when the base outlines an area in which no point is more than 12 1/2 in. (320 mm) from the nearest edge, or a clearance of at least 6 in. (150 mm) when any point is more than 12 1/2 in. (320 mm) from the nearest edge.

- D1.22.1.1 Legs, if provided, 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.
- D1.22.1.2 Casters, if provided, shall be durable and of a size that will permit easy movement of the equipment.

## D1.23 Guards and Other Safety Devices

D1.23.1 Guards required by a 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.

## D1.24 Recirculated Cooling Media

D1.24.1 Recirculated cooling media shall be nontoxic and properly protected. Mandrels, piping, and other equipment cooled by recirculated cooling media shall be designed to preclude leakage of cooling media or condensate into product or onto product contact surfaces.

## D1.25 Nonproduct Contact Surfaces

D1.25.1 Nonproduct contact surfaces shall have a smooth finish, be free of pockets and crevices, and shall be readily cleanable. Surfaces to be coated shall be effectively prepared for coating.

#### D1.26 Information Plates

- D1.26.1 Where manufacturers provide an information plate, this plate shall be affixed to a surface in such a manner as to be effectively sealed.
- D1.26.2 The information plate shall also provide the following information: "This packaging equipment **[Insert one of the following]** designed for steam sterilization.

(a) is (b) is not

- D1.26.3 This packaging equipment is designed with these fittings and design criteria to be part of an aseptic processing system where applicable.
- D2 Special Fabrication Requirements Formers, fillers and sealers shall also comply with the following fabrication criteria when applicable to the specific filler type.
- D2.1 Defoamer Systems
- D2.1.1 Milk and milk products from continuous defoamers shall not be returned directly to the filler bowl. (See Appendix, Section H.)
- D2.1.2 If a defoamer system is provided, all surfaces from which foam may drain, drop, or be drawn into the product shall be constructed in conformance with D1.6.1 and D1.6.2. All surfaces of blower or vacuum lines subject to contact with foam shall be constructed in

such a manner as to be readily accessible for cleaning and sanitizing.

1

## D2.2 Supplementary Fitments

D2.2.1 If supplementary fitments or devices are attached to the container within the unitized equipment, the fitment or device applicator shall be designed, installed and operated such that the attachment of the fitment or device is performed in such a manner that open and unsealed containers are not subject to contamination. If shielding is provided, it shall be properly designed and installed to preclude contamination of open containers.

## D2.3 Automatic Sanitizer Fogging/Spraying Systems for Equipment Surfaces

- D2.3.1 When supplied by the manufacturer, equipment for the intermittent fogging or spraying of sanitizing solutions on equipment surfaces shall be installed in such a manner that it does not interfere with access to product contact surfaces for cleaning and inspection, and shall be accessible and easily cleanable if it is located such that it constitutes a splash contact surface or a product contact surface.
- D2.3.2 Automatically timed intermittent systems shall operate only after the filling operation has been stopped and all containers which have entered the product or splash contact area of the machine have been removed. Sufficient time shall be allowed for solutions to drain from the equipment before filling is resumed.

## D2.4 Single Use Fill Nozzle Screen Assemblies

- D2.4.1 Woven wire screen assemblies or assemblies of perforated plates which are installed and removed as unitary assemblies may be used in fill nozzles to minimize the generation of foam in the containers.
- D2.4.2 When used, single use fill nozzle screen assemblies shall be readily accessible for removal and replacement.
- D2.4.3 Single use fill nozzle screen assemblies shall be constructed such that the edges of the screens are pressed, bonded, or otherwise treated to prevent unraveling or the shedding of material into the product.
- D2.4.4 Single use fill nozzle screen assemblies shall be removed and replaced according to Appendix, Section I.

## D2.5 Multiple Use Fill Nozzle Screens

- D2.5.1 Woven wire screens or perforated plates may be used in fill nozzles to minimize the generation of foam in the containers.
- D2.5.1.1 Woven wire screens or perforated plates shall be designed so they are readily accessed

sible for cleaning, sanitizing, and inspection. (See Appendix, Section J.)

- D2.5.1.2 In woven wire screens, screen wires shall be circular in cross section and shall be no less than 0.010 in. (0.25 mm) in diameter.
- D2.5.1.3 Woven wire screens shall have no more than 40 wires per in. (25 mm).
- D2.5.1.4 In woven wire screens, the edges of the screens shall be pressed, bonded, or otherwise treated to prevent unraveling.
- D2.5.1.5 Holes in perforated plates used in filler nozzles to minimize the generation of foam in the containers may be round, square, or rectangular. If round, the holes shall be a minimum of 1/32 in. (1 mm) in diameter. If square or rectangular, 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).
- D2.5.1.6 Spacers between screens and/or perforated plates, if used, shall be accessible for cleaning and inspection.

## D2.6 Culinary Steam

D2.6.1 Steam used as the sterilizing medium of product contact surfaces, when produced or transported within the unitized equipment, shall meet the criteria for culinary steam as specified in 3-A Accepted Practices for a Method of Producing Steam of Culinary Quality, Number 609-.

## D2.7 Coding and Dating Equipment

D2.7.1 If coding and/or dating is to be performed within the unitized equipment, coding and/ or dating devices shall be designed, installed, and operated such that these operations are performed in such a manner that open or unsealed containers are not subject to contamination. If shielding is provided, it shall be properly designed and installed to preclude contamination of open containers.

## D2.8 Aseptic Equipment

- D2.8.1 Filling equipment intended for aseptic operation shall be designed so that adjustments necessary during operation may be made without jeopardizing the sterility of the unit.
- D2.8.2 Filling equipment intended to be part of an aseptic processing system shall be equipped with appropriate fittings for required instruments and recording devices.
- D2.8.3 Packaging machines used in a processing system to be sterilized by heat and operated at a temperature of 250°F (121°C) or higher shall comply with the following additional criteria:
- D2.8.4 The construction shall be such that all product contact surfaces can be (1) steril-

ized 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.

D2.8.5 Packaging machines that have a product contact surface(s) to be used in such a processing system, not designed so that the system is automatically shut down if the product pressure in the system becomes less

product pressure in the system becomes less than that of the atmosphere and cannot be restarted until the system is re-sterilized, shall have a steam or other sterilizing medium chamber surrounding the valve stems in the sterile areas, if required, to maintain sterility. The packaging machine shall be constructed so that the steam chamber or other sterilizing medium chamber may be exposed for inspection.

D2.8.6 Where steam or other sterilizing medium is used, the connection(s) on the packaging machines shall be such that the steam lines or other sterilizing medium lines can be securely fastened to the packaging machines. The packaging machines shall be constructed so that the steam or other sterilizing medium chamber may be exposed for inspection.

D2.8.7 The seal(s) in a packaging machine 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.

## D2.9 Cappers and Capping Equipment

D2.9.1 When supplied as part of the unitized equipment by the manufacturer, all components of the capping equipment that touch product contact surfaces of the cap or closure including but not limited to sorters, hoppers, magazines, chutes, and applicators shall comply with the applicable sections of D1.

D2.10 Container Disinfection or Sterilization Systems

D2.10.1 Filling equipment which introduces disinfecting or sterilizing chemicals into packages or onto product contact surfaces shall have a means to control the amount of chemical remaining on product contact surfaces.

D2.10.1.1 Residual chemicals in the package shall not exceed FDA allowable limits for that chemical.

## D2.11 Air Under Pressure

D2.11.1 When supplied by the manufacturer, or transported within the unitized equipment, all air under pressure used in contact with product or product contact surfaces shall be in compliance with 3-A Accepted Practices for Supplying Air Under Pressure in Contact with Milk, Milk Products, and Product Contact Surfaces, Number 604-.

## D2.12 Modified Atmosphere Injection Systems

- D2.12.1 Modified atmosphere injection systems, when fitted as part of the unitized equipment, shall comply with D2.11 above.
- D2.12.1.1 The gas (e.g. nitrogen, carbon dioxide, etc.)<sup>9</sup> used in a modified atmosphere injection system shall be of a purity suitable for its intended use. The gas quality shall meet the appropriate FDA Food Quality Specification.

## D2.13 Self-Contained Mechanical Cleaning Systems

D2.13.1 When furnished as a part of the unitized equipment, self-contained mechanical cleaning systems shall meet the Materials and Fabrication criteria described above for product contact surfaces.

## D2.14 Filling Nozzle Gangs

- D2.14.1 The area between the filling nozzles shall be defined as a product contact surface, unless shielding per paragraph D1.11 is installed.
- D2.15 Paper Forming or Scoring Equipment
- D2.15.1 Radii of less than 1/32 in. (1 mm) may be used in equipment when required for essential functional reasons such as mandrel relief patterns and for paper scoring.

## D2.16 Hollow Rollers

D2.16.1 Hollow rollers shall not be used where they form product contact surfaces or splash contact surfaces, unless the inside of the roller meets the cleanability criteria of this standard or is sealed to prevent ingress of soil or product.

## APPENDIX

## E STAINLESS STEEL MATERIALS

Stainless steel conforming to the applicable composition ranges established by AISI for wrought products, or by ACI for cast products, should be considered in compliance with the requirements of Section 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 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 composition of these cast grades are covered by ASTM specifications A351/A351M, A743/A743M and A744/A744M.

## F ELECTROLESS NICKEL ALLOY

An electroless nickel alloy coating having the following composition is deemed to be in compliance with C1.1 herein:

Nickel - 90% minimum.

Phosphorus - 6% minimum and 10% maximum as a supersaturated solution of nickel phosphide in nickel.

Trace amounts of carbon, oxygen, hydrogen and nitrogen.

No other elements.

## G PRODUCT CONTACT SURFACE FINISH Surface finish equivalent to 150 grit or better as obtained with silicon carbide, properly applied on stainless steel sheets, is considered in compliance with the requirements of Section D1 herein. A maximum R<sub>a</sub> of 32 μin. (0.80 μm), when measured according to the recommendations in American National Standards Institute (ANSI)/American Society of Mechanical Engineers (ASME) B.46.1 -Surfaces Texture, is considered equivalent to a No. 4 finish.<sup>11</sup>

## H HANDLING OF COLLECTED MILK If the milk or milk product collected in the defoamer system is intended to be used for human

consumption, the following procedures are recommended:

- H1 It should be protected from contamination during collection and in subsequent handling.
- H2 It should be maintained at or below 45°F (7°C).
- H3 It should be re-pasteurized.
- I RECOMMENDED REPLACEMENT OF SINGLE USE NOZZLE SCREENS

Single use nozzle screen assemblies should be removed from the filling machine at the end of a production period and should be discarded.

New single use nozzle screen assemblies or packs should be installed in the filling machine immediately prior to sanitizing of the filler prior to production.

J RECOMMENDED CLEANING AND SANITIZING OF MULTIPLE USE NOZZLE SCREENS

The screens should be removed, inspected, cleaned, and autoclaved at 250°F (121°C) for 30 min. After cooling the screens should be reassembled in the filler nozzle immediately prior to sanitizing the filler.

<sup>1</sup>Additional information on surface modification is contained in Advanced Materials and Processes, Vol. 137 (1), January 1990; p. 59 – "Coating and Coating Practices" by H. Herman and p. 61 – "Surface Modification" by F. A. Schmidt, ASM International, Materials Park, OH 44073 (216-338-5151).

<sup>2</sup>MIL-S-13165C (1), November 27, 1991. Military Specification: Shot Peening of Metal Parts. Available from Standardization, Document Order Desk (Department of Navy), 700 Robbins Avenue, Building 4, Section D, Philadelphia, PA 19111-5094 (215-697-2179).

<sup>3</sup>QQ-C-320B – Federal Specification for Chromium Plating (Electrodeposited), June 1954 with Amendment 4 on April 10, 1987. QQ-N-290A – Federal Specification for Nickel Plating (Electrodeposited), November 12, 1971. Available from the General Services Administration, Federal Supply Services Bureau, Specification Section, 470 East L'Enfant Plaza, Suite 8100, Washington, D.C. 20407 (202-755-0325).

<sup>4</sup>Additional information on arithmetical mean ( $R_a$ ) is contained in ANSI B46.1-1978, available from the American National Standards Institute, 1430 Broadway, New York, NY 10018 (212-354-3300).

<sup>5</sup>The data for this series are contained in the AISI Steel Products Manual, Stainless & Heat Resisting Steels, November 1990, Table 2-1, pp. 17-20. Available from the Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086 (412-776-1535).

<sup>6</sup>Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016 (708-299-9160).

<sup>7</sup>MIL-C-26074E NOT 2, August 22, 1995. Military Specifications: Coatings, Electroless Nickel, Requirements For. Available from Standardization, Document Order Desk (Department of Navy), 700 Robbins Avenue, Building 4, Section D, Philadelphia, PA 19111-5094 (215-697-2179).

<sup>8</sup>Adhesives shall comply with 21 CFR Part 175 – "Indirect Food Additives: Adhesives and Components of Coatings." Document for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (202-783-3238).

<sup>9</sup>Nitrogen shall comply with 21 CFR Part 184.1540 and carbon dioxide shall comply with 21 CFR Part 184.1240 – "Direct Food Substances Affirmed as GRAS." Document for sale by Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (202-783-3238).

<sup>10</sup>Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959 (610-832-9500).

<sup>11</sup>Available from the American Society of Mechanical Engineers, 345 E. 47th Street, New York, NY 10017-2392 (212-705-7722).

These revised standards are effective November 23, 1996, at which time the 3-A Sanitary Standards for Fillers and Sealers of Single-Service Containers for Milk and Milk Products, Number 17-07 are rescinded and become null and void.

Dairy, Food and Environmental Sanitation, Vol. 16, No. 9, Pages 594-601 (opyright@ UMMFES, 6200 Aurora Ave., Suite 200W, Des Moines, IA 50322

## 3-A Sanitary Standards for Centrifugal and Positive Rotary Pumps for Milk and Milk Products, Number 02-09

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

It is the purpose of the IAMFES, USPHS and DIC in connection with the development of the 3-A Sanitary Standards program to allow and encourage full freedom for inventive genius or new developments. Milk pump specifications heretofore or hereafter developed which so differ in design, material, construction, or otherwise, as not to conform with the following standards, but which in the manufacturer's or fabricator's opinion are equivalent or better may be submitted for the joint consideration of the IAMFES, USPHS and DIC at any time. **NOTE:** Use current revisions or editions of all referenced documents cited herein.

## A SCOPE

- A1 These standards cover the sanitary aspects of centrifugal and positive rotary pumps for milk and milk products.
- A2 In order to conform with these 3-A Sanitary Standards, centrifugal and positive rotary pumps shall comply with the following design, materials, and fabrication criteria.

## **B DEFINITIONS**

- B1 Product: Shall mean milk and milk products.
- B2 Surfaces
- B2.1 *Product Contact Surfaces:* Shall mean all surfaces which are exposed to the product and surfaces from which liquids may drain, drop, or be drawn into the product.
- B2.2 Nonproduct Contact Surfaces: Shall mean all other exposed surfaces.

## B3 Cleaning

- B3.1 *Mechanical Cleaning or Mechanically Cleaned:* Shall mean soil removal by impingement, circulation or flowing chemical detergent solutions and water rinses onto and over the surfaces to be cleaned by mechanical means in equipment or systems specifically designed for this purpose.
- B3.2 *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 tanks(s) which may be fitted with recirculating pump(s) and with all cleaning aids manipulated by hand.

- B4 Surface Modification<sup>1</sup>
- B4.1 Surface Treatments: Shall mean a process whereby chemical compositions or mechanical properties of the existing surfaces are altered. There is no appreciable, typically less than 1 µm build-up of new material or removal of existing material.
- B4.1.1 Surface treatments include:
  - 1. Mechanical (shot peening,<sup>2</sup> glass beading, polishing)
  - 2. Thermal (surface hardening laser, electron beam)
  - 3. Diffusion (carburizing, nitriding)
  - 4. Chemical (etching, oxidation)
  - 5. Ion Implantation
  - 6. Electropolishing
- B4.2 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.
- B4.2.1 Coating processes include:
  - 1. Chemical (conversion coatings)
  - 2. Electrodeposition<sup>3</sup>
  - Spraying (pneumatic, flame, plasma, arc spray)
  - 4. Physical Vapor Deposition
  - 5. Chemical Vapor Deposition

- B5 Simple Hand Tools: Shall mean implements normally used by operating and cleaning personnel such as a screwdriver, wrench or hammer.
- B6 Substantially Flush: Shall mean mating surfaces or other juxtaposed surfaces shall be within 1/32 in. (0.794 mm).
- B7 *Readily or Easily Removable:* Shall mean quickly separated from the equipment with the use of simple hand tools if necessary.
- B8 *Easily or Readily Accessible:* Shall mean a location which can be safely reached by an employee from the floor, platform, or other permanent work area.

## C MATERIALS

## C1 Metals

- C1.1 Product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI) 300 Series<sup>4</sup> or corresponding Alloy Cast Institute (ACI)<sup>5</sup> types (See Appendix, Section E1) or metal which under conditions of intended use is at least as corrosion resistant as stainless steel of the foregoing types, and is nontoxic and nonabsorbent, except that:
- C1.1.1 Rotors, shafts, seals, rotor and impeller retaining devices, and housings may also be made of a metal or an alloy that is as corrosion resistant as AISI 300 Series Stainless Steel and be nontoxic and nonabsorbent under the conditions of intended use. (See Appendix, Section E2.)
- C1.1.2 Product contact surfaces made of the materials provided for in C1.1 and C1.1.1 may have their surfaces modified by surface treatment or coating(s).
- C1.1.3 Solder, when used, shall be silver bearing 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 and bactericidal treatment or sterilization.
- C2 Surface Modification Materials
- C2.1 Surface modification materials that become a part of the parent material on product contact surfaces shall comply with the appropriate provisions of one or more of the following:
- C2.1.1 FDA Regulation 21 CFR 175 Subpart C<sup>6</sup>, Substances for Use as Components of Coatings.
- C2.1.2 FDA Regulation 21 CFR 177 Subpart B<sup>6</sup>, Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces.
- C2.1.3 FDA Regulation 21 CFR 177 Subpart C<sup>6</sup>, Substances for Use Only as Components of Articles Intended for Repeated Use.

- C3 Nonmetals
- C3.1 Rubber and rubber-like materials may be used for rotors, stators, liners, gaskets, O-rings, seals and parts having the same functional purposes.
- C3.1.1 Rubber and rubber-like materials when used for the above specified application(s) shall conform with 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-.
- C3.2 Plastic materials may be used for rotors, stators, liners, gaskets, O-rings, seals and parts having the same functional purposes.
- C3.2.1 Plastic materials when used for the above specified application(s) shall conform with 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-.
- C3.3 Rubber and rubber-like materials and plastic materials having product contact surfaces shall be of such composition as to retain their surface and conformational characteristics when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization.
- C3.4 The final bond and residual adhesive, if used, on bonded ceramic, on bonded rubber and rubberlike materials, and on bonded plastic materials shall be nontoxic.<sup>7</sup>
- C3.5 Where materials having certain inherent functional purposes 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 bactericidal treatment or sterilization. These materials must meet the requirements of C2 or be generally recognized as safe (GRAS) by the FDA.

## C4 Heat-Resistant Materials

C4.1 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 centrifugal and positive rotary pump(s) 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.

#### C5 Nonproduct Contact Surfaces

C5.1 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 Surface Finish

D1.1 All product contact surfaces shall have a finish at least as smooth as a No. 4 ground finish on stainless steel sheets and be free of imperfections such as pits, folds and crevices in the final fabricated form. (See Appendix, Section E3.)

## D2 Permanent Joints

- D2.1 All permanent joints in metallic product contact surfaces shall be continuously welded. Welded areas on product contact surfaces shall be at least as smooth as a No. 4 ground finish on stainless steel sheets, and be free of imperfections such as pits, folds, and crevices when in the final fabricated form except that:
- D2.1.1 In such cases where welding is impractical, soldering, press-fitting or shrink-fitting may be employed where necessary for essential functional reasons such as bushings, internal bearings, pins and mechanical seal components. (See Appendix, Section E4.)
- D2.1.2 Silver bearing solder may be used around pins for sealing joints and producing fillets for minimum radii.
- D2.1.3 Press-fitting, shrink-fitting or soldering shall produce product contact surfaces which are at least as smooth as a No. 4 ground finish on stainless steel sheets which are free of imperfections such as pits, folds and crevices. (See Appendix, Section E3.)

## 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 or sterilization.
- D3.2 The minimum thickness of electrodeposited coatings shall not be less than 0.0002 in. (0.005 mm) for all product contact surfaces when used on stainless steel or other corrosion resistant alloy. (See C1.1 and C1.1.1).
- D3.3 Ceramic materials used as coatings shall be at least 0.003 in. (0.08 mm) thick.
- D3.4 Plastic materials, when used as a coating, shall be at least 0.005 in. (0.125 mm) thick.

## D4 Cleaning

- D4.1 Centrifugal and positive rotary pumps that are to be mechanically cleaned shall be designed so that the product contact surfaces of the pump and all nonremoved appurtenances thereto can be mechanically cleaned and are easily accessible and readily removable for inspection.
- D4.2 Product contact surfaces not designed to be mechanically cleaned shall be easily accessible for cleaning and inspection when in an assembled position or when removed. Demountable parts shall be readily removable.

## D5 Draining

D5.1 All product contact surfaces shall be drainable when disassembled.

## D6 Fittings

- D6.1 All sanitary fittings and connections shall conform with the 3-A Sanitary Standards for Sanitary Fittings for Milk and Milk Products, Number 63-.
- D6.2 Rectangular flanges or round flange-type fittings may be used for specific applications such as connectors to hoppers or feeders.

#### D7 Seals

D7.1 The shaft seal(s) shall be sanitary in design with all product contact parts demountable and accessible for inspection or cleaning, and shall not be of the packing type.

## D8 Gaskets

- D8.1 Gaskets having a product contact surface shall be removable or bonded.
- D8.2 Grooves in gaskets shall be no deeper than their width.
- D8.3 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 Section D6.1.
- D8.4 Gaskets, when used, shall be self positioning and form a substantially flush interior joint.

#### D9 Radii

- D9.1 All internal angles of less than 135° on product contact surfaces shall have radii of not less than 1/8 in. (3.18 mm) except that:
- D9.1.1 Smaller radii may be used when they are required for essential functional reasons, such as those in seal components and rotors to body clearance areas. In no case shall such radii be less than 1/32 in. (0.794 mm) except that:

- D9.1.1.1 The radius at the intersection of press-fits, shrink-fits and flat scaling surfaces is zero by nature of the design and definition of this type of fabrication.
- D9.1.2 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 D6.1.
- D9.1.3 Radii in standard O-ring grooves shall be as specified in Appendix E6.
- D9.1.4 Radii in nonstandard O-ring grooves shall be those radii closest to a standard O-ring as specified in Appendix E6.
- D10 Springs

Coil springs having product contact surfaces shall have at least 3/32 in. (2 mm) openings between coils including the ends when it is in a free position.

## D11 Threads

- D11.1 There shall be no threads on product contact surfaces except for holding the impeller or rotor to the shaft.
- D11.2 Shaft threads must conform to one of the following thread specifications:

## D11.2.1 Exposed Threads

- 1. Pumps with exposed shaft threads shall be designed for manual cleaning.
- 2. Threads shall conform to Appendix E5, Figure 1.
- 3. Threaded angles shall be not less than 60°.
- There shall not be more than 8 threads per in. (25. mm).
- 5. The nut shall be of the open type.
- 6. The length of the nut shall not exceed three-fourths of the thread's basic diameter.

## D11.2.2 Enclosed Threads

- 1. Pumps with enclosed shaft threads shall be designed for mechanical cleaning.
- 2. These are threads that have been sealed from the product by means of an O-ring, gasket or similar type seal.
- 3. Thread specifications are designated by the manufacturer.
- 4. The rotor or impeller locking nut shall be the enclosed type.

## D12 Bonded Parts

- D12.1 Pump impellers, rotors, stators or housings may be made of, covered with or bonded with rubber, rubber-like or plastic materials.
- D12.2 Housing liners shall be removable or bonded.
- D12.3 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 or sterilization the rubber and rubber-like material or the plastic material does not separate from the base material to which it is bonded.

D12.4 Components within seal assemblies may be bonded with adhesives.

## D13 Sterilization Systems

- D13.1 Pumps designed to be used in a processing system to be sterilized by heat shall comply with the following:
- D13.1.1 All product contact surfaces shall be in compliance with Section C4.
- D13.1.2 Pumps to be used in a processing system not designed so that the system automatically is shut down if the product pressure in the system becomes less than that of the atmosphere and cannot be started until the system is re-sterilized shall have a steam or other sterilizing medium chamber surrounding (1) the shaft(s), (2) the portion of the inlet and outlet connection adjacent to the product, and (3) the pump cover.
- D13.1.3 Where steam or other sterilizing medium is used, the connection(s) on the pump(s) shall be such that the steam lines or other sterilizing medium lines can be securely fastened to the pump(s). The pump(s) shall be constructed so that the steam or other sterilizing medium chamber may be exposed for inspection.

## D14 Inspectibility

- D14.1 A pump shall be designed that (See Appendix, Section E7):
- D14.1.1 The open area between the exterior of the driver or gear case housing to the exterior of the product chamber shall be 1/2 in. (12 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.
- D14.1.2 At least 1/4 in. (6mm) of the shaft(s) exclusive of the seal components shall be visible.
- D14.1.3 Guards required by a 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.

## D15 Nonproduct Contact Surfaces

D15.1 Nonproduct contact surfaces shall have a smooth finish, free of pockets and crevices, and be readily cleanable and those surfaces to be coated shall be effectively prepared for coating.

## D16 Supports

## D16.1 Baseplate Mounted

- D16.1.1 A baseplate mounted unit consists of some or all of the following components:
  - 1. Pump
  - 2. Motor
  - Mechanical reduction unit such as a gearbox, gearhead drive, variable speed drive, chain and sprocket system or belt and pulley system.
  - 4. Pedestal
  - 5. Coupling
  - 6. Guard
  - 7. Baseplate
  - 8. Legs
- D16.1.2 The baseplate(s) shall be constructed of (a) solid metal plate(s) or (b) tubular metal that has all open ends sealed by welding.
- D16.1.3 The metal shall be stainless steel or coated or painted mild steel.
- D16.2 Legs
- D16.2.1 Legs, when used, shall be adjustable or fixed with rounded ends or have flat load bearing feet suitable for mounting to the floor and have no exposed threads.
- D16.2.2 Legs made of hollow stock shall be sealed.
- D16.2.3 Legs shall be of sufficient length to provide a minimum clearance between the lowest part of the base, pump, motor or drive and floor no less than 4 in. (100 mm) on pumps with legs designed to be fixed to the floor or pumps having a horizontal base area of more than 1 ft<sup>2</sup> (0.095 m<sup>2</sup>).
- D16.2.4 Legs shall be of sufficient length to provide a minimum clearance of 2 in. (50 mm) on pumps having a horizontal base area of 1 ft<sup>2</sup> (0.095 m<sup>2</sup>) or less and not designed to be fixed to the floor.
- D16.2.5 If casters or wheels 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 in. (101.6 mm). Casters or wheels, if provided, shall be easily cleanable, durable, and of a size that will permit easy movement of the centrifugal or positive rotary pump.

## E APPENDIX

E1 Stainless Steel Materials

Stainless steel conforming to the applicable composition ranges established by AISI for wrought products or by ACI (Steel Founders Society of America) for cast products should be considered in compliance with the requirements of Section C1.1 herein. Where welding is involved, the carbon content of the stainless steel should not exceed 0.08%. The first reference cited in C1.1 sets forth the chemical ranges and limits of acceptable stainless steels of the 300 series. Cast grades of stainless steel corresponding to type 303, 304, 316 and 316L are designated CF-16F, CF-8, CF-8M and CF-3M respectively. The chemical compositions of these cast grades are covered by ASTM specifications<sup>8</sup> A351/A351M, A743/A743M and A744/A744M.

- E2.1.1 Metals other than the above may be as corrosion resistant as the 300 Series Stainless Steel. This may be shown when metals are tested in accordance with ASTM G31 · "Laboratory Immersion Corrosion Testing of Metals" and have a corrosion rate of less than 10 mil (250 µm) per year. The test parameters, such as the type of chemical(s) and their concentration(s) and temperature(s) should be representative of product cleaning and sanitizing conditions used in dairy equipment. Alloys containing lead or leachable copper should not be used.
- E3 Product Contact Surface Finishes Surface finish equivalent to 150 grit or better as obtained with silicon carbide, properly applied on stainless steel sheets, is considered in compliance with the requirements of Section D1.1 herein. A maximum R<sub>2</sub> of 32 µin. (0.80 µm), when measured according to the recommendations in American National Standards Institute (ANSI) and American Society of Mechanical Engineers (ASME) B46.1 -Surface Texture, is considered to be equivalent to a No. 4 finish.<sup>9</sup>

#### E4 Press 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 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 Ave., New York, NY 10157.

## E2 OPTIONAL METAL ALLOY

E2.1 The following alloys or metals have been shown to be as corrosion resistant as the 300 Series Stainless Steel:

	UNS N08367 ASTM A743 Grade	UNS UNS UN N08367 S21800 S20 ASTM ASTM A743 A743 Grade Grade	UNS 520161	UNS N26055	UNS N26455 ASTM A494 Grade	UNS S17400 ASTM A747 Grade	UNS S15500 ASTM A747 Grade	UNS \$32900	UNS R20500 ASTM A560 Grade	UNS R50400 ASTM B67 Grade
				ASTM A494 Grade						
	CN-3MN	CF-10 SMnN		CY5SaBIM	CW-2M	CB7Cu-1	CB7Cu-2		50Cr-50Ni	C-2
С	0.03	0.10	0.15	0.05	0.02	0.07	0.07	0.20	0.10	0.10
Mn	2.00	7.00-9.00	4.00-6.00	1.5	1.00	0.70	0.70	1.00	0.30	
SI	1.00	3.50-4.50	3.00-4.00	0.5	0.80	1.00	1.00	0.75	1.00	
P	0.040	0.040	0.040	0.03	0.03	0.035	0.035	0.040	0.02	
S	0.010	0.030	0.040	0.03	0.03	0.03	0.03	0.030	0.02	
Cr	20.0-22.0	16.00-18.00	15.0-18.0	11.0-14.0	15.0-17.5	5.50-17.7	14.0-15.50	23.0-28.0	48.0-52.0	
NI	23.5-25.5	8.00-9.00	4.00-6.00	Balance	Balance	3.60-4.60	4.50-5.50	2.50-5.00	Balance	
Mo	6.0-7.0			2.0-3.5	15.0-17.5			1.00-2.00		
Съ						0.15-0.35	0.15-0.35			
Cu	0.75					2.50-3.20	2.50-3.20			
N	0.18-0.26	0.08-0.18	0.08-0.20			0.05	0.05		0.30	
Fe	Balance	Balance	Balance	2.00	2.00	Balance	Balance	Balance	1.00	0.30
Sa				3.0-5.0						
BI				3.0-5.0						
w					1.0					
п									0.50	Balance
AI									0.25	
other										H = 0.015 N = 0.03 O = 0.25

\* Percentage is maximum unless range is given.

<sup>1</sup>Additional information on surface modification is contained in Advanced Materials and Processes, Vol. 137 (1), January 1990; "Coatings and Coating Practices" by H. Herman, p. 59; and "Surface Modification" by F. A. Smidt, p. 61. ASM International, Materials Park, OH 44073 (216) 338-5151.

<sup>2</sup>MIL-S-13165C (1), November 1991. Military Specification: Shot Peening of Metal Parts. Available from Standardization, Document Order Desk (Department of Navy), 700 Robbins Avenue, Building 4, Section D, Philadelphia, PA 19111-5094 (215) 697-2179.

<sup>3</sup>Federal Specification #QQ-C-320B for Chromium Plating (Electrodeposited), June 1954 with Amendment 4 on April 10, 1987. Federal Specification #QQ-N-290A for Nickel Plating (Electrodeposited), November 12, 1971. Available from the General Services Administration, Federal Supply Services Bureau, Specification Section, 470 East L'Enfant Plaza, Suite 8100, Washington, D.C. 20407 (202) 755-0325.

<sup>4</sup>The data for this series are contained in the AISI Steel Products Manual, Stainless & Heat Resisting Steels, November 1990, Table 2-1, pp. 17-20. Available from the Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086 (412) 776-1535.

<sup>5</sup>Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016 (708) 299-9160. <sup>6</sup>For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (202) 783-3238.

<sup>7</sup>Adhesives shall comply with 21 CFR Part 175 – "Indirect Food Additives: Adhesives and Components of Coatings." Document for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (202) 783-3238.

<sup>8</sup>Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959 (610) 832-9500.

<sup>9</sup>Available from the American Society of Mechanical Engineers, 345 E. 47th Street, New York, NY 10017-2392 (212) 705-7722.

<sup>10</sup>The document establishing these standard dimensions is Aerospace Standard (AS) 568, published by SAE, 400 Commonwealth Drive, Warrendale, PA 15086 (412) 776-4970.

<sup>11</sup>The document establishing these standard dimensions is ISO 3601-1: 1988 (E) published by the International Organization for Standization (ISO), 1 Rue de Varembe, Case Postale 58, CH 1 1211, Geneva, Switzerland (41-22-734-1240).

E5 Threads

E5.1 American Standard Stub Acme Thread

## AMERICAN STUB ACME THREAD



P = PITCH	$\mathbf{P} = 1/\mathbf{T}.\mathbf{P}.\mathbf{I}.$		
S.D. = SINGLE DEPTH	S.D = 0.433 x P		
T.F. = TOP FLAT	T.F. = 0.250 x P		
B.F. = BOTTOM FLAT	B.F. = 0.227 x P		
T.P.I. = THREADS PER INCH			

## E6 O-Ring Groove Radii

O-Ring Cross Section,	O-Ring Cross Section,	O-Ring Cross Section,	Minimum Groove	
Nominal (AS 568 <sup>10</sup> )	Actual (AS 568)	Actual (ISO 3601-1 <sup>11</sup> )	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)	

**TABLE 1 - Groove Radii Dimensions for Standard O-Rings**
#### E7 Diagrams

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



These revised 3-A Sanitary Standards are effective November 24, 1996, at which time the 3-A Sanitary Standards for Centrifugal and Positive Rotary Pumps for Milk and Milk Products, Number 02-08 are rescinded and become null and void.

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## Amendment 8 to 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-17

Formulated By

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

It is the purpose of the IAMFES, USPHS, and DIC in connection with the development of the 3-A Sanitary Standards Program to allow and encourage full freedom for inventive genius or new developments. Multiple-use plastic materials used as product contact surfaces for dairy equipment heretofore or hereafter developed which so differ in design, materials, and fabrication or otherwise as not to conform to the following standards but which, in the fabricator's opinion, are equivalent or better, may be submitted for the joint consideration of the IAMFES, USPHS, and DIC at any time. **NOTE:** Use current revisions or editions of all referenced documents cited herein.

The 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-17 are hereby amended as indicated for the following sections:

H5 Certification of each formulation for compliance with FDA regulations and/or FD&C Act requirements and compliance with the criteria herein are to be maintained by the manufacturer and supplier. Test results and a statement of compliance by the testing laboratory shall be kept by the manufacturer and supplier. This information shall be made available to distributors, users, and regulatory agencies upon request. (See Appendix, Section P for the information required on a certification form.)

TABLE 1 - Plastics Included in These Standards	Maximu	m % Wei	ght Gain
Generic Classes (Code of Federal Regulations Citation <sup>1</sup> )	Section E - Cleanability Response	Section F - Product Treatment (Solution I)	Section F - Product Treatment (Solution J)
Acrylics (21 CFR 177.1010) Acrylonitrile butadiene styrene (21 CFR 177.1020) Chlorinated polyether (21 CFR 177.2430) Cross-linked polyester resins (vinyl ester-styrene copolymer) (21 CFR 177.2420) Epoxy resin as coating (21 CFR 175.300) (a) Isopropylidenediphenol Hardener-TETA Triethylenetetramine (b) Phenol-Formaldehyde Polymer, glycidyl ether (silica filled) Hardener - DETA Adduct Ethylene-vinyl acetate copolymers (21 CFR 177.1350) Fluorocarbons (21 CFR 170.39, 177.1380, 177.1550, 177.2510) (a) CTFE, PTFE, FEP, PFA, and ETFE types (b) Vinylidene fluoride types Nylon (21 CFR 177.1500) (a) Nylon Type 610 (c) Nylon Type 610 (c) Nylon Type 6 Plasticized polyvinyl chloride (21 CFR 175.300) (a) For contact with high-water, Iow-fat products (s8% milk fat) (b) For contact with high-fat products (>8% milk fat) Polyarylsulfone resin (21 CFR 177.1580) Polyetherimide (21 CFR 177.1580) Polyetherimide (21 CFR 177.1595) Polyethylene (21 CFR 177.1520) (a) ASTM Type II (c) ASTM Type III Polyethylene phthalate polymers (21 CFR 177.1630)	0.20 0.30 0.05 0.20 0.10 0.15 0.25 0.05 0.05 2.00 1.00 2.00 0.25 0.10 0.40 0.10 0.20 0.20 0.20 0.20 0.20 0.20 0.2	(Solution 1) 0.50 0.45 0.05 0.02 0.15 0.15 0.55 0.05 0.20 0.80 0.15 0.25 0.20 0.80 0.25 0.25 0.20 0.30 0.25 0.55 0.20 0.55 0.25 0.55 0.20 0.55 0.25 0.55 0.20 0.55 0.20 0.55 0.20 0.55 0.20 0.55 0.20 0.55 0.20 0.55 0.20 0.55 0.20 0.55 0.20 0.55 0.20 0.55 0.20 0.55 0.20 0.55 0.20 0.55 0.20	(Solution J) 1.50 0.90 0.05 0.20 0.25 2.0 0.10 0.05 0.15 8.00 4.00 8.00 0.90 0.55 1.50 0.25 0.75 0.20 0.25 0.75 0.20 0.25 0.75 0.20 0.25 0.75 0.20 0.5 0.5 0.5 0.5 0.20 0.5 0.20 0.5 0.20 0.5 0.20 0.5 0.20 0.25 0.20 0.10 0.05 0.15 0.20 0.05 0.20 0.10 0.05 0.15 0.20 0.05 0.15 0.20 0.05 0.15 0.20 0.05 0.15 0.20 0.15 0.20 0.25 0.20 0.15 0.20 0.15 0.20 0.25 0.20 0.15 0.20 0.25 0.15 0.20 0.25 0.20 0.15 0.25 0.20 0.15 0.25 0.20 0.25 0.15 0.25 0.20 0.25 0.15 0.25 0.20 0.25 0.25 0.15 0.25 0.25 0.25 0.25 0.25 0.25 0.25 0.20 0.25 0.20 0.55 0.20 0.20 0.20 0.55 0.20 0.20 0.20 0.55 0.20 0.20 0.55 0.20 0.20 0.55 0.20 0.55 0
Polymethylpentene (21 CFR 177.1520) Polyoxymethylene copolymer (21 CFR 177.2470) Polyphenylene oxide (21 CFR 177.2460) Polyphenylene sulfide (21 CFR 177.2490) Polyphenylene sulfide-PTFE (alloy) (21 CFR 177.2490, 177.1380) Polypropylene - (unmodified and modified for impact resistance) (21 CFR 177.1520) Polystyrene - Normal (unmodified) Type 3 of ASTM D703-78 (21 CFR 177.1640) Polystyrene - Modified (impact), Type III, Grade 6, of ASTM D1892-78 (21 CFR 177.1640) Polysulfone-PTFE (alloy) (21 CFR 177.1655, 177.1380) Polysulfone-PTFE (alloy) (21 CFR 177.1655, 177.1380) Polyuethane (21 CFR 177.1680) Polyurethane (21 CFR 177.1680) Propoxylated bisphenol-A fumarate polyester-styrene copolymer (21 CFR 177.2420) Reinforced epoxy, molded, natural (no color added), and black (21 CFR 175.300) Styrene-acrylonitrile (21 CFR 177.1040) Thermoplastic polyether-ester (21 CFR 177.2600)	0.10 0.25 0.10 0.06 0.06 0.10 0.10 0.10 0.05 0.30 0.10 1.22 0.20 0.20 0.20 0.35	0.20 0.60 0.15 0.08 0.20 0.10 0.10 0.1 0.45 0.15 1.59 0.20 0.25 0.25 0.50 1.1	0.20 1.00 0.25 0.08 0.30 0.20 0.10 0.10 0.1 0.45 0.65 1.29 0.20 0.35 0.50

#### K2 Certification of Plastic Materials with Multiple Trade Names or Product Names

K2.1 Plastic materials which already meet 3-A criteria may be certified by suppliers under other trade names and/or product designations. A company manufacturing the final plastic product from a plastic material already meeting 3-A criteria may certify its trade name and its type or grade meets the 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20- without requalification provided:

<sup>1</sup>Citations are by title, part, and section number, thus 21 CFR 177.1010 refers to Title 21, Part 177, Section 1010. CFR references include the basic polymers, optional adjuvants, specifications, and limitations and conditions of use.

#### APPENDIX P: CERTIFICATION FORM EXAMPLE

1/101 $1000$	PART 1:	To be completed by all.	suppliers. Ple	ease type all inform	nation except Signatu
--	---------	-------------------------	----------------	----------------------	-----------------------

I certify that	{name of plastic, including generic class as listed er the terms of the test regimen contained in 3-A Sanitary Standards for Multiple-Use Plastic Materials Used iry Equipment, Number 20- as amended, and complies with the limitations set forth under Section H of those
Federal Regulations. Samples of	the material were/were not {choose one} submitted to testing by the company listed below.
Name	
Company Na	ne
Address	
Signature	
Date	

**PART 2:** To be completed as provided in K2 if the plastic material being certified was not submitted for testing by the company listed above.

The name of the plastic material originally tested, and currently certified is \_\_\_\_\_\_\_\_\_ {name of plastic, including generic class as listed in Table 1}. I certify that this plastic is the same formulation as that originally tested and is not alloyed or blended with another polymer. Attached is a copy of the Certification Form and a statement of compliance by the testing laboratory used for the initial certification of this material.

Signature	 	
Date	 	

#### **PART 3:** To be completed by all suppliers.

	% WEIGHT CHANGE ALLOWED <sup>2</sup>	% WEIGHT CHANGE OBSERVED
Section E - Cleanability Response		
Section F - Product Treatment (Solution I)		
Section F - Product Treatment (Solution J)		
Average Weight Loss	0.05%	

#### PART 4: To be completed by all suppliers.

The surface comparison of the test samples when compared to the original sample and to stainless steel with 150 grit finish when subjected to the cleanability responses and product treatment test regimens showed no change and was at least as smooth as 150 grit stainless steel. {yes/ no}.

<sup>2</sup>See Table 1. <sup>3</sup>Averages.

These amendments to 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-17 are effective November 23, 1996.

# Coming**Events**

#### OCTOBER

·2-4, International Conference on New Developments in **Refrigeration for Food Safety and** Quality Call for Papers, Co-sponsored by IAMFES. Lexington, KY. Conference papers are sought from all areas of food refrigeration. The purpose of this conference is to provide an opportunity for food technologists, food processors, and refrigeration engineers from around the world to exchange current information on the role of refrigeration in the food chain. For further information, contact Food Refrigeration Conference, Univ. of Kentucky, 128 Agriculture Engineering Bldg., Lexington, KY 40546-0276; phone (606) 257-3000 ext. 111; fax (606) 257-5671; e-mail wmurphy@bae.uky.edu.

•5-9, Water Environment Federation's 69th Annual Conference, at the Dallas Convention Center in Dallas, TX. This year's conference theme focuses on environmental education. For conference information, in the U.S. and Canada call (800) 666-0206; outside the U.S. and Canada call (703) 684-2452; or in the U.S. and Canada fax (800) 444-2WEF; outside the U.S. and Canada (908) 885-6417.

•8-9, Associated Illinois Milk, Food, & Environmental Sanitarians 1996 Fall Meeting, at Jumer's Castle Lodge in Peoria, IL. The seminar will focus on Processing Plant Design. Registration in advance is \$50 (members)/\$60 (nonmembers), on site \$60/ 70. Registration includes a continental breakfast and lunch for both days. For further information, contact Bob Crombie at (815) 726-1683.

•8-12, 1st World Congress on Calcium and Vitamin D in Human Life, Rome, Italy. Discussion will include the need to protect consumers through improved food quality and measures to enhance the quality and safety of food. Emphasis will be given to public communication and education, including reaching high-risk groups. For further information, contact Congress Secretariat, Maxitraveland s.r.l.-Via Zoe Fontana 220,00131 Rome, Italy; tel. +39.6.4131415; fax +39.6.4191868.

•9-10, Iowa Association of Milk, Food and Environmental Sanitarians, Inc. Annual Conference, Waterloo, IA at the Starlight Best Western. For further information, contact Janet Burns at (319) 927-3212.

•10, Special Symposium: Qualitätssicherung in der Umweltanalytik (Quality Assurance in Environmental Analysis). For further information, contact Dr. L. Kiessling, Gesellschaft Deutscher Chemiker, Abteilung Tagungen, Postfach 90 04 40, D-60444 Frankfurt, Germany or phone 069-7917-368; fax 069-7917-475.

·15-16, Symposium on Microbial Food Spoilage, Copenhagen, Denmark. Participants are invited to present posters related to microbial food spoilage. An abstract of maximum one page should be sent before September 1 to: Lene Jensen, Danish Institute of Fisheries Research, Dept. of Seafood Research, Technical University of Denmark, Bldg. 221, DK-2800 Lyngby, Denmark; phone +45 4525 2580; fax +45 4588 4774; email: lej@ffl.min.dk. For further information on registration phone +45 88 33 22; fax +45 45 88 47 74; e-mail: fish@ ffl. min.dk.

·16-18, 16th-Food Microbiology Symposium and Workshop, Univ. of Wisconsin, River Falls, WI. The workshop is designed to provide practical demonstrations and discussion of various tests and instruments available for rapid detection, isolation and characterization of foodborne pathogens and toxins as well as prediction of shelf-life and checking hygiene and sanitation in food processing facilities. For further information, contact Dr. Purnendu C. Vasavada, Professor of Food Science, Extension Specialist-Food Safety and Microbiology, University of Wisconsin-River Falls,

Animal and Food Science Dept., River Falls, WI 54022 or phone (715) 425-3150; fax (715) 425 3372; e-mail: purnendu.c.vasavada@uwrf.edu.;http: //www.uwrf.edu/food-science/

·16-18, Food Regulations & Their Impact on Product Development Seminar, at Hotel International, Basel, Switzerland. This seminar provides comprehensive information about food regulations in the EC/EU, USA, and Latin America, using real-world examples to illustrate the effects of legislation, and how to achieve compliance. For detailed seminar agenda and registration information, please contact: Program Division: TECHNOMIC Publishing Co., Inc., 851 New Holland Ave., Box 3535, Lancaster, PA 17604 or phone (717) 291-5609/(800) 233-9936; fax (717) 295-9637.

•20-23, The 1996 International Exposition for Food Processors\* (IEFP) will Host "El Congreso de las Americas," at San Francisco's Moscone Center. IEFP attracts visitors from around the world in every segment of the processing industry, including canning and freezing, dairy, beverages, meat, pharmaceuticals and other industry segments. For more information, contact Janet Palmisano, Communications Coordinator at (703) 684-1080.

·27-29, International Whey Conference, sponsored jointly by the American Dairy Products Institute (ADPI), the U.S. National Committee of IDF (USNAC), and the International Dairy Federation (IDF) at the Westin Hotel O'Hare, Rosemont, IL. This international conference will bring together manufacturers of whey and whey products, firms manufacturing equipment used in whey processing, business leaders of the industry, and government and university researchers from throughout the world to discuss current topics of interest relating to the production, research, marketing and utilization of whey and whey products. Anyone interested in presenting papers at the

#### (omingEvents, con

conference should contact Dr. Warren S. Clark, Jr., Chief Executive Officer, American Dairy Institute, 130 N. Franklin St., Chicago, Il 60606; phone (312) 782-5455; fax (312) 782-5299.

·28-31, Demands on Animal **Hygiene Education and Research** Seminar, sponsored by Universidad Autonoma Metropolitana (UAM). An analysis of American and European requirements. The main subjects of discussion are: concepts on animal hygiene and environment; teaching methodology on animal hygiene; and theoretical and practical aspects. For more information, contact Dr. Jorge Saltijoral, UAM, Departamento de Produccion Agricola y Animal, Calzada del hueso 1100, Col. Villa Quietud, Coyoacan, C.P. 04960 Mexico D.F., or fax (525) 723-5480; e-mail oaxaca@cueyatl.uam.mx.

•31-Nov. 2, NAMA National Convention and Exhibition, Cervantes Convention Center, St. Louis, MO. Exhibitors of vending machines, food products and services related to the industry. For additional information, contact Larry Eils at (312) 346-0370.

#### NOVEMBER

•7, Tennessee Association of Milk, Water and Food Protection 1996 Fall Meeting, at the Ellington Agricultural Center Auditorium in Nashville. Forfurther information, contact Dennis Lampleyat (613) 360-0157.

•13-14, The 16th Annual Northwest Food Sanitation Workshop, at the Columbia River-Red Lion Hotel in Portland, OR. Experts from industry, government and academia will present timely information on food sanitation topics. For further information, contact Reitha McCabe, Food Science and Technology, 100 Wiegand Hall, Oregon State University, Corvallis, OR 97331-6602 or call (541) 737-3463; fax (541) 737-6525.

•14-15, International Workshop "Women Meet Women in Meat," in Utrecht (The Netherlands). The two-day workshop will be jointly organized by ECCEAMST, VVDO and the Dutch Network for Women in the Meat Sector. The central theme of the workshop is the position and experiences of women in the meat sector and quality assurance in the various companies, organizations and countries. For further information, contact VVDO & Network for Women in the Meat Sector: Mrs. S. A. Burt; phone +31 30 2535350/67 or ECCEAMST: M.J.B.M. Weijtens; phone +31 30 2534402.

•17-18, Second Conference on Quality Management in Clinical Laboratories, Antwerp, Belgium. For further information, contact Congress Makers, fax +31-172-443680; e-mail: hoonhout@pi.net.

•17-21, The American Public Health Association's 124th Annual Meeting & Exposition, at the New York Coliseum in New York City. For further information call (202) 789-5646.

·20-22, 2nd Annual Strategic **Environmental Research and De**velopment Program (SERDP) Symposium in Vienna, VA. The Symposium provides a forum for the three federal SERDP partners - Department of Defense, the Department of Energy, and the Environmental Protection Agency-to share the results of SERDP supported research and development projects. For more information, contact Erin Cannelli, Registrar, Labat-Anderson Inc., 8000 Westpark Dr., Suite 400, McLean, VA 22102 or phone (703) 506-1400, ext. 512; fax (703) 506-0946; e-mail: Erin\_Cannelli @ laib.labat.com.

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