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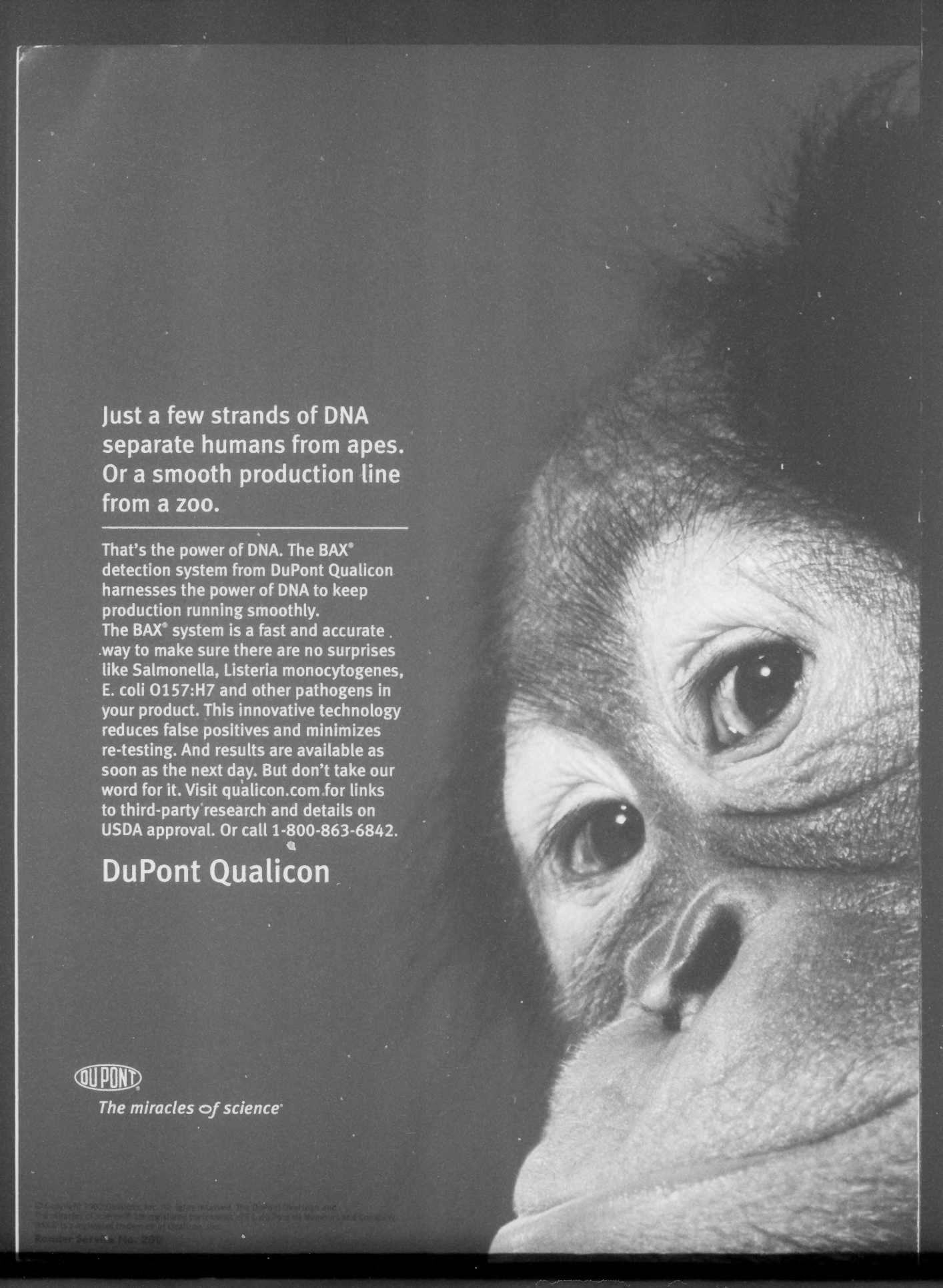
DAIRY, FOOD AND ENVIRONMENTAL

Sanitation

A PUBLICATION OF THE INTERNATIONAL ASSOCIATION FOR FOOD PROTECTION, INC. DECEMBER 2002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Sanitation

International Association for Food Protection

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Editor's Note:

In the September 2002 issue of *DFES*, Table 2 on page 672 was a duplication from page 664. Please disregard Table 2 on page 672. We apologize for this error.

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International Association for Food Protection®
6200 Aurora Avenue, Suite 200W
Des Moines, IA 50322-2864, USA
Phone: 800.369.6337 • 515.276.3344
Fax: 515.276.8655
E-mail: info@foodprotection.org
Web site: www.foodprotection.org

DAIRY, FOOD AND ENVIRONMENTAL

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New Orleans, Louisiana

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THOUGHTS FROM THE PRESIDENT

By ANNA M. LAMMERDING
President

"We need to be informed about clinical, epidemiological, current research, and prevention strategies"

The American Academy of Microbiology recently released a report entitled: *Resolving the Global Burden of Gastrointestinal Illness: A Call to Action* (available at http://www.asmusa.org/acasrc/academy.htm). The report presents the conclusions of 24 international scientists with expertise in microbiology, infectious diseases, water safety, pollution and public health. It states, "In the next 15 seconds, a child somewhere in the world will die from diarrheal disease. Globally, it is estimated that between 6 to 60 billion cases of gastrointestinal illness occur annually".

The document highlights the current state of knowledge and appropriate future directions for the clinical work, research, education, disease prevention, and communication. It is not a lengthy document, only 25 pages, but it provides an excellent summary of where we are now, and where we need to go. An important underlying message is that the magnitude of the social and economic burden of food and waterborne gastrointestinal diseases is not fully recognized by a majority of the population, including policy makers. The perspective of the contributors to the report was very much a broad, global view, recognizing that the same types of problems exist in all countries, both developed and developing, although clearly differing in the extent of the problems.

The recommendations from the report address issues that IAFP Members are familiar with including: developing standardized definitions for the relevant parameters of gastrointestinal disease; the need for interdisciplinary research; coordination of research funding programs among agencies responsible for different segments of the food chain, water quality, and human disease; validation of intervention techniques such as educational methods and hygiene measures used in efforts to control gastrointestinal disease; quantify exposure routes and health effects; a better understanding of host factors and the dose-response relationship for enteric pathogens; implementing basic sanitation and preventative strategies; communicating research findings to health professionals and public health organizations; and general communication and education in gastrointestinal disease issues for policy makers and the general population.

A final recommendation was for the education and training of scientists. Although interdisciplinary research is recognized as critical, the current education system fails to provide this type of environment for students. It was noted that there is also a need for interdisciplinary communication training to help individuals in different fields of specialization exchange information and work together effectively.

In my perspective, these are all goals that our Association strives to achieve. It can be seen in the scope of our journal and the information presented during the workshops, symposia and technical sessions at our Annual Meeting. The battle against food and waterborne diseases requires many different types of "intelligence", that is, information, and many different types of weapons used in concert at all points from production to consumer, including the environment.

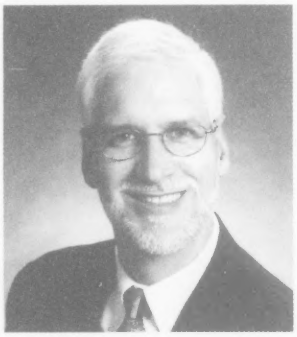
We need to be informed about clinical, epidemiological, current research, and prevention strategies, regardless of our specialization, and we need to educate and communicate about our own work!

I hope then that you have abstracts written up for submission, and that you have next year's meeting in New Orleans, August 10 – 13, marked on your calendar! (For some of us in the northern climes, at this time of year, it's nice just thinking about New Orleans!) I especially encourage our young scientists to take advantage of the just-right size of the meeting and the informal atmosphere to present their work and discuss with colleagues. And, all students are encouraged to submit their paper for the Developing Scientist Competitions.

As the year draws to a close, I would just like to say "May the best of 2002 be the worst of 2003"... for all of us!

COMMENTARY

From the Executive Director



By DAVID W. THARP, CAE
Executive Director

"Please help us by doing your part to promote IAFP to your colleagues at every opportunity"

The past year has been both rewarding and disappointing. Rewarding in the accomplishments we achieved; disappointing in the financial results we must report. The accomplishments were many. We again had record attendance at the Annual Meeting, excellent participation by our exhibitors and sponsors, and we enjoyed an abundance of people attending our social events. The Annual Meeting workshops were well attended, we experienced an increase in Silver and Gold Sustaining Members, and our overall Membership remained stable during a year when many economic events kept the world unstable.

During the year, we placed the *Journal of Food Protection* Online. In addition to the current year issues, this past fall we began placing the 2001 volume online. Soon, we expect to have two full years of *JFP* Online available to our users. This allows instant access anywhere in the world to the leading food science journal! That was the driving force behind our decision to make *JFP* available in an online version. You can now access full-text articles through *JFP* Online, even prior to the month of publication, if you have the online option added to your IAFP Membership.

We also undertook the change of name for *Dairy, Food and Environmental Sanitation*. Beginning with the January 2003 issue, *DFES* will become titled *Food Protection Trends*. *Food Protection Trends* will be more easily identified as a journal dealing with "all" food safety issues, not just "dairy" or "sanitation" issues. In addition, the new name will be effortlessly linked to IAFP with the common words "Food Protection" in both the journal name and our Association name.

IAFP continued our support of the 3-A Sanitary Standards during the year by assisting in the establishment of a new entity named "3-A Sanitary Standards, Inc." The new entity will conduct all business for 3-A including standards writing functions, administration and authorization for the 3-A Symbol use. There will be a separate office created for 3-A that should be up and running at the beginning of 2003.

During 2002, we established a new system that allows online Membership renewals. In the first couple of months there was a 25% renewal rate using the online method and more recently we have seen close to a 33% usage. These are very promising numbers and will help improve our efficiency and speed the renewal process for all Members. In addition, we implemented both a front-end (for new Members) and a traditional (for expiring Memberships) retention program to keep the Members we now have. You may have received a phone call or an E-mail from our staff encouraging your quick Membership renewal. Believe it or not, this is one sure way that you can save the Association from spending our resources. If you renew on the first contact, you save our time, paper costs,

postage costs, and / or long-distance telephone costs. You can see the savings – please help us to reduce costs by renewing your Membership promptly.

Our financial results for the year ending August 31, 2002 are presented on page 1045. The general fund results show a loss of $62,000 for the year. This is the disappointing news referred to in the first paragraph. We had our sights set much higher than this as the past few years had helped us to reduce our negative general fund balance to a mere $1,500 at the beginning of this fiscal year. There are many factors that led us to this result, and I want to share a few with you.

The first and largest factor was a loss on our investments of about $20,000. Just so you are aware, the Association has an investment policy that is very clear about what investments can be made with Association funds and of course; it is very conservative on what type of investments can be made. Otherwise, we might have incurred a much larger loss. These results are disappointing especially when compared to our budget projection showing a $20,000 gain on our investments!

Another place where we strayed from budget involved *JFP* Online. This was not in our budget for FYE August 31, 2002, but we saw advantages to completing this project prior to the end of the fiscal year. We expended about $10,000 to get *JFP* Online up and running. We did collect some revenue to offset this expense, but not in full. We also incurred expense exceeding budget to print and mail both the *Journal of Food Protection* and *Dairy, Food and Environmental Sanitation*. This was due to increasing the number of pages printed to accommodate an additional flow of articles submitted for publication.

Although we had an increase in Annual Meeting attendance, San Diego was an expensive location to hold our Meeting and we came up about $10,000 short on our net income results when compared to what we budgeted. Our workshop financial results were similar to the Annual Meeting. We ended up about $10,000 short of what we projected to make on our workshops.

None of these results or unplanned expenses was terribly harmful by themselves, but when they are all combined, they totaled a result that makes us very disappointed. We have made changes to address the financial shortcomings and look forward to a much brighter financial future for IAFP! Please help us by doing your part to promote IAFP to your colleagues at every opportunity. You are our best source for growing the Membership in IAFP.

So as this year closes, the staff at IAFP wishes you and your family a happy holiday season and a most successful New Year!

Dairy, Food and Environmental Sanitation, Vol. 22, No. 12, Pages 970-975

Ideas and Practices Related to Preharvest Food Safety for Large Swine Producers in Illinois

David A. Barber,[1] Peter B. Bahnson,[1]* Gay Y. Miller,[2] and Michelle M. Michalak[1,3]
[1]Department of Veterinary Clinical Medicine, College of Veterinary Medicine, University of Illinois, 1008 W. Hazelwood Dr., Urbana, Illinois 61802, USA
[2]Department of Veterinary Pathobiology, College of Veterinary Medicine, University of Illinois, 2001 Lincoln Ave., Urbana, Illinois, 61802, USA
[3]Maria Stein Veterinary Clinic, 8155 State Rt. 119, Maria Stein, OH 45860, USA

SUMMARY

The purpose was to examine ideas and practices relevant to preharvest pork food safety among large swine producers in Illinois. Sixteen producers were interviewed to gather information about specific practices and to identify these producers' ideas, plans and perceived needs that were relevant to food safety. The sixteen survey participants produced approximately 21% of the gilts and barrows slaughtered in federally inspected plants in Illinois in 2000. The number of pigs marketed by surveyed producers was well above the mean number of pigs marketed by the 5,100 Illinois producers in 2000. All sixteen producers agreed that they share in the responsibility for pork safety, along with packers and consumers. Fourteen (87.5%) producers reported that finishing barns were completely emptied of pigs and cleaned prior to refilling, using all-in-all-out (AIAO) pig flow. Fifteen (93.8%) participants said that they monitored the effectiveness of cleaning between batches of pigs. Eleven (68.8%) cited animal identification, traceback, and accountability as important components of a strong producer/packer relationship. Fourteen (87.5%) producers believed it was likely that reduction of *Salmonella* in live pigs on the farm would result in reduced foodborne illness from those organisms. Responses of these producers help to identify current food safety practices and needs in swine production. Results identify the need for additional information, strategies, and technology for the preharvest control of microbial foodborne pathogens in swine.

A peer-reviewed article.

*Author for correspondence: Phone: 608.265.1855;
Fax: 608.265.8020; E-mail: bahnsonp@svm.vetmed.wisc.edu

INTRODUCTION

Food safety in animal production has come under increasing scrutiny, especially as food safety regulations begin to address microbial pathogens, as has been done in the United States since 1997 (*2*). Several hazards, including certain chemical, physical, and microbiologic hazards, originate on farms. As packer/processors develop programs to control these hazards, they are likely to look to their suppliers (farmers) to reduce the risk of these hazards in primary production. This, in turn, is likely to stimulate farmers to reduce or eliminate these hazards on their marketed pigs. The development of farm-specific systems to control hazards on farms, such as application of the Hazard Analysis Critical Control Point (HACCP) approach, has been advocated as a relatively simple approach that integrates with systems developed for slaughter and processing (*7*). Processors in the highly integrated poultry industry already depend heavily on preharvest pathogen reduction in order to meet pathogen reduction standards in the processing plant (*9*).

The USDA/Agricultural Marketing Service (AMS) Quality Systems Certification Program (QSCP) has certified two integrated pork producer/processor chains as producing under consistent procedures, some of which relate to food safety (*8*). Additionally, Illinois pork producers believe that there is market advantage to be gained from enhanced pork safety (*8*).

Effective enhancement of on-farm food safety requires knowledge of the pre-existing beliefs and practices of farmers. An investigation of Illinois pork producers suggested that these practices and beliefs differ based on the size of the farm (*3*). However, because this study selected farms randomly, few of the largest farms were included in the sampling frame.

Farms producing pigs have become larger over time. As of December 1995, 3% of operations had more than 2,000 pigs and accounted for 43% of US national inventory. Five years later, 8% of US pig operations had more than 2,000 pigs on their farms and accounted for 72% of the total US inventory, and 2.4% of operations accounted for 50.5% of inventory (*5*). Understanding the current ideas, attitudes and practices of larger swine producers related to production food safety will be important in the development of successful strategies to increase food safety. Preharvest pathogen control and reduction among this group of producers has the greatest potential impact because of the volume of product they supply to the market. In addition, the innovations embraced by larger producers may influence other sectors of pork farms because of the leadership role that these larger farmers might hold.

The objective of this study was to examine the ideas and practices of large Illinois swine producers relevant to preharvest pork food safety. Information provided by our survey will be useful to swine producers, swine veterinarians, processors, regulatory agencies, policy makers, and consumers.

METHODS

Seventeen prospective survey participants were selected on the basis of number of pigs marketed, according to information obtained from the Illinois Pork Producers Association and from the University of Illinois Cooperative Extension Service. All Illinois slaughter pig producers marketing more than 25,000 finishing gilts and barrows between January 1 and December 31, 2000 were eligible for this survey. Production of slaughter weight hogs was chosen as a selection criterion because this class of swine represents the largest number of hogs destined for human consumption.

The goals of the survey instrument were to gather information about specific practices of large producers and to identify ideas, plans, and needs of these producers that were relevant to food safety. The survey was developed through a collaborative effort of the co-authors, whose areas of expertise include swine production, epidemiology, agricultural economics, microbiology, and clinical veterinary medicine. The survey was pretested (*1*) by interviewing the manager of the swine research farms at the University of Illinois, College of Veterinary Medicine, and two swine producers in another midwestern state (Ohio). These test interviews facilitated clarification of some questions prior to interviews with the actual survey subjects. The final survey contained 10 questions, five of which had multiple parts. Questions were used to characterize operations and confirm that participants fit selection criteria; solicit opinions and ideas about food safety in general swine production; identify perceived industry needs; identify procedures on the participants' production operations; pose a hypothetical situation about implementing a certified *Salmonella* reduction/control program; and ask whether the participant planned to include food safety practices on their farm as a part of any future marketing agreement.

Conversation and experience with livestock producers suggested that contact by telephone without previously preparing producers to expect a survey of this type might result in some skepticism and guarded responses, or refusal to participate. Producers might incorrectly suspect that the interviewer was not trustworthy. To prevent such responses or refusals, an advance letter (*1*), printed on University of Illinois letterhead, was mailed to all prospective Illinois participants approximately one week before initial telephone contact was attempted. The purposes of the letter were to confirm the legitimacy of our approaching phone call and to briefly introduce the topic of our research.

All telephone interviews were conducted by the same co-author (D. Barber). Permission was requested to record the conversations and to make written records of sur-

vey responses. All 16 qualified participants agreed to participate and all 16 agreed to recording of their interviews. Interviews were approximateiy 15 minutes in duration. The recorder was activated after the interviewer and participants had been identified, and tape recordings were identified according to a code assigned to the producer prior to telephone contact. Recordings did not contain information that would identify producers or operations by name or location; thus, anonymity of respondents was assured. Tapes of the interviews were transcribed to facilitate review and confirm responses. The interviewer utilized completed survey forms, taped recordings, and transcribed records from the interviews to compile a record of responses. Some responses were direct answers to survey questions. Participants were encouraged to offer further comments in addition to directly answering the survey questions. Some responses were therefore supplemental comments from participants, who were not necessarily confined to answering survey questions. Such additional comments were noted and compiled by the interviewer as a record of the expressed pre-harvest food-safety ideas, attitudes, and practices of participants.

RESULTS

Of the 16 producers who participated in the survey, 14 raised pigs from conception to slaughter weight. One operation reared pigs from weaning to slaughter weight, and another from approximately 10 weeks of age to slaughter weight. Operations were located in 13 different Illinois counties. No more than two producers were located in any single county. Geographically, seven participants were in the northern third of the state, seven were located in the middle third, and two were located in southern counties. Distribution was uniform between eastern and western portions of the state.

The number of market hogs sold by respondents during 2000 ranged from 29,000 to 370,000 (mean = 112,813; median = 60,000) for a total of 1,805,000 during 2000. Thus, the sixteen producers surveyed sold approximately 21% of the total number of gilts and barrows slaughtered in Illinois in 2000. Twelve participants were owners of the operation that they represented. Four participants were non-owner, employed managers. All 16 producers agreed that pork producers, along with packers and consumers, share in the responsibility for pork safety. Five participants specifically cited the need for more information about effective control of microorganisms in the production environment. In addition to information, there was a perceived need for better disinfectants, more rapid detection methods, and new technology for cleaning facilities. One participant indicated a need for vaccines that could be administered in drinking water or other simple routes.

Respondent suggestions for improved microbiological pork safety included good facility ventilation, all-in-all-out pig flow, diligent pest control, genetics related to disease resistance, proper stocking density, and animal identification systems. Some participants indicated that they had little or no knowledge of human health problems associated with *Salmonella*, *Campylobacter*, and *Yersinia*. Five of the participants said that they needed more information about microbial foodborne pathogens in swine. Another five participants indicated that they did not believe that their operation had a problem with microbial organisms if their pigs were not "sick". Participants were asked how they would structure the ideal producer/packer food safety relationship. The factor named most frequently was good mutual communication between packers and producers, which all 16 identified as an important factor. Animal identification, traceback, and accountability were also cited, by eleven, as important components of a strong producer/packer relationship. Six participants specifically mentioned a need for packers to share with producers the revenue benefits that result from preharvest pork safety efforts, because this would be an effective motivator for exploring and implementing new food safety procedures. Opportunity for premiums was described as being more desirable than being forced to change their production practices to avoid price discounts. Three identified process verification and audits as being important. Twelve spoke of the value of food safety improvements in increasing consumer demand for pork. Ten also discussed the possibility of losing consumer confidence and losing their market through food safety failures. Seven individuals expressed concerns that increasing biosecurity costs on the farm might not be offset by financial returns.

One participant detailed a partnership in which the processor should actually send a representative to the farm to see how the pigs are produced, thereby gaining an appreciation for the producer's efforts and gaining an opportunity to make informed constructive suggestions. Likewise, the producer would go or send a representative to the processing plant to observe procedures there, opening up avenues for changes in production that could help the processor improve microbiological pork safety, at least as influenced by the pork producer.

Participants were instructed to consider four compartments of the food continuum: farm/animal production, packing/processing, distribution, and retail/restaurant/consumer. They were then asked to categorize the farm influence as least important, intermediate, or most important. Two producers thought the farm influence was most important, five chose intermediate, while eight thought the farm was least important of the four compartments. One producer cited a lack of sufficient knowledge to offer an opinion.

Fourteen producers believed it was likely that reduction of *Salmonella* in live pigs on the farm would result in a reduction in human foodborne illness from those organisms. One said that it would not

TABLE 1. Responses from surveyed producers when asked whether they believed that each of these specific activities was relevant to food safety and whether their operation had written standard operating procedures (SOPs) for each activity

Activity	Relevant to Food Safety?			SOPs in Effect?	
	Yes	No	Don't Know	Yes	No
Rodent Control	15	0	1	16	0
Cleaning and Sanitation	16	0		15	1
Injectable Treatments	16	0		16	0
Carcass Disposal	13	3		16	0
Euthanasia	10	5	1	11	5
Water Medicator Use	14	1	1[a]	14	1
Feed Grade Medication Use	15	1		15	1
Loading and Handling	9	7		14	2
Transportation Procedures	12	4		13	3

[a]This producer did not use any water medication.

and one answered, "don't know". Among those who said that there would be a reduction in foodborne illness, 5/14 said that there would be very little reduction while 9/14 said there would be moderate reduction.

Participants were asked whether they believed that specific activities were relevant to food safety and also whether their operations had written standard operating procedures (SOPs) for those activities (Table 1). The mean number of producers with written SOPs for the 9 respective activities was 14.3, and the mean number of producers who deemed respective activities relevant to pork food safety was 13.3. Among all 144 responses (nine questions times 16 respondents), 123 (85.4%) were believed to be relevant to production food safety. Six of the nine (66.7%) items were identified by at least one participant as not relevant to pork food safety. The number of respondents who did not identify each item as important to food safety are as follows (number of responses in parentheses): rodent control (1) "don't know" carcass disposal (3); euthanasia (5); euthanasia (1) "don't know"; water medicator use (1); I did not use medications in water, (1) "not applicable"; feed grade antibiotic use (1); loading and handling (7), transportation (4).

Three participants stated that they had a verbal understanding with personnel about some activities, although they had no written SOPs. Participants were asked how closely written SOPs were followed in their production system. Twelve believed that SOPs were followed nearly 100% of the time, one 90%, one 80%, one 75%, and one 70%. The most common reason, cited by ten participants, for deviation from SOPs was inexperience of personnel. Other reasons cited were labor shortage and employee turnover, resulting in personnel who were inadequately trained or in a hurry or both, resulting in deviations from SOPs. Deviations from SOPs were also attributed to failure of personnel to fully comprehend the scope of potential consequences of deviating from SOPs. The mundane, repetitive nature of some tasks was reported to contribute to some deviations from SOPs. One reported that personnel tried to save labor/time, believing that they had a "better way" than the SOPs. Physical features of specific buildings reportedly presented obstacles to strict adherence to SOPs that had been developed for a multi-site system. An example given was that certain buildings could not be washed between batches of pigs if the temperature was colder than -20 degrees Fahrenheit but that no qualifying statement related to this criterion was included in the washing SOP. Acute disease breaks were cited as another circumstance that might lead to deviation from SOPs.

Fourteen producers reported that finishing barns were completely emptied of pigs and cleaned prior to refilling, using all-in-all-out (AIAO) pig flow. One said that AIAO pig flow was used for more than 99% of the pigs and the remainder could be easily switched to AIAO. One said that 80% of the pigs were managed AIAO and that switching the remaining 20% would be difficult. Fifteen participants said that they monitored the effectiveness of cleaning between batches of pigs. All fifteen used visual inspection and two used both visual inspection and bacterial culture to monitor hygiene.

Participants were told that *Salmonella* is a bacterial organism that can cause disease in both pigs and people and that the associated foodborne disease in people can come from contaminated pork. They were then asked, "If an on-farm *Salmonella* control program would reliably reduce the risk of *Salmonella* in finishing hogs, would your farm adopt the program at a cost of $1.00 (US) per head?" Fourteen responded that they would be willing to implement the program. Two indicated that they would not implement the program as described. One producer who would not implement the program indicated that if they identified a problem, they would depopulate and then repopulate with the intention of eradicating the problem. The other producer who would not implement the program suggested that there was no *Salmonella* problem in the swine industry that warranted such a program. When asked why they would implement a control program and how a producer could justify such a program, producers gave the following responses (number of respondents sharing response in parentheses):

1. Reduction of *Salmonella* would be expected to reduce clinical or subclinical disease in pigs, resulting in benefits to pig health and productivity. (9)
2. Participants would expect some financial return from the packer on the basis of enhanced pork safety. (8)
3. Documented efforts to reduce *Salmonella* might ensure salability of product, avoid discounts and secure shackle space. (6)
4. Program implementation would be expected to provide a competitive advantage on the basis of pork safety, securing or enhancing market share. (3)
5. Part of an overall commitment to pork safety. (3)

All participants were asked whether they would implement the hypothetical *Salmonella* control program if it resulted in only cost recovery; that is, the program costs $1.00 per head and the total benefits would equal $1.00 per head. Fifteen said that they would implement the program on those terms.

The final question in the survey asked producers if they were including pork safety practices on their farm as a part of a future marketing agreement. Twelve responded "yes"; two said no; two were undecided.

DISCUSSION

Between January 1, 2000 and December 31, 2000 there were 8,460,800 gilts and barrows slaughtered in federally inspected facilities in Illinois (6). There were 5100 hog operations in Illinois that year (6). The mean number of market hogs sold per hog operation in Illinois in 2000 was 1,659. The farms selected for this study in this survey produced between 17 and 230 times more pigs than the average number marketed by individual Illinois farms. Consequently, the beliefs, decisions and practices of these producers can be expected to have a disproportionate influence on the Illinois swine industry if only on the basis of the large number of hogs that they raise. However, as prominent and successful producers, the participants of this survey might also be expected to be trendsetters for other Illinois swine producers. The producers in this survey provided very thoughtful and candid responses to the survey questions. Still, the guarantee of confidentiality helped producers freely discuss what they viewed as shortcomings in their own operations and in the industry.

All producers in this survey said that they shared in the responsibility for pork food safety. Evidence that their food safety commitment was genuine was found in the fact that each participant had written SOPs for multiple activities related to pork food safety. Participants shared several good, practical suggestions for production improvements of microbial pork safety. Consistent with an earlier study of a random survey of smaller Illinois pork producers (3), responses in this survey indicated an incomplete awareness of fundamental aspects of foodborne microbial pathogens. For example, there was apparently an incomplete awareness among participants that asymptomatic swine can carry and shed *Salmonella* and other microbial foodborne pathogens. Five of the participants voiced their need for more information about microbial foodborne pathogens in swine. The limited familiarity with microbial pathogens is similar to a broader survey of 297 Illinois producers of varying sizes, in which 12.8–90.5% of responses to basic questions about food safety pathogens were correct (3). Taken together, responses to these two surveys indicate the need for additional information on microbial foodborne pathogens in swine.

Although pride in their product and concern for consumer welfare play a definite role in pork safety decisions of these producers, economics also have an important influence on attitudes and decisions. Animal identification, trace back mechanisms, and producer accountability were identified as desirable aspects of a producer/packer relationship. These producers indicated that if their operations can demonstrate that they produce a superior product they should be compensated accordingly. Several producers indicated that, although avoiding discounts for substandard hogs was a motivator for quality assurance, premiums for superior quality would be a preferred motivator. Avoiding a discount or retaining the ability to sell to a specific packer is associated with merely meeting a minimum standard set by government or packers. Potential for increased profit would do more by motivating producers to continuously strive to raise their standards to surpass other producers, thus continuously raising overall industry standards.

Several producers mentioned that perceived increases in consumer pressure for preharvest food safety were driving changes throughout the food production industry. Whether market demand

will reward the development and certification of improved production practices to reduce the incidence of foodborne illness is an important and open question for pork producers (*4*). Many respondents to our survey expressed doubt that increased consumer spending associated with increased food safety would be equitably distributed back to producers. They were concerned that new revenue would not be forthcoming to offset new expenses required for implementing new food safety practices on the farm. Although some producers view themselves as receiving meager returns for their improvements in preharvest food safety, many describe that inequity as an unavoidable aspect of securing a market for their product.

These producers are interested in on-farm food safety. Although most believed the farm was the least important of the links in the food safety continuum, several still believed that the farm component is important because it is the only segment of food safety over which they have any control. However, they also expressed concern that much can go wrong with regard to pork safety after the pigs have left their control. For example, one producer said, "We could deliver a perfectly healthy, clean animal and if somebody does something wrong in the plant or restaurant or home, people could still get sick and blame us."

All producers in this survey reported having SOPs for multiple activities that might have direct or indirect relevance to microbial pork safety in swine production. Even when a producer did not consider a specific activity to be relevant to pork safety, there were often SOPs in effect for the activity, presumably because of other motivators. Euthanasia was the activity that participants most frequently deemed irrelevant to pork safety and for which written SOPs were not consistently in place. Management of euthanasia might be directly related to food safety, as it can be an important part of reducing pathogen propagation and transmission. Pigs that are candidates for euthanasia commonly suffer from serious injuries or illnesses and are often stressed animals. If afflicted animals are not removed from the herd they can serve as a source of increased disease risk for other animals, and this risk may include agents such as *Salmonella*. Because swine producers are in the business of keeping pigs alive and healthy, stockmen might tend to avoid such an unpleasant task as euthanasia, especially if the standard procedures are not written into SOPs. Consequently, including a specific SOP for euthanasia may enhance food safety.

Effective SOPs should be site specific and employees should be equipped with the means to carry out SOPs on a consistent basis. One participant reported that some locations in their operation could not be cleaned and disinfected between batches of pigs if temperatures were too cold, forcing a deviation from the SOP. Such a deviation might be expected to undermine worker confidence in the overall value of those SOPs and lead to additional "unplanned deviations" from SOPs. Furthermore, working conditions that prevent employees from doing their job according to prescribed standards might lead to job dissatisfaction and higher turnover. A simple solution would be to revise the SOP to reflect a contingency for expected deviations necessitated by external circumstances.

Responses of these producers help to identify current food safety practices and needs in swine production. Large producers such as the participants in this study produce the majority of pigs in the United States and often hold positions of industry leadership. Responses indicate that there is a high level of commitment to preharvest pork food safety among the producers in this survey. Results identify the need to further develop the knowledge, technology, and economic incentives available for the on-farm management of microbial food safety hazards in swine production. The participant responses indicated that SOPs for a multi-site system could sometimes not be carried out because of site-specific factors, suggesting the need for site-specific systems that promote consistent application of pre-harvest food safety procedures in swine production.

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Development and Evaluation of an Advanced HACCP Workshop for Meat Processors

Mindy Brashears,[1*] Dennis Burson,[2] Liz Boyle,[3] Fadi Aramouni,[3] Jason Mann,[1] and Mark Murphy[3]
[1]Texas Tech University, Department of Animal and Food Sciences
204E Food Technology Building, Lubbock, TX 79409
[2]University of Nebraska, Department of Animal Science, Lincoln, NE
[3]Kansas State University, Department of Animal Sciences and Industry, Manhattan, KS

SUMMARY

A one-day advanced HACCP workshop was developed by Extension Specialists at the University of Nebraska and Kansas State University. The overall goal of this workshop was to increase the knowledge of small meat processing establishments so that they could more effectively manage HACCP systems in their facilities. Topics discussed in the workshop included; HACCP verification, HACCP validation and experimental design, sampling plans, USDA in-depth verification reviews (IDV), reassessment, auditing, HACCP-based inspection model programs (HIMP), and the relationship of HACCP to total quality management (TQM) programs and statistical process control (SPC). The workshop was delivered as a pilot test program to processors to ensure that the content addressed current industry needs. The format for topic delivery was 30 min presentations by extension specialists. Additionally, participants completed working group activities that allowed them to design studies to validate or change CCPs in a plan, to apply pathogen modeling programs to specific processes and to subject data collected during HACCP monitoring to SPC in order to identify trends. The participants completed an evaluation after each activity and a focus group analysis was conducted at the end of the workshop. Although most participants were familiar with the topics covered, 100% of them indicated that presentations contained information that were useful in their businesses. The working group exercises were also helpful to most participants, with 60% and 87% of the participants indicating that the HACCP validation case studies and SPC activities would be useful, respectively. Focus group results also indicated that all topics were important to meat processors in the day-to-day management of their plans. The meat processors indicated that ongoing HACCP training was important to them and that the advanced topics covered in this workshop should continue to be included in future advanced workshops. They indicated that one-day workshops were a good form of training because such workshops resulted in relatively little time away from their businesses and kept them up to date on current issues. Based on these results, the advanced HACCP course will continue to be offered in a format similar to that used with the pilot group.

A peer-reviewed article.

*Author for correspondence: Phone: 806.742.2469;
Fax: 806.742.2427; E-mail: mindy.brashears@ttu.edu

INTRODUCTION

In 1996 *The Final Rule on Pathogen Reduction: Hazard Analysis Critical Control Point (HACCP) Systems* was published in the Federal Register *(1)*. These new regulations called for pathogen reduction measures and set microbiological performance standards that all meat and poultry processors must meet. One aspect of the new USDA/FSIS regulatory requirements with regard to pathogen reduction is the implementation of HACCP plans in meat and poultry processing facilities. All federally inspected meat and poultry processors were required to implement HACCP by January 2000. Large and small processors implemented HACCP in 1998 and 1999, respectively, whereas very small processors implemented in 2000. Additionally, each processor must have one person trained in the HACCP principles.

HACCP was initially developed by NASA and Pillsbury to provide the safest food possible for the space program. The National Advisory Committee for the Microbiological Criteria for Foods has standardized the original HACCP concept into 7 step-by-step principles that can be used by the food processing industry to reduce, prevent or eliminate biological, chemical, and physical hazards in the final food product *(2)*. A properly written, implemented plan should reduce hazards if the appropriate hazards are identified in the hazard analysis and if the critical limits (CL), and corrective actions are based on sound scientific data. However, much of the scientific information needed to develop scientifically sound HACCP plans is not available, especially in processing environments where there are no "kill" steps. Meat and poultry processors producing a raw final product typically must rely on temperature control to prevent the growth of pathogens. They have been faced with the challenge of collecting and interpreting data generated in their processing plant in order to validate their plans.

Additionally, processors are facing "Phase II" of HACCP implementation, in-depth verification (IDV). Currently, IDV is conducted "for cause" only, but processors will soon be randomly selected to undergo an IDV. Eventually, most processors will be subjected to this in-depth analysis of their HACCP plan.

During an IDV, the FSIS will send a team of scientists and regulatory officials to review the adequacy of the HACCP plan and SSOP programs *(3)*. The current FSIS protocol uses a checklist system to document that the HACCP plan is scientifically valid. Each section of the HACCP plan is evaluated and particular emphasis is given to the hazard analysis critical control point (CCP) sections. Decisions made in these sections must be science-based and must be applicable in the processing plant environment. Scientific data used to support decisions must be validated in a processing plant environment as well as in laboratory studies. Currently there is a lack of scientific data to bridge the gap between laboratory studies and in-plant applications.

Since the Final Rule was adopted, several groups, including universities, trade and professional associations, and private consulting groups, have offered the traditional 3-day introductory to HACCP workshop. These workshops have been instrumental in training processors in the principles of HACCP and the basics of writing a HACCP plan.

As all the implementation dates have passed, meat and poultry processors are faced with new challenges. Most are related to HACCP validation, verification and auditing. To assist processors in overcoming these challenges, a 1-day advanced HACCP workshop was developed.

METHODS

A team of scientists and extension specialists worked together to identify the topics included in the HACCP workshop. Team members were extension specialists and associates from University of Nebraska and Kansas State University with expertise in meat processing, food processing and food microbiology. All team members had extensive experience in delivering introductory HACCP workshops and assisting processors in writing, implementing and validating HACCP plans.

The following topics were chosen to be included in the workshop:

- HACCP Plan Verification
- Validation of HACCP Plans and Experimental Design
- Sampling Plans for Microbiological Analysis
- USDA In-depth Verification Reviews
- Reassessment of HACCP Plans
- Auditing HACCP
- HACCP Based Inspection Modeling Programs
- HACCP, Total Quality Management, and Statistical Process Control

The course also included working group activities in HACCP verification and in SPC.

A brief description of the specific information included in each section of the course follows.

Verification

The details of HACCP principle #6, verification, were discussed in this presentation. Included were discussions of the purpose of verification, verification activities, and examples of verification activities; review of records; thermometer calibration; pre-shipment review; reassessment and documentation of reassessment activities; and scheduling of verification activities.

Validation of HACCP Plans

Validation was discussed separately from verification to emphasize the relationship between the two. We specifically discussed the differences between validation and verification, as well as when to validate and when to verify. Validation using existing scientific literature

as well as generation of new scientific data to validate unique processes was covered in the presentation. A brief discussion of experimental design was included to teach processors how to take samples and how to determine sample sizes, so that they can design validation studies in their processing plants.

In-depth verification reviews

The regulatory aspects of in-depth verification reviews were discussed. Topics included the ten checklists used by the USDA review team as well as the types of individuals on the review team. Preparing for an IDV and how to communicate with the IDV team were discussed in detail.

HACCP reassessment

HACCP plan reassessment was discussed from both regulatory and non-regulatory perspectives. Information was presented on how to conduct the reassessment, including which documents to reassess and how to verify that the reassessment was done.

HACCP-based inspection models project

The history and current regulatory status of the HIMP project was discussed. Responsibilities of the plant and of the FSIS were covered. The "traditional" inspection programs were compared to the HIMP inspection process to clarify how a conversion to the alternative system could be accomplished. The data from the pilot HIMP project was discussed.

Microbial sampling for HACCP verification

The current regulatory requirements for microbial testing were discussed, as well as how to design a sampling plan to detect pathogens in the final product or in the raw product. The elements of a sound sampling plan were identified and the types of samples were discussed. Emphasis was given on the interpretation of data and what negative and/or positive results indicate in terms of product safety. A detailed example of developing a sampling plan for control of *Listeria* was discussed.

HACCP, TQM, and SPC

The relationship between TQM and HACCP was discussed in terms of HACCP as a TQM program. The steps involved in developing a TQM plan were presented, as well as how to implement a TQM plan. Basic statistics were discussed with regard to SPC. Specific examples were included of how SPC could be utilized to track HACCP data and to pinpoint problem areas through a statistical thought process.

The following are the case studies used in the workshop to allow processors to apply the information learned in the course:

Validation case study

1. A meat processor is fabricating carcasses into subprimal cuts. The processor wants to measure the carcass temperature as it enters the processing area (maintained at 50°F) as the CCP. The processor must assume that the subprimal cuts will remain cold during processing. What data can the processor collect to ensure that the final product will be cold?
2. A processor wants to change the CL of a CCP cooking temperature to 150°F instead of 160°F. What data should be collected to ensure that the product is safe?
3. A processor has recently implemented a HACCP plan and is monitoring the amount of visible fecal contamination on beef carcasses by selecting 10 carcasses/hour and checking them for visible contamination. The processor has recently lost several employees and has decided to monitor the carcasses every 2 hours instead of every hour. What should the processor do to validate that the longer monitoring interval is still resulting in a safe product?

SPC and HACCP activity

Data sets were given and the participants were required to calculate the following:

mean,
median,
mode,
and standard deviation.

They were then required to graph means over a period of time to pinpoint trends in the data.

Each group was given one hour to complete each activity, after which results were presented to the entire group.

The topics were chosen based on the needs that team members identified after having spent the past several years working with processors and identifying new needs as HACCP implementation was completed and more advanced issues became apparent.

The goal of the workshop was to teach processors how to validate HACCP plans, by using either currently available scientific data, or pathogen modeling programs, or by collecting data in their own processing environments. Additionally, we wanted to teach processors how to prepare for IDV reviews and audits and give them basic information on HIMPs.

Course format and evaluation

The course consisted of power point presentations delivered by the team members, followed by working group activities in which knowledge learned from the presentations was applied.

Fifteen processors were invited to pilot test and evaluate the workshop. They were allowed to attend

TABLE 1. Evaluation of workshop participants to determine usefulness of advanced HACCP workshop topics

	I Already Knew This Information		This Information will be Useful to Business	
	Yes	No	Yes	No
HACCP Plan Verificotion				
Verificotion Activities Needed				
CCP Verificotion Activities				
Colibration				
Record Review				
Employee Audits				
Overoll HACCP Plan Verification				
Volidotion of HACCP Plans/Experimental Design				
Whot is Validation				
When and What to Validate				
Experimentol Design				
Doto Collection ond Interpretation				
Case Study/Group Exercise				
Sampling Plans for Microbiological Analysis				
Importance of Sompling Plons				
Sample Collection				
Risk Assessment				
Types of Sampling Plans				
Determining Sample Sizes				
USDA In-Depth Verificotion Reviews				
What is an IDV				
Review Process				
IDV Checklist				
Preparing for an IDV				
Reassessment of HACCP Plans				
USDA Regulotions				
Conducting a Reossessment				
Chonges to Consider during a Reossessment				
Reassessment Reminders				
Auditing HACCP				
Frequency of Audits				
All Pertinent Records and Activities				
Internal vs. External				
HACCP-based Inspection Model Program				
Introduction/Purpose of HIMP				
Plant Responsibilities/Inspection				
Improvements in Plants				
Performonce Stondords for HIMP				
HACCP, TQM, and SPC				
Whot is TQM				
Integration of HACCP into o TQM Progrom				
Application of SPC to HACCP				
Group Activity				

TABLE 2. Pilot group testing questions to determine the effectiveness and usefulness of the course content in an advanced HACCP course

1. Would each of you describe how you work with HACCP plans in your company? A general description is ok and you do not need to report items that may be specific to your company.
2. What topics in the workshop do you think were important for you and your company to know?
3. Of these important topics just mentioned, which do you feel are critical for maintaining your current HACCP plan?
4. What topics do you feel were the least important for you and your company as you work with HACCP?
5. What are some of the most important HACCP-related issues you or your company has addressed within the past year? What HACCP-related issues do you expect to have in the coming year? Has inspection (FSIS) told you about In-depth Verification Reviews?
6. Was there a good mix of lectures and group activities?
7. Which group activities did you find to be the most useful?
8. Have you been to other advanced HACCP workshops?
9. How does this workshop on advanced HACCP Validation, Verification, and Auditing compare to other advanced HACCP workshops?
10. How would this workshop help small processors of less than 500 employees?
11. Would you send others from your company to attend this workshop and who are the people (position title only) who need this information?

Other comments or concerns:

the workshop free of charge and gave input into the course content. An evaluation form was given to each participant to obtain information on whether the course information was new and/or useful to the participants. The complete evaluation form is presented in Table 1. Following the workshop, an independent individual, not involved with the course, delivered the questions to the group participants. The complete set of focus group questions is presented in Table 2.

Following pilot testing, the course was modified based on the comments from the pilot group prior to delivering the course in its final version.

RESULTS

Although advanced HACCP courses commonly cover the seven principles of HACCP, the only overlap of information between this course and the introductory HACCP course was the information on HACCP plan verification. We did not review all the 7 principles of HACCP, because participants are expected to have obtained this information from attending an introductory HACCP course. Data indicated that even though most of the information presented was not new to the participants, they still thought that it was useful for their businesses (Fig. 1). This section was not altered after focus group testing.

Experimental design, data collection, and sampling plans were new topics to 100% of the participants (Fig. 2 and 3). All participants felt that the topic of HACCP plan validation was useful and that they would use it in their businesses. The working group activities were re-worded and more information was given to participants in subsequent courses to ensure that the case study scenarios were clear to the working groups. In addition, in subsequent workshops we gave the processors more flexibility in that they could identify their own scenarios, which were more relevant to their processes.

The information presented on USDA In-Depth Verification Reviews was new to most participants (Fig. 4). All participants indicated that the topics would be beneficial in their businesses. No changes were made to this section after pilot testing.

Most of the course participants were aware that USDA regulations required them to conduct an annual re-assessment of their HACCP plans, but most did not know how to do this (Fig. 5). They felt that this information was beneficial, and no changes were made to this section of the workshop after testing. Af-

Figure 1. Pilot group response to activities and presentations on the topic of HACCP Plan Verification

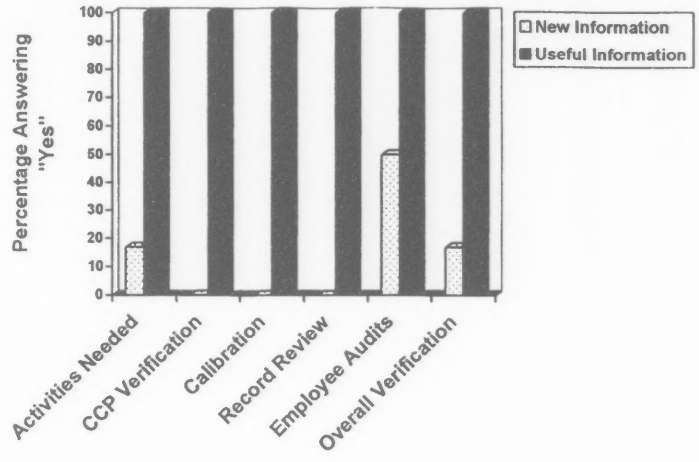
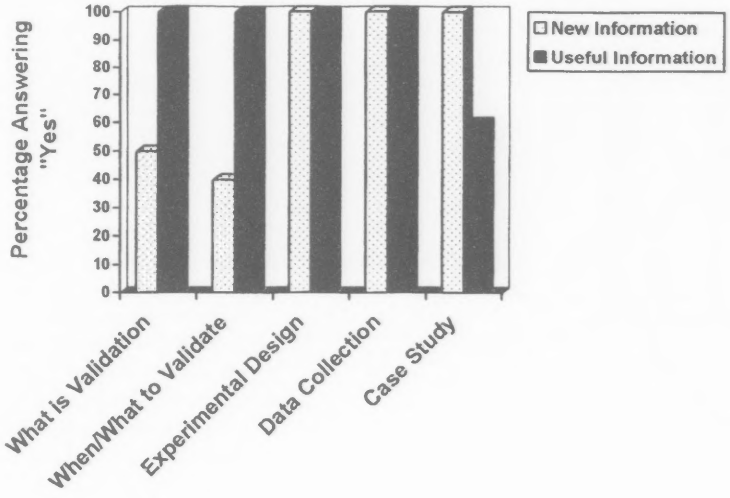


Figure 2. Pilot group response to activities and presentations on the topic of Validation of HACCP Plans/Experimental Design



ter focus group testing, we added information on how to document the re-assessment process.

Most participants indicated that the information presented in the HACCP Auditing section was useful (Fig. 6). Very few participants had received previous information on this topic. This section was modified slightly to remove some information that overlapped material presented in other sections.

Very few participants were familiar with the topic of HIMP (Fig. 7). Although the majority of them thought that the information would be beneficial to their businesses, the response was not 100% as had been observed in the other sections. The lack of enthusiasm was partially due to the legal issues pending at the time of the workshop. We decided to keep the presentation in the workshop.

The final topics – HACCP, SPC and TQM – were new to most participants, who nevertheless felt that they would use the information in their businesses (Fig. 8). The participants wanted more information about developing a TQM team and how to relate this team to the HACCP team. No modifications were made to this section after testing.

The focus group testing following the workshop resulted in the following responses:

1. Would each of you describe how you work with HACCP plans in your company? A general description is ok and you do not need to report items that may be specific to your company.
   - The plant manger uses the plans for pre-shipment and incoming shipments.
   - They use HACCP plans for checking and keeping records.
   - Another use was for the quality control division.
   - They use the plans for re-assessment and verification of records.
   - They use them to review SSOPs.
2. What topics in the workshop do you think were important for you and your company to know?
   - The IDV was important.
   - The sampling of microbiology and in depth reviews of HACCP.
   - The temperature logs and CD.
   - The reassessment section.
3. Of these important topics just mentioned, which do you feel are critical for maintaining your current HACCP plan?
   - They felt the IDV, reassessment, TQM, SSOP, HIMP, SPC, and temperature recordings are the most critical topics.

Figure 3. Pilot group response to activities and presentations on the topic of Sampling Plans for Microbiological Analysis

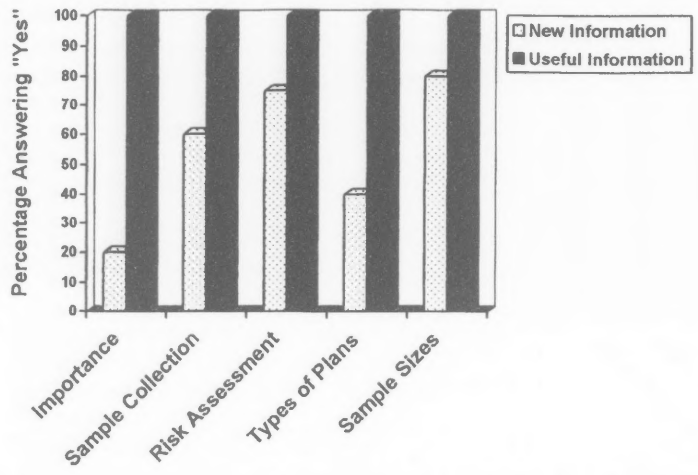
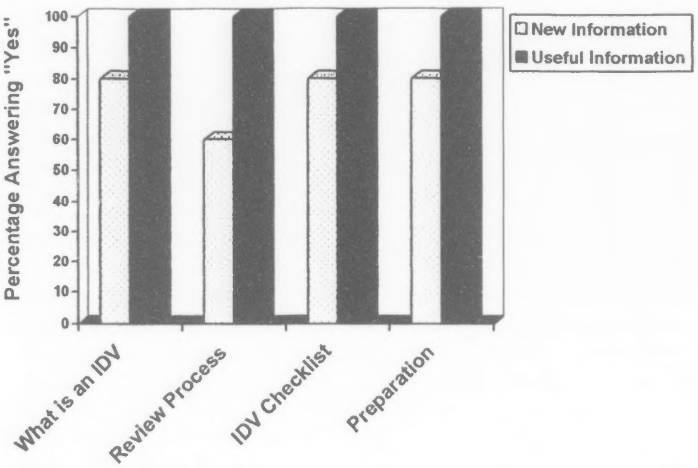


Figure 4. Pilot group response to activities and presentations on the topic of USDA In-Depth Verification Reviews



4. What topics do you feel were the least important for you and your company as you work with HACCP?
   - Everybody thought all of the topics were important.
5. What are some of the most important HACCP related issues you or your company has addressed within the past year? What HACCP related issues do you expect to have in the coming year? Has inspection (FSIS) told you about In-depth Verification Reviews?
   - Some issues in the past year were using scientific data to make modifications to the HACCP plans.
   - Another was adding ingredients to a product that involved changing the HACCP plan.
   - Training people about using and following the HACCP plan was difficult especially when there are part time employees coming and going.
   - Doing reassessment when things change on the product line or in the actual process flow of production.
   - Some of the issues expected in the future were reassessment of the HACCP plans, scientific backup, keeping track of records for different operations and keeping other things in order so there are no mandates.
   - On the last part of this question about the FSIS, there was a general consensus that the FSIS was not keeping the group informed about In-depth Verification Reviews. In fact one of the comments made was that the FSIS told the employer "they were out there" and nothing else was said.
   - Another overall concern was that the FSIS was still developing issues, which have not been set in stone, or that some things are still unclear. One other comment was "it's a guessing game and there are a lot of questions with no answers."
6. Was there a good mix of lectures and group activities?
   - Yes, there was a good mixture of lectures, but there were some activities and lectures that were not useful because they were discussed too quickly for the participants to understand.
   - Also, the consensus was that there were not a lot of group activities.

Figure 5. Pilot group response to activities and presentations on the topic of Reassessment of HACCP Plan

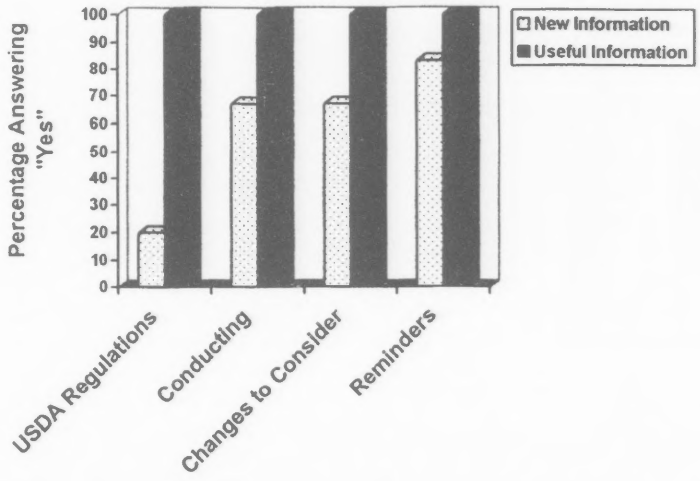
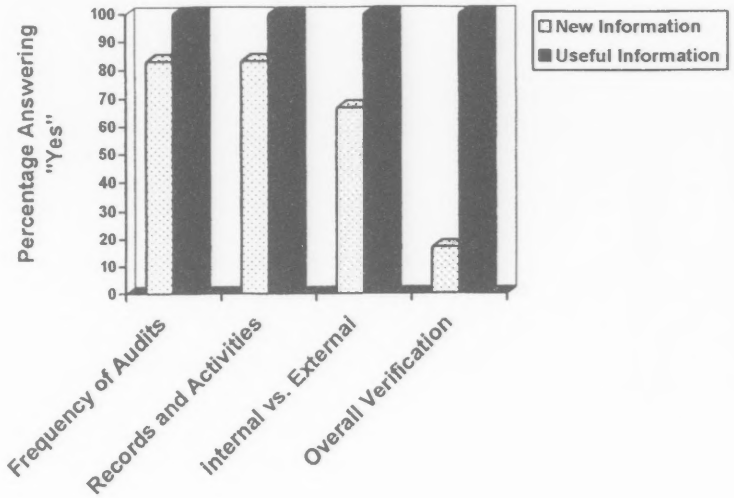


Figure 6. Pilot group response to activities and presentations on the topic of Auditing HACCP



7. Which group activities did you find to be the most useful?
   - Everybody in the group thought the first activity was the most useful.
8. This question was skipped because it was already asked in the course evaluation.
9. Have you been to other advanced HACCP workshops?
   - One person reported attending an IDV workshop in Kansas City.
10. How does this workshop on advanced HACCP Validation, Verification, and Auditing compare to other advanced HACCP workshops?
    - In comparison to other advanced HACCP workshops, our workshop seemed more laid back and is less expensive. On the other hand, the workshop in Kansas City had more analytical discussion in the discussion groups.
    - Another difference was that Kansas City had other inspectors and other ideas from different plants on how to handle certain situations. There were more ideas on how to respond to different documentation.
11. How would this workshop help small processors of less than 500 employees?
    - It would help small processors by making them aware of the rules, regulations, and documentation required by the FSIS.
    - This workshop would also help get people prepared, such as employers, employees, HACCP coordinators and other personnel, that need to know FSIS regulations. This will save people in the long run.
12. Would you send others from your company to attend this workshop, and who are the people (position title only) who need this information?
    - The overall consensus was "yes," they would send other people to this workshop. Some of the people they would send would be: Quality Assurance, Plant Managers, Quality Control Supervisors and HACCP Coordinators.

Other comments or concerns:

- There was overall agreement that there should be more of these one-day workshops where people could be updated on what's going on with the FSIS, because nobody from the FSIS is keeping people informed.

Figure 7. Pilot group response to activities and presentations on the topic of HACCP-based Inspection Modelling Plans (HIMP)

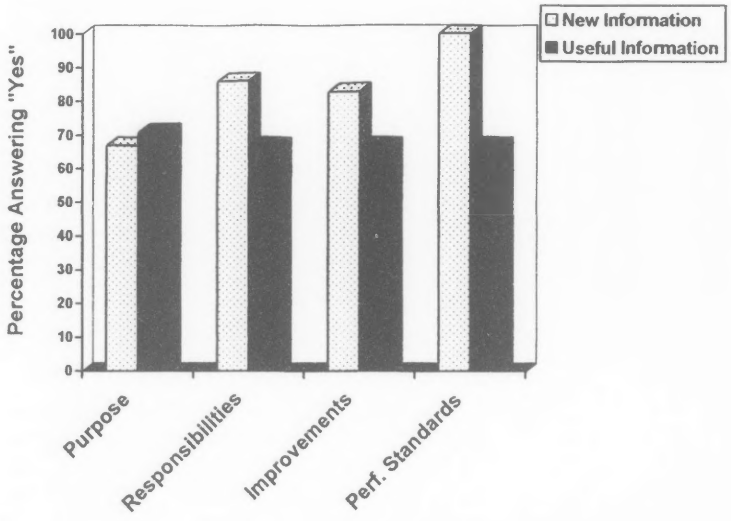
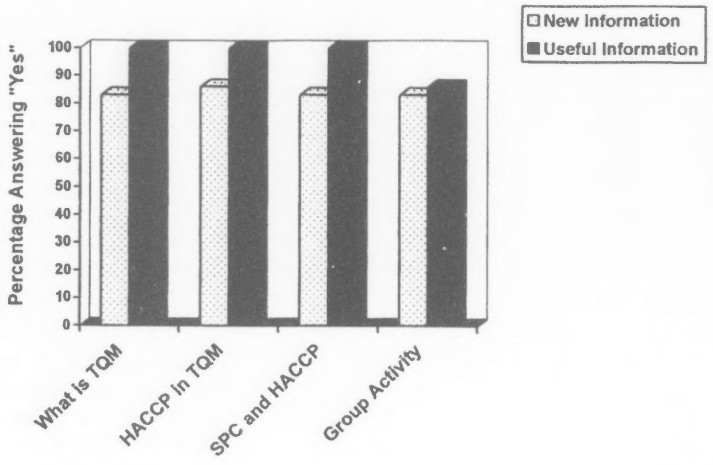


Figure 8. Pilot group response to activities and presentations on the topic of HACCP, Total Quality Management (TQM) and Statistical Process Control (SPC)



- The one-day workshop is a great idea because people (small processors) can get away for a day without being concerned if they can leave plant for one day.
- There should be a section mentioned about Recall issues.
- One comment made was "We need to know what our suppliers are doing even if they don't slaughter." This comment reflects the fact that there needs to be documentation so when something does go wrong they can trace the source of the problem.
- Another comment was made to the effect that there was a lot of repetition in some of the discussions, but that participants always learn something new from each workshop they attend.

CONCLUSIONS

The overwhelmingly positive response of workshop participants in the focus group indicated that the topics presented were timely, and needed and that they would assist the processors attending the workshop to meet the ongoing challenges associated with HACCP implementation. HACCP is an important tool in providing consumers with the safest possible food supply, and it is important that processors receive the information they need to continue to meet regulatory requirements and produce safe products.

Since the focus-group testing, the workshop has been modified and offered to other audiences. The response continues to be positive, and processors continue to offer suggestions to further improve the workshop.

ACKNOWLEDGMENT

The authors thank the USDA Food Safety and Quality Initiative for funding this project.

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1. Federal Register. 1996. Pathogen reduction: hazard analysis and critical control point (HACCP) systems: final rule. USDA-FSIS. Fed. Register 61:38805–38989.
2. National Advisory Committee on Microbiological Criteria for Foods. 1998. Hazard Analysis and Critical Control Point principles and application guidelines. J. Food Prot. 61(6):762–775.
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Code of Practice on Managing Food Allergens

National Food Processors Association

Introduction

Food allergies affect only a small percentage of consumers. However, some of these sensitive consumers can develop serious or life-threatening allergic reactions if exposed to certain allergenic proteins. Currently, there is no cure for food allergy. The only successful method to manage food allergy is avoidance of foods containing the allergen.

Food processors must be diligent in informing consumers about the presence of allergenic ingredients in their products. Appropriate measures also must be taken to minimize the risk to allergic consumers of coming in contact with food allergens that are inadvertently present in a product and consequently not declared on the label.

Allergenic proteins in and derived from the following foods are the major food allergens in the United States: crustacea (e.g., crab, crayfish, lobster, and shrimp), egg, fish, milk, peanuts, soy, tree nuts (e.g., almonds, Brazil nuts, cashews, hazelnuts/filberts, macadamia nuts, pecans, pine nuts, pistachios, and walnuts), and wheat. Ingredients made from these foods that do not contain protein are not allergenic.

It is estimated that the allergens from the list account for approximately 90% of all food allergies in the United States. As more scientific evidence becomes available, the list may change.

Code of Practice

To address the issue of food allergens, the National Food Processors Association (NFPA), the scientific trade association for the food processing industry, has developed a Code of Practice. The purpose of the Code is to delineate the general practices that can ensure effective strategies of food allergen management. This Code, which was developed and approved with input from food companies, states that NFPA Members subscribe to the following practices:

1. NFPA Members label, in terms commonly understood by consumers, the major food allergens in their ingredient declarations, including those that are part of natural and artificial flavors, or other food ingredients.
2. NFPA Members use Good Manufacturing Practices (GMPs) and other allergen control strategies to manage and minimize the potential cross-contact of the major food allergens. These strategies include, but are not limited to, training, separation, sanitation, and scheduling.
3. In those instances where GMPs and other allergen control strategies are being followed but are not reliable in sufficiently minimizing the risk of allergen cross-contact, then ingredient declaration or supplementary information, such as allergen labeling or inclusion of additional food allergen information, would be appropriate.
4. NFPA Members will take an active role in educating employees, business partners, food service customers, and consumers about food allergens.
5. NFPA and its Member companies continue to develop processing, analytical, and operational strategies to further reduce the risk to allergic consumers of ingesting food allergens.

Food Allergy Q & A

The following Q&A was adapted from material developed and approved for use by the IFIC Food Allergy Forum.

Continued on next page

Editor's Note: The above material was submitted for publication by the National Food Processors Association, 1350 I Street NW, Suite 300, Washington, D.C. 20005-3305; Web site: www.nfpa-food.org.

Q. What is a food allergy?

A. Food allergy is a reaction of the body's immune system to something in a food or an ingredient in a food—usually a protein. It can be a serious condition and should be diagnosed by a board-certified allergist.

Q. How many people have a food allergy?

A. According to the National Institutes of Health, approximately 5 million Americans, (5 – 8% of children, and 1 – 2% of adults) have a true food allergy. Many people with any type of food sensitivity have food intolerances. Fewer people have true food allergy involving the immune system.

Q. What foods trigger allergic reactions?

A. There are eight major food allergens, including milk, eggs, peanuts, tree nuts (such as walnuts and almonds), soy, wheat, fish, and shellfish. These eight foods are the most common food allergens and cause more than 90% of all food allergic reactions. Among children, allergy to milk, eggs and peanuts are most common.

Q. What are the symptoms of food allergy?

A. Symptoms of food allergy differ greatly among individuals. They can also differ in the same person during different exposures.

Allergic reactions to food can vary in severity, time of onset, and may be affected by when the food was eaten.

Common symptoms of food allergy include skin irritation such as rashes, hives, and eczema, and gastrointestinal symptoms such as nausea, diarrhea, and vomiting. Asthma, runny nose, and shortness of breath can also result from food allergy.

Some individuals may experience a more severe reaction called anaphylaxis, a rare but potentially fatal condition in which several different parts of the body experience allergic reactions. These may include itching, hives, swelling of the throat, difficulty breathing, lower blood pressure, and unconsciousness.

For more information about food allergens, visit our web page at www.nfpa-food.org.

Highlights of the Executive Board Meeting September 23, 2002

Following is an unofficial summary of actions from the Executive Board Meeting held by teleconferenee on September 23, 2002:

Approved the following:

- Minutes of June 28-July 4, 2002 Exeeutive Board Meeting

Discussed the following:

- Name ehange for *DFES* and implementation timeline
- *DFES* & *JFP* update — manuscript status examined, *JFP* Online reviewed
- Web site e-commeree transaction totals
- Membership remains steady
- Advertising sales exceed budget projections
- July finaneial statements reviewed and compared to budget
- Retirement plan eontribution
- Fall Affiliate Newsletter distributed via E-mail
- IAFP Offieer made presentation at one Affiliate meeting this summer. Six are scheduled for fall meetings
- Non-compliant Affiliates — seeond letters to be mailed October 31
- Affiliate Membership Aehievement Award restrueturing
- Potential new Affiliate organizations
- International Food Safety Icons — reviewed proto-types
- Foundation Fund — new Committee Members
- Finaneial results from IAFP 2002
- IAFP 2003 — tours and events
- IAFP 2005 — Baltimore, MD
- Future Annual Meeting site seleetion
- IAFP 2002 workshop finaneial results
- Costa Rica workshop on produee
- IAFP on the Road — USDA / FSIS — Thinking Globally-Working Locally, Conferenee on Food Safety Eduеation, September 18-20, 2002 — excellent interest.
- IAFP on the Road —Food Safety Summit, Mareh 18-20, 2003
- 3-A Sanitary Standards, Inc. update
- Sponsorship of session(s) for Food Safety Summit
- Corporate Challenge update
- World Health Organization Non-Governmental Organization
- European Assoeiation Services offered

Next Exeeutive Board meeting: January 19-20, 2003

Call for Abstracts

IAFP 2003
The Association's 90th Annual Meeting
August 10-13, 2003
New Orleans, Louisiana

General Information

1. Membership in the Association is not required for presenting a paper at IAFP 2003.
2. All presenters must register for the Annual Meeting and assume responsibility for their own transportation, lodging, and registration fees.
3. There is no limit on the number of abstracts registrants may submit. However, presenters must present their presentations.
4. Accepted abstracts will be published in the Program and Abstract Book. Editorial changes may be made to accepted abstracts at the discretion of the Program Committee.
5. Abstracts must be submitted Online or via E-mail.

Presentation Format

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

Instructions for Preparing Abstracts

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

Abstract Submission

Abstracts submitted for IAFP 2003 will be evaluated for acceptance by the Program Committee. Be sure to include all ten (10) items requested in the "Instructions for Preparing Abstracts" above; failure to do so may result in rejection. Information in the abstract data must not have been previously published in a copyrighted journal.

Abstracts must be received no later than January 6, 2003. Submit abstracts through one of the following methods:

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

Selection Criteria

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

Rejection Reasons

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

Projected Deadlines/Notification

Abstract Submission Deadline: January 6, 2003. Submission Confirmations: On or before January 7, 2003. Acceptance/Rejection Notification: February 14, 2003.

Contact Information

Questions regarding abstract submission may be directed to Bev Corron, 515.276.3344 or 800.369.6337; E-mail: bcorron@foodprotection.org.

Program Chairperson

Lynn McMullen
University of Alberta
Agricultural, Food and Nutritional Science
4-10 Agriculture/Forestry Center
Edmonton, Alberta T6G 2P5 Canada
Phone: 780.492.6015
Fax: 780.492.8914
E-mail: lynn.mcmullen@ualberta.ca

Abstract Form

DEADLINE: Must be Received by January 6, 2003

(1) Title of Paper _____

_____

(2) Authors _____

_____

(3) Full Name and Title of Presenter _____

_____

(4) Institution and Address of Presenter _____

_____

(5) Phone Number _____

(6) Fax Number _____

(7) E-mail _____

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

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

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

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

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

Call for Entrants in the Developing Scientist Awards Competitions

Supported by the International Association for Food Protection Foundation

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

Purpose

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

Presentation Format

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

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

General Information

1. Competition entrants cannot have graduated more than a year prior to the deadline for submitting abstracts.
2. Accredited universities or colleges must deal with environmental, food or dairy sanitation, protection or safety research.
3. The work must represent original research completed and presented by the entrant.
4. Entrants may enter only one paper in either the oral or poster competition.
5. All entrants must register for the Annual Meeting and assume responsibility for their own transportation, lodging, and registration fees.
6. Acceptance of your abstract for presentation is independent of acceptance as a competition finalist. Competition entrants who are chosen as finalists will be notified of their status by the chairperson by May 30, 2003.
7. All entrants with accepted abstracts will receive complimentary, one-year Association Membership, which includes their choice of *Dairy, Food and Environmental Sanitation* or *Journal of Food Protection*.
8. In addition to adhering to the instruction in the "Call for Abstracts," competition entrants must check the box to indicate if the paper is to be presented by a student in this competition. A signature and date is required from the major professor or department head.

Judging Criteria

A panel of judges will evaluate abstracts and presentations. Selection of up to five finalists for each competition will be based on evaluations of the abstracts and the scientific quality of the work. All entrants will be advised of the results by May 30, 2003. Only competition finalists will be judged at the Annual Meeting and will be eligible for the awards.

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

Judging criteria will be based on the following:

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

Finalists

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

Awards

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

Award winners will also receive a complimentary, one-year Membership including *Dairy, Food and Environmental Sanitation* and *Journal of Food Protection*.

Policy on Commercialism

for Annual Meeting Presentations

1. INTRODUCTION

No printed media, technical sessions, symposia, posters, seminars, short courses, and/or other related types of forums and discussions offered under the auspices of the International Association for Food Protection (hereafter referred to as to Association forums) are to be used as platforms for commercial sales or presentations by authors and/or presenters (hereafter referred to as authors) without the express permission of the staff or Executive Board. The Association 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 (hereafter referred to as 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 the Association forums.

2. TECHNICAL CONTENT OF SUBMISSIONS 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 Committee chairperson, technical reviewers selected by the Program Committee chairperson, session convenor, and/or 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 Program Committee chairperson and/or technical reviewers selected by the Program Committee chairperson 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 Program Committee chairperson, technical reviewers selected by the Program Committee chairperson, session convenor, and/or 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 not be publishable because it is proprietary to the author's agency or company or to the user. However, the scientific principles and validation of performance parameters must be described for such products or services. Conclusions and/or comparisons may be made only 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 goods or services must not be the focal point of the slide. Names or logos may be shown on each slide so long as they are not distracting from the overall presentation.

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 Program Committee chairperson, session convenor, and/or 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 Program Committee chairperson, session convenor, staff, or other reviewers designated by the Program Committee chairperson.

4. INTERPRETATION AND ENFORCEMENT

4.1 Distribution

This policy will be sent to all authors of submissions and presentations in the Association 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 staff and technical reviewers selected by the Program Committee chairperson. All reviewer comments shall be sent to and coordinated by either the Program Committee chairperson or the designated 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 receiving a printed copy of this policy, all authors presenting in a forum will be reminded of this policy by the Program Committee chairperson, their session convenor, or the 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 Program Committee chairperson and staff of the action taken.

4.5 Enforcement

While technical reviewers, session convenors, and/or staff may all check submissions and presentations for commercialism, ultimately it is the responsibility of the Program Committee chairperson to enforce this policy through the session convenors and staff.

4.6 Penalties

If the author of a submission or presentation violates this policy, the Program Committee chairperson 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, the Association reserves the right to ban the author and the author's agency or company from making presentations in the Association forums for a period of up to two (2) years following the violation or violations.

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Mail all correspondence to:
G. M. Gallaspy
P.O. Box 303017, Suite 1250
Montgomery, AL 36130-3017
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780.492.6015
E-mail: lynn.mcmullen@ualberta.ca

BRAZIL ASSOCIATION FOR FOOD PROTECTION

Pres., Mariza Landgraf ..... São Paulo
Vice Pres., Maria Teresa Destro ..... São Paulo
Sec'y., Ivone Delazari ..... São Paulo
Treas., Bernadette D.G.M. Franco ..... São Paulo
Delegate, Maria Teresa Destro ..... São Paulo

Mail all correspondence to:
Maria Teresa Destro
Univ. São Paulo
Av Prof. Lineu Prestes 580 Bl14
São Paulo, SP 05.508-900 Brazil
55.113.818.2399
E-mail: mtdestro@usp.br

BRITISH COLUMBIA FOOD PROTECTION ASSOCIATION

Pres., Clive Kingsbury ..... Surrey
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Treas., John Boyce ..... Vancouver
Delegate, Clive Kingsbury ..... Surrey

Mail all correspondence to:
Clive Kingsbury
J. M. Schneider
5523 - 176th St.
Surrey, BC V3S 4C2 Canada
604.576.1191 ext. 3740
E-mail: ckingsbury@home.com

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Recording Sec'y., Ross Henderson-McBean ..... Paso Robles
Delegate, John Bruhn ..... Davis

Mail all correspondence to:
John C. Bruhn
101B Cruess Hall
Dairy Research and Information Center
University of California-Davis
Food Science and Technology
Davis, CA 95616-8598
530.752.2192
E-mail: jcbruhn@ucdavis.edu

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Delegate, Carl Custer ..... Washington, D.C.

Mail all correspondence to:
Brett W. Podoski
FDA-CFSAN
Mail Stop HFS-615, Room 3C-032
5100 Paint Branch Pkwy.
College Park, MD 20740-3835
301.436.2048
E-mail: brett.podoski@cfsan.fda.gov

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Delegate, Michael Rhodes ..... Raleigh, NC

Mail all correspondence to:
Michael U. Rhodes
NC Dept. of Environment and Natural Resources
1632 Mail Service Center
Raleigh, NC 27699-1632
919.715.0930
E-mail: michael.rhodes@ncmail.net

CONNECTICUT ASSOCIATION OF DAIRY AND FOOD SANITARIANS

Pres., David Pantalone ..... Milford
Sec'y., John McGuire ..... Milford
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Delegate, Frank Greene ..... New Hartford

Mail all correspondence to:
Frank Greene
CADFS
280 Gilette Road
New Hartford, CT 06057
860.713.6160
E-mail: frank.greene@po.state.ct.us

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Delegate, Peter Hibbard ..... Oviedo

Mail all correspondence to:
Zeb E. Blanton
FL Dept. of Agri. & Consumer Service
3125 Conner Blvd., Room 288
Tallahassee, FL 32399-1650
850.488.3951
E-mail: blantoz@doacs.state.fl.us

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Vice Pres., Robert Brooks ..... Gainesville
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Sec'y., Frederica Copeland ..... Lithonia
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Mail all correspondence to:
Traci L. Sayer
Silliker Laboratories
2169 W. Park Ct., Suite G
Stone Mountain, GA 30087
770.469.2701
E-mail: traci.sayer@silliker.com

IDAHO ENVIRONMENTAL HEALTH ASSOCIATION

Pres., Paul Guenther ..... Lewiston
Past Pres., Edgar Hale ..... Coeur d Alene
Sec'y. Treas., Jim Lane ..... Twin Falls
Delegate, Frank Isenberg ..... Boise

Mail all correspondence to:
Frank Isenberg
Bureau of Env. Health and Safety
450 W. State St., P.O. Box 83720
Boise, ID 83720-0036
208.334.5947
E-mail: isenberg@idhw.state.id.us

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Sec'y., Larry Terando ..... Champaign
Treas., Nicolette Oates ..... Chicago
Delegate, Steve DiVincenzo ..... Springfield

Mail all correspondence to:
Larry Terando
Illinois Dept. of Public Health
2125 S. First St.
Champaign, IL 61820-7499
217.333.6914
E-mail: lterando@idph.state.il.us

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Sec'y., Margaret Voyles ..... Indianapolis
Delegate, Helene Uhlman ..... Hammond

Mail all correspondence to:
Helene Uhlman
Hammond Health Dept.
649 Conkey St., East
Hammond, IN 46324-1101
219.853.6358

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Treas., Jim Mills ..... Sibley
Delegate, Randy Stephenson ..... Stacyville

Mail all correspondence to:
Phyllis Borer
AMPI
1020 - 4th Ave., P.O. Box 36
Sibley, IA 51249
712.754.2511
E-mail: borerp@ampi.com

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Delegate, Angela Kohls ..... Topeka

Mail all correspondence to:
Tim Wagner
Sedgwick Co. Code Enforcement
1144 S. Seneca
Wichita, KS 67213
316.383.7951
E-mail: twagner@sedgwick.gov

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Pres. Elect, Sue Jewell ..... Florence
Past Pres., David Burton ..... Bowling Green
Sec'y., Brenda Haydon ..... Frankfort
Treas., Kim True ..... Frankfort
Delegate, Sue Jewell ..... Florence

Mail all correspondence to:
Sam Burnett
275 E. Main St.
Frankfort, KY 40621
502.564.3689 ext. 3684
E-mail: Sam.Burnette@mail.state.ky.us.

KOREA ASSOCIATION OF MILK, FOOD AND ENVIRONMENTAL SPECIALISTS

Pres., Duck-hwa Chung ..... Kyungnam
Vice Pres., Dong-Suck Chang ..... Pusan
Past Pres., Kook-Hee Kang ..... Kyunggido
Sec'y., Deog-Hwan Oh ..... Kangwondo
Delegate, Dong-Kwan Jeong ..... Pusan

Mail all correspondence to:
Deog-Hwan Oh
Division of Food and Biotechnology
Kangwon National University
192-1, Hyoja 2 Dong
Chunchon, Kangwondo 200-701, South Korea
82.361.250.6457
E-mail: deoghwa@cc.kangwon.ac.kr

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Vice Pres., Barry Searle ..... Westfield
Past Pres., Gail Stathis ..... Springfield
Sec'y. Treas., Lisa Hebert ..... Greenfield
Delegate, Barbara Kulig ..... West Springfield

Mail all correspondence to:
Barbara A. Kulig
Town of West Springfield
Municipal Office Bldg.
26 Central St.
West Springfield, MA 01089
413.263.3204

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Sec'y. Treas., Carol A. Schwar ..... Washington, NJ
Delegate, Fred Weber ..... Hamilton, NJ

Mail all correspondence to:
Carol Schwar
Warren County Health Dept.
319 W. Washington Ave.
Washington, NJ 07882
908.689.6693
E-mail: mncschwar@enter.net

MEXICO ASSOCIATION FOR FOOD PROTECTION

Pres., Alejandro Castillo ..... Guadalajara
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Treas., Nanci E. Martinez-Gonzalez ..... Guadalajara
Delegate, M. Rufugio Torres-Vitela ..... Guadalajara

Mail all correspondence to:
Lydia Mota De La Garza
Avenida 479 No. 35, Seccion 7
Unidad Aragon Del Gustavo A. Madero CP 07920 Mexico
01.5794.0526
E-mail: lgarza88@hotmail.com

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Treas., Becky Ouellet ..... Jackson
Sec'y., Alan Hauck ..... Ann Arbor
Delegate, Bruce DuHamel ..... Hemlock

Mail all correspondence to:
Bruce DuHamel
Mid-Michigan District Health Dept.
615 N. State St., Suite 2
Stanton, MI 48888
989.831.5237 ext. 304
E-mail: bduhamel@mmdhd.org

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Pres., Jesse Shields ..... Tupelo
Vice Pres., Anne Hogue ..... Canton
Past Pres., Willie Brown ..... Jackson
Sec'y./Treas., Rick Hill ..... Ripley
Delegate, Jesse Shields ..... Tupelo

Mail all correspondence to:
Jesse Shields
Public Health District II
P.O. Box 199
Tupelo, MS 38802
601.841.9015

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Past Pres., Joel VanHoose ..... Jefferson City
Sec'y., Andrew Hoffman ..... Warrenton
Treas., Gala Jaramillo ..... Jefferson City
Delegate, Linda S. Haywood ..... Springfield

Mail all correspondence to:
Linda S. Haywood
Dairy Farmers of America Inc.
800 W. Tampa, P.O. Box 1837
Springfield, MO 65801-1837
417.829.2788
E-mail: lhaywood@dfamilk.com

NEBRASKA ASSOCIATION OF MILK AND FOOD SANITARIANS

Pres., Dianne Peters ..... Lincoln
Vice Pres., Tom Tieso ..... Lincoln
Past Pres., Gary Hosek ..... Lincoln
Treas., Jill Schallehn ..... Omaha
Delegate, Tom Tieso ..... Lincoln

Mail all correspondence to:
Tom Tieso
Nebraska Dept. of Agriculture
3703 S. 14th
Lincoln, NE 68502
402.471.2176
E-mail: tomlt@agr.state.ne.us

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Past Pres., John Schrade ..... Jamaica
Council Chairman, John Grom ..... Vernon
Exec. Sec'y., Janene Lucia ..... Ithaca
Delegate, Steve Murphy ..... Ithaca

Mail all correspondence to:
Janene Lucia
NYS Assn. for Food Protection
172 Stocking Hall
Ithaca, NY 14853
607.255.2892
E-mail: jgg3@cornell.edu

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Past Pres., James Schothorst ..... Grand Forks
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Treas., Lisa Well ..... Bismarck
Delegate, John E. Ringsrud ..... Lakota

Mail all correspondence to:
John E. Ringsrud
ND Dept. of Ag/Milk Certification Program
600 E. Boulevard Ave.
Bismarck, ND 58505
701.247.2730
E-mail: jringsru@state.nd.us

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2nd Vice Pres., Virginia Meacham ..... Cincinnati
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Delegate, Gloria Swick-Brown ..... New Lexington

Mail all correspondence to:
Donald Barrett
Ohio Health Dept.
6855 Diley Road NW
Canal Winchester, OH 43110
614.645.6195
E-mail: donb@cmhhealth.org

ONTARIO FOOD PROTECTION ASSOCIATION

Pres., Robert Serapiglia ..... Weston
Vice Pres., Gail Evans Seed ..... Bright
Past Pres., D. Wayne Sprung ..... Mississauga
Sec'y. Treas., Melodie Wynne ..... Guelph
Delegate, Robert Serapiglia ..... Weston

Mail all correspondence to:
Glenna Haller
Ontario Food Protection Association
28-380 Eramosa Road, Suite 279
Guelph, Ontario N1E 7E1 Canada
519.823.8015
E-mail: ofpa-info@worldchat.com

PENNSYLVANIA ASSOCIATION OF MILK, FOOD AND ENVIRONMENTAL SANITARIANS

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Past Pres., Troye Cooper ..... Lebanon
Sec'y., Eugene R. Frey ..... Lancaster
Treas., Robert K. Mock ..... Boyertown
Delegate, Eugene R. Frey ..... Lancaster

Mail all correspondence to:
Eugene R. Frey
Land O'Lakes, Inc.
307 Pin Oak Place
Lancaster, PA 17602-3469
717.397.0719
E-mail: efrey@landolakes.com

QUEBEC FOOD PROTECTION ASSOCIATION

Pres., Marie-Claude Lamontagne ..... St. Anselme
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Sec'y., Noël Brousseau ..... Candiac
Treas., Carl Pietrazsko ..... St. Anselme
Delegate, Marie-Claude Lamontagne ..... St. Anselme

Mail all correspondence to:
Marie-Claude Lamontagne
J. M. Schneider Inc.
254 Rue Principale
St. Anselme, Quebec G0R 2N0 Canada
418.855.4474 ext. 3409
E-mail: mlamonta@jms.ca

SOUTH DAKOTA ENVIRONMENTAL HEALTH ASSOCIATION

Pres., Clark Hepper ..... Pierre
Pres. Elect, Mark Shuttleffel ..... Sioux Falls
Past Pres., Rod Coker ..... Pierre
Sec'y. Treas., Cindy Koopman-Viergets ..... Spearfish
Delegate, Darwin Kurtenbach ..... Pierre

Mail all correspondence to:
Clark Hepper
SD Dept. of Health
Office of Health Protection
600 E. Capitol
Pierre, SD 57501
605.773.3364
E-mail: clark.hepper@state.sd.us

SOUTHERN CALIFORNIA ASSOCIATION FOR FOOD PROTECTION

Pres., Margaret Burton ..... San Diego
Pres Elect., Jennylynd James ..... Westlake Village
Vice Pres., Howard Malberg ..... Anaheim
Sec'y., Robert Delmore ..... Los Angeles
Delegate, Jennylynd James ..... Westlake Village

Mail all correspondence to:
Margaret Burton
Jack in the Box
9330 Balboa Ave.
San Diego, CA 92123
858.571.2441
E-mail: margaret.burton@jackinthebox.com

TENNESSEE ASSOCIATION OF MILK, WATER AND FOOD PROTECTION

Pres., Robert Owen ..... Murfreesboro
Past Pres., Jim Howie ..... Waxhaw
Sec'y. Treas., F. Ann Draughon ..... Knoxville
Delegate, Robert Owen ..... Murfreesboro

Mail all correspondence to:
F. Ann Draughon
University of Tennessee
Food Safety & Processing Center
2605 River Road
Knoxville, TN 37996
865.974.8400
E-mail: draughon@utk.edu

TEXAS ASSOCIATION FOR FOOD PROTECTION

Pres., Gregory G. Crishi ..... Dallas
Past Pres., Mike Giles ..... Tyler
Sec'y. Treas., Ron Richter ..... College Station
Delegate, Gene Wright ..... Austin

Mail all correspondence to:
Ron Richter
Texas A & M University
Dept. of Animal Science
2471 TAMU
College Station, TX 77843-2471
979.845.4409
E-mail: rlr8942@acs.tamu.edu

UPPER MIDWEST DAIRY INDUSTRY ASSOCIATION

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Past Pres., Dale Heinz ..... Eyota
Gen. Mgr., Gene Watnass ..... Vining
Sec'y. Treas., Paul Nierman ..... Mounds View
Delegate, Dan Erickson ..... North St. Paul

Mail all correspondence to:
Paul Nierman
DQCI Services, Inc.
5205 Quincy St.
Mounds View, MN 55112-1400
763.785.0484
E-mail: paul@dqci.com

VIRGINIA ASSOCIATION OF SANITARIANS AND DAIRY FIELDMEN

Pres., Jim Byington ..... Blountville
Past Pres., Doug Greenway ..... Roanoke
Sec'y. Treas., Mary Jane Wolfinger ..... Orange
Delegate, Mary Jane Wolfinger ..... Orange

Mail all correspondence to:
Mary Jane Wolfinger
17066 Tyson's Center Road
Orange, VA 22960
540.854.6208

WASHINGTON ASSOCIATION FOR FOOD PROTECTION

Pres., Robert Brooke ..... Seattle
Pres. Elect, Joseph Muller ..... Seattle
Past Pres., Michael Nygaard ..... Seattle
Sec'y. Treas., Bill Brewer ..... Seattle
Delegate, Stephanie Olmsted ..... Kent

Mail all correspondence to:
Bill Brewer
12509 10th Ave., NW
Seattle, WA 98177-4309
206.363.5411
E-mail: billbrewer1@juno.com

WISCONSIN ASSOCIATION OF MILK AND FOOD SANITARIANS, INC.

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Pres. Elect, Goeff Marcks ..... Brownsville
1st Vice Pres., Virginia Deibel ..... Madison
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Past Pres., Dean Sommer ..... Waupun
Sec'y., Randall Daggs ..... Sun Prairie
Treas., Neil Vassau ..... Verona
Delegate, Randall Daggs ..... Sun Prairie

Mail all correspondence to:
Randall Daggs
State of Wisconsin
6699 Prairie View Drive
Sun Prairie, WI 53590-9430
608.837.2087
E-mail: rdaggs@juno.com

WYOMING ENVIRONMENTAL HEALTH ASSOCIATION

Pres., Roy Kroeger ..... Cheyenne
Pres. Elect, Sherry Maston ..... Wheatland
Past Pres., Shirley Teshannon ..... Lander
Sec'y., Renee King ..... Laramie
Treas., Doug Evans ..... Gillette
Delegate, Sherry Maston ..... Wheatland

Mail all correspondence to:
Sherry Maston
208 Washington Road
Wheatland, WY 82201
307.322.9671
E-mail: smasto@state.wy.us

New Members

AUSTRALIA

Peter S. Sutherland
SafeFood NSW
Sydney South, NSW

CANADA

Ken Chew
Canadian Food Inspection Agency
Dartmouth, Nova Scotia

Valerie Davidson
University of Guelph
Guelph, Ontario

Yvonne Liang
Vancouver, British Columbia

Diane Medeiros
Health Canada
Ottawa, Ontario

FINLAND

Elina Jaaskelainen
University of Helsinki
Helsinki

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University of Limerick
Limerick

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Unilever Bestfoods Schweiz GmbH
Thayngen, Schaffhausen

TAIWAN

Deng-Fwu Hwang
National Taiwan Ocean University
Keelung

UNITED KINGDOM

Phil Hindley
Avecia Protection and Hygiene
Blackley, Manchester

UNITED STATES

Alabama

Gitika Panicker
University of Alabama-Birmingham
Birmingham

California

Kyle-Mitchell Hyde
FSC, Los Angeles

Janus Pawlak
Fine Line Foods, El Cajon

Connecticut

Frank Greene
CT Dept. of Consumer Protection
Hartford

Georgia

Vincent J. Radke
CDC, Atlanta

Illinois

Lauren S. Jackson
FDA, Summit Argo

Sam Saltzman
All American Chemical, Des Plaines

Indiana

Neal Singletary
USHHS, Indianapolis

Iowa

Sujin S. Paik
Iowa State University, Ames

Natalia A. Weinsetel
Iowa State University, Ames

Kansas

Angela Kohls
KDHE, Topeka

Louisiana

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Louisiana State University
Baton Rouge

Mississippi

Hyun-Gyun Yuk
Mississippi State University
Mississippi State

New York

Trish M. Lobenfeld
New York University
New York

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Saratoga Springs

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Leeanne M. Hudson
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Pennsylvania

John W. Czajka
Battelle Memorial Institute
West Grove

Texas

Jeff W. Savell
Texas A & M University
College Station

Washington

Robert Brooke
Brooke & Rowen Consulting, Inc.
Seattle

Wisconsin

Sarah E. Heathcock
SC Johnson, Racine

Ali M. Mohseni
American Foods Group
Green Bay

Wyoming

Bryan J. Grapes
Wyoming Dept. of Agriculture
Torrington

UpDates

Mark McClellan New Head of FDA

On October 21, 2002 the Senate unanimously confirmed Dr. Mark B. McClellan as the new head of the Food and Drug Administration (FDA), according to the Wall Street Journal. The agency has been without a commissioner for nearly two years.

Dr. McClellan served in the Clinton administration as deputy assistant secretary of the treasury for economic policy. President Bush nominated Dr. McClellan, a 39-year-old physician and economist.

Dr. McClellan was educated at Harvard University and MIT, and has taught both medicine and economics at Stanford University. He is also a member of the Council of Economic Advisors.

Levy is Appointed as CEO for Bell Laboratories, Inc.

Bell Laboratories has appointed Steve Levy as its new CEO. Formerly Bell's general manager, Levy oversees all aspects of Bell business, from sales and marketing to product development and research.

Prior to joining Bell in 2000, Levy worked in management and marketing positions for Bayer, Nestle Foods, Oil-Dri and the Golden Cat Corporation.

Levy holds an MBA from University of North Carolina at Chapel Hill and dual bachelor's degrees in economics and psychology from University of California at Los Angeles.

IDFA, MIF, NCI, and IICA Associations Welcome 2002-2003 Officers

At the associations' annual business meetings held Oct. 2-3, 2002, new officers were elected to lead International Dairy Foods Association (IDFA), Milk Industry Foundation (MIF), National Cheese Institute (NCI), and International Ice Cream Association (IICA).

The 2002-2003 IDFA officers are: chair, Gary Wells, Wells' Dairy, Inc.; vice-chair, Lou Gentine, Sargento Foods, Inc.; and secretary/treasurer, Rick Beaman, Dean Foods Co.

The 2002-2003 MIF officers are: chair, Rick Beaman, Dean Foods Co.; vice chair, Geoff Covert, The Kroger Co.; secretary, Tracy Noll, National Dairy Holdings, L.P.; and treasurer, Miriam Erickson Brown, Anderson-Erickson Dairy Co.

The 2002-2003 NCI officers are: chair, Lou Gentine, Sargento Foods, Inc.; vice chair, Mary Kay Haben, Kraft Foods; secretary, Gary Vanic, Great Lakes Cheese Co.; and treasurer, Mike Reidy, Leprino Foods Co.

The 2002-2003 IICA officers are: chair, Gary Wells, Wells' Dairy, Inc.; vice chair, Paul Kruse, Blue Bell Creameries, L.P.; secretary, Roger Capps, Prairie Farms Dairy, Inc.; and treasurer, Jim Green, Marigold Foods, LLC.

Silliker Names Rowell Technical Services Manager

Silliker, Inc., Homewood, IL, announces the appointment of Kristen Rowell as technical sales manager of its Chicago Heights, IL, testing facility. A graduate of the University of Iowa with a master's degree in chemistry, Ms. Rowell will oversee sales activities in the Midwest region of the US.

Board of Directors Launches New 3-A Entity

The inaugural Board of Directors met recently to launch a brand new 3-A entity that would combine all facets of the 55 year-old 3-A Sanitary Standards Program into one organization, 3-A Sanitary Standards, Inc. 3-A Sanitary Standards, Inc. (SSI) is composed of five Founding Member Organizations, the Food & Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the 3-A Steering Committee. The five Founding Members include the International Association of Food Industry Suppliers (IAFIS), the International Association for Food Protection (IAFP), the International Dairy Foods Association (IDFA), the 3-A Sanitary Standards Symbol Administrative Council, and the American Dairy Products Institute (ADPI).

Board members representing these organizations include Charles W. Bray, IAFIS and Dean B. Girton, Girton Manufacturing Co. Inc. (IAFIS); David W. Tharp, IAFP and Ronald Schmidt, University of Florida (IAFP); Allen Sayler, IDFA and Gregory A. Marconnet, Kraft Foods (IDFA); Larry Hanson, Sani-Matic, Inc. and David Fry (3-A Sanitary Standards Symbol Administrative Council); Warren Clark, Jr., Executive Consultant and Lee Blakely, Cheese and Protein International (ADPI); Robert F. Hennes (FDA); Duane Spomer (USDA); and Tracy Schonrock (3-A Steering Committee).

The Board elected Charles W. Bray as Chair; David W. Tharp as Vice Chair; Warren Clark, Jr. as Secretary; and Gregory A. Marconnet as Treasurer.

3-A Sanitary Standards, Inc., under the leadership of a new Executive Director, will manage the 3-A Standards writing process and the transition from self-certification to Third Party Verification and 3-A Symbol authorization. Its office, expected to open in January 2003, will be located in McLean, VA.

International Association for Food Protection®

Food Agency Proposes to Allow Continued Import of Raw Milk Very Hard Cheeses

Food Standards Australia New Zealand (FSANZ) invited public comment on a proposal to allow the continued importation and domestic production of very hard cheeses, such as grana padano and parmigiano reggiano, made from unpasteurized milk. FSANZ managing director Ian Lindenmayer said the agency was proposing a change to the new Food Standards Code, which comes into effect on December 20, 2002. The provision would apply only to Australia and would not apply to soft and semi-soft raw milk cheeses, such as roquefort. "Cheese sold in Australia and New Zealand must be made, with some limited exceptions, from pasteurized milk. Alternatively the milk must be thermized (a less severe heat treatment than pasteurization) and the cheese matured for at least 90 days," Mr. Lindenmayer said. This requirement in the Food Standards Code offers protection to consumers from the risk of microbiological pathogens such as *Salmonella*.

"The proposal under consideration would allow the importation and sale of very hard grating cheeses made from unpasteurized milk, using a specific process. Our safety assessment has found that, with good hygienic and manufacturing processes, these cheeses can be made safely. These cheeses have been imported and sold safely in Australia since 1994. However, as a result of technical changes to the new Code, without this assessment these cheeses could no longer be sold in Australia."

Mr. Lindenmayer said FSANZ had now conducted a risk assessment of raw milk very hard cheeses and had released a Draft Assessment Report for public comment on its Web site. FSANZ is proposing that raw milk very hard cheeses with a moisture content of less than 36 per cent, after being stored at a temperature of no less than 10 degrees celsius for a period of no less than six months from the date of manufacture, should be allowed to be sold in Australia. Further information: The Draft Assessment Report for the safety assessment of raw milk very hard cheeses and a fact sheet are at www.foodstandards.gov.au.

USDA Strengthens Food Safety Policies

In a continuing effort to strengthen food safety programs and protect public health, the US Department of Agriculture, through its Food Safety and Inspection Service, has announced a series of new measures designed to reduce the incidence of *E. coli* O157:H7 contamination of raw ground beef. The actions are a result of FSIS's ongoing in-depth review of the current program and are based on scientific data that demonstrate the pathogen is more prevalent than previously estimated.

"Strengthening food safety programs that protect consumers from foodborne hazards continues to be a top priority at USDA," said Secretary of Agriculture Ann M.Veneman. "These actions will further help ensure that meat and poultry plants address ways to reduce the presence of *E. coli* O157:H7."

"The scientific data show that *E. coli* O157:H7 is more prevalent than previously estimated. These action steps move beyond detection of this hazard and on to preventing it," said under secretary for food safety Dr. Elsa Murano.

In December 2001, FSIS announced that it would conduct a comprehensive review of current food safety regulations, including provisions of the 1996 Pathogen Reduction/Hazard Analysis Critical Control Points (PR/HACCP) rule, to help improve the efficiency and accountability of FSIS programs and personnel. The following actions will be published in the Federal Register as a notice. USDA will: Require beef slaughter and grinding plants to acknowledge that *E. coli* O157:H7 is a hazard reasonably likely to occur in their operations, unless they can prove otherwise; Require, based on the above assumption, plants to perform a comprehensive re-examination of their food safety systems and include a step to eliminate or reduce the risk of *E. coli* O157:H7 in their product. In the case of grinding operations, this could consist of a requirement for their suppliers to certify the utilization of a decontamination method in their operation; Verify through increased USDA inspection that intervention steps implemented by establishments are validated, in that they are effective under actual in-plant conditions; Eliminate current exemptions from FSIS microbiological testing. This will result in random testing of all beef grinding operations by FSIS personnel and; Issue guidance to grinding facilities regarding additional prevention actions including: (1) increased plant testing for *E. coli* O157:H7; and (2) avoiding mixing product from different suppliers to reduce the chance of cross contamination and facilitate traceback investigations.

The Bush Administration continues to strengthen the nation's meat and poultry food safety programs through record-level funding for food safety inspectors and the programs they support. The actions being taken today are in addition to the other actions recently announced by FSIS including: Immediately informing the suppliers of an establishment where an *E. coli* O157:H7 positive occurs so that a trace back investigation is begun; The placement of 100 Consumer Safety Officers (CSO), scientifically trained inspection personnel, to ensure that plants have properly designed and functioning HACCP plans. FSIS will continue to increase CSOs in the next fiscal year; Improve the implementation of *Salmonella* performance standards to ensure problem plants are targeted for action earlier and public health is protected; Establishment of the Office of Program Evaluation, Enforcement and Review to scrutinize FSIS programs and policies to ensure they are implemented and monitored correctly; Develop and strengthen current review and management systems to help gauge and improve the performance of inspectors; Ongoing refinement of inspector HACCP training through the new Center for Learning; Establishment of a formal regulatory testing regime to verify the absence of spinal cord tissue in Advanced Meat Recovery (AMR) produced beef; Sharing of product distribution lists with state and local government authorities through a Memorandum of Understanding (MOU) when there is a recall; and A series of scientific symposia designed to help FSIS apply the latest scientific knowledge to address food safety issues and improve public health.

Detecting Possible *E. coli* Contamination on Fruit and Produce

The chance of fecal bacteria contaminating fresh produce or fruit juices could become nil when fruit- and produce-packing plants have a completely automated food safety inspection system installed in the near future. Yud-Ren Chen, an agricultural engineer with the Agricultural Research Service's Instrumentation and Sensing Laboratory in Beltsville, MD, is leading a group developing "machine-vision" systems to detect contamination the human eye can't see. This would prevent *Escherichia coli* O157:H7 from tainting apple cider and juices made from apples and other fruits. This *E. coli* strain infects people who drink contaminated, unpasteurized cider or juices.

Chen is starting with apples, but he expects the system to work with all fruits and produce. His on-line system would direct a camera to take three spectral images of each apple through different color filters. A computer would then analyze the spectral images to detect the tell tale signatures of fecal contamination or fly specks, as well as of fungi, rot or other diseases.

One of Chen's team members, biophysicist Moon Kim, brought his expertise in remote sensing of vegetation to ARS from the National Aeronautics and Space Administration. To detect fecal contamination, he is still sensing photosynthetic pigments from plants. But now he's working barely two feet from his targets, rather than from sensors aboard airplanes or satellites. Apple packinghouses currently have automated ways to sort for sizes and colors. When Chen's system is commercialized, it would likely be merged with those sorting systems, as well as with others in the pipeline.

More Needs to be Done to Protect Consumer Health from Risk of *E. coli* O157 Infection

The Food Safety Authority of Ireland (FSAI) has issued a strong warning in relation to the prevalence of *E. coli* O157:H7 in Irish minced beef and beef burgers. The warning comes as a result of a year long survey looking for the presence of the *E. coli* O157:H7 in minced beef and beef burgers sold in retail stores. The study, carried out on behalf of the FSAI by Teagasc – The National Food Centre (NFC), has found that 2.8% of samples of minced beef and beef burgers on retail sale examined in the survey were contaminated with *E. coli* O157:H7 sometimes at levels as high as 10,000 bacteria per gram of product.

Commenting on the findings Dr. Patrick Wall, Chief Executive, FSAI said that as these bacteria can cause kidney failure and can be fatal, this degree and level of contamination is too high. It is estimated that the presence of as few as ten *E. coli* O157:H7 bacteria in food could cause serious illness to susceptible people.

"It is a concern that this many samples of raw minced meat and beef burgers on sale to consumers are contaminated and the levels pose a serious, ongoing risk to consumers. The results of this survey show that the only element preventing illness being associated with these products is the diligence shown by consumers cooking the product thoroughly in the home. Therefore, it is so important that consumers are aware of the need to cook minced beef and beef burgers thoroughly to prevent themselves and their families from falling ill. This advice will have to remain paramount until such time as the risk can be reduced further back in the food chain. There is no room for complacency as one human case associated with *E. coli* O157:H7 is one too many given the serious nature of illness it causes," said Dr Wall.

"The consumer is taking an unacceptable share of the responsibility to control these bacteria. It is only when everything that can be done is being done that it is reasonable to expect consumers to eliminate any residual risk by cooking in their kitchens. At this level of contamination it does not appear that current practices on farms and in abattoirs are having the desired risk reduction effect and more needs to be done," he continued.

Infection with *E. coli* O157:H7 presents a wide range of clinical symptoms, including: non-bloody diarrhea, haemorrhagic colitis (bloody diarrhea), haemolytic uraemic syndrome (HUS), and thrombotic thrombocytopenic purpura (TTP).

Human infection with *E. coli* O157:H7 has been increasing since the early 1980s and has been reported from over 30 countries on six continents. Since 1996, the number of reported cases of *E. coli* O157:H7 in Ireland had steadily increased from 8 reported cases in 1996 to 76 cases in 1998, with 41 reported cases in 2000 and 52 in 2001. In 1999 the FSAI published its report entitled 'Prevention of *E. coli* O157:H7 Infection: A Shared Responsibility' (www.fsai.ie). In it the FSAI pointed out that to control of *E. coli* O157:H7, action was needed at every stage of the food chain and attention to detail must be paid to ensure people do not fall ill.

Livestock are the most important reservoir for most *E. coli* O157:H7, with cattle (both dairy and beef cattle) being the principal source. The bacteria can be part of the normal gut flora of the livestock and do not make the animals ill. Internationally it is recognized that fecal shedding in cattle is intermittent, with maximum shedding rates being observed in the spring and summer months. Recent studies in the UK have shown that 23% of the cattle herds in Scotland and 44% of herds in England and Wales carry these bacteria. There is limited information on the prevalence of *E. coli* O157:H7 in the animal population in Ireland and more studies on cattle in Ireland are needed. The source of contamination of foods is usually animal fecal material transferred into milk at milking, onto vegetables on manuring or onto meat carcases at carcase dressing.

The FSAI/NFC study was carried out from March 2001 to April 2002 and involved the analysis of 1,533 samples of minced beef and beef burgers bought in supermarkets and butcher shops in each of the 26 counties. Samples were collected from each shop on four occasions; once in each quarter of the year. Forty-three samples were found to contain *E. coli* O157:H7 (2.8%) and laboratory analysis revealed that each of the 43 bacteria isolates possessed the potential to cause serious disease. There was no significant difference in the contamination rates of *E. coli* O157:H7 in different minced beef products bought in different retail outlets. The number of *E. coli* O157:H7 found in positive samples ranged between 1 and 10,000 bacteria per gram of product with 63% of samples containing less than 10 bacteria per gram.

Given the morbidity and mortality associated with *E. coli* O157:H7, if the present production and processing of minced meat in Ireland is unable to reduce the risk sufficiently then additional efforts must be made. More definitive typing needs to be undertaken if a greater understanding of the problem is to be

achieved and protection interventions targeted appropriately. For example, pre-cooked frozen beef burgers are already available in Ireland and irradiation is a proven process for eliminating pathogenic microorganisms in raw meat products. The provision of minced beef products that are rendered free from *E. coli* O157:H7 by these means should at least be considered for those catering for vulnerable groups of the population, such as the elderly and young infants. Definitive typing of all isolates of *E. coli* O157:H7 from humans, animals and foods is essential to fully understand the sources and the routes of transmission of this pathogen. The current arrangements in Ireland do not adequately address this requirement and most human cases are not traced back to a food source and an animal reservoir. A copy of the survey report is available on the FSAI website www.fsai.ie.

Commission Adopts First EU Report on Irradiated Food

The European Commission has adopted a report on food irradiation in the EU, which includes information on whether irradiated food placed on the EU market is correctly labeled. The report, the first of its kind, is based on the results of checks undertaken by national authorities in the Member States. In general, the report indicated a high level of compliance with the requirements of the EU food irradiation Directive. However, the United Kingdom authorities found evidence of irradiation in 42% of certain dietary supplements. As most of these supplements cannot be irradiated legally in the EU, the Commission has asked the other Member States to check this particular sector.

David Byrne, EU commissioner for health and consumer affairs, said: "This report helps us to identify where we should focus our attention in the future as regards to irradiated food, to ensure that the rules are respect-ed and that consumers are properly informed."

The irradiation of dried aromatic herbs and spices is authorized across the whole of the EU. Five Member States (Belgium, France, Italy, Netherlands, UK) also allow the marketing of certain irradiated foods, for example, fresh and dried fruits and vegetables, poultry, shrimp, fish or frog legs on their national territory. Directive 1999/2/EC requires all irradiated foods to be labeled with the words "irradiated" or "treated" with ionizing radiation to allow consumers to make an informed choice. This labeling requirement also applies to irradiated food ingredients, present in small amounts in compound foods. Analytical methods can determine whether or not foods have been irradiated. The Directive also states that irradiation of food can only take place in facilities approved by the competent authorities of Member States, and that such facilities must provide information on the amounts of foods treated. Member States are required to report to the Commission on an annual basis.

The Commission report compiles the results of these checks for the period September 2000 to December 2001. In this period, only six Member States gave approval to facilities on their territory to irradiate foods (Belgium, Germany, Denmark, France, Netherlands, UK). The individual reports of the Member States indicate that the facilities mostly complied with the requirements of the Directive.

Eight Member States (Austria, Germany, Finland, Greece, Ireland, Netherlands, Sweden, UK) performed checks on foods placed on the market. The results show that only a few irradiated products are on the market which are not correctly labeled. These products are herbs, spices or foods containing herbs or spices, frog legs, shrimps and vegetables.

However, in the United Kingdom, the authorities found that 42% of certain dietary supplements are irradiated (aloe vera, alfalfa, cat's claw, devil's claw, garlic, ginger, ginkgo biloba, ginseng, guarana, kava kava, saw palmetto, silymarin, turmeric). As the treatment of these products except garlic and ginger by ionizing radiation is not allowed in the EU, other Member States have been asked by the Commission to check specifically this sector additionally to the UK, in order to ensure that the requirements of the Directive are respected.

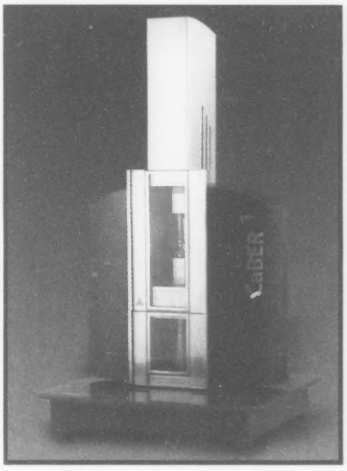
In total, more than 6,500 food samples have been checked of which 1.5% were found to have been irradiated but were not labelled as such.

Irradiation is a physical treatment of food with high-energy, ionizing radiation. It can be used to prolong the shelf life of food products and/or to reduce health hazards associated with certain products due to the presence of pathogenic micro-organisms.

The list of products authorized for irradiation within the EU contains only one food category: "dried aromatic herbs, spices and vegetable seasonings". The marketing of any product not complying with the Directive has been prohibited since March 20, 2001.

The report is available in all languages at: http://europa.eu.int/comm/food/fs/sfp/fi_index_en.html (section Annual Reports).

Industry Products



Thermo Haake

Thermo Haake Material Characterization Unveils the CaBER™1 Extensional Rheometer

Thermo Material Characterization introduces the Thermo Haake CaBER™1 Extensional Rheometer, the market's first commercially available rheometer for measuring elongational properties of fluids such as polymer solutions, suspensions, melts, adhesives, emulsions and a variety of other materials. The CaBER™1 was developed by the Cambridge Polymer Group (CPG) using innovative research in capillary breakup rheometry.

Knowledge of the elongational behavior of fluids is crucial in many industrial and research settings in order to examine complex flows containing strong extensional components, such as extrusion, coating, contracting and fiber spinning flows. The CaBER™1 analyzes the thinning and break-up of a fluid filament, providing valuable information about a material's physical properties that rotational rheometers cannot provide.

The CaBER™1 can function as either an analytical instrument or a quality control tool. Standard features include: computer control, a Class 1 laser micrometer, a linear motor drive with variable speed, automatic repeated testing and a closed temperature-controlled sample chamber. The rheometer is ideal for applications like adhesives, food products, consumer goods, industrial resins, surfactants and associated polymers.

Thermo Haake, Madison, WI

Reader Service No. 296

Eriez Magnetics Prescription for "E-Z" Metal Detection

Eriez' new highly sensitive E-Z Tec® Pharmaceutical Metal Detector improves process purity through detection of minute metal contaminants during the production of any capsule or tablet-based product. The unit's advanced electronic design simplifies setup, ensures reliable operation, provides instantaneous recovery from phase adjustments and requires minimal operator training. E-Z Tec Pharmaceuticals are designed to fit most any production line configuration.

E-Z Tec simplifies setup and operation. A new 5-minute *QuickStart* feature allows users to pass sample product, test and begin production in less than five minutes. By fixing the downslope of the unit's polished stainless steel head at 30 degrees lengthy timing adjustments of downstream reject equipment are eliminated, while the easy-clean chute reduces cross-contamination during product charges.

E-Z Tec Pharmaceutical Metal Detectors feature an industry lifetime warranty on the coil construction and can be configured with a wide array of reject devices, alarms and relays.

Eriez Magnetics, Erie, PA

Reader Service No. 297

Spectronics Corporation UV Lamp Reveals Rodent Filth!

Sanitation engineers in food processing plants have a powerful weapon in the war against contamination. It's the Spectro-line® BIB-150P ultraviolet lamp, which quickly and positively confirms the presence of trace amounts of rodent urine and droppings, oil, grease, dust and other impurities that cause health violations.

Contamination should be avoided like the plague, because rats and mice thrive on it. These rodents carry disease-bearing bacteria in their fur and droppings, and can infect nearby food supplies and food handling equipment. It's imperative that tainted areas be discovered early to prevent further spread.

The BIB-150P ultraviolet lamp makes rodent hair and excrement fluoresce brightly. Hair glows blue-white and urine glows

yellow-white when dry, bluer when fresh. Other contamination, such as lubrication oils and greases, bleaches and sulfide waste matter fluoresce different colors under the 3 UV lamp.

The BIB-150P delivers super-high UV intensity at an economical price. Its rugged polymer housing is impact-resistant and dent-proof. The lamp weighs only 3 1/4 pounds (1.5 kg). A unique Built-in-Ballast™ bulb eliminates the need for a cumbersome, external transformer. The vinyl-coated, stainless-steel wraparound heat guard also acts as a convenient lamp stand.

Spectronics Corporation,Westbury, NY

Reader Service No. 298

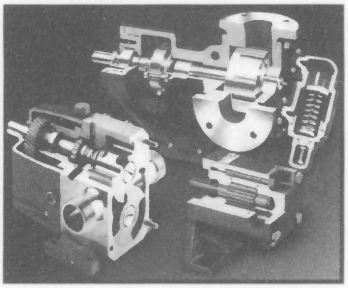
L. J. Star New Bulletin Describes Ultra-Miniature Luminaire for Sanitary System Illumination

The data sheet provides detailed information on electrical specs, mounting options, materials of construction and available options. The luminaires are designed to be used in either single-port, combination light/sight port applications or where separate sight/light ports are used. They may be mounted on a hinged bracket or directly onto the sight port.

Close-up photos illustrate the bracket-mount and direct-mount alternatives and a detailed dimensional drawing is provided, plus specific information on the various standards met and approvals obtained. Using halogen filament lamps, two power ratings are available, 5 and 20 watts, based on power supplies of 12 and 24 volts respectively. The 20-watt version comes standard with a push-button on-off switch.

L. J. Star Incorporated, Twinsburg, OH

Reader Service No. 299



Viking Pumps, Inc.

Viking's Rotary Positive Displacement Pumps Offer an Alternative to Centrifugal Pumps

Viking Pump's rotary positive displacement pumps, using gear and lobe principles, offer an alternative to centrifugal pumps in applications where system pressure or fluid viscosity fluctuates. In comparison with centrifugal pumps where flow rates often change and efficiency is lost, Viking positive displacement pumps provide a near-constant flow rate with minimal efficiency change, regardless of changes in system pressure or viscosity. Viking's high NPSH^R capabilities keep fluid moving with less chance of cavitation in processes where a suction lift is required or where a high vapor pressure fluid is being pumped. And, while centrifugal pumps can handle fluids to about 2,500 SSU (550 cSt) viscosity, Viking pumps can handle fluids from 28 to 2,000,000 SSU (1-440,000 cSt) viscosity. Viking pumps also feature low shear, reversible direction of flow, low pulsation and high mechanical efficiency.

Available in internal or external gear styles, Viking's gear pumps utilize a drive gear and driven gear that unmesh to draw fluid in and re-mesh to force fluid out. Viking's extensive line of internal gear pumps is available in stainless steel, steel or iron, and offers capacities from 1.5 to 1,500 gpm (0.3 to 340 m^3/h) at pressures to 250 psi (17 bar). For hazardous fluids and zero-emission applications, the Viking Mag Drive® sealless internal or external gear pumps eliminate shaft leakage completely.

Viking's rotary lobe pumps utilize non-contacting lobes in bi-wing and multi-lobe designs. Viking's rotary lobe pump lines feature both sanitary/hygienic and industrial models ideal for lower-shear or higher-pressure applications where cleanability or periodic dry-running is required. Constructed of stainless steel, the lobe lumps offer capacities to 820 gpm (184 m^3/h) at pressures to 400 psi (27 bar).

Viking Pump Inc., Cedar Falls, IA

Reader Service No. 300

Systemate Numafa's Auto-Feed Improves Convenience of CWM Vat Washer Offers Better Ergonomics and Reduced Cross Contamination

A new automatic in-feed and discharge system from Systemate Numafa improves the operational efficiency of the company's CWM series washers, which are suitable for cleaning large stainless steel vats and plastic combo-bins, which are typically 48" tall by 50" wide.

The conveyor system provides a near-continuous feed of bins and vats to the washer. This allows for increased throughput while maintaining consistent wash quality.

An electric gear motor, rather than hydraulic or pneumatic cylinders, lifts the vat into the washer, which reduces operating and maintenance problems and costs. Vats are tilted 180 degrees, which permits the stainless steel nozzles to have closer contact with the sidewalls and bottom to

improve cleaning and promote faster drainage. The vats are then unloaded in the original position.

Vats soiled with heavy emulsions can be cleaned at a rate of 20 per hour. A capacity of 30 vats per hour can be achieved with light to moderate soil loads. The washer's adjustable timer can meet the individual need of shortened or prolonged wash applications.

The CWM washers are ergonomically engineered to reduce handling, lifting and the opportunity for injury to personnel.

For 25 years, Systemate Numafa has developed, manufactured and serviced cleaning systems. The company's product line includes cleaning smoke trees, screens, racks, totes, lugs and baskets.

Dapec, Inc., Canton, GA

Reader Service No. 301

Labconco's Purifier® PCR Enclosure Offers a Controlled Environment to Perform Polymerase Chain Reaction Experiments

Labconco Corporation offers the Purifier PCR Enclosure Integral blower and a 99.9% efficient HEPA filter constantly circulate filtered, Class 100 air down across the work area, providing a particulate-free working space to minimize sample contamination risk.

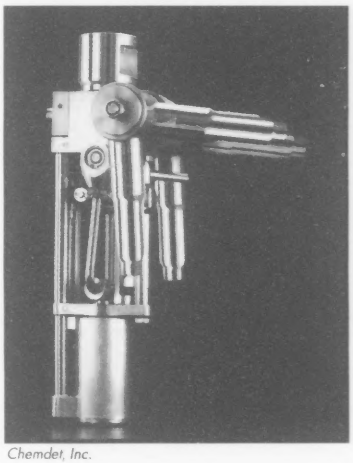
Available in 2 and 3-foot widths, the Purifier PCR Enclosure features a self-contained UV lamp with solid state timer which provides a five minute exposure to deactivate DNA and RNA contaminants. The UV light automatically switches off in preparation of the next experiment. Front mounted switches for fluorescent and UV lights and blower are located within easy reach of the operator. Made of 3/16" thick safety glass, the side panels permit additional illumination of the work surface.

The variable speed blower with solid state speed control maintains proper air velocities through the HEPA filter, removing 99.99% of all particles 0.3 micron or larger. A replaceable pre-filter traps larger particles to extend the life of the HEPA filter.

The benchtop design can be placed on existing casework or on an accessory gray, solid epoxy work surface and stand.

Labconco Corporation, Kansas City, MO

Reader Service No. 302



Chemdet, Inc.

Chemdet, Inc.'s High-Impact Tank Washers Focus Wash Pattern in 180° ARC to Concentrate Cleaning and Reduce Fluid Consumption

Fury 180° Open Top tank washers from advanced cleaning equipment resource Chemdet, Inc., feature a unique piston design that permits one direction cleaning in sweeping or straight-line wash patterns from 65° to 180° to concentrate cleaning action on soiled areas of storage and process tanks, railcars, tank trailers and other bulk containers. Ideal for fast, efficient cleaning of foods, beverages, dairy products, pulp and paper residues, coatings, chemicals, pharmaceuticals and other materials, the versatile Fury models 400/OT and 600/OT 180° Open Top tank washers force powerful jets of water, detergents, solvents, acids, caustics or other cleaning fluids only where needed, cutting both fluid consumption and wastewater volume.

Fury models 400/OT and 600/OT 180° Open Top tank washers replace high-speed turbines and complex gear mechanisms with a low speed piston design that harnesses the cleaning fluid to drive and lubricate the unit. Greases and oil lubricants are eliminated, wear and maintenance are reduced and operating life is extended. Engineered with 316 stainless steel, the Fury models 400/OT and 600/OT 180° Open Top tank washers mount rigidly within the tank or container to accommodate the potent striking force while maintaining accuracy of the wash pattern.

The Fury model 400/OT operates at pressures ranging from 45 to 175 psi and at flow rates ranging from 10 to 80 gpm with a cleaning radius of 16 to 28 feet and a wetting radius from 23 to 41 feet. The Fury model 660/OT operates at pressures ranging from 10 to 240 psi and flow rates from 17 to 186 gpm with a cleaning radius from 16 to 53 feet and a wetting radius from 29 to 66 feet. Both Fury Open Top tank washers withstand operating temperatures up to 203°F and ambient temperatures up to 248°F. Fury models 400/0T and 600/OT 180° Open Top tank washers may be customized to suit specific cleaning requirements.

Chemdet Inc., Port Washington, NY

Reader Service No. 303

Dairy, Food and Environmental Sanitation, Vol. 22, No. 12, Pages 1009-1019

3-A® Sanitary Standards for Stainless Steel Automotive Transportation Tanks for Bulk Delivery and Farm Pick-Up Service, Number 05-15

Formulated by
International Association of Food Industry Suppliers (IAFIS)
International Association for Food Protection (IAFP)
United States Public Health Service (USPHS)
The Dairy Industry Committee (DIC)
United Stated Department of Agriculture — Dairy Programs (USDA)

It is the purpose of the IAFIS, IAFP, USPHS, DIC, and USDA 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 transportation tank specifications heretofore or hereafter developed which so differ in design, materials, and fabrication or otherwise as not to conform to the following standards but which, in the fabricator's opinion, are equivalent or better, may be submitted for the joint consideration of the IAFIS, IAFP, USPHS, DIC, and USDA at any time. The 3-A Sanitary Standards and 3-A Accepted Practices provide hygienic criteria applicable to equipment and systems used to produce, process and package milk, milk products and other perishable foods or comestible products. Standard English is the official language of 3-A Sanitary Standards and 3-A Accepted Practices.

A **SCOPE**

A1 These standards cover the sanitary aspects of automotive transportation tanks for milk, fluid milk products, and other liquid comestible products.

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

B **DEFINITIONS**

B1 *Bulk Transportation Tank*: Shall mean an over the road truck or trailer tank used to transport milk, fluid milk products or other liquid comestible products. It may have more than one compartment.

B2 *Farm Pick-Up or Multiple Pick-Up and Delivery Tank*: Shall mean a bulk transportation tank as defined in B1 with transfer attachments and facilities, including a pump and/or hose cabinet, as specified herein.

B3 *Product*: Shall mean the milk, fluid milk product or other liquid comestible product transported in the tank.

B4 **Surfaces**

B4.1 *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.

B4.2 *Nonproduct Contact Surfaces*: Shall mean all other exposed surfaces.

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

B5 **Cleaning**

B5.1 *Mechanical Cleaning or Mechanically Cleaned*: Shall mean soil removal by impingement, circulation, or flowing chemical detergent solutions and water rinses onto and over the surfaces to be cleaned by mechanical means in equipment or by systems specifically designed for this purpose.

B5.2 *Manual (COP) Cleaning*: Shall mean soil removal when the equipment is partially or totally disassembled. Soil removal is effected with chemical solutions and water rinses with the assistance of one or a combination of brushes, nonmetallic scouring pads and scrapers, high or low pressure hoses and tank(s) which may be fitted with recirculating pump(s), and with all cleaning aids manipulated by hand.

B6 *Product Outlet*: Shall mean the opening in the lining of a tank or a compartment and the outlet passage for product to the exterior of the tank or compartment. The outlet passage starts at the opening in the lining and terminates at the connection for the outlet valve.

B7 *Pump and/or Hose Cabinet*: Shall mean a cabinet used to house the pump and/or transfer hose and may also house a compartment for product sample trays and samples.

B8 *Deck Plate*: Shall mean the personnel access port dust cover seat or that part of the outer jacket on which the cover rests.

B9 *Soil*: Shall mean the presence of unwanted organic residue or inorganic matter, with or without microorganisms, including food residue, in or on the equipment.

B10 *Sanitizing or Sanitization*: Shall mean a process applied to a cleaned surface which is capable of reducing the numbers of the most resistant human pathogens by at least 5 $\log_{10}$ reductions (99.999%) to 7 $\log_{10}$ reductions (99.99999%) by applying accumulated hot water, hot air, or steam, or by applying an EPA-registered sanitizer according to label directions. Sanitizing may be effected by mechanical or manual methods.

B11 *Easily or Readily Removable*: Shall mean quickly separated from the equipment with the use of simple hand tools if necessary.

B12 *Easily or Readily Accessible*: Shall mean a location which can be safely reached by personnel from the floor, platform, or other permanent work area.

B13 *Inspectable*: Shall mean all product contact surfaces can be made available for close visual observation.

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

B15 *Nontoxic Materials*: Shall mean those substances which under the conditions of their use are in compliance with applicable requirements of the Food, Drug, and Cosmetic Act of 1938, as amended.

B16 *Corrosion Resistant*: Shall mean the surface has the property to maintain its original surface characteristics for its predicted service period when exposed to the conditions encountered in the environment of intended use, including expected contact with product and cleaning, sanitizing, or sterilization compounds or solutions.

B17 *Close Coupled*: Shall mean mating surfaces or other juxtaposed surfaces that are less than twice the nominal diameter or cross section of the mating surfaces or a maximum 5 in. (127 mm).

C **MATERIALS**

C1 **Metals**

C1.1 Product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI) 300 Series[2] (excluding, 301, 302) or corresponding Alloy Cast Institute (ACI) types[3], or metal which under conditions of intended use is at least as corrosion resistant as stainless steel of the foregoing types, and is nontoxic and nonabsorbent. (See Appendix, Section E.)

C2 **Nonmetals**

C2.1 Rubber and rubber-like materials may be used for flexible transfer tubing, gaskets, seals, vents and parts having the same functional purposes.

[2] The data for this series are contained in the *AISI Steel Products Manual, Stainless & Heat Resisting Steels*, Table 2-1. Available from the American Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086 (412) 776-1535.

[3] Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016 (708) 299-9160.

C2.1.1 Rubber and rubber-like materials, when used for the above-specified application(s), 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-.

C2.2 Plastic materials may be used for flexible transfer tubing, gaskets, seals, vents, hose/pump cabinets and parts having the same functional purposes.

C2.2.1 Plastic materials, when used for the above-specified application(s), shall comply with the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-.

C2.3 Rubber and rubber-like materials or plastic materials having product contact surfaces shall be of such composition as to retain their surface and conformational characteristics when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment.

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

C2.5 Where materials having certain inherent functional purposes are required for specific applications, such as agitator bearing surfaces and rotary 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.

C3 **Nonproduct Contact Surfaces**

C3.1 All nonproduct contact surfaces shall be of corrosion-resistant material or material that is rendered corrosion resistant. If coated, the coating 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.

C3.2 The lining of the pump and/or hose cabinet shall be stainless steel or equally corrosion-resistant and durable material.

C3.3 Gasket material for cabinet doors and dust covers for both personnel access ports and outlet valves shall be smooth, easily cleanable and nonabsorbent.

C3.4 Sample trays and insulated sample boxes that will be in the pump and/or hose cabinet shall be made of stainless steel, plastic or other equally corrosion-resistant durable material.

C3.5 Nonmetallic composite materials may be used as a supportive backing for the tank liner or the outer shell or both.

D **FABRICATION**

D1 **Tank Liner Thickness**

D1.1 The minimum gauge of material for the lining shall be determined by one of the following:

D1.1.1 16 U.S. Standard Gauge for tanks of capacities of 1,000 gal (3,785 L) or less; 14 U.S. Standard Gauge for tanks of capacities of over 1,000 gal (3,785 L) and not exceeding 2,000 gal (7,570 L); 12 U.S. Standard Gauge for tanks of over 2,000 gal (7,570 L) capacity.

D1.1.2 Lighter gauges of material shall be permitted if shell stress analysis on specific design application demonstrates they are so supported that they will have equal resistance to denting, buckling, sagging, and fatigue failures as provided by the three gauges specified above for the respective sizes of tanks.

D2 **Surface Texture**

D2.1 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 F.)

D3 **Permanent Joints**

D3.1 All permanent joints in metallic product contact surfaces shall be continuously welded.[5]

[4]Adhesives shall comply with 21 CFR 175 - Indirect Food Additives: Adhesives and Components of Coatings. Document for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (202) 512-1800.

D4 **Bonded Materials**

D4.1 Bonded rubber and rubber-like materials and bonded plastic materials having product contact surfaces shall be bonded in a manner that the bond is continuous and mechanically sound, so that when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment, the rubber and rubber-like material or the plastic material does not separate from the base material to which it is bonded.

D5 **Cleaning and Inspectability**

D5.1 Transportation tanks that are to be mechanically cleaned shall be designed so that the product contact surfaces of the transportation tanks and all nonremoved appurtenances thereto can be mechanically cleaned and are easily accessible, readily removable, and inspectable.

D5.2 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.

D6 **Draining**

D6.1 All product contact surfaces shall be self-draining except for normal clingage. Tanks shall be so constructed that the lining will not sag, buckle or prevent complete drainage of water when the tank has a pitch of not more than 1 in. (25.4 mm) in 100 in. (254 mm).

D7 **Tank Height**

D7.1 The height of the vertical axis of the lining of the tank shall not be less than the minimum heights shown in the following tables:

TABLE 1. Tanks Having Uniform Vertical Axes
Note: 1 in. = 25.4 mm

Tank Size	Minimum Height
Up to and including 500 gal (1,892L)	36 in. (914.4 mm)
Over 500 gal (1,892 L) and up to and including 2,000 gal (7,570 L)	40 in. (1,016 mm)
Over 2,000 gal (7,570 L) and up to and including 2,800 gal (10,598 L)	42 in. (1,069 mm)
Over 2,800 gal (10,598 L) and up to and including 3,500 gal (13,248 L)	44 in. (1,118 mm)
Over 3,500 gal (13,248 L)	46 in. (1,168 mm)

TABLE 2. Tanks Having Varying Vertical Axes
Note: 1 in. = 25.4 mm

Tank Size	Min. Front Height	Min. Rear Height
Up to and including 500 gal (1,892 L)	36 in. (914.4 mm)	36 in. (914.4 mm)
Over 500 gal (1,892 L) and up to and including 2,000 gal (7,570 L)	40 in. (1,016 mm)	40 in. (1,016 mm)
Over 2,000 gal (7,570 L) and up to and including 2,800 gal (10,598 L)	41 in. (1,041 mm)	51 in. (1,295 mm)
Over 2,800 gal (10,598 L) and up to and including 3,500 gal (13,248 L)	43 in. (1,092 mm)	55 in. (1,397 mm)
Over 3,500 gal (13,248 L)	43 in. (1,092 mm)	57 in. (1,448 mm)

D8 **Fittings, Valves and Connections**

D8.1 All sanitary fittings and connections shall conform to the applicable provisions of the 3-A Sanitary Standards for Sanitary Fittings for Milk and Milk Products, Number 63-.

D8.2 All sanitary valves shall conform to the applicable provisions of the 3-A Sanitary Standards for Plug-Type Valves for Milk and Milk Products 51-, 3-A Sanitary Standards for Thermoplastic Plug-Types Valves for Milk and Milk Products, Number 53-, 3-A Sanitary Standards for Boot Seal-Type Valves for Milk and Milk Products, Number 55-, 3-A Sanitary Standards for Tank Outlet Valves for Milk and Milk Products, Number 57-, 3-A Sanitary

[5] Criteria for hygienic welds may be found in AWS/ANSI D18.1 — *Specification for Welding of Austenitic Stainless Steel Tube and Pipe Systems in Sanitary (Hygienic) Applications*. Available from the American Welding Society, 550 N.W. LeJeune Rd., Miami, FL 33126, phone: (305) 443-9353, fax: (305) 443-7559, e-mail: info@amweld.org; and EHEDG Doc. 9 —Welding Stainless Steel to Meet Hygienic Requirements. Available from the European Hygienic Equipment Design Group, Ellen Moens, Avenue Grand Champ 148, 1150 Brussels, Belgium.

Standards for Caged-Ball Valves for Milk and Milk Products, Number 66-, or 3-A Sanitary Standards for Ball-Type Valves for Milk and Milk Products, Number 68- except that materials conforming to C2.1.1 or C2.2.1 may be used for caps of sanitary design for the protection of the terminal ends of sanitary tubes, fittings or vents.

D8.3 All instrument connections having product contact surfaces shall conform to the applicable provisions of the 3-A Sanitary Standards for Sensors and Sensor Fittings and Connections Used on Fluid Milk and Milk Products Equipment, Number 74-.

D8.4 All hose assemblies shall conform to the applicable provisions of the 3-A Sanitary Standards for Hose Assemblies for Milk and Milk Products, Number 62-.

D9 **Sanitary Tubing**

D9.1 All metal tubing shall conform to the applicable provisions for welded sanitary product pipelines found in Section G in the 3-A Accepted Practices for Permanently Installed Product and Solution Pipelines and Cleaning Systems Used in Milk and Milk Product Processing Plants, Number 605- and with the 3-A Sanitary Standards for Polished Metal Tubing for Dairy Products, Number 33-.

D10 **Gaskets**

D10.1 Personnel access port cover gaskets shall be readily removable and easily cleanable.

D10.2 Grooves in gaskets shall be no deeper than their width.

D10.3 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.

D11 **Radii**

D11.1 Minimum radii for fillets of welds where the head(s) and the partition wall(s) join the lining of the tank shall not be less than 3/4 in. (19.05 mm).

D11.2 All internal angles of less than 135° on product contact surfaces shall have radii of not less than 1/4 in. (6.35 mm) except that:

D11.2.1 The minimum radius of any internal angle in a gasket groove or gasket retaining groove shall be not less than 1/16 in. (1.59 mm).

D11.2.2 When the thickness of one or both parts jointed is less than 3/16 in. (4.76 mm), the minimum radii for fillets of welds on product contact surfaces shall be not less than 1/8 in. (3.18 mm).

D12 **Threads**

D12.1 There shall be no threads on product contact surfaces, except for male threaded fittings that comply with Section D8.1 necessary for making mechanical cleaning connections.

D13 **Insulation**

D13.1 The tank and divider between the compartments of a multi-compartment tank shall be insulated in such a manner that, in a 48-h period, when the tank is full of water, the average change in the temperature of the water will not exceed 4°F (2°C) when the average difference between the temperature of the water and that of the atmosphere surrounding the tank is 30°F (17°C). Insulating material shall be installed in such a manner as to prevent shifting or settling.

D14 **Outlet and Outlet Valve**

D14.1 Each tank or compartment shall have a separate outlet passage. The outlet shall be of all welded construction. The inside diameter of the outlet shall be at least as large as that of 2 in. (50.80 mm) 3-A sanitary tubing. The outlet(s) shall provide complete drainage of the tank(s) or compartment(s). In multi-compartment or multi-tank units, the top of the outlet passage(s) of the front compartment(s) or the front tank(s) shall be as low as the low point of the lining at the outlet and shall provide for complete drainage toward the outlet. The horizontal distance from the opening in the lining to this point shall not be more than four times the diameter of the outlet passage. The outlet passage downstream of this point shall pitch towards the connection for the outlet valve. The terminal end of the outlet passage shall not extend more than 6 in. (152.4 mm) beyond the inside lining of the tank or compartment(s). The outlet passage may be increased in length provided that:

D14.1.1 The outlet passage is straight or is straight downstream of the elbow(s) or bend(s) used either to change the direction of product flow from a bottom outlet or to comply with the requirement in D13.1 that at a specified point the top of the outlet passage shall be as low as the point of the lining at the outlet.

D14.1.2 The outlet and outlet passage may be adequately cleaned manually or the tank or compartment with the increased outlet passage is provided with a

fixed spray device(s) so that the outlet passage may be mechanically cleaned and sanitized.

D14.1.3 The outlet passage is insulated sufficiently that the temperature rise of water in the outlet passage does not exceed the allowable average temperature rise of the tank full of water specified in D13.1.

D14.1.4 The outlet passage is protected against damage (denting) and is braced and sloped.

D14.2 Outlet valves, when provided, shall conform to D8.2 or if the valve is within the lining or in the outlet passage, and the seat is an integral part of the lining or the outlet passage, a compression-type valve conforming to the applicable provisions of D14.2.1 may be used.

D14.2.1 Compression-type valves when used in the tank or outlet passage shall have a metal to metal or rubber, or rubber-like materials to metal seat. The rubber or rubber-like material may be either removable or bonded.

D14.3 The tank outlet and valve bore shall be the same size and concentric or the product passage of the outlet valve (s) shall have an inside diameter no less than that of the tank outlet and (2) shall be self-draining.

D14.4 A cap conforming to D8.2 shall be furnished for the outlet opening of the outlet valve, except when the outlet opening of the valve is located in the pump and/or hose cabinet that is connected to the pump piping.

D14.5 Unless the outlet valve is located in the pump and/or hose cabinet, it shall be provided with a dust cover which (1) encloses the entire valve assembly, (2) is dust proof and (3) has a smooth interior finish. Dust covers shall be provided with means of sealing to prevent opening or removing the cover without breaking the seal.

D15 **Personnel Access Ports and Covers**

D15.1 A personnel access port(s) shall be provided and shall be not less than 16 in. (406.4 mm) by 20 in. (508.0 mm) oval or 18 in. (457.2 mm) in diameter. It shall be located in the top portion of the tanker and approximately in the center of each compartment.

D15.2 The upper edge of a deck plate opening shall be not less than 3/8 in. (9.52 mm) higher than the surrounding area and if an exterior flange is incorporated in it, it shall slope and drain away from the opening, so that liquids or debris may not accumulate around the opening, the lid and lid gasket under conditions of use or other adverse environmental conditions such as freezing.

D15.3 Personnel access ports shall be located so that the solutions from mechanical cleaning device(s) are applied to all product contact surfaces.

D15.4 A sanitary vent of sufficient free opening to prevent excess vacuum and/or internal pressure during filling or emptying, shall be installed in the personnel access port cover under the personnel access port dust cover. The air vent shall be designed so that parts are readily accessible, easily removable and readily cleanable. (See Appendix, Section G.)

D15.5 Permanently installed mechanical device(s), if used, shall be designed and installed so that solutions are applied to all product contact surfaces.

D16 **Personnel Access Port(s) Dust Covers**

D16.1 Each personnel access port shall be provided with a dust cover.

D16.2 The interior finish of the dust cover shall be smooth, readily cleanable and free from bolts and screws. Round or oval head rivets shall be deemed acceptable.

D16.3 Welded interior attachments shall have minimum radii of 1/16 in. (1.59 mm).

D16.4 A suitable vent shall be provided to relieve vacuum and pressure when the dust cover is closed. The vent shall be located on the side of the rear half of the dust cover or be suitably protected from conditions of use that may overcome the intended purpose of the vent.

D16.5 The dust cover when closed shall provide an effective seal to prevent entrance of dust.

D16.6 The dust cover shall be provided with means of sealing to prevent opening the dust cover without breaking the seal.

D16.7 If a rubber or rubber-like, or plastic gasket is used as a seal, it shall be smooth, either removable or firmly bonded to the dust cover to provide a smooth, easily cleanable surface without crevices.

D16.8 Deck plate, if attached to the outer jacket, shall be effectively sealed and firmly bonded.

D17 **Agitation**

D17.1 When specified, the tank or compartment thereof shall be provided with means for mechanical or air agitation (See Appendix, Section J) that, when operated 20 minutes in whole milk that has been stored 24 hrs. at 40°F (4.4°C) will result in the milk fat content of the product throughout the tank or compartment being within a variation of ± 0.1% by an official AOAC[6] milk fat test.

D17.2 The agitator, if not designed for mechanical cleaning, shall be located in such a manner that it shall be readily accessible for manual cleaning and inspection.

D17.3 A mechanical agitator shall have a seal of the packless type, sanitary in design with all parts accessible for cleaning.

D18 **Appurtenances for Air Agitation and Mechanical Cleaning (See Appendix, Section J.)**

D18.1 Tubing, tubing supports, and attachments for spray cleaning devices within the tank shall be designed to be mechanically cleaned.

D18.2 Openings for air agitation, mechanical cleaning applications or both shall be protected against contamination by means of a removable dust cover, except where such openings are within the pump and/or hose cabinet. The dust cover shall be provided with means of sealing to prevent opening the dust cover without breaking the seal.

D18.3 Permanently mounted air or solution tubing shall be constructed and installed so that it will not sag, buckle, vibrate or prevent complete drainage of the tank or tubing, and shall be located so that the distance from the outside of the tubing to the lining is at least 2 in. (50.80 mm), except at point of entrance. The tubing and all related fittings shall be self-draining.

D18.4 Means for mechanically cleaning the tank or compartment, when provided, shall clean the product contact surfaces and all nonremoved appurtenances thereto except those areas that may be manually cleaned without entering the tank. (See Appendix, Section H.)

D18.5 Mechanical cleaning tubing shall be close coupled where it extends through the outer shell.

D19 **Baffles**

D19.1 Baffles, when provided, shall not interfere with the free drainage of the tank or compartment.

D19.2 The area of any one baffle plate shall not exceed 40% of the cross-sectional area of the tank and the entire baffle shall be on one side of the longitudinal center line of the tank. If more than one baffle is installed, consecutive baffles shall be installed on opposite sides of the tank and shall be at least 48 in. (122 cm) apart. Baffles shall be so designed that walk-through accessibility will be provided to all areas for inspection, and if the tank is not provided with means for mechanically cleaning the tank or compartment, for cleaning purposes.

D19.3 Baffles shall be welded to the tank. There shall be no sharp edges on baffles.

D20 **Hose/Pump Cabinets**

D20.1 The lining of cabinets, doors and fixed attachments shall be smooth.

D20.2 All permanent metallic joints in the lining shall be continuously welded. All welded areas in the lining shall be at least as smooth as the adjoining surfaces.

D20.3 If plastic material is used to fabricate or to line the hose/pump cabinets, it shall meet the applicable criteria found in 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-. It shall be fabricated so that all joints are welded, bonded, or permanently sealed to be watertight and as smooth as the adjoining surfaces.

D20.4 The bottom shall be constructed so that it will not sag, buckle or prevent complete drainage when the truck is on a level surface.

D20.5 All inside corners shall have minimum radii of 1/8 in. (3.18 mm).

D20.6 Cabinets shall be dust tight and doors shall be equipped with a compression type closing device. Gasket material for sealing cabinet doors may be installed on the face of the cabinet or on doors

[6]The method of making these will be found in the following reference: Official Methods of Analysis: Available from AOAC International, 481 N. Frederick Ave., Suite 500, Gaithersburg, MD 20877. (301) 924-7077.

except along a drainage area where it shall be attached to the doors. Gasket material shall be removable or firmly bonded to provide smooth, easily cleanable surfaces without crevices.

D20.7 A roof overhang or suitable drip molding shall be provided over the cabinet doors.

D20.8 A carrier bracket shall be provided to support the flexible transfer tubing. Means shall be provided to support the loose end of the tubing above the cabinet floor.

D20.9 Fixed attachments such as pump support brackets, tubing carrier brackets and brackets for belt and pulley guards shall be easily accessible for cleaning.

D20.10 The size and location of the cabinet shall be such that will afford easy accessibility for assembly and disassembly of removable parts and provide ample clearance around permanently installed equipment and parts. (See Appendix, Section I, Facilities for Extra Fittings.)

D21 **Pumps**

D21.1 Pumps, when furnished, shall conform to the 3-A Sanitary Standards for Centrifugal and Positive Rotary Pumps, Number 02-. A sanitary closure shall be furnished for the outlet opening of the pump.

D21.2 A pump having a base area of 1 ft^2 (930 cm^2) shall be installed so that there will be a minimum clearance of 2 in. (50.80 mm) between the base and the cabinet floor and 3 in. (76.20 mm) between the pump assembly and the cabinet walls. The minimum clearance between the base and the cabinet floor shall be increased to 3 in. (76.20 mm) if the base area of the pump exceeds 1 ft^2 (930 cm^2). A pump assembly that is to be mounted on the floor of the cabinet shall have solid base and be installed with a nonabsorbent sealing gasket. It shall be installed in a position that (1) will not interfere with drainage and (2) will provide minimum clearance of 3 in. (76.20 mm) between the pump assembly and the cabinet walls. A side wall mounted pump assembly shall be installed with a nonabsorbent sealing gasket.

D22 **Motors for Pumps**

D22.1 An electric or hydraulic motor when located in the pump compartment, shall be totally enclosed and nonventilated. Electric wiring, if used, shall be waterproof and shall be conducted through the wall of the pump cabinet with watertight connections.

D22.2 Storage space for the pump motor electrical extension cord shall be located outside the pump compartment.

D23 **Flexible Transfer Tubing**

D23.1 The minimum inside diameter of the transfer tubing shall be 2 in. (50.80 mm). A sanitary closure shall be furnished for the open end(s) of the tubing.

D23.2 If two lengths of flexible tubing are used, they shall be connected by the use of sanitary coupling meeting Section D8.4 herein.

D23.3 A piece of flexible tubing meeting Section D8.4 may be used for the connection from the pump to the tank.

D23.4 No product connections shall be allowed between independent transportation tankers.

D24 **Sample Tray, Insulated Sample Box and Sample Compartments**

D24.1 Sample trays and insulated sample boxes that are to be in the pump and/or hose cabinet shall be of sanitary design and readily cleanable.

D24.2 Facilities shall be provided for keeping the samples cold.

D24.3 Permanently installed insulated sample boxes shall (1) be attached to the cabinets by continuously welding or with bolted connections which have nonabsorbent sealing gaskets in the joints, (2) have the supporting member(s) continuously welded if supported from the floor of the cabinet and (3) be installed so there is a minimum clearance of 6 in. (152.4 mm) between the insulated sample box and the cabinet floor.

[7]Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959. Phone: (610) 832-9500.

[8]Available from the American Society of Mechanical Engineers, 345 East 47th Street, NY, NY 10017-2392. (212) 705-7722.

D25 **Nonproduct Contact Surfaces**

D25.1 Nonproduct contact surfaces shall be relatively smooth, relatively free of pockets and crevices and be readily cleanable and those to be coated shall be effectively prepared for coating.

D25.2 The outer shell shall be smooth and effectively sealed except for vent or weep holes in the outer shell of the tank. The vent or weep holes shall be located in a position that will provide drainage from the outer shell and shall be vermin proof. The outer jacket and doors of the pump and/or hose cabinet shall be smooth and effectively sealed. Outside welds need not be ground.

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 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 steel of the 300 Series. Cast grades of stainless steel corresponding to types 303, 304, and 316 are designated CF-16F, CF-8, and CF-8M, respectively. The chemical compositions of these cast grades are covered by ASTM specifications[7] A351/A351M, A743/A743M and A744/A744M.

F **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 roughness average (Ra) of 32 µin. (0.80 µm.) when measured according to the requirements of the American National Standards Institute (ANSI)/American Society of Mechanical Engineers (ASME)[8] B46.1 — Surface Texture, is considered to be equivalent to a No. 4 finish.

G **AIR VENTING**

To insure adequate venting of the tank which will protect it from internal pressure or vacuum damage, the critical relationship between minimum vent size and maximum filling or emptying rates should be observed.

A venting system of sufficient capacity to provide for venting during filling and emptying is not adequate during mechanical cleaning. During the cleaning cycle, tanks when cleaned mechanically should be vented adequately by opening the manhole cover to prevent vacuum or pressure build-up due to sudden changes in temperature of very large volumes of air.[9]

Means should be provided to prevent excess loss of cleaning solution through the manhole opening. The use of tempered water of about 95°F (35°C) for both pre-rinsing and post-rinsing is recommended to reduce the effect of flash heating and cooling.

H **MECHANICAL CLEANING**

The mechanical cleaning system shall be so designed that solution is applied to all product contact surfaces except those areas requiring manual cleaning. When being cleaned, the tank bottom should have sufficient pitch to accomplish draining and to have a fast flushing action across the bottom. The pitch should be at least 1/4 in. per ft (6.4 mm per 30 cm). Means should be provided for manual cleaning of all surfaces not cleaned satisfactorily by mechanical cleaning procedures. Cleaning and/or sanitizing solutions should be made up in a separate tank □ not in the transportation tank.

I **FACILITIES FOR EXTRA FITTINGS**

If extra sanitary fittings are supplied by the manufacturer of the farm pick-up tank, facilities should be provided in the pump compartment to adequately protect such items.

J **AIR UNDER PRESSURE**

Equipment and means for applying air under pressure for direct air agitation should conform to the applicable provisions of the 3-A Accepted Practices for Air Under Pressure, Number 604-.

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[9]For example, when a 6,000 gal tank with 800 ft³ of 135EF (57EC) hot air after cleaning is suddenly flash cooled by 50EF (28EC) water sprayed at 100 gpm the following takes place:
Within one second, the 800 ft³ of hot air shrinks approximately 51 ft³ in volume. This is the equivalent in occupied space of approximately 382 gal of product. This shrinkage creates a vacuum sufficient to collapse the tank unless the vent, manhole, or other openings allow air to enter the tank at approximately the same rate as it shrinks. It is obvious, therefore, that a very large air vent such as the manhole opening is required to accommodate this air flow.

K **TEMPERATURE OF THE PRODUCT**

The temperature of the product being loaded into the precooled tank should be sufficiently below the final receiving temperature requirements to make up for heat gain during transportation as outlined in Section D13.1.

L **INSULATING VALUES**

Table 3 lists the insulating value for some common insulating materials.

TABLE 3. Amount of Insulation Material Equivalent to R=4.0 at 75°F (24°C)

Material Type	Amount
High Density Fiberglass Sheets	0.88 in. (22.3 mm)
Soft Fiberglass Rolls	1.12 in. (28.4 mm)
Polystyrene Foam Sheets	1.02 in. (25.9 mm)
Corkboard Sheets	1.04 in. (26.4 mm)
Polyurethane Sheets	0.66 in. (16.8 mm)

M **ENGINEERING DESIGN AND TECHNICAL CONSTRUCTION FILE**

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

M1 **Purpose**

M1.1 To establish and document the material and fabrication requirements for the engineering design and technical construction files for all products, assemblies, and sub-assemblies supplied by the manufacturer thereof to be in compliance with the sanitary criteria found in 3-A Sanitary Standards or 3-A Accepted Practices. It is recommended that the engineering and construction file or files be submitted with applications for 3-A Symbol use authorization.

M2 **Scope**

M2.1 This EDTCF applies to equipment specified by:

M2.1.1 3-A Sanitary Standards for Stainless Steel Automotive Transportation Tanks for Bulk Delivery and Farm Pick-Up Service, Number 05-15.

M2.1.2 List all applicable 3-A Sanitary Standards and 3-A Accepted Practices.

M3 **Responsibilities**

M3.1 This EDTCF is maintained by: The Engineering Manager (or other company official) {name and title of responsible official} is responsible for maintaining, publishing, and distributing this EDTCF.

M3.2 Implementation: All divisions, specifically development engineering, standards engineering, sales engineering, and product departments are responsible for implementing this EDTCF.

M4 **Applicability**

M4.1 The 3-A Sanitary Standards and 3-A Accepted Practices are voluntarily applied as suitable sanitary criteria for dairy and food processing equipment. 3-A Sanitary Standards are referenced in the Grade A Pasteurized Milk Ordinance: "Equipment manufactured in conformity to 3-A Sanitary Standards complies with the sanitary design and construction standards of this Ordinance."

M5 **References**

M5.1 List any additional regulations that apply to the equipment or system covered by this EDTCF.

M5.2 Date of conformity or 3-A Symbol Authorization and certificate number, if authorized.

M6 **Design and Technical Construction File**

M6.1 The Engineering Design and Technical Construction File may consist of the following:

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

manufactured in conformity to the provisions of the 3-A for serial manufacturing, the internal measures that will be implemented to insure that the equipment will continue to be manufactured in conformity to the provisions of the 3-A Sanitary Standards or 3-A Accepted Practices;

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

M6.2 The file does not have to include detailed plans or any other specific information regarding the sub-assemblies, tooling, or fixtures used for the manufacture of the product unless a knowledge of them is essential for verification of conformity to the basic sanitary requirements found in 3-A documents.

M6.3 The documentation referred to in M6.1 above need not permanently exist in a material manner in the EDTCF, but it must be possible to assemble them and make them available within a period of time commensurate with its importance (one week is considered reasonable time). As a minimum, each product EDTCF must physically contain an index of the applicable document of M6.1 above.

M7 **Confidentiality**

M7.1 The EDTCF is the property of the manufacturer and is shown at their discretion, except that all or part of this file will be available to the 3-A Symbol Council or a regulatory agency for cause and upon request.

M8 **File Location**

M8.1 The EDTCF shall be maintained at {location}.

M9 **File Retention**

M9.1 The EDTCF (including all documentation referred to in M6.1) shall be retained and kept available for 12 years following the date of placing the product in use or from the last unit produced in the case of series manufacture.

These standards are effective November 24, 2002.

Dairy, Food and Environmental Sanitation, Vol. 22, No. 12, Pages 1020-1030

3-A® Sanitary Standards for Equipment for Packaging Viscous Products, Number 23-04

Formulated By
International Association of Food Industry Suppliers (IAFIS)
International Association for Food Protection (IAFP)
United States Public Health Service (USPHS)
The Dairy Industry Committee (DIC)
United Stated Department of Agriculture – Dairy Programs (USDA)
The European Hygienic Engineering Design Group (EHEDG)

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

A SCOPE

A1 These standards cover the sanitary aspects of unitized equipment for holding, opening, forming, dispensing, filling, closing, sealing, or capping containers for viscous products, or wrapping viscous products, and all parts essential to these functions. The equipment shall perform one or more of the following functions:

1. Holding the container preparatory to further processing
2. Opening the container
3. Forming the container
4. Dispensing a preformed container
5. Applying and sealing a supplementary fitment
6. Other processing equipment, as defined herein
7. Filling the container
8. Closing the container
9. Sealing the container
10. Capping the container
11. Wrapping the container
12. Applying a tamper-evident security seal.

The equipment shall start at the point(s) where the product, container, container blank, container material or wrapping material first enters the equipment. The equipment shall end where the packaged product exits the unitized 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 nonviscous products.

A3 In order to conform to these 3-A Sanitary Standards, equipment for packaging viscous products shall comply with the following design, material, and fabrication criteria and the applicable documents referenced herein[1].

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

B DEFINITIONS

B1 *Product:* Shall mean viscous comestibles such as frozen desserts, cottage cheese, sour cream, yogurt, butter, spreads, cream cheese, processed cheese and other similar viscous products, including added ingredients.

B2 *Viscous:* Shall mean semifluid product which is pumpable or flowable at packaging condition.

B3 *Container:* Shall mean a single service packaging enclosure or material being formed into the package, including its body, cap, cover, fitment or closure, and a wrapper or other structure, capable of holding the product.

B4 *Mechanical Holding, Opening, Forming, and Dispensing Equipment:* Shall mean the equipment for performing all or part of the following integral functions of feeding, holding, forming, seaming, opening and dispensing the containers.

B5 *Mechanical Filling Equipment:* Shall mean the equipment for filling the container with the product.

B6 *Mechanical Capping, Closing, Sealing, and Wrapping Equipment:* Shall mean the equipment for capping, closing, sealing the container and applying the security seal, or wrapping the product.

B7 *Other Processing Equipment:* Shall mean product handling equipment such as pumps, mixers, blenders, hoppers, ingredient feeders, and texturizers, integral to the filler equipment, which process, treat, flavor or add supplements to the product immediately prior to filling.

B8 *Unitized:* Shall mean the connection, assembly, or attachment of functional subunits, in a permanent manner (e.g., welding or with fasteners), to form the complete machine.

B9 **Surfaces**

B9.1 *Product Contact Surfaces:* Shall mean all surfaces which are exposed to the product, surfaces from which liquids may drain, drop, or be drawn into the product or into the container, and surfaces that touch the product contact surfaces of the container.

B9.2 *Nonproduct Contact Surfaces:* Shall mean all other exposed surfaces.

B9.2.1 *Splash Contact Surfaces:* Shall mean all other nonproduct contact surfaces that during normal use are subject to accumulation of soil and which require routine cleaning.

B10 **Cleaning**

B10.1 *Mechanical Cleaning or Mechanically Cleaned:* Shall denote cleaning solely by circulation and/or flowing chemical detergent solutions and water rinses onto and over the surfaces to be cleaned, by mechanical means.

B10.2 *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.

B11 **Surface Modifications**[2]

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 include:

1. Mechanical (shot peening[3], polishing)
2. Thermal (surface hardening 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. The coating material does not alter the physical properties of the substrate.

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[2]Additional information on surface modification is contained in Advanced Materials and Processes, Volume 137(1), Coatings and Coating Practices by H. Herman, Surface Modification by F. A. Smidt. ASM International, Materials Park, OH 44073 (216) 338-5151.

[3]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.

[4]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, DC 20407 (202) 755-0325.

B11.2.1 Coating processes include:

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

B12 *Bond*: Shall mean the adhesive or cohesive forces holding materials together. This definition excludes press and shrink fits.

B13 *Arithmetical Mean (R_a):* Shall be the arithmetical mean of the absolute values of the profile departure within a sampling length[5].

B14 *Sanitizing or Sanitization:* Shall mean a process applied to a cleaned surface which is capable of reducing the numbers of the most resistant human pathogens by at least 5 $\log_{10}$ reductions (99.999%) to 7 $\log_{10}$ reductions (99.99999%) by applying accumulated hot water, hot air, or steam, or by applying an EPA-registered sanitizer according to label directions. Sanitizing may be effected by mechanical or manual methods.

B15 *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 seals.

B16 *Sterilization:* Shall mean a process effected by heat, chemicals, or other mechanical means that destroys all vegetative bacteria and inactivates relevant bacterial spores.

B17 *Easily or Readily Removable:* Shall mean quickly separated from the equipment with the use of simple hand tools if necessary.

B18 *Easily or Readily Accessible:* Shall mean a location which can be safely reached by personnel from the floor, platform, or other permanent work area.

B19 *Inspectable*: Shall mean all product contact surfaces can be made available for close visual observation.

B20 *Simple Hand Tools:* Shall mean implements normally used by operating and cleaning personnel such as a screwdriver, wrench, or mallet.

B21 *Nontoxic Materials:* Shall mean those substances which under the conditions of their use are in compliance with applicable requirements of the Food, Drug, and Cosmetic Act of 1938, as amended.

B22 *Corrosion Resistant:* Shall mean the surface has the property to maintain its original surface characteristics for its predicted service period when exposed to the conditions encountered in the environment of intended use, including expected contact with product and cleaning, sanitizing, or sterilization compounds or solutions.

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[6], (except 301 and 302), or corresponding Alloy Cast Institute (ACI) types[7] or metal which under conditions of intended use is at least as corrosion resistant as stainless steel of the foregoing types, and is nontoxic and nonabsorbent, (See Appendix, Section E), except that:

C1.1.1 Surfaces of container holding, forming, opening, dispensing, closing, capping, sealing, or wrapping components which touch the product contact surfaces of the container or from which liquids may drain, drop, diffuse or be drawn into the container made of the materials provided for in C1.1 may have their product contact surfaces modified by surface treatments or coatings.

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[5]Additional information on arithmetical mean (R_a) is contained in ANSI B.46.1-1978. Available from The American National Standards Institute, 1430 Broadway, New York, NY 10018 (212-354-3300).

[6]The data for this series are contained in the *AISI Steel Products Manual, Stainless & Heat Resisting Steels*, Table 2-1. Available from the American Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086 (412) 776-1535.

[7]Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016 (708) 299-9160.

[8]MIL-C-26074E. Military Specification: Coatings Electroless Nickel, Requirements for. Available from Standardization, Document Order Desk (Department of Navy) 00 Robbins Ave., Bldg. 4, Section D, Philadelphia, PA 19111-5094, (215) 697-2167.

C1.2 Surfaces of container holding, forming, opening, dispensing, closing, capping, sealing, or wrapping components which touch the product contact surfaces of the container or from which liquids may drain, drop or be drawn into the container may also be made of other nontoxic structurally suitable metals(s) that have their product contact surfaces modified by coating(s)[8].

C2 **Nonmetals**

C2.1 Rubber or rubber-like materials may be used for filling nozzles, plungers, compression-type valve plugs, gaskets, diaphragms, O-rings, rollers, belts, sealing rings, slingers, drip shields, protective caps for sanitary connections, container opening, dispensing, forming, capping, wrapping and closing parts, filler valve parts, seals, short flexible tubing, agitators, agitator seals, scrapers, rotors, augers, impellers, mixing paddles, stators and housings and parts having the same functional purposes. These parts may be made of, or covered with, rubber or rubber-like materials.

C2.1.1 Rubber and rubber-like materials when used for the above-specified applications shall conform to the applicable provisions of the 3-A Sanitary Standards for Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-.

C2.2 Plastic materials may be used for filling nozzles, plungers, compression type valve plugs, gaskets, O-rings, diaphragms, rollers, belts, sealing rings, slingers, drip shields, agitator seals, agitator bearings, scrapers, protective caps for sanitary connections, container opening, dispensing, forming, capping, wrapping and closing parts, filler valve parts, self- adhesive release surfaces, seals, short flexible tubing, short connectors, viewing ports, rotors, agitators, augers, impellers, mixing paddles, stators and housings and parts having the same functional purposes. (These parts may be made of, coated, or covered with plastic materials.)

C2.2.1 Plastic materials when used for the above-specified applications shall conform to the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-.

C2.3 Rubber and rubber-like materials and plastic materials having product contact surfaces shall be of such composition as to retain their surface and conformation characteristics when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment, or sterilization.

C2.4 The adhesive, if used, on bonded rubber and rubber-like materials and bonded plastic materials shall be nontoxic[9].

C2.5 Rubber and rubber-like materials and plastic materials having product contact surfaces that are a bonded coating or a covering shall be of such composition as to retain their surface and conformation characteristics when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization.

C2.6 When materials having certain inherent functional properties are required for specific applications, such as rotary seals and container forming parts, carbon and/or ceramic materials may be used. Carbon and ceramic materials shall be inert, nonporous, nontoxic, nonabsorbent, insoluble, resistant to scratching, scoring and distortion when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization.

C3 **Sterilizability**

C3.1 In a processing system to be sterilized by heat and operated at a temperature of 250°F (121°C) or higher, all materials having product contact surface(s) used in the construction of the 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 Nonproduct contact surfaces shall be of corrosion-resistant material or material that is rendered corrosion resistant. If coated, the coating used shall adhere. Nonproduct contact surfaces shall be relatively nonabsorbent, durable, and cleanable.

[9]Adhesives shall comply with 21 CFR 175 – Indirect Food Additives: Adhesives and Components of Coatings. Document for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (202) 512-1800.

Parts removable for cleaning having both product contact and nonproduct contact surfaces shall not be painted.

D FABRICATION

D1 Surface Texture

D1.1 All product contact surfaces shall have a finish at least as smooth as a No. 4 (R_a 32.0 in. or 0.80 µm) 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 F), except that:

D1.1.1 Surfaces used to apply sterilizing chemicals to the product contact surfaces of the package shall have a surface finish at least as smooth as an R_a finish of 125 µin. (3.18 µm).

D1.1.2 For equipment used for packaging mozzarella cheese, butter and related products, the product contact surfaces finish of augers, auger troughs, auger components, auger supports, fill necks, discharge ports, hoppers, bodies, baffles, and dividers, may be modified to R_a 125 µin. (3.18 µm) finish by shot peening.

D2 Permanent Joints

D2.1 Permanent joints in metallic product contact surfaces shall be continuously welded[10].

D2.2 Hoses with permanently attached sanitary fittings when used for short flexible connections shall comply with 3-A Sanitary Standards for Hose Assemblies for Milk and Milk Products, Number 62-.

D3 Bonded Materials

D3.1 Bonded rubber and rubber-like materials and bonded plastic materials having product contact surfaces shall be bonded in a manner that the bond is continuous and mechanically sound, so that when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment, the rubber and rubber-like material or the plastic material does not separate from the base material to which it is bonded.

D4 Coatings

D4.1 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.

D4.2 The minimum thickness of electrodeposited coatings shall not be less than 0.0002 in. (0.005 mm) for all product contact surfaces.

D4.3 The minimum thickness of a coating of electroless nickel alloy, as specified in C1.2 shall not be less than 0.002 in. (0.05mm).

D4.4 Plastic or rubber and rubber-like materials, when used as a coating, shall be at least 0.001 in. (0.025 mm) thick.

D5 Cleaning and Inspectability

D5.1 Packaging equipment that is to be mechanically cleaned shall be designed so that the product contact surfaces of the packaging equipment and all nonremoved appurtenances thereto can be mechanically cleaned and are easily accessible, readily removable, and inspectable.

D5.2 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.

D6 Draining

D6.1 All product contact surfaces shall be self-draining except for normal adherence. The bottom of the filler bowl or hopper shall have a minimum slope of 1/8 in. per ft (10 mm per m) toward the plane of the outlet(s).

D6.2 All filler bowls and product hoppers shall be effectively enclosed or covered and covers shall be self-draining.

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[10]Criteria for hygienic welds may be found in AWS/ANSI D18.1 – *Specification for Welding of Austenitic Stainless Steel Tube and Pipe Systems in Sanitary (Hygienic) Applications*. Available from the American Welding Society, 550 N.W. LeJeune Rd., Miami, FL 33126, phone: (305) 443-9353, fax: (305) 443-7559, e-mail: info@amweld.org; and EHEDG Doc. 9 – Welding Stainless Steel to Meet Hygienic Requirements. Available from the European Hygienic Equipment Design Group, Ellen Moens, Avenue Grand Champ 148, 1150 Brussels, Belgium, phone: +32 2 761 7408, fax: +32 2 763 0013, e-mail: moens@nsf.org.

D7 **Openings and Covers**

D7.1 Filler bowls or product hoppers 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. (9.52 mm) along all edges. The edges of all cover openings shall extend upward at least 3/8 in. (9.52 mm) or be fitted with a permanently attached sanitary pipeline connection conforming to D14.

D7.2 Nonremovable covers for filler bowls or product hoppers or other assemblies (1) shall be of a type that can be opened and maintained in an open position, (2) shall be designed to be self-draining when in the closed position, (3) shall be designed so that when the covers are in any open position, liquid from the exterior surface shall not drain into the product, or on to a product contact surface, and (4) shall be designed so that when in the fully open position condensation from the underside of the cover will not drain into the product or onto a product contact surface. Covers of openings that will be held in place by gravity or vacuum may be of the lift-off type and may be provided with a clamp(s) or other device(s) to maintain them in position.

D8 **Agitators**

D8.1 Agitator shaft openings through the bridge or top enclosure shall have a minimum diameter of 1 in. (25.4 mm) on packaging equipment which requires removal of the agitator shaft for cleaning, or be of a diameter that will provide a 1 in. (25.4 mm) minimum annular cleaning space between the agitator shaft and the inside surface of the flange for the opening on packaging equipment which does not require removal of the agitator for the cleaning. A shield that can be raised or dismantled to permit the cleaning of all its surfaces shall be provided with means to protect against the entrance of dust, oil, insects and other contaminants into the packaging equipment through the annular space around the agitator shaft.

D8.2 Agitators, mixing paddles and similar devices, if not designed for mechanical cleaning, shall be readily accessible for manual cleaning and inspection either in an assembled position or when removed. A seal for a shaft, if provided, shall be of a packless type, sanitary in design, and durable, with all parts readily accessible for cleaning.

D9 **Accessibility**

D9.1 The packaging equipment shall be so designed that adjustments necessary during the operation may be made without raising or removing the product hopper or filler bowl cover(s).

D9.2 Packaging equipment for aseptic or extended shelf-life operation shall be designed so that adjustments necessary during the operation may be made without jeopardizing the sterility of the unit.

D10 **Shafts and Bearings**

D10.1 Shafts of packaging equipment shall have a seal that is of a packless type and is sanitary in design, and shall be readily accessible and inspectable.

D10.2 Where a shaft passes through a product contact surface, the portion of the opening surrounding the shaft shall be protected to prevent the entrance of contaminants.

D10.3 Bearings having a product contact surface shall be of a nonlubricated type.

D10.4 Lubricated bearings, including the permanently sealed type, shall be located outside the product contact surface with at least 1 in. (25.4 mm) clearance open for inspection between the bearing and any product contact surface.

D11 **Gaskets**

D11.1 Gaskets having a product contact surface shall be removable or bonded.

D11.2 Grooves in gaskets shall be no deeper than their width, unless the gasket is readily removable and reversible for cleaning.

D11.3 Gasket grooves or 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) cross-section and those provided for in the sanitary fittings specified by Section D15.

D12 **Radii**

D12.1 All internal angles of less than 135° on product contact surfaces shall have radii of not less than 1/4 in. (6.35 mm) except that:

D12.1.1 Smaller radii may be used when they are required for essential functional reasons, such as those in filler nozzles, paper scoring devices, mandrels and forming molds. In no case shall such radii be less than 1/32 in. (0.794 mm).

D12.1.2 The radii in gasket retaining grooves and grooves in gaskets shall be not less than 1/8 in. (3.18 mm), except for those for standard 1/4 in. (6.35 mm) and smaller O-rings, and those provided for in the sanitary fittings specified in D15.

D12.1.3 Radii in standard O-ring grooves shall be as specified in Appendix, Section H.

D12.1.4 Radii in nonstandard O-ring grooves shall be those radii closest to a standard O-ring as specified in Appendix, Section H.

D12.2 The minimum radii for fillets of welds in product contact surfaces shall be not less than 1/4 in. (6.35 mm) except that the minimum radii for such welds may be 1/8 in. (3.18 mm) when the thickness of one or both parts joined is less than 3/16 in. (4.76 mm).

D13 **Guards and Other Safety Devices**

D13.1 Covers, diverting aprons, shields, or guards shall be provided as necessary and shall be so designed and located to prevent liquid or other contaminants from draining or dropping into the container or product, or onto product contact surfaces, except that:

D13.1.1 Shields and guards may not be required in equipment designed for aseptic or extended shelf-life operation if the assembly is of sanitary design and the system provides 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 provided that fill lines and filler bowls shall be located or otherwise protected so that condensate drippage into open containers is precluded.

D13.2 Guards required by a safety standard shall be readily removable for cleaning and inspection.

D13.3 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:

D13.4 Deflector shields may not be required in a system sanitarily designed to prevent the formation of condensate in critical areas. The formation of condensate in critical areas can be prevented by (1) maintaining a valve block temperature higher than the dew point of its operating environment, by either warming the valve block or chilling the ambient air, (2) dehumidifying the ambient air, or (3) maintaining a flow of unsaturated air, across the valve block, of sufficient volume and velocity to prevent the formation of condensate.

D14 **Threads**

D14.1 There shall be no threads on product contact surfaces except as provided for in Section D15 and D20.2.

D15 **Fittings and Valves**

D15.1 Sanitary fittings and valves shall conform to the applicable provisions of the 3-A Sanitary Standards for Sanitary Fittings for Milk and Milk Products, Number 63-; 3-A Sanitary Standards for Plug-Type Valves for Milk and Milk Products, Number 51-; 3-A Sanitary Standards for Compression-Type Valves for Milk and Milk Products, Number 53-; 3-A Sanitary Standards for Diaphragm-Type Valves for Milk and Milk Products, Number 54-; 3-A Sanitary Standards for Ball-Type Valves for Milk and Milk Products, Number 68-; 3-A Sanitary Standards for Caged-Ball Valves for Milk and Milk Products, Number 66-; 3-A Sanitary Standards for Rupture Discs for Milk and Milk Products, Number 60-; 3-A Sanitary Standards for Thermoplastic Plug-Type Valves for Milk and Milk Products, Number 52-; 3-A Sanitary Standards for Hose Assemblies for Milk and Milk Products, Number 62-; except that materials conforming to C2.1.1 or C2.2.1 may be used for caps of sanitary design for the protection of terminal ends of sanitary tubes.

D16 **Sight and Light Openings**

D16.1 All sight and light openings, if provided, shall conform to 3-A Sanitary Standard for Sight and Light Windows and Sight Indicators in contact with Milk and Milk Products, Number 65-.

D17 **Sensors and Sensor Connections**

D17.1 All sensors or sensor connections having product contact surfaces shall conform to the 3-A Sanitary Standard for Sensors and Sensor Fittings and Connections Used on Fluid Milk and Milk Products Equipment, Number 74-.

D18 **Refractometers**

D18.1 All optical sensor devices used shall conform to the 3-A Sanitary Standard Refractometers and Energy-Absorbing Optical Sensors for Milk and Milk Products, Number 46-.

D19 **Sanitary Tubing**

D19.1 All metal tubing shall comply with the applicable provisions of Section G for welded sanitary product pipelines found in the 3-A Accepted Practices for Permanently Installed Sanitary Product Pipelines and Cleaning Systems with Amendment, Number 605, and with 3-A Sanitary Standards for Polished Metal Tubing for Dairy Products, Number 33-.

D20 **Ancillary Equipment**

D20.1 Flow meters, if used, shall conform to the applicable provisions of 3-A Sanitary Standards for Flow Meters for Milk and Milk Products, Number 28-.

D20.2 Pumps, if used, shall conform to the applicable provisions of 3-A Sanitary Standards for Centrifugal and Positive Rotary Pumps for Milk and Milk Products, Number 02- or 3-A Sanitary Standards for Homogenizers and Pumps of the Plunger Type, Number 04-.

D20.3 When provided by the manufacturer, equipment for producing air under pressure and/or air piping which is supplied as an integral part of the filling equipment shall conform to the applicable provisions of the 3-A Accepted Practices for Supplying Air Under Pressure in Contact with Milk, Milk Products and Product Contact Surfaces, Number 604-.

D20.4 If coding and/or dating is to be performed, 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.

D20.5 Variegators, ingredient feeders and similar equipment, when provided by the manufacturer shall meet all applicable sections of this standard.

D21 **Sterilization Systems**

D21.1 Packaging equipment 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:

D21.1.1 The construction shall be such that all product contact surfaces can be (1) sterilized by saturated steam or water under pressure (at least 15.3 psig or 106 kPa) at a temperature of at least 250°F (121°C) and (2) operated at the temperature required for processing.

D21.1.2 Packaging equipment that has product contact surface(s) to be used in such a processing system, not designed so that the system is automatically shut down if the product pressure in the system becomes less than that of the atmosphere and cannot be restarted until the system is 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 equipment shall be constructed so that the steam chamber or other sterilizing medium chamber may be exposed for inspection.

D21.1.3 Where steam or other sterilizing medium is used, the connection(s) on the packaging equipment shall be such that the steam lines or other sterilizing medium lines can be securely fastened to the packaging equipment. The packaging equipment shall be constructed so that the steam or other sterilizing medium chamber may be exposed for inspection.

D21.1.4 The seal(s) in packaging equipment 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.

D21.1.5 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-.

D22 **Springs**

D22.1 Coil springs having product contact surfaces shall have at least 3/32 in. (2.38 mm) openings between coils including the ends when the spring is in a free position. Coil springs shall be readily accessible for cleaning and inspection.

D23 **Supports**

D23.1 The means of supporting packaging equipment shall be one of the following:

D23.1.1 If legs are used they shall be smooth with rounded ends or with a flat, load-bearing foot suitable for sealing to the floor, and have no exposed threads. Legs made of hollow stock shall be sealed. Legs shall provide a minimum clearance between the lowest part of the base and the floor of not less than 6 in. (152 mm).

D23.1.2 If casters are used they shall be of sufficient size to provide a clearance between the lowest part of the base and the floor of not less than 6 in. (152 mm). Casters, if provided, shall be easily cleanable, durable and of a size that will permit easy movement of the packaging equipment.

D24 **Nonproduct Contact Surfaces**

D24.1 Nonproduct contact surfaces shall have a relatively smooth finish, relatively free of pockets and crevices, and be cleanable and those surfaces to be coated shall be effectively prepared for coating. Exposed threads shall be minimized. Exposed braided coverings of cable or hose shall not be used. No continuous or piano-type hinges shall be used on the equipment or its control cabinets. Electrical and utility connections shall be as remote as practical from the product areas. Riveted nameplates or appendages shall not be used. Socket head cap screws shall not be used. Knurled surfaces shall not be used. Nameplates shall be welded or effectively sealed to the equipment. Supporting structures, braces, catwalks, stairs, handrails and guards are not considered as nonproduct contact surfaces of the equipment and are considered as part of the building structure. Panels or doors shall be provided to allow easy access to the interior of the equipment. They shall be constructed in a manner that will prevent air entrance. Use of hinges, wing nuts, latches, and similar easy-opening fastening devices are recommended to allow easy access without special tools.

D24.2 There shall be no exposed threads on splash contact surfaces, except that:

D24.2.1 Exposed threads are permitted on removable clamps or other components which can be easily removed for cleaning.

D24.2.2 Exposed threads are permitted when required for essential functional reasons. Such exposed threads shall be easily accessible for cleaning.

APPENDIX

E **STAINLESS STEEL MATERIALS**

Stainless steel conforming to the applicable composition ranges established by AISI for wrought products (Table 1), or by ACI for cast products (Table 2), should be considered in compliance with the requirements of Section C1 herein. Where welding is involved, the carbon content of the stainless steel should not exceed 0.08%. The first reference cited in C1 sets forth the chemical ranges and limits of acceptable stainless steel of the 300 Series.

TABLE 1

WROUGHT PRODUCTS TYPICALLY USED			
UNS #	ASTM[11]	AISI/SAE[6]	Properties
S30300	A-582	303	Free-Machining S.S.; Austenitic
S30400	A-276 A-666	304	Austenitic S.S.
S30403	A-276 A-666	304L	Low Carbon Austenitic S.S.
S31600	A-276 A-666	316	Austenitic S.S. plus Mo*
S31603	A-276 A-666	316L	Low Carbon Austenitic S.S. plus Mo*

*Molybdenum

TABLE 2

CAST PRODUCTS			
UNS #	ASTM[11]	ACI[7]	Common Names
J92500	A-351 A-743 A-744	CF-3	Cast 304L
J92800	A-351 A-743 A-744	CF-3M	Cast 316L
J92600	A-351 A-743 A-744	CF-8	Cast 304
J92900	A-351 A-743 A-744	CF-8M	Cast 316
J92180	A-747	CB7 Cu — 1	Cast 17-4 PH
J92110	A-747	CB7 Cu —2	Cast 15-5 PH
N26055	A-494	CY5Sn BiM	Alloy 88
J92701	A-743	CF-16F	Free Machining Austenitic S.S.

F **PRODUCT CONTACT SURFACE FINISH**

Surface finish equivalent to 150 grit or better as obtained with silicon carbide properly applied to stainless steel sheets is considered in compliance with the requirements of Section D1 herein. A maximum R_a of 32.0 µin. (0.80 µm), when measured according to the recommendations in American National Standards Institute (ANSI)/American Society of Mechanical Engineers (ASME)[12] B46.1 – *Surface Texture*, is considered to be equivalent to a No. 4 finish.

G **CULINARY STEAM**

Steam used as the sterilizing medium for product contact surfaces should meet the criteria for culinary steam as specified in the 3-A Accepted Practices for a Method of Producing Steam of Culinary Quality, Number 609-.

H **O-RING GROOVE RADII**

TABLE 3

Groove Radii Dimensions for Standard O-Rings			
O-Ring Cross Section, Nominal (AS 568[13])	O-Ring Cross Section, Actual (AS 568)	O-Ring Cross Section, Actual (ISO 3601 1[14])	Minimum Groove Radius
1/16 in.	0.070 in.	1.80 mm	0.016 in. (0.406 mm)
3/32 in.	0.103 in.	2.65 mm	0.031 in. (0.787 mm)
1/8 in.	0.139 in.	3.55 mm	0.031 in. (0.787 mm)
3/16 in.	0.210 in.	5.30 mm	0.062 in. (1.575 mm)
1/4 in.	0.275 in.	7.00 mm	0.094 in. (2.388 mm)

I **ENGINEERING DESIGN AND TECHNICAL CONSTRUCTION FILE**

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

I1 **Purpose**

I1.1 To establish and document the material, fabrication, and installation (where appropriate) requirements for the engineering design and technical construction files for all products, assemblies, and sub-assemblies supplied by the manufacturer thereof to be in compliance with the sanitary criteria found in 3-A Sanitary Standards or 3-A Accepted Practices. It is recommended that the engineering and construction file or files be submitted with applications for 3-A Symbol use authorization.

I2 **Scope**

I2.1 This EDTCF applies to equipment specified by:

I2.1.1 3-A Sanitary Standards for Equipment for Packaging Viscous Dairy Products, Number 23-04.

I3 **Responsibilities**

I3.1 This EDTCF is maintained by: The Engineering Manager (or other company official) **{name and title of responsible official}** is responsible for maintaining, publishing, and distributing this EDTCF.

I3.2 Implementation: All divisions, specifically development engineering, standards engineering, sales engineering, and product departments are responsible for implementing this EDTCF.

I4 **Applicability**

I4.1 The 3-A Sanitary Standards and 3-A Accepted Practices are voluntarily applied as suitable sanitary criteria for dairy and food processing equipment. 3-A Sanitary Standards are referenced in the Grade A Pasteurized Milk Ordinance: "Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this Ordinance."

[11]Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959. Phone: (610) 832-9500.

[12]Available from the American Society of Mechanical Engineers, 345 East 47th Street, New York, NY 10017-2392 (212) 705-7722.

[13]The document establishing these standard dimensions is Aerospace Standard (AS) 568, published by SAE, 400 Commonwealth Drive, Warrendale, PA 15086 (412-776-4970).

[14]The document establishing these standard dimensions is ISO 3601-1: 1988 (E), published by the International Organization for Standardization (ISO), 1 Rue de Varembe, Case Postale 58, CH 1 1211, Geneva, Switzerland (41-22-734-1240).

I5 **References**

I5.1 List any additional regulations that apply to the equipment or system covered by this EDTCF.

I5.2 Date of conformity or 3-A Symbol Authorization and certificate number, if authorized.

I6 **Design and Technical Construction File**

I6.1 The Engineering Design and Technical Construction File may consist of the following:

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

I6.2 The file does not have to include detailed plans or any other specific information regarding the sub-assemblies, tooling, or fixtures used for the manufacture of the product unless a knowledge of them is essential for verification of conformity with the basic sanitary requirements found in 3-A documents.

I6.3 The documentation referred to in I6.1 above need not permanently exist in a material manner in the EDTCF, but it must be possible to assemble them and make them available within a period of time commensurate with its importance (one week is considered reasonable time). As a minimum, each product EDTCF must physically contain an index of the applicable document of I6.1 above.

I6.4 The EDTCF may be in hard copy or software form.

I7 **Confidentiality**

I7.1 The EDTCF is the property of the manufacturer and is shown at their discretion, except that all or part of this file will be available to the 3-A Symbol Council or a regulatory agency for cause and upon request.

I8 **File Location**

I8.1 The EDTCF shall be maintained at **{location}**.

I9 **File Retention**

I9.1 The EDTCF (including all documentation referred to in I6.1) shall be retained and kept available for 12 years following the date of placing the product in use or from the last unit produced in the case of series manufacture.

These standards are effective November 24, 2002.

Dairy, Food and Environmental Sanitation, Vol. 22, No. 12, Pages 1031-1036

3-A® Sanitary Standards for Equipment for Packaging Dry Milk and Dry Milk Products, Number 27-05

Formulated by
International Association of Food Industry Suppliers (IAFIS)
International Association for Food Protection (IAFP)
United States Public Health Service (USPHS)
The Dairy Industry Committee (DIC)
United States Department of Agriculture – Dairy Programs (USDA)

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

A SCOPE

A1 These standards cover the sanitary aspects of equipment for performing the functions of holding, forming, dispensing, filling, weighing, deaerating, closing, and/or sealing containers, and all parts which are essential to these functions when they are performed as an integral part of the packaging operation. These standards do not pertain to the container nor to a duct(s) which is not a part of the packaging equipment.

A2 In order to conform to these 3-A Sanitary Standards, equipment for packaging dry milk and dry milk products shall conform to the following design, material, and fabrication criteria and the applicable documents referenced herein.[1]

B DEFINITIONS

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

B2 *Container:* Shall mean a packaging enclosure holding the product, including multi-wall bags.

B3 *Holding, Opening, Forming, and Dispensing Equipment:* Shall mean all equipment for holding, opening, forming, and dispensing the empty container.

B4 *Filling Equipment:* Shall mean the equipment for mechanically filling the container with the product.

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

B5 *Closing and Sealing Equipment:* Shall mean the equipment for mechanically closing and sealing the container.

B6 **Surfaces**

B6.1 *Product Contact Surfaces:* Shall mean all surfaces which are exposed to the product, surfaces from which other materials may drain, drop, or be drawn into the product or into the container, and surfaces that touch product contact surfaces of the container.

B6.2 *Nonproduct Contact Surfaces:* Shall mean all other exposed surfaces.

B7 *Coatings:* Shall mean the results of a process where a different material is deposited to create a new surface. There is appreciable, typically more than 1 µm, build-up of new material. The coating material does not alter the physical properties of the substrate.

B7.1 Coating processes include:

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

B8 *Scale Pans:* Shall mean removable filling equipment components used for holding or transporting product.

B9 *Sintered Material:* Shall mean a porous component which is molded by bonding small particles of a base material(s) through a combination of heat and pressure.

C **MATERIALS**

C1 **Metals**

C1.1 Product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI) 300 Series[3] or corresponding Alloy Cast Institute (ACI) types[4] (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 Bearings may be made of metal covered with an engineering plating of nickel, chromium, or equally corrosion-resistant nontoxic material.

C1.1.2 Surfaces of container holding, forming, opening, dispensing, closing, or sealing components which touch the product contact surfaces of the container or from which contaminants may drain, drop, or diffuse into the container may be made of a nontoxic, nonabsorbent metal that is corrosion resistant under conditions of intended use or may be made of metal made corrosion resistant and wear resistant by surface coatings.[2]

C1.2 Silver soldered or brazed areas and silver solder or brazing material shall be nontoxic and corrosion resistant.

C2 **Nonmetals**

C2.1 Rubber and rubber-like materials may be used for container opening, dispensing, and closing parts, filling nozzles, flexible connectors, plungers, bonded or removable gaskets, diaphragms, shields, filling valve members, seals, and parts used in similar applications.

C2.1.1 Rubber and rubber-like materials, when used for the above specified applications, shall conform to the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-.

C2.2 Plastic materials may be used for container holding, opening, forming, dispensing, and closing parts, filling nozzles, flexible connectors, plungers, bonded or removable gaskets, diaphragms, shields or guards, filling valve members, covers, seals, diverting aprons, screening and perforated media, screen frame assemblies, sintered deaeration probes, and parts used in similar applications.

[2]Federal Specification #QQ-C-320B for Chromium Plating (Electrodeposited), with Amendment 4. Federal Specification #QQ-N-290A for Nickel Plating (Electrodeposited). Available from the General Services Administration, Federal Supply Services Bureau, Specification Section, 470 East L'Enfant Plaza, Suite 8100, Washington, DC 20407 (202) 755-0325.

[3]The data for this series are contained in the *AISI Steel Products Manual, Stainless & Heat Resisting Steels*, Table 2-1. Available from the American Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086 (412) 776-1535.

[4]Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016 (708) 299-9160.

C2.2.1 Plastic materials, when used for applications specified in C2.2, shall conform to the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Plastic Materials Used on Product Contact Surfaces for Dairy Equipment, Number 20-, except for sintered deaeration probes which shall meet the requirements of 21 CFR Parts 170-199 or otherwise accepted by Food and Drug Administration for food contact.

C2.3 The final bond and residual adhesive, if used, of bonded rubber and rubber-like materials and bonded plastic shall be nontoxic[5].

C2.4 Rubber and rubber-like materials and plastic materials used for bonded gaskets 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.

C2.5 Single-service gaskets of a sanitary type may be used on parts which must be disassembled for cleaning.

C2.6 Cotton, linen, or synthetic materials may be used for single service filter media. These materials shall be nontoxic, nonshedding, relatively insoluble, and shall not impart a flavor to the product.

C3 **Nonproduct Contact Surfaces**

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

D **FABRICATION**

D1 **Surface Texture**

D1.1 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 (See Appendix, Section F) except for:

D1.2 Screens and perforated media.

D1.3 The use of selected stainless steel sheets with a No. 2B finish free of imperfections such as pits, folds and crevices in the fabricated form for product contact surfaces is permitted and limited to dry product contact surfaces.

D1.4 Deaeration probes may be a sintered material.

D2 **Permanent Joints**

D2.1 Permanent joints in metallic product contact surfaces shall be flush and continuously welded. If it is impractical to weld, they may be silver soldered or brazed. An exception is made to the foregoing for product connections which may have rolled-on sanitary pipeline ferrules or flanges. Welded or silver soldered or brazed areas of product contact surfaces shall be at least as smooth as a No. 4 ground finish on stainless steel sheets, and be free of imperfections such as pits, folds, and crevices.

D3 **Sintered Deaeration Probes**

D3.1 The sintered material of deaeration probes shall be designed to be discarded after they have become plugged.

D3.2 The manufacturer shall provide guidance concerning the handling and storage of sintered deaeration probes temporarily removed from service. See Appendix I for an acceptable method.

D4 **Coatings**

D4.1 The minimum thickness of engineering plating shall not be less than 0.0002 in. (0.005 mm) for all product contact surfaces, except that when the parts listed in C1.1.2 that are to be plated are other than stainless steel, the minimum thickness of the engineering plating shall be 0.002 in. (0.05 mm).

D4.2 Plastic or rubber and rubber-like materials, when used as a coating, shall be at least 0.001 in. (0.025 mm) thick.

D5 **Cleaning and Inspectability**

D5.1 Product contact surfaces shall be easily accessible, visible for inspection, and readily cleanable, either when in an assembled position or when removed. Removable parts shall be readily demountable.

[5]Adhesives shall comply with 21 CFR 175 – Indirect Food Additives: Adhesives and Components of Coatings. Document for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (202) 512-1800.

D6 **Draining**

D6.1 Product contact surfaces shall be self-draining or self purging except for normal clingage.

D7 **Instrument Connections**

D7.1 Product hoppers integral with the filler shall be equipped with dust-tight covers, gasketed if necessary, and have drop flanges which overlap the rim of the hoppers by at least 3/8 in. (10 mm). The edges of openings in the hopper cover shall extend upward at least 3/8 in. (10 mm) or be fitted with a permanently attached sanitary pipeline connection conforming to D14. Openings in the hopper cover, except those fitted with a permanently attached sanitary pipeline connection, shall be provided with dust-tight covers, gasketed if necessary, and have a downward flange of not less than 1/4 in. (6 mm) so designed as to prevent contaminants from entering the hopper. Covers shall be self-draining.

D7.2 The filling equipment shall be so designed that adjustments necessary during the operation may be made without raising or removing the hopper cover(s).

D8 **Gaskets**

D8.1 Gaskets having a product contact surface shall be removable or bonded so as to be smooth and easily cleanable.

D8.2 Bonded rubber and rubber-like materials and bonded plastic gaskets shall be bonded in such a manner that the bond is continuous and mechanically sound, and so that when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment, the rubber and rubber-like material or the plastic material does not separate from the base material.

D8.3 Grooves in gaskets shall be no deeper than their width, and the minimum radius of any angle shall be not less than 1/8 in. (3 mm) unless the gasket is readily reversible for cleaning.

D8.4 Gasket retaining grooves in product contact surfaces for removable gaskets shall not exceed 1/4 in. (6 mm) in depth and, except those for standard O-Rings smaller than 1/4 in. (6 mm), shall be at least 1/4 in. (6 mm) wide.

D9 **Radii**

D9.1 Internal angles of 135° or less on product contact surfaces shall have radii of not less than 1/4 in. (6 mm) except that:

D9.1.1 Where smaller radii are required for essential functional reasons, such as those in filler nozzles, scale pans, and screw conveyors, the radii shall be not less than 1/32 in. (1 mm).

D9.1.2 The radii in gasket retaining groove for removable gaskets, except those for standard 1/4 in. (6 mm) and smaller O-Rings, shall be not less than 1/8 in. (3 mm).

D9.1.3 The radii in grooves for standard 1/4 in. (6 mm) O-Rings shall be not 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).

D10 **Openings and Covers**

D10.1 Covers, diverting aprons, shields, or guards shall be provided and shall be so designed and located so as to prevent contaminants from draining or dropping into the container or product, or onto product contact surfaces.

D11 **Lubrication**

D11.1 Where lubrication is required, the design and construction of the equipment shall be such that the lubricant cannot leak, drain, be forced, or be drawn into the product or onto product contact surfaces. Lubricated bearings shall be located outside the product contact surface with at least 1 in. (25 mm) clearance between the product contact surface and the bearing.

D12 **Threads**

D12.1 There shall be no exposed threads on product contact surfaces.

D13 **Shafts and Bearings**

D13.1 A shaft seal, if provided, shall be of a packless type, sanitary in design, with all parts accessible for cleaning.

D14 **Fittings and Valves**

D14.1 Sanitary fittings and connections, if used, shall conform to the applicable provisions of the 3-A Sanitary Standards for Sanitary Fittings for Milk and Milk Products, Number 63-.

D15 **Springs**

D15.1 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.

D16 **Filters**

D16.1 Perforated stainless steel materials, woven stainless steel wire, or woven materials provided for in Section C2.2 may be used for screening media. Cotton, linen, or synthetic materials provided for in Section C2.6 may be used for single-service filter media on vacuum packaging machines.

D17 **Air Under Pressure**

D17.1 Equipment for producing air under pressure and/or air piping which is supplied as an integral part of the filling equipment shall conform to the applicable provisions of the 3-A Accepted Practices for Supplying Air Under Pressure in Contact with Milk, Milk Products and Product Contact Surfaces, Number 604-.

D18 **Supports**

D18.1 The means of supporting the equipment shall be legs or casters, or the equipment shall be mounted on a slab or island and shall conform to the applicable provisions of the following:

D18.1.1 Legs or casters shall 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 of the base, 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.

D18.1.2 Legs, if provided, shall be smooth with rounded ends and have no exposed threads. Legs made of hollow stock shall be sealed.

D18.1.3 Casters, if provided, shall be easily cleanable, durable and of a size that will permit easy movement of the equipment.

D18.1.4 If the equipment is to be mounted on a slab or island, the base shall be designed (1) for sealing to the slab or island (See Appendix, Section G), and (2) to permit adequate cleaning, drainage, and drying of the interior of the base.

D19 **Guards and Other Safety Devices**

D19.1 A guard(s) required by a safety standard that will not permit accessibility for cleaning and inspection in place shall be designed so it (they) can be removed without tools.

D20 **Nonproduct Contact Surfaces**

D20.1 Nonproduct contact surfaces shall be smooth, free of pockets and crevices, and be readily cleanable. Those to be coated shall be effectively prepared for coating.

D20.2 Panels or doors shall be provided to allow easy access without tools for the cleaning and inspection of mechanical areas of the equipment which are not dust-tight.

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 C1 sets forth the chemical ranges and limits of acceptable stainless steel of the 300 Series. Cast grades or stainless steel corresponding to types 303, 304, and 316 are designated CF-16F, CF-8, and CF-8M, respectively. These cast grades are covered by ASTM[6] specifications A351/A351M, A743/A743M and A744/A744M.

F **PRODUCT CONTACT SURFACE FINISH**

Surface finish equivalent to 150 grit or better as obtained with silicon carbide, properly applied on stainless steel sheets, is considered in compliance with the requirements of Section D1 herein. A maximum R_a of 32 µin. (0.80 µm), when measured according to the recommendations in American National Standards Institute (ANSI)/American Society of Mechanical Engineers (ASME)[7] B46.1 – *Surface Texture*, is considered to be equivalent to a No. 4 finish.

[6]Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959. Phone: (610) 832-9500.

[7]Available from ASME, 345 East 47th Street, New York, NY 10017-2392. Phone: (212) 705-7722.

G **SLABS OR ISLANDS**

When the equipment is designed to be installed on a slab or island, the dimensions of the slab or island should be such that the base of the equipment will extend beyond the slab or island at least 1 in. (25 mm) in all horizontal directions. The slab or island should be of sufficient height so that the bottoms of all product connections are not less than 4 in. (100 mm) above the floor. The surface of the slab or island should be coated with a thick layer of waterproof mastic material, which will harden without cracking. The junction of the equipment and the slab or island should be sealed.

H **SCREEN AND PERFORATED MEDIA**

H1 Recommended screen opening sizes are shown in the following table. Similar opening sizes are recommended for perforated media. Other opening sizes might be used depending upon the powder being filled.

DESCRIPTION	MAXIMUM SIEVE OPENINGS
Primary Screen or Perforated Media	.0026 in. (0.065 mm)
Support Screen or Perforated Media	.0341 in. (0.865 mm)

Screen opening dimensions may be obtained by any desired combination of wire thickness and number of wires per inch. For instance, if the screening surface is made of stainless steel woven wire, a 0.028 in. (0.711 mm) opening might be obtained by using 24 x 24 mesh market grade screen cloth made of wire 0.014 in. (0.356 mm) thick (about 45% open area), by using 30 x 30 bolting cloth screen made of wire 0.0065 in. (0.165 mm) thick (about 65% open area), or by using many other mesh-wire thickness combinations. Also, multiple screens of various open areas might be used in combination. These combinations allow a wide choice to obtain desired balance between screen strength and open area. If materials other than stainless steel are used to construct the screening surface, similar combinations may be employed to achieve desired opening configuration.

H2 Screens and perforated media should be kept dry at all times. When the media cannot be adequately cleaned by dry cleaning techniques, they should be discarded. The media should not be wet cleaned and reused.

I **SINTERED DEARATION PROBE HANDLING AND STORAGE**

I1 Handling

I1.1 Probes should be removed prior to wet washing of equipment

I1.2 Hands should be washed, sanitized, and dried. Clean, disposable sanitary gloves should be worn when handling the probes.

I1.3 Probes that become contaminated through contact with unsanitary surfaces or become wetted should be discarded.

I2 Storage

I2.1 Probes should be stored in a gasketed, stainless steel cabinet, maintained clean and dry. The cabinet should be located in the area of use.

I2.2 The cabinet should have a rack or shelves and be large enough to store each probe in a sanitary manner.

I2.3 The probes should be stored inside a cleanable or single use, sealed, sanitary container.

I2.4 The probe storage cabinet should not be used for other purposes.

These standards are effective November 24, 2002.

The index and/or table of contents has been removed and photographed separately within this volume year.

For roll film users, this information for the current volume year is at the beginning of the microfilm. For a prior year volume, this information is at the end of the microfilm.

For microfiche users, the index and/or contents is contained on a separate fiche.

Coming Events

JANUARY

·**13-14, HACCP 1: Documentating Your HACCP Prerequisite Program,** Guelph, Ontario, Canada. For more information, contact Marlene Inglis at 519.821.1246, ext. 5028; E-mail: minglis@gftc.ca.

·**14-15, Third International 5 A Day Symposium,** International Congress Centre, Berlin, Germany. For more information, call ++49.30.254 80 677; E-mail 5aday@pconcept.com.

·**22-23, ServSafe® for the Food Industry and Food Service,** Guelph, Ontario, Canada. For more information, contact Marlene Inglis at 519.821.1246, ext. 5028; E-mail: minglis@gftc.ca.

·**23, Southern California Association for Food Protection Annual Meeting,** SureBeam Corporation Facility, Vernon, CA. For more information, contact Margaret Burton at 858.571.2441.

·**26-29, National Mastitis Council 42nd Annual Meeting,** Fort Worth, TX. For more information, call 608.224.0622.

·**27-28, United Fresh Fruit & Vegetable Assn. Produce Inspection Training Program, Introductory Course,** Fredericksburg, VA. For more information, contact United at 703.836.3410.

·**29-31, United Fresh Fruit & Vegetable Assn. Produce Inspection Training Program, Advanced Course,** Fredericksburg, VA. For more information, contact United at 703.836.3410.

FEBRUARY

·**17-19,29th Annual ABC Research Corporation Technical Seminar,** DoubleTree Hotel, Orlando, FL. For more information, contact Jim Rorie at 352.372.0436, ext. 337; E-mail: info@abcr.com.

·**18-20, California Association of Dairy and Milk Sanitarians Industry Conference,** Radisson Hotel, Stockton, CA. For more information, contact John Bruhn at 209.957.9090.

·**19, HACCP: A Management Summary,** Guelph Food Technology Centre, Guelph, Ontario, Canada. For more information, contact Marlene Inglis at 519.821.1246; E-mail: minglis@gftc.ca.

·**26, Processing Foods Safely,** Guelph Food Technology Centre, Guelph, Ontario, Canada. For more information, contact Marlene Inglis at 519.821.1246; E-mail: minglis@gftc.ca.

MARCH

·**12-14, Michigan Environmental Health Association 59th Educational Conference,** Valley Plaza Hotel, Midland, MI. For more information, contact Bruce DuHamel at 989.831.3637.

·**18-20, Idaho Environmental Health Association Annual Meeting,** Boise, Idaho. For more information, contact Frank Isenberg at 208.334.5947.

·**24-25, United Fresh Fruit & Vegetable Assn. Produce Inspection Training Program, Introductory Course,** Fredericksburg, VA. For more information, contact United at 703.836.3410.

·**26-28, United Fresh Fruit & Vegetable Assn. Produce Inspection Training Program, Advanced Course,** Fredericksburg, VA. For more information, contact United at 703.836.3410.

·**27, Ontario Food Protection Association Annual Spring Meeting,** Mississauga Convention Centre, Mississauga, Canada. For more information, contact Glenna Haller at 519.823.8015.

APRIL

·**2-4, Missouri Milk, Food and Environmental Health Association Annual Educational Conference,** Ramada Inn, Columbia, MO. For more information, contact Linda Haywood at 417.829.2788.

·**26-May 1, 29th National Conference on Interstate Milk Shipments,** Doubletree Hotel, Seattle, WA. For more information, contact Leon Townsend at 502.695.0253; E-mail: ltownsend@ncims.net.

MAY

·**6-8, PACex International,** Toronto International Centre, Toronto, Canada. For more information, contact Maria Tavares at 416.490.7860 ext. 219; E-mail: mtavares@pacexinternational.com.

·**8-11, 3rd International Exhibition and Conference for Food Technology,** International Trade Fairs Ground (Hall 2), Cairo, Egypt. For more information, contact Mahmoud Helmy at 202.30.50.898; E-mail: info@agd-exhibitions.net.

·**13-14, Pennsylvania Association of Milk, Food and Environmental Sanitarians Spring Meeting,** Nittany Lion College. For more information, contact Eugene Frey at 717.397.0719.

JUNE

·**13-20, International Workshop/Symposium on Rapid Methods and Automation in Microbiology XXIII,** Kansas State University, Manhattan, KS. For more information, contact Daniel Y. C. Fung at 785.532.5654; E-mail: dfung@oznet.ksu.edu.

·**14-18, Association of Food and Drug Officials,** Chicago, IL. For more information, call 717.757.2888.

·**25-27, South Dakota Environmental Health Association Annual Meeting,** Ramkota Convention Center, Pierre. For more information, contact Clark Hepper at 605.773.3364.

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Vol. 65 **December 2002** **No. 12**

* Asterisk indicates author for correspondence.

ADVERTISING INDEX

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General Fund Statement of Activity
For the Year Ended August 31, 2002

Revenue:	
Advertising	$ 121,784
Membership & Administration	396,357
Communication	662,367
Annual Meeting	515,499
Workshops	29,400
Total revenue	$ 1,725,407
Expense:	
Advertising	112,736
Membership & Administration	558,193
Communication	656,591
Annual Meeting	435,472
Workshops	24,876
Total expense	$1,787,868
Change in General Fund	**$ (62,461)**
Net Assets as of 8/31/02:	
General Fund	(64,007)
Foundation Fund	167,164
Restricted Fund	43,262
Total net assets	$ 146,419

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- ❒ D1040 Ether Extraction Method for Determination of Raw Milk
- ❒ D1060 Frozen Dairy Products
- ❒ D1070 The Gerber Butterfat Test
- ❒ D1080 High-Temperature, Short-Time Pasteurizer
- ❒ D1090 Managing Milking Quality
- ❒ D1100 Mastitis Prevention and Control
- ❒ D1110 Milk Plant Sanitation: Chemical Solution
- ❒ D1120 Milk Processing Plant Inspection Procedures
- ❒ D1130 Pasteurizer - Design and Regulation
- ❒ D1140 Pasteurizer - Operation
- ❒ D1150 Processing Fluid Milk (slides)

ENVIRONMENTAL

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- ❒ M4050 Personal Hygiene & Sanitation for Food Processing Employees
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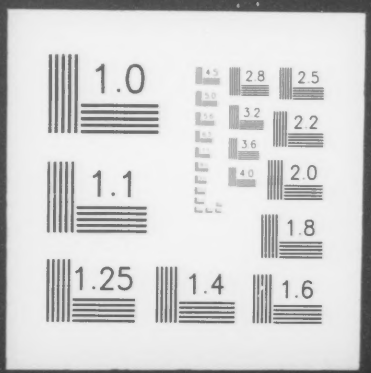
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