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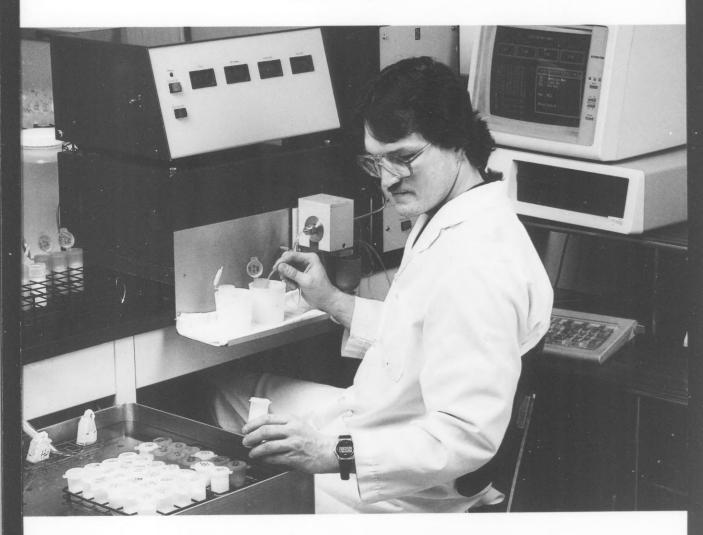
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DAIRY, FOOD AND ENVIRONMENTAL SANITATION/MARCH 1992 129

# On My Mind . . .



By Steven K. Halstead, CAE IAMFES Executive Manager

... is paying the dues

Last Saturday night was our annual Lion's Club Pancake and Sausage Supper in Bondurant. It was my turn to be the general chairman, so I attacked the job as any red blooded association manager would — with Organization!

On my own, and with virtually no more instructions than "we've always done it that way" I set out. I first identified the committees we would need and then named club members to the committees. Along the way, I developed job descriptions for each committee.

I handed out the committee assignments and job descriptions six weeks before the big event. Plenty of time, I thought. As it ends up, it was too soon — the club wasn't ready to think about the Pan-

cake Supper, yet. By the big event, most of the guys (no, we're not liberated yet) forgot their assignments and just showed up to help.

This should have been a hint of the problems to come.

It should have been clear that this group was "reactive" not "pro-active." Crisis management was their only way to handle any situation. As I said, I should have seen it. I didn't.

The first bit of trouble came when Donnie told me that he couldn't work with Ted. That he "always" cooked the sausage and that Marv, Roger, Larry and he "always" did it and that they didn't need any help.

Then Leon told me that he "always" lined up the entertainment and expected to do it again. (Leon was on the Beverage Committee). Then Vern — Chairman of the Entertainment Committee — told me he didn't line up any entertainment "cause it didn't go over very well last year."

The straw that broke the camel's back came when the Supplies Committee Chairman told me he wasn't going to be at the supper, but "that's okay because nobody has ordered any supplies for me to get."

Then I knew we had a crisis, but then as I pointed out, this group works best in a crisis.

I complained to my wife, who in her great wisdom, told me to go with the flow and not to worry about it. "They've never been organized before and they don't know how to handle it," she said. She was so right!

I took her advice and stopped worrying about chain of command, job descriptions, committee chairs, and who was doing what. Instead I worried about sanitation.

> I distributed copies of our "Sanitation for Temporary Food Service" sheets and insisted that the concepts it contained be followed. This energy consumed the frustration the "organization man" within

The Club had fun, made some

money . . . and nobody got sick!

me was generating and neutralized it.

End Result? The supper was a raging success (in spite of my efforts). Everybody did their thing as they "always" had except that this year we were careful about food safety.

The club had fun, made some money, greeted lots of friends, and . . . nobody got sick!

Did I learn anything? I hope so! Will I do it again? Probably. But this time, I kept track of who did what and with whom. Next time, I'll be prepared. I'll organize them into the committees and jobs they want to do anyway!

Did I pay the dues? Boy, did I. Wanna bet how it will go next year?

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# Consumer Perceptions: Safety Means More Than Microbiology

Christine M. Bruhn Consumer Food Marketing Specialist, Center for Consumer Research, University of California, Davis, CA 95616

This paper was presented as part of the Symposium "Perspectives on a Safe Muscle Foods Supply" at the Institute of Food Technologists Annual Meeting, June 2-5, 1991, Dallas, TX.

Consumer concerns about animal products center around personal health and safety and, to a lesser extent, ethical issues. The consumer's perception of health and safety includes microbiological and chemical safety, but also encompasses nutrition and the emerging concerns of hormonal and antibiotic residues.

Nutritional issues are significant to many consumers. A recent national poll conducted by Gallup (1990) for the American Dietetic Association found that almost 90% of women and about 75% of men say they are concerned that what they eat affects their future health. Similarly, others found 70% of women and 53% of men very concerned with the nutritional value of food (Center for Produce Quality, 1991). Dietary fat and cholesterol were concerns of the largest percentage of both men and women with 65% of women responding with "very concerned" for fat and 60% for cholesterol. Responses from men were at 43% and 44% respectively. As a result of this concern, people say they are cutting down on some foods, increasing their consumption of others. Forty-five percent of consumers said they were cutting down on red meat, and 28% said they had quit eating red meat all together (Gallup, 1990).

People may over estimate their behavior changes, but consumption patterns of meat, poultry, and fish reflect, in part, nutrition concerns. From 1976 to 1990, beef consumption has dropped from a high of 88.9 to 63.9 pounds per person. During that same period poultry has risen from 36.5 to 63.9 pounds per person (Putnam, 1990). Fish and seafood consumption for that period has risen from 12.9 to 15.7 pounds per person. The popularity of fish and poultry has increased even though prices for these products rose faster than for beef and pork.

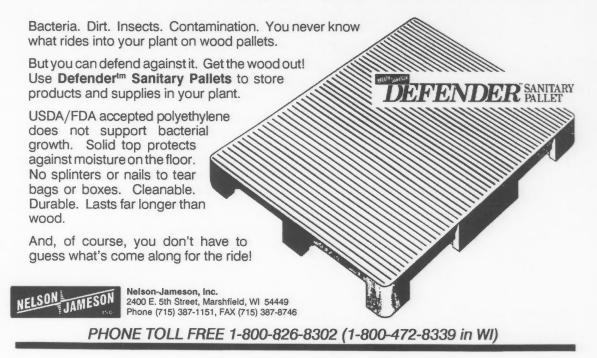
People's enjoyment of food has been lessened because of concerns about health issues, fat, and cholesterol (Gallup, 1990). Low fat diets have been stressed to such a degree that 65% of the sample believe that all foods should contain less than 30% calories from fat. One third of the people do not realize that fat is a vital nutrient, and 44% do not believe that a higher fat food can be part of a healthy diet if balanced with low fat choices. This concern opens the opportunities to technologies to enhance availability of lower fat options and supports the importance of appropriate labeling of "lite" or "reduced fat" products.

The second area of animal product concern is microbiological hazards. Although concern about pesticide residues has received extensive media coverage, unaided consumer response, such as the national survey done by Food Marketing Institute, found bacteria (germs) was the food safety hazard mentioned by the most consumers (Opinion Research, 1990). Among both men and women, concern about salmonella is almost as high as that for pesticides or cholesterol (Center for Produce Quality, 1991). Consumer sensitivity to microbial safety will continue to be high. Cases of food borne illness may well increase because of changing lifestyle which involves eating out more frequently and because of changing demographics. As older people live longer, and as medical advances prolong the life of people with chronic illness, the number in the population at risk for food borne illness increases. The efforts by USDA and others to provide consumers with information on safe food selection and handling will continue to provide visibility to this area. Increased implementation of HACCP and adoption of technologies to reduce microbial hazards should continue to be a high priority.

The presence of harmful levels of antibiotics and hormones is a high concern of few consumers. In the national Food Marketing Institute survey, it was volunteered as a hazard by only 2% of the sample. When specifically identified as a possible hazard, 56% of the sample considered it serious (Opinion Research, 1990). A survey that includes all issues, rates this concern less than that of microbial contamination, comparable or less than that of food additives (Center for Produce Quality, 1991). This suggests it is a latent concern among a broad segment of the population. The importance of this area would increase if there was widespread violations of current standards or if current safeguards were claimed to be inadequate. It would be appropriate to lay a foundation of information for consumers. Educational programs that identify usage, benefits, and measures to control risks should be conducted.

Some are marketing to antibiotic and hormone concern by offering organic beef and chicken in the supermarkets. I am concerned about a possible misconception that can develop from these marketing efforts. Definitions of organic currently vary from state to state, but in most areas, a sick animal, can be given antibiotics and still sold as organic when the legal withdrawal time is observed. Most consumers believe "organic" applied to fruits and vegetables, means no pesticide has been applied. I would expect that they believe that organic applied to animals means antibiotics have never been used. Organic producers believe the issue is the use of low levels of antibiotics throughout the animals life com-

### Guess what's riding on your wood pallets?



pared to use of therapeutic levels for a sick animals. Consumers, however, may feel deceived should they discover that organic cattle have received medication.

Several factors contributed to the "outrage" consumers felt when the Alar incident occurred. One factor was the apparent lack of government knowledge of producer practices. Estimates of use differed widely and laboratory analysis found the chemical in a large number of samples. Without strict industry-wide controls, the meat/poultry industry could find itself in a comparable situation of being less able to trace, isolate, and control a violation. The "Verified Production Control" sticker assures the product contains no harmful levels of antibiotics and hormones. This program gives the USDA direct entry into the animal facilities and also sets up specific standards that must be followed. These standards are not radically different from the existing program, but the program gives a complete paper trail should a problem occur. This type of program should be adopted industrywide. In this world of mass communication, one significant violation can taint an entire industry. Therefore it benefits an industry to aggressively address and enforce standards.

California has also adopted a model law to identify and halt any grower whose animals test for illegal residues. The California Department of Food and Agriculture can issue civil damages, like writing a ticket. Violators are subject to triple damages and fines. They also have an option to attend a residue school instead of paying fines. In this way the program is correctional rather than punitive.

Animal welfare is another area of concern to some consumers with the potential of generating increased sensitivity. The veal industry has been the brunt of complaints regarding small individualized pens in which animals can not turn or lay down at will. The Cattlemen's Association in California has adopted a code of ethics, worked out with animal welfare groups. They have pledged not to defend the conduct of persons violating the code.

Consumer concern about BST, the protein hormone which can increase milk production an average of 10% to 15%, is in part related to animal treatment. A study done in Virginia and New York found up to 40% of the sample believed it was inhumane to inject BST into cows; another 36% were uncertain (McGuirk and Kaiser, 1991).

To anticipate and respond to consumer issues, the industry should aggressively modify through application of technology and position meat as a healthful, low fat choice. USDA nutritional labeling, in the development stage, can inform consumers about "lite" and "lower fat" options. The industry should adopt model legislation and handling codes to boost regulatory control and encourage self-policing regarding chemical uses and humane animal treatment.

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# Impact of Seafood Inspection on the Muscle Foods Industry

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This paper was presented as part of the Symposium "Perspectives on a Safe Muscle Foods Supply" at the Institute of Food Technologists Annual Meeting, June 2-5, 1991, Dallas, TX.

No matter what you call it, or how you try to describe it, or how you disguise it, Hazard Analysis Critical Control Point type program inspection is the wave of the future.

What is important however, is the fact that a major muscle food commodity, namely seafood, is leading the way.

Historically, how do we find ourselves in this position?

Seafood consumption in the United States has grown 23 percent during the last decade to a record high in 1989 of 15.9 pounds per person. During this period, product variety expanded rapidly, as did fish imports, exports and aquaculture production. Imports account for 65 percent of the U.S. supply. Aquaculture operations produce about 10 to 15 percent of the total U.S. supply.

While the health benefits of eating fish have been well publicized in the U.S., media stories in the 1980's raised concerns about seafood contamination and the adequacy of Federal inspection programs. Both the growth of per capita consumption and the impact of nutrition signaled a greater degree of regulatory attention to seafoods.

During the 1960's and 70's several congressional attempts were made, calling for increased fish inspection, none of which either got out of committee or were able to pass both Houses of Congress.

Seafood inspection legislation again resurfaced in the early 1980's with the publication of reports by the congressional research service and public voice for food and health policy, a Washington, D.C. based consumer advocacy group, and the introduction of legislation in 1983 and again in 1987 by Congressman Byron Dorgan (D-ND).

In 1985, the National Fisheries Institute's Board of Directors, after a two-year investigation of the issue, voted to seek legislation establishing an inspection system based upon the Hazard Analysis Critical Control Point (HACCP) System recommended that year by the National Academy of Sciences. As a first step, the NFI sought funding for a twoyear study needed to design such a system for the seafood industry. Such funding was provided, thanks to the leadership of Senator Ted Stevens, in an appropriation measure (HR 5161) which provided:

For the express purpose of designing a program of certification and surveillance to improve the inspection of fish and seafood consistent with the Hazard Analysis Critical Control Point System. DOC/NOAA/NMFS shall complete the design of such a program in consultation with the Food and Drug Administration, the U.S. Department of Agriculture, Fish and Seafood Industry, and several states. The committee directs that on or before the expiration of the 24month period following the date of enactment of this Act, NOAA shall report to the Congress the results of the study, together with its comments and recommendations, and the comments and recommendations of the Food and Drug Administration, the U.S. Department of Agriculture and the states including the public and private cost of implementing such a program.

During this period, public voice issued a report on fish inspection calling for a mandatory program with these components:

- Certification of fishing vessels;
- Microbial and chemical residue standards;
- Recordkeeping to trace products;
- Uniform State requirements;
- Sanitary plant and transportation standards;
- · Better enforcement authority; and
- A public education program.

In response to this request from public voice, the NMFS decided in 1987, to divide the task of designing a HACCPbased system into two major components. The first was an examination of the potential health hazards to be studied by the National Academy of Sciences and the second was to design a HACCP system for specific seafood operations.

The National Fisheries Institute is cooperating with the National Marine Fisheries Service in a congressionally mandated study on mandatory seafood inspection. The purpose of this study is to design a mandatory seafood inspection program based on the HACCP concept. HACCP or the Hazard Analysis Critical Control Point Concept, separates the nice from the necessary by identifying those points in the processing of various products that are critical to product safety, wholesomeness and economic fraud. This process would place the major responsibility on industry to carry out the inspection program with government monitoring and enforcement.

The objectives of the HACCP study are to:

- Develop inspection programs for all segments of the seafood industry including processing plants, vessels, aquaculture, wholesale and distribution, retail and food service.
- 2. Develop strategies and recommendations for inspection of imports and for sampling seafood for inspection.

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- Determine the economic impact of a mandatory seafood inspection program on the seafood industry. The HACCP development process consists of:
- Industry workshops to develop inspection models for a particular commodity or industry sector
- Appointment of industry steering committees to monitor the HACCP process
- Tests of the HACCP workshop models in industry facilities
- Meetings of industry steering committees to review results of HACCP model tests
- Development of final HACCP inspection models and HACCP quality assurance manuals

#### Results

#### HACCP Workshops

Forty nine industry workshops have been held since this project began in the fall of 1987.

The workshops include the following:

 24-Processing Sector - which includes shrimp, rawfish, molluscan shellfish, blue crab, breaded and specialty products, smoked and cured fish, lobster, scallops, west coast crab, crawfish, imports, sampling and special product safety considerations

- 16 Fishing craft and vessels
- 3 Aquaculture
- 4 Wholesale/Distribution
- 2 Multipurpose

#### HACCP Model Tests

Tests of all HACCP models have been completed. Tests were carried out in 277 industry facilities nationwide. Following is a breakdown of the HACCP model tests:

179 Processing

- 70 Fishing craft and vessels
- 18 Aquaculture
- 10 Wholesale/Distribution

#### Industry Steering Committee Reviews

All steering committee reviews have been completed. A total of 19 industry steering committee meetings have been held to review results of HACCP model tests and to provide input in developing the final HACCP inspection models.

#### Reports

Reports for all of the workshops are completed. Final reports have been completed for all but the vessel sector.

- Economic studies are completed for breaded, cooked and raw shrimp and raw finfish.
- An interim report to Congress on the HACCP project has been completed by NMFS.

Additional work is ongoing to develop a HACCP training program for industry and develop inspection models for retail, food service and foreign country programs.

In August 1988, the general accounting office (GAO) published a report *Seafood Safety: Seriousness of Problem* and *Efforts to Protect Consumers* in which it concluded that "there does not appear to be a comprehensive mandatory Federal seafood inspection program similar to that for meat and poultry."

A preliminary report of this study, was issued in March, 1990. It recommends that a HACCP program be implemented over the next three years which would require plant registration and inspection, sampling and testing of products, equal treatment of domestic and imported products, public education and research. The report from the National Academy of Sciences was released last month.

In April, 1989, the NFI decided to no longer wait for completion of the HACCP study. Immediately following this decision, NFI asked White House officials for their views on this issue. This prompted a series of interagency meetings during which USDA, FDA and NOAA each argues that it should conduct the HACCP-based seafood program. FDA wanted more inspectors and a funding increase. USDA argued for a \$30-80 million program. OMB opposed any program unless it was paid for with user fees. The White House decided in May, 1989 to defer making a decision and the official position of the administration throughout 1989 was to oppose any legislation "at this time."

At the end of 1989, NFI organized a coalition of food trade associations in support of a bill. This coalition asked the White House for its views in December. There was no response. Instead, the President's budget for fiscal year 1991 proposed that FDA and NOAA use their existing authorities to institute a voluntary user-fee program. In addition, the administration's budget proposed a \$9 million increase for FDA's seafood activities, and the imposition of at least \$5 million in user fees to increase FDA's fish inspection activities.

On June 27, 1990 the FDA and NMFS published an advanced notice of proposed rulemaking announcing their intent to establish a voluntary program following HACCP principles (55 Fed. Reg. 26334). At the same time they solicited forms to participate in a two-month pilot study of the new program (55 Fed. Reg. 26339).

During the 101st Congress, consumer advocates and industry leaders contended that a more aggressive and comprehensive inspection program was needed. In response, two separate seafood inspection bills were reported by Senate committees. The Senate, on September 12, approved a seafood inspection bill (S. 2924) supported by the National Fisheries Institute, public voice and many other organizations. The measure, which was sponsored by Senate majority leader George Mitchell and others, would have given the Agriculture Department the primary responsibility for inspections. The FDA would continue to set tolerances for products and the National Marine Fisheries Services would oversee the Biology of Fisheries Management and Growing Waters.

Prior to approving S. 2924, the Senate rejected, by a vote of 59 to 39, a proposal of Senators Ernest Hollings, Edward Kennedy and Ted Stevens which would give inspection duties to both the FDA and NMFS. In floor debate, Senator Mitchell and others successfully argued that the lack of a lead agency would "muddle lines of authority and accountability." Organized labor groups and some consumer groups supported the Hollings proposal because it would have protected workers from reprisals if they walked

off the job or protested over alleged food safety violations. S. 2924 did not include these provisions.

In its official statement, the Office of Management and Budget advised Congress that "Senior Advisors" to the President would recommend a veto of any bill unless it was funded through user fees and gave "overall responsibility" to the FDA. Administration lobbyists worked hard to block senate passage of S. 2924. To no avail.

Three different bills saw floor action in the House, the first supported by Agriculture Committee Chairman Kika de la Garza (HR 3508), a second by Commerce Committee Chairman John Dingell (HR 3155) and the third by Fishery Subcommittee Chairman Gerry Studds (HR 2511). The administration also proposed a new regulatory program under existing FDA authorities.

On October 24, 1990, the House of Representatives voted on legislation similar to the Senate Bills by E. "Kika" de la Garza, Chairman of the House of Agriculture Committee, and a competing measure sought by Representative John D. Dingle, Chairman of the Energy and Commerce Committee. The Dingle substitute -- which would authorize an 18 month study of seafood inspection by the administration and leave inspection authority to FDA -- was approved by the House.

Prospects for enactment of mandatory seafood inspection legislation in 1990 ended when time did not permit the Congress to hold a conference committee to iron out differences between the House and Senate versions of the legislation before Congress adjourned.

We understand that several Congressional staff committee meetings have been held on this issue since the new Congress has convened, but to date no bills have been introduced.

Where do we presently stand?

Industry cooperation and involvement in the HACCP study has been very significant and important with more than 1,000 industry members attending workshops and or participating in tests of HACCP inspection models.

Results to date show that the HACCP concept offers a systematic approach for a mandatory seafood inspection program for all segments of the seafood industry. We can expect that HACCP will be the key ingredient of future seafood inspection activities in this and other countries.

#### 101st Congress Seafood Inspection Legislative Activity

#### Bills introduced:

- Mandatory Fish Inspection Act of 1989 (H.R. 1387), introduced March 14, 1989 by Rep. Byron Dorgan (D-MD).
- Consumer Seafood Safety Act of 1989 (H.R. 2511), introduced May 25, 1989 by Rep. Gerry Studds (D-MA).
- Federal Fish Inspection Act (S. 1245), introduced June 22, 1989 by Sen. George Mitchell (D-ME).
- 4. Fish and Fish Products Safety Act of 1989 (H.R. 3155), introduced August 4, 1989 by Rep. John Dingell (D-

MI).

- Consumer Seafood Safety Act of 1989 (H.R. 3369) introduced September 28, 1989 by Rep. Dan Glickman (D-KA).
- Consumer Seafood Safety Act of 1989 (H.R. 3481), introduced October 17, 1989 by Rep. Dan Glickman (D-KA)\*.
- Federal Inspection for Seafood Healthfulness Act of 1989 (H.R. 3508) introduced October 23, 1989 by Rep. de la Garza (D-TX).
- Consumer Seafood Safety Act of 1989 (S. 1983), introduced November 21, 1989 by Sen. Patrick Leahy (D-VT).
- Fish Safety Act of 1990 (S. 2924), introduced July 26, 1990 by Sen. George Mitchell (D-ME)\*\*.
- Consumer Seafood Safety and Quality Assurance Act (Amendment No. 2431), introduced July 27, 1990 by Sen. Fritz Hollings (D-SC)\*\*.
- \* Substitute bill correcting errors in H.R. 3369.
- \*\* Under an unanimous-consent agreement ordered on July 25, 1990 (136 Cong. Rec. S.10588), Senator Mitchell reintroduced an amended version of S. 1245 on July 26 as S. 2924 (136 Cong. Rec. S. 10780) and Senator Hollings refiled an amended version of S. 2228 on July 27 as Amendment No. 2431 (136 Cong. Rec. S.11017).

#### Hearings held:

- 1. House Energy and Commerce Committee on June 5, 1989 (Unpublished).
- House Subcommittee on Fisheries and Wildlife Conservation and the Environment on June 7, 1989 (Serial No. 101-23).
- 3. House Subcommittee on Health and Environmental on September 15, 1989 (Unpublished).
- 4. House Agriculture Committee on October 17, 1989 (Unpublished).
- Senate Committee on Agriculture, Nutrition and Forestry on October 24, 1989 (Unpublished).
- House Subcommittee on Fisheries and Wildlife Conservation and the Environment on November 9, 1989 (Serial No. 101-59).
- House Subcommittee on Fisheries and Wildlife Conservation and the Environment on April 25, 1990 (Serial No. 101-82).
- Senate Committee on Commerce, Science and Transportation on May 24, 1990 (Unpublished).

#### Reports filed:

- Senate Committee on Agriculture, Nutrition, and Forestry, Report on S. 1245 (S. Report 101-335).
- Senate Committee on Commerce, Science and Transportation, Report on S. 2228 (S. Report 101-369).

#### Floor debate:

- 1. July 25, 1990 (136 Con. Rec. S. 10577).
- 2. September 12, 1990 (136 Con. Rec. S. 12927).

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### Residue Concerns in Seafoods

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This paper was presented as part of the Symposium "Perspectives on a Safe Muscle Foods Supply" at the Institute of Food Technologists Annual Meeting, June 2-5, 1991, Dallas, TX.

#### ABSTRACT

Naturally occurring and man-made chemical contaminants enter the food chain of fish and shellfish through microscopic plants that absorb the chemicals. Mercury, selenium, dioxins, PCBs, kepone, chlordane, dieldrin, and DDT are primarily a concern with sport caught fish and shellfish, and are not considered a significant problem in commercially harvested seafood. Sources of chemical contaminants and measures taken to protect the public from unwanted residues in seafood vary. Some states warn sport recreational anglers that a public health hazard exists in eating fish and shellfish from certain locations, and others restrict fishing in waters where contaminated fish and shellfish may occur.

Contaminants in seafoods can include heavy metals, industrial contaminants, environmental contaminants, food additives, aquaculture feed additives, naturally occurring toxins, parasites, bacteria and viruses. This review focuses on metal, environmental contaminant, and chlorinated hydrocarbon pesticide residues in seafoods. The National Academy of Science recently published a comprehensive report on public health risks associated with seafood consumption, including microorganisms and parasites, natural toxins, and chemical residues (Ahmed, 1991).

Natural and man-made chemical contaminants enter the aquatic environment through industrial waste and water runoff. Microscopic aquatic plants absorb the chemicals, and small aquatic animals eat the contaminated plants. Fish and shellfish accumulate contaminants through their food chain. The extent of accumulation depends on geographic location, species, feeding patterns, solubility and lipophilicity of the chemicals, and their persistence in the environment. Because aquatic animals in human diets are generally predators of other animals, or predators of predators, contaminants may become more concentrated through bioaccumulation (Ahmed, 1991).

In ranking hazards associated with seafood, the National Academy of Science ranked chemically contaminated seafood fourth in order of importance after 1) bacteria and viruses in raw molluscan shellfish, 2) naturally toxic fish, and 3) naturally toxic shellfish. Potential risks from chemical contaminants are from freshwater species, and from specific marine areas and species. Potential risks are highest for subsistence and recreational anglers in certain areas, pregnant women, and children (Ahmed, 1991).

#### METAL RESIDUES

Metals in seafoods with major potential for toxicity in humans include arsenic, cadmium, lead, mercury, and selenium (Ahmed, 1991).

#### Arsenic

Arsenic occurs naturally in the environment, and is a byproduct of mining and smelting operations (Buck, 1978). Chemical companies use arsenic in the manufacture of pesticides and other agricultural products. Inorganic arsenic is toxic to humans and teratogenic in lower animals (Earl and Vish, 1978). The predominant form of arsenic in the edible portions of aquatic animals is the organic form, either arsenobetaine or arsenocholine. There are no reports of toxic effects from these organic arsenic compounds in animals or humans (Ahmed, 1991).

The National Oceanic and Atmospheric Administration (NOAA), National Status and Trends (NS&T) program monitors levels of toxicants annually in shellfish and fish (NOAA, 1989). NS&T sites with the highest arsenic levels in bivalve mollusks (2.9604-5.1312 ppm wet weight) were Cape Fear, NC; Cedar Key, Charlotte Harbor, and Rookery Bay, FL; Charleston Harbor, SC; and Sapelo Sound and Savannah River Estuary, GA. NS&T sites with the highest arsenic levels in fish (6.16-8.17 ppm wet weight) were Coos Bay, OR; Lutak Inlet and Nahbu Bay, AK; Dana Point, CA; and Narragansett Bay, RI. Freshwater sites with highest arsenic levels were in Lake Michigan at Saugatuck, MI and Sheboygan, WI (Ahmed, 1991).

The most recent NS&T data for bivalve mollusks indicate increases of arsenic levels in 6 and decreases in 8 of 177 sites studied. NS&T data for arsenic in freshwater fish indicated no increase in the 1978-81 sampling period (Ahmed, 1991).

The estimated seafood-related consumption of arsenic is 82µg/day, almost twice the mean daily intake in the U.S. Food and Drug Administration (FDA) total diet study (Gunderson, 1988) (Table 1). The FDA study did not include all seafood species, and arsenic from seafood included in the study (43.8µg/day) represented over 97% of overall dietary arsenic exposure. The estimated seafood-related consumption of arsenic is about 45% of the Food and Agriculture Organization of the United Nations/World Health Organization of the United Nations (FAO/WHO), Provisional Tolerance Daily Intake limit (PTDI) of 182µg/day of inorganic arsenic. Estimated arsenic in a 250-g seafood serving ranges from  $62.5\mu g$  for fish to  $5,157\mu g$  for squid (Ahmed, 1991). There are no reported cases of arsenic toxicity from seafood in the U.S., and no FDA Action Level for arsenic in seafood (FDA, 1987).

#### Cadmium

Aquatic cadmium sources include solid waste dumping (paint pigments), cadmium-containing sewage sludge, the use of phosphatic fertilizers, electroplating and galvanizing manufacture, and zinc and lead mining waste water (Sherlock, 1986; Sloan and Karcher, 1985). Cadmium can alter cell permeability, and chronic occupational exposure can cause kidney damage (Viarengo, 1985; Ahmed, 1991).

NS&T sites with the highest cadmium levels in bivalve mollusks (0.9324-1.56 ppm wet weight) were Copano Bay and Corpus Christie, TX; Delaware Bay, DE; Chesapeake Bay, MD; Hudson/Raritan Estuary, NY; and Mississippi Sound. NS&T sites with the highest cadmium levels in fish (1.31-4.89 ppm wet weight) were Southhampton Shoal and Dana Point, CA; Nisqually Reach, WA; and Columbia River, OR. Freshwater sites with the highest cadmium levels were Columbia River at Grand Coulee, WA; Colorado River at Lake Powell, AZ; Verdigris River at Oologah, OK; and Kansas River at Bonner Springs, KS (Ahmed, 1991).

The most recent NS&T data for cadmium in bivalve mollusks indicate increases in 4 and decreases in 17 of 177 sites studied. Cadmium concentrations for freshwater fish declined significantly from 1972 to 1979, but no decline occurred between 1978 and 1981 (Ahmed, 1991).

The estimated seafood-related consumption of cadmium is  $2\mu g/day$ , about 13% of overall dietary exposure, and about 3-4% of the FAO/WHO acceptable daily intake limit (Table 1). Estimated cadmium in a 250-g seafood serving ranges from 0.15µg for fish to 157.5µg for squid (Ahmed, 1991). There are no reported cases of cadmium toxicity from seafood in the U.S., and no FDA Action Level for cadmium in seafood (FDA, 1987).

#### Lead

Lead is in food, water, and air, and environmental levels have increased over the last 200 years. Environmental lead is a product of storage battery, ammunition, solder, pigment, pipe, brass, and red lead manufacture. Tetraethyl lead is a component of gasoline antiknock additives. Occurrences of lead toxicity are usually acute and due to the ingestion of inorganic lead (Ahmed, 1991).

NS&T sites with the highest lead levels in bivalve mollusks (0.7356-2.7996 ppm wet weight) were Marina Del Rey and Anaheim Bay, CA; Hudson/Raritan Estuary and Long Island Sound, NY; Boston Harbor, MA; and Narragansett Bay, RI. NS&T sites with the highest lead levels in fish (0.288-1.85 ppm wet weight) were Casco Bay, ME; Elliott Bay and Commencement Bay, WA; West Long Island Sound, NY; Buzzards Bay, MA; and Narragansett Bay, RI. Freshwater sites with the highest lead levels were Manoa Stream, Honolulu, HI; Connecticut River at Windsor Locks, CT; and Hudson River at Poughkeepsie, NY (Ahmed, 1991). Table 1. Acceptable daily intake limits of trace metals in  $\mu\text{g}/\text{day}$  (Ahmed, 1991).

Metal	FAO/WHO PTDIª	NRC-NAS ESADDI⁰	FDA Mean Daily Intake <sup>c</sup>	Mean Daily Intake from Seafood <sup>d</sup>
Arsenic	182		45	82
Cadmium	57-72		15	2
Lead	429		41	10
Mercury	33-43°		3.9	2.1
Selenium		50-200	152	14

<sup>a</sup>Food and Agriculture Organization of the United Nations/World Health Organization of the United Nations (FAO/WHO), Provisional tolerance daily intake limits (PTDI); calculated from the provisional tolerance weekly intake limits for a 70 kg human.

<sup>b</sup> National Research Council of the National Academy of Sciences (NRC-NAS) estimated safe and adequate daily dietary intake (ESADDI).

<sup>c</sup> Total Diet Studies for 25-30 year old males (FDA market basket program).

<sup>d</sup> Calculated average daily intake of each element if a consumer were to eat 15 pounds of seafood per year at the weighted average concentration observed in a massive (more than 20,000 measurements) stratified survey of the U.S. marine fishery; freshwater and imported seafood are not included.

<sup>e</sup> Lowest value is methylmercury, highest total mercury.

The most recent NS&T data for lead in bivalve mollusks indicate increases in 5 and decreases in 1 of 177 sites studied. Lead concentrations for freshwater fish declined significantly from 1972 to 1979, but no decline occurred between 1978 and 1981 (Ahmed, 1991).

The estimated seafood-related consumption of lead is 10µg/day, about 24% of overall dietary exposure, and about 2% of the FAO/WHO acceptable daily intake limit (Table 1). Estimated lead in a 250-g seafood serving ranges from 2.0µg to 575µg (Ahmed, 1991). There are no reported cases of lead toxicity from seafood in the U.S., and no FDA Action Level for lead in seafood (FDA, 1987).

#### Mercury

There are natural and industrial sources of mercury that enter aquatic environments. Mercury exists as both inorganic and organic forms, and the organic methylated form is the most toxic to humans. Anaerobic bacteria form methylmercury from inorganic mercury in the aquatic environment.

In the 1950's and 1960's, residents of Minamata, Japan, suffered from mercury poisoning caused by eating fish contaminated with methylmercury from local industrial wastes. The poisoning caused severe birth defects including mental retardation (Harada, 1978). In the U.S. in the late 1960's, a woman developed mild mercury poisoning symptoms after consuming 12 1/2 oz. of swordfish daily for about 10 months (Korns, 1972).

NS&T sites with the highest mercury levels in bivalve mollusks (0.0372-0.0576 ppm wet weight) were Tampa Bay and Charlotte Harbor, FL; Hudson/Raritan Estuary and Moriches Bay, NY; Barber's Point, HI; Matagorda Bay, TX; and Boston Harbor, MA. NS&T sites with the highest mercury levels in fish (0.238-1.55 ppm wet weight) were Dana Point, Southhampton Shoal, San Diego Harbor, and Oakland, CA. Freshwater sites with the highest mercury levels were Columbia River at Cascade Locks, WA; Red River of the North at Noyes, MN; Colorado River at Imperial Reservoir, CA; Truckee River at Fernley, NV; and Merimack River at Lowell, MA (Ahmed, 1991).

Commercial species affected include older and larger swordfish. Some of the sport species affected are black crappie, brown bullhead, channel catfish, flathead catfish, hitch, largemouth bass, musky, northern pike, rainbow trout, rock bass, Sacramento blackfish, smallmouth bass, striped bass, sturgeon, walleye, white catfish, and yellow perch (NYSDH, 1990; WDH, 1990; NFI, 1991; Price, 1991).

The most recent NS&T data on mercury in bivalve mollusks indicate increases in 11 and decreases in 4 of 177 sites studied. Mercury concentrations in freshwater fish declined significantly from 1972 to 1977, but no decline occurred between 1978 and 1981 (Ahmed, 1991).

The estimated seafood-related consumption of mercury is  $2.1\mu$ g/day, about 54% of overall dietary exposure, and about 5-6% of the FAO/WHO acceptable daily intake limit (Table 1) (Ahmed, 1991). The FDA Action Level for mercury in fish, shellfish, crustaceans, and other aquatics is 1.0 ppm and the Canadian action level is 0.5 ppm (FDA, 1987; Ahmed, 1991).

#### Selenium

Selenium is a natural element in soils, but also enters aquatic environments through fossil fuel combustion and from paint, alloy, photoelectric battery, and rectifier manufacture (Fishbein, 1983; Sorenson et al., 1984). Selenium toxicity in humans is relatively rare and most often due to occupational exposure or chronic exposure to contaminated water or food (Ahmed, 1991).

NS&T sites with the highest selenium levels in bivalve mollusks (0.5364-0.9804 ppm wet weight) were Honolulu Harbor and Barber's Point, HI; Arkansas Bay, Espiritu Santo, and Copano Bay, TX; Marina Del Rey and Point Conception, CA; and Unakwit Inlet, AK (Ahmed, 1991).

The most recent NS&T data for selenium in bivalve mollusks indicate increases in 12 and decreases in 2 of 177 sites studied. Selenium concentrations in freshwater fish declined significantly from 1972 to 1979, but no decline occurred between 1980 and 1981 (Ahmed, 1991).

The seafood-related consumption of selenium is about 14µg/day, about 9% of overall dietary exposure, and 7-28% of the National Research Council of the National Academy of Sciences (NRC-NAS) estimated safe and adequate daily dietary intake (ESADDI) of 50-200µg (Ahmed, 1991). There are no reported cases of selenium toxicity from seafood in the U.S., and no FDA Action Level for selenium in seafood (FDA, 1987).

Selenium is a regional, freshwater problem, e.g., the Kesterson National Wildlife Refuge that receives extensive irrigation tile drainage in California. Some of the sport species affected in California are corvina, croaker, orangemouth, sargo, and tilapia (Price, 1991). Calculated values of intake from site-specific studies are 125-3,225µg/250-g serving. These values prompted health alerts in parts of California for recreational anglers (Ahmed, 1991).

#### ENVIRONMENTAL CONTAMINANTS

#### Polychlorinated Biphenyls (PCBs)

PCBs include more than 200 different compounds that were used in various formulations as liquid insulators in electrical equipment, as encapsulating agents, in carbonless carbon paper, and in hydraulic fluids. PCBs are suspected human carcinogens based on animal studies and suggestive epidemiological studies (Ahmed, 1991).

NS&T sites with the highest PCB residues in bivalve mollusks (>0.2 ppm wet weight) were Hudson/Raritan Estuary, NY; New York Bight, NJ; San Diego Bay, CA; Galveston Bay, TX; and Boston Harbor and Buzzards Bay, MA. NS&T geographic sites with the highest PCB residues in fish (1.99-4.93 ppm wet weight) were Elliott Bay, WA; Boston Harbor, MA; and Seal Beach and San Diego Harbor, CA. The most recent NS&T data for bivalve mollusks indicate no increases in PCBs and decreases in 13 of 177 sites studied (Ahmed, 1991).

Commercial species affected include striped bass, lobster, flounder and grey trout. Some of the sport species affected are bluefish, bullhead, carp, catfish, eels, lake brown trout, lake chinook salmon, lake coho salmon, lake trout, northern pike, smallmouth bass, walleye, white croaker, white sucker, and yellow perch (NYSDH, 1990; UWSGI, 1990; NFI, 1991; Price, 1991). The FDA Action Level for PCBs in fish and shellfish is 2.0 ppm (Ahmed, 1991).

#### Dioxin

2,3,7,8-Tetrachlorodibenzo-*p*-dioxin (TCDD) is a contaminant of products made from trichlorophenol, including some chlorophenoxy herbicides. TCDD is also a byproduct of pulp and paper mills using chlorine or chlorine compounds as part of a bleaching process. In humans, TCDD has been linked to severe dermatitis; fetal toxicity and numerous other effects have been observed in experimental animals (rodents) at very low doses. In standard animal test systems, TCDD is one of the most potent carcinogens known (Ahmed, 1991).

Environmental Protection Agency (EPA) survey data indicate TCDD contamination at approximately 85 sites throughout the country including the Great Lakes, major river systems such as the Ohio and Mississippi Rivers, and waterways with significant industrial activity (EPA, 1988a; EPA, 1988b). Other areas with dioxin contamination include Lake Ontario; Lower Niagara River, NY; Samoa Peninsula, CA; Sacramento River, CA; Passaic River, NJ; and Saginaw Bay, MI (NYSDH, 1990; NFI, 1991; Price, 1991).

Some of the sport species affected are carp, catfish, lake trout, squawfish, sucker, trout, white sucker (NYSDH, 1990; NFI, 1991; Price, 1991). The FDA Action Level for dioxin in fish and shellfish is 10 parts per trillion (NFI, 1991).

#### Polycyclic Aromatic Hydrocarbons (PAHs)

PAHs are common environmental contaminants found in petroleum, soot, or tar from incomplete combustion, lubricants, and domestic sewage. Many are well-established carcinogens and are highly toxic (Ahmed, 1991).

NS&T sites with the highest PAH residues in bivalve mollusks (0.6360-2.7600 ppm wet weight) were Elliott Bay,

WA; Hudson/Raritan Estuary and Long Island Sound, NY; St. Andrew Bay, FL; Barber's Point, HI; and Boston Harbor, MA. The most recent NS&T data for PAHs in bivalve mollusks indicate increases in 8 and decreases in 10 of 177 sites studied (Ahmed, 1991). There is no FDA Action Level for PAHs in seafood (FDA, 1987).

#### CHLORINATED HYDROCARBON PESTICIDES

The broad group of relatively lipid soluble chlorinated hydrocarbon pesticides came into widespread use immediately after World War II. These compounds were largely phased out of production in the U.S. during the 1970's because of concerns for carcinogenicity and ecological effects (Ahmed, 1991).

#### Dichlorodiphenyltrichloroethane (DDT) and Metabolites

The use of DDT was banned in the U.S. in 1972. DDT and its metabolites are persistent substances of uncertain health significance in humans. They bioaccumulate at higher levels of the food chain resulting in toxicity to birds and aquatic organisms. Subacute effects at high doses include central nervous system signs in humans, and liver toxicity and estrogenic effects in rodents. Dichlorodiphenyldichloroethane (DDE), a metabolite of DDT causes liver tumors in rodents (Ahmed, 1991).

DDT residues in seafood have declined as much as 100fold nationally in the last 15 years (NOAA, 1988). NS&T sites with the highest DDT residues in bivalve mollusks (0.0322-0.1330 ppm wet eight) were Hudson/Raritan Estuary, NY; San Pedro Harbor, Palos Verdes, Anaheim Bay, and San Francisco Bay, CA; Choctawahatchee Bay, FL; New York Bight, NJ; and Buzzards Bay, MA. The highest residues reported in the 1986 NS&T fish liver study (0.967-4.66 ppm wet weight) were San Pedro Beach, Seal Beach, Santa Monica Beach, and San Diego Harbor, CA (Ahmed, 1991). The most recent NS&T data for DDT in bivalve mollusks indicate increases in 4 and decreases in 6 of 177 sites studied (Ahmed, 1991).

Some of the sport species affected are carp and white croaker (NFI, 1991; Price, 1991). The FDA Action Level for DDT, DDE and diphenylethanedichlorophenylethane (TDE) in fish is 5.0 ppm (FDA, 1987).

#### Dieldrin

Dieldrin, like DDT, affects the central nervous system, but is more toxic and has caused acute human fatalities. It causes increased liver tumors when fed at relatively low levels to rodents.

Although virtually all dieldrin uses were banned more than 15 years ago, it is a common contaminant of inland and estuarine fish. Dieldrin residues in inland fish are higher than for open water marine fish and even estuarine fish. Definite declines in residues are occurring at inland and marine sites. There was a slight decline in the mean concentration of dieldrin nationally in whole freshwater fish from 0.05 ppm in 1976-77 to 0.04 ppm in 1980-81 (Ahmed, 1991). Some of the sport species affected are bass, carp, catfish, and crappie (NFI, 1991). The FDA Action Level for dieldrin in fish and shellfish is 0.3 ppm (FDA, 1987).

#### Chlordane Compounds

Chlordane is a probable human carcinogen, and is less toxic than dieldrin. Chlordane compounds are common contaminants of coastal fish of Hawaii and freshwater fish throughout the U.S. mainland. Through 1986, there was widespread use of chlordane as a termite killer. Chlordane residues in U.S. freshwater fish are neither decreasing nor increasing (Ahmed, 1991).

Some of the sport species affected are bass, carp, catfish, eels, lake trout, and lake salmon (NFI, 1991). The FDA Action Level for chlordane in fish is 0.3 ppm (FDA, 1987).

#### Heptachlor

Heptachlor and heptachlor epoxide compounds are chlorinated pesticides with toxicity similar to dieldrin. Thirtynine percent of freshwater fish samples contained total heptachlor residues above 0.01 ppm wet weight in the 1980-81 National Pesticides Monitoring Program (NPMP) surveys, but heptachlor does not appear to be a prominent contaminant of marine fish and shellfish (NOAA, 1988; Ahmed, 1991). The FDA Action Level for heptachlor and heptachlor epoxide in fish and shellfish is 0.3 ppm (FDA, 1987).

#### **Other Pesticides**

Kepone contamination is limited to the Virginia James River ecosystem where residues in fish and crabs were 0.2-0.8 ppm wet weight in the mid 1980's (NOAA, 1988; Ahmed, 1991). The FDA Action Level for kepone in fish and shellfish is 0.3 ppm. (FDA, 1987).

Toxaphene may be an important regional contaminant in Georgia, California and Texas. Nearly 88% of freshwater fish contained toxaphene above the detection limit of 0.01 ppm in one survey (Ahmed, 1991). The FDA Action Level for toxaphene in fish is 5.0 ppm (FDA, 1987).

Endosulfan residues (0.021-1.4 ppm wet weight) occurred in California fish and shellfish at sites near heavy agriculture regions, and may be a problem for recreational anglers. Chlorophenol residues (0.003-0.008 ppm wet weight) occurred in Galveston Bay oysters and Puget Sound clams. Pentachlor-anisole and hexachlorobenzene (>0.01 ppm wet weight) were detected in 24% of whole fresh water fish in 1980-81 NPMP surveys (Ahmed, 1991). 1,2,4trichlorobenzene was detected in fish near a sewage outlet in southern California. Mirex was detected in 18% of freshwater fish in the 1980-81 NPMP surveys, mainly in the Great Lakes and Southeast (NOAA, 1988). Data from recent surveys indicates no significant nationwide lindane contamination in fish and shellfish (Ahmed, 1991).

#### FEDERAL AND STATE ACTIVITIES

The FDA, NOAA, EPA, the U.S. Fish and Wildlife Service, state agencies, and university researchers take part in identifying and/or monitoring contaminant residues in seafood (Ahmed, 1991). States also publish health advisories on contaminant residues for recreational anglers, and, in some cases, close contaminated areas to fishing. Some states and universities publish cleaning, trimming, and cooking information for recreational anglers to reduce contaminant levels in fish (UWSGI, 1990; WDH, 1990).

#### CONCLUSIONS

A small percentage of fish and shellfish is contaminated with potentially hazardous chemical contaminants from environmental and man-made sources. There is huge variation in the extent of contamination with geographic location and species. Generally, open water marine fish contain lower contaminant residues than coastal and estuarine species; coastal and estuarine species contain lower residues than freshwater fish and shellfish.

Risks from chemical contaminants are highest for consumers of recreational and subsistence fish and shellfish products. Risks from chemical contaminants in commercially harvested fish and shellfish are low, providing consumers consume a variety of species.

Most chemical contaminant residues in fish and shellfish are low and are declining. Continued reduction of residues will require increased federal and state surveillance, and significant changes in our waste and waste water disposal methods.

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# Residue Concerns for Land-Based Animal Derived Food

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Residues of foreign chemicals are present in the food we eat. They arise from a number of different sources: food additives and preservatives, naturally occurring toxins, industrial and environmental contaminants, as well as drugs and feed additives administered to animals for health and production purposes. The regulatory process for establishing tolerances and compliance with the approved uses ensure the safety of our food supply with respect to animal drugs and feed additives. Included in the regulatory procedure is the role of residue analysis. The methods for residue analysis and the developing use of rapid screening methods in particular will play a major role in food protection in the coming decade.

#### Introduction

Everyone is aware that the food we eat can contain residues from many sources. The primary sources of food contamination that readily come to mind are the environment, including exposure to natural toxins such as aflatoxin, as well as to pesticides, food additives, animal drugs and feed additives given to animals. Most of these sources are regulated by government agencies and a safety data base has been developed for many of the compounds of interest.

The objective is to outline the procedure by which animal drugs and feed additives are approved by the FDA. Hopefully, you will come to the conclusion that the animalderived food is safe and that residues present therein do not pose a health hazard. This assurance is limited to the context of approved animal drugs. The procedure by which residues in meat are regulated has an extensive scientific basis and the risk of harm from residues of this type is insignificant provided that the producer follows the approved conditions of use.

To begin, the **definition of a residue** has been around for a long time. Although it may not be the first, one of the definitions of a residue that exists today comes from the 1958 food additive amendments (see Federal Food, Drug, and Cosmetic Act, As Amended) Sec. 409, which addresses residues from the standpoint of methods as well as safety:

(b)(2)(D) a description of practicable methods for determining the quantity of such additive in or on food and any substance formed in or on food, because of its use;

(c)(5)(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

The definition of a residue has not changed significantly over time. For example, a recent definition that was given in an FDA 1985 proposed regulation ( see reference SOM proposal) is:

"Residue" means any compound present in edible tissues of the target animal that results from the use of the sponsored compound, including the sponsored compound, its metabolites, and any other substances formed in or on food because of the sponsored compound's use.

We use the phrase drug residues synonymously with residue and the same concepts apply whether the residue comes from feed additives or animal drugs. The following outlines our current definition of residues.

#### **Drug Residues**

- 1. Parent compound
- 2. Metabolites- addition, cleavage, oxidation, reduction of functional groups
- Conjugates- small molecules (glucuronides, etc.) macromolecules (bound residues)

Another important part of the 1958 amendments was the inclusion of the anticancer proviso or the so called Delaney Amendment which stated: Sec. 409 (c)(3)(A)...That no additive shall be deemed safe if it is found to induce cancer when ingested by man or animal or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, . .

Four years later in 1962 section 409 was again amended, same section quote, (c)(3)(A), to exempt feed additives through the so called DES PROVISO by stating after the above wording...that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the proposed conditions of use ...such additive will not adversely affect the animals... and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary ...) in any edible portion of such animal after slaughter or in any food yielded or derived from the living animal; When the FD&C Act was amended in 1968 to include a new section (Section 512) on New Animal Drugs, the wording of the DES Proviso was included in that section, Sec. 512 (d)( 1 )(H).

The part of the DES Proviso that employs the terminology -"no residue by a method prescribed or approved by the

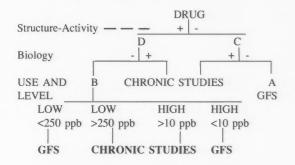
Secretary"- has become the foundation by which we regulate not only carcinogenic but also non-carcinogenic animal drugs. Through a series of Federal Register documents beginning in 1973, the FDA attempted over a period of 14 years to finalize a regulation to implement the concept by which carcinogenic animal drugs can be approved. The final regulation was published on December 31, 1987 (see reference SOM final rule). Although its title is "Sponsored Compounds in Food-Producing Animals; Criteria and Procedures for Evaluating the Safety of Carcinogenic Residues; Final Rule", it has become known as the Sensitivity of the Method (SOM) document because it is based on the concept that the Secretary prescribes or approves the methods for carcinogens as permitted by the DES Proviso mentioned above, and through this process determines the level (or sensitivity) required to be considered no residue. It is well understood scientifically that once a drug is given to an animal, residues will not deplete to absolute zero. Therefore, the focal point of the document became the procedure by which no residue was determined.

The approach discussed in the regulation is in fact a simple one. It basically involves extrapolating cancer data from laboratory animal models (usually mice or rats or sometimes other animals) from the observed natural or background incidence to a predicted increased incidence of I tumor in I million test animals. These calculations involve the number of animals with tumors, the total number of animals exposed at a dose in their diet over a lifetime. The regulation discusses various mathematical models to calculate the 1 in 1 million dose and which of the models that the agency prefers. The 1 in 1 million dose becomes the permitted concentration that is used to calculate the no residue level required for the method of analysis for residues in food for human consumption. While this value is involved in the calculation, an additional calculation is needed to take into consideration total residues in the food animal before it can become a specific value by which the drug residue is regulated. The procedure by which this is done will be outlined in the following paragraphs.

#### Carcinogenic Residues and General Food Safety-A Unified Concept

During the period prior to its final publication, the SOM concept had become fully integrated into a general food safety concept that the FDA had been developing throughout most of the period using a similar design for determining the tolerance for residues for any compound including "no residue" for a carcinogen. The unified concept encompassed both carcinogens and noncarcinogens because before the carcinogenicity of a compound could be evaluated, all compounds had to be treated similarly to assess their carcinogenic potential. The SOM document outlined an initial decision tree approach that all compounds must undergo. That process is known as the Threshold Assessment. The decision process initially involves a structureactivity assessment to determine whether the sponsored compound is a suspect carcinogen. In addition, the compound must be tested in a battery of mutagenicity tests and must undergo subchronic 90 day studies -usually rat and dog. These biological tests help to determine the carcinogenic potential of the compound. If any of the tests signal a potential for carcinogenicity, then chronic lifetime studies are required. When negative results are obtained, the level of residue in edible tissues further determines whether a sponsored compound has to undergo chronic studies. The threshold assessment is now outlined to help understand the interaction of the various elements.

#### **Threshold Assessment Decision Tree**



A critical part of the threshold assessment is the battery of genetic toxicity and mutagenesis assays. The agency relies heavily on these tests to determine the carcinogenic potential of sponsored compounds. The tests currently used are as follows:

#### **Mutagenicity Test Battery**

- 1. Bacterial point mutation assay such as the Ames assay with and without S9 activation
- Mammalian point mutation assay using mouse lymphoma, chinese hamster ovary or hamster V-79 cells or Chrosomal aberations (CAbs), in vitro or in vivo
- Unscheduled DNA repair in mammalian cells in culture If the threshold assessment is a decision that chronic

bioassays are required to resolve questions involving the carcinogenic potential of the sponsored compound, then the following procedures are employed.

#### **Carcinogenicity Studies**

•Carcinogenicity studies are conducted in the event that toxicology studies along with structure analysis, mutagenicity testing, and allowable residue levels suggest that the compound is a potential carcinogen or must be tested because of residue levels in combination with the other factors.

• Chronic carcinogenicity bioassay (feeding) studies generally employ two rodent species (rats and mice). Both sexes and at least 50 animals/ dose/ sex are typically used in a three dose plus control experiment.

• Dosing is conducted until one group of a given sex reaches 20% survival, but not to exceed 30 months duration.

Other toxicology requirements not previously mentioned but still needed because of special toxicological concerns are a teratology study, a multi-generation reproduction study and a 90 day feeding study in a non-rodent species such as the dog. If the compound is *not* a carcinogen, a no-observedeffect-level or **NOEL** will be determined from non-carcinogenic toxicity end points. The NOEL used in calculating permitted levels for residues is a level of sponsored compound in the diet of the toxicity test species for the most sensitive end point (lowest level) where there was no observed effect. This level is then used in a calculation of the safe concentration (S.C.) for the compound that uses safety and food factors as well as a scale up factor for the body weight of man (60 kg):

NOEL(mg/kg in lab species) X 60 kg

S.C. = -

#### SAFETY FACTOR X 0.5 kg (meat in diet)

The safety factor may be 100 or 1000 depending on the length of the study and the total diet is assumed to be 1.5kg. The food factor expressed here as 0.5 kg represents 1/3 of the diet as muscle meat. The permitted amounts of residue are then considered on the basis on a conservative portion of the diet that the food may be consumed. At present the Center for Veterinary Medicine at FDA uses the following consumption factors as multipliers of the safe concentration calculated above which is for muscle meat: milk =1/3; eggs = 1; liver = 2-5 depending on the species; kidney = 3-5 depending on the species.

When a compound is determined to be a carcinogen, the linear extrapolation procedure of Farmer Et al, 1982 is used to determine the level of insignificant risk which is considered to be 1 in 1 million. The mathematically derived value is called the  $S_o$  and it too is multiplied by consumption factors for the various tissues as described above.

The  $S_0$  calculation or the S.C. that have been discussed give a permitted concentration for **total residues** of a particular compound in edible tissues of food-producing animals. They have been calculated from a NOEL or from an extrapolated 1 in 1 million risk in the diet of animals which exhibited a carcinogenic response in lifetime feeding studies. The concept of total residues was discussed earlier and derives from the definition of a residue. Therefore, all residues that arise from administering a feed additive or an animal drug to a food animal are considered as potentially toxic as the parent compound that was fed to laboratory animals unless additional studies are done to exonerate them from concern.

#### **Chemistry Studies**

A detailed outline of how the chemistry portion of animal drugs and feed additives are regulated will now be addressed. The approach includes several factors: (1) the total residue concept, (2) the need to determine that the laboratory test animal has been exposed to all residues of toxicological concern; (3) the determination of an appropriate tolerance for residues in meat, milk or eggs as determined by an acceptable method of analysis and (4) setting a withdrawal time after administration of the drug or feed additive when the animal or milk may not be marketed for human food. Eggs are not permitted to have a withdrawal time since a withdrawal time for eggs is not considered compatible with husbandry practice.

tions. The usual way to determine total residues is to use a radiolabeled drug with <sup>14</sup>C the label of choice. While tritium (<sup>3</sup>H) labeling is sometimes used, the sponsor must confirm that the label is in a stable location in the molecule since it uses is well known that tritium can easily exchange with the protons in water from some locations in most molecules. At the same time, FDA must also agree that even a <sup>14</sup>C labeled molecule is suitably labeled, since some carbons can be metabolized and cleaved from the parent molecule, e.g., carboxyl and methyl carbons. The radiolabeled studies are the cornerstone of the chemistry requirements because they fulfill two critical

chemistry requirements because they fulfill two critical functions. Through these studies the metabolites of the drug are determined as well as the kinetic behavior of the residue as it depletes following cessation of the drug treatment. These aspects of the guidelines have been previously outlined in some detail (Weber, 1983) and will be sketched again here for completeness.

The first chemistry consideration is to determine the

total residue derived from the feed additive or animal drug

when administered to the animal according to label direc-

A typical total residue study will involve a dozen or more animals which are dosed with the radiolabeled drug according to label directions and are subsequently slaughtered at several time points. The radioassay of tissue samples from those animals will determine the residue depletion kinetics for total residues in all four principal edible tissues (muscle, liver, kidney and fat-milk and eggs when appropriate). After applying the consumption factors mentioned previously, and plotting the results on a semi-log graph, the last tissue to deplete to its consumption factor adjusted safe concentration is usually selected as the target tissue. The target tissue is that tissue in which residues having depleted to their safe level will assure the regulatory official that all of the tissues in the animal are below their permitted safe concentrations. A graphical presentation of the selection of the target tissue is presented in figure 1.

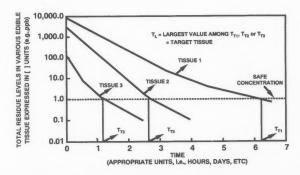


Figure 1. Total residue depietion curves used to select the target tissue, e.g., muscle, liver, kidney and fat.

#### Metabolism Studies

After the sponsor determines the likely choice of target tissue, the four principal edible tissues are examined for their metabolic profiles over time to select a *marker residue* that may serve to monitor the total residue during residue depletion in the target tissue. Metabolic profiles should be examined in tissues other than the target tissue to determine that no additional metabolites are present. One of the residues (metabolite or parent compound) in the target tissue is selected to be the marker residue and its proportion to the total residue is obtained at the point on the total residue depletion curve where this line crosses its permitted safe concentration. The level of the marker residue at that point is called the required level for the marker or  $R_m$  and is also called the tolerance in the Code of Federal Regulations. 21 CFR part 556 contains most of the tolerances for approved animal drugs and feed additives. A graphical presentation of establishing an  $R_m$  or tolerance is seen in figure 2.

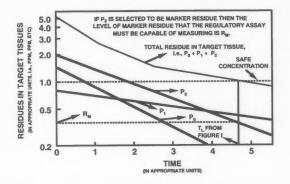


Figure 2. Selection of a marker from among the Individual residues (metabolites) of the target tissue. The  $R_m$  (tolerance) represents the concentration of the marker residue when the total residue achieves its safe concentration.

#### Comparative Metabolism in Laboratory Animals

Another major part of the human food safety requirements is a comparative metabolism study in one of the laboratory test species. The objective of this study is to confirm that the animal has been exposed to all of the major metabolites found in the food producing species to which people will be exposed in their diets. Typically, rats or mice are fed the radiolabeled drug at doses that they were exposed to during toxicity testing for several days to induce drug metabolizing enzymes. Feces and urine are collected and profiled to determine whether all of the major metabolites seen in food animals are also produced in the laboratory test animal. Major metabolites are considered as those making up 10% or more of the residue observed in the food animal.

If one or more of the food animal metabolites is not detected in the excreta of the test animal, organs such as the liver and kidney of those animals are then tested. If major metabolites from the food animal are still not found, then the sponsor must determine the metabolite profiles of the other laboratory species until all of the major food animal metabolites have been accounted for. Finally, if a major metabolite from the food producing species remains unaccounted for in the test species, then separate feeding studies of the untested major metabolite must be undertaken unless it's toxicity can be evaluated by some other means. Profiling usually employs chromatographic techniques such as high performance liquid chromatography. Examples of this type of metabolic evaluation are readily available in the literature. (Paulson and Feil, 1987).

#### Analytical Methods for Residues

Once the marker residue and target tissue have been identified and a level ( $R_m$  or tolerance) has been set, the sponsor develops a determinative and a confirmatory method for the marker residue at the tolerance. The determinative method must be a practical and rugged method that can be used for routine surveillance monitoring of residues in USDA field laboratories. The confirmatory method is one in which the marker residue is determined unequivocally so that the identity as well as the amount of an above tolerance residue can be supported in a court of law. Methods that are capable of this level of specificity ordinarily employ mass spectrometry in one form or another.

After the analytical methods are presented to the FDA and undergo a desk review, they are subjected to a method trial in at least three government laboratories. Typically, one USDA and two FDA laboratories test the methods. Additional methods for the marker residue are often developed after the drug is approved. Most often the marker is included in a screening test by USDA after the drug is approved and broader surveillance by rapid tests is desired by USDA. Tests of this nature are not required of drug sponsors at this time as a condition of approval. However, due to the need of USDA to screen large numbers of samples, the development of a screening test or the inclusion of the marker residue in an existing screening procedure may be required as part of the methods package needed for approval in the not too distant future.

#### Establishing a Withdrawal Time

Having developed acceptable methods for residues, the sponsor then determines a withdrawal time for the compound by running a residue depletion study under field use conditions. The objective of this study is to select the times so that at least three of them are usable, i.e. they lie on the first order portion of the curve running through the tolerance. The compound is administered to the food animal under the maximum prescribed conditions of use. Ordinarily, the drug is given to 20 animals which are slaughtered by normal practice at appropriate times after stopping treatment. Four or five animals at each interval and four or five regularly spaced intervals are usually employed. The selection of slaughter intervals is critical and is best determined by means of a pilot study. When an acceptable data set is available, it is then used to determine a withdrawal time by a statistical tolerance limit procedure as outlined in agency guideline VI (see SOM reference 1987, implementing guidelines). The tolerance limit selected is the 99th percentile with 95% confidence. This procedure sets the withdrawal time so that we can be assured with 95% confidence that 99% of the animals will deplete to the tolerance within the specified time. A graphical representation of the procedure is seen in figure 3.

#### Conclusions

The procedure that FDA has established to regulate food additives and drugs that are used in food producing animals has been reviewed. Although the procedure is complex, the historical basis for the process, the development of the scientific concepts and their subsequent incorporation into

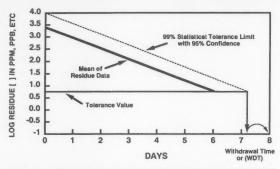


Figure 3. Determination of the withdrawal time from the 95% confidence bound on the 99% statistical tolerance limit on the residue depletion data rounded to the next day.

guidelines have been delineated. We have come from the definition of a residue and the will of Congress to permit the use of carcinogens in food animals through a procedure whereby a threshold assessment begins the process of regulating a sponsored compound. The use of appropriate toxicity testing procedures ultimately yields a permitted safe concentration for total residues. Chemistry studies are run employing the radiolabled compound and determine a target tissue, a marker residue, and a tolerance for the marker residue in meat as well as milk and eggs where appropriate. Methods for analyzing the target tissue and confirming those residues are developed and evaluated by government laboratories and are subsequently used under field conditions to

set a conservative withdrawal time which, if followed, assures that residues are well below a conservatively set permitted safe concentration. Hopefully, this outline and the referenced material permit the conclusion that residues of approved animal drugs and food additives when used in food-producing animals under approved conditions of use will yield a residue picture that is well within the meaning of safe as determined by a set of scientific principles and acceptable societal opinion.

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## Safe Meat and Poultry: An Industry Achievement<sup>1</sup>

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This paper was presented as part of the Symposium "Perspectives on a Safe Muscle Foods Supply" at the Institute of Food Technologists Annual Meeting, June 2-5, 1991, Dallas, TX.

Many industry critics would not agree with the title of this presentation which states that meat and poultry are safe foods. And, indeed, to make such a claim it is first necessary to define "safe." Websters primary definition is "free from harm, injury, or risk." The dictionary goes on to say that in modern usage "safe" is often used interchangeably with secure, and further adds that secure is "about that which one needs to feel no anxiety." In that context, our meat and poultry products could be considered foods which one needs to feel no anxiety about consuming. We all recognize that "safe" does not necessarily mean zero risk. Dr. Paul Hopper, former President of IFT, said we need to shift our thinking from the concept of "zero risk" to the more realistic concept of "insignificant risk."

There are still those however, who disagree with the concept of insignificant risk. This may in fact be due to their own "hidden" agenda and/or vested interests. For example, let's examine the answers to some of the following questions:

What would happen to the food regulators who could relax if we all agreed that meat and poultry products were safe foods?

What about the consumer advocates who would have little left to advocate if we all agreed that meat and poultry products were safe foods?

What about the USDA inspectors whose positions might be threatened if we all agreed that meat and poultry products were safe foods?

What about researchers who might have increased funding problems if we all agreed that meat and poultry products were safe foods?

What about the media who would not have anything to investigate and report if we all agreed that meat and poultry products were safe foods?

Former USDA Deputy Secretary, Jack Parnell, speaking to a subcommittee of the House of Representatives, put it best when he said, "The U.S. food supply is the safest in the world. The public perception that the food supply is unsafe is not supported by the scientific data." He added, "We must address the public perception and work to correct misinformation." My point is, that safety, like beauty, is in the eye of the beholder; we must address the perception problem.

Let's look at some of the quality assurance and HACCP (Hazard Analysis and Critical Control Points) programs that have been used by the meat and poultry industries to improve the safety of their products. The National Advisory Committee on Microbiological Criteria for Foods endorsed the HACCP system and stated that it is "an effective and rational approach to the assurance of food safety." GMP's (Good Manufacturing Practices) and HACCP have both played important roles for three decades in American food processing quality assurance programs. HACCP gained a highly visible role in 1987 when a committee of the National Research Council (1987) recommended that FSIS shift focus from the present bird-by-bird inspection system to a system based on a random sampling of carcasses. The Council described a risk assessment program, which is the HACCP system that is now being introduced into many food plants. One can only imagine the consternation in the inspector corps to see bird-by-bird inspection, and possibly some of their positions, threatened by science.

The first important principle in the development of HACCP, as the USDA has described it, is the identification of a "hazard." USDA has defined hazard as "any biological, chemical, or physical property that may cause an *unacceptable* risk. "Risk" has been defined as "an estimate of the likely occurrence of such a hazard." One still is forced to answer the question regarding whether or not there is such a thing as an acceptable consumer health risk.

The problem for the poultry industry was, and still is, that we have not developed data to estimate microbiological hazards and associated risks for our products. We just don't have the numbers. USDA and the poultry industry have relied almost exclusively on the use of the whole carcass rinse technique (Cox et al., 1983) to ascertain the prevalence, or the proportion, of poultry carcasses that are either positive or negative for salmonellae. USDA surveys in both 1967 and 1979 (Green, 1987), reported positive incidence rates of 39 and 35%, respectively. No change in salmonellae incidence rates in 20 years is quite unbelievable given all the changes in processing productivity and procedures that occurred during that period. But the point is, to make the statement that 36%, or whatever percent, of broiler carcasses are positive for salmonellae, or any other pathogenic organism, is simply not a measure of a hazard or an estimation of risk. This would be similar to an automobile insurance company calculating risks based on the number of miles driven, or the number of trips taken, regardless of whether you are a teen

<sup>&</sup>lt;sup>1</sup>Published with the approval of the Director of the Arkansas Agricultural Experiment Station.

or adult, or whether you live in Los Angeles, or Fayetteville, Arkansas. Stating that a raw food product is salmonellae positive is nearly as informative as using "protein positive" on a nutritional label.

Data indicating the levels of microbiological contamination at various stages of poultry processing, are urgently needed so that we can estimate hazards and associated risks, and more importantly, evaluate intervention procedures for possible improvements in overall product safety. Surkieweiz et al. (1969) at USDA used a whole carcass rinse technique, which by that time had gained wide acceptance, to estimate levels of salmonellae on broiler carcasses (Figure 1). Campbell et al. (1983) reported similar results (Figure 2). When the results of several broiler processing trials were considered, Surkieweiz et al. (1969) stated that "on average, passage through the chillers neither decreased or increased the incidence of Salmonellae-positive carcasses, although there was a tendency for the salmonellae counts per carcass to decrease." From the recent media reports the presently used chilling system is the poultry industry's worst enemy, but this simply can not be supported by scientific data. The EEC has completely banned immersion chilling; however, there are no data that indicate this has decreased salmonellae contamination of raw poultry products. Fain et al. (1988) reported salmonellae incidence rate of 31% in broilers processed in France which were not subjected to immersion chilling, but to a combination of spray and air-blast chilling.

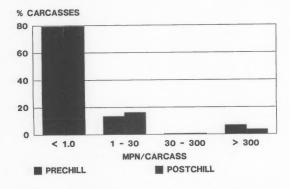


Figure 1. Saimoneliae Levels on Broller Carcasses from Surklewicz et al., 1969.

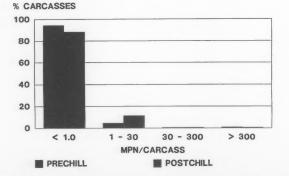


Figure 2. Saimoneilae Levels on Broller Carcasses from Campbell et al., 1983.

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It's hard to believe that 31% is significantly different from the 36% incidence rate that is usually reported in our country.

In a related study, Fain et al. (1988) compared the whole carcass rinse procedure (Cox et al., 1983) for the microbiological examination of poultry carcasses with an excised 25g skin and muscle sample in order to more accurately compare procedures commonly used for other muscle foods. All samples were preenriched in lactose broth followed by standard salmonellae culture procedures. According to the authors, "excision samples of 25 g from breast, or leg and thigh, . . . were significantly less productive in recovering salmonellae in comparison to the whole carcass wash." The actual number of salmonellae in the recovered rinse fluid ranged from 5 to 1200 per 100 mL. It is interesting to note however, that greater than 85% of the carcasses exiting the chillers harbored less than 100 salmonellae in the 100 mL rinse. Again, does < 100 salmonellae on a raw food product pose a significant risk? Unless we are talking about extreme abuse which would have to include cross-contamination from the raw carcass to other products which were not going to be subjected to any heat treatment prior to consumption, the answer would have to be, "No!"

Green (1987) conducted a study, using semi-quantitative methods, to estimate the level of salmonellae contamination in poultry chill water. Results indicated that 79% of the samples had salmonellae counts of less than 10 per 100 mL of water. Lillard (1979) conducted a study to evaluate various treatments in the chill water and found that control samples harbored from 0 to 40 salmonellae per 100 mL. In a study designed to determine the sensitivity of a commercially available DNA probe (Izat et al., 1989), researchers sampled prechill carcasses and chill water. The level of salmonellae recovered at the prechill location ranged from 0.03 to 15 organisms per carcass. The levels of salmonellae in the chill water (20 ppm chlorine) ranged from 0.03 to 11 organisms per 100 mL, or less than 0.1 organisms per mL. The poultry industry conducted an extensive study in 1987. Over 80 plants participated in this study, but, unfortunately, the data were never published. However, results from this study indicated that salmonellae levels on processed broiler carcasses averaged 30 organisms, and levels in chill water ranged from 0 to 10 organisms per 100 mL. The objective of reviewing this data is not to defend immersion chilling or the poultry industry in general, but to demonstrate that the levels of pathogenic organisms we are discussing, and the media are getting so excited about, are extremely low.

Over the last 20 years numerous studies have been conducted in efforts to estimate the salmonellae incidence rates on broiler carcasses at various stages of processing. However, little information is available concerning the actual numbers of salmonellae present on pre-and postprocessed broilers. Salmonellae enumeration can be accomplished using a most probable number (MPN) procedure combined with conventional culture procedures or an MPN can be combined with any of the now commercially available rapid tests. Researchers in the Department of Animal and Poultry Sciences at the University of Arkansas have conducted a series of experiments to determine the levels of salmonellae on pre- and post-processed broilers.

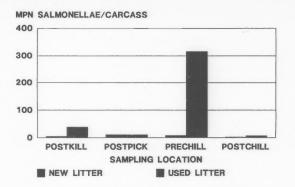


Figure 3. Salmonellae Levels on Broiler Carcasses at various processing locations as affected by litter condition (Reiber et al., 1990).

In a study designed to investigate the effects of litter condition on salmonellae contamination of broilers, Reiber et al. (1990) sampled broilers at four locations (Figure 3). These locations were postkill (feathers, feet, and head included), postpick, prechill, and postchill. The levels of salmonellae at the postkill (4.8/bird for new; 38.9/bird for used) and prechill (8.7/carcass for new; 316/carcass for used) locations were affected by litter condition. At both locations salmonellae levels were lower when birds were reared on new litter. However, at the postpick (11.5/carcass for new; 11.0/carcass for used) and postchill (2.3/carcass for new; 7.2/carcass for used) locations there were no significant differences in salmonellae levels due to litter condition. Results from the study suggest that salmonellae levels on the fully processed carcass are not significantly affected by litter condition. This study and others have also suggested that old litter may inhibit colonization of the ceca and external contamination of the surface of the bird through the process of competitive exclusion.

In a study designed to evaluate the efficacy of using formic acid or calcium formate in broiler feed to influence cecal colonization or external contamination of the skin surface, researchers again evaluated samples for levels of salmonellae (Izat et al., 1990a). In this series of studies the levels of salmonellae in the ceca ranged from 0.003 to 1.7 organisms per gram of cecal material. The level of salmonellae on the prechill carcasses ranged from 1.5 to 89 organisms per carcass.

A study was conducted to evaluate possible differences in salmonellae incidence, levels, and serotypes between conventionally reared and processed broilers and "organically" grown and hand-processed broilers (Izat et al., 1991). There were no significant differences between the two groups of carcasses in any of these microbiological parameters. Incidence rates on the retail carcasses ranged from 17 to 50% while levels of salmonellae ranged from 5 to 34 organisms per carcass. Serotypes recovered include *typhimurium, paratyphi*, and *arizonae*.

Other studies (Izat et al., 1988) evaluating the incidence and levels of another pathogen associated with poultry, *Campylobacter jejuni*, suggest that this organism, when present on poultry carcasses, is also there at very low levels (< 75 organisms/carcass). Recent data (Jones et al., 1991) suggest that 52% of postchill broiler carcasses and 31.6% or broiler carcasses at retail are contaminated with *Campylobacter jejuni*. The authors did not make any attempt to enumerate the organism at either location.

In practically all of the studies that have evaluated the effects of modern poultry processing procedures on levels of pathogenic organisms on the surface of broiler carcasses, results have demonstrated that processing procedures presently used are actually causing decreases in levels of total organisms and pathogens. However, studies have also shown that some of the processing procedures presently used (scalding, feather removal, immersion chilling) may increase the incidence of cross-contamination.

Researchers used to blame the processing plant for contamination problems related to salmonellae. Recent research has demonstrated that the live bird is contaminated prior to entering the processing plant (Izat et al, 1990b; Reiber et al. 1990). Therefore, controlling salmonellae during live production through various means (feed additives, management practices, competitive exclusion, litter treatment, control of rodents and insects, sanitation, etc) should prove to be effective intervention points. Of course, a certain degree of cross-contamination will continue to occur at the processing facility, but this should be minimized if an effective HACCP program is strictly followed and monitored.

Lillard (1989) indicated that many microorganisms are firmly attached to the skin of poultry and she suggested that the numbers of pathogens on carcasses may be grossly underestimated. However, in an earlier report, in which the above author participated, it was concluded that rinsing with 2 to 4 L of water removed up to 89% of firmly attached cells (Carson et al., 1987). The authors of the latter study stated that only "3 to 10% of the remaining organisms were able to detach and transfer from skin to stainless steel surfaces." We submit that if the majority of salmonellae are indeed "firmly" attached to the skin surface, that normal handling in the kitchen would not result in a significant degree of cross-contamination.

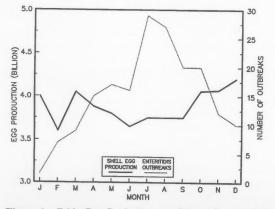
In summary, the typical raw broiler carcass leaving the modern poultry processing facility most likely harbors less than 30 salmonellae. This is certainly an insignificant risk, even for that portion of our population at highest risk, unless the product is abused or inadequately cooked (which is not usually the case with poultry products) prior to consumption. A recent CDC report (CDC, 1990) indicated that only 4.3% of the reported cases of foodborne illness were due to errors made by the manufacturer. If this is in fact the case, why do we continue to see exposés like the "60 Minutes" program first aired on March 29, 1987, or "New Problems with Poultry" by the Washington D.C. NBC affiliate WRC-TV, or read headlines like "Salmonella strikes U.S. Wallets" in the Arkansas Democrat (of all places) last month, or "Poisoned Poultry" in the New York Post. Part of this may be due to those hidden agenda that we mentioned earlier. Some of the fuel for these consumer outrage events comes from those persons, even scientists in some cases, who are willing

to take scarce data and project them into estimates (guesses) that get accepted as hard fact after being published in a few places.

In a Canadian report, Todd (1988) multiplied reported cases of foodborne illness by 350 to estimate the total number of cases. Why? Apparently because that "multiplier factor" had been used by others to account for underreporting. Multiplier factors used for estimated cases of human salmonellosis in U.S. reports range from 700 to 1274; for all foodborne diseases the average factor is 862. Almost every author reporting estimates of foodborne illness uses a different multiplier factor. No one disagrees that foodborne illness is under-reported in the U.S. and other countries, but apparently no one agrees by how much. Because of these discrepancies between estimates it is again very difficult to evaluate hazards and associated risks.

Not only are there numerous discrepancies in the literature concerning the importance or significance of salmonellosis to the population, but recently some extremely brash statements and general conclusions have been made which are simply not supported by scientific data. One such statement was made by Dr. Morris Potter at the CDC. He stated that "The combination of chicken consumption increasing and Salmonella cases increasing translates in my mind to a reasonable conclusion that contamination on chicken meat is a public health concern." This statement has justifiably angered many scientists because it is obvious that over that last 20 years many other factors, besides an increase in poultry consumption, may have led to or attributed to the increasing number of cases of foodborne illness. These factors include the increase in the percent of meals consumed away from the home, the increased use of the microwave oven for cooking and reheating foods, the increased number of fully cooked foods available at the deli, the increased number of salad bars, etc. All of this reminds me of the significant correlation between the stock market and the height of women's skirts - financial friends say it's almost perfect

The next three figures are not designed to demonstrate that foodborne illness is not a serious problem, or that meat and poultry are not involved. Rather, we are trying to demonstrate that it is extremely difficult and very hard to prove that correlations between various factors really have



Filgure 4. Table Egg Production vs. *Salmonella enteritidis* Outbreaks by month of the year in 1990.

any meaningful relationship. For example, egg production and subsequent consumption is relatively stable throughout the year (Figure 4). However, cases of salmonellosis attributed to Salmonella enteritidis are significantly higher in the summer months suggesting that other factors, for example improper food handling or inadequate refrigeration, may be much more significant in regards to the increase in the number of cases than is consumption (Figure 4). Chicken consumption is also very stable throughout the year, but there is a significant increase in the number of cases in the summer months (Figure 5). Again, this suggests that other factors, not simply consumption, are contributing to rise or fall in number of reported cases (Figure 6). If one examines the number of cases of foodborne illness by age of the affected person, you will note that there is a "blip" in the number of cases for the 20-29 age category (Figure 7). Is this due to this group consuming significantly more poultry, or as suggested by Dr. Robert Tauxe, CDC, is this group simply learning, and making mistakes, regarding how to handle and cook foods in their new homes. There is increasing evidence that they, and many others, have not learned their food safety lessons very well!

There has been a long-standing disagreement between epidemiologists, microbiologists, and food animal producers on the projections of foodborne illness made from actual

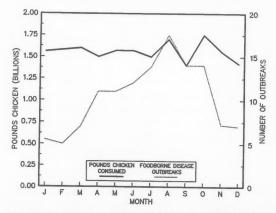


Figure 5. Poultry Consumption and Outbreaks of Salmonellosis by month of the year in 1990.

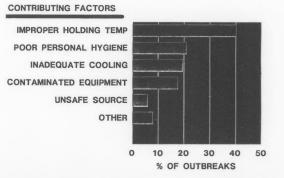


Figure 6. Factors Contributing to Foodborne Illness as reported by the Centers for Disease Control in 1990.

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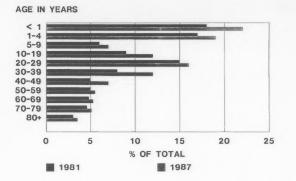


Figure 7. Age Distribution of Persons from whom *Salmonella* was isolated and case was reported to the Centers for Disease Control in 1981 and 1987.

reports, as we indicated earlier. Dr. Ken May, a poultry industry consultant, contends that CDC projections of foodborne illness from meat and poultry are "pure speculation and guesswork." Participants from CDC, the Southeast Poultry Research Laboratory, and members of the National Advisory Committee on the Microbiological Criteria for Foods, in a conference on May 14, 1991, agreed that available data are inadequate to quantify risks. The section drafted by CDC's Dr. Morris Potter, and approved by the Committee, now read "Epidemiological data are adequate to identify many microbiological hazards in meat and poultry products. However, existing data are not sufficient to qualify risks of each of the hazards, nor to rank the human health risks associated with specific microorganisms, products, processes, or behaviors. Generalizing from existing data has resulted in confusion and conflicting views on the magnitude of foodborne illness from meat and poultry. Therefore, the data bases must be improved through additional research to permit quantitative risk assessment."

So where do we go from here? Obviously, we will continue our research efforts to improve the safety of muscle food products. We did not stop designing airplanes with the development of the DC-3 because it was the safest airplane ever designed. But, we must put more effort on education and training for foodservice, retail, and home food handlers. It is evident that we need more research data to successfully build a sound epidemiological base in order to establish the real incidence and severity of foodborne illnesses, so that when improvements in processes are developed, we will be able to subjectively measure our progress. We have just initiated an epidemiological research project at the Arkansas Childrens' Hospital in Little Rock to accomplish this objective.

Roberts and Smallwood (1991) indicated that we need "better data on the incidence, severity, and economic dimensions of foodborne disease from microbial agents (bacteria, parasites, fungi, viruses), chemicals (insecticides, herbicides, fertilizers, animal drugs, environmental contaminants, food additives), and natural constituents (including the product of biotechnology)." They further cite the Office of Management and Budget as stating "No data source exists with definitive estimates of the number of illnesses caused by foodborne sources or the distribution of disease severity."

Until the factual information and scientific interpretation of the data is available, we will probably have to look forward to, and respond to the occasional media outrage. The *Food Safety Consortium* at Iowa State, Kansas State, and the University of Arkansas is developing not only good science, but good communication tools to move that day forward.

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# Updates . .

# U of M to Host Symposium on Value-Added Meat Products

Producing and marketing value-added meat products will be the focus of an upcoming University of Minnesota symposium.

The Value-Added Meat Products Symposium will be March 26 at the Northland Inn Conference Center in Brooklyn Park. It is intended for small to medium-sized meat processors, livestock producers, extension educators, entrepreneurs and other interested persons.

The location is northwest of Minneapolis, immediately off I-94/I-694 at the Boone Avenue exit.

The event will begin with registration from 8:30-9:30 a.m., and will run until 5 p.m. Topics and speakers during the morning will be: Food trends and the changing consumer, Jean Kinsey, University of Minnesota agricultural economist; Marketing specialty meat products, Paul Hugunin, Minnesota Department of Agriculture; Ingredient systems for specialty markets, Hugo Wistreich, B. Heller Seasonings and Ingredients, Inc., Bedford Park, IL.

Topics and speakers during the afternoon will be: Technology of restructured meat products, Roger Mandigo, University of Nebraska animal scientist; Technology of low-fat emulsified sausages, Robert Rust, Iowa State University animal scientist; New technologies for meat products, Blaine Breidenstein, Agricultural Utilization Research Institute; Update on labeling for processed meat products, Kathleen Leddy, U.S. Department of Agriculture.

The final hour will feature new, specialty or value-added meat products. Presenters will include Dave Ledebuhr, Winona, who does buffalo processing, and Sharon Baker, Morris, who produces roaster pigs. There will also be a presentation on deer farming and venison processing by a speaker yet to be determined.

Registration fee for the symposium is \$75. The Agricultural Utilization Research Institute, a non-profit organization created by the Minnesota Legislature, is providing up to 100 scholarships to the symposium at \$50 each. The scholarships are for Minnesota residents involved in agricultural production, manufacturing, processing or marketing. There is a limit of two scholarships per family or organization.

Those meeting the scholarship criteria can register by sending a check for \$25 to Extension Special Programs, 405 Coffey Hall, University of Minnesota, St. Paul, MN 55108-6068. Further information is available by calling 1-800-367-5363.

The symposium precedes the convention of the Minnesota Association of Meat Processors March 27-29. Sponsoring the symposium are the University of Minnesota's Center for Alternative Plant and Animal Products, Department of Animal Science and Minnesota Extension Service. Other sponsors are the Agricultural Utilization Research Institute, Minnesota Association of Meat Processors, Minnesota Beef Council and Minnesota Pork Producers Association.

For more information contact Gerald Wagner at (612)625-1978.

### Police Nab City Worker for Doing His Job

The city inspector found himself handcuffed face down in a parking lot with an officer's gun on him.

Steve Drane was doing his job, which was to shoot noisemaking flares in downtown Des Moines to scare away roosting crows.

Police Detective Doug Harvey was doing his job, which was to stop people who appear to be committing a crime — like shooting guns downtown.

To the surprise of both, they met last week. Before it was over, Drane — a city environmental-health inspector — found himself handcuffed face down in a parking lot with an officer's gun aimed at him.

After discovering that Drane was a city colleague on the job, officers let him go. But not before they strongly suggested the crow squad get some clothes identifying them as city employees. Drane wore casual clothes with no city logo the night of Feb. 2 when he was approached near Third and Park streets.

Drane identified himself orally when Harvey approached, and his city car was nearby. Drane took a city ID card from his pocket as Harvey walked toward him.

Police said they apologized to Drane. But Drane's boss, Steve Gunson, head of the environmental-health department, still isn't happy.

"It concerns me a lot to have one of our guys drawn down and cuffed while he's doing his job," Gunson said.

Drane said the officers were "very businesslike" and did not handle him roughly. Nevertheless, he said he did not enjoy having a gun pulled on him.

"I was there with my peashooter and he pulls a .38-caliber," Drane said, comparing the flare gun to a police revolver.

Gunson said his staff had been shooting the flares Sunday through Thursday for about four years. Police and representatives of other departments approved the program, Gunson said.

Police say they were courteous throughout the incident.

When Detective Doug Harvey heard the pop of a firearm and found Drane with a gun, he called for backup and ordered Drane to the ground.

Police Sgt. Mark Morgan arrived shortly thereafter. Acting on police orders, Drane said he put the gun down, got down on his stomach, rolled over to his back, squirmed away from the gun, and finally rolled to his stomach and put his hands on his back so the officers could handcuff him.

Drane repeatedly told the officers he worked for the city's environmental-health department, and they confirmed that with his ID card.

Assistant Police Chief William McCarthy said Detective Harvey apparently handled the situation professionally.

Reprinted from the Des Moines Sunday Register, February 9, 1992.

# Northland Food Labs added to USDA Certification List

Northland Food Laboratory, Inc. is pleased to be added to the USDA list of laboratories certified to test for protein, fat, moisture, and sodium. Andy Krause is the Director of Analytical Chemistry. Northland Food Laboratory, Inc. has locations in Green Bay and Manitowoc, Wisconsin. Northland Food Laboratory, Inc. was also placed on the recognized list of laboratories proficient for testing *Listeria* and *Salmonella* by the Food Safety Inspection Service of the USDA in 1990.

Analytical chemistry and microbiological recognition is obtained by testing proficiency on split samples sent at various times of the year. The laboratory is a full service microbiological and nutritional chemistry laboratory. Our USDA number for food chemistry is 5591. For *Listeria* and *Salmonella* our USDA number is 0031.

We look forward to helping you with all of your nutritional labeling testing needs. If you have any questions please write or call Northland Food Laboratory, Inc., 2415 Western Avenue, P.O. Box 160, Manitowoc, WI 54221-0160; (414)682-7998 or 1044 Parkview Road, Green Bay, WI 54304, (414)336-7465.

### Silliker Laboratories Opens Fresno, California, Laboratory

Silliker Laboratories, one of the leading independent food testing laboratories in the United States, recently announced the opening of its newest laboratory in Fresno, CA. Silliker Laboratories of California, Inc., 4720 W. Jennifer Avenue, will provide new and existing clients with microbiology, analytical chemistry, consulting and research services related to the safety, stability, and nutritional value of food. The Fresno facility is Silliker's twelfth in the United States and Canada.

In announcing the opening of the new laboratory, Dr. Russel S. Flowers, president, Silliker Laboratories Group, Inc., said the facility will provide the Fresno area, the leading agricultural county in the United States, with the organization's internationally respected spectrum of responsive and professional services. Robert A. Robbins, a food industry professional with over 15 years of experience, was named Laboratory Director.

"Under the direction of Rob Robbins, Silliker Laboratories of California, Inc. will serve the Fresno region with the highest standards technical expertise and responsiveness. This has been a hallmark of the Silliker organization for the past 25 years," Dr. Flowers said.

Headquartered in Chicago Heights, IL, Silliker Laboratories are located in Chicago Heights, IL, Columbus, OH, Garwood, NJ, Stone Mountain, GA, Sinking Spring, PA, Carson, CA, Hayward, CA, Fresno, CA, College Station, TX, Grand Prairie, TX, San Antonio, TX, and Mississauga, Canada.

For more information on Silliker Laboratories of California, Inc. (Fresno), contact Rob Robbins, laboratory director at (209)277-8085, or write: Silliker Laboratories of California, Inc., 4720 W. Jennifer Avenue, Suite 105, Fresno, CA 93722.

#### **New Book Announcement**

### Strategies for Assessing the Safety of Foods Produced by Biotechnology

Report of a Joint FAO/WHO Consultation
1991, iv + 59 pages (available in English; French and Spanish in preparation)
ISBN 92 4 156145 9
Sw. fr. 11-./US \$9.90
In developing countries: Sw.fr. 7.70
Order No. 1150369

This book records the conclusions reached by a joint FAO/WHO consultation convened to establish a scientific basis for the safety assessment of novel foods, food ingredients, and processing aids produced by biotechnology. Emphasis is placed on the safety of new technologies that promise dramatic improvements in the food supply, whether through the production of nutritionally superior cereal and grain crops or the development of farm animals that are disease resistant, produce lean meat, and grow more efficiently. New techniques that can increase the efficiency and reduce the costs of the food processing industry are also thoroughly assessed.

The main aim of the book is to identify the scientific principles and procedures needed, on a case-by-case basis, to assure that foods produced by biotechnology are toxicologically safe and nutritionally adequate for human consumption. Addressed to regulatory authorities as well as to the food industry, the book also aims to provide a solid scientific basis for the development of comprehensive, well enforced food regulations that can keep pace with technological advances.

The book opens with a review of current and future applications of biotechnology in food production and processing, with separate sections devoted to applications in microorganisms, plants, and food animals. While many of these applications build on conventional techniques of breeding and strain selection, others offer new opportunities to increase the genetic diversity of breeding stocks, isolate and copy superior breeding lines, enhance the immune response of animals, block infection by viruses, alter patterns of fat or protein production, and manipulate the fatty acid composition of microbial lipids used in food processing. Gene transfer is identified as the most promising new technology.

The main part of the book consists of separate chapters devoted to the safety assessment of foods derived from microorganisms, plants, and animals generated by biotechnology. Adopting a highly cautious approach, each chapter first identifies all possible hazards, discusses the likelihood that such hazards will arise in practice, and describes the scientific principles and procedures needed to assure the safety of the finished food. Potential hazards identified include the activation of silent genes and the creation of new toxins, changes in nutritional content or in the bioavailability of nutrients, and allergic reactions to new or altered proteins. An effort is also made to distinguish between new health hazards and hazards that have long been a part of conventional breeding practices.

A concluding section stresses the need for a new framework of safety assessment that relies on a characterization of food in terms of its molecular, biological, and chemical properties, and uses the resulting data to determine the need for toxicity tests. The report also notes that the new techniques of molecular biology provide powerful tools, not only for improving the world's food supply, but also for conducting more sensitive safety assessments.

### American Association of Cereal Chemists offers Short Course

*Food Safety and Sanitation* is the subject of the AACC's short course to be held April 29-30, 1992 at the Sheraton Park Place, Minneapolis, MN.

This course is designed to meet the growing needs of food manufacturing firms for solutions to safety and sanitation problems. Attendees will acquire key background information, as well as learn about techniques and procedures that can be put to immediate use.

The material presented in the course will update you on food safety considerations, including all of the basics and some specifics on how to engineer and process safe food for the consumer.

Course Highlights:

- Good manufacturing practices (GMPs)
- · Food & drug laws and regulations
- Identifying microbiological and other safety hazards
- Principles of HACCP
- · Handling FDA and other inspections
- ISO-9000 quality certification
- Developing a food safety program

For more information or registration materials, please contact AACC Headquarters, 3340 Pilot Knob Road, St. Paul, MN 55121-2097, U.S.A., telephone (612)454-7250; FAX (612)454-0766.



William Wilson, Marketing Manager, Anderson Instrument Co., Inc.

### William Wilson Named Marketing Manager of Anderson Instrument Company

William 'Bill' Wilson has been recently named Marketing Manager of the Anderson Instrument Co., Inc.

Mr. Wilson began his career with Anderson in 1980 as a Regional Sales Manager, and was promoted to Manager of Technical Services in 1986. Reporting to Bill in his new role are the Technical Service, Customer Service and Marketing Communications Departments.

Mr. Wilson received a B.S. Degree in Biology from Syracuse University, as well as a B.S Degree in Forest Biology from State University of New York in 1979.

He resides in Gloversville, New York with wife, Joni, son, Brett (age eight) and daughter, Jenelle (age five).

The Anderson Instrument Co., Inc., of Fultonville, New York, is a leading manufacturer of process instrumentation used in the production of food and dairy products, beverages and pharmaceuticals.

For more information contact Anderson Instrument Company, Inc., R.R. #1, Auriesville Road, Fultonville, NY 12072; (518)922-5315, FAX (518)922-8997.

### "What All Plant Employees Should Know About Good Manufacturing and Good Sanitation Practices"

L. J. BIANCO & ASSOCIATES have just completed a series of three much needed GMP-GSP Good Manufacturing and Good Sanitation Practice booklets to help cope with the increasing bacteriological, sanitation and extraneous matter product quality problems facing the Food Industry.

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"GMP-GSP Guideline Rules for Food Plant Employees" "GMP-GSP Guideline Rules for Food Plant Management" "Spanish GMP-GSP Guideline Rules for Food Plant Employees"

These new training materials provide practical technical aids for both management and hourly employees. They serve to assure that company rules concerning personal appearance, hygiene, equipment and facility cleanliness and product quality and sanitation controls are readily understood by all employees.

The management booklet covers GMP's and GSP's as well as HACCP and audit inspection quality control programs, etc.

The employee booklets in English and Spanish help make hourly employees more aware of the importance and necessity of using GMP's and GSP's when working in Food Plants.

The booklet prices can be obtained by contacting L. J. BIANCO and ASSOCIATES, 850 Huckleberry Lane, Northbrook, IL 60062, Tel: (708)272-4944; FAX (708)272-1202.

### Gist-brocades Food Ingredients, Inc. Announces Personnel Change

Douglas Pangier, former Technical Service Manager of Gist-brocades Food Ingredients, Inc., has been promoted to the new position of Technical Director, Dairy Ingredients Group.

Located at the Dairy Headquarters in Menomonee Falls, WI, Pangier will report to Barry James, Vice President of Dairy Ingredients, North America.

Gist-brocades Food Ingredients is a world leader in Maxiren®, fermentation-produced Chymosin, and a leading manufacturer of quality yeast, yeast extracts and enzymes.

For more information contact Maria Novak at (800)662-4478.



### Food and Environmental Hazards to Health

#### Fish Botulism—Hawaii, 1990

On July 22,1990, the Hawaii Department of Health (HDH) was notified that three adults from the same family had been hospitalized July 20-22 with clinical manifestations consistent with botulism. The first patient, a Hawaiian woman of Filipino origin, had onset on July 18 of double vision, difficulty swallowing and speaking, and muscle weakness. When admitted to the hospital on July 20, she had bilateral ptosis, extraocular movement dysfunction, absence of gag reflex, and prominent muscle weakness. During the next 3 days, she developed progressive respiratory impairment and respiratory acidosis. On July 21, her mother was hospitalized with similar manifestations but without respiratory difficulty. On July 22, the index patient's husband was hospitalized with transient ptosis, blurred vision, and dysphonia. All patients were treated with botulinal antitoxin on July 23 and survived. Serum specimens obtained from all three patients after initiation of antitoxin therapy were negative for botulinal toxin. However, stool cultures obtained from the index patient and her mother yielded type B Clostridium botulinum. A common meal of palani (surgeon fish) had been prepared and eaten at home on the evening of July 17. Samples of leftover fish were tested at CDC and contained type B C. botulinum toxin; culture of the samples yielded type B C. botulinum.

The palani, a reef scavenger fish eaten by local residents, had been purchased fresh and cleaned at a retail fish market on July 17, the day of the meal; the index patient's husband cooked the palani directly on the grill at home. After grilling the palani on both sides, he opened the fish with his fingers and noted remnants of the intestines inside the fish. Both the index patient and her mother ate the palani's intestines and the meat around it; the index patient's husband used his fingers to eat the meat near the head and tail, but avoided the intestines. A fourth family member present at the same meal ate meat from the back of the palani only and had no symptoms.

The palani had been sold to the market by local fishermen sometime during July 2-13; the length of time the palani had been held by the market could not be determined. An inspection of the market on August 7 found that fish were kept on ice in a display freezer case with nonfunctional cooling equipment; the internal temperature of the fish on top of the ice in the display freezer was 52 F (11 C). The HDH instructed the market to properly refrigerate the fish and recommended that fish be thoroughly cleaned and rinsed at the market when requested by customers; otherwise, customers should be clearly instructed to clean the fish thoroughly and dispose of all internal organs.

Editorial Note: Foodborne botulism is caused by consumption of a neurotoxin produced by *C. botulinum*. Illness is characterized by cranial nerve dysfunction and descending muscle paralysis, which can progress to respiratory compromise. In the United States, most cases are associated with home-canned or preserved products. The diagnosis of botulism can be confirmed by detection of neurotoxin in serum samples collected before antitoxin administration, by demonstration of neurotoxin in samples of stool or food, or by isolation of *C. botulinum* from a patient's stool. Because antitoxin may prevent progression of paralysis if administered shortly after onset of symptoms, clinicians should not wait for laboratory confirmation to consider antitoxin administration. Careful monitoring of respiratory function and intubation, if necessary, can be lifesaving. Testing of clinical or food specimens and acquisition of antitoxin can be arranged through state health departments.

The association between botulism and consumption of contaminated fish has been well established. From 1950 through 1989, 48 (13%) of 365 foodborne outbreaks of botulism in the United States were associated with consumption of fish. In all of these incidents, the fish had been processed and held before consumption. However, this report of fish-associated botulism from Hawaii is unusual because fresh (unpreserved and unfermented) fish was implicated as the source; this appears to be the first report in the United States of botulism caused by consumption of apparently fresh fish. This report is also unusual because most fish-associated cases of botulism are caused by type E *C. botulinum*; only three of the previous fish-associated outbreaks in the United States were caused by type B *C. botulinum*.

*C. botulinum* spores are common in marine sediments and are frequently detected in fish intestines. Previous outbreaks of botulism in California, New York, and Israel were associated with consumption of kapchunka, an uneviscerated, fresh-water fish soaked in brine and air-dried. In these outbreaks, salt concentrations, adequate to inhibit growth of *C. botulinum* in the flesh of the kapchunka, were considered to have been lower in the intestines, allowing *C. botulinum* organisms to produce toxin. In Hawaii, clinical manifestations were most severe in the two persons who ate fish intestines. Localization of toxin within the fish may be important because the consumption of fish intestines may be common in some ethnic groups.

Because refrigeration had been inadequate at the market, the internal temperature of the fish may have been elevated for lengthy periods. The conditions around the retained gut may have facilitated an anaerobic environment, allowing production of toxin. Although botulinal toxin is heat labile, cooking was insufficient to inactivate the toxin.

Because ethnic foods, such as kapchunka and possibly other ungutted fish, may continue to be rare sources of botulism in the United States, public health measures to prevent this problem must take into account local cultural practices. When botulism is suspected, state health departments should be contacted immediately, as rapid intervention may prevent additional cases and prompt administration of antitoxin may halt progression of symptoms.

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### Lyme Disease Surveillance—United States, 1989-1990

Surveillance for Lyme disease (LD) was initiated by CDC in 1982, and in January 1991, LD became nationally reportable. Forty-six states reported cases in 1989 and 1990; but the occurrence in nature of the causative bacterium, *Borrelia burgdorferi*, has not been documented in all of these states. From 1982 through 1989, the annual reported number of cases of LD increased 18-fold (from 497 to 8803, respectively) and from 1986 through 1989, nearly doubled each year. The provisional total of 7997 cases for 1990 suggests a plateau in this trend of rapid annual increase. This report summarizes surveillance of LD during 1990 in Connecticut, Georgia, Michigan, Missouri, New Jersey, and Wisconsin.

#### Connecticut

In 1990, the Connecticut Department of Health Services (CDHS) reported 704 cases (22 per 100,000 population) of LD based on the new national surveillance case definition adopted by the Council of State and Territorial Epidemiologists (CSTE) in 1990. This total represented a 9% decrease from the 1989 total of 774 cases, but that total was based on the previous CDC case definition in use in 1989. The total number of case reports received by CDHS (i.e., including those reports that did not meet the case definition in use), however, increased slightly (4%) from 1269 in 1989 to 1318 in 1990.

One criterion of the new national surveillance case definition is that the characteristic skin lesion of LD, erythema migrans (EM), must be  $\geq 5$  cm in diameter. In 1990, CDHS assessed the impact of this criterion on LD reporting in Connecticut by requesting physicians to record the EM diameter on the CDHS case report form (telephone followup was done when information was not provided). Of the 1318 LD total case reports received by CDHS in 1990,597 (45%) were based on reports of EM alone. Of these 597 reports, the EM diameter was ≥5 cm for 388 (65%),<5 cm for 35 (6%), and unspecified for 174 (29%). Telephone follow-up for the 174 unspecified reports indicated the EM diameter was ≥5 cm for 82 (47%),<5 cm for 35 (20%), and remained unspecified for 57 (33%). If information on EM diameter had not been collected, the surveillance total for 1990 based on the official case definition would have been 831, including the 597 cases with EM alone and 234 cases with late manifestations and a supporting positive serologic test; instead, the CDHS assessment resulted in a 15% (127/ 831) reduction in cases.

#### Georgia

The Georgia Department of Human Resources (GDHR) recorded a total of 62 cases of LD from 1982 through 1988, compared with 715 cases in 1989. In 1990, however, the total number of reported cases declined to 161. Potential explanations for these shifts are that 1 ) free serologic testing was offered through the state public health laboratory in 1989 but was discontinued in July 1990; 2) the cut-off for serologic positivity used by the state public health laboratory (1:128 by immunofluorescent assay) was lower than that used by many laboratories in the country (1:256); 3) in 1989

GDHR and other institutions sponsored a series of state-wide educational seminars on LD, including two programs for physicians; and 4) the new national surveillance case definition was implemented in 1990.

#### Michigan

In Michigan, the number of reported LD cases with onset in 1990 (134) declined 19% when compared with 1989 (165), although the same case definition was used in both years.

#### Missouri

During 1990, the Missouri Department of Health (MDOH) reported 205 cases of LD, a 90% increase from 1989 (108 cases). MDOH implemented the new national surveillance case definition in 1990, but had used the previous CDC case definition in 1989.

#### New Jersey

In 1990, the New Jersey State Department of Health (NJDOH) recorded a 58% increase in the number of confirmed cases of LD compared with 1989 (1074 cases and 680 cases, respectively), although the number of cases with EM increased modestly (680 and 716 cases, respectively). Potential explanations for these increases include: 1) use of a new generic case report form for communicable diseases that had been implemented by NJDOH in June 1990 to facilitate reporting by physicians; and 2) broadening of the case definition from only cases with documented EM to the new national surveillance case definition that includes persons with EM as well as persons with a positive serologic test result and rheumatologic, neurologic, or cardiac signs of LD.

#### Wisconsin

In 1990, the Wisconsin Division of Health (WDOH) noted a 54% decrease in total LD case reports when compared with 1989 (909 and 1996, respectively), although the same case definition was used in both years. The number of confirmed cases also declined from 1989 to 1990 (762 and 337 cases, respectively). This is the first decrease in reported LD cases in Wisconsin since 1985. Potential explanations that may account for some of this change include: 1) a decrease in media coverage of LD; 2) a decreased prevalence of Ixodes dammini, the tick vector of B. burgdorferi in that region, based on anecdotal reports from entomologists to WDOH; and 3) success of educational efforts to prevent tick bites. In addition, from 1989 through 1990, use of commercial and reference laboratories for LD serology declined: in 1990, the Wisconsin State Laboratory of Hygiene tested 8309 specimens compared with 17,222 specimens in 1989. This decrease in laboratory use may reflect a true decrease in incidence, changing medical practices, or other factors; the effect on case reporting is unknown.

Editorial Note: Different surveillance case definitions for LD have been used throughout the United States since 1982; each definition has incorporated a combination of elements of early and late manifestations of illness, a history of endemic exposure, and a positive serologic test result. On January 1, 1991, LD became nationally reportable in the United States. However, the new standardized surveillance

case definition, which had been approved by CSTE was used by some states in 1990.

The findings in this report suggest that the factors affecting trends in LD reporting are multiple and complex, and require further definition. For example, in Connecticut, a 1-year assessment that focused on reporting of EM resulted in a 15% decrease in cases that otherwise would have been included in the annual total. The findings in Georgia highlight how heightened physician awareness and laboratorybased surveillance for LD may affect reporting. In Missouri, case reports continued to increase despite the use of the new case definition, possibly reflecting increased awareness and reporting compliance and/or a true increase in incidence. Of note, however, is that B. burgdorferi, the etiologic agent of LD, has not been isolated from ticks, vertebrate hosts, or human case-patients in Georgia or Missouri. In New Jersey, use of the new case definition appeared to identify cases with late manifestations of illness. In Michigan and Wisconsin, case reports may have declined as a result of ecologic or other factors unrelated to a change in case criteria.

The new national surveillance case definition was developed to achieve greater specificity in case identification. This effort to exclude non-cases may have also excluded true cases from national totals. The impact of the new case definition can be further assessed after this definition has been implemented uniformly by all states and in use for at least 1 full year.

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#### Shigella dysenteriae Type 1 -- Guatemala, 1991

On March 14, 1991, physicians at a hospital in Guatemala City reported to the Institute of Nutrition of Central America and Panama (INCAP) that a 2-year-old boy living in an orphanage in Guatemala City had been hospitalized with dysentery; stool cultures yielded *Shigella dysenteriae* type 1. Another child from the orphanage had recently died from dysentery. During March 18-21, two other young children from the orphanage were diagnosed with *S. dysenteriae* type 1. On March 21, health officials in Rabinal, in the department of Baja Verapaz, reported more than 100 cases of dysentery to the Division of Epidemiology and Disease Control of the Ministry of Health (MOH). This report summarizes the investigation of these outbreaks.

#### **Guatemala City**

The orphanage house's approximately 150 children. No new children had been admitted to the orphanage in 1991, and no illness had been reported among staff members. The index patient was treated with trimethoprimsulfamethoxazole; however, a stool culture yielded *S. dysenteriae* type 1 that was resistant to trimethoprimsulfamethoxazole as well as to ampicillin, chloramphenicol, and tetracycline. Stool cultures from the two children who became ill after the index patient also yielded *S. dysenteriae* type 1 with the same resistance pattern as the initial isolate. Stool cultures from 39 children most likely to have had contact with the index patient were negative, except for one isolate of *S. flexneri* type 4. No additional cases of dysentery have been reported from the orphanage.

#### Rabinal, Baja Verapaz

On March 21, the MOH received a request from health officials in the department of Baja Verapaz (116 miles [186 km] north of Guatemala City) for drugs to treat suspected amebiasis; the health officials reported that more than 100 cases of dysentery had occurred in residents of Rabinal, a community of approximately 10,000 persons. To determine the cause of the outbreak, INCAP investigators traveled to Rabinal and collected stool specimens in Cary-Blair transport medium from 16 persons with dysentery. Eleven samples yielded *S. dysenteriae* type 1, resistant to chloramphenicol and tetracycline. Based on these results, ill persons were treated with trimethoprim-sulfamethoxazole.

On April 2 and 10, investigators from INCAP and the MOH again visited Rabinal. Surveys done by personnel of the local health post showed that at least 540 persons had developed dysentery since early March; two infants had died. Stool samples were obtained from 46 patients with dysentery; 12 grew *S. dysenteriae* type 1. For 10 patients, strains were indistinguishable from those obtained in March. Strains from two patients were resistant to ampicillin, chloramphenicol, tetracycline, and trimethoprim-sulfamethoxazole. One of these resistant strains was from a boy who had taken trimethoprim-sulfamethoxazole prophylaxis for respiratory illness in mid-March. By the end of April, local personnel reported that the number of new cases of dysentery was declining.

Editorial Note: Pandemic *S. dysenteriae* type 1 (the Shiga bacillus) affected Central America from 1969 through 1972. In Guatemala, there were more than 112,000 cases and at least 10,000 deaths. The outbreak spread quickly, with high attack rates in all age groups and the highest incidence and mortality rates in young children. The case-fatality rate estimated from village surveys was 7.4%. Many cases were misdiagnosed as amebiasis, and treatment with antiamebic drugs contributed to the high mortality. Treatment was further complicated by resistance of the epidemic strain of *S. dysenteriae* type 1 to sulfathiazole, chloramphenicol, and tetracycline, drugs commonly used at that time to treat dysentery.

Since 1972, no major outbreaks of dysentery caused by the Shiga bacillus have occurred in Central America. However, in 1988, the number of these infections reported in the United States increased fivefold over the annual mean from the preceding decade, and most ill persons had recently visited the Yucatán peninsula in Mexico. The antimicrobial resistance pattern and plasmid profile were similar to those of the 1969-1972 pandemic strain. In 1989, the number of imported cases decreased in the United States, and outbreaks of documented Shiga infection have not been reported from Mexico.

Appropriate antimicrobial therapy decreases the severity and duration of dysentery caused by *Shigella*. Nalidixic acid is effective therapy for strains resistant to other antimicrobials; the newer quinolones are also effective, but are costly and have not been approved for use in children. Moreover, *Shigella* can rapidly acquire resistance, and are likely to do so in settings in which antimicrobials are commonly used and shigellosis is endemic. The recent cases in Guatemala underscore the need for continued surveillance for enteric pathogens, especially those associated with dysentery. Once *Shigella* are identified, determination of the antimicrobial resistance pattern and the modes of transmission are important in designing control measures. As during the 1969-1972 pandemic, the recent cases in Rabinal were initially misdiagnosed as amebiasis, a misdiagnosis that may be common in some locations. Prompt culturing facilitated the correct diagnosis and appropriate therapy. The appearance of the Shiga bacillus in two locations separated by more than 100 km suggests this pathogen may be present in other areas of Guatemala. The detection of trimethoprim-sulfamethoxazole-resistant strains early in the outbreak highlights the need for continued monitoring of resistance. The MOH and INCAP have requested that any clusters of bloody diarrhea among persons in Guatemala be reported. Training in techniques to identify *S. dysenteriae* type 1 has been incorporated into the courses for workers from regional laboratories; these courses were initiated in response to the current cholera epidemic.

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# **Federal Register**

### **Department of Agriculture**

### **Food Safety and Inspection Service**

### Policy Change; Oversight of Poultry Custom Exempt Establishments

Agency: Food Safety and Inspection Service, USDA.

Action: Notice of policy change.

Summary: The Food Safety and Inspection Service (FSIS) is changing its policy regarding the oversight, in designated States, of poultry custom exempt establishments, i.e., establishments that only conduct poultry custom exempt activities and are not subject to the routine inspection requirements of the Poultry Products Inspection Act (PPIA). The change in policy will result in the discontinuance of the current quarterly reviews of such establishments. Instead, FSIS will vary the frequency of reviews of such establishments and will intensify its review efforts on those custom exempt poultry establishments with a history of noncompliance with the custom exempt requirements of the PPIA, as well as the adulteration and misbranding provisions of the PPIA. FSIS is not, however, changing its review process for custom exempt operations which are conducted at federally inspected establishments.

### Effective date: February 28, 1992.

For further information contact: Dr. Lester Nordyke, Director, Federal-State Relations, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202)720-6313.

### Supplementary Information: Background

Section 15 of the PPIA (21 U.S.C. 464) provides that certain specified slaughtering and preparation operations, referred to herein as custom exempt activities, that are conducted at establishments that conduct such operations for commerce, are not subject to the routine inspection requirements of the PPIA, provided that the specified slaughtering and preparation operations meet the requirements set forth in section 15 of the PPIA and the regulations promulgated thereunder. When these custom exempt activities comprise the total business of an establishment, the establishment is not subject to the routine inspection requirements of the PPIA. However, although these custom exempt activities are not subject to the routine inspection requirements of the PPIA.

In particular, section 15(c) of the PPIA (21 U.S.C. 464(c)) provides that custom operations conducted at an establishment that conducts such operations for commerce are not subject to the routine inspection requirements of the PPIA, if the establishment complies with the regulations promulgated under that section (9 CFR 381.10(a)(4)), which provide, among other things, that: (1) Custom-exempt activities must be conducted under sanitary conditions; (2) custom prepared product must bear the owner's name and address and the statement "Exempted — Public Law 90-492"; (3) the custom slaughter by any person must be of poultry delivered by the owner thereof for such slaughter, and the processing by such slaughterer and transportation in commerce of the poultry products must be exclusively for use, in the household of such owner, by him and members of his household and his nonpaying guests and employees, and (4) the custom slaughterer does not engage in the business of buying or selling any poultry products capable of use as human food.

The custom exempt provisions of section 15(c) of the PPIA (21 U.S.C. 464 (c)) also apply to custom exempt activities conducted at establishments that conduct their operations solely within a State designated for Federal inspection, either because it does not have or is not effectively enforcing an inspection program which imposes requirements at least equal to those of the PPIA. In nondesignated States, i.e., States that operate their own inspection programs, custom exempt activities conducted at establishments that operate solely within that State are governed by the laws of the nondesignated State. However, such States must provide for and effectively enforce State inspection programs that impose requirements which are at least equal to those of the PPIA.

FSIS conducted an in-depth study of its custom exempt activities in red meat custom exempt establishments and in February 1986, issued a report titled "Oversight of Custom Exempt Activities". The study was concluded to assess the effectiveness and uniformity of procedures utilized in regard to red meat custom exempt activities and to develop options and recommendations for improving the oversight of red meat custom exempt activities. As a result of this study, the Agency concluded that the practice of conducting quarterly reviews of red meat custom exempt establishments, referred to in the study as custom exempt plants, was an inefficient use of Agency resources. With rapidly escalating inspection costs and severe budget constraints, FS1S is compelled to make the most efficient use possible of its limited resources, while at the same time continuing to protect the health and welfare of consumers. Therefore, on December 14, 1988, FSIS published a notice in the Federal Register (53 FR 50273) which announced that, instead of quarterly reviews, red meat custom exempt establishments would be reviewed on a risk basis. That is, Agency resources would be allocated to focus more frequently upon those red meat custom exempt establishments that present the greatest possible amount of potential risk to consumers in regard to violating the adulteration, misbranding, or custom exempt provisions of the FMIA (21 U.S.C. 623).

The Agency has determined that custom exempt poultry establishments will also be reviewed on the same risk basis as red meat custom exempt establishments. Since poultry custom exempt establishments are subject to sanitation, adulteration, and misbranding provisions which are similar to those applicable to red meat custom exempt establishments, the Agency is convinced that a similar risk based review system, which has proven to be effective in red meat custom exempt establishments, will be equally effective for reviewing custom exempt poultry establishments.

FSIS will institute an oversight program that will provide for reviews to be scheduled on the basis of a risk assessment of each poultry custom exempt establishment. The frequency of the reviews will be based on the establishment's history of compliance with the custom exemption, adulteration and misbranding provisions of the PPIA, prior reviews, and other information which may be available to FSIS on the establishment's activities. Based on this information, poultry custom exempt establishments will be assigned one of four risk categories. The number of reviews of each establishment will range from a minimum of once a year to once every quarter of a year, with follow-up reviews as necessary depending on the risk category of the establishment.

The four risk categories are differentiated on the basis of risk of public health and/or failure on the part of poultry custom exempt establishments to comply with adulteration and misbranding provisions of the PPIA and the sanitation requirements of the Federal poultry products inspection regulations.

Establishments will receive a Risk Category 1 designation if, upon review, at least one critical deficiency is found, or the owner/operator continuously fails to correct deficiencies. Critical deficiencies are those that are certain to result in adulterated product entering commerce. Risk Category 1 establishments will be reviewed at least quarterly with a follow-up review within 5 days to determine the acceptability of the corrective action. Additional follow-up review may be made if FSIS determines it is necessarily.

Establishments will be designated as Risk Category 2 if, upon review, at least one major deficiency is found. Major deficiencies are those that are likely to result in adulterated product entering commerce. Establishments designated as Risk Category 2 will be reviewed quarterly, with a follow-up on required corrective actions during the next quarterly review to determine that corrective action has been taken.

Establishments designated as Risk Category 3 will be reviewed biannually. These establishments have been found, upon review, to have only minor deficiencies. Minor deficiencies are those that are not likely to result in adulterated product entering commerce.

Establishments designated as Risk Category 4 have been found, upon review, to have no deficiencies. Such establishments will be reviewed annually.

By using a risk-based assessment of poultry custom exempt establishments, the Agency will be able to conduct more frequent reviews of those establishments with a history of noncompliance with the requirements for custom exempt establishments under the PPIA, as well as the adulteration and misbranding provisions of the PPIA.

Under Section 5 of the PPIA (21 U.S.C. 454), the Secretary of Agriculture is authorized, whenever he determines that it would effectuate the purposes the PPIA, to cooperate with the appropriate State agencies in developing and administering State poultry inspection programs that have requirements that are at least equal to those under the PPIA. Under such cooperative agreements, the Federal Government is authorized to contribute up to 50 percent of the estimated total cost of the State program. States that are approved to participate in such a cooperative program maintain a State poultry inspection program and as a part of this program conduct reviews of State establishments that are exempt from inspection under the State laws and regulations. Such reviews are conducted in a manner that is at least "equal to" reviews conducted under the Federal inspection program.

States with their own poultry inspection program will continue their review of poultry custom exempt establishments under the existing cooperative agreements with the Department.

California and Minnesota, which do not operate State inspection programs, and are therefore designated States, presently are conducting compliance reviews of custom exempt establishments in those States under a cooperative agreement with FSIS in accordance with the provisions of 7 U.S.C. 450. Under these cooperative agreements, FSIS reimburses the States for the expenses of reviews. These agreements will be revised to incorporate a risk-based approach to review of poultry custom exempt establishments. FSIS encourages the Governors of any States who desire to enter into a cooperative agreement for conducting compliance reviews of poultry custom exempt establishments that distribute product solely within their borders to contact the appropriate FSIS regional office reviewing custom exempt establishments in their States.

Implementation of this alternate approach to determining the frequency of reviews of custom exempt poultry establishments will not in any way relieve poultry custom exempt establishments of the responsibility to comply with currently applicable provisions of the PPIA and regulations thereunder. The Agency intends to use all its available enforcement tools, where appropriate, to assure that poultry custom exempt establishments comply with all of the applicable provisions of the PPIA and regulations. Such enforcement actions can include, under appropriate circumstances: The detention of poultry and poultry products; the retention of poultry and poultry products and their condemnations, the seizing and condemnation of poultry and poultry products pursuant to judicial procedure; the use of injunctions to prevent establishments from operating in violation of the PPIA and regulations issued thereunder; the institution of criminal action against establishments, their operators and other persons responsibly connected to the establishment; and the removal of exempt status from the establishment.

FSIS would also like to make it clear at this time that when custom exempt establishments that operate in commerce or within a designated State violate the provisions of section 15(c) of the PPIA, they lose their exempt status and can no longer produce product without inspection.

Done al Washington, DC, on November 25, 1991. Ronald J. Prucha, Acting Administrator. (FR Doc. 92-2091 Filed 1-28-92; 8:45 am) Federal Register/Vol. 57, No. 19/Wednesday, January 29, 1992/ Notices.

### HACCP - An Industry Food Safety Self-Control Program - Part III

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### Critical Control Points in the Sequence of Illness, Disease, and Injury Causation

### Input - Precontrol

The diagram, Critical Control Points in the Sequence of Illness, Disease, and Injury Causation, presents the sequence of knowledge and actions which are necessary to control foodborne illness, and points out what can occur without control. It begins by stating that hazards must be correctly understood.

### Poor Government Specification of Controls

Today, hazards are not correctly defined by the government. Hence, the current inspection process looks for defects that are not related to hazards. In order for the industry not to be penalized by the government, it focuses on non-hazard related defects. Unfortunately, the word, "sanitation", is related to most of the unimportant or low-priority variables, to include floors, walls, ceilings, and construction materials of equipment. Even sanitizing can be included in this category because a chemical or heat process to reduce pathogenic and spoilage microorganisms on surfaces is largely ineffective if a surface is not clean. A good cleaning agent, scrubbing/mechanical action, and proper surface rinsing are the key variables in making food contact surfaces microbiologically safe.

Also, risks must be correctly prioritized. A minor case of diarrhea caused by *Clostridium perfringens* is not as serious as death caused by *Campylobacter jejuni* in chicken or turkey. The high-priority pathogens must be addressed first.

Hazards must be correctly controlled. These controls are listed on the diagram.

### **Process** - Operation

Following input, mistakes in the operation must be made, which allow pathogens to multiply to a level which will make people ill, or allow hard foreign objects or chemicals to be passed on to the consumer. Someone must then be exposed to the hazard, and first aid attempts (e.g., the Heimlich maneuver to remove objects lodged in the throat) must be unsuccessful.

### Output

At the output stage, illness can spread. Many people become ill. Some die. Eventually, immunity begins to develop within the community, in the case of pathogens. The community also takes evasive action such as increased hand washing, and the illness/ disease is brought under control.

### Prevention through Improved Knowledge

A critical element of hazard analysis and effective control is the recording of foodborne illness data regarding causes every time a foodborne illness occurs. These data become part of the input process for improved knowledge in order to teach people what to do to prevent foodborne illness. Lack of data is a current major deficiency. The Centers for Disease Control is at least four to five years behind in relating the causes of foodborne illness. The reporting system rarely gives a technical interpretation of the process problems that allow foodborne illnesses to occur. Hence, it is up to the food industry to network, identify threats, know when threats become hazards, and to know and apply the optimum procedures and standards for controlling hazards.

### Foodborne Illness Hazards: Threshold and Quality Levels

### Government Food Safety Standards

While the government acknowledges, as part of its HACCP focus, that one must establish microbiological levels, it refuses to set levels for control. Only three government microbiological standards exist in the U.S. today. For pasteurized chilled food, *Salmonella* spp. and *Listeria monocytogenes* must be undetectable in a 25-gram sample from a lot. The lot size is undefined, which means that a lot could be 2 pounds, or it could be 4,000 pounds of food. This is a weak standard, but nonetheless seems to be sufficient to produce chilled foods that are safe to consume even by immune-compromised people. The standard for canned food is that the center of the can will receive a thermal treatment sufficient to destroy 10<sup>12</sup> proteolytic *Clostridium botulinum* types A or B per gram of product.

### Human Illness Thresholds

There is no such thing as "zero" in microbiology and chemical. Everything has the possibility of being slightly cross-contaminated. "Low" levels are not hazardous. It is impossible to totally keep pathogens out of pasteurized food, and particularly out of raw vegetables and fruits that are served directly to customers. Pathogens will be present in low levels. The table, Foodborne Illness Hazards: Threshold and Quality Levels, lists thresholds at which normally healthy people can be made ill.

### Low-Level Infective Pathogens

Some important points are evident from this table. First of all, *Campylobacter jejuni* is infective at a very low number of microorganisms; 500 in 180 ml milk has been shown to make people ill. Since this microorganism is frequently found in poultry products at levels of 10,000 per gram and higher, it is a major crosscontamination concern in the food preparation environment. *Salmonella* spp., as shown in the table, is not a significant problem, compared with *Campylobacter jejuni*. *Shigella* spp., which is a human fecal pathogen, becomes the control organism for hand washing. In the case of *Shigella dysenteriae*, as few as 10 organisms consumed during a meal can make a person ill.

Currently, the standards for Hepatitis A virus and Norwalk virus are unknown. However, they are probably quite low, in the range of 10 to 100 organisms consumed during a meal. This again highlights the need for a very effective method to remove feces and vomit from fingertips and under fingernails before handling food.

### Toxic Chemicals

The toxic levels of chemicals have been developed and standards have been set by the government to control chemicals. These standards seem to be more than adequate to ensure the safety of food in terms of chemical additives.

biological, chemical, and particulate hazards are correctly understood. The vectors by which they enter the process (people, incoming packages, pests, animals, food, supplies, beverages, water, air, etc are correctly understood. are correctly prioritized and identified as to cause (human or equipment failure).
<ul> <li>ds are correctly controlled.</li> <li>Drganization safety authority and responsibility are assigned.</li> <li>Management has a safety improvement program, and provides resources, follow-through and enforcement.</li> <li>The regulatory authority has correct hazard control goals and requires industry self-control programs.</li> <li>Society requires a safety and legal system that punishes willful industry wrong-doing.</li> <li>Facilities and equipment capability are adequate.</li> <li>Process safety assurance policies, procedures, and standards are effective:</li> <li>Microorganisms multiplication and destruction time, temperature, a<sub>w</sub>, E<sub>h</sub>, pH, preservatives, vacuum or gas atmosphere, competitive microflora.</li> <li>Purposeful and accidental chemical addition and removal.</li> <li>Hard foreign object addition and removal.</li> </ul>
Purposeful microbiological or biological material addition. byces are trained with correct knowledge and hazard control performance is certified before they are given a task to do.
$\downarrow$
PROCESS — Operation
I S

- Safety alarms fail and the food spoils.
- A person is exposed to the hazard. The level is high enough to cause illness, discase, or injury.
- · No one takes evasive action: spitting out the food; washing out the mouth; giving Heimlich Maneuver, etc.
- A person or people become ill or injured. First aid is inadequate.

### $\downarrow$

### OUTPUT

- · Personal illness or injury becomes life-threatening. Illness spreads. People die.
- · Immunity develops in the community.
- Community takes evasive action.
- · Illness/disease diminishes to background level.

### ↓ PREVENTION THROUGH IMPROVED KNOWLEDGE

- Knowledge is gained from mistakes. The system is corrected so that there is less risk of the hazard(s) causing a problem in the future.

### Food Product and Human Pathogen Contamination

In the retail food environment, the major sources of contamination will be the **incoming food products** and the **people who work with the food** (Smith, 1991). The table, **Food Product Pathogen Contamination/Human Pathogen Contamination**, shows that our food is grossly contaminated with microorganisms. Contamination is random, and originates from the farm, ranch, etc., where animals are raised and crops are grown. Fish taken from contaminated water contribute to the problem. Fertilizer containing contaminated manure and contaminated irrigation water are also sources.

### Food Product Pathogen Contamination

Millions of pounds of food products enter the marketplace every day, without any microbiological standards controlling contamination. One must therefore begin with the premise that **all food is contaminated**, in order to have an effective hazard control program, unless one's food suppliers are willing to provide microbiological data and pathogen control information. In the case of foods that are to be eaten raw or rare (cooked to less than 140°F for 12.1 minutes) such as raw beef, shellfish, eggs, etc., it is critical that suppliers provide "pathogen-free" product. This is probably a level of less than one highly infective pathogen such as *E. coli* O157:H7 per 25 grams. This is possible, but the government has no initiative in place to make sure that this will happen.

### Human Pathogen Contamination

Another source of contamination is people. One in 50 people who come to work each day sheds pathogenic organisms without feeling ill. Foodborne illness-causing pathogens can originate from the individual who shows no sign of illness but is shedding pathogens while handling food. Food handlers can bring contaminating pathogens into the food preparation area from the home environment, where one changes baby diapers, helps elderly people, cleans up vomit from sick children, cleans up after pets, etc.

Since people do not always detect their own illnessess or realize that pathogens from other sources may remain on their hands, the only control is **effective removal of transient pathogens from the fingertips and underneath fingernails**, upon arrival at work and after using the toilet.

### Foodborne Illness Hazards: Threshold and Quality Levels

Agent	(Estimated illness	HITM Suggested Purchaser Raw Food Quantity Standards
Bacteria	(Number of microorganisms)	(Number of microorganisms)
Bacillus cereus	3.4 x 10 <sup>4</sup> to 9.5 x 10 <sup>8</sup> /	/g <10 <sup>2</sup> /g
Campylobacter jejuni	5 x 10 <sup>2</sup> in 180 ml mil	k <1/g
Clostridium botulinum	3 x 10 <sup>3</sup> [a]	<1/g [b]
Clostridium perfringens	10 <sup>6</sup> to 10 <sup>7</sup> /g	<10 <sup>2</sup> /g
Escherichia coli	106 to 107 (dose)	
Salmonella spp.		
S. anatum	$10^5$ to >10 <sup>8</sup> (dose) [c]	<10/g
S. bareilly	10 <sup>5</sup> to >10 <sup>6</sup> (dose) [c]	<10/g
S. derby	10 <sup>7</sup> (dose) [c]	<10/g
S. meleagridus	10 <sup>7</sup> (dose [c]	<10/g
S. newport	10 <sup>5</sup> (dose) [c]	<10/g
S. pullorum	$10^9$ to >10 <sup>10</sup> (dose) [c]	<10/g
S. typhi	$10^4$ to >10 <sup>8</sup> (dose) [c]	<10/g
Shigella spp.		
S. flexneri	$10^2$ to >10 <sup>9</sup> (dose)	<1/g
S. dysenteriae	10 to $>10^4$ (dose)	<1/g
Staphylococcus aureus	$10^{5}$ to > $10^{6}/g$ [d]	<10 <sup>2</sup> /g
Vibrio cholerae	10 <sup>3</sup> (dose)	<1/g
Vibrio parahaemolyticus	106 to 109 (dose)	<10/g
Yersinia enterocolitica	3.9 x 10 <sup>7</sup> (dose) [e]	<10 <sup>2</sup> /g
Viruses		
Hepatitis A virus		<1/g
Norwalk virus		<1/g
Chemicals	(Amount in Food)	(Amount in Food)
Monosodium glutamate	0.5% (dose)	<0.05%
Sodium nitrate,		<500 ppm
residuals in smoked fis	h	
Sodium nitrite, residuals in smoked fis	h	<200 ppm
Sulfites	>0.7mg/kg body weigh	ht/day <10 ppm

 [a] Indicates the number of bacteria necessary to produce sufficient toxin for mouse LD<sub>sy</sub>.

- [b] If a product is to be considered shelf-stable above 50°F, then it should be heat processed to reduce a spore population of *Clostridium botulinum* types A and B by  $10^{12}$ , or have a water activity  $(a_w) < 0.86$ , or the pH of the product should be 4.1 or less, or a combination of processes should be used to control the growth of *Clostridium botulinum* types A and B and *Salmonella* spp.
- [c] Results from feeding studies. Data from outbreaks indicate lower values.
- [d] Indicates number of pathogenic bacteria necessary to produce sufficient amount of illness producing toxins.
- [e] Probably lower.

### Food Product Pathogen Contamination

Bacteria	Food	Percent Contaminated
Salmonella spp.	Raw poultry	40-100
	Raw pork	3-20
	Raw shellfish	16
Staphylococcus aureus	Raw chicken	73
	Raw pork	13-33
	Raw beef	16
Clostridium perfringens	Raw pork and chicken	39-45
Campylobacter jejuni	Raw chicken and turkey	45-64
Escherichia coli O157:H7	Raw beef/pork/poultry	1.5-3.7
Bacillus cereus	Raw ground beef	43-63
	Raw rice	100
Listeria monocytogenes	Fresh potatoes	26
	Fresh radishes	30
Yersinia enterocolitica	Raw pork	49
	Raw milk	48
	Raw vegetables	46
Vibrio spp.	Raw seafood	33-46

### Human Pathogen Contamination

Microorganism	Source	Percent Contaminated
Shigella spp., Hepatitis A,		
Norwalk virus, E. coli,	Feces	
Salmonella spp., Giardia lan	mblia	1 in 50 (2 percent) of the employees who
Norwalk virus	Vomit	come to work each day are highly infective.
Staphylococcus aureus	Skin, nose.	,
	boils and	
	skin infect	ions
Streptococcus	Throat	

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# Sanitary Design

### A Mind Set (Part IX)

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### **Pest Control**

Pests cause many seizures of food products by regulatory agencies each year. They are a major factor in the thousands of food complaints reported to these same regulatory agencies, and they feature prominently in many of the prosecutions taken under the regulations.

As discussed in these articles, sanitary design and the control and exclusion of pests such as rodents and insects are closely associated. The subjects cannot be separated when designing new processing plants or renovating existing ones. Pest control must be high on the priority list for each step of the design. After-the-fact remedial procedures are expensive to maintain, hard to implement and must be continuous in order to be effective. If pest control is designed into the facility, the entire sanitation program including the pest control program employed during operations is significantly more effective.

To review designed-in pest control efforts, they start with the outside of the facility. The grounds must be sloped so water flows away from the building and is not allowed to stand in puddles. Puddles make water available to pests and attract them close the facility. The rodent lip installed twenty four inches down on the foundation and extending out twelve inches prevents rats from burrowing under the slab and entering the plant by chewing through felt expansion joints or through drains inside the building. The rodent lip or shelf is often overlooked as a basic design weapon that can prevent rodents from burrowing under the slab. Once under the slab or floor their numbers increase rapidly. Then they find places they can chew through and enter the warehouse, plant and receiving areas.

Pest harborages in food processing facilities can be found within the very structure of the building unless it is designed and constructed to specifically exclude them. If false ceilings must be installed or are already in place, they must have access points installed for inspecting for infestation and instituting control programs. Cavities within walls must be avoided since they become nests for rodents and insects. All parts of the structure should be capable of being easily cleaned including ledges, scale pits and elevator pits.

The design and installation of cables, electrical lines, conduit and electrical motors should eliminate sites for harborage. Motor housings for refrigerators make ideal nesting sites for mice. In addition, structural damage such as holes in walls, loose tiles, and damaged doors should be repaired immediately to prevent infestation of insects and rodents. All ventilation stacks must be equipped with adequate screening to keep out pests. All intake ventilation openings must be adequately proofed to keep the pests from being taken into the HVAC systems. The thinking engineer will look at the food facility with new eyes once there has been exposure to the need for keeping pests out of the facility. The fact that a mouse can enter a plant through a 1/4 inch hole and the largest rat, the Norway Rat, can enter through a hole or opening of only 1/2 inch gives ample evidence that rodent proofing a food plant must be done by conscious effort at each step of a design.

All rodents need moisture so good tight roofs, gutters that will not drip and the elimination of standing water in and around the plant will make the area unattractive to all forms of pests.

However, despite good proofing design and built-in precautions, rodents, insects and birds will sometimes get into a building. There is, however, a large difference between the occasional invader and the establishment of a stable population running wild in and around the establishment. To control these occasional invaders there must be a sanitation and pest control program in place and adhered to by the plant personnel. Authority and responsibility for such programs should be assigned to a senior person within a company who should be held responsible for the effectiveness of the program.

### **Employee Facilities**

Pest control is a concern for the entire food processing facility. It is not confined to just the processing or warehouse and storage areas. Prime locations for pest infestations are the employee facilities. These areas are usually built to be comfortable for employees and therefore present optimum conditions for other creatures.

Breakrooms and lunchrooms are especially vulnerable due to the presence of food in the form of crumbs, moisture and constant exposure to people coming and going from the outside. These facilities should be designed and built with cleanable interiors, coved wall floor junctions and smooth, water impermeable walls. The ceilings can be the drop type but there should be good access to the overhead space for control programs. Fixtures installed in break and lunchrooms such as drinking fountains, vending machines, ice machines etc., are to be mounted far enough away from the walls so the space between the back of the fixture and the wall is visible and accessible for routine cleaning. They should be mounted high enough off the floor (at least six inches) so the floor can be cleaned under them. A workable alternative to mounting them permanently is to install them on wheels so they can be rolled aside for cleaning. The plant sanitation program should also include these employee areas. Depending on the degree of usage, these areas require pickup and cleanup after each major break and a thorough washdown at least once a day. It is given that wherever and whenever people congregate there will be a need for a cleanup after they leave.

The correct design of restrooms and locker rooms is often given short shrift in the overall sanitary design of a food processing facility. Every food processing facility should have a place separate from the processing, storage or warehouse where employees can safety store their personal belongings and street clothes while working on the processing lines. Usually these places are locker rooms adjacent to toilet facilities.

The basic design criteria for the location of toilet facilities and locker rooms places them away from the processing areas. In a properly designed plant, toilets, locker rooms etc., shall not open directly into a processing room or any area where there is exposed food, ingredients or product in progress. These toilet facilities should operate under negative air pressure and the internal air shall be exhausted directly to the outside. Older plants that have toilets opening directly onto the process floor should be renovated so these toilets are moved to another location or a vestibule or modified air lock system of doors can be installed.

Good locker room designs include washable floors, coved wall-floor junctions and easy access for cleaning. The lockers themselves should be mounted tight to a pedestal so there are no spaces for insects to inhabit and lodge. The tops of the lockers should be sloped at a sixty degree angle so nothing can be stored on their tops. In addition, a routine program that requires employees to periodically clean out their lockers to allow the plant sanitarian to inspect, clean and effect a pest control program, if needed, is necessary in order to prevent this area from becoming a source of contamination for the rest of the plant.

Personal hygiene and providing facilities that promote personal hygiene cannot be overstressed in the design and operation of a food processing plant. Employees that are in direct contact with food in process or with exposed finished product should have good access to hand washing facilities on the process floor as well as in the restrooms.

Some food handling procedures require the employees to sanitize their hands after washing them prior to handling the food. Most food plants provide dip stations containing sanitizing solution appropriate to the types of products being produced. One company has introduced an automatic hand washer and sanitizer which can be used to replace the manual dip stations. There are a number of reports of tests results that accompany the literature for the equipment that show it is effective in reducing the microbe counts on the hands of food handlers.

Some of the more common organisms that cause foodborne illness that can be traced to the lack of personal hygiene in food handlers are as follows:

> Campylobacter Dysentery Escherichia coli Staphylococcus aureus Hepatitis A virus Salmonellosis Typhoid and paratyphoid

In a well-designed plant the criteria established for the restrooms and lockers rooms for the line workers should also apply to similar facilities designed for supervisory and office personnel, especially if they are required to be on the process floor or have occasion to visit the processing lines.

### References

Springer, Richard A. 1991. Hygiene for Management, pp. 72-79, Highfield Publications, England.

# **Industry Products**



### New Temperature Cycler -Autogene II

Science/Electronics announces a new temperature cycler, AUTOGENE II, with enhanced performance and reliability. This unit responds to the increasing requirement for automation of laboratory procedures in the area of molecular biology and related disciplines.

Autogene II delivers exceptional accuracy ( $\pm 0.5^{\circ}$ C) and uniformity ( $\pm 0.2^{\circ}$ C). It employes a small stirred bath, taking advantage of the excellent thermal transfer properties of water. The performance and temperature control obtained are enhanced by the addition of stirring. This allows for fast cooling rates and significantly reduced cycle time resulting in reduced time for the entire program.

The user can be confident that the protocols are precisely repeatable and that procedures can be carried out efficiently and with maximum productivity. The exceptional uniformity of temperature ensures the same high yield from all reaction vessels.

The Autogene II is compact, rugged and easy to maintain. Programming is done on a front membrane key panel. LED's and a mimic display guide the user through the programming procedure and allow the user to identify status during temperature cycles. A cycle consists of up to (3) user-defined temperature set points and old periods. Up to (50) programs can be stored, each composing up to (99) repeats of a cycle as well as pre- and post-temperature parameters. This allows the user to run programs repeatedly without needing to reset the parameters. This new machine has the facility to link programs, providing greater flexibility and allowing parameters to be varied throughout the procedure. Up to (10) programs can be linked and stored for re-use. SCIENCE/ELECTRONICS - Dayton, OH

> Please circle No. 266 on your Reader Service Card

# Automated Enumeration of Bacteria

Radiometer America Inc. is pleased to announce the availability of the "Conversion" software for use on the Malthus 2000 microbiological analyzer. Results of conductance microbiological tests can now be expressed as number of organisms, as well as, detection time.

This new feature will benefit the microbiological laboratory by increasing the automation of data analysis, simplifying and improving the efficiency of report production.

The Malthus 2000 microbiological analyzer is providing rapid automated microbiological testing in QC and R&D laboratories in the food and cosmetics industries worldwide. In addition to the cost benefit of rapid results, and the confidence of internationally approved testing methods, Radiometer America Inc. ensures that the latest software developments are available to benefit its users.

Radiometer America Inc. - Westlake, OH

Please circle No. 267 on your Reader Service Card

New Brochure Describes Features of Tank Washing Nozzles for Industrial and Food Processing Markets

A new eight-page bulletin published by Spraying Systems Co. focuses on the design features of fixed and rotary spray nozzles and tank washers that clean any vessel interior from keg size to tank cars.

Performance data graphs accompany each of the eight product lines while specifying flow rates at varying pressures and pipe extension lengths. Dimensions and inlet connection sizes are also given.

Products treated in the brochure include the new TEFLON® Rotary Washing Nozzle with multiple orifice contiguration and 360° coverage. Other products include motor-driven and airdriven tank washers, multiple orifice nozzles and special nozzles for cleaning drums and kegs.

Spraying Systems Co. manufactures more than 19,000 different types of spray nozzles and accessories for hundreds of industrial applications.

Spraying Systems Co. - Wheaton, IL

Please circle No. 268 on your Reader Service Card



### Carl Zeiss Inc. Introduces New Line of Microphotometers with Wide Spectral Range

Carl Zeiss, Inc. has introduced a new line of microscope photometers, models MPM 400 and MPM 800, to fulfill the most exacting microspectro-analysis demands. Used in a variety of disciplines, including bio-medical research, material science, industry, and forensics, the MPM series cover a wide spectral range from the UV (240 nm) to the NIR (2100 nm). This flexibility allows the user to maximize accurate sample information non-destructively with precision and accuracy.

Zeiss research microscopes, featuring ICS (Infinity Color Corrected System) form the cornerstone of the MPM series, providing ideal optical conditions for top performance photometry.

For special analysis the MPM 400 features a detector side grating monochromator, while the MPM 800 can be equipped with illumination side and detector side monochromators - both with a resolution of up to 1 nm. The MPM provides simple and quick measurement such as transmission/absorbance, reflectance and fluorescence spectra.

An optional high precision motorized scanning stage with a resolution of .25 micron and a large overall travel is available.

Dedicated software permits spectrophotometric analysis, statistical and kinetic analysis, as well as one or two dimensional photometric mapping. Even a minute object or substance of 1 square micron may be reliably located and analyzed.

Carl Zeiss, Inc. - Thornwood, NY

Please circle No. 269 on your Reader Service Card



### New Ashcroft 1032 Sanitary Gauge

The New Ashcroft 1032 Sanitary Gauge serves pharmaceutical, dairy, food processing, biotechnology and filtration applications where clean surfaces and easily removable instruments are prime concerns. These instruments are also very suitable for quick connect clamping utilized in breweries, distilleries, wineries and citrus juice production plants.

The patented Ashcroft® Duralife spring suspended movement resists the effect of pulsation and vibration and contributes to an extended gauge life which reduced down time normally associated with pressure gauge repairs.

Dresser Industries -Stratford, CT

Please circle No. 270 on your Reader Service Card

### Tri-Clover Offers New Catalog Featuring T-Series Pumps

A new catalog, featuring the T-Series Modular Rotary Lobe Pumps, is currently available from Tri-Clover, Inc.

The four color, eight page catalog offers detailed descriptions of all three basic models the TSR, TSK and TSC — that comprise the series. The catalog offers an overview of the series' modular concept and its adaptability to a variety of uses.

In addition, the catalog features a cut-away diagram detailing key elements of each pump group, and the various option each offers. Performance ranges, actual pump dimensions and a chart depicting product numbering system are also included in the catalog.

Headquartered in Kenosha, WI, Tri-Clover, Inc. is a leading manufacturer of sanitary stainless steel valves, pumps and fittings, as well as flow control, batch/weigh and Clean-in-Place (CIP) systems.

Tri-Clover, Inc. - Kenosha, WI

Please circle No. 271 on your Reader Service Card



### Introducing 1991 Gratings & Floorings Catalog from McNichols Company

McNichols Co. is pleased to introduce their newest catalog edition for **Gratings & Floor**ings. Featured are their new product lines:

> Diamondback™ Deck Plate Lambda-Lok® Pro-Kote™ Floor Plate

Other products covered in his edition are: Grate-Lock Grating, Tread Grip Flooring, Grip Strut Grating, Open-Grip Grating, Unagrate, Flexmat Flooring, Bar Grating and more. The catalog also includes the latest technical information such as product specifications, load tables, applications and many new photographs.

McNichols Company - Tampa, FL

Please circle No. 272 on your Reader Service Card

### New Medium for Detecting and Enumerating Enterobacteriaceae including Salmonella and Shigella

Detection and enumeration of *Enterobac*teriaceae from food and dairy products is now possible using Violet Red Bile Glucose Agar. This medium which contains glucose clearly shows the presence of glucose fermenting *Enterobacteriaceae* including *Salmonella* and *Shigella* by the pour plate technique. The presence of these organisms in processed foods demonstrates unsatisfactory processing and a failure in Good Manufacturing Practices or recontamination of the food.

The World Health Organization recommends the analysis of *Enterobacteriaceae* when examining foodstuffs due to the considerable variation in results when using coli-aerogenes or the coliform group. Violet Red Bile Glucose Agar is widely used in Europe for evaluating food processing practices.

The ingredients and composition of Violet Red Bile Glucose Agar will inhibit the growth of non-fermenting Gram-negative bacilli and Grampositive bacteria, while supporting growth of glucose fermenting *Enterobacteriaceae*. Included in the *Enterobacteriaceae* group are important glucose fermenters such as *Salmonella*, *Shigella*, non-lactose fermenting strains of *E. coli*, *Kleb siella* and *Citrobacter*. Since it has been noted that *Klebsiella* and *Citrobacter* are more resistant to heat, a medium such as Violet Red Bile Glucose Agar which detects these organisms, can be especially beneficial for analyzing food safety. **Difco Laboratories - Detroit, MI** 

> Please circle No. 273 on your Reader Service Card



### New! Pocket Digital Thermometer introduced by Universal Enterprises

Filling the need for a high quality yet affordable, pocket digital thermometer, UEI has introduced the PDT300. Unlike other pocket thermometers currently on the market, the PDT300 is designed with data hold operation, auto power off, a  $-40^{\circ}$ F to 300°F temperature range, and it fits in your pocket just like a pen — with no bulky head or small parts to get in the way or lose. The PDT300 is also ruggedized and water resistant for added durability.

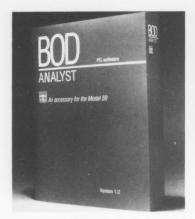
The unique data hold button on the PDT300 allows measurements to be taken in tough-toread locations. By pressing the button, the temperature reading will be held on the LCD display, allowing the unit to be moved to a readable location without loss of accuracy.

To preserve battery life, the PDT300 features an on/off button and auto power off. After three and one half minutes not in use, the unit automatically shuts off.

The PDT300 can be used to measure and monitor temperatures in the Climate Control, Automotive, Laboratory/Scientific, and Food Service Industries.

Universal Enterprises - Beaverton, OR

Please circle No. 274 on your Reader Service Card



### New PC Software Automates BODs Using YSI DO Meter

BOD Analyst, exclusive new PC software from YSI, automates 5-day BODs using the YSI 59 Dissolved Oxygen Meter.

The menu-driven software manages collection of the data, matches initial and final results, does the calculations and prints the results in a report.

The program organizes the BOD analysis into samples, sets of samples and batches, which the user defines. The program will prompt the user for a bottle number and the DO readings for each dilution in a batch. The user can enter bottle numbers directly with an optional bar code reader, from the Model 59 keypad or from the PC keyboard.

YSI, Inc. - Yellow Springs, OH

Please circle No. 275 on your Reader Service Card

### Tekmar Offers A Full Line of PTFE Labware

Here is the complete line of PTFE labware to meet practically any of your laboratory needs. All these products are suitable for a wide range of laboratory applications due to their high chemical inertness. Manufactured of pure PTFE, they can be safely used in a wide temperature range (cryogenic - ca. 280°C) and if accidentally heated above their 370°C melting point, they will remain rigid. Items include: screw cap bottles, beakers, stirring rods, stirring bars, grinders, bellows connectors, glass joint sleeves, and a reagent dispenser.

Tekmar Company - Cincinnati, OH

Please circle No. 276 on your Reader Service Card



### LabSolutions™ Detergent Makes Laboratory Glassware Sparkle

Labconco Corporation, Kansas City, Missouri, offers LabSolutions Detergent, specially formulated to clean labware in Labconco SteamScrubbers and FlaskScrubbers or any automatic laboratory glassware washer which uses a powder formula detergent.

LabSolutions effectively removes most lab contaminants such as grease, blood, agar and protein digestates from glassware. LabSolutions then rinses completely leaving clear spot-free sanitized glassware for even the most critical procedures.

LabSolutions' special formulation prevents damage to machine pumps, seals and gaskets, and its non-foaming action prevents leaks caused by excessive suds. LabSolutions is available in 10 and 30 pound pails. A scoop is included inside every container to ensure accurate measurement.

> Labconco Corporation -Kansas City, MO

Please circle No. 277 on your Reader Service Card

### Weber Scientific's NEW Products for Dairy, Water and Food Analysis Catalog

Weber Scientific announces the publication of their 1992 Catalog featuring products for dairy, food, and water analysis. This greatly expanded catalog contains 72 pages with over 1000 items arranged by test category for easy reference.

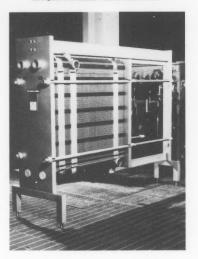
Highlights include a comprehensive selection of bacteria detection supplies (including direct microscopic methods); a broad selection of sterile and reusable sampling containers; apparatus and reagents for testing butterfat (Gerber, Babcock and Mojonnier methods), antibiotic and mycotoxin residue tests; specialized thermometers, refractometers and pH meters. Also featured are sanitarian supplies, general laboratory apparatus as well as equipment for testing moisture, sediment and pasteurization efficiency.

A new 11-page section, devoted to water testing, features EPA clean sampling supplies, BOD and membrane filtration equipment, handheld testers and EPA accepted instrumentation and test kits.

This easy-to-use handbook, dedicated to dairy, water and food testing, is being distributed to thousands of laboratories throughout the United States and Canada.

Weber Scientific - East Windsor, NJ

Please circle No. 278 on your Reader Service Card



Worldwide Intro of "ClipLine" Plate Heat Exchangers by Alfa-Laval at DFISA Expo in Chicago

Alfa-Laval Food & Dairy Group recently announced the worldwide introduction of the ClipLine, a line of newly-designed, easy-maintenance plate heat exchangers.

Features of the ClipLine include gluc-free, clip-on gaskets for easy re-gasketing; high thermal efficiency; gentle product treatment; and the availability of a wide range of plate materials, including stainless steel and titanium.

Alfa-Laval's patented flow distribution pattern permits high uniformity of product flow across the plates. The plates are available in two chevron designs with high or low turbulence values which utilize a thermal-efficient pattern with a deep pressing that minimizes fouling. The largest of the plate heat exchangers can pasteurize up to 160,000 pph with high heat recovery. Plates can remain hanging in the frame while the clip-on gasket is changed, simplifying maintenance.

"The Clip 8, the first in the ClipLine, represents the culmination of Alfa-Laval's more than fifty years of design and manufacturing experience in the field of plate heat exchangers," said Don Bohner, Product Manager, Alfa-Laval Food & Dairy Group. "Its higher heat transfer coefficients, attractive pricing, and other distinctive features make it right for food and dairy industry applications."

> Alfa-Laval Food & Dairy Group-Pleasant Prairie, WI

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# Synopsis of Papers for the 79th Annual Meeting

The following are abstracts of papers to be presented at the 79th Annual Meeting of the International Association of Milk, Food and Environmental Sanitarians, Inc., to be held in Toronto, Ontario, July 26-29, 1992.

Isolation of *Salmonella enteritidis* from Pooled Egg Samples as a Screening Method for Detecting Infected Laying Hens, Richard K. Gast\*, Microbiologist, USDA, ARS, Southeast Poultry Research Lab, 934 College Station Road, Athens, GA

The association of human Salmonella enteritidis (SE) outbreaks with the consumption of eggs has necessitated the implementation of programs to identify SE-infected flocks of laying hens. These programs have generally applied serological and bacteriological tests to samples from hens and poultry houses. Sampling eggs for SE would provide a much more direct assessment of the risk to public health posed by particular flocks, but contaminated eggs are evidently produced infrequently and often contain very small numbers of SE.

The present study sought to evaluate the effectiveness of sampling pools of fresh eggs for detecting SE-infected flocks of laying hens. Artificially contaminated eggs were used to examine methods for sampling egg pools of various sizes. A method involving incubation of homogenized pools of egg contents before culturing was found to be capable of recovering the small numbers of SE likely to be encountered in naturally contaminated eggs. When such a method was applied to eggs from experimentally infected laying hens, egg sampling was at least as effective as serological testing or bacteriological sampling of voided fecal material for detecting infected hens.

Survival of *Listeria monocytogenes* on the Surface of Egg Shells and During Frying of Whole and Scrambled Eggs, R. E. Brackett\*, Assoc. Professor, and L. R. Beuchat, Food Safety and Quality Enhancement Laboratory, University of Georgia, Griffin, GA 30223

The survival of Listeria monocytogenes on shell eggs and after cooking raw whole and scrambled eggs by frying was determined. Samples were inoculated with low or high populations of a five strain mixture of L. monocytogenes. Survival of the organism on shells of unbroken eggs was monitored over a 6week storage period at 5° and 20°C. Presence and populations of L. monocytogenes were determined using enrichment in tryptic soy broth and/or plating on Lee Modified Oxford (MOX) agar. Both low (10<sup>2</sup> cfu/egg) and high (10<sup>4</sup> cfu/egg) populations of L. monocytogenes on the surface of egg shells decreased to < 10 cfu/ egg after 6 days of storage at 5 and 20°C. Frying whole eggs reduced both low (10<sup>2</sup> cfu/g) and high (10<sup>5</sup> cfu/g) populations of L. monocytogenes by only about 0.4 log10 cfu/g. In contrast, frying 1 or 3 scrambled eggs reduced low ( $10^2$  cfu/g) populations of L. monocytogenes to undetectable and  $< 10^2$  cfu/g, respectively. Frying 3 scrambled eggs containing high (10<sup>5</sup> cfu/g) populations caused a reduction of about 3 log<sub>10</sub>. Frying 1 scrambled egg containing a high population resulted in  $< 10^2$  cfu/g populations. Both low (10<sup>4</sup> cfu/g) and high (10<sup>7</sup> cfu/g) populations of L. monocytogenes remained unchanged or decreased slightly where raw slightly beaten whole eggs were allowed to stand for up to 3 h at 20°C.

Heat Stability of *Listeria Monocytogenes* in Liquid Egg, Dr. F. M. Bartlett\*, A. Hawke and G. E. Millard, Centre for Food and Animal Research Agriculture Canada, Ottawa, Ontario K1A 0C6

Pasteurized liquid egg products have become increasingly popular with the food industry, especially the hotel-restaurantinstitutional (HRI) sector because of their convenience and versatility. The current pasteurization procedures were developed primarily for the destruction of Salmonella however, there is now concern about their effectiveness in controlling Listeria monocytogenes. In this study the heat resistance of three strains of L. monocytogenes was determined in liquid whole egg and liquid volk, with and without added NaCl or sucrose. Decimal reduction times (D-values) were determined for each strain at temperatures from 60 to 70°C. The results showed that L. monocytogenes, especially the Scott A strain, could survive the typical pasteurization treatment of 60°C for 3.5 min. in whole egg. The addition of 10% (w/w) NaCl to the whole egg and the yolk dramatically increased this pathogen's heat resistance with D-values in excess of 20 minutes at 63°C. It was concluded that existing egg pasteurization treatments are not sufficient to ensure that such products will be free of Listeria.

Health Risk Assessment of Undrawn (New York Dressed) Poultry in Ontario, Dr. P. Johnson\*, Meat Scientist, T. Baker, M. Getz, J. Lynch, and M. Brodsky, Livestock Inspection Branch, Ontario Ministry of Agriculture & Food, RR 5, Box 10330, Guelph, Ontario N1H 6N1

Undrawn or New York Dressed (NYD) poultry is exempt from inspection in Ontario, but has traditionally been graded by Federal graders. Change to Federal legislation prohibits grading of uninspected product, thereby prohibiting sale since provincial legislation requires grading before sale. This study was developed to assess the health risks associated with this product and to determine the feasibility of an inspection system based on onfarm, antemortem and external inspections with in-plant sampling for post-mortem inspection. Five plants participated in the study, which involved collection of on-farm flock history from producers. Following antemortem inspection all NYD-processed birds were inspected externally. A sample ranging from 3-10% depending on volume was randomly selected for post-mortem inspection. Microbiological sampling was conducted on five each of Control (eviscerated), NYD, NYD with feet removed, NYD with head removed, for aerobic plate count, coliform/E. coli, Campylobacter jejuni and Salmonella; each plant was visited three times. Bird types included ducks, fowl, capons, broiler chickens and roasting chickens. Differences in microbiological profile were more strongly related to plants, growers and bird types than to process. External inspection resulted in few condemnations; condemnation rates based on external inspection were strongly correlated with bird type. Post-mortem condemnation rates were related more to bird type than to process. This study has allowed the development of inspection standards for processing of NYD poultry.

# Affiliate News



Steven Halstead (1), Executive Manager, IAMFES, presents Paul Derman (r) a certificate of Appreciation for his outstanding work as NYSAMFS Executive Secretary.

### NYSAMFS Hold 68th Annual Meeting in Syracuse

The 68th Annual Conference of New York State Association of Milk and Food Sanitarians was held September 24-26, 1991 in cooperation with Cornell University Food Science Department, Institute of Food Science, New York State Department of Health and New York State Department of Agriculture and Markets. Held at the Sheraton Inn, Liverpool, NY, around 300 persons registered for the event.

Formal activities began on Tuesday evening with a talk on Chemical Dependency in the workplace given by Christopher Cederquist from Help People, Crouse-Irving Memorial Hospital. The General Session on Wednesday began with President John B. Baker's Presidential Address. Keynote speakers for this general session included Robert Bliss, ICI Professional Products, who discussed the topic "Food Watch." Also, a talk on "Thoughts on Handling Adversarial Situations" was given by Donald Tobias of Cornell University. The 1992 IAMFES Annual Meeting scheduled for Toronto was addressed by Michael Brodsky of Toronto, Ontario, Canada.

Concurrent Sessions highlighted the Wednesday afternoon program for laboratory, field and food personnel.

Flavor Defects and Corrective Actions, Potable Water Testing for Coliform & E. coli., Environmental Sampling and Sanitation in Plants and a USPH Update were subjects of experts in the laboratory session. At the same time, in the fieldman's session, topics included presentations on Consumer Perspectives on Food Safety, a Question and Answer Panel on Farm Inspection and Farm Equipment Problems, PMO Changes and Equipment Approval Process for Aseptic Products.

At the Food Session, conferees heard discussions on Supermarket Deli training, Anaerobic Ecology of Reduced

### Upcoming IAMFES Affiliate Meetings

1992

### APRIL

•1, Ohio Association of Milk, Food & Environmental Sanitarians Annual Meeting will be held at the Monte Carlo Restaurant, Columbus, OH, located at 1-270 and Cleveland Avenue. Registration 8:30 a.m. Featured speaker will be Doug Young, OH Department of Health. For more information contact Don Barrett, Health Department, 181 S. Washington Boulevard, Columbus, OH 43215; (614)645-6195.

•7-10, Missouri Milk, Food and Environmental Health Association's Annual Educational Conference will be held at the Ramada Inn, Columbia, MO. For more information contact Richard Janulewicz, Clay County Health Department, 1940 W 152 Highway, Liberty, MO 64068; (816)781-1600.

•9, Associated Illinois Milk, Food & Environmental Sanitarians Spring Conference will be held at the Carlisle, 435 E. Butterfield Road, (Rt. 56), Lombard, IL. For more information contact Robert A. Crombie, Secretary, AIMFES, 521 Cowles, Joliet, IL 60435; (815)726-1683.

### MAY

•5-6, California Association of Dairy and Milk Sanitarians will meet in Sacramento, CA. For more information contact John Bruhn at (916)752-2191.

•11-12, Florida Association of Milk, Food and Environmental Sanitarians Annual Meeting (Taste of the Future — Food Safety), will be held at the Marriott, International Drive. For more information contact John Chrisman, General Mills, (407)850-5330 or Jack Dodd, Florida Department of Agriculture, (904)487-1470.

### JUNE

•2-3, Texas Association of Milk, Food & Environmental Sanitarians Annual Meeting will be held at the Howard Johnson South Plaza, 3401 South IH-35, Austin, TX. For more information contact Janie Park, P.O. Box 2363, Cedar Park, TX 78613-2363; (512)458-7281.

•5, Tennessee Association of Milk, Water & Food Protection's Annual Meeting will be held at the Ramada Airport, Nashville, TN. For more information contact Dennis Lampley, 7346 Sack Lampley Road, Bon Aqua, TN 37025; (615)360-0157.

Oxygen Foods, Label Statement Refrigeration Guidelines, Hand Contact with Exposed Foods and the Hazards in Food.

Triple Sessions on Thursday morning, September 26th, included Fieldman Topics on Refrigeration Requirements and Troubleshooting, Driver Safety and an FDA Update. Laboratory Personnel heard about Safety Infractions and Fines, OSHA On-Site Inspections and Use of HPLC's in the Contract Laboratory Environment. At the Food Sanitarians Session, conferees heard discussions on Supermarket Deli Training, Anaerobic Ecology of Reduced Oxygen Foods, Label Statement Refrigeration Guidelines, Hand Contact with Exposed Foods and the Hazards in Food.

Both the Past Presidents and the Council of Affiliates held luncheon meetings. At the council luncheon, the Penn-York Sanitarians Affiliate received the annual "Affiliate of the Year Award."

At the Awards Banquet, five major awards were presented including the Emmet R. Gauhn Memorial Award which was given to Douglas Friend, long time member and supporter of our association and former Chair and Laboratory Practices Committee member. The EMMET R. GAUHN Memorial Award is the Association's highest honor and is given in memory of the Association's first President whose foresight, diligence and devotion to the cause of progressive milk sanitation serve as an inspiration and guide to the members of the association. Following the award presentations, Leonard H. Jones, Dairy Specialist and Area Sales Manager, IBA Inc., Vernon, New York was advanced to President of the New York Association. Mr. Jones succeeded John B. Baker, Supervising Food Inspector, NYS Dept. Ag. & Markets. Walter C. Wasserman, Milk Marketing Specialist, New York State Cooperative Extension was elected to the Executive Board. There was, of course, a full course of activities for the spouses.

### Illinois Affiliate Plans for 1992 Meetings Announced

The Spring Conference of AIMFES will be held on Thursday, April 9th at the Carlisle, 435 E. Butterfield Road, (Rt. 56) in Lombard. Registration will begin at 8:00 a.m. and the morning session at 9:00 a.m. The morning session is titled "T.Q.M" (Total Quality Management) and, after the included lunch in this famous banquet facility, two afternoon sessions. One will be on food regulation and safety, the other on dairy industry issues. The conference is open to members and all interested in these issues. For further information contact the Secretary.

AIMFES, in cooperation with U.S. Food & Drug Administration and the Illinois Department of Public Health Division of Food, Drug and Dairies, will sponsor a series of one-day dairy farm and Grade A processing workshops in Illinois. There will be a nominal charge for registration. Contact IDPH at (217)782-6562 or Charles Price, FDA, at (312)353-9407 or the AIMFES Secretary.

Farm workshops will include current policy and inspection procedures relating to drug residue screening, water supplies and general inspection criteria. Producers, fieldmen, regulatory sanitarians, farm equipment installers and other interested parties are invited. Dates and locations are: March 17, 1992 at Carlinville, IL; March 19, 1992 at Freeport, IL. (Specific locations TBA).

The plant workshops will include current policy and inspection procedures on drug residue screening, new process technology and plant inspectional criteria and procedures. Plant operators, department supervisors, quality control people and regulatory sanitarians are especially invited. Any interested person may also attend. Dates and locations are: June 2, 1992 at McDonalds Corporation, McDonald Plaza, Oakbrook, IL; June 4, 1992 at Springfield, IL. (Location TBA).

The AIMFES fall seminar and annual meeting will be at the Carlisle on October 20, 1992.

Additional information on all these conferences will be provided in the AIMFES, Newsletter. To be sure you are on the mailing list, or for further information contact: Robert A. Crombie, Secretary, AIMFES, 521 Cowles, Joliet, IL 60435; (815)726-1683.

### Developing Scientist and GAFES Young Investigator Award

At the Annual IAMFES Meeting, students have the opportunity to compete for the best student research paper and presentation. In 1991, Eric Line, a Ph.D. student in Food Science and Technology at the University of Georgia, received the third place award.

Earlier in the year, Eric received the GAFES Young Investigator Award. GAFES presents this award annually to provide travel assistance to students to attend the Annual IAMFES Meeting and to compete in the Developing Scientist Competition. GAFES encourages other students involved in food sanitation or microbiology research to apply for the Young Investigator Award this year.

Reprinted from the GAFES Report, Vol. 6, No. 1, January, 1992.

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# Preview of the 79th IAMFES Annual Meeting

### Monday Morning, July 27

### **Technical Session - Foodborne Pathogens**

- Isolation of Salmonella enteritidis from pooled egg samples as a screening method for detecting infected laying hens
- Survival of Listeria monocytogenes on the surface of egg shells and during frying of whole and scrambled eggs
- Heat stability of Listeria monocytogenes in Liquid Egg
- Health risk assessment of undrawn (New York Dressed) poultry
- in Ontario
   A comparison of antilisterial activity of two lactic starter cultures in chicken summer sausages
- · Control of Escherichia coli O157:H7 by Fermentation
- Thermal Destruction of Listeria monocytogenes in Reduced Salt Uncured-Restructured Meat Product
- Bacterial growth and survival in vacuum packaged beef during extended refrigerated storage
- Effect of growth nutrients on attachment of Listeria monocytogenes to stainless steel
- Simultaneous growth of Listeria monocytogenes and Listeria innocua in pure culture and food systems
- Accelerated growth of Listeria monocytogenes by moulds
- The 1991 Cholera Epidemic in Latin America and the FDA Actions in Response

### Technical Session - Dairy Microbiology

- Detection of latent coliforms in pasteurized milk
- Identification of milk enzymes for monitoring heat-treatments applied to milk
- · Adaption to Acid Promotes Survival of Salmonella in Cheese
- Microbiological Safety of Blue and Cheddar Cheeses Containing Naturally Modified Milk Fat
- Behavior of Listeria monocytogenes in Cold-pack Cheese Containing Nisin During Storage
- Extension of shelf-life of cottage cheese using monolaurin
- The use of epifluorescent and phase microscopy in evaluating mixed biofilms
- Elimination of Surface-Attached Bacteria by Detergent Washing and Chemical Sanitation in a Dynamic Flow System
- A Novel System of Sanitation, Disinfection and Sterilization Effective Against Biofilms
- Effect of cold temperature on germicidal efficacy of quaternary ammonium compound, iodophor and chlorine on *Listeria*
- Assessment of handling conditions and quality of milk in Oregon public schools
- A comparison of commercially processed fluid milks held at 7.2°C (45°F) for 10, 12 and 14 days

### Milk Quality Symposium

- Making Decisions for Therapy of Clinical Mastitis: Impact on Potential Residues
- Factors Associated with Inhibitor Violations on Ontario Dairy Farms
- Cowside Antibiotic Residue Tests: Current Status on Availability, Use and Interpretation

- Verotoxigenic E. coli Contamination of Milk and Associated Risk Factors
- Milk Quality Improvement Initiatives for the Ontario Dairy Industry
- Dynamics and Trend Analysis of Bulk Milk SCC Data
- Relationship of Milking Machine Design and Function to Milk
   Quality

### Scientific Poster Session

- The growth and survival of *Vibrio* sp. as determined by pH, acidulant, time and temperature
- Rapid assay for *Bacillus* proteinases in raw milk as detected by a simple casein denaturation method
- Application of a recording thermometer to monitor cleaning and sanitizing procedures for farm raw milk transport lines
- Microbial and Chemical Analysis of Mexican White Soft Cheese and its Relationship with the Content of Histamine and Tyramine
- Survival of Salmonella typhimurium, Escherichia oli O157:H7 and Listeria monocytogenes Scott A During Storage on Beef Sanitized with Organic Acids
- Use of phenols and liquid smoke to control Listeria monocytogenes
- Fate of Listeria monocytogenes in modified-atmosphere packaged turkey roll
- Fate of *Escherichia coli* O157:H7 in Fermented, Dry Sausage and in Modified Atmosphere Packaged Beef
- Frequency of false presumptive positive results obtained using a commercial ELISA kit to screen retail ground beef for *Escherichia coli* O157:H7
- Incidence of low levels of enterotoxin-producing Bacillus cereus in routine surveillance food samples
- Dimorphism in shigella sonnei as it related to Retention of Biochemical and Serological Characteristics
- Accessibility to chlorine of bacteria attached to or entrapped in poultry skin
- Low Dose UV and Gamma Radiation on Shelf-life of Peaches
- Incidence of bacteria on smear-ripened cheeses able to inhibit Listeria monocytogenes
- Effectiveness of a Modified Salmonella-Tek<sup>™</sup> Enzyme Immunoassay for the Recovery of Salmonella from Selected Low-Moisture Foods
- Microbial growth rate of two minimally processed vegetables packaged in modified atmosphere package
- Ultrasonic killing of Listeria monocytogenes and Salmonella typhimurium in milk
- Evaluation of PC Based Software in the Dairy O.C. Laboratory
- Improvement of Lactic Cultures Through Organic Solvent Treatment
- Virulence of an *Escherichia coli* O157:H7 sorbitol positive mutant
- Quantitative effects of pH and lactic acid concentration on the kinetics of *Listeria monocytogenes* inactivation
- Survey of spoilage bacteria in raw milk at Egyptian markets and farms
- Fate of enterotoxigenic Staphylococci in fish subjected to curing
- Actual and Perceived Incidences of Perforation in Surgical and Examination Gloves
- The Effect of Ultraviolet Light-C on Storage Rots and Ripening of Tomatoes

### Video Theatre

All day Monday, Tuesday morning and all day Wednesday

### Monday Afternoon, July 27

### Update of Foodborne Pathogens Symposium

- Overview of Foodborne Illnesses
- Listeria monocytogenes: methods, perspective on tolerance limits in foods
- Verotoxigenic E. coli (VTECS) including O157:H7 (significance, advances in methods, trends)
- Foodborne toxoplasmosis

### **Technical Session - Laboratory Methods**

- Effective Method for Dry Inoculation of Salmonella Cultures
- Evaluation of Enrichment and Plating Media for Isolation of Virulent Yersinia enterocolitica from Ground Meat
- Comparison of 25g and 375g composite samples for detection of Listeria
- Development of Culture Media for the Rapid Detection of Lactobacillus Species in High Acid Foods Using Impedance Microbiology
- Effective Recovery of Campylobacter in the Presence of Mixed Culture
- Recovery of Campylobacter spp. from poultry through enrichment in 10 ml or 100 ml volumes
- Rapid Method for Assessing Microbiological Quality of Egg Washwater Using Resazurin
- Rapid Fluorometric Analysis of Acid Phosphatase Activity in Cooked Poultry Meat
- Fluorometric Analysis of Alkaline Phosphatase Inactivation Correlated to Salmonella and Listeria Inactivation
- Shelf life prediction of pasteurized fluid milk using the Charm II System

### Sanitation and Disaster Control Symposium

- · Oh God, We're Going to Die Food Safety at Disaster Time
- Ready? or Sorry!! The Need to Exercise Emergency Plans
- Hurricane Hugo and its Aftermath (Sanitation and Disaster Control)
- Disaster Control/Prep. Canada

### **Tuesday Morning, July 28**

### **Technical Session - Foodborne Microbiology**

- · Predictive modeling of psychrotrophic Bacillus cereus
- Microbial Ecology of Modified Atmosphere Packaged Pork
- Method for classifying foods with a similar microbiological risk
- Processing and Fermentation of Soy Yogurt Made from Rapid Hydration Hydrothermal Cooked Soy Milk
- Microbiology HACCP determination at a Poultry Processing Plant
- Combined Effects of Monolaurin, Ethanol, and Lactic Acid Against Listeria monocytogenes
- Lethal effect of dimethyl dicarbonate on *Listeria* and *Salmonella*, and its potential for use in the treatment of fresh produce
- Simultaneous production of Yeast Polygalacturonase and Lactate Dehydrogenase from Sauerkraut Brine

### NAC on Microbiological Criteria for Foods Symposium

- Listeria Overview
- Raw poultry/meat, model HACCP
- Campylobacter
- Revised NACMCF HACCP document

### Automation in Dairy Process Control Symposium

- Process Design and Extended Shelf Life of Dairy Products
- Documentation of Automated Processes
- Automation in Cleaning and Sanitizing
- Aseptic Dairy Processing
- Regulatory Aspects/Inspections

### **Tuesday Afternoon, July 28**

### **General Session - International Food Standards**

- · Development of IDF Standards and Bulletins
- Food Standards and Food Safety in Japan
- International Labeling and Advertising Requirements: The Effect on Trade
- Food Safety Issues in Europe An Update

### Wednesday Morning, July 29

### Seafood Regulatory Symposium

- The United States Food and Drug Administration's Office of Seafood; Update on Activities
- Canadian Seafood Inspection
- Seafood Issues Within CODEX
- · Seafood Issues Within ICMFS
- National Advisory Committee on Food Safety, Seafood Issues

### **Dairy Symposium**

- · Bacillus cereus in Dairy Products
- · Bioluminescence and Detection of Pathogens in Milk
- · Biofilms from a cleaning and sanitizing perspective
- The Bifidobacterium and dairy products

### Consumer's and Scientist's Views on Irradiation and Food Safety Symposium

- The Consumer's View of Food Safety
- The Epidemiologist Perception
- Limitations of Our Current Approach for Assessing Microbiological Food Safety
- · Safety Ramifications of Food Irradiation
- The Public Perceptions Toward Irradiation of Foods Media Presentation
- Round Table Discussion Closing the Gap Between Perception and Reality or, How do we get there from here?

### Wednesday Afternoon, July 29

### Seafood Safety Symposium

- Enteric Viruses and Seafood Safety
- Bacterial Pathogens and Seafood Safety
- New Insights into Seafood Toxin Research
- Chemicals and Seafood Safety
- Seafood HACCP Programs

### Food Irradiation Symposium

- Food Irradiation: Introductory Overview
- · Safety and Wholesomeness of Irradiated Food
- Microbial Aspects of Food Irradiation
- International Regulatory Status and Harmonization of Food Irradiation
- Marketing Irradiated Food
  - Radiation Processing of Food for Quarantine Control

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# IAMFES

# 79th Annual Meeting Spouse/Companion Tours

A Get-Acquainted Tour of Toronto and CN Tower

Monday, July 27, 1992 9:00 a.m. - 12:00 noon

Explore the unique personality of the world's "newest great city" on this get-acquainted tour of Toronto!

With emphasis on the blending of residential, commercial and recreational facilities and the eye-catching combination of old and new, your guide will share interesting and unusual anecdotes about Toronto and its residents as you tour through distinct areas of the city, including: the downtown financial district with its stunning skyline of skyscrapers, many of which are constructed from a different material (for example, the Royal Bank building with windows containing real gold dust); the midtown section, where fashionable boutiques and galleries of Yorkville are just a stones' throw from the Victorian Gothic of the Ontario Parliament Buildings; and uptown Toronto, where the playing fields of two of Canada's most prestigious private schools back on to the residences of a few of its more famous personalities!

Some of the other attractions included in today's look at Toronto will be the Royal Ontario Museum and McLaughlin Planetarium; Roy Thomson Hall; Old Towne of York, where Toronto had its beginnings; O'Keefe and St. Lawrence Centre for the Arts; Old and New City Halls; Ontario Parliament Buildings; the Eaton Centre, with its stunning glass domed galleria; Chinatown; the Art Gallery of Ontario and innovative Village by the Grange residential and shopping developments; parks; theatres, and numerous other places of interest in and around the city.

Then to complete your morning, "Zoom" to the clouds via a thrilling 58-second ride in a glass sided elevator up the CN Tower, the world's tallest free standing structure and marvel at modern technology. Whilst revelling in the magnificent bird's eye panoramic view of Toronto from 1,150 feet above the ground, your knowledgeable guide will also conduct a unique aerial tour of the city and its surrounding area.

### Historic Tour of Downtown and Restored Theatres

Monday July 27, 1992 2:00 p.m. to 5:00 p.m.

Take an exciting tour "behind the scenes" and discover the hidden world that transforms fantasies to realities! Third in the world behind New York and London, Toronto is proud of its first class theatres and concert halls, however, the ultimate treasures are found in two magnificently restored vaudeville houses of the 1920's. Look back to a time of extravagance with visits to the historic Elgin and Winter Garden Theatres the only active stacked theatres in the world. The restorations for this complex began in March 1987 and lasted for 33 months with artists, historians, carpenters, plasterers, painters and many others painstakingly repairing or re-creating every detail of the original theatres' design. Vaudeville was presented here until 1930 when the Elgin became exclusively a movie house. Situated directly above is the Winter Garden Theatre, which opened in February 1914. As this theatre was strictly a vaudeville house, it too became passé and had its last performance in 1928, after which its doors were simply closed and the theatre left to slumber for sixty years. Walking an English fantasy garden. Both the Elgin and the Winter Garden Theatre with its hand painted walls and leaves suspended from the ceiling is reminiscent of a stroll through an English fantasy garden. Both the Elgin and the Winter Garden Theatres are designated national historic sites.

Following your theatre tour, this Historic walking tour of Downtown will continue by highlighting two of Toronto's most imposing buildings which are reflections of the city's past and present - The Old and New City Halls. Located across the street from each other, these two buildings share an important part of the city's architectural and historic identity. Begin your walking tour at New City Hall with a view of the Peace Garden, Henry Moore's famous sculpture "The Archer", and finally the beautiful rotunda inside.

Across the street from new City Hall, but light-years removed in architectural style, stands Old City Hall. It was completed just in time to ring in the 20th century at 1/10 the cost of the New City Hall. Marvel at the magnificent wood paneling, high ceilings and marble columns, and elaborate 300 foot high clock tower.

Finally, your guide will escort you to the Church of the Holy Trinity which, set against the Eaton Centre's high-tech glitter, looks more impressive today than it did even a century ago. Right next door is the home of the first rector of Holy Trinity, Rev. Henry Scadding. This Georgian/Gothic style house was built in 1857 and its intriguing balcony once commanded a view down to the harbour and around the entire town.

### Niagara Falls and Niagara-on-the-Lake

Tuesday, July 28, 1992 8:00 a.m. to 5:00 p.m.

This spectacular showcase of Niagara has been specially designed to offer delegates attending the IAMFES 1992 Convention an excellent opportunity to experience first hand, the beauty and excitement of the Niagara Peninsula.

Begin your day with a pleasant journey to the Niagara Peninsula and feel the thrill of excitement and anticipation as your approach the majestic and thunderous Falls! Upon arriving at this magnificent splendor, your first impressions will be that of the powerful surging waters of the Canadian and American Falls. First your guide will take you on a short orientation tour of the area, pointing out such attractions as the Oaks' amphitheatre, the scenic tunnels, the Maid of the Mist and superb gardens. Then time will be available for those who wish to climb aboard the *Mold of the Mist* tour boat for a thrilling and exciting close-up look at the base of the thundering falls. (Tour boat ride at your own expense).

On leaving the Falls for Niagara-on-the-Lake, journey along the Niagara Parkway, where participants will have a chance to see the impressive Niagara Gorge, with its swirling whirlpool rapids; the massive power stations which provide hydro-electricity to southern Ontario and the north-eastern part of New York; the floral clock, one of the largest of its kind in North America.

A picnic lunch today will take place in the area of one of the famous battlefields of the war of 1812 between British and American armies at Queenston Heights Park. The picnic area is located on the brow of the Niagara escarpment and has a spectacular view of the broad Niagara River and fruitlands.

After lunch you will continue your trip on to Niagara-on-the-Lake, a charming 19th Century town which, as the first capital of Upper Canada, has a rich history and culture. The home of the world renowned Shaw Festival which draws both international performers and audiences, this tranquil town offers participants an opportunity to meander through quaint boutiques and tree-lined streets. Visit an old fashioned apothecary, explore some of the fine examples of 19th Century homes, and perhaps indulge in freshly made fudge and preserves.

### Blue Jay Baseball and dinner at Windows

Tuesday, July 28, 1992 7:30 p.m. to 11:00 p.m.

Let's go Blue Jays!

Enjoy an evening watching the Toronto Blue Jays play in the fabulous SkyDome Stadium. The SkyDome-billed as "like no other in the world" is being talked about by virtually every sports fan in North America. This incredible multi-use facility provides 55,000 to 70,000 fans with spectacular views in all directions and outstanding sight lines for a variety of activities, including all major sporting events and star-studded concerts. It is more than merely a sports stadium. This magnificent complex also includes a 450 room hotel with 77 rooms overlooking the playing field, a health club, a movie theatre, bars and restaurants.

Windows on SkyDome is an elegant, three tiered restaurant overlooking the stadium and features a delicious buffet dinner. A section of this unique restaurant, has been specially reserved for delegates attending the IAMFES 1992 Convention. Some tables offer full viewing of the playing field and others offer monitor viewing only, therefore seating will be assigned on a "first come-first serve" basis.

# **New IAMFES Members**

### Arkansas

William L. Clayton Arkansas Department of Health Little Rock

### California

Lesley D. Herring Kraft General Foods Anaheim

Rob Robbins Silliker Laboratories Fresno

Abraham Wubishet Corp. Extension San Bernardino

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John A. Lynch Ontario Ministry of Ag & Food Guelph, Ontario

Margaret Maiss Caterair International Calgary, Alberta

W. Earl McAllister Kraft General Foods - Canada Div. Ingleside, Ontario

Larry Mendes J.M. Schneider, Inc. Kitchener, Ontario

Sandra Noonan Health & Welfare Canada Hamilton, Ontario

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### Iran

Tahereh Tajvar Shiraz University Shiraz Israel

Ilan Amitay Hod Lavan Turkey Products Ltd. Emek Hefer

### Korea

Chung Choong-Il Konkuk Food Integration Seoul

### South Korea

Jung-Hee Kim Nam Yang Dairy Products Co. Chungnam

### Taiwan

Guo-Jane Tsai National Taiwan Ocean University Keelung

### **United Kingdom**

Ian Wilson Belfast City Hospital Belfast, Northern Ireland

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### 3-A Sanitary Standards for Air Driven Sonic Horns for Dry Milk and Dry Milk Products, Number 49-00

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

It is the purpose of the IAMFES, USPHS, and DIC in connection with the development of the 3-A Sanitary Standards Program to allow and encourage full freedom for inventive genius or new developments. Air-driven sonic horns specifications heretofore or hereafter developed which so differ in design, materials, and fabrication or otherwise as not to conform to the following standards but which, in the fabricator's opinion, are equivalent or better, may be submitted for the joint consideration of the IAMFES, USPHS, and DIC at any time.

### A

### SCOPE

### A.1

These standards cover the sanitary aspects of air-driven sonic horns that dislodge particulates, enhance atomization, augment fluidization or are used in other ways to enhance the drying and/or recovery of dry milk and dry milk products. Sonic horns shall begin at the downstream face of the filter element located at the compressed air connection of the driver and terminate at the discharge of the acoustic bell.

### A.2

In order to conform with these 3-A Sanitary Standards sonic horns shall comply with the following design, material, and fabrication criteria.

### B

### DEFINITIONS

B.1

Product: Shall mean dry milk or dry milk products.

**B.2** 

*Sonic Horns*: Shall mean compressed air driven equipment that includes a driver, diaphragm, and bell which produces and directs acoustic energy.

<sup>\*2</sup> The data for this series are contained in the AISI Steel Products Manual, Stainless & Heat Resisting Steels, December 1974, Table 2-1,pp. 18-20. Available from the Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086 (412-776-9460).

<sup>\*3</sup> Alloy Casting Institute Division, Steel Founders Society of America, Cast Metal Federation Bldg., 455 State St., Des Plaines, IL 60016 (708-299-9160).

### **B.2.1**

*Driver*: Shall mean that part of the sonic horn that houses the diaphragm, compressed air connections, vents and compressed air reservoir cavities.

### B.2.2

*Diaphragm*: Shall mean a flat, circular plate that is housed in the driver, and is vibrated between two metal seats by compressed air to produce the sound.

B.2.3

*Bell or Horn*: Shall mean the hollow cone or tube protruding from the driver which amplifies the sound created by the diaphragm.

### **B**.3

### Surfaces

B.3.1

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

### B.3.2

Non-Product Contact Surfaces: Shall mean all other exposed surfaces.

### **B.4**

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.

**B**.5

*Engineering Plating*: Shall mean plated to specific dimensions or processed to specific dimensions after plating.\*<sup>1</sup>

### MATERIALS

C.1

С

Product contact surfaces shall be of stainless steel of the AISI 300 Series<sup>\*2</sup> or corresponding ACI<sup>\*3</sup> types (See Appendix, Section E.), or metal which under conditions of intended use is at least as corrosion-resistant as

<sup>&</sup>lt;sup>\*1</sup> QQ-C-320b, Federal Specification for Chromium Plating (Electrodeposited) June 17, 1985, Amendment 4, 1987.QQ-N-290a, Federal Specification for Nickel Plating (Electrodeposited) November 12, 1971. Both documents available from the General Services Administration, 18th & F Sts., NW, WFC1A, Washington, DC 20405 (202-472-2205).

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stainless steel of the foregoing types, and is non-toxic and non-absorbent, except that:

### C.1.1

Driver parts may be covered with an engineering plating of chromium or nickel.

### C.1.2

Rubber and rubber-like materials may be used for O-Rings, removable or bonded gaskets and parts having the same functional purposes.

### C.1.3

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 Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-00.

### C.1.4

Plastic materials may be used for O-Rings, removable or bonded gaskets and parts having the same functional purposes.

### C.1.5

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 20-14 as amended.

### C.1.6

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

### C.1.7

The final bond and residual adhesive, if used, of bonded rubber and rubber-like materials and bonded plastic materials shall be non-toxic.<sup>\*4</sup>

C.2

Non-product contact surfaces shall be of corrosionresistant material or material that is rendered corrosionresistant. If coated, the coating used shall adhere. Nonproduct contact surfaces shall be relatively non-absorbent, durable, and cleanable. Parts removable for cleaning having both product contact and non-product contact surfaces shall not be painted.

### D

### FABRICATION

**D**.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.).

D.2

All permanent joints in metallic product contact sur-

faces shall be continuously welded. Welded areas on product contact surfaces shall be at least as smooth as a No. 4 ground finish on stainless steel sheets, free of imperfections such as pits, folds, and crevices.

### **D**.3

Appurtenances having product contact surfaces shall be easily removable for cleaning, or shall be readily cleanable in place.

D.4

Product contact surfaces shall be easily accessible for cleaning and inspection either when in an assembled position or when removed. Removable parts shall be readily demountable with standard hand tools.

### D.5

Sonic horns that are to be mechanically cleaned shall be designed so that the product contact surfaces of the sonic horns and all non-removable appurtenances thereto can be mechanically cleaned and are accessible for inspection. Removable parts shall be demountable using simple hand tools used by operating or cleaning personnel.

### D.6

All product contact surfaces not designed to be mechanically cleaned shall be easily accessible for cleaning and inspection either when in an assembled position or when removed. Removable parts shall be demountable using simple hand tools used by operating or cleaning personnel.

D.7

The thickness of engineering plating shall not be less than 0.0002 in. (0.005 mm) for all product contact surfaces when used on stainless steel. When these surfaces are other than stainless steel, the thickness of engineering plating shall not be less than 0.002 in. (0.05 mm).

### D.8

Product contact surfaces shall be drainable except for normal clingage.

### D.9

All sanitary fittings and connections shall conform with the applicable provisions of 3-A Sanitary Standards for Fittings Used on Milk and Milk Products Equipment and Used on Sanitary Lines Conducting Milk and Milk Products, Number 08-17 as amended.

### D.10

All tubing shall comply with the applicable provisions for welded sanitary product pipelines found in the 3-A Accepted Practices for Permanently Installed Sanitary Product-Pipelines and Cleaning Systems, With Amendment, Number 605-04, and/or with 3-A Sanitary Standards for Polished Metal Tubing for Dairy Products, Number 33-00.

### D.11

### Gaskets

D.11.1

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

D.11.2

Bonded rubber and rubber-like materials and bonded

<sup>&</sup>lt;sup>\*4</sup> Adhesives shall comply with 21 CFR Part 175 - Indirect food additives. Adhesives and components of coatings. Document for sale by the Superintendent of Documents, U.S. Government Office, Washington, DC 20402 (202-783-3238).

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.

### D.11.3

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

### D.11.4

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

### D.12

Radii D.12.1

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

D.12.1.1

Smaller radii may be used when they are required for essential functional reasons, such as those on intricately machined parts. In no case shall such radii be less than 1/32 in. (1 mm).

### D.12.1.2

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

### D.12.1.3

The radii in grooves for standard 1/4 in. (6 mm) O-Rings shall not be less than 3/32 in. (2 mm) and for standard 1/8 in. (3 mm) O-Rings shall be not less than 1/32 in. (1 mm).

### D.12.1.4

The minimum radii for fillets of welds in product contact surfaces shall be not less than 1/4 in. (6 mm) except that the minimum radii for such welds may be 1/8 in. (3 mm) where the thickness of one or both parts joined is 3/16 in. (5 mm) or less.

### D.13

Compressed air used for operation or purging of sonic horns shall comply with the applicable criteria contained in the 3-A Accepted Practices for Supplying Air Under Pressure in Contact with Milk, Milk Products and Product Contact Surfaces, Number 604-03, except for those found in Section D.4.2 of 3-A 604-03.

### D.14

There shall be no threads on product contact surfaces. D.15

### Mounting Criteria

D.15.1

The method of mounting the sonic horn to the equip-

<sup>\*5</sup> Available from ASTM, 1916 Race St., Philadelphia, PA 19103-1187 (215-299-5400). ment shall allow all or part of the sonic horn to be easily removed from the equipment and mounting apparatus for complete inspection and cleaning.

### D.15.2

The mounting apparatus shall be of such design and construction that the inner surfaces drain into the equipment and if the equipment is designed for mechanical cleaning, the inner surface of the mounting apparatus shall be relatively flush with the inner surface of the equipment.

### D.15.3

The exterior flare shall be pitched so that liquids cannot accumulate.

D.16

E

Non-product contact surfaces shall have a smooth finish, be readily cleanable and those surfaces to be coated shall be effectively prepared for coating. Non-product contact surfaces shall be free of cracks and crevices.

### APPENDIX

### STAINLESS STEEL MATERIALS

Stainless steel conforming to the applicable composition ranges established by AISI<sup>\*2</sup> for wrought products, or by ACI<sup>\*3</sup> 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 percent. The first reference cited in C.1 sets forth the chemical ranges and limits of acceptable stainless steel of the 300 Series. Cast grades of stainless steel corresponding to types 303, 304, and 316 are designated CF-16F, CF-8, and CF-8M, respectively. These cast grades are covered by ASTM\*<sup>5</sup> specifications A351/A351M, A743/A743M and A744/A744M.

### 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 D.1 herein.

### G

F

### RECOMMENDATIONS FOR CLEANING SONIC HORNS

### G.1

### **Dry Cleaning Program**

G.1.1

Remove driver from the bell and dry clean and thoroughly vacuum all product contact surfaces.

### G.1.2

Thoroughly clean all external parts of the sonic horn.

G.2

### Wet Cleaning Program

G.2.1

Remove the driver and dry clean as described in G.1.1 Remove all loose dry product and hand wash or mechanically clean the bell.

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### G.2.2

Allow all parts to air dry completely prior to re-assembly.

### General

G.3.1

G.3

Provide means to prevent operation of the horn during cleaning.

G.3.2

Vacuum cleaning is preferred to brush cleaning or cleaning with air under pressure as it decreases dustdrift to other parts of the plant.

### G.3.3

Brushes or vacuum cleaner fittings used for cleaning

product contact surfaces should not be used for cleaning non-product contact surfaces or for other uses which might result in contamination. Such tools should be made of materials that can be cleaned and sanitized and should not have wooden parts nor be of mild steel or other iron products that will rust. Such brushes and special fittings should be stored in an enclosed cabinet when not in use. For protection and housekeeping considerations, such cabinets should be of non-wood construction and should have open mesh metal shelving.

These standards shall become effective September 28, 1992.

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### 3-A Sanitary Standards For Level Sensing Devices For Dry Milk and Dry Milk Products, Number 50-00

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

It is the purpose of the IAMFES, USPHS, and DIC in connection with the development of the 3-A Sanitary Standards program to allow and encourage full freedom for inventive genius or new developments. Dry milk and dry milk product level sensing device specifications heretofore or hereafter developed which so differ in design, material, fabrication, or otherwise, as not to conform to the following standards but which, in the fabricator's opinion, are equivalent or better, may be submitted for the joint consideration of the IAMFES, USPHS, and DIC at any time.

### Α

### SCOPE

### A.1

These standards cover the sanitary aspects of devices, excluding load cells, which have product contact surfaces and are used on dry milk and dry milk products storage vessels or equipment for sensing product level.

### A.2

In order to conform with these 3-A Sanitary Standards, dry milk level sensing devices shall comply with the following design, material, and fabrication criteria.

### DEFINITIONS

### B.1 B.2

B

Product: Shall mean dry milk or dry milk products.

### Surfaces

### **B**.2.1

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

### B.2.2

*Non-Product Contact Surfaces*: Shall mean all other exposed surfaces.

<sup>\*3</sup> Alloy Casting Institute Division, Steel Founders Society of America, Cast Metal Federation Bldg., 455 State St., Des Plaines, IL 60016 (708-299-9160).

<sup>\*4</sup> Aluminum Association, 518 Connecticut Ave., NW, Washington, DC 20006 (202-862-5100).

### **B.2.3**

*Engineering Plating*: Shall mean plated to specific dimensions or processed to specific dimensions after plating.<sup>\*1</sup>

**B.3** 

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.

### MATERIALS

C.1

C

All product contact surfaces shall be of stainless steel of the AISI 300 series<sup>\*2</sup> or corresponding ACI<sup>\*3</sup> types (See Appendix, Section E.), aluminum alloys conforming to the Aluminum Association designations 5052 and 6061<sup>\*4</sup>, or metal which under conditions of intended use is at least as corrosion-resistant as stainless steel of the foregoing types, and is non-toxic and non-absorbent, except that:

C.1.1

Product contact surfaces made of materials provided for in C.1 may be covered with an engineering plating of chromium.<sup>\*1</sup>

Rubber and rubber-like materials may be used for gaskets, diaphragms, bonded coatings and coverings, and parts having the same functional purposes.

C.1.3

Rubber and rubber-like materials when used for the above specified applications shall comply with the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-00.

C.1.4

Plastic materials may be used for bearings, bushings, connecting rods, gaskets, bonded coatings and cover-

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<sup>&</sup>lt;sup>\*1</sup> QQ-C-320b Federal Specification for Chromium Plating (Electrodeposited) June 17, 1985 Amendment 4, 1987. QQ-N-290a, Federal Specification for Nickel Plating (Electrodeposited) November 12, 1971. Both documents available from the General Services Administration, 18th F Sts., NW, WFCIA, Washington, DC 20405 (202-472-2205).

<sup>&</sup>lt;sup>\*2</sup> The data for this series are contained in the AISI Steel Products Manual, Stainless & Heat Resisting Steels, December 1974, Table 2-1,pp. 18-20. Available from the Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086 (412-776-9460).

C.1.2

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ings, and parts having the same functional purposes.

C.1.5

Plastic materials when used for the above specified applications shall comply with the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-14 as amended.

### C.1.6

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

### C.1.7

The final bond and residual adhesive, if used, of bonded rubber and rubber-like materials and bonded plastic materials shall be non-toxic.<sup>\*5</sup>

C.1.8

Where materials having certain inherent functional purposes are required for specific applications, such as rotary seals, carbon and/or ceramic materials may be used. Carbon and/or ceramic materials shall be inert, non-porous, non-toxic, non-absorbent, 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.

C.2

Non-product contact surfaces shall be of corrosionresistant material or material that is rendered corrosionresistant. If coated, the coating used shall adhere. Nonproduct contact surfaces shall be relatively non-absorbent, durable and cleanable. Parts removable for cleaning having both product contact and non-product contact surfaces shall not be painted.

### D

### FABRICATION

**D**.1

All 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 in the final fabricated form. (See Appendix, Section F.)

D.2

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

D.3

The minimum thickness of engineering plating shall not be less than 0.0002 in. (0.005 mm) for all product contact surfaces when used on stainless steel. When these surfaces are other than stainless steel, the thickness of engineering plating shall not be less than 0.002 in. (0.05 mm).

D.4

Product contact surfaces not designed to be mechanically cleaned shall be readily accessible for cleaning and inspection either when in an assembled position or when removed. Removable parts shall be readily demountable.

D.5

Sensing devices that are to be mechanically cleaned shall be designed so that the product contact surfaces of the sensing device can be mechanically cleaned, and all non-removable appurtenances thereto can be mechanically cleaned and are readily accessible for inspection.

D.6

Product contact surfaces shall be self-draining except for normal clingage.

D.7

All sanitary fittings and connections shall conform with the applicable provisions of 3-A Sanitary Standards for Fittings Used on Milk and Milk Products Equipment and used on Sanitary Lines Conducting Milk and Milk Products, Parts I and II, 08-17 as amended.

**D.8** 

All instrument connections having product contact surfaces shall conform to the 3-A Sanitary Standards for Instrument Fittings and Connections Used on Milk and Milk Products Equipment, Parts I and II, Number 09-08.

D.9

Gaskets

D.9.1

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

D.9.2

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.

D.9.3

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

### D.9.4

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

D.10 Radii

D.10.1

All internal angles of 135 degrees or less on product contact surfaces shall have radii of not less than 1/4 in. (6 mm), except that:

<sup>&</sup>lt;sup>\*5</sup> Adhesives shall comply with 21 CFR Part 175 - Indirect food additives. Adhesives and components of coatings. Document for sale by the Superintendent of Documents, U.S. Government Office, Washington, DC 20402 (202-783-3238).

<sup>190</sup> DAIRY, FOOD AND ENVIRONMENTAL SANITATION/MARCH 1992

### D.10.1.1

Smaller radii may be used when they are required for essential functional reasons, such as those in rotary seals. In no case shall such radii be less than 1/32 in. (1 mm).

### D.10.1.2

The radii in gasket grooves, gasket retaining grooves or grooves in gaskets, except those for standard 1/4 in. (6 mm) and smaller O-Rings, shall be not less than 1/16 in. (2 mm).

### D.10.1.3

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).

### D.10.1.4

The minimum radii for fillets of welds in product contact surfaces shall be not less than 1/4 in. (6 mm) except that the minimum radii for such welds may be 1/8 in. (3 mm) when the thickness of one or both parts joined is less than 3/16 in. (5 mm).

### D.11

There shall be no threads on product contact surfaces.

### D.12

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.

D.13

There shall be no braided or twisted cable used as product or non-product contact surfaces.

### D.14

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

### D.15

Bearings having product contact surfaces shall be of the non-lubricated type. Lubricated bearings, including the sealed type, shall be located outside the product contact surface with at least 1 in. (25 mm) of clearance, open for inspection, between the bearing and any product contact surface. 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.

### D.16

Equipment for producing air under pressure and/or piping which is supplied as an integral part of the sensing equipment shall comply with 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 604-03, except that:

1) A sanitary check valve is not required, and

2) A disposable media filter is not required close to the point of air application if corrosion resistant piping,

<sup>\*6</sup> Available from ASTM, 1916 Race St., Philadelphia, PA 19103-1187 (215-299-5400). such as stainless steel tubing or flexible plastic tubing, is used to conduct the air from an upstream-located pipeline filter which meets the requirements of Section C.2.2 of 3-A Accepted Practices for Supplying Air Under Pressure in Contact with Milk, Milk Products and Product Contact Surfaces, Number 604-03.

D.17

E

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

### APPENDIX

### STAINLESS STEEL MATERIALS

Stainless steel conforming to the applicable composition ranges established by AISI<sup>\*1</sup> for wrought products, or by ACI<sup>\*2</sup> for cast products, should be considered in compliance with requirements of Section C.1 herein. Where welding is involved, the carbon content of the stainless steel should not exceed 0.08 percent. The first reference cited in C.1 sets forth the chemical ranges and limits of acceptable stainless steel of the 300 series. Cast grades of stainless steel corresponding to types 303, 304, and 316 are designated CF-16F, CF-8, and CF-8M, respectively. These cast grades are covered by ASTM<sup>\*6</sup> specifications A351/A351M, A743/A743M and A744/A744M.

F

G

### PRODUCT CONTACT SURFACE FINISH

Surface finish equivalent to 150 grit or better as obtained with silicon carbide properly applied, on stainless steel sheets is considered in compliance with the requirements of Section D.1 herein.

### LOCATION OF LEVEL SENSING DEVICES

The installer of level-sensing devices should locate them to allow easy access from adjacent floor levels or catwalks so the devices can be easily dismantled for manual cleaning and/or inspection whenever wet washing of the tank or other vessel is performed.

These 3-A Sanitary Standards are effective September 28, 1992.

# **Business Exchange "Classifieds"**



Services / Products



# **Coming Events**

1992

### April

**•6-7, Advanced Pest Control**, sponsored by the American Institute of Baking, to be held at AIB, 1213 Bakers Way, Manhattan, KS 66502. For registration information call AIB at (913)537-4750, (800)633-5137 or FAX (913)537-1493.

•7-9, Basic Pasteurization Course, sponsored by the Texas Association of Milk, Food and Environmental Sanitarians, will be held at the Econo Lodge, 333 Northwest Loop 410, San Antonio, TX. For registration information contact Ms. Janie F. Park, TAMFES, P.O. Box 2363, Cedar Park, TX 78613-2363, (512)458-7281.

•9, Associated Illinois Milk, Food and Environmental Sanitarians Spring Conference will be held at the Carlisle, Lombard, IL. For further information contact Robert A. Crombie, Secretary, AIMFES, 521 Cowles, Joliet, IL 60435, (815)726-1683.

•10-11, International Lyme Diease Conference includes Public Health and Veterinary Track, Stamford, CT, contact The Lyme Disease Foundation (203)871-2900.

•12-15, Application of Predictive Microbiology and Computer Modeling Techniques for the Food Industry (SIM International Conference), will be held at the Hyatt Regency Hotel, Tampa, FL. For information contact the Society for Industrial Microbiology at (703)941-5373 or FAX (703)941-8790.

•13, Radiation Safety Seminar, sponsored by the American Type Culture Collection, will be held in Rockville, MD. For more information contact ATCC/Workshops, 12301 Parklawn Drive, Rockville, MD 20852; (301)231-5566; FAX (301)770-1805.

•25-29, The Sixth Conference for Food Protection will be held at the Tremont Plaza Hotel, Baltimore, MD. For further information contact Leon Townsend, Executive Secretary, Conference for Food Protection, 110 Tecumseh Trail, Frankfort, Kentucky 40601, (502)695-0253.

•27-28, 10th Annual Biotechnology Patent Conference, sponsored by the American Type Culture Collection, will be held in Rockville, MD. For more information contact ATCC/ Workshops, 12301 Parklawn Drive, Rockville, MD 20852; (301)231-5566; FAX (301)770-1805.

-•29-30, Food Safety and Sanitation Short Course, sponsored by the American Association of Cereal Chemists, to be held in Minneapolis, MN. For more information, contact AACC, 3340 Pilot Knob Road, St. Paul, MN 55121-2097; (612)454-7250; FAX (612)454-0766.

### May

•3-6, Centennial Conference of the Ice Cream Short Course to be held at the J.O. Keller Conference, The Pennsylvania State University, 306 Ag. Administration Building, University Park, PA 16802. For further information call (814)865-8301, FAX (814)865-7050. •4-5,Food Safety for Zero Defects Seminar, sponsored by ASI Food Safety Consultants', will be held in St. Louis, MO. For more information call Christine VerPlank or Nancy Sullivan toll-free at (800)477-0778 or, in MO, (314)725-2555, or write, ASI, P.O. Box 24198, St. Louis, MO 63130.

•4-6, Food Processing Automation Conference, sponsored by the Food & Process Engineering Institute, will be held at the Hyatt Regency, Lexington, KY. For more information, contact Jon Hiler, Conference Manager, FPEI, 2950 Niles Road, St. Joseph, MI 49085-9659; Phone (616)429-0300, FAX (616)429-3852.

•6, Reclamation and Environmental Concerns in the Food Industry, sponsored by ASI Food Safety Consultants', will be held in St. Louis, MO. For more information call Christine VerPlank or Nancy Sullivan toll-free at (800)477-0778 or, in MO, (314)725-2555, or write, ASI, P.O. Box 24198, St. Louis, MO 63130.

•7, Employee Health, Hygiene and Practices in the Food Industry, sponsored by ASI Food Safety Consultants', will be held in St. Louis, MO. For more information call Christine VerPlank or Nancy Sullivan toll-free at (800)477-0778 or, in MO, (314)725-2555, or write, ASI, P.O. Box 24198, St. Louis, MO 63130.

•11-14, Purdue Aseptic Processing and Packaging Workshop to be held at Purdue University. For more information contact James V. Chambers, Food Science Department, Smith Hall, Purdue University, West Lafayette, IN 47907, Phone: (317)494-8279.

•13-15, Microscopy/Photomicrography, sponsored by the American Type Culture Collection, will be held in Rockville, MD. For more information contact ATCC/Workshops, 12301 Parklawn Drive, Rockville, MD 20852; (301)231-5566; FAX (301)770-1805.

•15-17, Food Safety for Dietitians will be held at the Holiday Inn Decatur Conference Plaza, Atlanta, GA. For more information contact the Department of Nutrition and Dietetics, College of Health Sciences, Georgia State University, Atlanta, GA 30303-3083 (or call Toni Scoggins (404)651-3066; FAX 404/651-3231).

•19-22, Hybridomas & Monoclonal Antibody Techniques, sponsored by the American Type Culture Collection, will be held in Rockville, MD. For more information contact ATCC/ Workshops, 12301 Parklawn Drive, Rockville, MD 20852; (301)231-5566; FAX (301)770-1805.

•20-22, South Carolina Public Health Association, Inc., will meet at the Myrtle Beach Hilton, Myrtle Beach, SC. For more information contact Joyce Mathis at (803)737-4067.

•25-29, Trace Elements in Health and Disease, Third ISTERH (International Society for Trace Elements Research in Humans) Conference, and Fourth NTES (Nordic Trace Elements) Conference, to be held in Stockholm, Sweden. For more information contact ISTERH/NTES 1992, Scientific Secretariat, Dr. Lars-Olof Plantin, Clinical Research Centre, Huddinge Hospital, S 141 86 HUDDINGE, Sweden; Phone: +46-8 746 55 68; FAX: +46-8 746 74 83.

### June

•2-3, Milk Procurement Workshop, sponsored by the organizations of the International Dairy Foods Association, will be held at the Loews Giorgio Hotel Denver, Denver, CO. For more information contact IDFA Marketing & Training Institute, Attn: Registrations, 888 Sixteenth Street, NW, 2nd Floor, Washington, DC 20006-4103; (202)296-4250.

•2-3, Texas Association of Milk, Water and Food Protection's Annual Meeting will be held at the Howard Johnson South Plaza, Austin, TX. For more information please contact Janie Park, TAMFES, P.O. Box 2363, Cedar Park, TX 78613-2363, (512)458-7281.

•5, Tennessee Association of Milk, Water and Food Protection's Annual Meeting will be held at the Ramada Airport, Nashville, TN. For more information contact Dennis Lampley at (615)360-0157.

•10-12, Freezing & Freeze-Drying of Microorganisms, sponsored by the American Type Culture Collection, will be held in Rockville, MD. For more information contact ATCC/ Workshops, 12301 Parklawn Drive, Rockville, MD 20852; (301)231-5566; FAX (301)770-1805.

•14-17, International Conference on Seafood Irradiation to be held at the Omni Royal Orleans, New Orleans, LA. For more information contact M. Kilgen or M. Cole at (504)448-4700, Nicholls State University, Thibodaux, LA 70310.

### July

•10-17, International Workshop on Rapid Methods and Automation in Microbiology XII and Mini-Symposium (July 10-11) at Kansas State University. Contact Daniel Y.C. Fung, Director, (913)532-5654 or FAX (913)532-5681, 207 Call Hall, KSU, Manhattan, KS 66506.

•14-16, Basic Pasteurization Course, sponsored by the Texas Association of Milk, Food and Environmental Sanitarians, will be held at the Holiday Inn, Emerald Beach, 1102 S. Shoreline Blvd., Corpus Christi, TX. For registration information contact Ms. Janie F. Park, TAMFES, P.O. Box 2363, Cedar Park, TX 78613-2363, (512)458-7281.

•26-29, 79th International Association of Milk, Food and Environmental Sanitarians Annual Meeting to be held at the Sheraton Centre, Toronto, Ontario. For more information, please contact Julie at IAMFES, (800)369-6337 (US), (800)284-6336 (Canada) or FAX (515)232-4736.

### August

•4-7, Fermentation Microbiology, sponsored by the American Type Culture Collection, will be held in Rockville, MD. For more information contact ATCC/Workshops, 12301 Parklawn Drive, Rockville, MD 20852; (301)231-5566; FAX (301)770-1805.

-•9-14, The 49th Annual Meeting of the Society for Industrial Microbiology, Workshop I - "Controlling Biotechnology Risks: A Holistic Approach to Safety and Environmental Protection" (August 9); and Workshop II - "Clean Room Management" (August 9), to be held at the Town & Country Hotel, San Diego, CA. For more information contact the Society for Industrial Microbiology at (703)941-5373 or FAX (703)941-8790.

•10-14, Biotechnology: Principles and Processes to be held at the Massachusetts Institute of Technology. For more information contact the Director of Summer Session, MIT, Room E19-356, Cambridge, MA 02139, Phone: (617)253-6721.

•11-14, Fermentation Microbiology, sponsored by the American Type Culture Collection, will be held in Rockville, MD. For more information contact ATCC/Workshops, 12301 Parklawn Drive, Rockville, MD 20852; (301)231-5566; FAX (301)770-1805.

•24-28, Advanced Recombinant DNA Methodology, sponsored by the American Type Culture Collection, will be held in Rockville, MD. For more information contact ATCC/ Workshops, 12301 Parklawn Drive, Rockville, MD 20852; (301)231-5566; FAX (301)770-1805.

•25-28, International Dairy Federation Seminar on "Milkfat & Protein Processing" will be held in Munich. For more information contact Verband der Deutschen Milchwirtschaft, c/o Mr. T. Kützemeier, Meckenheimer Allee 137, D-5300 Bonn 1 (Germany), Tel: 228/638270; FAX: 228/638425.

### September

•1-4, Diagnostic Virology, sponsored by the American Type Culture Collection, will be held in Rockville, MD. For more information contact ATCC/Workshops, 12301 Parklawn Drive, Rockville, MD 20852; (301)231-5566; FAX (301)770-1805.

•14, Radiation Safety Seminar, sponsored by the American Type Culture Collection, will be held in Rockville, MD. For more information contact ATCC/Workshops, 12301 Parklawn Drive, Rockville, MD 20852; (301)231-5566; FAX (301)770-1805.

•14-15, Food Safety for Zero Defects, sponsored by ASI Food Safety Consultants', will be held in St. Louis, MO. For more information call Christine VerPlank or Nancy Sullivan toll-free at (800)477-0778 or. in MO, (314)725-2555, or write, ASI, P.O. Box 24198, St. Louis, MO 63130.

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### October

•20-22, Basic Pasteurization Course, sponsored by the Texas Association of Milk, Food and Environmental Sanitarians, will be held at the Le Baron Hotel, 1055 Regal Row, Dallas, TX. For registration information contact Ms. Janie F. Park, TAMFES, P.O. Box 2363, Cedar Park, TX 78613-2363, (512)458-7281.

•26, GMPs for the Food Industry, sponsored by ASI Food Safety Consultants', will be held in Chicago, IL. For more information call Christine VerPlank or Nancy Sullivan toll-free at (800)477-0778 or, in MO, (314)725-2555, or write, ASI, P.O. Box 24198, St. Louis, MO 63130.

### November

•8-12, PACK EXPO 92, The World of Packaging Technology, sponsored by Packaging Machinery Manufacturers Institute (PMMI), will be held at the McCormick Place, Chicago, IL. For more information contact Bonnie E. Kilduff, Exposition Manager, PMMI at (202)347-3838 or FAX (202)628-2471.

### 1993

### May

•6-12, INTERPACK 93, 13th International Trade Fair for Packaging Machinery, Packaging Materials and Confectionery Machinery, will be held at the fairgrounds in Dusseldorf, Germany. For further information on exhibiting at or attending INTERPACK 93, contact Dusseldorf Trade Shows, Inc., 150 North Michigan Avenue, Suite 2920, Chicago, IL 60601,(312)781-5180; FAX (312)781-5188.

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