

**JOURNAL**  
of the  
**ASSOCIATION OF FOOD AND DRUG OFFICIALS**

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**ASSOCIATION OF FOOD AND DRUG OFFICIALS**  
**CONFERENCE SCHEDULE**

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**2005**

June 4–8, 2005  
Westin Crown Center  
Kansas City, MO

**2006**

June 17–21, 2006  
Crown Plaza Albany - City Center  
Albany, NY

**2007**

June 15–20, 2007  
Crown Plaza - Riverwalk  
San Antonio, TX

# ASSOCIATION OF FOOD AND DRUG OFFICIALS

## Mission Statement

The Association of Food and Drug Officials (AFDO), established in 1896, successfully fosters uniformity in the adoption and enforcement of science-based food, drug, medical devices, cosmetics and product safety laws, rules, and regulations.

AFDO and its six regional affiliates provide the mechanism and the forum where regional, national and international issues are deliberated and resolved to uniformly provide the best public health and consumer protection in the most expeditious and cost-effective manner.

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## FROM THE EDITOR

As the year draws to a close, our *Journal* has been blessed with a generous inflow of manuscripts. This is, without a doubt, the result of some hard prospecting by our Editorial Board, for which I am ever so grateful. The papers you will find here are an interesting mix of science, regulatory, personal health, and food and drug safety issues. These are important issues that drive our professional lives and bear on the needs of the public we serve. Making this *Journal* relevant to the needs of our Association's membership is a goal for which your Editorial Board strives. I think you will find our final issue of 2004 comes fairly close to achieving that goal. Let us hope that we can continue to achieve such a goal in 2005 and beyond. If you have thoughts of your own on this matter, by all means, let us hear them. Meanwhile, your Editorial Board will be working to turn out a quarterly product that our membership will find useful, timely and interesting.

Our best wishes to all of our readers for an interesting and fulfilling 2005.

Thomas W. Brooks,  
Editor

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## ABOUT THE AUTHORS

**R. Doug Saunders** received his Bachelor of Science degree in Animal Science from Virginia Polytechnic Institute and State University in 1976. Following graduation, he was employed by the Virginia Department of Agriculture and Consumer Services as a Food Inspector, with the responsibility for enforcing the Virginia Food Laws within a territory that encompassed 11 counties in the southern portion of Virginia. He was promoted to the position of Regional Supervisor in 1978 and relocated to the main Food Inspection office in Richmond, VA. Since that time, he has served as Assistant Supervisor and Program Supervisor for Food Safety, and in 1997 was promoted to his current position of Consumer Protection Program Manager for the Office of Dairy and Foods within the Department's Division of Animal and Food Industry Services. The Office of Dairy and Foods has regulatory responsibility for more than 10,000 food manufacturing, warehousing and retailing establishments, and the entire milk industry with the exception of grade "A" processing plants.

Doug has been an active member of the Association of Food and Drug Officials of the Southern States (AFDOSS) since 1979. He has served as that organization's President, and as a member of the AFDOSS Executive Board. He also served as the Chairman of the Audit Committee for three years, and has been elected to two four-year terms as the AFDOSS affiliate representative to the AFDO Board of Directors, the first term beginning in 1998, and the second term he was just recently elected to in April 2003.

**Betsy Woodward** is retired from the Florida Department of Agriculture Food Safety program after 34 years of service. She currently serves as a Special Advisor to the Association of Food Drug Officials Board of Directors for Uniformity Legislation and is a member of the Florida Food Safety and Food Security Advisory Council. In these capacities she has worked in food safety policy, participated in the development of training courses, and developed data and positions to support state and local food safety and security programs.

While employed with Florida's Division of Food Safety, she served as Chief, Bureau of Food & Residue Laboratories. In that capacity she was responsible for a multidiscipline food laboratory program that included four laboratories, 70 FTEs, a \$2.25 million state budget and over \$1 million in Federal Contracts, Grants, and Cooperative Programs directing program resources; maintaining expertise in food law and all types of food analyses, as well as policy issues in food safety, labeling, and economic fraud. Prior to that she served as Chief for the Bureau of Food Laboratory's Division of Chemistry and Assistant Bureau Chief, Chemist Administrator, and Chemist.

**Jim Austin** has spent 13 years employed in local government environmental health programs in Oklahoma and Colorado, serving the majority of that time as a food safety program director. Jim has served as AFDO's Technical Grants Administrator for the past four years.

**Joseph Corby** is Director, Division of Food Safety and Inspection for the New York State Department of Agriculture and Markets. He has been with the Department since 1970 and was appointed to his current position in 1999. Mr. Corby is responsible for the development of numerous food safety training programs for regulators and industry, the design of the Division's Hazard Analysis Critical Control Point (HACCP) inspection protocol and report and authoring the state's smoked fish regulations. He was nominated four consecutive years for the Governor's Productivity Award. He is an FDA-Commissioned Officer and a Cornell University Certified Instructor for Human Resources Development. He also serves on the Advisory Council of Cornell University's Institute of Food Science. Mr. Corby is a frequent speaker at FDA state Training Branch's Seafood Safety, Vacuum Packaging and Retail Food Protection courses. Mr. Corby has been with the Association of Food and Drug Officials (AFDO) since 1985 and became AFDO President in June 1998. In 2001, he was awarded the Association's coveted Harvey W. Wiley Award.

**William R. Krueger** is the Director of the Laboratory Services Division at the Minnesota Department of Agriculture. The Laboratory Services Division provides comprehensive laboratory testing of samples submitted in support of inspection activities and service programs of the Department's Regulatory Divisions.

Since 1997, Mr. Krueger has been actively involved in efforts to integrate national systems for improving food safety and to counter terrorism. In this effort, he has served as a member of the Steering Committee for the National Integrated Food Safety System (NFSS) and as Chairperson for the NFSS Laboratory Operations and Coordination Workgroup. Additionally, Mr. Krueger has served as Chairperson for AOAC International's Electronic Compilation of Analytical Methods (e-CAM) Advisory Group, which facilitated a significant NFSS strategy for providing laboratories rapid access to validated methods.

Most recently, Mr. Krueger was appointed to serve on the National Food Emergency Response Network (FERN) Steering Committee for providing oversight and coordination of the nation's federal, state and local laboratories' response to counter terrorism.

Mr. Krueger has a Bachelor of Arts in Chemistry and Microbiology, which he received in 1974 from Mankato State University, Mankato. He attended the University of Minnesota, Minneapolis, Minnesota from 1974-1975 with postgraduate studies in Biochemistry.

**Ilisa B.G. Bernstein, Pharm.D., J.D.**, is Senior Advisor for Regulatory Policy in the Office of the Commissioner at the U.S. Food and Drug Administration (FDA). In this capacity, she advises on domestic and international issues related to the regulation of medical products, including drugs, biologics, dietary supplements, and medical devices. In particular, she focuses on the U.S. drug distribution system, advertising and promotion issues, prescription and OTC drug labeling, the drug approval process, Internet issues, and dietary supplement issues. From 1991 to 2002, she was a Senior Science Policy Advisor in the Office of the Commissioner. Ilisa started her career at FDA in 1988 as a Pharmacokinetic Reviewer in the Center for Drug Evaluation and Research, where she was responsible for reviewing and evaluating the pharmacokinetic aspects of investigational drugs used for AIDS and HIV infection.

From 2002 to 2003, Ilisa was a Senior Associate Director at Pfizer, Inc., in the Regulatory Liaison Office in Rockville, Maryland. She served as a liaison between Pfizer and FDA, and provided guidance and advice on emerging policies, regulations, and legislation and their impact on Pfizer's global operations. She was instrumental in establishing the office for the company and assisted in managing the day-to-day operations.

Ilisa completed a post-doctoral residency at the National Institutes of Health, focusing on clinical and research pharmacokinetics.

**Rachel Bryant** is a student in the Psychology department at McDaniel College. Her areas of interest include the intersection of nutrition and psychology. She has presented her past research on portion size at Eastern Sociological Society meetings.

**Lauren Dundes** is Associate Professor of Sociology at McDaniel College and received her doctoral degree from the Johns Hopkins Bloomberg School of Public Health and specializes in Medical Sociology. Her prior publications are in such journals as the *American Journal of Public Health*, *Journal of Health and Social Policy*, *Academic Medicine*, *Journal of Clinical Epidemiology*, *Illness, Crisis and Loss*, *Journal of Environmental Health*, *American Journal of Infection Control* and the *AFDO Journal*.

**Catherine Cutter, Ph.D.** received her B.S. and M.S. degrees from the University of Connecticut and a Ph.D. in Food Technology from Clemson University, SC. She was employed as a Research Microbiologist with the USDA-Agricultural Research Service, U.S. Meat Animal Research Center in Clay Center, Nebraska, for over seven years. In 1999, she joined the faculty of the Department of Food Science at Penn State. Dr. Cutter's current research interests include examining methods or interventions to reduce or eliminate pathogenic and spoilage bacteria

on muscle foods (meat, poultry, seafood) during slaughtering, processing, and fabrication. Her Extension/teaching programs include food safety education for food processors, sanitation, general food microbiology, irradiation, wild game meat safety, control of *Listeria monocytogenes*, and Hazard Analysis of Critical Control Points (HACCP) for meat and poultry processors. She has authored or coauthored over 60 journal articles, book chapters and proceedings, 25 abstracts, and 15 Extension publications.

**Anne Muñoz-Furlong** is founder and CEO of The Food Allergy & Anaphylaxis Network (FAAN), a nonprofit 501(c)3 organization with over 27,000 members. Her interest in food allergies began with the birth of her second child, who was allergic to eggs and milk. The lack of practical, scientifically accurate information about food allergies made her determined to create a clearinghouse for such information.

In the thirteen years since its founding, FAAN has become the international leader in raising public awareness of food allergies and anaphylaxis and the issues surrounding these allergic disorders.

Anne has spoken internationally on the work of FAAN and the patient's perspective to the food industry, schools, health professionals, and government organizations. To help those in other countries start up patient advocacy groups, she founded the Food Allergy & Anaphylaxis Alliance, an international group with member organizations in eight countries.

Anne holds a bachelor's degree in Business Administration and Journalism from George Mason University in Fairfax, Virginia. She is a member of the American Academy of Allergy, Asthma & Immunology, and sits on committees of the American Academy of Allergy, Asthma & Immunology and the American College of Allergy Asthma & Immunology. She is also a member of the National Institutes of Health National Advisory Allergy and Infectious Diseases Council and the National Association of College & University Food Services' Education Advisory Board.

**Jill Hollingsworth, DVM**, is the Group Vice President of Food Safety Programs for the Food Marketing Institute, providing guidance to food retailers and wholesalers in all areas of food safety and regulatory compliance. She served as the Assistant Deputy Administrator in the office of Public Health and Science at the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS). There, she had direct oversight of the investigation of foodborne disease outbreaks involving meat and poultry products and for the recall of contaminated or adulterated food products. Before that, she served in a variety of positions in FSIS including Deputy for the Hazard Analysis and Critical Control

Points Program, Director of the Inspection Division and as a National Disease Correlator.

Dr. Hollingsworth received a USDA Award for Excellence for her role in investigating the Jack-in-the-Box *E.coli* O157:H7 outbreak, and received a superior service award for establishing the FSIS Emergency Response Team. Dr. Hollingsworth earned a B.S. degree in Agriculture and a doctorate in Veterinary Medicine from the University of Georgia.

AFDO POSITION STATEMENT  
**IMPORTANCE OF THE BIOTERRORISM PREPAREDNESS AND  
RESPONSE ACT OF 2002**

The Association of Food and Drug Officials  
Comments to the U.S. House of Representatives  
Energy and Commerce Committee

June 25, 2004

R. Douglas Saunders, Chair, AFDO Food Security Task Force  
and  
Betsy Woodward, Special Advisor to the AFDO Board of Directors

Mr. Chairman, and members of the Committee, I am here today as a representative of the Board of Directors and a past president of the Association of Food and Drug Officials (AFDO) to provide testimony on the importance of the Bioterrorism Preparedness and Response Act of 2002 (hereinafter referred to as the Bioterrorism Act). I would like to thank you for this opportunity to share the perspective of AFDO on an issue that is so vital to the protection of the food and agriculture critical infrastructure of our nation.

For 108 years, AFDO has served as a major voice for food safety officials in the United States and Canada. AFDO proudly represents state and local government food safety officials at public meetings or briefings where consensus opinions or official comments are presented on a host of food safety and security issues. Today, more than ever, there is a call for unity among health officials in government at all levels and the need to coordinate all available food safety and security resources, particularly those at the sentinel nodes of our detection system. From that perspective, we would like to offer the following comments relative to the Bioterrorism Act.

With respect to the four major issues addressed by the Bioterrorism Act, AFDO fully supports the U.S. Food and Drug Administration (FDA) as they implement regulations to address those provisions. Specifically, those provisions include: Prior notification of imported foods coming into the United States; Registration of food establishments; Record keeping to ensure effectiveness of tracebacks, traceforwards and recall activities; and Administrative detention of food products.

Prior notification of incoming shipments of imported foods and registration of food establishments are absolutely imperative if we are to have any ability at all to effectively control the movement or distribution of foods that are suspected of being compromised through acts of terrorism. We believe that such requirements provide the basis for having greater control of suspect foods and will enhance the

capability to more quickly detect non-intentional or intentional adulteration and facilitate immediate removal of suspect foods from the channels of commerce. Early detection and rapid response are essential elements in defending the integrity of our food supply. Prior notification and establishment registration can only improve those elements. However, we also believe that these components of the bioterrorism act must be augmented by additional measures. With imported foods, FDA must do more. The concept of evaluating the safety of imported foods solely at one of the 400 border points is inadequate, in our view. FDA needs to move back the borders to the manufacturing site and perform inspections of these food establishments to significantly enhance our ability to detect, detain, and ultimately remove from commerce intentionally adulterated foods. Currently, such inspections only take place with respect to low-acid canned foods. This authority must be expanded to cover all food manufacturers located outside of our borders that ship food products into the United States.

In addition, FDA must work more closely with state and local government agencies relative to imported foods that are distributed domestically. Some may suggest that imported foods are a regulatory concern for federal agencies alone. These individuals would be wrong. Once imported foods get through the scrutiny of our federal partners, they become primarily the concern of state and local regulatory agencies. Many states report recalls, and food seizures or embargoes are commonplace for issues that include undeclared allergens, unapproved color additives, undeclared preservatives, and pathogens. FDA must develop a means for obtaining this information and utilizing it, where appropriate, to institute import alerts. FDA must also consider how to best use state and local laboratory resources, as well.

The record keeping requirements provided by the Bioterrorism Act certainly improve the likelihood that effective tracebacks, traceforwards, or recalls will be facilitated in the event of a terrorist act against our food supply. Improved traceback, traceforward, or recall capabilities will significantly enhance the expeditious tracking and removal activities of the FDA when adulteration is detected. It must be noted, however, that historically, traceback or traceforward activities are usually performed by state food safety agencies. It is safe to assume that with the limited resources that are available to the FDA, most traceback and traceforward activities will continue to be performed by the states, in cooperation with the FDA.

Administrative detention is a tool that FDA has needed for many years, and a tool that will provide immediate results when it becomes necessary to prevent further distribution of suspect food products. Prior to granting of this authority by Congress, FDA had to request states to detain, seize or embargo food products when suspect food products were encountered. Through cooperative agreements, FDA has utilized the states' detention authority for many years. Because the

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Bioterrorism Act contains specific requirements that define when FDA can utilize administrative detention, it will still be necessary for FDA to maintain these cooperative agreements with the states to ensure that suspect foods that do not meet the Federal definition but are still of considerable concern relative to adulteration, continue to be legally restrained. Consequently, through the FDA's new detention authority, and through continuing cooperative agreements between FDA and the states, the nationwide network of detention capabilities will be substantially strengthened.

For as long as FDA has existed, the cooperative relationships between the FDA and state and local food safety agencies have worked very effectively in protecting our nation's food supply. These coordinated activities have led to a maximized utilization of Federal, state and local food safety and security resources, while eliminating the duplication of food protection activities. Through these cooperative efforts, state and local food safety agencies have been able to supplement the food safety and security activities of the FDA. In 2002, AFDO conducted a survey of state activities showed that, during 2001, state programs performed:

- More than 2.5 million inspections of food establishments
- More than 3,000 foodborne illness investigations
- Investigation of over 46,000 consumer complaints
- Response to over 2,800 emergencies or disasters involving food products
- More than 128,000 enforcement actions, including, but not limited to, embargos, seizures and stop sales; injunctions; criminal prosecutions; warning letters; informal hearings; and food recalls; and collection and analyses of over 328,000 food samples, including more than 252,000 microbiological samples.

Based on these figures, more than 80% of the food safety and security activities in the United States are performed at the state or local levels. Consequently, it is clear that state and local food safety programs provide the major portion of the shields that must be in place to detect any sort of terrorist act. With the increasing threat of terrorist activities against our food supply, it is paramount that this cooperative and highly integrated Federal, state and local food safety and security system be maintained and strengthened for the deterrence, prevention and detection of terrorist activities. With that focus in mind, AFDO would like to call attention to a piece of Federal legislation that threatens to eviscerate this system. The ramifications of this bill, intended or not, will dissolve our nation's biodefense capabilities.

H.R. 2699, the National Uniformity for Food Act of 2003, as presently cast, undermines our nation's whole biosurveillance system by preempting and invalidating many of the state and local food safety laws and regulations that

provide the necessary authority for state and local agencies to operate food safety and security programs. The pre-9/11 concept embodied in this bill is very much out of line with current threats that confront our food safety and security system. Preempting and invalidating state and local food safety and security activities will lead to serious ramifications that will be difficult, if not impossible, for our nation to recover from. Specifically, FDA's ability to detect, much less respond, to acts of terrorism will be severely hampered. The cost to the FDA to replace the infrastructure and food safety and security activities currently accomplished at the state and local levels is estimated to exceed \$500,000,000. Our current food safety and security system will be significantly disrupted for many years to come, and our inability to track suspected acts of intentional adulteration will be exploited by those who seek to do harm to our nation. Passage of H.R. 2699, in its current form, which would invalidate state and local food safety laws and regulations, will effectively eliminate our nation's food biosecurity shields, and will undermine our whole food safety and biosurveillance capability.

In conclusion, the Bioterrorism Preparedness and Response Act of 2002 is an immeasurably important and necessary law that further solidifies our nation's food safety and security system by providing FDA with much needed and long overdue authorities, and it ensures the continuing, cooperative efforts of state and local agencies. However, these new FDA authorities can only remain effective if the cooperative relationships between the FDA and state and local food safety and security programs can be maintained and improved. Consequently, for the effectiveness of the Bioterrorism Act to be fully realized, it is absolutely imperative that our current food safety and security programs at all levels remain fully functional and active, and that we continue to seek ways in which we can strengthen this highly integrated and cooperative system.

Once again, thank you for this opportunity to provide our comments.

AFDO POSITION STATEMENT  
**CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS**

Department Of Health And Human Services  
Food and Drug Administration [Docket No. 2004N-0230]  
21 CFR Part 110 Food;  
Current Good Manufacturing Practice Regulations;  
Public Meetings

September 3, 2004

Joseph Corby, AFDO Director of Public Policy

The Association of Food and Drug Officials (referred to henceforth as “AFDO”) is pleased to provide the following additional comments to the U.S. Food and Drug Administration regarding 21 CFR Part 110 – “Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food.”

AFDO recognizes the importance of modernizing Part 110 and wishes to provide more specific recommendations than those which were previously provided to FDA both verbally and in written form.

Many states have adopted 21 CFR Part 110 in whole or in part and it is generally recognized that this regulation serves as a foundation to other regulations that have been promulgated at the state level. A number of states will also apply Part 110 to retail processing establishments along with their own version of the FDA Model Food Code. Clearly, there is widespread application of Part 110 at the state level. For this reason, AFDO believes these regulations must be comprehensive, science-based and have a clear food safety focus.

As states conduct more than 80 percent of all food safety inspections of food processors and distributors and as the number of contract inspections to the states are increasing, AFDO again wishes to recommend that FDA seek “buy in” from the states on what proposed new changes or philosophy the new GMPs may encompass.

Our specific Section by Section recommendations are as follows:

**Part 110.3 Definitions**

We believe the following definitions should be removed from the regulation:

- “Batter”
- “Blanching”
- “Microorganisms”

- “Quality Control Operation”
- “Should”

We believe the following definitions should be added to this Section:

“Adulterated” has the meaning stated in the Federal Food, Drug, and Cosmetic Act, §402.

“Approved” means acceptable to the regulatory authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

“Critical control point” means a point or procedure in a specific food system where loss of control may result in an unacceptable consumer health risk. (Note: Modification of current definition).

“Food employee” means an individual working with unpackaged food, food equipment or utensils, or food-contact surfaces.

“HACCP plan” means a written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by The National Advisory Committee on Microbiological Criteria for Foods to prevent food from becoming adulterated within the meaning of the Act.

“Hazard” means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

“Person in Charge” means the individual present at a food establishment who is responsible for the operation at the time of inspection.

“pH” means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

“Potentially Hazardous Food” means a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting:

- The rapid and progressive growth of infectious or toxigenic microorganisms
- The growth and toxin production of *Clostridium botulinum* or
- In raw shell eggs, the growth of *Salmonella enteritidis*.

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“Potentially hazardous food” includes any food of animal origin that is raw or heat-treated; a food of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified under Subparagraph (a) of this definition.

“Potentially hazardous food” does not include:

An air-cooled hard-boiled egg with shell intact, or a shell egg that is not hard-boiled, but has been treated to destroy all viable *Salmonellae*;

A food with an aW value of 0.85 or less;

A food with a pH level of 4.6 or below when measured at 240C (750F);

A food, in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;

A food for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of *S. enteritidis* in eggs or *C. botulinum* can not occur, such as a food that has an aW and a pH that are above the levels specified under Subparagraphs (C)(ii) and (iii) of this definition and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms; or

A food that does not support the growth of microorganisms as specified under Subparagraph (a) of this definition even though the food may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness.

“Ready-to-Eat Food” means food that is in an edible form without the need for additional preparation.

“Regulatory authority” means the local, state, or federal enforcement body or authorized representative having jurisdiction over the food establishment.

“Risk” means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

“Sanitize” means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a

reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

“Scheduled process” means the process selected by a processor as adequate for use under the conditions of manufacture for a food to achieve and maintain a food that will not permit the growth of microorganisms having public health significance. It includes control of pH and other critical factors equivalent to the process established by a competent processing authority.

“Standard Sanitation Operating Procedures (SSOPs)” – means all daily sanitation procedures conducted by a food plant to prevent direct contamination or adulteration of product(s). SSOPs shall describe the activity and how to properly complete the task, as well as specify the frequency with which each procedure is conducted and identify the employee(s) responsible for the implementation and maintenance of the SSOP.

#### **Part 110.10 Personnel**

Section (a) name should change from Disease Control to Employee Health. This Section should be more in tune with the 2001 FDA Model Food Code as it relates to food employees including listing the big 4 (Hepatitis A virus, Salmonella typhi, Shigella, and Shiga toxin producing e-coli). The section should also include a list of symptoms associated with foodborne illness, (Diarrhea, Fever, Vomiting, Jaundice, or Sore Throat with fever in addition to the lesions and open wounds already addressed by this section. This section should also apply to current employees as well as applicants to whom a conditional offer of employment is offered. Some thought should be given to including high-risk activities that might lead to secondary infection. “Exclusion and restriction” needs to be defined along with specific steps necessary for a restricted/excluded employee to resume duties. An employee must be required to report symptoms or illness to the Person in Charge immediately and the Person in Charge must be required to notify the regulatory authority that a food employee is diagnosed with one of the aforementioned illnesses.

Section (b) (1) should indicate that no street clothing would be allowed unless protective outer garments are worn.

Add the following to (b) (4):

“While preparing food, food employees shall not wear jewelry on their arms and hands. This does not apply to jewelry on the hand which is covered and protected.”

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Add the following to (b) (5):

“The gloves shall be of an impermeable material unless covered by a durable tight-fitting disposable glove made of impermeable materials.” This Section should also include a statement related to minimizing bare hand contact with Ready-to-Eat foods. Fingernails should also be addressed in this section.

Part (c) must be mandated. Remove “should” and replace with “shall” in 2 areas for education and training.

Section (d) supervision should include some or all of the following related to demonstration of knowledge by the Person in Charge:

Based on the risks of foodborne illness inherent to the food operation, during inspections and upon request the Person in Charge shall demonstrate to the regulatory authority knowledge of foodborne disease prevention, application of the Hazard Analysis Critical Control Point principles, and the requirements of this regulation. The person in charge shall demonstrate this knowledge by:

- a) Complying with this Code by having no critical violations during the current inspection;
- b) Being a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program; or
- c) Responding correctly to the inspector’s questions as they relate to the specific food operation. The areas of knowledge include:

Describing the relationship between the prevention of foodborne disease and the personal hygiene of a food employee;

Explaining the responsibility of the person in charge for preventing the transmission of foodborne disease by a food employee who has a disease or medical condition that may cause foodborne disease;

Describing the symptoms associated with the diseases that are transmissible through food;

Explaining the significance of the relationship between maintaining the time and temperature of potentially hazardous food and the prevention of foodborne illness;

Explaining the hazards involved in the consumption of raw or undercooked meat, poultry, eggs and fish;

Stating the required food temperatures and times for safe cooking of potentially hazardous food including meat, poultry, eggs, and fish;

Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of potentially hazardous food;

Describing the relationship between the prevention of foodborne illness and the management and control of the following:

- Cross contamination
- Hand contact with ready-to-eat foods
- Hand washing
- Maintaining the food establishment in a clean condition and in good repair and
- Explaining the relationship between food safety and providing equipment that is:
  - Sufficient in number and capacity, and
  - Properly designed, constructed, located, installed, operated, maintained, and cleaned;
  - Explaining correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment;
  - Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections;
  - Identifying poisonous or toxic materials in the food establishment and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to law;
  - Identifying critical control points in the operation from purchasing through sale or service that, when not controlled, may contribute to the transmission of foodborne illness, and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this regulation;
  - Explaining the details of how the person in charge and food employees comply with the HACCP plan if a plan is required by the law or an agreement between the regulatory authority and the establishment.

### **Section 110.20 Plant and Grounds**

This section is written in fairly general terms, which we believe is good. We also think it's good to address outdoor operations because so many wineries have

outdoor fermentation tanks. The language should be expanded so that it is not limited to fermentation tanks. Many operations have their first step (receiving) outside and a slightly broader term could address these other outdoor activities.

The language in 110.20 (3) should be rewritten as follows:

“The plant and facilities shall take the proper precautions to protect food in outdoor storage or processes such as receiving, initial product washing or bulk fermentation tanks.”

### **Section 110.35 Sanitary Operations**

We would propose a rewrite of this Section as follows:

**General Maintenance.** Buildings, fixtures, and other physical facilities of the plant shall be kept in good repair and shall be maintained in a sanitary condition to prevent food from becoming adulterated/contaminated within the meaning of the act. Washing, rinsing, and sanitizing of utensils and equipment shall be conducted in a manner that prevents adulteration/contamination of food, food-contact surfaces, or food-packaging materials.

Substances used in cleaning and sanitizing; storage of toxic materials.

Cleaning compounds and sanitizing agents used in washing, rinsing, and sanitizing procedures shall be free from undesirable physical, chemical and microbial contaminants and shall be safe and adequate under the conditions of use as specified in 21 CFR, Section 178.1010. Compliance with this requirement shall be verified by food establishment management by any effective means including purchase of these substances under a supplier’s guarantee or certification, or examination of these substances for contamination. Documentation of compliance shall be retained on file for a period of 2 years. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

- Those required to maintain clean and sanitary conditions;
- Those necessary for use in laboratory testing procedures;
- Those necessary for plant and equipment maintenance and operation; and
- Those necessary for use in the plant’s operations;

Toxic and/or potentially toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified by a complete label, held, and stored in a manner that prevents adulteration/contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, state, and local government agencies for the application, use, or holding of these

products shall be followed. In the event of an apparent conflict among those rules and regulations the order or priority for compliance, in descending order, is Federal, state, and then local government rule/regulation.

**Pest Control.** No pests shall be allowed in any area of a food plant. Service animals shall be allowed only in those areas of a plant where the presence of the animals will not result in contamination of food, food-contact surfaces, or food-packaging materials. An effective preventive and treatment program shall be in place to exclude pests from the processing and holding areas and to protect against the contamination of food, food equipment, and utensils on the premises by pests. The use of insecticides, pesticides, or rodenticides approved for use in a food establishment is permitted only under precautions and restrictions indicated on the insecticide, pesticide, and/or rodenticide manufacturer's label that will protect against the adulteration/contamination of food, food-contact surfaces, and food-packaging materials.

**Sanitation of food-contact surfaces.** All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the food-contact surfaces are wet-cleaned, they shall be washed, rinsed, sanitized, and thoroughly air-dried before subsequent use.

In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be washed, rinsed, sanitized, and air-dried before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be washed, rinsed, sanitized, and air-dried as necessary but in no event less frequently than once each 24-hour production day.

Non-food contact surfaces of equipment used in the operation of food plants shall be cleaned as frequently as necessary to protect against contamination of food.

Single-service articles (such as utensils intended for one-time use, paper cups, paper towels, food wrappers, food boxes, and food containers) shall be stored in appropriate, closed containers and shall be handled, dispensed, used, and disposed of in a manner that prevents adulteration/contamination of food or food-contact surfaces.

Sanitizing agents shall be effective for the intended use and safe under conditions of use as specified in 21 CFR, Section 178.1010. Any facility, procedure, or machine is acceptable for washing, rinsing, and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and properly sanitized.

Storage and handling of cleaned portable equipment and utensils. Clean and sanitized portable equipment with food-contact surfaces and utensils shall be stored in a location and manner that protects food-contact surfaces from contamination.

### **Section 110.37 Sanitary Facilities and Controls**

We believe requirements for a standard sanitation operating procedure should be required and language added as follows:

Each food plant shall implement and maintain written standard operating procedures for sanitation (SSOPs) in accordance with the following requirements:

The SSOP shall describe all procedures the food plant will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).

The SSOP shall be signed and dated by the person with overall authority on site. This signature shall signify that the establishment will implement the SSOP as specified and will maintain the SSOP in accordance with the requirements of this part. The SSOP shall be signed and dated upon initially implementing the SSOP and upon any modifications to the SSOP.

Procedures in the SSOP that are to be conducted prior to operations shall be identified as such and shall address, at a minimum, the daily cleaning of food contact surfaces of facilities, equipment and utensils.

The SSOP shall specify the frequency with which each procedure in the SSOP is to be conducted by the food plant and identify the employee(s) responsible for the implementation and maintenance of such procedure(s).

Each food plant shall conduct the pre-operational procedures in the SOP before the start of operations and shall conduct all other procedures as specified in the SSOP.

The person in charge of the food plant shall monitor the daily implementation of the SSOP.

The operator of the food plant shall evaluate the procedures contained in the SSOP to prevent direct contamination or adulteration of product(s) and shall revise the SSOP as necessary to keep the procedures effective and current with respect to changes in facilities, equipment, utensils, operations or personnel.

The operator of the food plant shall take appropriate corrective action(s) when either the establishment or department representative determines that the establishment's SSOP failed to prevent direct contamination or adulteration of product(s). Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the SSOP.

Each food plant shall maintain daily records sufficient to document the implementation and monitoring of the SSOP and any corrective actions taken. The establishment employee(s) specified in the SSOP shall authenticate the record with his or her initials and the date. These records shall be maintained for at least six months and made available to a department representative upon request. All such records shall be maintained at the food plant.

### **Part 110.80 Processes and Controls**

The flexibility in this Section is an overall strength of the regulation. We believe this strength could be enhanced by requiring the application of a scheduled process for the manufacture of certain "potentially hazardous foods." The determination of what foods would require a scheduled process would be determined by the regulatory authority and based on illnesses associated with the products, how the products are packaged (reduced oxygen packaging), or other recognized concern. With reference to Parts 110.80(b)(3)(I) and (ii) – We believe the temperature requirements for refrigerated foods and foods held hot should be harmonized with the FDA Retail Food Code (i.e., refrigerated @ 41 degrees F and held hot @ 135 degrees F).

We further believe a requirement for food facilities to establish a written recall procedure should be included in this Section.

### **Part 110.93 Warehousing and Distribution**

We recommend this Section be rewritten as follows:

All storage and transportation of foods shall be under conditions that will protect food against chemical, physical, and microbiological contamination, or

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accelerated deterioration that would render the food unfit for consumption [Section 402(a)(3) situation – “...decomposed substance, or...otherwise unfit for human consumption”].

Food Storage.

Facilities and grounds.

Food storage facilities shall be kept free of rodents, insects, birds, and other pests which may contaminate food.

Food storage facilities shall be properly constructed and maintained. All walls, ceilings, and floors shall be intact to preclude entry of vermin and environmental contaminants.

Doors and loading docks shall be tight-fitting and kept closed at all times when not in use, or adequately screened during normal operating hours to prevent entry of rodents, birds, insects, or other pests.

Outer premises, including trash receptacles, shall be kept clean and free of odors, debris, high weeds, or standing water which could harbor or attract vermin. All trash receptacles shall either be tightly covered or inverted if not in use.

Adequate protected lighting shall be provided to facilitate cleaning and inspection of stored foods and to prevent the unintentional contamination of foods or food ingredients.

Refrigeration units for storage of potentially hazardous foods (or whatever new name FDA comes up with) shall be adequate for properly cooling and maintaining all product at an internal temperature of 41 degrees Fahrenheit within safe time frames. Refrigeration units for storage of shell eggs (only) shall be adequate to maintain at an ambient air temperature of 45 degrees Fahrenheit.

Freezer units shall be adequate to maintain all frozen foods in a frozen state at all times.

All chemicals shall be properly labeled, stored, and physically separated from food storage at all times to preclude contamination.

Hand-washing and toilet facilities shall be provided and adequately maintained, including hot and cold running water, hand soap or approved hand sanitizer, and single-service towels as deemed appropriate (by the regulatory authority) for the types of foods handled.

Wastewater shall be disposed of in a sanitary and legal manner (as deemed by the regulatory authority).

Only pesticides approved by the Environmental Protection Agency (EPA) for use in a food warehouse and/or food processing facility may be used. Pesticides shall be used only according to label directions. Rodenticides shall be placed inside enclosed bait boxes or other approved receptacles. Only a licensed pesticide applicator may apply restricted-use pesticides.

#### Food Safety Operations.

All potentially hazardous foods shall be maintained at an internal temperature of 41 degrees Fahrenheit or less at all times except as permitted in 2 c) below.

All frozen foods (that are either potentially hazardous or that are subject to decomposition that would render them unfit for human consumption) shall be kept frozen at all times.

After initial packing, shell eggs must be stored under refrigeration at an ambient temperature of 45 degrees Fahrenheit or less at all times. If the United States Department of Agriculture and the U.S. Food and Drug Administration determine that a lower temperature must be maintained, the lower temperature shall prevail.

The temperature of molluscan shellstock from the harvester through the original shellfish dealer shall be maintained in accordance with the requirements of the National Shellfish Sanitation Program Model Ordinance. Raw molluscan shellstock shall be adequately iced or refrigerated to maintain an ambient air temperature of 45 degrees Fahrenheit or less during storage and distribution. Post-harvest treated shellstock shall be maintained at an internal temperature of 41 degrees Fahrenheit.

All foods, including refrigerated and frozen foods, shall be stored off the floor and away from the walls to help prevent contamination by vermin (rodents and insects, for example) and moisture, and to facilitate cleaning, inspection, and proper application of pesticides and insecticides.

All damaged, distressed, and infested foods including swollen, leaking, and severely dented canned foods shall be segregated and stored in a "morgue area" adequately separated from undamaged food storage areas. Such foods shall be disposed of in a timely manner to preclude further contamination including by vermin.

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All incoming foods and raw materials shall be inspected for insect or rodent contamination, temperature abuse, or other evidence of adulteration prior to being placed in storage.

Foods and ingredients shall be rotated on a “first in, first out” basis or by the oldest date of pack.

Distressed foods salvaged in-house shall be reconditioned (we say “according to [our food salvage rules]” prior to sale except as indicated in (A)(2)(j) of this Subsection.

If the state in which the facility resides requires licensing and inspection of food salvage establishments, distressed foods may be distributed only to an establishment in compliance with state law. (I don’t know that FDA has ever included such information before, but it would be ground-breaking if FDA were to ensure that applicable state laws that do not conflict with federal laws were mandated by FDA...such as in the area of food salvaging.)

### Transportation of Foods.

Transportation vehicles shall be kept clean and free of rodents, insects, birds, and other pests which may contaminate food.

Vehicles used to transport foods may not be engaged in the back-hauling of any materials that could cause physical, chemical, or microbiological contamination of foods. Such activity is expressly forbidden unless the vehicle can be and is adequately cleaned and sanitized to prevent such contamination between uses.

Vehicles used to transport frozen or refrigerated potentially hazardous foods, including shell eggs and molluscan shellfish, must maintain the proper temperature of such foods at all times according to the temperatures listed in (A)(2)(a-d) of Subsection (A) above.

Vehicles used for transporting potentially hazardous foods or frozen foods must be equipped with a continuous recording thermometer or an equivalent means to document and ensure that proper food temperatures are maintained at all times. Such temperature recording equipment must be calibrated according to the manufacturer’s specifications, including the frequency of re-calibration, but not to exceed six months. Written records of all transportation temperatures and recalibration must be kept for a period of one year and are subject to review by the [regulatory authority] upon request.

In lieu of compliance with (4) above, a Hazard Analysis Critical Control Point (HACCP) system may be used to ensure that potentially hazardous foods remain

safe during transportation, including the identification, monitoring, verification, and validation of all critical control points.

Food transportation vehicles must be equipped with locking and/or tagging devices to ensure foods are not subject to intentional contamination (tampering) during transport.

If non-food items capable of causing contamination of food, such as cleaners or pesticides, are carried at the same time as food on the same vehicle, adequate precautions must be made to ensure that the food remains safe from cross-contamination.

Vehicles used to transport food shall be kept clean and free of excessive dust, dirt, spillage, and other debris, including excess moisture.

Staging of potentially hazardous foods shall be done in a manner that does not cause the food to become adulterated, either from filth or from being out of proper temperature for an extended period of time that could permit pathogen growth or toxin formation. The amount of time such foods may be staged must encompass such factors as the temperature of the food when staged, the time out of refrigeration, and the time it takes to bring the food temperature back to a safe range. Frozen foods must remain frozen.

We appreciate the opportunity to provide these additional comments.

## **AFDO FOOD SECURITY ACTIVITIES**

R. Douglas Saunders, Chair, AFDO Food Security Task Force

AFDO has always demonstrated a tremendous focus on the safety of our nation's foods, drugs, medical devices, cosmetics and other consumer commodities. Now that our concerns must also include protection of those commodities from intentional contamination by those who seek to do our nation harm, AFDO has also placed a significant amount of time and energy into activities with the goal of enhancing our capabilities to more effectively secure our nation's food and agriculture infrastructure. With so many federal, state and local government agencies, private industries, academicians and others having to focus on such concerns, it is absolutely imperative that such activities throughout the nation should be coordinated so that resources can be maximized, best practices can be shared and built upon, and duplication of activities can be kept at an absolute minimum.

Over the past two years, AFDO has devoted substantial effort in attempting to unify the food security activities that are taking place throughout the nation. Among the numerous food security activities that AFDO has been involved in, the following are of particular note:

➤ **Multi-State Food Security Task Force**

With the intent of developing a national uniform food security strategy, AFDO formed a Multi-State Food Security Task Force in August 2003. Membership on this task force included at least two representatives from each of AFDO's six regional affiliate associations; Jim Austin, AFDO's grants coordinator; Denise Rooney, AFDO's Executive Director; and representatives from the Food and Drug Administration (FDA), the Food Safety and Inspection Service (FSIS), the Centers for Disease Control and Prevention (CDC), the Department of Homeland Security (DHS), the National Association of State Departments of Agriculture (NASDA), the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officers (NACCHO), and the Food and Agriculture Information Sharing and Analysis Center (ISAC), a partnership of food industry associations coordinated by the Food Marketing Institute.

This task force has held several face-to-face meetings and numerous conference calls to develop a plan for a national uniform food security strategy. As a component of that development, this task force has prepared plans for holding a 50-state food security meeting to involve multiple attendees from each state, representatives from the food

industry, academicians, and our partners from each of the federal agencies who have food security responsibilities. This task force remains optimistic that such a meeting will take place in the not-too-distant future and that a truly public/private partnership between government agencies, academia, and the food industry will develop the nationwide, uniform food security strategy that AFDO believes is so necessary to ensure that our food supply is as secure as possible against acts of terrorism.

➤ **The Food and Agriculture Sector Coordinating Council (FASCC)**

The food and agriculture sector formally organized itself on June 24, 2004 into a Sector Coordinating Council to address homeland security issues. The FASCC is an industry owner and operator-led council and the Government Coordinating Council (GCC) is a component of, and works in full partnership with the overall FASCC. The GCC is composed of twelve key representatives from federal, state and local government organizations. AFDO serves as an ex officio member and is able to benefit the GCC through our extensive expertise with foods and agriculture. AFDO is able to attend all meetings and participate in conference calls in a non-voting capacity; although, AFDO does not have a vote on this council, our participation has already proven to be extremely beneficial to the activities of this council. We look forward to continuing to provide favorable and worthwhile input into the activities of this extremely important council.

➤ **The Bioterrorism Preparedness and Response Act of 2002**

AFDO was invited to provide testimony on the Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). On June 25, 2004, Betsy Woodward and Doug Saunders traveled to Washington, DC and provided this testimony in front of the U.S. House of Representatives, Energy and Commerce Committee. In addition to voicing support for the requirements of the Bioterrorism Act, AFDO also requested the following:

- Closer cooperation and coordination with state and local governments and our federal government partners;
- Greater emphasis on imported foods; and,
- Careful consideration of the negative effect that H.R. 2699, the National Uniformity for Food Act of 2003, will have on states' and localities' ability to act to protect citizens in the event of a terrorist act against the food supply.

➤ **Nationwide Food Security Survey**

As one of the activities of the Multi-State Food Security Task Force, AFDO prepared and conducted a nationwide food security survey to:

- Document state-level resources currently dedicated to food security activities;
- Characterize the range of state-level food security and emergency preparedness activities already undertaken; and,
- Identify opportunities to leverage state food program resources, expertise, and initiatives to assist in consistent implementation of national homeland security policies.

As a result of that survey, AFDO was able to establish the following conclusions and recommendations:

- State agencies and the associations that represent them should work with their federal counterparts to define specific roles and responsibilities for state food program staff to ensure effective integration within the National homeland security system;
- A mechanism/forum should be established to ensure effective two-way communication of food security related information between policy makers and technical staff from all levels of government (local, state and federal) and the private sector;
- Additional guidance regarding vulnerability assessment methods is needed to facilitate consistent planning and risk-based resource allocation;
- Training materials, model documents, and best practices for state food programs are needed to foster increased consistency under federal leadership in pursuit of National homeland security policies; and,
- AFDO should initiate discussions with federal partners and other state and local agency associations (NASDA, ASTHO, NACCHO, etc.) to identify appropriate and sustained funding mechanisms that increase availability of federal preparedness assistance and other homeland security funding to state and local food programs.

➤ **NASDA Cooperative Agreement with USDA, FDA and DHS**

The National Association of State Departments of Agriculture signed a cooperative agreement with FSIS, FDA and DHS to develop best practices for coordinating emergency preparedness/response between federal and state agencies when responding to incidents affecting the

nation's food supply. The goals and outcomes of this cooperative agreement include:

- Gathering information on state emergency response systems and how food/agricultural safety and security emergencies will be handled within the various states, including commonly used response plan models;
- Developing an interagency response plan that includes state and local participation;
- Conducting tabletop exercises/pilots to test functionality of the emergency response plan, and refine the plan based on lessons learned and other input; and,
- Developing guidelines for federal food and agricultural regulatory agencies to cooperate with state and local emergency response efforts, thus facilitating federal assistance to be made available more quickly and appropriately to assist the local response and recovery efforts.

AFDO was requested to serve on the steering advisory committee for this cooperative agreement, and Doug Saunders was appointed to act in this capacity. The initial face-to-face meeting and numerous conference calls have already taken place, and AFDO's input has been and will continue to be invaluable as this activity moves forward.

➤ **Survey of States – Distribution of CDC Bioterrorism Funding**

AFDO conducted a survey during 2002 to determine the level of CDC bioterrorism funding that had been devoted to food safety programs to deal with food security issues. The majority of this funding had been designated for use in traditional public health programs, but AFDO believes that traditional public health activities must begin to recognize the important role that food safety and security has in the protection of public health. The results of this survey clearly demonstrated that only a very small percentage of the millions of dollars of funding was devoted to food security activities, and only in a very few states. Although the initial funding was mostly targeted at traditional public health issues, the results of this survey made it clear to AFDO that a paradigm shift is necessary if food safety and security activities are going to be able to receive the attention and funding that will be necessary to ensure the ongoing safety and security of our nation's food supply.

These are but a few of the food safety and security activities that AFDO has been actively involved with since the devastating events of September 11, 2001. AFDO also conducted a very well received Food Security Seminar in New

Orleans, LA in March 2002; participates on the National Food Processors Association Food Security Alliance; interacts regularly with the Uriah Group, a food security consulting company; is in the process of updating its website to enhance security communications capabilities among AFDO members; and plans to establish a standing Food Security Committee within AFDO to provide continuing attention on the ever important arena of food and agricultural security.

Through the ongoing efforts of AFDO and its members, as well as the activities of many others throughout the nation, it is our desire that food and agricultural security will soon receive the attention, the coordination, and the resources that are so necessary to properly protect our nation's food and agricultural infrastructure.

## **SURVIVING THE NORTHEAST POWER OUTAGE OF 2003**

Joseph Corby

Director, Division of Food Safety & Inspection  
NY Department of Agriculture and Markets

Much is said and written about how government regulatory officials conduct food safety inspections and investigate foodborne illness. Our efforts to ensure a safe food supply are continually scrutinized by others relative to our effectiveness and the time it takes us to respond.

An area where I believe we perform extraordinarily well and where little is said and written about is our work in response to disasters and emergency situations. It is in these circumstances that we are at our best and this presentation is a testimony to all public health officials who accept this responsibility with little fanfare and whom assume a critical role when things are at their worst. It just comes with our profession.

This story is not about New York, but it is about all who are asked to respond to disasters and emergencies. What we do in New York is not any different than what is performed in other states or in other communities. We do whatever we can to help or offer assistance and, sometimes, just provide a little hope to distressed citizens.

Thursday, August 14, 2003, was just like any other day and, as 4:00 pm rolled by, everyone was thinking about going home for the evening. For some strange reason when the lights went out at 4:10 pm, we knew that something huge and unique was happening. Soon we heard from our Region Offices in Buffalo, Rochester, Syracuse and New York City, all reporting widespread power outages. Our entire field staff was put on stand-by and we began to consider the possible impacts of what was occurring.

We now know that what was occurring at that moment would affect 50 million people and that 21 power plants would shut down in a matter of three minutes.

Streetlights went off, elevators and subways stopped and refrigeration units stopped functioning. Time became our biggest enemy.

Experience reminds us that the roles and responsibilities assumed by public health officials during disasters are not always clear and well defined. While we recognize our responsibilities relative to food safety, what we may do following an emergency situation will many times depend on the most immediate need of the moment. I can relate to this by pointing to four other huge emergency situations which occurred during my career in New York:

- In 1972 after several days and nights of solid rain, the cities of Elmira and Corning, NY, received major and widespread flooding. Restaurants and grocery stores had much of their stocks of food underwater. Even liquor store inventories of wine and liquor became submerged in flood waters and mud. And when the water receded, Food Inspectors were assigned to work with the US Army National Guard to identify unsalvageable food and drink, inventory amounts to be destroyed, assist in loading US Army trucks with the damaged products, and witness its destruction at neighboring landfills.
- Buffalo receives an unfair, unwarranted reputation for losing four football games and all because of the Blizzard of '77. This freak snowstorm created snow drifts of up to 25 feet and the city was declared a disaster area by President Jimmy Carter. Food Inspectors helped to identify communities within the city where food supplies were depleted and in immediate demand. We, also, networked with industry to identify available food sources in and around the city. This information was provided to transportation officials who would then prioritize roadways that needed to be plowed and opened so food could be delivered to needy citizens. Abandoned trucks and railway cars containing canned food and drink resulted in the freezing of these products, causing them to swell and stress their lids and seams. This became a potential food safety hazard that had to be assessed as well.
- A huge and prolonged ice storm in 1998 greatly affected dairy farmers in Northern New York, Vermont, and Southern Ontario. Although temperatures remained cold throughout, limiting the impact of food spoilage in food stores left without electricity, the impact to dairy farmers who had no alternative power source was devastating. One of our major roles became shuttling gas generators to dairy farmers so that cows could be milked. We were receiving loaned generators from as far away as Texas to help Upstate farmers who were otherwise unable to milk their cows. The potential impact of this episode to dairy farmers was nothing short of economic disaster.
- September 11, 2001, may very well be America's worst day. The roles of Food Inspectors following this tragedy were many. Temporary food service sites for volunteer workers were monitored for food safety by city and state health agencies. State veterinarians provided evaluation and treatment for the dogs used to sniff around the hot rubble, causing their paws to blister or bleed. Food supplies for those living around Ground Zero became depleted and we worked with industry to get food

into that community. We did anything that needed to be done, working side by side with many state and city agencies and industry.

Sometimes there are events that occur that may not seem to be disasters but stress the limitation of food protection programs. Examples of these are garbage strikes in large cities and the Democratic and Republican National Conventions. Ask Food Inspectors who have worked during these episodes for their impressions. Some may suggest they were disasters as well.

The major roles and responsibilities for Food Inspectors responding to disasters or emergency situations are as follows:

- Conduct food safety assessments
- Assist in assuring food supplies
- Network with other government agencies and industry
- Assist in recovery measures

For some reason, many believed that the power outage of 2004 only affected New York State, which is untrue. Areas of Pennsylvania, Ohio, Michigan, and Canada were affected as well. It was not too long after the event began that each state blamed the other and both countries blamed one another.

New York City Mayor Bloomberg assured us all that this was not a terrorist event, which was something we needed to know. As you would expect, New Yorkers have a great sensitivity to this.

When it became clear the power outage might last longer than hoped for in certain areas of New York City, our inspection staff was alerted and informed that food safety assessments would be performed. The weather was hot and humid with temperatures in the nineties. And while we were preparing for our work New Yorkers were attempting to tolerate another struggle in their own “New York” way.

With traffic lights not functioning, automobile and bus traffic was not moving. The subways and rail traffic were temporarily shut down and, other than those individuals who were willing to walk away from the city, people were settling into office and hotel lobbies to spend the evening. Dining by candlelight and barbeque grilling on the streets was commonplace. You could still get a pint of beer and a great meal cooked on a gas stove, but time and hot humid temperatures presented a clear food safety and food spoilage problem.

It is suggested that spoiled foods hurt poor persons the most. Large food stores in more affluent areas seem to more easily handle these types of episodes. They can employ alternative refrigeration methods and most probably have insurance to

address any potential economic harm. This may not be true in our inner cities where food stores are known to operate under small profit margins and less apt to discard foods. Individuals living near these stores have few choices of where to shop, as they may not have transportation to take them elsewhere to purchase their food.

Our strategies for responding to this power outage were as follows:

- 1) The State Emergency Management Office (SEMO) was activated in Albany, NY, and all relative state agencies provided 24-hour representation.
- 2) We set up Incident Command Systems in Brooklyn and Manhattan, which were the hardest-affected areas in the state.
- 3) Our communications were enhanced through direct connect capability (walkie-talkies), as regular cell phone use became overloaded and inoperable.
- 4) Food Inspectors would conduct food safety assessments in all regulated food establishments. Educational materials and guidance relating to refrigeration and potentially hazardous foods were to be provided to establishment operators. When off-temperated or off-conditioned foods were found being offered for sale, appropriate enforcement actions were taken. This included a failing inspection, food seizure, and witnessing product destruction.
- 5) Reports to the Incident Command Systems from field inspectors would be provided twice each day. Incident Command Systems would likewise report to the Albany Central Office and SEMO.
- 6) The recovery phase would continue for several weeks, with identification of any increase in foodborne illnesses. Media releases would be made as deemed necessary.

A number of alternative measures for refrigerating or delaying thawing of potentially hazardous foods are available and include the following:

- Use of back-up generators
- Refrigerated vehicles
- Dry ice
- Relocating refrigerated foods to freezer compartments
- Covering foods to delay warming

There is guidance information available for inspection personnel.

Retail stores, particularly small businesses, may need guidance documents as well. We have the following documents to provide them with during such episodes.

- 1) Guide for Safely Refreezing Thawed Food
- 2) Temperature Abused Food Guidelines
- 3) Water Emergency Procedures
- 4) Damaged-Seized Food Notice

(Available at [www.agmkt.state.ny.us/fs/general/consumerinfo.html](http://www.agmkt.state.ny.us/fs/general/consumerinfo.html))

Following the event, we learned that a spike in the increase in diarrheal illnesses was reported by hospital emergency rooms to the NYS Department of Health. The media suggested spoiled foods were the probable reason.

New York Agriculture and Markets, Division of Food Safety and Inspection reported the following activities following the power outage:

1,137 food safety assessments performed  
57 violative actions (5%)  
13,695 lbs. of food seized and destroyed  
721,033 lbs. of food voluntarily destroyed

As with all other disasters and emergencies we have been involved in, we learn some very valuable lessons. We learned the value of direct connect communications, the effectiveness of incident command, and the critical importance of government and industry interaction.

I'm proud to say government food safety officials are truly there when needed the most.

## **AFDO GRANTS SUMMARY**

Jim Austin, AFDO Technical Grants Administrator

### **A Study of State Food Safety Programs Collecting Data on *Listeria monocytogenes* in Ready-to-Eat Foods at Retail Food Establishments**

Project Period: May 11, 2004 through May 10, 2005

#### **Long-Term Objective:**

FSIS expects this agreement to result in an enhanced knowledge and understanding of the prevalence and levels of LM in RTE foods at retail establishments. This information may be used, at the Agency's discretion, to inform decision makers at FSIS and facilitate the continued development of Agency positions on the control of LM. FSIS hopes to utilize this understanding to make informed decisions on future LM interventions.

#### **Short-Term Objective:**

The objective of this project is to better understand the hazard posed by LM in RTE foods at retail. This objective will be met by collecting and analyzing data on LM prevalence and level while evaluating the sampling protocols used to monitor LM at retail. Building upon a project completed in 2002, this study proposes contacting 63 identified State Agriculture and State Health Departments that conduct microbiological sampling programs. The laboratory results from these programs include both food samples and environmental swabs. The data will be compiled and analyzed by a workgroup for prevalence information on LM in RTE foods regulated by FSIS and the environment of those foods at retail.

#### **Methodology:**

FSIS will enter into this cooperative agreement with the Association of Food and Drug Officials (AFDO) to collect and evaluate prevalence and level data of LM at retail as sampled by state food safety agencies. AFDO will survey state food safety programs to determine whether they conduct any LM surveillance sampling at regulated food establishments. Laboratory results from this surveillance sampling will then be gathered from those agencies. A project workgroup will compile and evaluate this collected LM surveillance data. The workgroup will then complete and communicate an evaluation of this data.

**Description of Work Activities:**

- A project workgroup will be assembled and it will consist of the following individuals: three state Food Safety Program representatives, two academia representatives, and at least three USDA/FSIS representatives.
- The project workgroup will meet on at least two occasions for the purpose of completing project work.
- The workgroup will identify state programs that conduct LM surveillance (sampling and analysis) of foods through an email survey. The survey content will be developed by the workgroup and the survey will be conducted by AFDO.
- AFDO will collect the data and present it to the working group in both electronic and paper format.
- Upon receipt of the data from AFDO, the workgroup will compile the data, evaluate the protocols used to collect the data, and draw conclusions regarding the overall prevalence and level of LM at retail.
- AFDO will publish and duplicate all materials developed by this project workgroup and make them available to state programs.

**Progress to Date:**

The workgroup held their initial meeting in Washington DC on September 15, 2004, to develop the survey. It has been distributed to the food safety programs in all state health departments and all state agriculture departments.

**A Program to Develop and Promote the Use of Science-Based Education and Outreach Materials on Preventing *Listeria* Contamination of Ready-to-Eat Foods**

Project Period: August 12, 2004 through August 11, 2005

**Long-Term Objectives:**

1. Promote the use of science-based education and outreach materials on preventing *Listeria* contamination of ready-to-eat foods by state and local retail food regulatory programs and the retail food industry.
2. Promote the model response strategy to be employed by state and local regulatory agencies when responding to incidents of *Listeria* positive surveillance sampling.

**Short-Term Objectives:**

1. Develop educational materials for retail food establishments and state/local government agencies that regulate them on recognized intervention strategies to reduce or eliminate *Listeria monocytogenes* in retail food establishments.
2. Develop a model response strategy which can be employed by state or local regulatory agencies in response to positive *Listeria monocytogenes* surveillance samples collected at retail.

**Methodology:**

A project workgroup, representative of all stakeholders, will be assembled and will consist of the following individuals: One AFDO representative, one CFP representative, two state food safety program representatives, one academia representative (Penn State University), three retail food industry representatives, one FDA representative and one USDA/FSIS representative. The workgroup will communicate primarily through electronic means, but is expected to meet on two occasions for the purpose of completing project work.

The workgroup will assess the needs of state programs for information and materials on LM prevention and interventions by retail and food service establishments, and will develop appropriate educational materials to be distributed to state and local food safety programs and provided to restaurants and retail food establishments. The project workgroup will partner with Penn State University and the Food Marketing Institute in order to integrate existing educational materials. Penn State University will be responsible for the production, duplication and copying of all educational materials as described in their 2-page proposal transmittal and budget. The materials (videos, booklets, and

notebooks) will all contain HACCP-compatible verification elements and corrective actions, including the following:

- Verification of sanitation
- Facility design/product separation
- Employee hygiene and training
- Equipment sanitation
- Process verification
- Verification of program effectiveness through equipment monitoring (swab testing)
- Corrective action steps for positive swab or product samples
- The workgroup will develop a model response strategy, which can be employed by state and local regulatory agencies where positive *Listeria monocytogenes* samples are encountered.
- AFDO will actively promote the use of the educational materials and the model response strategy through its website, newsletter, email news, affiliate meetings and annual conference. AFDO will distribute the same to state food programs and will provide FSIS with reproducible copies of all materials.
- AFDO will evaluate whether recipients made effective use of the materials and what approaches proved most effective.

**Progress to Date:**

Workgroup members have been selected. The first workgroup meeting will be held on January 12, 2005, at USDA offices in Washington, DC.

### **States Helping States**

Project Period: September 30, 2004 through September 29, 2005

We have begun the 5th and final year of this cooperative agreement with the Centers for Disease Control and Prevention (CDC). Following are our anticipated major accomplishments for FY 2005:

#### **Objective #1: TRAINING OF ADDITIONAL STATE TRAINERS**

Conduct two Train-the-Trainer courses to prepare state individuals to deliver the applications course in FY2005. Potential state trainers will be recruited and trained to teach these courses, which will be held in Columbus, OH and Denver, CO in the fall of 2004.

#### **Objective #2: DELIVERY OF THE APPLICATIONS COURSE**

Conduct the 2-day applications course in New York City and Jackson, MS, in the spring or summer of 2005. These will be the initial course offerings for CEUs.

#### **Objective #3: WEB-BASED RESOURCE DEVELOPMENT**

Continue enhancing the States Helping States resources on the AFDO website. Our website will be undergoing a major redesign during the next 6–12 months. All website resources will be kept current and accurate.

#### **Objective #4: PROJECT PROMOTION**

Continue to promote all the grant-funded resources available to state and local food safety programs via presentations by the AFDO President at the six AFDO regional affiliate meetings and our annual educational conference by a display at the NACCHO 2005 annual meeting, and through other venues such as the AFDO website and eNEWS, AFDO training courses, and the FDA Division of Federal-State Relations website.

#### **Objective #5: PROJECT EVALUATION**

Use a survey to determine the reach of States Helping States to state and local food safety programs. The survey was developed in response to the technical review of our FY2004 continuation application and was approved by Vince Radke, our Project Officer. The survey will be given to attendees at the six AFDO regional affiliate meetings and at our annual educational conference.

**Progress to Date:**

The Columbus Train-the-Trainer course was held on October 19–21 and the Denver course will be held on December 7–9. Our website is undergoing a dramatic improvement and States Helping States resources will be displayed and promoted far more effectively. The website changes will positively affect every facet of AFDO, so look for more information in the near future on this exciting project!

**Develop and Implement an Active Surveillance System to Track and Report on the Adoption of the FDA Food Code by State and Local Agencies and by Tribal Nations of Native Americans**

Project Period: April 1, 2004 through February 28, 2005

We are in the final year of this contract with FDA. State agencies are regularly contacted about the status of their retail food codes and any rulemaking efforts in process. The FDA receives quarterly updates in order to have real time data on the progress of state adoptions of the Food Code. For the latest report, go to <http://www.cfsan.fda.gov/~ear/fcadopt.html>.

## **THE NATIONAL FOOD AND AGRICULTURE LABORATORY COMMITTEE (NFALC)**

William R. Krueger, Director  
Laboratory Services Division, Minnesota Department of Agriculture

State agriculture control laboratories are responsible for a broad range of food- and agriculture-related analytical activities. While these laboratories participate in a number of different associations, there is no single organization that represents their collective interests. Consequently, agriculture control laboratories lack a unified voice and identity.

Currently the diverse, fragmented food and agriculture system makes it difficult to coordinate and communicate with and among this group of laboratories. Yet food/agriculture protection and defense necessitate improved communication and coordination with associations, agencies, and regulators of food and agriculture products.

The National Food and Agriculture Laboratory Committee (NFALC) is being established to help resolve these concerns. This committee will help develop community within and a collective voice for the nation's state agriculture control laboratories engaged in the regulation and control of agriculture and food production.

In many ways, this Committee will have the look and feel of an association, similar and parallel to the Association of Public Health Laboratories (APHL) and the American Association of Veterinary Laboratory Diagnosticians (AAVLD). In reality, this Committee will be a "virtual association" formed as a consortium of laboratory committees and interests from multiple associations that represent control officials of agriculture and food.

These associations include:

- Association of Food and Drug Officials (AFDO)
- Association of American Feed Control Officials (AAFCO)
- Association of American Pesticide Control Officials (AAPCO)
- Association of American Plant Food Control Officials (AAPFCO)
- National Association of State Departments of Agriculture (NASDA)
- Association of Official Seed Analysts (AOSA)

For the purposes of this paper, the term "virtual association" is interpreted to mean a body of laboratories that leverage Web-based technology to create the community and coordination normally found in actual associations.

## 44 Association of Food and Drug Officials

There were several reasons for the decision to form a committee representing the interests of multiple associations rather than creating a whole new association. One major concern was to avoid the significant initial costs and input of resources necessary to create and support a new laboratory association. It was also noted that remaining an integrated part of separate and diverse associations would help this committee create synergy, cooperation and coordination within the infrastructure that regulates food and agriculture.

The formation of the NFALC began at the 108<sup>th</sup> AFDO Annual Conference on June 19 and 20, 2004. An interim ad hoc work group was set up to help define the mission, vision, and goals for this effort and to introduce protocols to govern the NFALC. This ad hoc work group's members were selected from laboratory directors who are currently actively involved in advocacy on a national basis for the interests of agriculture control official laboratories.

The participants included the following:

- Reuben Beverly - Georgia
- Bill Cusick - California
- Tom Jensen - Nebraska (Current Agriculture Representative to FERN)
- Bill Krueger - Minnesota (Current Agriculture Representative to FERN)
- Steve Reh - Michigan
- Dan Rice - New York
- Steve Sobek - Wisconsin
- Nancy Thiex - South Dakota

The United States Department of Agriculture (USDA) provided initial funding to host the charter meeting. The ad hoc work group developed mechanisms to select appropriate candidates to serve on a steering group for the new committee. Once formed, this larger steering group will help guide the formation and mobilization of the NFALC on a fifty-state basis.

As the NFALC begins to operate on a national scale, the formal steering group will be elected such that all states are represented. Consensus decision-making will be achieved through a voting process where input will be solicited from the steering group members of all fifty states. This will help ensure equal representation in leadership selection, policy development, and the organization/operation of this national body of laboratory control officials.

Over the two days of meetings in June, the ad hoc work group developed the following guidance for this new NFALC:

**Vision:** To be the national committee on technical, scientific, and policy issues representing state agriculture control laboratories to associations, agencies, and regulators of agriculture and food products.

**Mission:** To provide a voice and leadership for state agriculture control laboratories, this committee will:

1. Create a virtual association that helps build community within the body of state agriculture control laboratories by leveraging Web-based technology for communication and collaboration;
2. Provide a mechanism for sharing methods, expertise, and other analytical resources throughout the system;
3. Provide a mechanism to identify and rapidly communicate important issues throughout the nation's network of member laboratories;
4. Interface directly with associations, the Food Emergency Response Network (FERN) and other government entities on laboratory analytical issues related to food protection and defense. This would include technical, scientific, and policy concerns on a farm-to-table basis; and
5. Act as a conduit for the solicitation and allocation of additional national resources in support of state agriculture control laboratories to build laboratory capacity and capability in the areas of emergency response, research, training and development, and food safety and security, and all issues important to the protection and defense of the nation's food supply.

**Goals:** The following Committee Goals were established to give direction to this first year's activities:

1. Create a comprehensive list of state agriculture laboratories. Identify and contact all state agriculture control laboratories and provide them an opportunity to participate.
2. Develop a vehicle to capture information (laboratory profile) on what each agricultural laboratory does: capability (analytes assayed, methods used) and capacity, number of staff, and their respective expertise, available instrumentation, type and availability of space, test cost (if applicable), and historical information on numbers and types of samples tested and assays performed. Use laboratory profiles to assist eLEXNET's development of the Laboratory Directory of Integrated Resources (LabDir) component. This Directory is intended to reflect the

analytical capabilities, capacity, instrumentation and expertise of each laboratory that we are trying to integrate as resources for a nationally based laboratory system.

3. Provide a means on the NFALC website for laboratory directors to rapidly seek information from allied laboratories on a specific item. This could be: (1) a quick on-line survey, or (2) seeking answers to questions in forums or discussion groups.
4. Move AGLABS, <http://aglabs.sdstate.org/index.cfm>, a South Dakota-based website developed and supported on a voluntary basis by the AAFCO and AAPCO Laboratory Committees for resource sharing among state agriculture laboratories, to the NFALC website. It is important to keep the identity and function of this site intact as it transitions to the new site. Enhancement of AGLABS features are anticipated as funding for hardware, software, programming and paid technical support becomes available.
5. Develop a mechanism to post and search for PowerPoint presentations from workshops and conferences. It has been noted that combining video of the presentations, or adding presentation notes when available, will add greater value to this feature.
6. Post meetings and training opportunities and provide Internet links where possible. Develop a calendar system to facilitate scheduling and notification of meetings and/or training opportunities. Post news items of interest to the laboratories.
7. Provide a source to link to related Association websites. The individual association committees that are laboratory subcommittees of the full NFALC will maintain their separate association identities by having areas on the NFALC site to conduct their association committee business.
8. Provide a comprehensive source for links to other allied sites such as eLEXNET, Foodnet, FSnet, relevant press release sites, AOAC INTERNATIONAL, e-Cam, funding opportunities, grant opportunities from federal agencies, etc.
9. Provide accreditation justification information and guidance on how to expedite the accreditation processes. The NFALC site will provide information on ISO 17025 accreditation with a goal of being a one-stop shop for information sharing and links to other relevant sites such as the

American Association for Laboratory Accreditation (A2LA) and AOAC INTERNATIONAL.

10. NFALC must, over a period of time, develop a presence with the Washington, D.C., area, possibly through the location of staff.
11. Ensure good communication to all state agriculture laboratories and from member laboratories to USDA and FDA on issues where we have concerns and they need feedback. Develop a formal method to discuss issues and concerns of state food and agriculture laboratories and federal agencies.
12. Communicate with the two new Homeland Security “Centers for Excellence” regarding agriculture and food protection and defense; and assist in providing an applied science component to the validation of technologies coming out of the Centers. The two Centers established by the Department of Homeland Security (DHS) for Agro-Security are located at Texas A&M University and the University of Minnesota. Texas A&M University and its partners will focus on issues related to foreign animal and zoonotic diseases. The University of Minnesota and its partners will address issues related to post-harvest food protection.

The ad hoc work group proposed names as initial members of the Committee’s Steering Work Group. These candidates are intended to reflect a good cross section of the associations that would participate with NFALC and to ensure adequate representation of the diverse farm-to-table analytical interests that are performed by state agriculture control laboratories.

Proposed initial members:

Reuben Beverly - Georgia	Nancy Thiex - South Dakota
Bill Cusick - California	Rod Noel - Indiana
Tom Jensen - Nebraska	Mike Talkington - Oklahoma
Bill Krueger - Minnesota	Steve Reh - Michigan
Dan Rice - New York	Yvonne Hale - Florida
Beverly Byrum - Ohio	Steve Sobek - Wisconsin

This steering work group will also include any laboratory committee chairs not noted that are part of associations that represent control officials of agriculture and food.

During the June 2004 AFDO annual meeting, a resolution was passed supporting the initiative to form NFALC. The associations of AAFCO, AAPCO, and AAPFCO passed similar resolutions supporting this initiative during their

individual annual meetings held in August. The NFALC ad hoc work group will continue to work with these associations as well as NASDA and AOSA to complete the formation of NFALC. The ad hoc work group will also assist each association in the integration of NFALC into their organization structures. The website supporting this effort is being developed and should be functioning by December 2004.

For additional information on this initiative, please contact:

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## **NABP, FDA COMBINE EFFORTS IN BATTLE AGAINST COUNTERFEIT DRUGS**

Courtesy of National Association of Boards of Pharmacy® (NABP®)  
and the April 2004 *NABP Newsletter*.

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Park Ridge, Illinois.

On February 18, 2004, NABP participated in a joint news conference in Washington, DC, to discuss strategies for ensuring that the United States medication distribution system remains the most secure and protected in the world. The conference was assembled by US Department of Health and Human Services Secretary Tommy G. Thompson and Food and Drug Administration (FDA) Commissioner Mark McClellan.

In an FDA report entitled *Combating Counterfeit Drugs: A Report of the Food and Drug Administration* (the report), which was released at the news conference, FDA noted the important role states play in regulating wholesale drug distributors and supported NABP's efforts, and corresponding efforts of the states, to adopt and execute NABP's revised Model Rules for the Licensure of Wholesale Distributors, which is part of the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy. According to this report, ". . . the counterfeiting of medications is a particularly insidious practice. . . . Drug counterfeiters not only defraud consumers, they also deny ill patients the therapies that can alleviate suffering and save lives. . . . In recent years, . . . FDA has seen a growing evidence of efforts by increasingly well-organized counterfeiters backed by increasingly sophisticated technologies and criminal operations to profit from drug counterfeiting at the expense of American patients."

### **Partnership with the States**

FDA strongly supports the revised Model Rules and urges the states to adopt these Model Rules. The adoption of these rules will have a strong impact on the protection of the nation's drug supply by ensuring that all persons and entities involved in the wholesale distribution of drug products meet strict licensing criteria and maintain high ethical and business standards.

FDA goes on to explain in its report, "Counterfeiting is a problem that is not isolated to one state. . . . Widespread state adoption, implementation, and enforcement of the Model Rules would help combat counterfeiting."

NABP believes that the US distribution system can retain its integrity and continue to serve as a standard by which other medication distribution systems in

the world are compared through its partnership with federal and state regulators and the wholesale drug industry.

In a February 18, 2004 NABP news release, NABP President Donna S. Wall stated, ". . . [This] marks another historic achievement for FDA and NABP and a demonstration that a federal- state partnership works and provides the most effective means for combating counterfeit drugs."

### **Informing the Public**

Both NABP and FDA will work together to educate and protect the public from counterfeit drugs. By late 2004, NABP's Wholesale Distributor Clearinghouse will be operational. The Clearinghouse was created to accredit wholesale distributors for the state boards of pharmacy. President Wall encouraged the boards of pharmacy to recognize the Wholesale Distributor Clearinghouse as a means for developing standard licensure requirements that will prevent illicit wholesalers from operating in a state with less stringent requirements.

FDA is in the process of creating a Counterfeit Alert Network, which will link national organizations, consumer groups, and industry representatives to provide timely and effective notification to health care professionals and consumers about counterfeit events. In addition, FDA decided to use its voluntary health professional reporting program, MedWatch, to report suspect counterfeit drugs. According to Combating Counterfeit Drugs, FDA plans to change the instructions for the MedWatch reporting form, both paper and online, so those who report counterfeit drugs will know how and when to report suspect counterfeiters. Further, the MedWatch Web site ([www.fda.gov/medwatch/](http://www.fda.gov/medwatch/)) description of product problems to include suspect counterfeits will be amended.

### **NABP's National Specified List of Susceptible Products**

On February 20, 2004, NABP released the updated Model Rules for the Licensure of Wholesale Distributors. The updated Model Rules, part of the Model State Pharmacy Act, were provided to assist state boards of pharmacy in maintaining the integrity of the United States medication distribution system through the regulation of wholesale distributors. The updated Model Rules are the result of a concerted effort between NABP and other representatives from the pharmacy profession, government, and the wholesale distributor industry to protect the public from the ill effects of counterfeit drugs and devices.

In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are

particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products." In an attempt to reduce redundancy and confusion as states update and adopt regulation, it is highly suggested that states adopt the National Specified List of Susceptible Products that will be developed in conjunction with FDA, NABP, and other invited industry stakeholders. By mid 2004, NABP will appoint a standing committee, the National Drug Advisory Coalition. The National Drug Advisory Coalition will be primarily responsible for revising the National Specified List of Susceptible Products on no less than an annual basis. The Drug National Advisory Coalition will also be initially charged with drafting criteria that detail standards and guidance for the revision process.

The List, which was adapted from the Florida Statewide Pharmaceutical Services and Drug Wholesaler Advisory Council (Florida Department of Health), represents a starting point for states that have an imminent need for such direction. NABP is currently considering other additions to the List, but anticipates that the National Drug Advisory Coalition will revise the List by late 2004.

The Model Rules for the Licensure of Wholesale Distributors defines the "National Specified List of Susceptible Products" as a specific list of drugs or devices to be designated by the state, or a third party approved by the state; determined to be susceptible to adulteration, counterfeiting, or diversion; and posing the potential for a greater public health risk.

NABP hopes that through its revised Model Rules, its partnership with its member state boards of pharmacy, and the help of FDA, wholesale drugs counterfeiting will become more difficult in the future and distributors will be deterred from selling them.

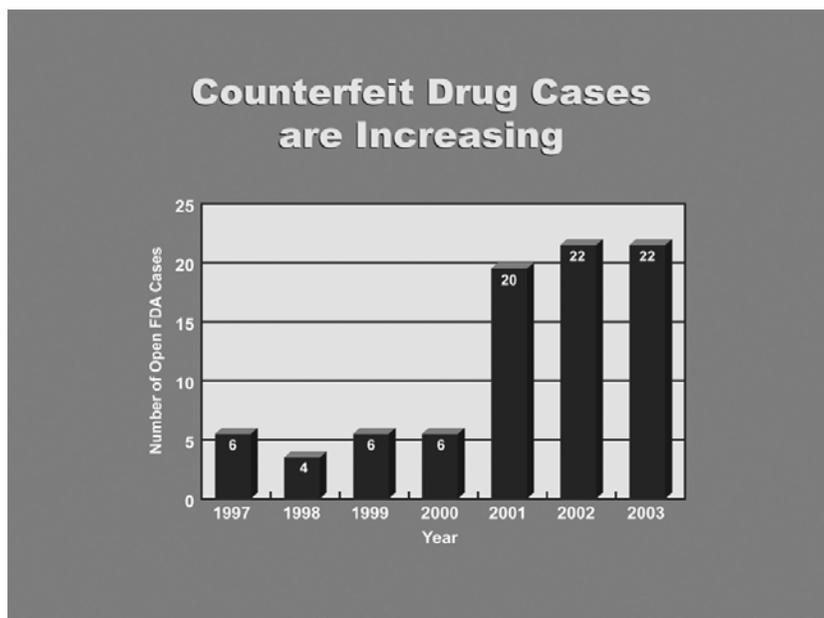
## OUR NATION’S DRUG SUPPLY: SAFE AND SECURE

Ilisa B.G. Bernstein, Pharm.D., J.D

Senior Advisor for Regulatory Policy in the Office of the Commissioner at the U.S. Food and Drug Administration (FDA)

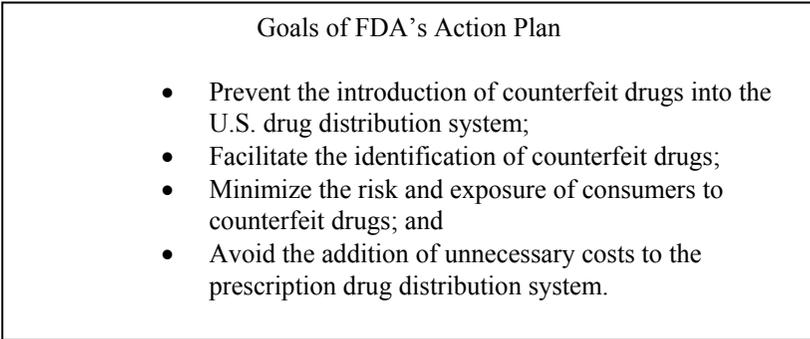
In February 2004, the FDA placed a call to action for private and public sector efforts to ensure the safety and security of our nation’s drug supply. These efforts were outlined in a report issued by FDA’s Counterfeit Drug Task Force.<sup>1</sup> Although the United States drug supply is among the safest in the world, there has been an increase over the past few years in the number of counterfeit drugs discovered in the U.S. drug distribution system. See Figure 1. FDA’s action plan is intended to curb this increasing, yet small, trend. Counterfeit drugs pose significant safety risks to patients. They may be sub-potent, super-potent, have no active ingredient, contain contaminants, or contain dangerous ingredients.

Figure 1



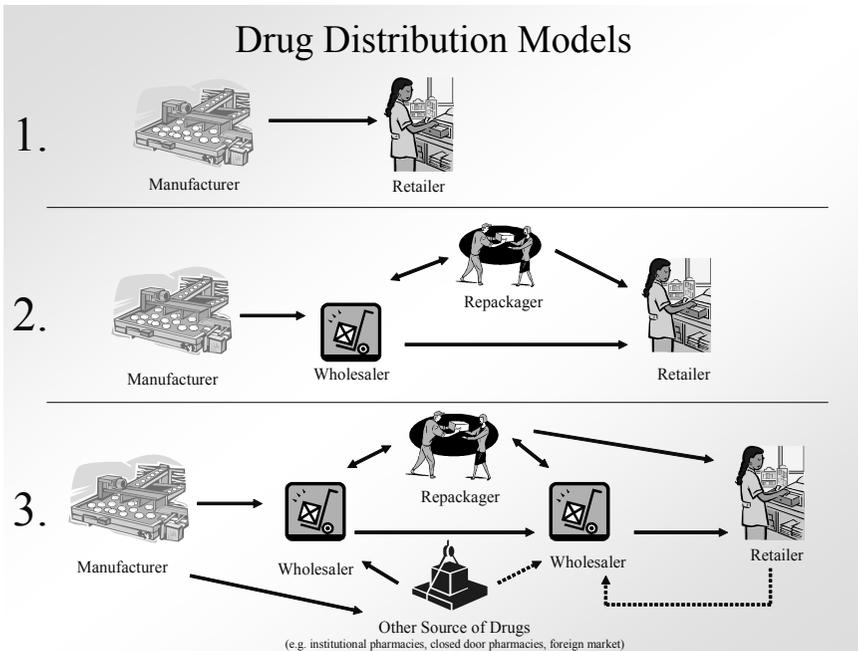
<sup>1</sup> U.S. Food and Drug Administration. “Combating Counterfeit Drugs: A Report of the Food and Drug Administration,” February 2004, ([http://www.fda.gov/oc/initiatives/counterfeit/report02\\_04.html](http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html)).

Figure 2



FDA took a systematic approach and identified the vulnerabilities in the drug distribution system, from the point of manufacture to the point of dispensing to the end user, and identified measures to curtail those avenues as entryways for counterfeit drugs to enter the system. Figure 3 shows the various ways that drugs move through the drug distribution system in the U.S.

Figure 3



FDA's plan focuses on:

- Securing the product and packaging
- Securing the movement of drugs through the supply chain
- Securing business transactions
- Ensuring appropriate regulatory oversight and enforcement
- Increasing penalties
- Heightening vigilance and awareness and
- International collaboration.

No one measure alone will protect the drug distribution system from counterfeit threats. However, when all of the pieces are in place, through public and private efforts, it is believed that the drug distribution system will be considerably less susceptible to these threats.

### **Securing the product and packaging**

Anti-counterfeiting technologies are rapidly evolving and becoming more sophisticated. Two types of anti-counterfeiting technologies, authentication and "track and trace," show promise for use by the pharmaceutical sector. Authentication technologies include holograms, color-shifting inks, taggants, and product finger-printing that can be used by members of the supply chain to verify that the product and packaging are genuine. Track and trace technologies provide a means to follow the drug as it moves through the supply chain to more precisely keep track of where the product is and has been. Bar codes (similar to what FedEx uses today) and radio frequency identification (RFID) are two means to track and trace products. For RFID, a small chip and antennae, with a unique serial number or "license plate," is affixed to the product's package or immediate container, and "readers" at strategic locations in the doorways and throughout warehouses and pharmacies monitor its location. FDA is working with RFID product developers, drug manufacturers, wholesalers, and retailers to ensure that FDA's regulations facilitate the development and safe and secure use of this technology. Recently, FDA released a compliance policy guide for implementing private sector RFID feasibility studies and pilot programs to evaluate the use of this technology.<sup>2</sup> FDA believes that the adoption and common use of reliable track and trace technology is feasible by 2007.

### **Securing the movement of drugs through the supply chain**

Track and trace technology, such as RFID, will help secure the integrity of the supply chain by providing an accurate "pedigree," which is a secure record documenting the chain of custody and possession of the drug as it moves through

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<sup>2</sup> <http://www.fda.gov/bbs/topics/news/2004/NEW01133.html>

the U.S. drug distribution system. Currently, some firms use paper pedigrees. However, they pose logistical and administrative challenges in their use and a paper record is vulnerable to forgery. When RFID and its infrastructure are developed, a *de facto* electronic pedigree will be generated and each time a product moves to a different place in the supply chain, that movement will be documented in a database. In addition, it is difficult to counterfeit the information RFID tags would carry for specific drug shipments. Therefore, RFID will help deter would-be counterfeiters while making it easier for industry and law enforcement to identify counterfeit drug products before they reach consumers, and find the responsible individuals.

### **Securing business transactions**

Business partners can protect against counterfeit drugs by ensuring the legitimacy of their business partners and refusing to do business with persons of unknown or dubious background. FDA's Task Force report called for drug producers, distributors, and dispensers to take effective actions to secure their business practices. Wholesalers have already drafted guidelines for secure business practices for their members and FDA will work with other members of the supply chain to develop and implement secure practices for their members. Such practices include measures to secure physical facilities against counterfeit drugs, knowing who you are doing business with and their background, and identifying an individual or team with primary responsibility to coordinate security and anti-counterfeiting activities.

### **Ensuring appropriate regulatory oversight and enforcement**

All levels of government, as well as the private sector, have a responsibility to protect and secure the nation's drug supply. In particular, because states license and regulate wholesalers, it is important that states have tough laws to make it difficult for illegitimate wholesalers to become licensed and transact business. Some states, such as Florida, Nevada, and California, have already strengthened their laws. FDA strongly supports the efforts taken by the National Boards of Pharmacy (NABP) to strengthen the Model Rules for Licensure of Wholesale Distributors and efforts by the states to adopt these Model Rules. FDA believes that adoption by all the states would have a significant impact on protecting the drug supply by ensuring that all persons and entities involved in wholesale distribution of drug products in the United States meet stringent licensing criteria and maintain high ethical and business standards.

### **Increasing penalties**

Stronger criminal penalties for drug counterfeiters would provide a deterrent for those who partake in this insidious crime. Currently, under Federal law,

counterfeiting a prescription drug label (bearing a registered trademark) is punishable by up to ten years in prison, while counterfeiting the drug itself, which carries a higher level of risk to the patient, is punishable by a maximum of only three years in prison. FDA plans to pursue means to amend the sentencing guidelines to substantially increase criminal penalties. NABP's Model Rules for Licensure of Wholesale Distributors contains a series of criminal and prohibited acts with harsher penalties for states to adopt.

### **Heightening vigilance and awareness**

All stakeholders in the drug distribution system and consumers have a role in ensuring that counterfeit drugs do not enter the supply chain, and if they do, recognizing the hazard and alerting the appropriate people. To this end, FDA has strengthened its internal procedures to rapidly respond to reports of suspect counterfeit drugs. In addition, FDA announced that reports of suspect counterfeit drugs should be reported to its MedWatch system, which is the agency's adverse event and product problem reporting system for health professionals and consumers.<sup>3</sup> In order to provide timely and effective notification of confirmed counterfeits to health professionals and the public, FDA created a Counterfeit Alert Network (CAN) of health professional and consumer groups who are ready to disseminate the alert to their members. CAN partners have also agreed to help disseminate educational messages and programming to avoid and recognize counterfeit drugs and what to do about them.

### **International collaboration**

Counterfeit drugs are a global challenge. FDA will collaborate with foreign stakeholders to develop strategies to deter and detect counterfeit drugs globally. The World Health Organization has taken a lead role in bringing together regulators from around the world to collaborate on developing and implementing strategies and FDA is participating in these discussions. Also, the agency is working with individual countries that want technical advice and assistance on combating counterfeit drugs.

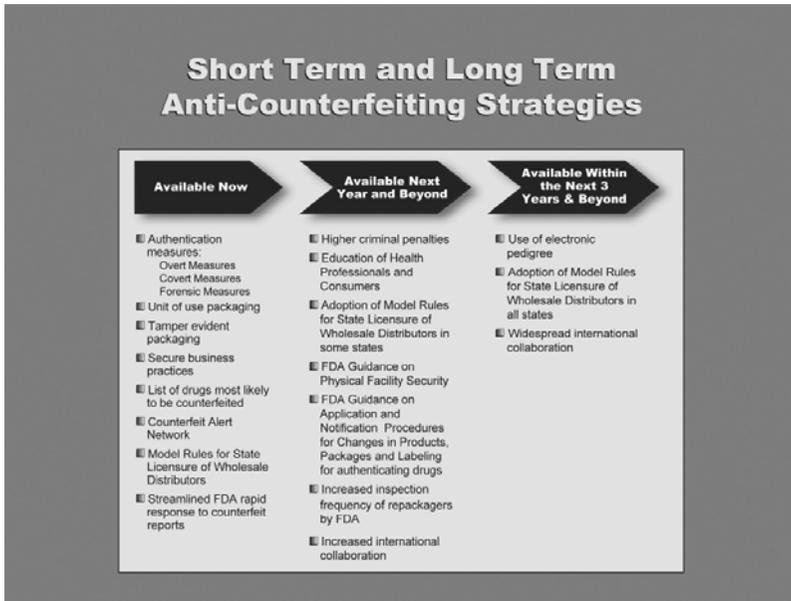
### **Conclusion**

Some of the elements described above are available today or will be in the near future, while others may take a few years to fully implement. Figure 4 shows an approximate time frame for when FDA believes that the pieces will fall into place to further secure the drug supply chain.

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<sup>3</sup> [www.fda.gov/medwatch](http://www.fda.gov/medwatch)

Figure 4



FDA is encouraged by the partnerships and collaborations that have been forming in the public and private sectors to develop strategies and implement the measures outlined in the Counterfeit Drug Task Force report. The responsibility of ensuring that our nation's drug supply remains safe and secure lies with all participants in the drug distribution system. Working together, FDA believes the goals outlined in the Task Force report are realistic and achievable.

## **AMERICAN INDIVIDUALISM AND THE OBESITY BATTLE: WOULD PEER PRESSURE HELP?**

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The majority of the literature dealing with the obesity epidemic in the United States examines the role of diet and exercise in combating this health problem and decries the lack of effective means to curb it (e.g., Critser, 2003; Kemper et al., 2004; Wansink, 2004). Largely absent from this discussion is the potential role of peer pressure in curbing overeating. This strategy would be particularly relevant to college students who tend to be sensitive to the influence of peer feedback, especially since such reactions from other students might occur in cafeteria-style dining settings commonly found on college campuses.

We hypothesized that self-consciousness might curb portion size among a college-aged population that typically dines in a close-knit setting. Furthermore, we predicted that self-consciousness about the amount of food placed on an individual's tray would increase in the presence of peers of the opposite sex. We felt that this discussion was warranted, especially in a population vulnerable to rapid and significant weight gain (known as the freshman 15 or, more recently, the freshman 20) (Gortmaker, 1993; Levitsky, 2004).

### **Methods**

In the fall of 2003 and the spring of 2004, seventy-four students from McDaniel College in Maryland (29 males and 45 females) completed a brief anonymous survey about the impact of various factors on portion size. Students were recruited from Sociology classes, primarily an introductory level course that fulfills general college requirements and thus includes a number of different majors. McDaniel College is a liberal arts college with an enrollment of about 1,600 students (57% female). Most students (75%) live in campus housing and have a meal plan at the college cafeteria, which offers buffet-style, all-you-can-eat food service. Only students who regularly ate at the dining hall completed the survey. The response rate was 100%. Although we do not have data about whether our respondents were overweight, according to national data, two-thirds of the students are at risk of becoming overweight or obese, although about two-thirds of college students are at an acceptable body mass index (Debate et al., 2001).

### **Findings**

While most students (88%: 91% of males and 86% of females) believed that the buffet-style arrangement of the college dining hall resulted in larger portion sizes, we found that most students did *not* believe that other students observing what they placed on their tray had any effect on the portions they allotted themselves.

Not surprisingly, the proportion of males who were self-conscious increased from 29% to 43% when they were around other males compared to females. Yet interestingly, slightly more females *also* reported that they decreased their portion size when surrounded by other females than when they were seated next to men, implying that females are deemed to be more likely to judge others' eating, regardless of the eater's sex (see Table 1). Nevertheless, most students did not believe that others viewing what they served themselves influenced their eating, indicating that peer observation is an ineffective tool for portion control. In addition, while many women (46%) reported that they are more likely to eat more when they are depressed, both women and men indicated that they are more apt to eat more when they are happy (54% of men and 40% of women) (see Table 2).

### **Discussion**

Because most of the college students in our sample did not feel self-conscious about others observing what they ate, peer observation may have only limited power to encourage portion control. What accounts for the relative failure of peer observation to curb eating in our sample of college students? The answer may lie in our cultural norms regarding the acceptability of intervening in another person's food choices. How many of us would volunteer advice about portion control? Few would likely feel comfortable telling peers that they should forgo a rich dessert or serve themselves smaller portions. Yet in order for peer pressure to be effective in curbing overeating, more direct peer feedback appears to be necessary. But while many would be willing to urge others to engage in healthy eating behavior, how many of us would be inclined to convey disapproval—either verbally or non-verbally—of a friend's overindulgence? Is it our place to try to help a person prevent or combat obesity? Such altruism might not only incur resentment, but it also would likely be ineffective since our culture embraces individual over group responsibility (Stewart and Bennett, 1991). Yet because it is not our business to tell someone else s/he is overeating, individuals need not fear overt negative feedback from others, which might otherwise limit their overeating.

Because our culture is highly individualistic, we are not only likely to take credit for our individual successes but also feel that we have to make our own mistakes, without the intervention of others. Indeed, this tactic has been a primary marketing tool for the embattled tobacco industry that cannot refute scientific data about the adverse impact of smoking on health, and thus encourages smokers to express their right to make their own choices, good or bad. Our culture's admiration for the maverick who does not succumb to social pressure is longstanding (as in cinema with characters venerated for their willingness to buck authority and break the rules). In fact, parents may have difficulty encouraging their children to conform to a healthy weight while simultaneously instilling in them the importance of expressing their individuality by withstanding pressures that include social cues to maintain a normal weight.

Sororities provide an example of an organization in which the preservation of the group's image sometimes supersedes an individual's welfare. Some sororities use peer pressure as a tool to help members maintain or return to an acceptable weight. While some may question the wisdom of peer criticism in this setting, the point is that it rarely occurs because Americans frown upon such pressure (especially from non-family members [Abramowitz, 2000; Kichler and Crowther, 2001]). Peer influence is key, however, as indicated by data about weight assessment among black women. African-American women assess their weight appropriateness according to how they compare to their same-race peers, rather than all those in their age group, underscoring the importance of peers' expectations in regulating body weight (Thompson, 1996).

While some might be reluctant to encourage peer pressure as a tool to help with weight control, it is important to be mindful of the prevalence of peer-based anti-drug, anti-alcohol, and drinking and driving ad campaigns. Designers of these media strategies recognize the limitations of adult authority figures in encouraging conformity to these health messages and hence have turned to the power of peer advice.

Applying such peer-based strategies to overeating, however, may be seen as adding undue additional pressure to attain a certain body ideal that is already conveyed by the media (Kilbourne, 1999; Posavac and Posavac, 2002). Nevertheless, most realize that images portrayed by the media are unattainable, and commonly reflect the intervention of a personal trainer, plastic surgeon, etc. This realization may even have fueled a backlash to the perfection depicted in the media in which goals to decrease portion size may be discarded as futile. Although peer pressure to curb overeating may have a greater potential than unrealistic media images to control eating, such tactics may also be deemed to be too rude or too likely to be rejected, especially by those who feel defensive about both food intake and their body image. Yet which is worse: peer pressure to maintain or lose weight, or peers' disdain of those who become obese or overweight? In other words, while we are uncomfortable with the strategy of monitoring each other's weight, we also acknowledge that we discriminate against and demean those who are overweight or obese. So we accept (or are resigned to) the condemnation of those who are obese but avoid direct suggestions that might help them achieve a normal weight.

Although inter-peer monitoring may not currently be an acceptable means to help control obesity, more radical tactics eventually may be considered if the problem of obesity continues to worsen. Perhaps vigilance could be targeted to periods in which students are most likely to overindulge. For example, our data indicate that college students' overeating relates not only to buffet-style dining but also to mood. Although many women said they are more likely to eat more when they

are depressed, both sexes had a tendency to consume more when they are happy, perhaps due to a media-promoted association of indulgence in fattening foods with celebratory occasions. (For example, Thanksgiving is a festive occasion in which overeating is common [Nestle, 2002]).

Because of the social role of food as a means of bringing people together for joyous celebrations, people have grown to view food as a symbol of love, comfort, and happiness and encourage each other to indulge themselves by consuming excessive amounts of calorie-laden food. We have been so eager to give individuals a sense of food freedom (the liberty to eat whatever they want whenever they want without guilt) that we have failed to hold them accountable for their poor eating choices. The results of our survey regarding the lack of self-consciousness of college students provides support for the culturally ingrained notion that food choices should be an individual choice free from others' scrutiny and comments, however well-intended such feedback may be. The situation could be improved by awareness of eating patterns in college, e.g., mood-related overeating and cultural views that overeating is an individual decision that others are supposed to blindly ignore.

### **Limitations**

Our conclusion is based on a small, non-random sample. In addition, we also are assuming that students' assessments of how they respond to their peers observing them are accurate. It is possible that respondents are unaware that they are reacting (modifying their portion size) because of the presence of others. Furthermore, some respondents may see themselves as the kind of person who is impervious to others' opinions and thus be unwilling to admit to themselves that they are susceptible to peer pressure.

### **Conclusion**

Our data from a college student sample reveal indifference to peers' observations of food consumption in a cafeteria setting. Perhaps normalizing peer feedback when a person overindulges could help counteract the tendency toward the instant gratification provided by readily available food. To help address the need for weight control in the United States, perhaps it is time to consider whether peer pressure could play a role in promoting healthy eating patterns. Reactions of peers that consist of direct cues to curb overeating might reduce excessive food consumption. This strategy would require extensive study to determine how to ensure that peer pressure serves as a positive force in the battle against obesity.

**Table 1**

The proportion of college students who said that other students' (same sex and opposite sex) had no effect on their self-served portion sizes at the college dining hall

N=74 (29 males and 45 females)

	<b>Same</b> sex peer observing what's on their tray	<b>Opposite</b> sex peer observing what's on their tray
% who said this factor affects the amount they serve themselves in the cafeteria	35%	38%
	29% of males 38% of females	43% of males 33% of females

**Table 2**

How mood affects portion size among college students

N=74 (29 males and 45 females)

	<b>Happy</b> mood	<b>Depressed</b> mood
No effect	35% (32%/37% m/f)	17% (22%/13% m/f)
Eat less	20% (14%/23% m/f)	49% (63%/41% m/f)
Eat more	45% (54%/40% m/f)	34% (15%/46% m/f)

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## INCORPORATION OF NISIN INTO A COLLAGEN FILM

Retains Activity Against *Listeria monocytogenes* and *Brochothrix thermosphacta* associated with a Ready-to-eat Meat Product

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### ABSTRACT

The foodborne pathogen, *Listeria monocytogenes* (LM) is associated with a variety of ready-to-eat (RTE) meat products. Vacuum-packaged, refrigerated meats also may be contaminated with spoilage organisms such as *Brochothrix thermosphacta* (BT). The antimicrobial peptide, nisin, is known to inhibit LM and BT on meats and is currently approved for use in some foods. In this study, collagen films were soaked in a nisin solution and dried to produce biologically active nisin-incorporated collagen films (NICF). Frankfurters were wrapped with NICF or collagen films without nisin (Control), vacuum-packaged, heated (30 min, 100C), cooled, and inoculated with approximately 3 log<sub>10</sub> CFU/g of LM or BT. Inoculated, NICF and control frankfurters were subjected to refrigerated storage (4C) for up to 14 days or temperature abused (24 h, 25C) and refrigerated (4C) for up to 14 days. Immediately after treatments and following refrigerated storage at days 4, 7, and 14, BT was reduced greater than 1.4 log<sub>10</sub> CFU/g, whereas LM was not reduced greater than 0.60 log<sub>10</sub> CFU/g. Following temperature abuse and 14 days of refrigerated storage, BT and LM were reduced by approximately 1 log<sub>10</sub> CFU/g. This research is the first to demonstrate the incorporation of nisin into a collagen film with activity against bacteria associated with RTE meat products.

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### INTRODUCTION

*Listeria monocytogenes*, a ubiquitous, gram-positive, intracellular pathogen is the causative agent of human listeriosis. The disease is characterized by septicemia, meningitis, and abortion, often causing 30 to 40% mortality among neonates and immunocompromised individuals. *Listeria monocytogenes* has been associated with foodborne illnesses from a variety of food products, including raw milk, cabbage, and ready-to-eat (RTE) foods, including cheese, jerky, frankfurters, sausages, sliced ham, and deli meats (Datta, 1997). As a result of the outbreaks and recalls associated with this pathogen, the U.S. Department of Agriculture (USDA) has issued a zero tolerance policy for the pathogen in RTE foods.

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*Brochothrix thermosphacta* is a gram-positive, psychrotrophic organism primarily responsible for the spoilage of vacuum-packaged meats. In several studies, *B. thermosphacta* has been shown to be sensitive to a variety of antimicrobials, including bacteriocins (Siragusa and Cutter, 1993; ten Brink et al., 1994; Gao et al., 1999), organic acids (Grau, 1980), and fatty acids or essential oils (Ouattara et al., 1997). Of these compounds, bacteriocins have attracted extensive interest in recent years due to their activity against various foodborne spoilage and pathogenic bacteria (Klaenhammer, 1993).

Nisin, a small bacteriocin (molecular weight = 3552) synthesized by *Lactococcus lactis* subsp *lactis*, has proven effective as an inhibitor of gram-positive pathogenic or spoilage bacteria in a variety of foods (Harris et al, 1991; Hurst and Hoover, 1993). In 1988, nisin was given GRAS (generally recognized as safe) status and currently is approved for use in pasteurized processed cheese spreads or pasteurized liquid whole egg to prevent outgrowth of *Clostridium botulinum* spores (FDA, 1988). Recently, nisin in combination with rosemary extract was approved for use in ready-to-eat meat products to control growth of *Listeria monocytogenes* (Danisco). Nisin is stable under refrigerated conditions, demonstrates heat stability, and is degraded easily by gut enzymes (Liu and Hansen, 1990). Numerous reports also have addressed the direct addition of bacteriocins to intact or processed meat products as a means of inhibiting pathogenic or spoilage bacteria (Bell and De Lacy 1986; Chung et al, 1989; Vignolo et al. 1996). Several additional reports have addressed the retention of antimicrobial activity against a variety of bacteria associated with meat surfaces following incorporation of nisin and into a variety of edible films, coatings, gels, or polymers (Cutter and Siragusa, 1996a; Padgett et al., 1998; Siragusa et al., 1999; Natrajan and Sheldon, 2000; Wilhoit, 1996). Incorporation of food grade antimicrobials into other types of edible films may provide additional barriers/hurdles to reduce the incidence of pathogenic or spoilage bacteria in meat products.

One such edible film type is collagen. The use of collagen films with meat products provides numerous processing and marketing advantages. Intact collagen films form a “skin” or edible film that becomes an integral part of the meat product during heat processing. Collagen films, also known as Coffi® films were developed for the meat industry to increase product yield by reducing cook shrink, increase juiciness, and improve product texture; allow for permeability of smoke to the meat product; improve netting removal ensuring a smooth surface after cooking; and bring out natural flavor and color of meat products (<http://www.globecasing.com/coffifilm.htm>).

The overall objective of the following experiment was to incorporate nisin into a collagen film, determine activity of the nisin-incorporated collagen films (NICF) in plate overlay assays against *L. monocytogenes* and *B. thermosphacta*, and

determine antimicrobial activity of NICF against the organisms associated with a ready-to-eat (RTE) meat system. The information obtained from this study may provide a means of improving the microbiological safety and quality of RTE meats.

## **MATERIALS AND METHODS**

### *Organisms*

*Brochothrix thermosphacta* ATCC 11509 and *Listeria monocytogenes* Scott A (American Type Culture Collection, Manassas, VA) were maintained in 75% glycerol at  $-20^{\circ}\text{C}$  and propagated for 18 h in tryptic soy broth (TSB; Difco Media, Becton Dickinson, Sparks, MD) at  $25^{\circ}\text{C}$  and  $35^{\circ}\text{C}$ , respectively, prior to use in experiments.

### **Preparation of Nisin Solution and Nisin-Incorporated-Collagen Films**

A 1% nisin solution was prepared by adding Nisaplin (Sigma, St. Louis, MO) to 0.02 N hydrochloric acid (HCl), filter sterilizing (0.2  $\mu\text{m}$  VacuCap™, Gelman Sciences, Ann Arbor, MI) and storing aseptically at  $4^{\circ}\text{C}$  until used.

Whole sheets of Coffi® collagen film (Brechtan Company, Chesterfield, MI) were cut into either individual 25  $\text{cm}^2$  (for plate overlay assays) or 230  $\text{cm}^2$  pieces (for meat experiments), UV-sterilized under a biosafety hood for 15 min (Cutter and Siragusa, 1994) on each side, and stored at  $25^{\circ}\text{C}$  in sterile petri dishes until treated with nisin solution.

For 25  $\text{cm}^2$  pieces, 10 ml of 1% nisin solution was poured into a sterile petri dish, the Coffi® film submerged for 15 minutes, and the nisin solution poured off. The Coffi® film was air-dried by inverting the petri dish under a flowing biological safety hood until remaining moisture disappeared (approximately 20-30 min). One  $\text{cm}^2$  pieces of nisin-incorporated Coffi® film (NICF) were cut aseptically and stored at  $4^{\circ}\text{C}$  until plate overlay assays were performed (see below). Coffi® film containing no nisin (CF) was also used as a control film in these studies.

For meat experiments, sheets of Coffi® film were cut into 20 cm x 11.5 cm pieces, aseptically soaked with a 1% nisin solution, and dried by clipping them to 2 sterile alligator clips attached to a steel 1  $\text{cm}^2$  x 9-inch rod and placing the apparatus over a large sterile beaker to dry under a flowing biological safety hood until remaining moisture disappeared (approximately 20–30 min). Resulting NICF were aseptically stored at  $4^{\circ}\text{C}$  until meat experiments were performed.

### Plate overlay assays

Nisin activity of the films used in this study was determined by using the seeded lawn overlay spot assay (Siragusa and Cutter, 1993). Briefly, tryptic soy agar (TSA; Difco Media, Becton Dickinson) plates were overlaid with 10 ml of semi-soft TSA (0.5% w/v agar) seeded with 100  $\mu$ l of an overnight broth culture of *B. thermosphacta* ATCC 11509 or *L. monocytogenes* Scott A. The seed density was approximately  $1 \times 10^7$  CFU/ml of overlay. The 1% nisin solution was diluted to 1:1024 in sterile BPW and 20  $\mu$ l of the dilutions spotted directly onto seeded lawns and air-dried under the flowing biological safety hood for 10 min. Twenty microliters of 0.02N HCl was also spotted directly onto seeded lawns and air-dried. Plates were scored for zones of inhibition after 24 h incubation at 26 and 35°C, for *B. thermosphacta* ATCC 11509 or *L. monocytogenes* Scott A, respectively. Plate overlay assays were duplicated and inhibition zones recorded. For detection of nisin activity from NICF and CF, 1-cm<sup>2</sup> pieces were placed aseptically on the seeded lawns following incorporation and incubated at respective temperatures described above.

To determine if heat treatments affected nisin activity of the films, individual 25 cm<sup>2</sup> pieces of NICF were placed in 25 ml of physiological saline with 0.1% Tween 20 (PST), BPW, or physiological saline (0.85% sodium chloride; PS). Tubes were placed in a boiling water bath and heated for 5, 10, 20, or 30 minutes and cooled. Heat-treated NICF from the different solutions were aseptically removed from the tubes and placed on seeded lawns. Due to the denaturation of the films during heat treatments, no specific size was obtainable for plate overlay assays, so cooled gels were applied directly to the seeded lawns.

For detection of nisin activity from NICF- or CF-wrapped, heat-treated frankfurters during the meat experiments (see below), approximately 1-cm slices of the treated frankfurters were placed aseptically onto seeded lawns *B. thermosphacta* or *L. monocytogenes*.

### Meat experiments

Cultures of *L. monocytogenes* and *B. thermosphacta* were serially diluted in sterile buffered peptone water (BPW; Difco Media, Becton Dickinson) to approximately 5 log<sub>10</sub> CFU/ml, transferred to sterile, handheld spray bottles (Walmart, Bentonville, AK) for spray inoculation of frankfurters (see below).

Frankfurters (100% beef) were used as a meat model system in this study. Frankfurters were purchased from a local grocery store, rinsed with sterile distilled water to remove any unattached bacterial cells, air-dried under a flowing biological safety hood, and (ultraviolet) UV-sterilized for 30 minutes with turning every ten minutes. Following UV sterilization, individual frankfurters were

wrapped in either an NICF or CF. The NICF- and CF-wrapped frankfurters were vacuum-packaged (Komet Plus Vac 2, Germany) individually in UV-sterilized 15 cm x 25 cm vacuum packaging pouches (3 mil nylon/polyethylene bag with oxygen transmission rate at 23°C of 52 cc/m<sup>2</sup>; Germany). NICF- and CF-wrapped frankfurters were dropped into a boiling water bath for 30 minutes and cooled to 4°C on ice. Heating of the frankfurters in this manner caused the films to denature and form a gel around the outer surface. Subsequent inoculation of the frankfurters with the microorganisms for meat experiments was conducted as described below.

Following heat treatment and cooling of frankfurters with NICF or CF as described above, vacuum-packaged pouches were aseptically opened and transferred to sterile trays. Approximately 2 ml of a 5 log<sub>10</sub> CFU/ml solution of *B. thermosphacta* or *L. monocytogenes* was applied by spray inoculation (Cutter and Siragusa, 1998) with turning, and allowed to attach for 15 min at 25°C to give approximately 4 log<sub>10</sub> CFU/g. Inoculated NICF- and CF- wrapped frankfurters were transferred to sterile bacon racks with ridges for separation, placed in UV-sterilized containers with lids, and stored at 4°C. Enumeration of remaining populations of *B. thermosphacta* or *L. monocytogenes* was performed at days 0, 4, 7, and 14.

An additional temperature abuse experiment was conducted using the parameters described above except that after inoculation, frankfurters were stored at 25°C for 24 h followed by refrigerated storage up to 14 days. Enumeration of remaining populations of *B. thermosphacta* or *L. monocytogenes* was performed at days 0, 7, and 14.

### **Microbiological analyses**

Following refrigerated storage at days 0, 4, 7, or 14, frankfurters from either the refrigerated or temperature abuse experiments were removed from the bacon racks. Approximately 25 g of frankfurter was aseptically cut and placed in a filtered Stomacher bag (Spiral Biotech, Bethesda, MD) along with 25 ml of BPW with 0.1% v/v/ Tween 20 (Fisher, St. Louis, MO) and pummeled for two minutes. Remaining populations of *B. thermosphacta* or *L. monocytogenes* were determined by either Spiral plating (Autoplate 4000 Spiral Plater, Spiral Biotech, Bethesda, MD) and/or spread plating (4 x 250 µl per plate) samples onto plates of TSA or Oxford (Difco Media, Becton Dickinson). Plates were incubated for 24 hours at 25°C and 35°C, respectively.

### **Calculations and statistical analyses**

After enumeration, bacterial populations from duplicate plates were averaged and converted to log<sub>10</sub> CFU/g. Least squared means (LSM) of bacterial populations

(log<sub>10</sub> CFU/g) from each treatment were calculated from three replications. Analysis of Variance and the General Linear Models procedure of SAS were used for analyses of data for only non-temperature-abused product (SAS for Windows, release ver. 6.12, SAS Institute, Inc., Cary, N.C.) Inoculum counts were used as a covariant to normalize data between treatment replications. Statistical significance was defined as  $P \leq 0.05$ , unless otherwise noted.

## RESULTS AND DISCUSSION

Nisin activity is retained following incorporation into a collagen film, as demonstrated by plate overlay assays and meat experiments. While *L. monocytogenes* appeared to be resistant to nisin in the overlay assays, as indicated by small to negligible zones of inhibition (Figure 1), *B. thermosphacta* demonstrated a marked sensitivity (Figure 2). Previous researchers have demonstrated a similar resistance/sensitivity pattern between *Listeria* spp. and *B. thermosphacta* associated with vacuum-packaged beef surfaces (Cutter and Siragusa, 1996b). In this study, heat treatments of the nisin-incorporated-collagen films (NICF) also demonstrated that nisin activity was retained. Several reports have documented the ability of nisin to withstand heating (Liu and Hansen, 1990; Bell and DeLacy, 1986; Fang and Lin, 1994; Siragusa et al., 1999). In this study, despite the gelation of collagen due to denaturation of the protein during the heat treatment, nisin activity remained, and in some cases, was enhanced (Tables 1 and 2). The heat stability of this compound lends itself to use in the formulation of pasteurized processed cheese spreads and pasteurized liquid eggs (FDA, 1988), as well as ready-to-eat meats (Danisco). Subsequent challenge experiments of gelled NICF with *B. thermosphacta* or *L. monocytogenes* associated with frankfurters also demonstrated nisin activity as indicated by reductions in bacterial populations following refrigerated storage up to 14 days (Figures 3 and 4). However, *L. monocytogenes* was not as sensitive to the NICF, as compared with *B. thermosphacta* in these experiments. An additional temperature abuse challenge study demonstrated that both *L. monocytogenes* and *B. thermosphacta* also were reduced by approximately 1 log<sub>10</sub> CFU/g by gelled NICF (Figures 5 and 6). Given the findings of this study, we have demonstrated that incorporation of a bacteriocin into a collagen film retains activity, both in plate overlay assays and on RTE meat surfaces during refrigerated and temperature-abused storage conditions.

## CONCLUSIONS

Nisin can be incorporated into a collagen film and retain antimicrobial activity against *Listeria monocytogenes* and *Brochothrix thermosphacta* as determined in plate overlay assays. Antimicrobial activity of nisin-incorporated-collagen films also was detected against *Listeria monocytogenes* and *Brochothrix thermosphacta* associated with frankfurter surfaces following a heat treatment and refrigerated

storage after 14 days or following heat treatment, temperature abuse, and refrigerated storage up to 14 days. This research is the first to demonstrate the incorporation of nisin into a collagen film with activity against bacteria associated with RTE meat products. Additional studies should determine whether activity is retained during the manufacture of other RTE products that utilize collagen films in the process. The information obtained from this study may provide a means of improving the microbiological safety and quality of RTE meats.

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**Note:** The Association of Food and Drug Officials presently has two (2) cooperative agreements with the U.S. Department of Agriculture (USDA) pertaining to *Listeria*:

1. A Study of State Food Safety Programs Collecting Data on *Listeria monocytogenes* in Ready-to-Eat Foods at Retail Food Establishments; and
2. A Program to Develop and Promote the Use of Science-Based Education and Outreach Materials on Preventing *Listeria* Contamination of Ready-to-Eat Foods.

Please refer to pages 36 and 38 of this Journal for details on these cooperative agreements.

**Table 1. Effect of Heat Treatments in Various Buffers on Nisin Activity from Nisin-Incorporated Collagen Films(NICF) or Supernatant Using Plate Overlay Assays Seeded with *Listeria monocytogenes***

Buffer	5 minutes		10 minutes		15 minutes		30 minutes	
	NICF	Super-natant	NICF	Super-natant	NICF	Super-natant	NICF	Super-natant
Buffered Peptone Water	-	-	-	-	(+)	(+)	(+)	(+)
Physiological Saline	-	-	-	(+)	(+)	(+)	(+)	(+)
Physiological Saline with 0.1% Tween 20	-	(+)	-	(+)	(+)	(+)	(+)	(+)

- = no nisin activity  
 + = nisin activity detected  
 (+) = some detectable/faint activity

**Table 2. Effect of Heat Treatments in Various Buffers on Nisin Activity from Nisin-Incorporated Collagen Films (NICF) or Supernatant Using Plate Overlay Assays Seeded with *Brochothrix thermosphacta***

Buffer	5 minutes		10 minutes		15 minutes		30 minutes	
	NICF	Super-natant	NICF	Super-natant	NICF	Super-natant	NICF	Super-natant
Buffered Peptone Water	+	+	+	+	+	+	+	+
Physiological Saline	+	+	+	+	+	+	+	+
Physiological Saline with 0.1% Tween 20	+	+	+	+	+	+	+	+

- = no nisin activity  
 + = nisin activity detected  
 (+) = some detectable/faint activity

Figure 1. Nisin Activity from Nisin-Incorporated Collagen Films (NICF), Collagen Films (CF) or 1% Nisin Solution Using Plate Overlay Assays Seeded with *Listeria monocytogenes*

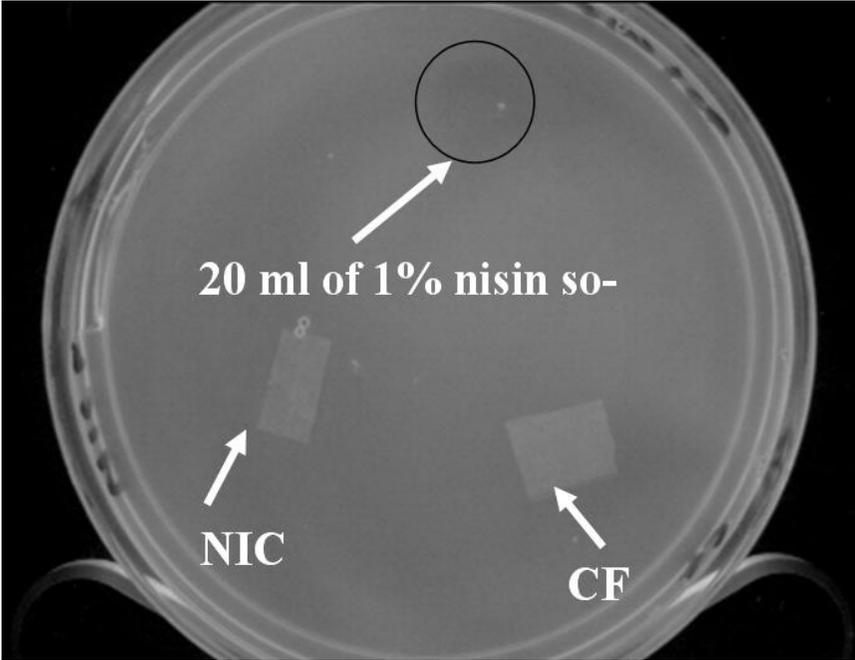
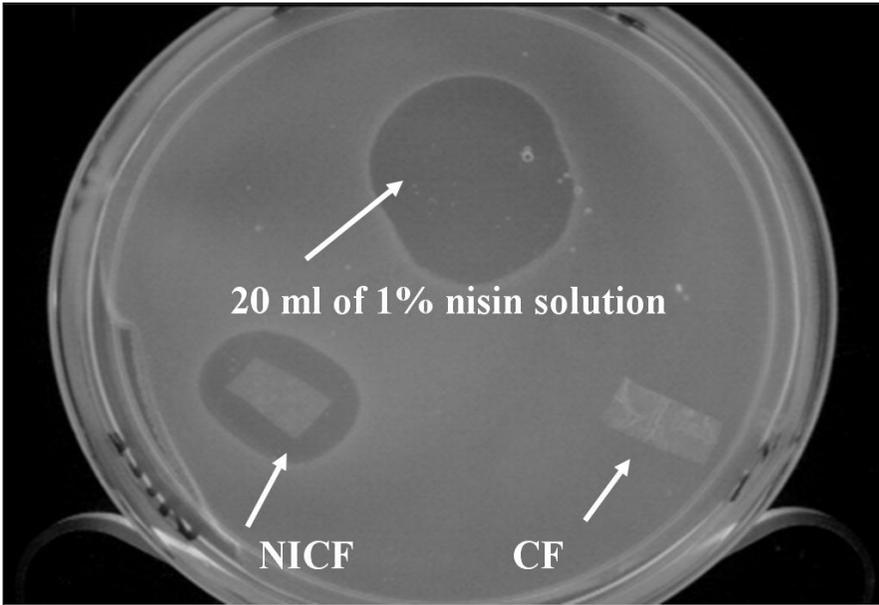


Figure 2. Nisin Activity from Nisin-Incorporated Collagen Films (NICF), Collagen Films (CF) or 1% Nisin Solution Using Plate Overlay Assays Seeded with *Brochothrix thermosphacta*



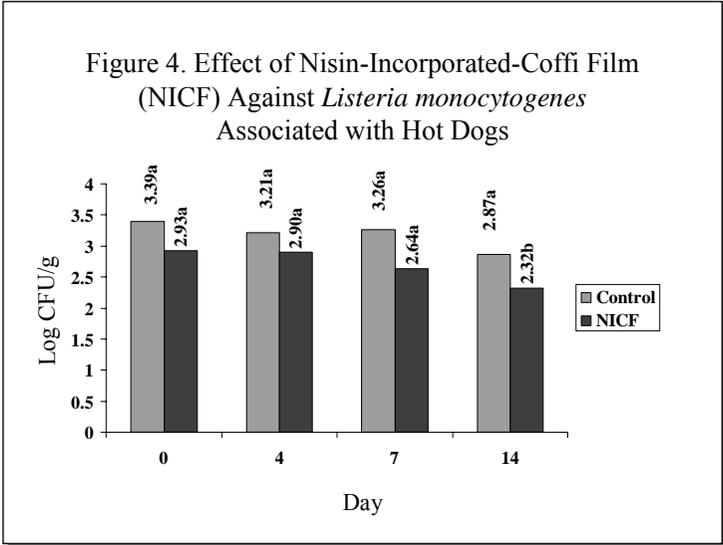
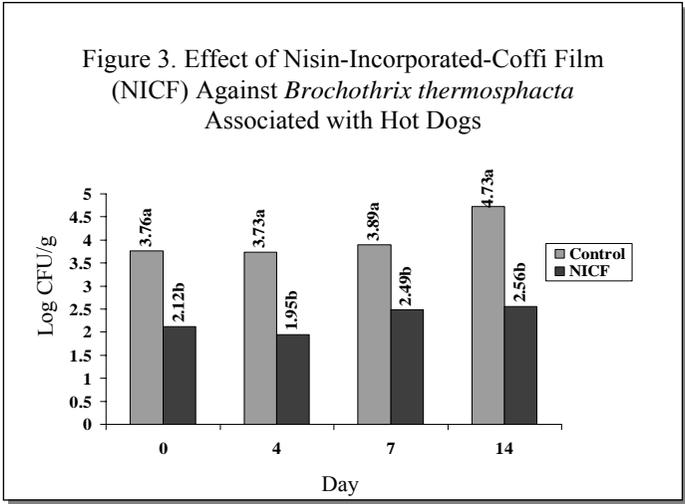


Figure 5. Effect of Nisin-Incorporated-Coffi Film (NICF) Against *Brochothrix thermosphacta* Associated with Temperature-Abused Hot Dogs

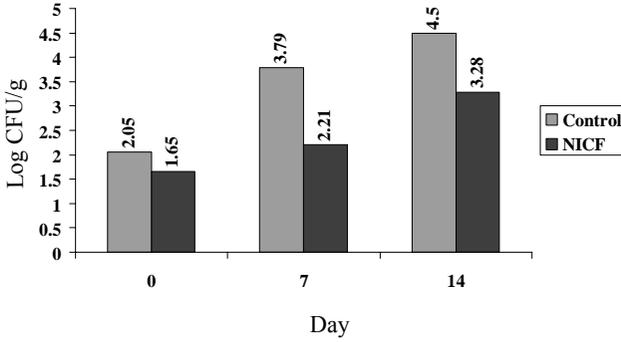
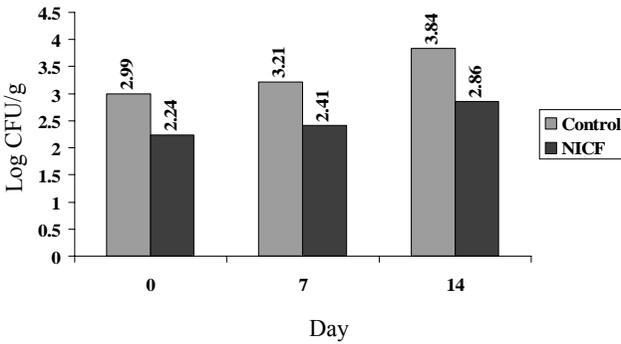


Figure 6. Effect of Nisin-Incorporated-Coffi Film (NICF) Against *Listeria monocytogenes* Associated with Temperature-Abused Hot Dogs



## **WHAT HAVE WE LEARNED ABOUT FATAL FOOD-ALLERGY-INDUCED REACTIONS?**

Anne Muñoz-Furlong

Founder and CEO of the Food Allergy & Anaphylaxis Network (FAAN)

Food allergies continue to increase in the United States and pose a food safety and public policy challenge. Scientists now estimate that 4% of the population, or 11 million Americans, are allergic to milk, eggs, fish, shellfish, peanuts, tree nuts, wheat or soy. (1)

A five-year follow-up study of the prevalence of peanut and tree nut allergy showed that peanut allergy in children doubled in the five-year period between 1997–2002. It is now estimated that there are 600,000 children with peanut allergy in the United States. (2) This allergy is believed to be the leading cause of the majority of the severe or fatal allergic reactions. (3, 4, 5)

The first ever study of the prevalence of fish or shellfish allergy in the U.S. showed 6.5 million Americans, or 2.3% of the population, reporting an allergy to these foods. For shellfish (2%), shrimp, crab, and lobster are reported to cause the majority of the reactions in this primarily adult population. Fish allergy (.4%) is reportedly most often caused by salmon, tuna, and catfish. (1)

Fish, shellfish, peanut, and tree nuts are considered lifelong allergies and cause the majority of the severe or fatal allergic reactions in this country. (3,6)

A study of 32 cases of food allergy-induced fatal reactions has provided many insights to the causes of these catastrophic events. The study, the largest of its kind to date, included individuals aged 2 to 33. The overwhelming majority of the deaths (94%) were caused by peanuts and tree nuts (63% and 31%, respectively). Milk (3%) and fish (3%) were also reported to have caused the fatal reactions, reminding us that any food could potentially cause a reaction or death.

Adolescents and teens aged 10 to 19 appear to be the highest risk group for having a fatal reaction (54%).(Figure 1) Those with asthma and food allergy (96%) are at a higher risk for a fatal reaction. The food came from a number of places including restaurant or food service (47%), packaged food (25%), home (22%) and other (6%). There are some important lessons to be learned from these fatalities.

The study has made it clear that education, awareness, and public policy changes are needed in order to prevent future deaths from food allergy reactions. Almost half of the reactions were from food served in restaurants or food service

facilities, including school cafeterias. The food-allergic individuals tried to avoid the food to which they were allergic and unknowingly ingested that food.

A number of the individuals reportedly inquired about the ingredients in the food they were about to eat, but were not given correct information. In one example, the individual asked several times about the ingredients in a meat sauce and was incorrectly assured it did not contain peanut. In another situation, the individual visually inspected a cookie and failed to see the crushed peanuts in the cookie.

Better education and awareness on the part of food service and restaurant staff may save a life. Restaurants and food service facilities must incorporate food allergy education into their staff training so that employees understand that food allergies can be deadly. While some chains have made progress, the restaurant and food service industry as a whole has been lagging behind other elements of the food industry in regard to food allergy training. Educational tools such as posters can help keep food allergy at the top of the minds of employees. (Figure 2)

One-fourth of the reactions were from pre-packaged foods. In one case, peanut rework had been added to non-peanut product. Other cases included incomplete or inaccurate ingredient information. The only way food-allergic individuals can prevent an allergic reaction is to read the ingredient label and avoid the foods to which they are allergic. Labels must be reliable and easy to read.

The new Food Allergen Labeling and Consumer Protection Act, signed into law in August, 2004, requires that all food allergens be declared on the ingredient label in language simple enough for a 7-year-old to read. This is a huge step forward for the 11 million Americans who have food allergies, and the millions of others who are reading labels on their behalf, including relatives, teachers, babysitters, coaches, and friends.

Four reactions occurred in a school or childcare setting. For parents of a young child who has food allergies, sending their child to be cared for by others poses a highly stressful situation. When a reaction occurs, quick action can mean the difference between life and death. Programs should be implemented, in partnership with the student's parents and school staff, to minimize the risk of an allergic reaction. Equally important is education of the staff to help ensure that if a reaction occurs, the student will get the necessary medical attention as quickly as possible.

From the patient's perspective, young adults and adolescents appear to be at particularly high risk for severe or fatal allergic reactions. This may be because they are beginning to spend more time away from home and often dine out with friends. As a result, they need to seek more ingredient information from others

and rely on them for assistance should a reaction occur. Anyone serving food to this age group, or anyone with a food allergy, should take all questions about ingredients seriously.

Factors leading to these deaths also included the individual not having been prescribed epinephrine (EpiPen®), the medication of choice for controlling a life-threatening allergic reaction. In one case, the family was told by their physician that having a prescription for epinephrine would unnecessarily burden the individual with worry.

Physicians must educate their patients or refer them to educational sources for the day-to-day management strategies that will keep them safe. They should prescribe epinephrine and provide a written emergency plan of action for patients who have food allergies and asthma.

Once a reaction occurs and 911 is called, patients expect those who arrive will be able to help them. In at least two cases, the family of the individual reported a delay in getting an ambulance that carried epinephrine. It is imperative that Emergency Medical Technicians who arrive on the scene be able to administer epinephrine, the drug of choice for controlling these life-threatening reactions.

In summary, food allergies are increasing; we don't yet know why although theories abound. Public policy changes are needed to ensure the health and safety of the growing number of adults and children who wonder if a food will nourish or harm them. Until there is a cure, education and awareness of the packaged food and retail food service industry, schools, and the general public are key in keeping food-allergic consumers safe.

The bottom line is, fatal food-allergy-induced reactions are preventable. If we work together, we can save lives and make a difference.

#### *About FAAN*

The Food Allergy & Anaphylaxis Network (FAAN) is a Virginia-based nonprofit organization with more than 27,000 members in the United States and worldwide. Established in 1991, FAAN's mission is to increase awareness, to provide education and advocacy, and to advance research on behalf of all those affected by food allergies and anaphylaxis. For more information, visit the FAAN website at [www.foodallergy.org](http://www.foodallergy.org) or call (800) 929-4040.

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Figure 1

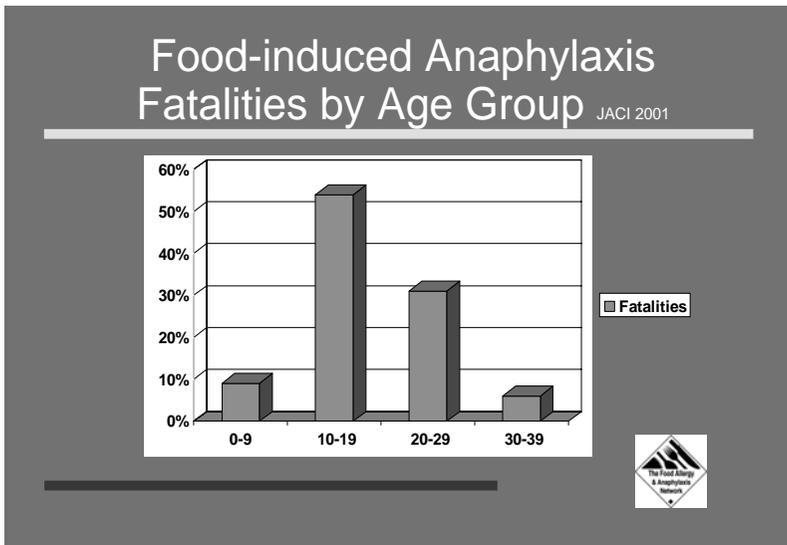


Figure 2

# Food Allergies

*what you need to know*



***Millions of people have food allergies that can range from mild to life-threatening.***

## Most Common Food Allergens

 <b>Peanuts</b>	 <b>Tree nuts</b>	 <b>Fish</b>	 <b>Shellfish</b>
 <b>Eggs</b>	 <b>Milk</b>	 <b>Wheat</b>	 <b>Soy</b>

**\* Take guest food allergy requests & questions seriously.**

**\* Always let the guest make their own informed decision.**

**When a guest informs you that someone in their party has a food allergy, follow the four R's below:**

- Refer the food allergy concern to the chef, manager, or person in charge.
- Review the food allergy with the guest and check ingredient labels.
- Remember to check the preparation procedure for potential cross-contact.
- Respond to the guest and inform them of your findings.

**\* If a guest has an allergic reaction, notify management and call 911.**

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**THE FOOD MARKETING INSTITUTE OFFERS SUPERSAFEMARK®  
ONE-STOP FOOD SAFETY EDUCATION, TRAINING AND  
CERTIFICATION  
FOR SUPERMARKET EMPLOYEES**

Jill Hollingsworth, DVM  
Group Vice President, Food Safety Programs, Food Marketing Institute

A supermarket is unlike any other food environment. It isn't the same as a restaurant or a food manufacturing plant. Yet at a supermarket, every day we handle, process and serve food to thousands of customers, sometimes 24/7. However, one thing supermarkets, restaurants and food manufacturers do have in common is a commitment to food safety.

Critical to ensuring a sustained, effective food safety program is training. The Food and Drug Administration (FDA) recently brought to retailers' attention the need for more effective strategies to improve food safety practices and highlighted areas that need improvement, including employee hand-washing, cold-holding potentially hazardous foods, date-marking ready-to-eat foods, and cleaning and sanitizing food-contact surfaces. In all these cases, proper training that targets the employee and the work situation can be a positive step to ensuring safe food practices.

The science and regulations that support food safety are well understood. The real challenge is making sure that the food safety training fits the environment, the people and the practices. Training for supermarkets must take into account the unique environment. A typical store stocks more than 30,000 food items, many of them potentially hazardous foods as defined by the *FDA Food Code*. Supermarkets handle many raw products, and they may be preparing and selling ready-to-eat products for immediate consumption or to take home, where the consumer may not always practice safe food-handling.

The risk factors at retail help us identify the "hot spots" or points where control can mean the difference between a safe or unsafe product. These factors, for example, include proper time-and-temperature controls, healthy employees, clean and sanitized equipment and prevention of cross-contamination.

We must rely on training as a key factor in ensuring that supermarket employees understand these risk factors and how to control them. In a March 2000 survey, food retailers expressed their frustration with existing training programs because they had to be modified or supplemented to directly apply to a supermarket. In response, the Food Marketing Institute (FMI), with the input of more than 20 food retailers, conducted a supermarket-specific job task analysis.

This effort led to the development of a food safety training program tailored to the unique characteristics of a supermarket environment: *SuperSafeMark*<sup>®</sup>. The training materials were produced by food safety experts from the supermarket industry and other FMI partners. Among those collaborating in the development of this program were Pearson Education/Prentice Hall and Learn Something, along with food safety scientists Richard Linton, Ph.D., of Purdue University and David McSwane, H.S.D., of Indiana University.

*SuperSafeMark*<sup>®</sup> is based on the *FDA 2001 Food Code* and the 2003 supplement. The training addresses control of all the risk factors and provides in-depth coverage on a wide variety of topics associated with food safety and sanitation. The materials include case studies, learning objectives, key retail terms and self-tests—all drawing upon the day-to-day activities in the supermarket. The program features a complete suite of materials, including:

- *Retail Best Practices and Guide to Food Safety and Sanitation*
- *Retail Best Practices and Supervisor's Guide to Food Safety and Sanitation*
- *Retail Best Practices and Quick Reference Guide to Food Safety and Sanitation*
- *Retail Best Practices and Trainer's Kit to Food Safety and Sanitation*, including five videos, a PowerPoint program, posters and other materials to facilitate training.

The program offers materials for all levels of employees, from the manager seeking certification to the hourly employee who needs the basics. The *Retail Best Practices and Guide to Food Safety and Sanitation* has been shown to be an effective tool for preparing food-handlers for the certification exam. The *Quick Reference Guide* was created to teach line workers about the basics of food safety and sanitation and works well for those with limited reading skills or language challenges.

Recognizing the need for manager certification, FMI has also teamed up with the National Registry of Food Safety Professionals to offer a *SuperSafeMark*<sup>®</sup> exam. Accredited by the American National Standards Institute and the Conference for Food Protection, the National Registry's *SuperSafeMark*<sup>®</sup> exam provides validity, reliability and legal defensibility for food managers.

In September 2004, the FDA released a study that further demonstrates the importance of food safety training. The *FDA Report on the Occurrence of Foodborne Illness Risk Factors* specifically looked at differences between those stores with and without a Certified Food Protection Manager (CFPM) from a program recognized by the Conference for Food Protection. According to the report, “The data suggest that the presence of a certified manager has a positive effect on the control of certain risk factors.... Poor personal hygiene appears to be the risk factor for which the presence of a certified manager had the most positive effect.”

Food establishments must also be prepared to respond to the changing face of the workforce. To support this need, the *SuperSafeMark*<sup>®</sup> materials are available in both English and Spanish. Adaptable to all training situations, the program is offered in traditional formats for a classroom setting and, for self-instruction, on a CD-ROM, and now the entire program is also available online. The materials can be customized to include corporate branding, policies and procedures.

The program is especially well suited for training employees working in a variety of retail food establishments, including supermarkets, superstores, food/drug combination stores, convenience stores, military commissaries and nontraditional food retailers.

The *Trainer’s Kit* includes all the tools a trainer may need to make a class effective and fun at the same time. Slides and posters contain illustrations and photos depicting real-world retail situations in the supermarket. The hallmark of all *SuperSafeMark*<sup>®</sup> materials is a bright, visual presentation that highlights safety concepts and key control techniques. The training can be adapted to the traditional eight-hour or two-day course or to self-instruction.

With training a must for every food establishment, supermarkets now have the option of selecting a complete training and certification program designed by food retailers for food retailers. To learn more about *SuperSafeMark*<sup>®</sup>, visit [www.supersafemark.org](http://www.supersafemark.org).

## **AFDO MISSION STATEMENT**

The Association of Food and Drug Officials (AFDO), established in 1896, successfully fosters uniformity in the adoption and enforcement of science-based food, drug, medical devices, cosmetics and product safety laws, rules, and regulations.

AFDO and its six regional affiliates provide the mechanism and the forum where regional, national and international issues are deliberated and resolved to uniformly provide the best public health and consumer protection in the most expeditious and cost-effective manner.

AFDO Accomplishes Its Mission by:

- ◆ Promoting education, communication and cooperation among government, industry and consumers.
- ◆ Fostering understanding and cooperation between industry, regulators and consumers.
- ◆ Promoting the adoption and uniform enforcement of laws and regulations at all levels of government.
- ◆ Providing guidance and training programs for regulatory officials and the regulated industry to promote nationally and internationally uniform inspections, analyses, interpretations and investigations.
- ◆ Identifying and resolving inconsistencies in consumer and public health protection laws, regulations, standards and policies.
- ◆ Providing a permanent working committee structure to research current issues, obtain input from interested parties and produce recommendations for action.
- ◆ Developing model laws, regulations and guidance documents and seeking their adoption throughout the United States.
- ◆ Conducting an Annual Educational Conference, where for over a century, AFDO has provided the opportunity for individuals from government, industry, and the public to participate in, listen to, and learn valuable information and develop initiatives concerning food, drug, medical device, cosmetic and product safety issues.

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### The Association of Food and Drug Officials

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## JOURNAL OF THE ASSOCIATION OF FOOD AND DRUG OFFICIALS

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 Email \_\_\_\_\_

**1. Individual Membership:**

<b>Individual Members</b>	<b>On-line Journal</b>	<b>Journal</b>
Alumni/Students	<input type="checkbox"/> \$50	<input type="checkbox"/> \$65
Regulatory	<input type="checkbox"/> \$50	<input type="checkbox"/> \$85
Consumers/Educational	<input type="checkbox"/> \$50	<input type="checkbox"/> \$85
Small Business/Consultants	<input type="checkbox"/> \$225	<input type="checkbox"/> \$275
Associate Industry	<input type="checkbox"/> \$325	<input type="checkbox"/> \$375

**2. Group Membership:** *Group membership applications must be submitted together.*

<b># of Group Members</b>	<b>Government</b>	<b>Non-Government</b>
5-10	<input type="checkbox"/> \$46 each	<input type="checkbox"/> \$300 each <input type="checkbox"/>
11-20	<input type="checkbox"/> \$44 each	<input type="checkbox"/> \$285 each <input type="checkbox"/>
21-50	<input type="checkbox"/> \$42 each	<input type="checkbox"/> \$270 each <input type="checkbox"/>
Greater than 50	<input type="checkbox"/> \$40 each	<input type="checkbox"/> \$255 each <input type="checkbox"/>

**3. Contributing Membership:** *Contributing membership applications must be submitted together.*

<b>Contributing Member Classifications</b>	<b>Government # of Memberships</b>	<b>Non-Government # of Memberships</b>
Platinum	5 for \$750 (\$150 ea.)	5 for \$2,500 (\$500 ea.)
Gold	3 for \$500 (\$166 ea.)	3 for \$1,750 (\$583 ea.)
Silver	2 for \$350 (\$175 ea.)	2 for \$1,250 (\$625 ea.)

FEDERAL I.D. #74-605-1887

Check payable in U.S. funds enclosed       Visa       MasterCard  
 Card Number: \_\_\_\_\_ Exp. Date: \_\_\_\_\_  
 Signature: \_\_\_\_\_

**AFDO ENDOWMENT FOUNDATION CONTRIBUTION FORM**

Association of Food and Drug Officials  
 2550 Kingston Road, Suite 311 • York, PA 17402  
 717-757-2888 (phone)/717-755-8089 (fax)/[afdo@afdo.org](mailto:afdo@afdo.org)

CONTACT INFORMATION:

Date: \_\_\_\_\_

Name \_\_\_\_\_

Company \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_

Email \_\_\_\_\_

DONATION/PLEDGE INFORMATION:

- Enclosed please find my year-end contribution in the amount of \_\_\_\_\_  
 In the memory of (optional) \_\_\_\_\_
- I pledge to make annual contributions of \$ \_\_\_\_\_ over the next  
 \_\_\_\_\_ years. Enclosed is my first donation in the amount of \$ \_\_\_\_\_.

PAYMENT INFORMATION:

Please make checks payable to “AFDO Endowment Foundation”

- Check/Money Order No. \_\_\_\_\_
- Visa       MasterCard

Card Number		Expiration Date	
Signature		Date	

Thank you for your support to the AFDO Endowment Foundation!



## **Are you planning to attend AFDO's 2005 Annual Conference?**

Here are a few reasons why you should consider a trip to the Westin Crown Center, Kansas City, MO in June, 2005:

- ✓ Conference Focus will be *Food Safety & Security* - what you need to know and what we still need to do
- ✓ Many educational and networking opportunities
- ✓ Professional sports:
  - Baseball - Catch a Kansas City Royals game
  - MLS Soccer - Go to a Kansas City Wizards game
  - Racing - Visit the Kansas Speedway
- ✓ Full-gaming casinos - Play the slots or hit the poker tables at one of the city's four full-gaming casinos. People can also place a bet at the Woodlands. The racetrack features live greyhound racing and simulcast horse racing year-round.
- ✓ Attractions:
  - Union Station - Home to the Science City museum, a giant-screen movie theater, a stage for live performances, restaurants, shops, traveling exhibits and much more.
  - Worlds of Fun - Make your way through 175 acres of excitement and family entertainment.
  - Kansas City Zoo - Over 200 acres offering visitors the unique experience of seeing wild animals at home in the wild.
  - Kansas City Symphony
- ✓ Museums
  - Kemper Museum of Contemporary Art
  - The Nelson-Atkins Museum of Art
  - *Arabia* Steamboat Museum
  - American Jazz Museum
- ✓ Theater
  - Kansas City Symphony
  - Lyric Opera
  - Kansas City Ballet
- ✓ Great places to eat
- ✓ Great places to shop
  - Country Club Plaza - Numerous shops, restaurants and fountains line this 14-square block entertainment district.
  - Crown Center - Over 70 unique places shop, eat and have fun.
  - The City Market - Largest farmers' market in the Midwest.
  - Outlet shopping
- ✓ Interesting places to relax and have fun