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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

In this issue of our Journal you will find much of the proceedings from our Association's 109th Annual Conference. The conference theme, "Implementing Strategies for Food Protection and Defense," reflects the importance now placed on food defense in addition to the traditional concerns for food safety in the world. No longer can we rely entirely on food safety laws and regulations to maintain a safe and wholesome food supply. Living, as we do now, with the threat of terrorist attacks on our agriculture and food supply adds a new dimension to the task of protecting consumers from unsafe food and drugs. While there are some who feel we do not yet take such matters as seriously as we should, AFDO's Annual Conference certainly addresses that concern. It is indeed important that we all remain aware of the vulnerabilities of our food and drug supply and do what is necessary to maintain their defense. We hope this issue of our Journal contributes to that awareness.

Thomas W. Brooks, Editor

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ABOUT THE AUTHORS

Margaret O’K. Glavin is currently the Associate Commissioner for Regulatory Affairs at the Food and Drug Administration, where she oversees the Office of Regulatory Affairs’ headquarters and field operations. Ms. Glavin provides executive-level policy and program direction for the FDA’s strategic, legislative, and inter-agency activities related to regulatory matters.

Prior to taking this position, Ms. Glavin was the Assistant Commissioner of Counterterrorism Policy & Planning at the FDA. In this position, Ms. Glavin served as the senior advisor on counterterrorism to the FDA Commissioner. The FDA’s primary roles in counterterrorism include protecting the food supply and ensuring the availability of safe and effective medical countermeasures.

Ms. Glavin has held executive positions at the Food Safety and Inspection Service and the Food and Nutrition Service of the U.S. Department of Agriculture. She was Associate Administrator and Acting Administrator of the Food Safety and Inspection Service, a 10,000-person regulatory public health agency responsible for the safety of the U.S. meat and poultry supply.

Prior to joining the FDA in 2003, Ms. Glavin spent a year as a Visiting Scholar at Resources for the Future, a Washington, D.C. think tank that conducts independent research and policy analysis. The emphasis of her work there was clarifying the goals of the U.S. food safety system and determining the appropriate roles and responsibilities of government, industry, and consumers in that system.

A graduate of Trinity College and Georgetown University, Ms. Glavin has published articles in numerous publications, including *Food and Agriculture* 2003, *SAIS (School of Advanced International Studies) Review*, and the *Food and Drug Law Journal*.

Debra Young was appointed as Director General at the Office of Regulatory and International Affairs, Health Products and Food Branch (HPFB) of Health Canada in April 2005.

Ms. Young holds a Bachelor of Arts (Honours) from the University of Toronto, and a Master of Arts in Sociology from Carleton University, where she has also carried out Doctoral Studies in Sociology. Ms. Young has held a number of senior positions with the federal government, including Director of Aboriginal Peoples and Human Rights with the Department of Canadian Heritage and most recently as Director General of the Social Development Directorate, with Social Development Canada.

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As Canada's national authority responsible for the expert regulation of health products and foods, HPFB evaluates and monitors the safety, quality and effectiveness of the thousands of drugs, vaccines, medical devices and other therapeutic products available to Canadians.

Dr. Barbara J. Masters was appointed Acting Administrator of the Food Safety and Inspection Service (FSIS) on March 1, 2004. In this position, she is responsible for managing FSIS' food safety activities.

Dr. Masters began her FSIS career 16 years ago as a veterinary medical officer near Hot Springs, Arkansas, and has since held a variety of posts throughout the agency, both in the field and at headquarters. Her previous positions include Director of the Slaughter Operations Staff, Branch Chief in Processing Operations, and a staff officer in the Technology Transfer and Coordination Staff. She has also served as an Inspector-in-Charge in a livestock slaughter and processing establishment and supervised the HACCP Hotline for employees and industry at the Technical Service Center. Her most recent position was Deputy Assistant Administrator for Field Operations.

Dr. Masters graduated from Mississippi State University with a Doctor of Veterinary Medicine degree, and served in a Food Animal Internship at Kansas State University. She has continued to further her education by participating in an FSIS educational program to study pathology as well as taking advanced coursework in biotechnology at Texas A&M University.

When not working, Dr. Masters and her family continue to enjoy the quiet life on a small farm in West Virginia.

Arthur Liang is director of the Food Safety Office at the Centers for Diseases Control and Prevention National Center for Infectious Diseases (CDC/NCID). He is a former CDC Epidemic Intelligence Service officer and former chief of the Communicable Disease Division, Hawaii Department of Health. He currently serves on the Executive Committee of the National Advisory Committee on Microbiological Criteria for Foods and is the CDC advisor to the Board of Directors of the Association of Food and Drug Officials. He is also a member of the Preventive Medicine Residency Advisory Committee for the Walter Reed Army Institute of Research, and a fellow and member of the Board Regents of the American College of Preventive Medicine. He is board-certified in General Preventive Medicine and Public Health. He holds a BA in Art History from Oberlin College, an MPH in International Health and Epidemiology from the University of Hawaii, and an MD from the University of Maryland.

Cameron Smoak is the Assistant Commissioner of the Consumer Protection Field Forces Division of the Department. He is primarily responsible for

supervising a staff of 234 inspectors, specialists and support personnel inspecting food sales establishments (grocery stores, convenience stores, bakeries, etc.), retail and wholesale seafood facilities, food and beverage processing plants, food salvage operations, dairies and dairy processing plants, organics, weights and measures, GAP and federal cooperative programs in poultry and egg grading. He's been with the Georgia Department of Agriculture for 30 years.

Cameron graduated from the University of Georgia with a Bachelor of Business Administration degree. Cameron has experience working with the Georgia Emergency Management Agency, dealing with relief efforts regarding food and water wholesomeness and sanitation, and livestock welfare during times of crises such as floods, hurricanes and tornadoes. He is a member of the Department's legislative liaison team to the Georgia General Assembly.

Cameron is the recent Past President of the Association of Food and Drug Officials (AFDO), which is a national organization for state, local and federal food and drug regulatory officials and includes members from academia and industry as associate members. Currently he serves as a member of the Georgia AgroTerrorism Subcommittee of the Georgia Homeland Security Committee and as a member of the Food and Agriculture Sector Government Coordinating Council (GCC) led by the United States Department of Homeland Security, United States Department of Agriculture and the United States Food and Drug Administration.

Dan Sowards received his B.S. in microbiology from the University of Texas in 1970. He was granted a Rotary International Fellowship and studied at the Swiss Federal Institute of Technology in Zurich, Switzerland. He has worked for the Texas Department of Health for 33 years, beginning as a field investigator and moving up to Director of the Manufactured Foods Division in 1994. The Division currently oversees the inspection of over 9,500 food and supplement manufacturers, 3,500 wholesale food distributors, over 4,000 water vending operations, and 175 food salvage establishments. FDA recognizes the Texas Department of Health, Bureau of Food and Drug Safety, and the Manufactured Foods Division program as a model and one of the best state programs in the U.S. Further, from July 2003 until September 2004, Dan was Acting Director for the Drugs and Medical Devices Division.

As of October 1, 2004, he has been designated by the "new" Texas Department of State Health Services as the Food and Drug Safety Officer of the Division of Regulatory Services, otherwise known as the Subject Matter Expert for food and drug safety, working directly for the Assistant Commissioner for Regulatory Services.

In December 2001, Dan was designated as Chief of Food and Drug Biosecurity for the Texas Department of Health, Bureau of Food and Drug Safety, on an interim (3-month) basis. During that time, Dan prepared the Bureau's responses for the security of our food supplies and had input on the new Appendix 6 of the Texas Emergency Management Plan.

Dan has been a very active member of the Association of Food and Drug Officials since 1980, serving as President in 2000. In 2003 Dan was presented with the Wiley Award, named after the father of food and drug law, Harvey W. Wiley. Dan has served as chair of numerous AFDO committees over the years, is presently active on five of them and is currently Chair of the Resolutions Committee. In 1991 Dan was honored with the AFDO Distinguished Service Award for his work in these areas. Dan currently serves as chair of the AFDO Resolutions Committee and the Dietary Supplement Work Group. As AFDO's Training Coordinator, Dan completed the arrangements for and hosted a Food Biosecurity Symposium in New Orleans for state regulatory officials and industry, coordinated Allergen Symposia, two symposia on recalls, and is currently working on a 1.5-day Recall Workshop, scheduled for October in Baltimore.

Dan is an active member of the Mid-Continental Association of Food and Drug Officials (MCA), having served as president twice, as well as chair of numerous committees. He has also received the MCA Recognition Award for Outstanding and Dedicated Service, and is a member of AFDOSS and WAFDO.

Dan was honored by being one of two state representatives to be selected for membership on the first-ever FDA Food Advisory Committee. During his tenure the Committee addressed such issues as approval of FDA's biotechnology policy, recombinant Bovine Somatotropin Hormone (rBST), approval of the "Flavr Savr Tomato," folic acid supplementation, and development of a "Risk-Based Inspection System" for all foods. Dan was also a member and chair of the Roles and Responsibilities Work Group of the National Food Safety System (NFSS) Project that was engaged in the development of a federal-state-local strategy for a fully integrated food safety system for the U.S. and implementation of former President Clinton's Food Safety Initiative.

Dan also presented a paper to the NSF International Conference on Food Safety, entitled "A State Perspective on National Uniformity, Federal Oversight, and the Impact on International Trade on State Programs and Food Safety." This paper was reprinted in its entirety in *Food Safety Magazine*. Dan also drafted the AFDO *White Paper* on implementation of a national strategy on food safety, presented last year to FDA.

Dan has written over 25 research papers and articles for national publications on such issues as food and drug law, enforcement/interpretations regarding food

labeling and advertising, and Hazard Analysis Critical Control Point (HACCP) as a tool to ensure safe food production. One article appeared in the New York Bar Association's *Food, Drug, Cosmetic, and Medical Device Law Digest*, and is entitled "*HACCP: The Answer to a Safe Food Supply?*."

Dan has given numerous presentations and testimony at the national level, including national and regional meetings of various industry, consumer, and regulatory associations. He was instrumental in the formation of the Texas State Food Safety Task Force, and currently serves as its Co-Chair. He has also been elected to the Advisory Board of FDLI (the Food and Drug Law Institute) in Washington, D.C., is a member of one of the FDLI Agency Value Team Work Groups, and has been appointed to the Advisory Board of the Institute of Food Science and Engineering at Texas A&M University. Dan was one of 15 individuals nationwide in the area of food and agriculture, and the only state official, who worked on a food bioterrorism prevention project at the national level with the ANSER Institute for Homeland Security. He is also a past President (twice) of the Health Department Chapter of the Texas Public Employees Association, a conservative, non-union organization of state employees throughout Texas.

Dan is a Fellow in the Texas Environmental Health Association and the Texas Public Health Association, and former Chair of the Environmental and Consumer Health Section and the Legislative Committee.

George Teagarden is the Livestock Commissioner for the State of Kansas, Kansas Animal Health Department. Mr. Teagarden was raised on a family farm in LaCygne, Linn County, Kansas. He graduated from Kansas State University with a Bachelor of Science Degree in Animal Husbandry. He also served in the Kansas House of Representatives from 1981–1994. Mr. Teagarden became Livestock Commissioner in 1994. He continues a cattle operation at LaCygne with his son.

Gordon Meriwether founded The Uriah Group (a security awareness and crisis planning company) in 2002 following a distinguished 30-year career in the development of systems solutions for commercial and government clients. In addition to risk management assessments and solutions, his systems experience includes space borne-sensors, avionics, integrated software, security systems, and professional IT services.

Beginning his career with the US Navy as a ship's officer, he transitioned to the Naval Intelligence community where he distinguished himself as a reserve intelligence officer, serving as Commanding Officer in London and New Orleans as well as two tours in the Pentagon. He retired in 2001 in the rank of Captain.

His civilian career has paralleled his military service, as he worked for General Electric, Unisys, CACI and DynCorp in various business development and project management capacities. Gordon has an MBA from George Washington University, a BS from the University of Alabama, and is a Sorensen Fellow at the University of Virginia. He is a certified Project Management Professional.

As a faculty member of the Graduate School of Business and Management at the University of Phoenix, both online and on campus, Gordon teaches Project Management, Operations Management, and Strategic Planning. He has served in various civic and local capacities, including chairman of the advisory committee to the local school board on technical studies.

Timothy Weigner is Director of Advanced Programs for The Uriah Group, bringing more than 25 years of experience in food science and technology. His previous position was Senior Director for Food Safety Programs for the Food Marketing Institute in Washington, DC where he managed and coordinated food safety and educational programs for FMI members. Tim represented FMI on various food safety and education committees, including the FMI SuperSafeMark Food Protection Manager Certification Program, Conference for Food Protection Food Manager Training, Testing and Certification Committee, Conference for Food Protection Facility Plan Review Committee, and NSF International Food Safety & Quality Advisory Council.

Tim retired from the U.S. Army Veterinary Services after 20 years as a Veterinary Services Warrant Officer specializing in food safety and quality assurance programs. The 20 years included unique and diverse assignments worldwide, including Food Safety Consultant for the Army Center for Health Promotion and Preventive Medicine; Training Officer with the U.S. Food and Drug Administration State Training Branch specializing in Risk Communication; Food Code and HACCP-based retail food safety and sanitation program; Food Safety Project Officer for the Office of the Surgeon General, U.S. Army; and Instructor with the U.S. Army Veterinary Science Division, U.S. Army Academy of Health Sciences, Fort Sam Houston, Texas.

Tim holds a B.S. in Food Science & Technology with emphasis in Dairy Manufacturing and Food Processing and Engineering from the University of Wisconsin, River Falls.

Mr. C. Patrick Duecy is a Partner in the Washington D.C. based consulting firm, Homeland Solutions, LLC.

Mr. Duecy has 35 years experience in the national intelligence community and was Director of the JITF CT during the design and implementation of JRIES, the forerunner of HSIN.

His company works primarily with state and local government in developing concepts of operations, business process and facility plans and procedures for homeland security program implementation.

Homeland Solutions, LLC also offers a full range of terrorism- and homeland security-related program training. Contact Information: Telephone: (202) 345-7994 - email: ducy@homeland-solutions.net.

FDA KEYNOTE

Margaret O’K. Glavin
Associate Commissioner for Regulatory Affairs
U.S. Food and Drug Administration (FDA)

Introduction

Good morning. I am pleased to be with you this morning to deliver the FDA’s keynote address on behalf of Dr. Crawford.

The theme of this year’s annual conference, as well as my attendance here, is like “coming home” for me. It is wonderful to see so many former colleagues, and I look forward to talking and interacting with you. And, in light of the theme of this year’s conference, Implementing Strategies for Food Protection and Defense, my attendance isn’t so much “coming home” as it is “I have never left”.

I appreciate the opportunity that my new position as FDA’s Associate Commissioner for Regulatory Affairs provides to apply the lessons I have learned as the Assistant Commissioner of Counterterrorism Policy & Planning at the Food & Drug Administration and as the Associate and Acting Administrator of the Food Safety and Inspection Service while at USDA. I also appreciate the opportunity, as the new ACRA, to address you at this 109th Annual AFDO Conference and to reconfirm our working relationship and partnership with AFDO and its members.

Overseeing and preserving the safety and security of the U.S. food supply is no longer the responsibility of any one or two Federal agencies or multiple state/local food safety agencies; nor, for that matter, is it the responsibility of any single entity in the food industry, nor a specific segment of the government.

The recognition of our food supply as an important component of our critical national infrastructure has gained unprecedented attention in recent years. The widespread public health, economic, and psychological consequences that a deliberate contamination of our food supply would have on society are monumental, and the loss of public confidence in something that is so “taken for granted” would be catastrophic. All of these factors contribute to the fact that, more than ever before in our history, there is an enormous interest in the manufacture, transport and importation of food.

My remarks this morning will focus on what we have going for us at our “core” – our capability and know-how; a history of working in tandem with our federal and state partners, a positive relationship with industry, successfully responding to challenges, and recent successes on food safety—and how we have used these

attributes to make positive, concrete, “real” contributions toward ensuring that the United States food supply is, indeed, the safest and most secure in the world.

Where We Have Been

We have long-standing systems in place to reduce foodborne pathogens, and these systems will assist us in preventing or responding to a terrorist attack.

Especially important is our reliance on science-based approaches to solving public health problems. Sound science is, without a doubt, the core both of food safety and of food defense.

FDA must uphold its responsibility for ensuring the safety and security of approximately 80 percent of the nation’s food supply. The possibility of food products being used as a vehicle for attack is particularly worrisome because such an event potentially affects everyone in the U.S. We must have the capability to assess, and then reduce, the risks associated with unexpected and potentially widespread health and safety threats.

Fortunately, because food safety and food security are inter-related, we can draw upon our past experiences dealing with food safety to assist us in dealing with, and scoping out, the implications of an event that could potentially impact food security.

Where We Are

It goes without saying that ensuring the safety and security of the food supply is a top priority for the FDA.

Over the past years, FDA has worked with food safety agencies at the federal, state and local levels to significantly strengthen the Nation’s food safety system across the entire distribution chain to better protect the safety of our food supply against natural and accidental threats. This cooperation has resulted in greater awareness of vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and faster response capabilities to foodborne illness outbreak. An effective food defense system is being built on the foundation of this strong food safety system.

In 2002, the President signed the Public Health Security and Bioterrorism Preparedness and Response (Bioterrorism Act). This landmark legislation represents the most fundamental enhancement to FDA’s food safety authorities in many years, and FDA has been working hard to implement this important legislation. As a result of the provisions included in the Bioterrorism Act:

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- In October 2003, FDA published Interim Final Rules to implement the requirement for domestic and foreign facilities to register and the requirement for prior notice of imported food;
- In December 2003, we signed a Memorandum of Understanding with Customs and Border Protection (CBP) to allow FDA to commission CBP officers in ports and other locations to conduct investigations and examinations of imported foods;
- In June 2004, FDA published a final rule to implement the administrative detention provision; and
- In December 2004, FDA published a final rule to implement the establishment and maintenance of records (the recordkeeping requirement).

Prior Notice

I would like to spend a few moments discussing the new enforcement tool provided to the Agency with the requirement for Prior Notice. Advance notice of import shipments allows FDA, with the support of the CBP, to target import inspections more effectively and help protect the Nation's food supply against terrorist acts and other public health emergencies.

With the prior notice requirement, specific information mandated by the Bioterrorism Act must be submitted to FDA before the imported food arrives in the United States. This allows FDA's and CBP's electronic systems to review and screen the shipments for potential serious threats to health (intentional or otherwise) before food arrives in the United States, and allows FDA staff to review the prior notice submissions for those products flagged by the systems as presenting the most significant risk.

Targeted, comprehensive, hands-on "import security reviews" are conducted on those products that have been identified as "high risk" through FDA's review of the prior notice submission tendered for the product. FDA's selection of candidates for import security reviews is not related to the volume of submissions. Rather, FDA uses defined risk factors to select candidates for import security reviews, based on intelligence reports and information about the shipper and/or consignee that indicate a potential bioterrorism or other risk to the U.S. consumer and the domestic market. The Prior Notice reviews complement the traditional import field exams.

As I mentioned, in December 2003 FDA and U.S. Customs & Border Protection signed a Memorandum of Understanding that allows ORA to commission

thousands of CBP Officers in ports and other remote locations to conduct, on FDA's behalf, investigations and examinations of imported foods. This agreement ensures that, regardless of the 300 ports through which imported food may be offered for entry into domestic commerce, adequate coverage of the commodity will be available.

FDA receives, on average, approximately 30,000 notifications about incoming food shipments each day, and works closely with the (CBP) at the Prior Notice Center which is co-located with CBP's National Targeting Center to ensure that the Prior Notice regulations promote a coordinated strategy for border protection. This integrated risk-management process increases our security and facilitates the movement of legitimate commerce.

Increased scrutiny has identified several shipments with potential terrorism links. For example, when a foreign manufacturer and an importer that had never done business in dairy products were observed shipping cheese, the shipment was flagged, and scrutiny revealed that the importer was the subject of an open investigation concerning the transportation of explosives with terrorist intent. A directed examination of the product did not uncover explosives but did reveal that the manufacturer was falsely identified for this shipment. The product was refused entry into the United States.

Additional, Ongoing Counterterrorism Activities

In addition to implementing the Bioterrorism Act, FDA has many other ongoing counterterrorism activities. For example, FDA has increased our emergency response capability by realigning resources to counterterrorism and by reassessing and strengthening our emergency response plans. FDA has also conducted numerous emergency response and preparedness exercises to further strengthen our response to a terrorist event involving our Nation's food supply. These exercises have included federal, state, local and industry partners.

We have distributed food security guidance documents to state and local agencies and to different segments of the food industry that identify the preventive measures the industry can take to mitigate risks to the food supply and optimize the safety and security of their operations so that the threat of tampering or other malicious, criminal, or terrorist actions directed at foods under their control is minimized.

We have more than doubled the number of ports that have an FDA presence, and increased our surveillance of imported food at the border.

Another major focus of the Agency has also been increasing laboratory surge capacity through the Food Emergency Response Network (FERN) and enhancing

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the early warning system to identify hazardous foods by expanding the number of Federal, state, and local laboratories providing data through our Electronic Laboratory Exchange Network (eLEXNET).

FERN

The Food Emergency Response Network, a joint effort between USDA/FSIS and HHS/FDA, is a nationwide laboratory network that integrates existing federal, state and local food testing laboratory resources by utilizing standardized diagnostic protocols and procedures. The mission of the FERN is to integrate the Nation's food testing laboratories at the local, state, and federal levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food, and to coordinate and work with other laboratory networks including the Laboratory Response Network and plant laboratory networks.

Along with FDA and USDA, other Federal agencies that have expressed interest in FERN include CDC, CBP, DOD, FBI, EPA, DOE, the Department of State, and DHS.

As funds are appropriated for this purpose, FDA will help fund the chemical and radiological laboratories involved in FERN, while USDA will fund the microbiological laboratories.

FDA and USDA envision approximately 100 federal, state and local laboratories in the FERN network. This number is based on a potential scenario in which 100,000 units of food are contaminated with a threat agent. Based on this scenario, we estimated that 100 laboratories would be required to provide the needed surge capacity to respond to the attack.

It should be noted that the 100 lab goal reflects laboratory capabilities for chemical and microbiological analysis rather than actual laboratory locations, because some laboratories will have the capability to analyze samples for both types of agents at one location. Although the FERN will strive to include laboratories with the ability to analyze for microbiological AND chemical types of agents, we recognize that some locations may have capabilities only for one type of threat agent, but not the other. So, the number of physical locations included within the FERN network could be fewer than 100. FERN Laboratories will need to be capable of being operational 24/7 (including two working shifts), have trained personnel, use validated methods, and have satisfactorily completed proficiency test samples.

FDA's plan is to fund 50 labs: 36 chemical and 14 radiological. USDA is planning to fund 50 microbiological screening and confirmatory laboratories.

Currently, 93 labs in 42 states and Puerto Rico have satisfactorily completed the FERN Laboratory Qualification Checklist, which provides vital information to determine if a lab meets the criteria for participation in FERN and is eligible for Federal funding.

I would like to acknowledge those members of AFDO who have been involved in promoting FERN and eLEXNET, and who have worked hard to ensure the integration of our Nation's federal, state and local laboratories.

CFSAN Efforts

Later this week, you will hear from officials in FDA's Center for Food Safety and Applied Nutrition (CFSAN) regarding their perspective on the current status of the Center's food defense activities and where we need to go. I will not go into detail regarding CFSAN's efforts, but I would like to mention briefly a few of CFSAN's activities.

CFSAN has conducted threat assessments of different categories of food for the relative risks of intentional contamination during various stages of food production and distribution. Last year, CFSAN and ORA distributed an unclassified version of FDA's current threat assessments on a range of FDA-regulated product/agent scenarios to state agriculture and public health officials and to industry. The purpose of providing this document is to assist our federal, state and industry partners in developing strategies to respond to food security issues. These threat assessments have also assisted the Agency in focusing on those commodities considered to be most at risk for intentional contamination, and have allowed government and industry to work together to develop specific, targeted mitigation strategies to address the vulnerabilities identified in our assessments. In addition, these assessments have assisted the agency in focusing intramural and extramural research on four major areas: new methods for detection of agents, prevention technologies, agent characteristics, and dose response.

Based on heightened security concerns during the time surrounding last year's national election, FDA determined that it was appropriate to issue a broad, nationwide food security assignment. CFSAN, in coordination with ORA, had the lead on this effort. This FDA security surveillance assignment (FSSA) was designed to be national in nature and to involve federal, state, local, and industry partners.

The six-week assignment began in October 2004, and targeted spring and mineral water; fruit and vegetable juice; liquid and powdered infant formula; fresh leaf and stem vegetables including cut vegetables; and fluid milk. Samples were

collected from all of the relevant food commodities during the assignment. In addition, the assignment was augmented by specific, directed instructions based on intelligence information derived from tailored entry screening data obtained by the Prior Notice Center.

The activities in the assignment were conducted in cooperation and collaboration with our state partners. This was intended to enhance both FDA's and the states' preparedness/response abilities and to heighten food security awareness. State inspectors augmented FDA's activities by identifying and inspecting firms that FDA was not otherwise aware of and by conducting inspections/sample collections of foods identified in the assignment.

Many of you here today were involved in that assignment, and I want to thank you again for your efforts. Your participation in the assignment was integral to its success and for helping us identify areas where we can all improve.

Additional Counterterrorism Activities

Other counterterrorism activities over the past three years include:

- Constructing and certifying three BSL-3 laboratories in the field (Northeast Regional Laboratory, Pacific Regional Laboratory-Southwest, and Forensic Chemistry Center in Cincinnati, OH) and supporting the construction of two mobile laboratories;
- Conducting research to improve our ability to detect contamination, focusing on rapid test methods for use in the field;
- Carrying out food defense activities under Homeland Security Presidential Directives, the Interagency Security Plan, the Secretary's Bioterrorism Strategic Plan, and FDA's Strategic Action Plan; and
- Enhancing FDA's ability to plan, manage, and respond to food emergencies through the Emergency Operations Network (EON), an electronic incident management system.

Where We Are Going

The activities I have mentioned regarding "where we are" provide a preview of "where we are going". I would like to mention several areas where FDA plans to advance its food safety/security agenda in the coming months.

HSIN (in lieu of ISACS)

FDA supports the Department of Homeland Security's efforts to implement a Homeland Security Information Network (HSIN). HSIN is an Internet-based platform that each critical infrastructure sector established on its respective web page. Federal, state and industry members of the HSIN will have a password that allows them to access, review and send information that is included on the network. The HSIN may also be used as a platform to issue alerts to the industry or other HSIN members. FDA has posted its food security guidance documents and other materials that are of value to food and agriculture sector members on the HSIN. The network is funded and administered by DHS and the AFDO Board has received a briefing on it from DHS on HSIN. The HSIN replaces the Information Sharing and Analysis Centers (ISACs), which were primarily set up by, and intended solely for, industry. The food and agriculture sector's HSIN web page is just rolling out, and you may contact your AFDO representative for more details.

Presidential Directives

On 12/17/03, President Bush issued Homeland Security Presidential Directive (HSPD) No. 7. This directive commanded Federal departments and agencies to identify and prioritize U.S. critical infrastructures and key resources and to protect them from terrorist attacks. The Administration has designated the food and agriculture sector, a critical infrastructure for which USDA and HHS share responsibility. Under HSPD 7, USDA and HHS must develop indications and early warning mechanisms, integrate their cyber and physical protection plans and submit regular status reports. We are also supportive of AFDO and state representatives who serve as members of the food and agriculture sector's government coordinating council.

On 1/30/04, HSPD 9 was issued to establish a national policy to defend the U.S. food and agriculture system against terrorist attacks, major disasters, and other emergencies. HHS, USDA, and EPA are the lead Federal agencies in this effort. The FY 2006 budget request includes additional funding to continue the Administration's progress on these homeland security initiatives.

FERN

In the development of the FERN, one of FDA's goals was to expand food laboratory surge capacity by capitalizing on existing laboratory capabilities throughout the country. As mentioned earlier in my remarks, these existing laboratories include federal, state, and local laboratories that have microbiological, chemical, and/or radiological capabilities. During response to a foodborne outbreak or an event where the safety/security of the food supply has

been compromised, FERN laboratories will be involved in both “screening” and “confirmatory” analyses when looking for the agent of concern in concert with other laboratory networks. FDA fully expects that some laboratories will have sufficient equipment and personnel to perform highly complex confirmatory analysis. Others may be equipped to perform initial screening methods to “rule in/rule out” a target analyte, at which point the sample would have to be forwarded to a laboratory that can perform further, confirmatory analysis. Both of these types of laboratories are critically important—the screening laboratory that has high “throughput” abilities and can analyze many samples and the confirmatory laboratory that has more specialized capabilities, but lower throughput potential.

FERN will continue to provide an infrastructure that helps to identify, coordinate and better utilize the existing capabilities and capacities of the Nation’s food testing laboratories, thereby greatly increasing its ability to respond to food safety (natural foodborne outbreak) and/or food security (intentional contamination) incidents.

However, just as building food safety/security measures INTO the food supply is not cheap, neither is MAINTAINING our ability to “detect” pathogens and agents of concern in that same food supply.

In FY 2005, FDA and USDA will provide funds via cooperative agreements to FERN laboratories that will perform surveillance testing. The agreements will highlight the need for laboratories to utilize FERN methods to analyze for microbiological threat agents (USDA) and chemical threat agents (FDA), and will also emphasize the improvement of laboratory capacities for surveillance and outbreak response.

The Cooperative Agreements will also support FERN threat agent method training, and the purchase of equipment that is required by selected methods. After laboratories are “trained” and demonstrate full “proficiency,” they will participate in validation studies with various food matrices, as well as surveillance activities.

USDA has published its Request for Cooperative Agreements (RFAs) for FERN labs involved in microbiological analysis in the Federal Register on April 20, 2005. FDA published its Request for Cooperative Agreements in the Federal Register on May 25, 2005.

In addition, FY 2005 money, which is not included in the RFAs for cooperative agreements, will be used by FDA to purchase equipment for state and local chemistry laboratories. FDA determined that it is more cost-effective to purchase the equipment “centrally” since it can procure discounts from manufacturers due

to the size of the order. Through this central purchase, FDA also ensures that laboratories will have consistent equipment needed to run FERN methods.

FDA will also continue to provide training to state FERN labs and will support proficiency testing at those labs in an attempt to maintain laboratories' capabilities in each analytical discipline (chemical, microbiological, and radiological). This training for state personnel will also be funded from FY 2005 appropriations. FDA will pay for a total of five courses in FY 2005 including two microbiology courses, two chemistry courses and one radiological course. And FDA will equip/fund its own FDA laboratories with "FERN training areas". This will ensure that FDA has the continuous capability to bring in and train state FERN participants regarding the laboratory equipment they will receive under the cooperative agreements.

The remainder of the funding for FERN will be used to support proficiency testing. Proficiency tests provide a useful tool by assessing the capabilities of laboratories to detect different analytes in different matrices. This assures that the laboratories in the network will be able to adequately perform surveillance testing, and real, actual analyses in an emergency situation. In FY 2006, the President's budget request for FDA includes \$18.5 million to maintain and expand the capabilities of FERN.

Food Facility Security Measures

FDA anticipates expanding upon its efforts to maximize the food industry's efforts to implement the best and "tightest" security measures at its facilities. We will continue to hand out our Food Security Guidance Documents to industry organizations and to individual facilities that we visit. We are also looking into ways we can work more closely with facilities to implement, improve upon, update, and stay "on top of" their security needs. In light of the very vast, diverse, and complex nuances of the food industry, we fully recognize that there is no "one size fits all" security plan that can be applied across the board. We are considering incorporating food security plan assistance into our inspections, where we will sit down side by side with firms, at their request, to review their security plans in light of what we observe during the inspection. As I said, this is very much in the "idea" stage and I welcome your insight and suggestions.

BT Act Implementation

FDA is committed to fully implementing the "letter and the spirit" of the regulations published in accordance with the BT Act, and will publish Final Rules to replace the Interim Final Rules for Registration and Prior Notice.

Also, we will continue in our efforts to make the rules themselves, and our enforcement intentions to fully implement them, as transparent as possible.

Lastly, we are committed to helping the public, via our education and outreach efforts, to understand the content of the rules and what they mean to them. Beginning this week, FDA is initiating a second series of public meetings around the country to provide an overview of FDA's Final Recordkeeping Rule.

Conclusion

In closing, FDA looks forward to continuing to work with AFDO, our other Federal, state and local partners—and the regulated industry—as we implement strategies for food protection and defense. I am confident that, collectively, we will achieve what no one of us could alone in our respective, yet mutual efforts to ensure the safety and security of our Nation's food supply.

Thank you for your attention, and have a wonderful conference.

CANADIAN KEYNOTE

Debra Young
Director General, Office of Regulatory and International Affairs (ORIA)
Health Products and Food Branch
Health Canada

Introduction

Thank you very much for that kind welcome.

As some of you will know, Diane Gorman, the Assistant Deputy Minister of Health Canada's Health Products and Food Branch, was originally scheduled to be here with you today but, due to unforeseen circumstances at home, was unable to do so.

As a newcomer to Diane's Branch—I've been with HPFB now for not quite two months—I'm very pleased to have the opportunity to be here in her stead today, to learn from all of you, and to speak to you about HPFB's activities over the past year.

Given the theme of this year's conference, I would like to begin by addressing an issue of profound concern to all of us—the safety of our food supply.

And, as a member of the federal organization in Canada that deals with foods and therapeutic products, I can assure you on Diane's behalf that Canada has been working very effectively—within our own borders and with key international partners like the U.S. and Mexico—to keep food safe from all natural and manmade threats.

Context

Canada has a strong track record in safeguarding the food supply of our citizens. Incidents of intentional food contamination are very rare; more often than not, the presence of microbial pathogens and chemical contaminants in food tends to result from the failure of a manufacturing process, rather than tampering or a terrorist act. A sin of omission, as it were, rather than commission.

As a result, Canadians and visitors to Canada are justified in their faith that the foods they purchase in stores will not make them ill, or worse.

However, that should not lead to complacency on anyone's part.

Threats to the food supply do occur with some frequency, and we should operate on the assumption that someday, a threat may be realized.

But I would also underline that HPFB defines the notion of a “threat” in the broadest possible sense: We must be ready for both intentional and unintentional threats to the food supply, including chemical spills or radioactive releases that may have an impact on food safety, as well as conventional foodborne pathogens, crop contamination or animal disease.

Moreover, given the integrated nature of the Canadian and U.S. economies, we need to think about food safety and security from a perspective that carries us beyond our own borders. Just because food *produced* in Canada is safe doesn’t mean that all food *available* in Canada will always be safe. Recognizing that the United States is our largest trading partner and our greatest ally, it is difficult to ignore the linkages between our economies, our societies, and our interests. Clearly, the threat environment facing the United States is also the threat environment facing Canada. In the context of food safety and the security of the food supply, this means that there are a whole host of unique challenges on the table.

That is why we are working hard on the domestic front and in concert with international partners, to preserve the safety of Canada’s food supply in line with our mandate to maintain and improve the health of Canadians. The 2004 *National Security Policy*, the first of its kind in Canada, highlighted the Government of Canada’s commitment to defend Canadians and Canadian interests from a whole range of threats, including public health emergencies and issues linked to the security of the food supply.

Government Structures

As in the U.S., responsibility for food safety in Canada is shared by several federal departments and agencies, as well as the provinces and territories. At the federal level, the Canadian Food Inspection Agency, or CFIA, has the lead in managing emergencies involving food safety, animal health, and plant protection.

The Food Directorate, which is part of HPFB at Health Canada, is Canada’s food safety regulator and sets policies and standards for the safety and nutritional quality of all foods sold in Canada. In the context of emergency management, including bioterrorism, the Food Directorate supports the CFIA by performing health risk assessments and by collaborating on research into methods of detection for priority chemical, biological, radiological, and nuclear threats that might use food as a deployment vector.

Other departments with a role to play in the area of food bioterrorism are:

- Agriculture and Agri-Food Canada
- The Public Health Agency of Canada, which was recently created as part of the Health Canada portfolio, and
- Our counterpart to your Department of Homeland Security—the department of Public Safety and Emergency Preparedness Canada. Under the 2004 *National Security Policy*, PSEPC plays a central coordinating role in counter-terrorism, which encompasses the security of the food supply.

Under the leadership of Defence Research and Development Canada, part of the Department of National Defence, several federal departments are also working on science- and technology-based solutions to national security threats posed by chemical, biological, radiological and nuclear—or CBRN—threats, including those to animals, crops, food and water. This program is called the CBRN Research and Technology Initiative.

Risk-based Approach to Food Safety

Canada is geographically vast, but we have a relatively small population. We have to invest our resources where they will be the most effective.

That is why we apply a *risk-based approach* to food safety and security.

On the premise that an effective food safety system delivers a level of protection commensurate with the risk, our objective is to identify and assess the broadest range of possible threats to the food supply.

We then apply scientific evidence to set standards and regulations for safe food production, handling, packaging and sales. The higher the potential risk to public health, the more stringent our regulation.

Finally, we invest in essential infrastructure, such as laboratories, to ensure high-quality monitoring of the safety of products.

This approach has resulted in a high level of confidence from Canadians. Polling consistently shows that the public considers food and pharmaceutical safety as two of the most vital responsibilities of Health Canada—and that the department’s performance in these areas is consistently strong.

Preventing Incidents

In Canada, safeguarding the food supply begins with good surveillance and inspection programs, aimed at preventing all threats to public health and safety—whether in food, animals or plants, whether through accidental or deliberate means.

For example, our food inspection agency cooperates with the Canada Border Services Agency to pinpoint high-risk shipments or travellers. The agency also shares information with the U.S. to head off any possible introduction into Canada of foreign plant and animal diseases and pests.

At the same time, the Chemical, Biological, Radiological and Nuclear Research and Technology Initiative projects are helping with the development of rapid-detection field tests. And, with 21 labs across the country, the Canadian Food Inspection Agency can respond quickly to suspected threats—everything from BSE, rabies, anthrax and SARS to pesticide residues and unidentified, suspicious agents.

Emergency Response

If, in spite of these protective measures, Canada detects a deliberate contamination of the food supply, our Food and Emergency Response System comes into play. This is a planning framework to deal with the agriculture and food components of a broader national emergency.

Several emergency protocols have been developed, targeting plant pests, foreign animal diseases and food safety in general. These are regularly put to the test in exercises like the TOPOFF series and similar international exercises.

Canada also has a well established emergency food-recall system to deal with crises such as an outbreak of foodborne illness. These protocols are also tested in national and international exercises, based on a variety of scenarios, including food tampering, sabotage and terrorism.

Longer-term Measures

In light of the evolving international environment, however, Canada recognizes the need to remain vigilant. That is why we have strengthened our legislative and regulatory authorities.

For example, with the passage of the *Public Safety Act* of 2002, we also amended the *Food and Drugs Act* to give the Minister of Health the power to issue interim emergency orders to manage situations that may threaten the health or safety of Canadians. We are also making food tampering a more explicit offence under Canadian law.

International Food Safety Activities

In addition to our domestic activities in the area of food security, Canada works closely with partners here in the United States, and through fora such as the G8, the Food Safety Quadrilateral group (involving the U.S., Australia and New Zealand), APEC's Counter-Terrorism Task Force, and the Canada-U.S.-Mexico Trilateral Cooperation initiative.

Last year, for instance, Health Canada hosted the second North American tabletop exercise, designed to review our readiness to communicate, share information and intelligence, and respond effectively to international food terrorism acts.

Canada is also a committed member of the Smart Border process with the United States, which, in conjunction with Mexico, recently expanded into the Security and Prosperity Partnership of North America. The SPP is an important initiative that we anticipate will contribute significantly to our bilateral security goals, including those linked to the protection of the food supply from deliberate attack.

Within Health Canada, we are using various open-source intelligence-gathering tools to monitor bioterrorism or agro-terrorism activity around the world.

For example, the upgraded Global Public Health Intelligence Network warns us of disease outbreaks, food contamination, bioterrorism, natural disasters and so on. Operating in seven languages, this network is a secure, Internet-based mechanism to collect early reports about public health concerns.

A special Information Gathering and Analysis Team within the Canadian Food Inspection Agency also works with domestic and foreign intelligence agencies to ensure we stay abreast of potential food-related threats.

General Food and Therapeutics Safety

Most of my remarks so far have focused on food safety from the "security" perspective: defending the food supply from those who would deliberately sabotage it.

But, as I have noted, the Health Products and Food Branch has broader responsibilities—to ensure that Canadian shelves are stocked with safe, healthy and nutritious foods, and safe and effective therapeutic products.

As we all know, the regulatory and industry landscape is shifting on all these fronts:

- High-profile events, such as the withdrawal of VIOXX, have brought a renewed public and political focus on the issue of drug safety
- In an increasingly global economy, regulatory authorities, including Health Canada, are collaborating internationally on regulatory requirements and product reviews as a way of doing business on a daily basis; and
- Canadians are demanding, rightly, that regulatory authorities and industry become more transparent about their business and about how decisions are made.

Before closing, I would like to spend just a few more minutes bringing you up to date on some of HPFB's recent initiatives in these areas.

Last year, the Branch released a strategic plan that commits us to enhance our regulatory efficiency, effectiveness and responsibility, increase our vigilance over public health issues, and provide more authoritative information to help Canadians make informed choices over their health.

A key mechanism in achieving our objectives is the Therapeutic Access Strategy. As you may recall, TAS, launched in 2003, aims to ensure that Canadians have timely access to safe and effective medications.

I am pleased to report that, over the past year, we have made noteworthy progress. By introducing modern procedures and processes, the Branch's Therapeutic Products Directorate has successfully streamlined the pharmaceutical submissions process, and we are now on track to achieve submission review times in line with international standards within the next year, despite being a much smaller organization than many of our international counterparts.

Canada's recently announced National Pharmaceuticals Strategy builds on the success of TAS by providing us with additional resources to focus on:

- Strengthening real world drug safety and effectiveness; and

- Accelerating access to breakthrough drugs for unmet health needs through new approaches to the drug review and approval process.

In a publicly funded health-care system, the NPS will help us pursue regulatory improvements under the guidance of clear public policy objectives—therapies that are safe, therapeutically beneficial, cost-effective and appropriately used.

Transparency and Openness

Regulatory authorities around the world are wrestling with another important issue—openness and transparency of the regulatory system and its decision-making processes. In Canada, our Minister of Health has made this a priority. He believes—as does the Health Products and Food Branch – that Canadians have the right to know how and why decisions about the safety of the therapeutic products they use are made.

In Canada, we are approaching this issue with a fundamental bias that this type of information should be publicly available. And that any restrictions must be clearly justified, such as those relating to intellectual property issues, for example.

It's about accountability. It's also about equipping people with information, so that they can make the best possible decisions regarding their own health.

And, last but not least, it's about engaging a broader circle of people—consumers, outside experts, stakeholders—so that we can draw on their perspectives, experience and insights, while cementing relationships of mutual trust.

Consistent with this philosophy, we have instituted a number of measures to open our processes to greater public scrutiny and involvement.

For instance, we are in the process of creating an ombudsman's office within Health Canada. Its role will be to receive concerns and feedback from individuals and organizations on how we are implementing Canada's Food and Drugs Act, and to help resolve disputes.

We are also opening an Office of Paediatric Initiatives, which brings together internal and external experts and stakeholders to focus on all child health issues, from food safety and nutrition to health promotion and product safety.

Last September's market withdrawal of VIOXX in Canada and the subsequent concern over the safety of the COX-2 class of pain relievers has helped to accelerate our move toward greater transparency.

For instance, we are working with international partners, industry, and other stakeholders to move toward greater disclosure of clinical trial information. Consumers, health care providers and researchers all have a direct and compelling interest in the whole picture—not just selected bits of it.

We are also opening up our post-market regulatory processes. The minister has committed to the establishment of a permanent Drug Safety Board, which will serve as a transparent and accountable vehicle for Canadians to engage in Health Canada's regulatory activities.

We are also examining the feasibility of mandatory reporting of adverse drug effects. And we are poised to hold a public forum, designed to meet the unique features of the Canadian environment, on the future use of selective COX-2 inhibitors in our country.

As we move forward to strengthen our processes on these and many other fronts, the steps we are taking—across the entire life cycle of pharmaceutical products—will result in some meaningful enhancements to a system of therapeutic safety that is already one of the best in the world.

Conclusion

As we move into what we firmly believe is a new era in how we ensure the safety and effectiveness of therapeutic products and the safety of our food supply, as well as how we communicate about our efforts to our respective citizens, there is one immutable fact—none of us can be successful in isolation. I feel very fortunate in my role as Director General of Health Canada's Office of Regulatory and International Affairs, because I have the great thrill of interacting regularly with my counterparts all over the world as we work together in addressing the opportunities and challenges we all share, and learning from each other's successes.

I am looking forward to building on the strong relationships Canada has established with its international partners and to look beyond Canada's borders to ensure our perspective is informed by the experiences of others.

Thank you for the opportunity to be here today.

USDA KEYNOTE

Barbara Masters, DVM
Administrator

U.S. Department of Agriculture, Food Safety and Inspection Service
(USDA/FSIS/OFO)

Introduction

Thank you, Marion. Good morning. I truly appreciate the invitation to be here at the AFDO annual conference.

We at the Food Safety and Inspection Service value our growing relationship with AFDO. FSIS membership has increased by more than 40 percent as compared with last year. I hope these numbers continue to increase. We are encouraging people from all levels within the Agency to work more closely with your organization.

FSIS Overview

For almost 100 years, American consumers have depended on the United States Department of Agriculture to ensure the safety of their meat, poultry and egg products. FSIS enters the next century confident in our ability to safeguard important segments of the nation's food supply.

Fulfilling this public health mandate is a demanding responsibility and an exciting challenge. Each year, more than 100 billion pounds of red meat, poultry and liquid egg products are verified safe and secure by more than 7,500 FSIS inspection personnel in approximately 6,300 plants.

We believe that any effective food safety and security system must be rooted in science. To meet its goal of protecting public health, FSIS will continue to review policies and regulations. We will also work with interested parties to modernize and further enhance our inspection and food safety and security verification efforts.

Food Safety Accomplishments

Fortunately, we are seeing a number of significant public health improvements, as evidenced by the decline in foodborne illness over the last seven years.

In April the Centers for Disease Control and Prevention reported continued reductions in foodborne illnesses from 1996 through 2004 stemming from *E. coli* O157:H7, *Listeria monocytogenes*, *Campylobacter*, and *Yersinia*. The CDC

attributes the changes in the incidence of these infections in part to the control measures implemented by government and industry leaders and enhanced food-safety education efforts.

At the same time, we are seeing improvements in the data we collect from our regulatory sampling programs. This year FSIS released data showing a 43.3 percent drop in *E. coli* O157:H7 positive ground beef regulatory samples collected in 2004 compared with 2003. Between 2000 and 2004 the percentage of positive samples in FSIS regulatory sampling has declined by more than 80 percent, which we consider to be an enormous accomplishment.

These data demonstrate the continuing success of our agency's strong, science-based policies aimed at reducing pathogens in America's meat, poultry and egg products.

FSIS is committed to continue making advancements. To continue being a successful public health regulatory agency, FSIS must ensure several things:

- Science-based policies are essential
- Effective communication is critical
- Management controls must be in place for all parts of the Agency, ensuring efficient and effective program management
- FSIS employees must be properly trained
- Inspection and enforcement must keep moving forward, both in the domestic and international arenas; and
- Food security must remain a top priority—we must continue to be vigilant.

I mention these to demonstrate food security is one of FSIS' top priorities. Now in keeping with the theme of this year's conference *Implementing Strategies for Food Protection and Defense*, I will focus my remaining remarks on our priority of food security.

FSIS has a significant role in food security.

Protection of the United States' food supply is critical for maintaining the safety and health of the nation's citizens and the security of our economy. FSIS has a solid and well-functioning food safety infrastructure in place to protect the public from contamination—whether this might be unintentional or intentional.

Within FSIS, a distinct program area, the Office of Food Security and Emergency Preparedness (OFSEP)—whose sole responsibility is food security—was established. OFSEP works in concert with other entities to ensure that food security activities are coordinated and resources are used efficiently.

Dr. Carol Maczka heads up OFSEP. She will be delivering a presentation this afternoon, which will go into more detail about the innovative projects FSIS currently has underway.

Food security cannot be done alone; partnership is a critical element for success.

As already discussed, it is important to understand that food security cannot be accomplished through one lone action nor through just one organization. Food security is a shared responsibility of FSIS and our many partners to prevent or respond to the contamination of food products, and we continue to make these multiple efforts a priority. We are all in this together, and partnering on local, state, Federal and even international levels is a critical element for success.

Federal Collaboration

FSIS works closely within USDA, the White House, the Department of Homeland Security, the U.S. Department of Health and Human Service, and other federal agencies to coordinate our food security efforts. The Agency continues to work with the White House Homeland Security Council's Interagency Food Working Group to develop a seamless interdepartmental strategy to best protect the food supply and minimize it as a target for terrorist activity.

Food Emergency Response Network

One collaborative food security activity is the Food Emergency Response Network (FERN). Since Ms. Glavin provided the details, I will keep my remarks brief here. FERN is a coordinated initiative led by FSIS and FDA to develop a laboratory network capable of providing ongoing surveillance and monitoring of food. FERN is also for the purpose of conducting the extensive sampling necessary in the event of a terrorist attack on the food supply.

Essentially, FERN was created to provide an integrated means of protecting the food supply at the local, state and national levels.

Specifically, laboratories participating in FERN are responsible for detecting and identifying biological, chemical and radiological agents in food.

Working in conjunction with FERN is the Electronic Laboratory Exchange Network (eLEXNET). eLEXNET is a Web-based database that provides for the

rapid reporting of laboratory results and the electronic exchange of food safety data and methods among FERN members.

We also acknowledge and appreciate AFDO support in this area.

Consumer Complaint Monitoring System

At this point, more internal to FSIS, we have the Consumer Complaint Monitoring System (CCMS). CCMS is a national surveillance system that records and tracks complaints from consumers, facilitating the identification of possible food hazards and the ensuing investigation.

CCMS is currently being upgraded to allow continuous, daily 24/7 coverage and an alert system. It will also include a comprehensive analytical tool that will analyze seemingly unrelated incidents, identify linkages, and trigger an alert of potential threats to food safety and security.

I want to recognize AFDO for their assistance in assembling a workgroup to help FSIS with the design of connecting CCMS to state partners. Your input has been vital in this effort. I know many of you are interested to know where we are in this process. To update you, FSIS is currently finalizing the statement of work. We hope, dependent on appropriations of course, to make awards to pilot states this fall.

FSIS is integrating databases such as CCMS and others within FSIS, together with a National Biosurveillance Integrations System to be used as an early warning system for potential threats to the food supply.

Expanding Interagency Relationships

FSIS is also working more closely with the intelligence and law enforcement communities. One of FSIS' initial actions was to hire Import Surveillance Liaison Officers who are responsible for the Agency's oversight of imported food security issues at ports of entry around the nation, particularly with the Customs and Border Protection (CBP).

Furthering this relationship FSIS worked with CBP's National Targeting Center to develop criteria to assist in targeting shipments of FSIS-regulated products that may require heightened inspection by CBP. The criteria include the high-risk products from countries identified as eligible to export to the United States in the import vulnerability assessment.

FSIS is also building relationships with important partners, such as the Federal Bureau of Investigation, the Central Intelligence Agency and local law

enforcement agencies. FSIS is providing information to these communities on food security concerns for intelligence collection and participating in information-sharing working groups sponsored by these agencies.

State Level Collaboration

To improve federal and state government coordination to prevent and respond to any act of intentional contamination, FSIS entered into a cooperative agreement with the FDA, DHS and the National Association of State Departments of Agriculture (NASDA). This cooperative agreement resulted in development of guidelines and procedures for state and local first responders and Federal food regulatory agencies. The interagency response plan will facilitate cooperation with state and local emergency efforts when responding to incidents involving the food supply.

In the future, FSIS is planning to work with states to coordinate Food Security Exercises. Utilizing our District Field Offices and existing reporting systems, these exercises will assist with identifying vulnerabilities across the farm-to-table continuum. They will also lead to the development of appropriate countermeasures to avoid potential deliberate acts of contamination of meat, poultry and egg products.

Stakeholders and the Agency have a shared responsibility to make sure that each link in the food chain is strong, and sharing information is vital for meeting those responsibilities. FSIS also continues to encourage industry, as well as consumers, to understand their roles and take the necessary actions to protect the food supply.

Local Level Collaboration

Recently, the Agency published an Industry Self-Assessment Checklist for Food Security. This self-assessment instrument was created to provide a tool for establishments to assess the extent to which they have secured their operations. It is vital that all food slaughter and processing establishments, and all import and export establishments, take steps to ensure the security of their operations.

The final outcome of this self-assessment should provide establishments with a relative measure of overall security of their operations and guide them in the development and/or revision of their food security strategies. This checklist is one of several outreach efforts by FSIS to help assure the security of regulated food products. The checklist is available on our web site (www.fsis.usda.gov).

Also available on our web site are four newly developed model food security plans. These model food security plans are designed to assist federal- and state-inspected meat, poultry and egg products establishments as well as import

facilities, and to develop their own security measures to deter the threat of intentional contamination and similar attacks on the food supply. FSIS is conducting workshops around the country and via webcast this summer to assist small and very small processors in the development of food security plans for their operations. We have found webcasts to be a popular method of increasing small and very small plant participation. We usually have 150 or more participants. The workshops are interactive, and participants leave with a basic plan for their operation.

The model food security plans are being issued in the form of guidance documents and are voluntary. However, FSIS believes that every establishment should have a written plan that describes and documents controls to ensure that the premise is secure from potential threats. Consequently, FSIS has included on its regulatory agenda a mandatory rule for the adoption of Food Security Plans by all FSIS-inspected establishments.

In response to input from the National Advisory Committee on Meat and Poultry Inspection (NACMPI), FSIS is assessing whether voluntary adoption of Food Security Plans at inspected establishments will fulfill the Agency's desire for all establishments to have written food security plans. FSIS expects to begin documenting whether establishments have a written plan and will use this information in determining whether mandatory plans should be required, and how quickly FSIS should pursue rulemaking.

International Collaboration

Finally, FSIS recognizes the importance of working with its partners outside the United States. We have entered into bilateral agreements with Canada and Mexico to share information to secure the food supply. FSIS is interested in developing similar agreements with other major trading partners. The goal is to ensure that safe and secure food keeps moving between the United States and all of its trading partners.

Closing

In summary, it takes cooperation from government, scientist, educators, consumers, industry and many others to protect public health most effectively. This cooperation is necessary when dealing with the complex issues of food safety and food security. Individuals and organizations all have valuable input and a different way of looking at things.

I encourage all of you to examine what you can do to increase food security through your own organizations. As I said earlier, each of us has a role in

ensuring a safe and secure food supply. There will always be more we can do, and we must continue our efforts in the months and years to come.

FSIS considers opportunities to address food security together with its stakeholders, such as during this important conference, pivotal for making further advancements.

I thank you for your dedication and efforts, and we look forward to working with AFDO and to your continued contributions in food safety and food security.

CDC KEYNOTE

Arthur P. Liang, MD, MPH
Director, Food Safety
Centers for Disease Control (CDC)

My talk today is neither a CDC talk nor much of an update. I hope to present some information that many of you may have seen before, but use it to raise some discussion of where we might go in the future.

The findings & conclusions in this presentation have not been formally disseminated by CDC & should not be construed to represent any agency determination or policy.

Briefly, I will present some data that suggests that the threat to the food supply from a terrorist attack today may be small. However, small is a relative term; and there are still things to do to be better prepared. Past experience suggests that an intentional contamination of the food supply could involve common foodborne pathogens, as much as select agents. And both would represent challenges to our food safety system, though different kinds of challenges. As you know, increased preparedness at CDC and for many state departments of health means increased ability to detect and respond to foodborne illness and outbreaks, in general. I would like to suggest that food regulators have an important role to play in detection and investigation of illness even though they may feel more comfortable focusing on problems with food rather than problems with people. Finally, I will provide a brief update of CDC's new guidance for the BT cooperative agreement with the states.

Much of the data that I will present today is not CDC data, but comes from two historic surveys of bioterrorism and crimes drawing from the open literature, including both scientific and news sources:

- *Bioterrorism & Biocrimes: The Illicit Use of Biological Agents Since 1900*, August 1998 (Revised Feb 2001), by W Seth Carus, Center for Counterproliferation Research, National Defense University, Washington, D.C.
- Tucker, Jonathan B, "Historical Trends Related to Bioterrorism: Empirical Analysis," *Emerging Infectious Diseases*, Vol 5, No 4, July–August 1999.

How Worried Should We Be?

The history of biological warfare is varied. We know that a number of governments have developed the expertise and capacity to develop, stockpile, and in some cases use biological weapons. During the 1930s and 1940s military

organizations in Japan, Great Britain, Germany, and the Soviet Union developed the technology to produce weapons of mass destruction, and they conducted a variety of experiments on humans and animals. During the 1940s and up until the 1970s, the US also developed biologic and chemical weapons. South Africa's and Iraq's programs are also well documented.

However, actual incidents of terrorist groups expressing interest, attempting to acquire, possess and/or use biological agents are rare. Few have demonstrated an interest and fewer still tried to acquire biological agents. Of 180 incidents identified by Professor Seth Carus between 1900 to 1999, in only 27 cases is there more than minimal evidence of terrorist groups' interest in the use of biologic weapons. Open source accounts mention at least 54 cases in which a terrorist group allegedly had an interest in biological agents, but there is little evidence to confirm most of the cases, according to Professor Carus, the author of *Bioterrorism & Biocrimes*.

Terrorist groups apparently acquired biological agents in only eight cases. Terrorists have used biological agents, but rarely and with relatively little effect. Of the 27 incidents, there are only 5 cases of terrorist groups actually using or attempting to use biological agents, and except for The Dalles OR (and of course, later the 2001 Anthrax letters), it is NOT clear that the attempted use resulted in significant illness or death.

Confirmed uses of illicit biological agent activity, 1900-1999

	Terrorist Group	All
Acquire & Use	5	21
Acquire	3	12
Interest	6	10
Threat/Hoax	13	137
Total	27	180

Center for Counter proliferation Research, National Defense University, Washington, D.C, 1998 (Revised Feb 2001)

This slide summarizes the 5 cases of terrorist groups that actually used or attempted to use biological agents, plus the October 2001 Anthrax event which occurred after Dr. Carus published his report.

Baghwan Shree Rajneesh commune

1984 Oregon & salad bars

751 culture-confirmed cases of *S. Typhimurium*

October 2001 Anthrax in mail

Aum Shin-rikyo cult 1994: Tokyo, Sarin.

Release anthrax spores & botulinum toxin, but failed X 10.

Dark Harvest group protesting British military bio-warfare program.

Dumped soil at site of British chem bio research.

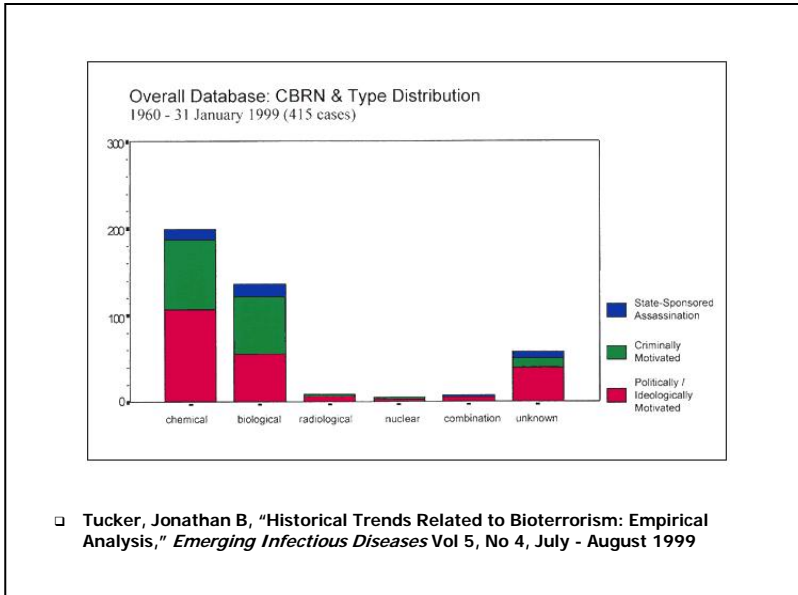
Mau Mau 1952 individuals associated with African independence movement use a plant toxin to poison livestock in what is now Kenya.

Polish Resistance

Early WWII, used bio agents against Germans

200 Germans were killed, but claim not confirmed

Dr Carus' series only looked at the use of biological agents. In this graph Dr.Tucker analyzed a series over a different time frame and including CBRN (chemical, biologic, radiologic, & nuclear) agents. As you can see, most incidents in his database involved chemical or biologic agents rather than radiologic or nuclear materials.



Dr. Tucker reaches similar conclusions as Dr. Carus. Actual terrorist incidents have been relatively rare. From 1960—1999, he documented 66 criminal events & 55 terrorist events, but mainly they were hoaxes.

So, the “good news” would be that “...the historical record suggests that future incidents of bioterrorism will probably involve hoaxes & relatively small-scale attacks, such as food contamination.” - *Jonathan B. Tucker, Monterey Institute of International Studies, USA*

Unfortunately, the “bad news” is that small is a relative term. History also tells us with “naturally occurring events” that, under the right circumstances, thousands of individuals can be affected in a given outbreak. In addition, almost every year since 1990, there has been at least one large, multi-state outbreak of foodborne illness. So the potential for an intentional event affecting a large number of individuals exists. Moreover, I suspect that this audience would not find Dr. Tucker’s phrase “such as food contamination” particularly reassuring.

Unfortunately, the other “bad news” is that the “good news” can never be counted on. Recent trends suggest that incidents are increasing. In the Carus analysis, forty of the 56 confirmed criminal cases occurred in the 1990s. Similarly, 19 of 27 confirmed terrorist cases occurred in the 1990s.

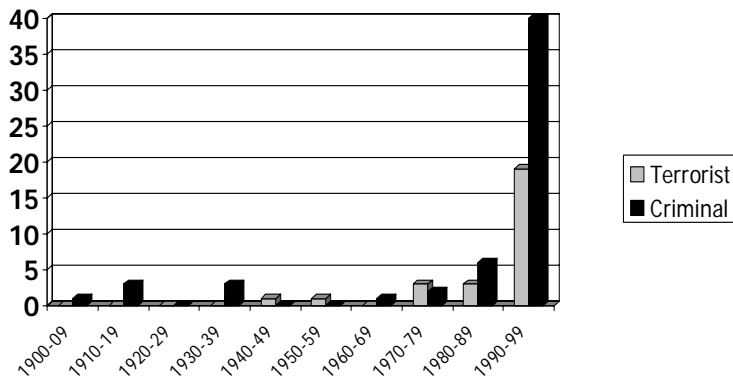
Before the late 1990s, the FBI typically investigated a dozen cases per year; however, they opened 74 such investigations in 1997 & 181 in 1998. (Parker-

Tursman J. "FBI briefed on district's terror curbs." *Pittsburgh Post Gazette*, May 5, 1999). Although 80% have been hoaxes, some were unsuccessful attacks (*NY Times* 1998 Apr 23; Sect A:12).

This may suggest a growing interest in the use of biological agents.

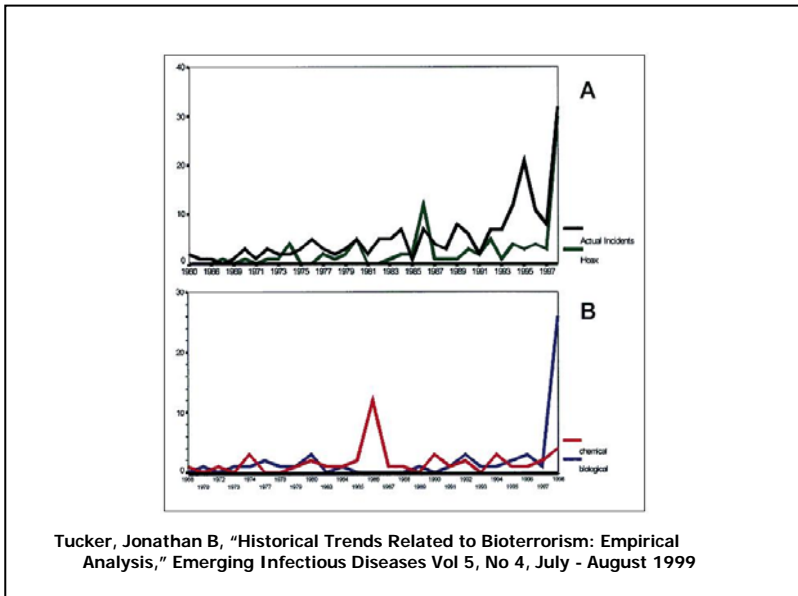
2. Bad news: Good news can't be counted on.

Trends in bioagent incidents, 1900-2000



W Seth Carus, Center for Counter proliferation Research, National Defense University

Tucker's analysis shows similar recent increases in both actual incidents as well as hoaxes.

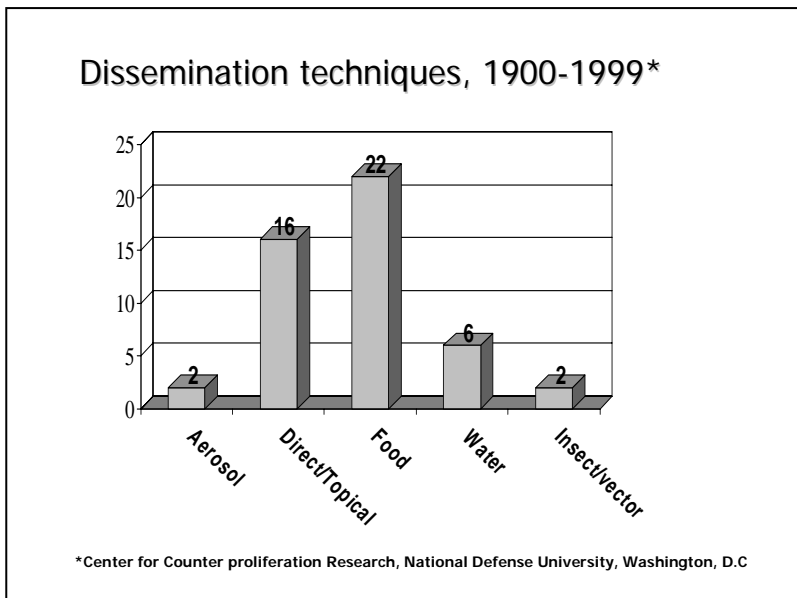


“According to 1997 testimony by DCI George Tenet, the intelligence community also has found evidence that foreign terrorist groups are showing greater interest in biological weapons. ‘We are increasingly seeing terrorist groups looking into the feasibility and effectiveness of chemical, biological, and radiological weapons.’ Overall, the CIA concluded, ‘The current WMD terrorist threat is considered low but increasing.’” (Source: *Bioterrorism & Biocrimes: The Illicit Use of Biological Agents Since 1900*, August 1998 (Revised Feb 2001), by W Seth Carus, Center for Counterproliferation Research, National Defense University, Washington, D.C.)

Finally, three days after this talk, this report appeared on the *Washington Post* web site describing how FBI agents had arrested a Pakistani American and his father in a California farming town after the son allegedly acknowledged that he attended an al Qaeda-run training camp in Pakistan and volunteered to carry out attacks on U.S. supermarkets and hospitals.

What Will Intentional Contamination Look Like?

In this “time of bioterrorism,” the chronic worriers among us are often convinced that our areas of responsibility are the most vulnerable. Those of us working in food safety may be paranoid, but we are apparently also correct. Historically, it appears that the most common vehicle for threatened or actually intentional contamination has been food.



Understandably, there is great concern about the use of select agents. And many of them can be used effectively to contaminate food.

Critical biological agents for preparedness

Agent	Syndrome	In Nature foodborne?
Anthrax	gi & pharyngeal	uncommon
Botulism	paralysis	common
Plague	pharyngeal(?)	rare
Tularemia	oro-pharyngeal	common
<i>Coxiella burnetti</i>	Q fever	(?)
<i>Brucella</i> species	Brucellosis	common
<i>Burkholderia mallei</i>	Glanders	?
Ricin toxin	gi syndrome	common
Epsilon toxin	gi syndrome	<i>C. perfringens</i>
Staph enterotoxin B	gi syndrome	common

However, when one looks at the actual events, “traditional” foodborne pathogens have been commonly used.

Agents Associated with Food, 1900-2000

Center for Counter proliferation Research, National Defense University, Washington, D.C

Confirmed

- *Salmonella Typhimurium*
- Cholera
- *Shigella*
- *Salmonella typhi*
- *Salmonella paratyphi*
- *Ascaris suum*
- Ricin
- Mushroom poison

Threat

- *Yersinia enterocolitica*
- HIV

Possible

- HAV
- Botulinum toxin

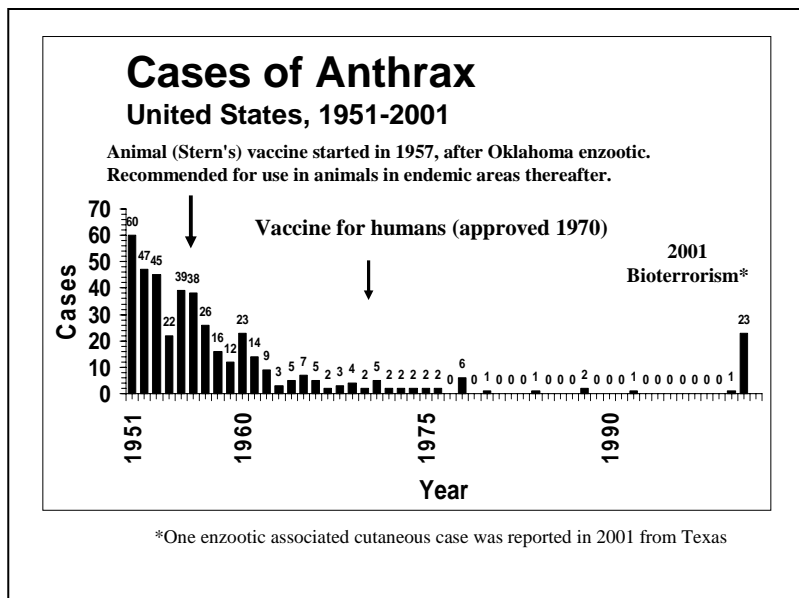
others to get involved if we hope to do effective, rapid detection and differentiation of natural events from intentional events.

Folks in this room are positioned to make a unique contribution. Distinguishing between a “natural” outbreak and possible bioterrorism often hinges on recognizing an unusual pattern of illness. Communicable disease control professionals would recognize something unusual in terms of a rare or unusual organism, or a “usual” agent occurring in some unusual pattern in terms of person, place, or time.

Clues to Possible Bioterrorism

- Outbreak of rare or novel disease.**
- Outbreak of disease in an unusual area.**
- Unusual vehicle or seasonality.**
- Unusual clinical presentation or age distribution.**
- Clusters of patients from a single locale.**
- Large # of persons with similar illness or cause of death**
- Single case of uncommon disease (e.g. smallpox)**
- Unusual illness for a specific population**

For example, the 2001 anthrax attack was recognized relatively quickly because anthrax had become a very rare event. Through the mid-20th century, it was not terribly surprising that anthrax was reported, especially in occupational settings. But by the end of the century, anthrax was essentially eliminated, such that finding two cases associated with a supermarket tabloid office was highly suspicious.



While disease control professionals would recognize something unusual in terms of person, place, or time, the people in this audience know food. You have the background and experience to detect an unusual event in terms of food patterns, how it is stored, handled, produced, and prepared. During the event in The Dalles, Oregon, it was a common pathogen—Salmonella—occurring in an unusual pattern, in different salad items, with different suppliers, at different restaurants and that was the clue pointing to an intentional contamination. The pattern just did not make sense as a “natural” outbreak.

The National Response Plan for bioterrorism recognizes that emergencies and their responses are initially local. At the moment, it is likely that detecting and responding to food emergencies are exclusively local. These data are taken from a Masters thesis looking at 4-5 years of outbreak investigations done in the Denver Metro area. They help show the extent to which responding to foodborne outbreaks is a local responsibility.

A survey done by the Council of State and Territorial Epidemiologists makes the same point. In most states, foodborne outbreaks are the responsibility of the cities and counties. Most local health departments have sanitarians; relatively few have an epidemiologist on staff. Like it or not, local food regulatory staff will need to do more if we are to detect intentional food contamination earlier.

CSTE Assessment of Epidemiologic Capacity in Food Safety
September 2002

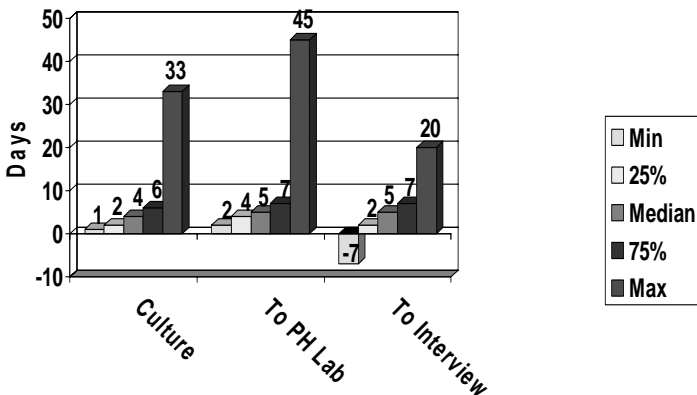
Responsibility for food-borne disease surveillance & epidemiologic response

- 63% say that local health dept covers their city/county; state covers multi-county & jurisdictions not covered.
- 11 of 46 (23.9%) say state is the sole entity

CSTE, *National Assessment of Epidemiologic Capacity in Food Safety: Findings & Recommendations*, September 2002

This slide shows preliminary data from a study done by a state health department that is considered one of the best at detecting and investigating foodborne outbreaks. What this shows is that, at best, it would take about two weeks for an outbreak to be detected at the state level. Using the normal laboratory-based and reportable-disease surveillance, one can see that the median time to beginning a case interview is 14 days. Can we afford to wait those 14 days before we can differentiate between a natural and a terrorist event?

Enteric Disease Timeline Study
E. coli 0157 (Days)



Preliminary data

I would submit that food safety professionals at the state and local level are positioned to do early detection for potential outbreaks by following FDA's National Retail Food Standards. Specifically, Standard #5 says that all complaints of foodborne illness should be investigated within 24 hours. Currently, a number of states are evaluating the utility of doing syndromic surveillance as a means of doing early detection. Typically this involves reviewing clinical records, for example emergency room visits. In this case, the sanitarians, not the emergency room doctors, would be doing the syndromic surveillance by investigating and analyzing the complaints in a timely manner.

**FDA's Voluntary National Retail Food
Regulatory Program Standards**

1. Regulatory Foundation
2. Trained Regulatory Staff
3. Inspection Program Based on HACCP Principles
4. Uniform Inspection Program
5. Food borne Illness Investigation & Response
6. Compliance & Enforcement
7. Industry & Community Relations
8. Program Support & Resources
9. Program Assessment

**Standard #5: Foodborne Illness
Investigation & Response (FDA)**

- Are reports of foodborne illness & injury investigated, analyzed, & documented in an effective manner?
- Does a coordinated approach for investigating foodborne illness & sharing of information exist?

I know many of you may be thinking, “We hardly have enough resources to do our routine inspections. Now this guy is asking us to try to do early detection of outbreaks by investigating foodborne illness complaints.” There are resources. The CDC has just posted its new Cooperative Agreement Guidance for Public Health Emergency Preparedness, and food is specifically mentioned a number of times in the document. A certain level of funding is guaranteed for each of your states. The challenge for you is to make a case to your public health leadership that you have activities that you would like to undertake that will help meet certain objectives of the cooperative agreement. This slide and the following slide outline the major objectives for this funding. If state and local food protection officials are ready to play a more active role in the early detection of foodborne outbreaks through a more active role in investigating and analyzing foodborne disease complaints, I believe a case could be made for a larger portion of federal BT funding being allocated to you to conduct these activities at least on a pilot basis.

Cooperative Agreement Guidance for PH Emergency Preparedness May 13, 2005

Prevent:

- (1) ↑ Use & development of interventions known to prevent human illness from chem, bio, radiological agents, & naturally occurring health threats.
- (2) ↓ Time to classify health events as terrorism or naturally occurring in partnership with other agencies.

Detect/ Report:

- (3) ↓ Time to detect & report chemical, biological, radiological agents in tissue, food or environmental samples.
- (4) Improve timeliness & accuracy of reporting by clinicians to those who need to know.

Investigate:

- (5) ↓ Time to identify causes, risk factors, & appropriate interventions for those affected.

Cooperative Agreement Guidance for PH Emergency
Preparedness May 13, 2005

Control:

(6) ↓ Time needed to provide interventions & guidance to those affected.

Recover:

(7) ↓ Time needed to restore health services & environmental safety to pre-event levels.

(8) ↑ Long-term follow-up provided to those affected.

Improve:

(9) ↓ Time needed to implement recommendations from after-action reports.

<http://www.bt.cdc.gov/planning/guidance05/index.asp>

Thank you.

PRESIDENTIAL ADDRESS

Delivered by Cameron Smoak
President, Association of Food and Drug Officials

WHAT A YEAR!! I have mixed emotions as my year as President comes to an end. When I look back, it seems to have gone by so quickly. I had an opportunity this year to learn from and work with some of the greatest people in the world.

I have often pondered the following questions:

The first: What is it about AFDO that makes it work?

ANSWER: It's the PEOPLE!

I want to say a special thank you to the AFDO Staff! What a great Staff! And two thirds of it is fairly new. Denise, you really know how to pick your folks! You have been so very helpful to me this past year and I appreciate your help more than you will ever know! To the AFDO Board, Committee Chairs and AFDO members, thank you for allowing me to have this experience and be President of such an awesome organization. Your support, advice and understanding of how we Southern folks operate has been the coal that kept the fire burning! To the Endowment Foundation, your passion shows in the many things that all of you continue to do—not only for the good of AFDO, but for the consuming public. Thank you for your financial support of our newest project, the enhanced web site.

The second: What causes these people to work so hard and put in so many extra hours?

ANSWER: It's the Passion!

The passion that you have for what you do is simply amazing. I know some of you appear to have more passion than others, "Lab Guy". But each of you brings to the table your own unique perspective on the many issues that tend to come up during a year. That's what makes each of you so valuable to this Association!

WHAT IS TEAMWORK?

Coming together is a beginning; keeping together is progress; working together is SUCCESS.

The year was 1897, when a few came together with a vision of better ways to accomplish the task at hand. Now here we are at the 109th CONFERENCE—only a few of you were probably around then. The journey toward uniformity began with a group of visionaries who had a desire to pull together and address the issues that faced them all. The road was apparently rough according to some of the Burditt Luncheon reenactments. Not much has changed, has it?

Actually, I think it has, and for the better, although we're still struggling with the issue of uniformity. Sometimes we get so wrapped up in particular issues that we tend to forget just how far we have come in the lifespan of AFDO. We had a beginning, we have made progress and, **yes**, we have had success!

We have accomplished much over the last 109 years. As always, there is still much work to be done. Many daunting issues face us in the coming days. However, as we focus so much of our resources toward defense we must not forget our primary purpose: the safety of consumer products, whether, food, drugs or medical devices. While we boast of having the safest food supply in the world, one of the biggest challenges to that proven system may well come from the current language of HR 2699. It is my understanding that a similar bill, if not the identical bill, will in fact come back during this 109th Congress.

I have two messages concerning this issue that I want to give you today. The first goes to industry. Look at the big picture! Do not risk the safety and welfare of our national food supply just for what might be a few individual's personal agendas or egos! We should be working together on a resolution to this issue! Let me ask you the same question that I asked a group meeting in my office in Atlanta late last year: Where does your food come from? Of course, it all comes from the same producers, processors and distributors. You eat at the same restaurants, buy from the same grocery stores that everyone else does. The larger companies have great procedures and policies in place and mean well. But sometimes those policies and procedures get left on the shelf with so many demands on management at the retail or plant level. We, the state and local regulatory entities, are a tool to help you be assured your policies and procedures are being followed. We are in this together and certainly better be working together for the safety of your families as well as ours. I truly believe that we can find some middle ground if uniform labeling and uniform standards are truly what you want!

The second message goes to the hundreds of individuals, associations and agencies throughout the United States that reviewed the legislation and then wrote letters, made phone calls and in some way got the "rest of the story" to their congressional members. I want to say thank you for a job well done. But be vigilant, for this issue is not yet resolved.

Another story of working together is the enhanced web site that has demanded many hours on the part of several of our staff and members. I will not elaborate much now on this major project that has the potential of taking AFDO to a level we may only have dreamed of before. We will hear more on this later during our Conference. To all who have worked on this project, I say thanks to each of you. This certainly is an example of the PASSION I mentioned earlier.

In conclusion, I want to say thanks again to all of you! You have made this an experience that I certainly will never forget. We are at an exciting point in AFDO history! I would not want to miss a second of it and I hope you won't either! Please keep the passion, and our future will have no limits!

GLENN W. KILPATRICK MEMORIAL ADDRESS

Dan Sowards
Food and Drug Safety Officer
Texas Department of State Health Services

Good afternoon, everyone. It is indeed an honor to have been asked to give the Glenn W. Kilpatrick Memorial Address. It truly makes one humble when you see the names of those who have preceded you, with the knowledge of the contributions these individuals have made to AFDO and to food and drug safety in this country.

I've been around long enough to have personally listened to 24 Kilpatrick Addresses. Some were truly memorial, some were stimulating and made you want to go back home and make some worthwhile contribution; others were significant in their perspectives of AFDO, and a few were not quite so memorial. Moreover, I certainly don't remember every presentation. But more to the point, when I see or think about certain individual members, those thoughts often bring me back to something that person did **FOR** this organization, not just what they said.

Glenn Kilpatrick worked for private industry, for state government, as well as for the FDA. He was strong on partnerships and working together, but more important, he was practical-minded and not afraid of change. Since his passing, this organization has honored this great man by anointing one of our own to once again review our efforts, make some critical judgments regarding those efforts, and encourage us to move ahead to greater achievements. In 1991 Tom Messenger spoke of change, a major change in the relationship between FDA and the states, which we embraced and which continues to move us forward. Dennis Baker spoke of changes going on within FDA, their potential effects on the states, *and* the impact AFDO had and is still having on some of those changes, not the least of which were the National Food Safety System project and eLEXNET. Joe Corby spoke with passion regarding his views of federal-state relations. I'm told that more than one person from the audience broke down in tears during that speech!! Also, George Burditt hit us gently but squarely in the face with his views on uniformity—which of course was one of the primary reasons that led to the formation of AFDO, and which continues to be our motto today.

While I admire those who have come before me on this day, I'm not here today to repeat the same information many of you have heard before. They say that we as individuals are the width and breadth of all of our experiences, our hopes, and our dreams. To this end, I would like first to take you back to some events in my career that have had a significant impact on me, in the hope that you, too, can relate in some way to those events, put them in perspective, and move forward

with a positive attitude, knowing that what we do as an organization and as individuals can have a significant impact on what we (collectively) can be and should be in the future. You should not take offense at any of the examples I give. They are for *illustrative purposes only(!)*, and hopefully in the end they will provide us with some insight into our individual and collective past, and will help us move into our future with a positive attitude.

I'd like to take you back in time now to 1972 and my first staff meeting with the Texas Department of Health, Division of Food and Drugs. For me as a young recruit it was an utter disaster. There were only about 15 of us at the time, all sitting around a long table one day, listening to the new FDA District Director Phil White give a presentation on who knows what. There were three of us who had been recently hired, but for the most part the individuals sitting around the table were old-timers—what today we often refer to as “old dog sanitarians.” Two were carrying on their own conversation near the back of the table. Another was cleaning out his pipe, periodically banging it on the table to loosen the burnt tobacco. Yet another was spinning his pocketknife round and round on the table. It appeared that no one was actually listening to the speaker. What a disillusioned sanitarian was I!! That evening we all piled into a motor home and traveled from Austin to San Antonio for dinner. I got so inebriated that I played with an old cowboy's hat on the trip—a BIG NO-NO IN TEXAS, and by the time we reached the restaurant I tried to read the menu upside down! The next morning I didn't even bother to show up for the meeting—the only time in my career I ever did this, no matter how bad I may have felt. Later, I regretted what I had done and vowed to try to change things rather than let them change me.

Later that same year, while training with one of our more seasoned and competent inspectors in Corpus Christi, we made a courtesy visit to the local health department. The old chief sanitarian asked us what we were up to, and when we expressed that we had been inspecting the shrimp houses along the coast, he proceeded to comment, “Well, I'll bet you got a trunk full,” followed by a sarcastic laugh. About that time my mentor took me by the arm, and in a flash we were outa there! Later my mentor told me that, yes, even to that day we still had some inspectors who took things they shouldn't, but that we were not going to get caught up in that mess! I learned right then and there that, yes, we had some staff with some integrity. And, fortunately for all concerned, these “old dogs” retired over the next several years.

That same year the FDA issued the very first Food Inspection Contract. There were actually 540 inspections on that contract, at a cost of \$138.00 per inspection (today the costs average around \$800.00). However, they were only for bakeries, bottling plants, and warehouses. Apparently there wasn't much trust at that time in the states to inspect the more sophisticated industries! I recall sitting through

training seminars on these three subjects that, even being the relative novice that I was, appeared superficial. Even so, we persevered.

A few years later, FDA banned Red Dye No. 2 for use in foods. During an FDA contract inspection of a very large candy manufacturer in San Antonio shortly thereafter, I came across over 800 30-pound cases of Starlight mints that had been manufactured using Red 2. I placed these under State Detention and contacted headquarters. Since this was an FDA contract, I was advised to take an FDA investigator with me during a conference with the company President, to determine what the company planned to do with the candy. During the conversation with the President, he asked me if he could ship the product to Mexico, where the company did quite a bit of business. I had already spoken to the office on this subject, so I was in a position to advise the owner that he could indeed re-label the product for export only if he had a letter from the Mexican health officials stating that the product was in compliance with Mexican law and fit for consumption in that country. To my surprise, the FDA investigator slapped his hand across my mouth in an effort to quiet me! Although quite startled, I firmly removed his hand and continued the conversation with corporate management.

Later I was informed by my supervisor that FDA investigators often received bonuses for large seizures, and that I might have cost the investigator some money!! Again, a learning experience I would never forget.

As the years passed, our working relationship with and respect for each other significantly improved. I can recall a joint inspection from 1980 in San Antonio. Again during an FDA contract inspection, there was a very large manufacturer of orange juice on the outskirts of the city. We had some suspicions that something was not quite right with this setup, so we decided to do this as a joint TDH/FDA investigation. While I went directly into the plant with the owner's son to examine the production that morning, the two FDA investigators proceeded to issue the mandatory FD-482, Notice of Inspection, and obtain the requisite information on the firm. I was able to take photos of a vat where a mixture of COJM (Concentrated Orange Juice for Manufacturing), Orange Pulp Wash, and Turmeric Food Coloring were being added to Invert Beet Sugar! As the FDA inspectors had come out of their meeting with the owner, I advised them of what I had observed, and they proceeded to collect official samples. I took the son into his office where, in his own handwriting, he wrote down the formula for what was being manufactured that day!

The case went to federal court, where FDA was able to seize over \$2.6 million worth of fake orange juice. Later, the attorney for the Department of Justice made the point that the total cooperative effort between the FDA and state is what made the case.

Moving ahead to around 1976, I recall participating in one of the very first low-acid canning schools put on by the FDA. In contrast to the “Bakery, Bottling Plant, and Warehouse” training received in 1973, this was quite complex and stimulating, and even more important, we were in an FDA class side by side with many otherwise very experienced FDA investigators. We were training with the FDA!

In 1980 I was elected President of the Mid-Continent Association of Food and Drug Officials. The same year my bosses in TDH evidently thought it a good idea for me to become active in AFDO. I joined the Food Committee, and I’ll never forget that first Committee meeting. There were only about 12 of us, sitting around the table discussing issues such as sodium labeling for canned foods and the fact that Kraft Foods had begun marketing a Light Mayonnaise. I mentioned that the use of the word “light” in the name of the product appeared to violate a standard of identity. FDA’s Deputy Director of CFSAN, who as I recall was the only FDAer present, immediately chimed in, rhetorically pronouncing, “What do you want FDA to do, take on Kraft Foods?!!!” I was immediately taken aback. Then I realized that my bosses had set me up on this one, as they had advised me to bring up the subject! Live and learn! Again, this is history, and today we had almost 100 in attendance at the Food Committee meeting, including a number of FDA and FSIS participants, working on numerous important issues, and we have another 16 committees all dealing with related matters.

Moving on, most of you will recall that it wasn’t until the 1990s that most of us had our first real contact with the U.S. Department of Agriculture’s Food Safety and Inspection Service, or FSIS. Previously the only contacts had been through our State Meat Inspection Programs. Then came *E. coli* O157:H7 and FSIS inspections of our retail establishments. At the time, some not-so-pleasant words were expressed by both sides, with the states accusing FSIS of stepping over their jurisdictional boundaries, and FSIS pointing out that the states and locals could do a much a better job of enforcing good sanitation practices at retail. Eventually things calmed down, and AFDO determined it was about time to add an FSIS advisor to the Board of Directors. That December the AFDO Board met for the first time at FSIS Headquarters in Washington, D.C., in order for USDA staff and the Board members to get to know one another. By this time Mike Taylor and Tom Billy had moved over to FSIS from FDA. As the Board members walked into the room for the initial meeting, you could see expressions on the USDA staff that seemed to be asking, “Who are these people, and what in the world is AFDO?!!” About that time Mike walked into the room, hugged Betsy Woodward, said “Hello, Dan, how are things back in Texas?” and personally greeted every member of the AFDO Board. You should have seen the wide-eyed expressions on the faces of the USDA staff who, at that time hadn’t a clue as to who we were!! And the point being? From that point on we have had a most excellent

working relationship with FSIS, with mutual respect on both sides. And I might add, many new and lasting friendships were born that day.

Of course, there have been many other memorable events in my 32 years with the state, some much more important overall than those I've mentioned today, and many other interactions with FDA, FSIS, and CDC—many pleasant and/or inspiring memories. These have been but a few of those that I hope I'll never forget. They may not have been the most important in some respects, but they stand out as examples of how relationships are shaped, how they progress, and how they become solid and stand the test of time.

Now you may ask, if you haven't figured it out yet, "How do these anecdotal stories relate to the purpose of a Kilpatrick Address?" Sure, they're interesting and it's fun to reminisce. But what's your point?

I'm not here today to make some earth-shaking, groundbreaking suggestions on how we can solve all of our problems. But perhaps something I have experienced or learned during the past 33 years can have an impact greater than the individual experiences of one man. Just as Glenn Kilpatrick saw the practical reasons for working together, others along the way, in FDA, USDA, CDC, and the states have seen the necessity of collaboration, uniform training, and the sharing of ideas and information. None of us can get the job done alone. None of us has a monopoly on good science or the answers to every important question. All of us as individuals, and collectively as agencies or industries or organizations, provide some measure of expertise and benefit to AFDO and to food and drug safety as a whole. The bottom line is we should respect each other and work together for the common good. Politics aside, I truly believe that AFDO has more to offer the citizens of this great nation than 99 percent of all of the other organizations that exist today. After all, collectively we are charged with ensuring the safety and/or efficacy of over 85 percent of all of the consumer commodities for sale today.

The whole is equal to the sum of the parts, and if we're either missing a part or fail to visualize the need for all of the parts, we're missing the boat. Each of us needs to realize that all of the parts are important, and that one part is not necessarily more important than the other. FDA, USDA, CDC, Homeland Security—they all need the states. In turn the states need the feds. And while we're at it, both need the locals, and vice versa. Further, we all need industry, consumers, and academia. While we regulatory officials may believe our job is to keep industry on their toes and consumers informed and protected, we all need industry and consumers to keep us on OUR toes. If you'll take a moment to think about it, how many times have we gotten off our behinds and done something we should have been doing all along because industry or consumers saw the need and prodded us, perhaps not in a way we appreciated, but nevertheless forced us to do what was best. Yes, perhaps we had to change our priorities, find more bodies to

do the work, and sometimes we felt that there were more important issues that we should be dealing with. Congress and our state legislatures often get involved, again occasionally forcing us to switch gears. We all have many examples of this. But again, we are all in this together and should treat each other as adults and move forward with a positive attitude.

Take a look at what has occurred since 9/11. After four years we are finally getting some worthwhile information that the states and locals can utilize to prepare for the inevitable. However, for the last four years each state has had to practically go it alone in developing their emergency plans to deal with a terrorist event—to deter, react, and abate. Consequently, we probably have hundreds if not thousands of different plans out there, if we also count the locals. Through members like Doug Saunders, AFDO has quite diligently tried to bring some cohesion to this process. We've been advocating for another 50 State Meeting for over two years now, but with little success. The best we've been able to do is lying before you for the next three days during the Annual Conference. And I must say that the program looks great. At the same time, that's not enough time to deal with all the issues and provide all of the training and specifics that are needed. This issue is a prime example of "WHY AFDO," as Jim Sevchik from NY used to say. It is a prime example of why we need to pull together as representatives of the states, the federal agencies, industry, academia, and consumers. Good leadership sees to it that the job gets done, and if that means letting the other guy get some credit, then do what needs to happen and get the job done. In retrospect, all of us in this room are extremely lucky that we've not had a major incident...yet. AFDO is the perfect organization to head up this effort. As Yul Brynner so effectively stated, "So let it be written, so let it be done!!"

We are at a crossroads, ladies and gentlemen. AFDO needs the support of everyone here, and many who are not here today, to survive. We have been around for 109 years now, only because we have had leaders with the foresight to acknowledge the need for change and who have seen to it that the organization met the challenge. Yes, the world would go on without us as an organization. FDA would continue to contract with the individual states, USDA and CDC would continue to obtain the services of the states through grants and cooperative agreements. But something very important and very valuable would be missing.

Do we believe for one moment that eLEXNET would have come along had Bill Kreuger and others not had the forum and the platform provided by AFDO and the National Food Safety System espoused by Dan Smyly? Do we believe we would have developed the ORA-U face-to-face training had it not been for AFDO, CDC, and Gary German in FDA getting together, determining the need, and seeing the project to fulfillment? Do you believe that we would have 49 model food and drug laws among the states and 36 model salvage laws if it hadn't been for AFDO? Despite the current rhetoric between AFDO and GMA, do you

really believe that we would have as much uniformity as we currently have, despite state legislatures, if it wasn't for AFDO? I think not!!

But look around you today. How many “younger” faces do you see? I understand that age is “relative” to many of us, but indeed we are an “older” group these days!! I was 32 when my bosses had the foresight to begin including me in AFDO. Where are all of the other 32-year-olds today? (I don't see many hands going up!!) We need desperately to begin pushing strongly for our younger and brighter staff to participate in AFDO. If we don't, the organization may die with us. Since I was first permitted to attend AFDO in 1980, TDH has had no Commissioner of Health who failed to understand the importance of AFDO to the nation and to our state. This isn't because they knew this intuitively, it's because we educated them. It's because they personally saw the benefits of our participation from the information we supplied them. How many of you do the same back home? How many of you push the envelope in an effort to obtain permission for your staff to attend AFDO? How many of you right now would be willing to step aside and let your younger and enthusiastic staff take your seat at the table?

Don't get me wrong. You are all very much needed. However, there are many ways each of us can move AFDO into the future. Mentoring our younger staff and permitting them to actively participate in AFDO are essential to AFDO's future.

Partnerships, contracts, grants, and cooperative agreements. Sound familiar? Until recently these have been AFDO's saving grace. Without them we may have survived our financial difficulties from the early 1990's, but we would not be the organization we are today. These funds permitted us to develop training materials and put on training we otherwise would not have been able to do. We have been able to fund travel for state officials who otherwise might not have been able to participate in the Conference. Even so, these funding mechanisms are not the answer to AFDO's long-range survival. They helped to ensure the short-range stability of the organization. However, to ensure the long-term viability of AFDO we are going to have to find some more permanent ways to finance the operations of the organization.

Although I'm not referring to donations, At the same time if you are genuinely interested and concerned about AFDO, a donation to the Endowment Fund is certainly in order. The Endowment Fund, once fully funded, would provide some small measure of financial stability for the organization but far from all that is needed.

What I'm really referring to is long-term stability. We need to identify all of the many things AFDO has to offer to others, or could offer with some forward

thinking, and expand on these efforts. Members like Bill Kreuger, Joe Corby, Betsy Woodward, Doug Saunders, and a handful of other idea men and women, are all volunteers cannot do it all. And to our federal counterparts, I hope you see the future benefits that AFDO can provide and act accordingly by fully supporting the organization for the long haul – including your presence, your time and energy, but most of all your agency’s financial support. For years we’ve heard from our federal counterparts that AFDO must identify ways in which we can meet THEIR needs (and I’ll add, short-term) in order to obtain some grant or contract or cooperative agreement. I say to our federal partners, look at what AFDO really is, who we are, what we have accomplished, and it should be clear to you that food safety and education would not be where they are today without this organization. I say to all of you, FIND ways in which AFDO can continue to move us ahead, long-term, and THAT will ensure both AFDO’s future and the future of food and drug safety in this hemisphere.

And I say to our friends from Canada and Mexico, we continue to be very pleased that you are active members of AFDO. But look ahead as well. How can AFDO provide greater benefit to your nations? The current controversy over drug importation should ring a big bell on this one! Yes, you mainly work with our federal partners in the U.S. At the same time, what can this organization do to improve food and drug safety throughout the hemisphere?

As I have witnessed for more than 25 years as a member of this organization, cooperation (the other half of our motto) is a necessity, but one that can also bring about further understanding and long-term friendships. Learn from the past, look to the future, and help AFDO build the capacity we will surely need.

Thanks very much for your attention. My hope is that you leave here next week thinking about what you can do both personally and professionally to move AFDO forward. Nothing could be more satisfying than to know you have in some way helped to provide for a brighter future for AFDO, for your colleagues, and for the citizens of our great nations and the rest of the world. Glenn would be proud.

PRESIDENTIAL PROCEEDINGS

To obtain copies of the following documents, please contact the AFDO office.

Correspondence Pertaining to the National Uniformity Bill

Letter to Manly Molpus, Grocery Manufacturers of America, Inc.
June 24, 2004

Letter to Governors, House Members, State Legislators, and the National
Governors Association
July 12, 2004

Letter to Bruce Silverglade, Center for Science in the Public Interest
July 15, 2004

Letter to Various Organizations as Detailed
August 1, 2004

E-Mail Correspondence to State Food and Health Officials
August 19, 2004

Letter to State and Local Food Program Managers
February 23, 2005

Correspondence Pertaining to Resolutions

Letter to Lester Crawford, US Food and Drug Administration
Attachment: Resolution Number 1 Concerning Imported Uncertified Shellfish
July 20, 2004

Letter to Secretary Tom Ridge, US Department of Homeland Security
July 20, 2004

Letter to Secretary Anne Veneman, US Department of Agriculture
July 20, 2004

Letter to Secretary Tommy Thompson, US Department of Health and Human
Services
Attachment: Resolution Number 2 Concerning 50-State Food Security Meeting
July 20, 2004

Letter to Secretary Tommy Thompson, US Department of Health and Human Services

July 20, 2004

Letter to Secretary Anne Veneman, US Department of Agriculture
Attachment: Resolution Number 3 Concerning Childhood Obesity

July 20, 2004

Correspondence Pertaining to Position Statements

Statement on the Bioterrorism Act

June 25, 2004

Statement on Food: Current Good Manufacturing Practice Regulations; Public Meetings

September 3, 2004

Statement on the Risk Assessment of the Public Health Impact from Foodborne *Listeria* in Smoked Finfish

April 19, 2005

Additional Correspondence

Letter to John Young, Young and Associates Re: Endowment Foundation

December 16, 2004

Letter to Mimi Hall, USA Today Re: News Article "Imported Food Vulnerable to Agroterrorism"

March 14, 2005

PRESENTATION OF ASSOCIATION AWARDS

The 2005 winner of the prestigious Wiley Award was **Steve B. Steinhoff** of the Wisconsin Department of Agriculture, Trade and Consumer Protection. The Harvey Wiley Award is presented annually to an AFDO member who has demonstrated, through the performance of duties, outstanding service and devotion to the administration of food, drug, and consumer protection laws of our country.

The award is named in honor of Dr. Harvey Washington Wiley, Chief of the Bureau of Chemistry of the USDA in the early 1900s. Dr. Wiley's contribution to science and consumer protection coupled with his progressive advocacy for change and reform of food and drug regulations culminated in the passage of the Pure Food and Drug Act of 1906.

The Associate Member Award was presented to **Dan J. Badia**, President, X-GEN Pharmaceuticals Inc., which is a generic drug company specializing in the production and distribution of "niche" generic pharmaceutical products for his long-term active membership in the Association, active involvement in committee work, development of model codes, and his tireless promotion of the objectives of AFDO.

This year's Achievement Award was presented to **Michael Neff**, a Food Sanitarian with the Pennsylvania Department of Agriculture. The award was presented for his sustained level of performance.

The George M. Burditt and the Betsy B. Woodward Scholarship Awards (each for \$1,500) were awarded to two deserving candidates. The first award went to **Mary Katherine Sonnen**, who is attending the University of Idaho in Moscow, Idaho, and will graduate with a Bachelor's Degree in Food Science and a Minor in Microbiology. Mary has maintained a high level of achievement while maintaining a GPA of 3.74.

Our second award went to **Emily Renae Bennett**, who is attending the University of Arkansas in Fayetteville, Arkansas. Emily will be graduating with a Bachelors Degree in Food Science. Emily has maintained a high level of achievement while maintaining a GPA of 3.88.

Committee Award Recipients:

- **Mike Govro** received a Committee Award in recognition of his exceptional performance and outstanding contributions as Co-Chair of the AFDO Food Committee.

- **Terri Wenger** received a Committee Award in recognition of her exceptional performance and outstanding contributions as Co-Chair of the AFDO Food Committee.
- **Shirley Bohm** received a Committee Award in recognition of her exceptional performance and outstanding contributions as a member of the AFDO Food Committee.
- **Allen Matthys** received a Committee Award in recognition of his exceptional performance and outstanding contributions as a member of the AFDO Food Committee.
- **David Read** received a Committee Award in recognition of his exceptional performance and outstanding contributions as Co-Chair of the AFDO Field Committee.
- **Guy Delius** received a Committee Award in recognition of his exceptional performance and outstanding contributions as Chair of the AFDO Laws and Regulations Committee.

Special Recognition Award Recipients:

- **Bill Krueger** received the President's Visionary Award, in grateful recognition for taking the extra step, thinking beyond the expected, seizing opportunities and overcoming obstacles. For going over, under, around and through and never giving up.
- **Cameron Smoak** received the Past President's Award, in grateful recognition for his dedication and service to the Association during his term as President of AFDO, June, 2004 – June, 2005.
- **Jack Maybee** received an AFDO President's Award in appreciation for his efforts and leadership of the Local Arrangements Committee in support of the 2005 AFDO Annual Educational Conference.
- **Mary Glassburner** received an AFDO President's Award in appreciation for his efforts and leadership of the Local Arrangements Committee in support of the 2005 AFDO Annual Educational Conference.
- **Karen Tannert** received an AFDO President's Award in appreciation for the development of the Drug and Device Session for the 2005 AFDO Annual Educational Conference.

- **Laurence Upjohn** received an AFDO President's Award in appreciation for the development of the Drug and Device Session for the 2005 AFDO Annual Educational Conference.
- **John Young** received an AFDO President's Award in salute of his untiring spirit and dedication to advance the goals of the Endowment Foundation.

Congratulations to all the winners for their well-deserved awards.

AFDO ENDOWMENT FOUNDATION AWARD

The AFDO Endowment Foundation Board of Trustees has created an award to be given annually for service to the Foundation. The first award was given to George Burditt at the annual conference in Kansas City on Sunday, June 5, 2005. The award, presented by John Young, Chairman of the Board of Trustees, is inscribed: "To George M. Burditt in appreciation and gratitude for your extraordinary vision, dedication, guidance and counsel. Without your initial and continuing contribution, there would be no Endowment Foundation today."

In accepting the award, Mr. Burditt said:

"If there were an award earned by a group and not by an individual, this is it. I am deeply honored to be the recipient of the first award for many reasons, not the least of which is the enormous respect I have for the tireless dedication of the Foundation's board. So many individuals have contributed to the success of the Foundation that it is dangerous to single out any one for honorable mention. But let me mention just a few:

"First, Merrill Thompson, a lawyer in Chicago and later in Bridgeton, Indiana, who represented Kraft so ably at many AFDO conferences. Merrill was the chief draftsman of all of the legal documents creating the Foundation, and was responsible for achieving Section 51(c)(3) status.

"Second, Irving Bell, originally the Kentucky state official and subsequently the Coca-Cola Company's representative, who persuaded his company to give \$50,000 to the Foundation, still the largest gift received. And Dan Smyly is now carrying on the great tradition of the Coca-Cola Company's support for AFDO and the Foundation.

"Third, Gale Prince of the Kroger Company, who has served as Treasurer of the Foundation from the very beginning.

"Fourth, Fred Hegele, recently retired from General Mills, who served as Chairman of the Foundation for several crucial years. Fred not only provided untiring leadership to the Foundation, but both his company and the Pillsbury Company, with which General Mills merged, each gave \$25,000 to the Foundation.

"Fifth, John Young, formerly in the Office of the Chief Counsel of FDA and now a lawyer in private practice who currently chairs the Foundation Board. With consummate grace and persuasive powers, John is leading the Foundation in its quest to reach a \$500,000 goal in 2005.

“Those five gentlemen all deserve this award, as do many others who have worked endlessly on behalf of the Foundation.

“To avoid even the appearance of impropriety, the Foundation’s Board consists only of industry representatives and retired government officials. Betsy Woodward, formerly of Florida, and Terry Macaig, formerly of Vermont, have joined the Board since their retirement and have made numerous contributions, financial and otherwise. As a matter of fact, Terry came up with a new idea: he has pledged up to \$2,000 to match contributions of \$100 or more made this year.

“The Foundation is looking for other retired government officials to join the Board. I hope you consider service on the Board such an enormous honor that you consider taking early retirement so that you can be eligible for Foundation Board membership!

“Gene Blake, formerly of New Hampshire who had been very active in NEFDOA has also come up with a great idea this year: NEFDOA is making a grant of \$1,000 to the Foundation and is challenging the other regional associations to match NEFDOA’s generosity.

“We have recently seen one benefit from the Foundation. AFDO needed financial assistance to help with its antiterrorist activities. The Foundation was very pleased to be able to give AFDO \$10,000 earmarked for that purpose. Hopefully gifts like that can be granted every year, and in increasing amounts once the Foundation reaches its initial goal of \$1 million.

“And now you know what I mean when I say the Endowment Foundation award should go to a group of dedicated, committed, innovative and hardworking group of loyal ‘AFDOers’. I am deeply honored and humbled to be the first recipient of the award.”

**FOOD & AGRICULTURE SECURITY –
ARE THEY ON THE RADAR SCREEN OF OUR
STATE HOMELAND SECURITY DIRECTORS?**

George Teagarden
Livestock Commissioner
State of Kansas, Kansas Animal Health Department

Kansas, and most other states, have developed emergency animal disease plans in cooperation with their state's Emergency Management organization. This planning will allow the state's assets to be brought to bear on any disease outbreak on our state's and/or nation's agricultural industry.

The Kansas Emergency Animal Disease annex to our State Emergency Plan is a cooperative effort between the state and federal government. In Kansas, the Kansas Animal Health Department will be the lead state agency in any outbreak, whether intentionally or accidentally introduced, of a foreign animal disease. We will work in direct cooperation with our USDA Veterinary Services component, other federal agencies and county government to initiate a quick and efficient control and eradication effort.

Our plan calls for a Governor's Declaration of Emergency so that all of the state's assets can be brought into action as needed. A Governor's declaration gives the governor extraordinary powers to deal with any emergency. We will also ask county officials in affected counties to declare an emergency, so that county assets will be available to assist.

In Kansas, we are building a partnership with counties and livestock producers through county emergency disease planning. At both the county and state level, livestock producers are involved in all of our planning. Because burial of infected and/or exposed animals is the main method of disposal, we are working with our confined livestock operations to develop pre-approved burial sites. This planning will speed up the process of disposal; with some diseases, every minute will count in our control and eradication effort.

Our plan calls for quick action. In Kansas, we will declare war on any foreign animal disease and mount a very aggressive effort to control and eradicate. We will be on the offensive.

Through efforts of our Kansas Bureau of Investigation, the Ford County Sheriff's Department and Kansas State University, an Agro*Guard Program has been developed and is being promoted throughout the state. This program is designed after the Neighborhood Watch programs that are in place throughout the United States. The Agro*Guard Program is a partnership of law enforcement and

livestock producers. The program educates producers on what to look for in regard to illegal or suspicious activities around livestock operations and how and when to report such activity. Warning signs have been produced and distributed. Community meetings are used to educate the livestock industry on the program.

Regional response teams have been working together, consisting of the Federal Bureau of Investigation, the Kansas Bureau of Investigation and the state/federal disease control staff. These teams are distributed across the state and will allow for quick action on any verified threat to our livestock industry.

Another initiative in Kansas is to crack down on illegal food products through Smuggled Food Interdiction Teams. Our local law enforcement is working with State and Federal Food Inspectors to identify, seize and destroy food products that have the potential of containing a foreign animal disease. Federal and state laws contain penalties for importation or possession of illegal food products.

Our Kansas Department of Agriculture has developed plans to deal with crop diseases that could be introduced into our state that potentially could cause millions of dollars in damages to our agriculture industry.

Yes, our Director of Homeland Security is engaged. In Kansas, the Adjutant General is the Director of Homeland Security for the state. Our Division of Emergency Management is part of the Adjutant General's Office, and the Adjutant General and his staff are very involved in our emergency disease planning. The Director is very much aware of the importance of agriculture to our state and national economy, and agriculture is represented in all Homeland Security decisions and planning in Kansas.

THE HOMELAND SECURITY INFORMATION NETWORK AND AFDO

C. Patrick Duecy
Partner, Homeland Solutions, LLC

It was my pleasure to address the recent AFDO Conference in Kansas City and to take part in the food defense and incident recovery exercise. I welcome this opportunity to summarize my presentation in your association's journal.

The Department of Homeland Security wants state and local government and the private sector to join the Department's information sharing and infrastructure vulnerability reduction partnership. As part of that initiative, the Department is offering private sector entities and their state and local government partners access to its Homeland Security Information Network, or HSIN, to facilitate information exchange and communications in support of attack prevention, vulnerability reduction and consequence and recovery management.

HSIN is a secure network that uses the Internet for communications. HSIN's user services feature Jabber™ collaboration and messaging and a Microsoft Sharepoint™ portal with information repositories where DHS, state, local and private sector users can contribute to information sharing.

The origin of HSIN is an example of imagination and initiative producing a practical and affordable solution to a pressing problem. In the wake of 9/11 the Department of Defense's Joint Intelligence Task Force for Combating Terrorism (JITF-CT) and state and local law enforcement agencies were desperately seeking to gain an understanding of the threats that might exist within the United States. There was no communication bridge between the Federal Government and state and local agencies across which information potentially pointing to terrorist activity could flow for analysis and sharing.

Enterprising military reservists serving in the JITF-CT, who were law enforcement officers in civilian life, came up with the idea that led to today's HSIN solution. They proposed using the Internet for no-cost communications to support secure, commercially encrypted information exchange with a simple array of information technology applications. A Microsoft Sharepoint™ portal and a peer-to-peer collaboration tool, Groove Virtual Office™, were selected as the applications of choice and those solutions were quickly implemented. The result was known as the Joint Regional Information Exchange System (JRIES), a term still often used synonymously with HSIN.

The entire JRIES network was designed, tested and implemented for operational use by the JITF-CT, the New York City Police Department and the California Anti-Terrorism Information Center (CATIC) between November of 2002 and

February 2003. The total cost was well under one million dollars. States and cities began signing up to use JRIES, and the network grew rapidly.

In the fall of 2004, the Department of Defense decided that the JRIES network should be transferred to another department more closely aligned with domestic law enforcement intelligence and counterterrorism missions. The Federal Bureau of Investigation declined to accept management of the program, but the new Department of Homeland Security readily agreed to do so in September 2003.

DHS Secretary Ridge officially launched the network in February of 2004, renaming it HSIN and broadening its application well beyond law enforcement and intelligence. HSIN became the backbone communications network for the department and was deployed to all 50 states and 50 cities between April 2004 and August 2004. Today HSIN is an umbrella system with a potentially wide range of participants including law enforcement, emergency managers and first responders, and state homeland security advisors. The private sector and critical infrastructure stakeholders are the newest groups to be invited to use HSIN.

The rapid DHS deployment of HSIN in just several months was an admirable technological achievement, but left significant problems in its wake that have yet to be fully resolved. HSIN was long on technological implementation, but short on management, governance, concept of operations, standard operating procedures and, importantly, DHS outreach to potential users to get their views and buy-in was lacking. Confusion and frustration remain a problem among many potential state, local and private sector participants who would benefit from clear and consistent guidance from DHS.

Meanwhile, DHS is in the process of deploying HSIN to all levels of government, beginning with a pilot program whereby a half-dozen states are asked to implement HSIN in their key agencies and counties in 2005. Concurrently, DHS is implementing the Homeland Security Data Network (HSDN), a secret level version of HSIN, in 2005. However, the HSDN deployment may be delayed owing to the DHS Inspector General's findings of DHS program management and planning shortcomings requiring correction before moving ahead.

AFDO government and private sector members interested in participating in HSIN should contact their state homeland security advisors for information on how to get started. Before accepting and implementing any technology solution, including HSIN, I would offer a cautionary note: make technology the enabler of your business process, not the driver.

Technology solutions should come after you have carefully studied and agreed on what you want to accomplish as an agency or business and as an association. States, municipalities and local agencies involved in homeland security are

realizing that technology is far less important than first establishing strong foundations in terms of business process analysis, requirements, concepts of operations, governance, security and operating procedures. Technology should only be selected and implemented once business process and security foundations are in place.

Lack of information sharing and threat awareness was a major factor leading to the 9/11 failures and losses. DHS is trying hard to remedy information sharing shortfalls and to partner with state and local government and the private sector in protecting infrastructure, reducing vulnerabilities and providing the means to recover from future attacks. I encourage you to begin working with DHS, but on the basis of first knowing what you want to be able to do and being firm in educating DHS on how it can best respond to your needs. HSIN may well be one of the solutions to your requirements.

2005 RESOLUTIONS

ASSOCIATION OF FOOD AND DRUG OFFICIALS

RESOLUTION 1

Submitted by: Association of the Food and Drug Officials of the Southern States

Date: April 13, 2005

Concerning: Presenting information and position statements to State Legislative officials considering changing food laws regarding sale of raw milk and raw milk products.

Whereas, there has been a well documented history of milk borne illnesses throughout the nation associated with the consumption of raw milk and raw milk products; and

Whereas, Federal agencies such as FDA and CDC and numerous states have reported recent illnesses and deaths associated with the consumption of raw milk and milk products such as cheeses produced from unpasteurized milk; and

Whereas, the FDA continues to report continued importation of significant amounts of cheeses manufactured from raw milk, with laboratory analysis of these cheeses confirming the presence of *Listeria* and various other pathogens; and

Whereas, AFDO supports mandatory pasteurization for all milk and milk products intended for direct human consumption except where alternative procedures to pasteurization are provided (i.e., curing of certain cheese varieties) to ensure the safety of finished products; and

Whereas, State Public Health and Agriculture Officials are reporting increased activity on the part of state legislatures to amend current laws or pass new laws that will allow for the sale of raw milk and raw milk products; therefore, be it

Resolved, that AFDO update the Position Statement on Raw Milk and Milk Products that was revised by the AFDO Board of Directors on June 14, 2003, to include current illness data associated with the sale of raw milk products, as well as position statements of various public health and industry entities; and be it further

Resolved that the AFDO Position Statement be sent throughout the nation to State Public Health and Agriculture Officials for presentation to their legislative representatives who may be considering adopting or amending dairy laws that would permit the sale of raw milk and milk products.

MINUTES OF THE BOARD OF DIRECTORS MEETINGS

The 2004-2005 Minutes of the Board of Directors can be viewed on the AFDO web site at www.afdo.org.

FINANCIAL REPORT

Association of Food and Drug Officials
Balance Sheet as of June 30, 2005

	<u>Jun 30, 05</u>
ASSETS	
Current Assets	
Checking/Savings	
1001 · CONFERENCE	\$36,958.84
1005 · CONFERENCE SAVINGS	7,855.18
1010 · GENERAL	30,089.92
1015 · GENERAL SAVINGS	40,590.80
1030 · GEN FUND RES - CASH MGMT	55,089.07
1040 · GEN FUND RES - STRAT PORT	
1041 · General Fund Strat Reserve-Cost	81,012.77
1042 · Unrealized Gain/Loss on Fund	-8,728.01
Total 1040 · GEN FUND RES - STRAT PORT	72,284.76
1070 · SCHOLARSHIP	
1072 · Scholarship - Cost	55,156.11
1071 · Unrealized Gain/Loss on Invest	-9,553.25
Total 1070 · SCHOLARSHIP	45,602.86
Total Checking/Savings	288,471.43
Total Current Assets	288,471.43
Fixed Assets	
1701 · Office Equipment	49,712.63
1710 · Accumulated Depreciation	-28,830.67
Total Fixed Assets	20,881.96
TOTAL ASSETS	<u>\$309,353.39</u>
LIABILITIES & EQUITY	
Liabilities	
Current Liabilities	
Other Current Liabilities	
2100 · Payroll Liabilities	2,572.96
Total Other Current Liabilities	2,572.96
Total Current Liabilities	2,572.96
Total Liabilities	2,572.96
Equity	
3900 · Net Assets	439,154.59
Net Income	-132,374.16
Total Equity	306,780.43
TOTAL LIABILITIES & EQUITY	<u>\$309,353.39</u>

2004-2005 FINAL COMMITTEE REPORTS

The 2004-2005 Final Committee Reports can be viewed on the AFDO web site at <http://www.afdo.org/afdo/Committee/04-05-Committee-Final-Reports.cfm>.

2005-2006 COMMITTEE CHARGES

The 2005-2006 Committee charges can be viewed by visiting the Committees pages on the AFDO web site at <http://www.afdo.org/afdo/Committee/index.cfm>.

RECOVERY PROCESS — HOW TO AVOID GETTING VOTED OFF THE ISLAND

Gordon Meriwether
Principal
The Uriah Group

and

Tim Weigner
Director, Advanced Programs
The Uriah Group

“It’s not whether you get knocked down; it’s whether you get up.”
Vince Lombardi

Overview, Objectives and Required Tasks: When the worst has happened when does the rebuilding start? Does the business or government agency wait for the all-clear to begin the recovery? What is the first critical task? Who can provide help? How does the business care for itself and its employees while fulfilling their responsibility to the public?

In the various food defense exercises my company (Uriah Group) has conducted for industry and government, the recovery phase is the least understood. When an event occurs, you can be sure you will have lots of “help” in investigating and responding to the well-being of the public and your customers. But when the smoke clears, and the emergency responders have returned to the ready status, you will be left standing (alone) with the shambles of your business. If the business is to survive, employees are to be paid, families fed, investors reassured and taxes revenues generated, the company with their government partners must be ready to take the wheel and guide the ship with conviction and resolve. In my naval career, we trained extensively on how to use our ship to attack and win against a determined enemy, the Soviet Navy. But we trained equally as hard on how to keep the ship afloat during a battle. We assumed the worst and prepared. This article will provide you with a top-level view of survival should the unthinkable occur. Although I have aligned the material with food defense in mind, it is equally applicable to any crisis situation that may confront your organization, whether industry, government or academia.

Because a crisis event is highly unlikely to occur, it’s hard to target significant company resources for practicing for the worst. A cautious senior management is not anxious to expose potential vulnerabilities to perpetrators or the public. There is the issue of brand image and stockholder perception that will always carry the day in corporate America. As a result, planning for recovery is all that should be

expected from an industry that has not been attacked and truly believes that their security is in the hands of the government. It's a hard sell to convince management that the best interest of their stakeholders will be served by planning for the worst. But this is the challenge. We must, as a nation and an industry, plan in advance of a terrorist incident. Recovery should be planned for and discussed at the senior management level, with actions and processes documented and distributed. Because of the diversity and unpredictability of any potential crisis, it is more important to have worked through the crisis in your "collective" heads than to have actually physically exercised any recovery plan. Understanding recovery as a process will prepare the business leadership team for the challenge of rehabilitation no matter what direction the crisis takes. There are common and effective steps you can take in addressing any crisis. This article will review those steps and provide you with a crisis management process.

Although we expect that every situation we face in food defense will be unique, there are commonalities. We divide these common elements into four action-oriented areas.

1. **Leadership:** The critical factor for successfully working through any crisis situation is leadership. There are a number of activities that determine successful leadership—and in their absence we can guarantee failure.
 - a. *Quick response to the incident.* Early aggressive action by the leadership team is the launching point for recovery. Hopefully the decisions will be the right ones, but without the aggressive charge into the fray the likelihood of a successful recovery is diminished. The time it takes for the leadership team to respond is inversely proportional to the potential for successful recovery.
 - b. *Empowered managers on the scene.* Time is of the essence in a crisis. It is the one commodity that can never be replaced and, used unwisely, will severely lessen the likelihood of the organization's successful recovery. This directly equates to empowered managers on site who can make informed decisions on the fly. The opportunities lost in awaiting approval of an aggressive early action by an on-scene manager will exponentially increase the complexity of the crisis as it develops from incident to response to recovery.
 - c. *Maintaining balance.* The leadership team must be trained to maintain balance during the crisis. Keeping your head when all about you are losing theirs provides unique response and recovery opportunities that will be wasted without the "Captain"

firmly in control of the ship. The leadership team must consciously avoid becoming a part of the chaos. Instead, they must leverage the activity toward containment and resolution. This will provide the unique opportunity to minimize the impact of the incident and maximize the effectiveness of the early recovery activities.

- d. *Maintain control:* In our Food Security or Food Defense workshops it is apparent that there is a proportional relationship between the amount and consistency of control that an organization maintains during the crisis and the likelihood of recovery. In the food industry with the highly regulated atmosphere and the fragmented level of control established by the government agencies, someone must stand to provide the leadership. Since the government agencies have their limitations and statutory boundaries they must deal with, the business must maintain as much control as the investigation and politics will allow. The government has primary responsibility for the health and welfare of the public. The business must maintain its focus on recovery throughout the incident and response phases.

(Case Study – See References)

Johnson & Johnson: Tylenol Contamination (1982)

2. **Communications:** With chaos ruling the day, you must use every aspect of your organization to communicate with your constituents. If you don't have a professional public affairs officer who has experience dealing with the media on your staff, get one. This is no time for amateurs. Be factual and truthful with all concerned in a crisis. If you lose your credibility with the media and the public, the game is over. Given that, a key theme of our approach to communications is to do everything with the target audience in mind.
 - a. *Identify the target audience.* Is it employees, investors, customers, media, community, government regulators? Understand your stakeholders.
 - b. *Develop the message for each of your target audiences.* Consolidate these messages to be focused and to the point for your constituents. Stay on message. When management begins to wander or freelance, the wheels come off.
 - c. *Coordinate the message and its release with authorities.* Nothing will undermine the confidence of your constituents in

your business and industry more than multiple contradictory messages released and debated in the media.

- d. *Communicate with the target audience in mind.* What medium is best suited to deliver your message to your internal and external target audience? Is it electronic, printed, or personal? Having employees hear the message on the local evening news may not be the best delivery method. There again it may be the only way in some circumstances.

The psychological consequences of an attack on the food supply “would extend far beyond the economic effects on the agricultural industry. Agroterrorism could create social panic, more so when human death and injury are involved.”¹ The impact not only on our employees but the public in general will require a substantive effort to rebuild the confidence in the safety of the food supply and the associated infrastructure.

(Case Study – See References)

Jack in the Box Restaurants E. coli (1993)

3. **Operations:** The business is reeling from the incident and the response. You must have the confidence and direction to stabilize the business operations environment and to begin the recovery process. Remember: The government doesn’t have a clue how your business runs. You cannot expect help without taking the step forward to lead and ask for their help. It’s up to you.
 - a. *Business Operations:* It goes without saying that contingency planning is a must. Hopefully, you thought through in advance the contingencies of the business in crisis to ensure a successful restart for not only your business but also for your suppliers. Recovery of critical data and reestablishing the infrastructure as quickly as possible will give you the backbone to begin the restart in an orderly fashion. You need to be addressing personnel issues at this point. What size staff and skills do you need and for how long? Have you maintained your clients?
 - b. *Product:* Of course, the product is at the heart of the recovery. Was there a recall? Is there a contaminated inventory issue? Can you salvage any of the product without real or perceived

¹ Iversen, Amy and Greenberg, Neil. “Food for Thought: Anticipating and Managing the Psychological Aspects of Food Chain Contamination and Terrorism.” *Psychiatric Annals*; September 2004: 34, 9, pp 720-727.

endangerment of your employees or staff. How do you dispose of the contaminated product? How do you maintain a contaminated product for a lengthy investigation without crippling the business? And if there is a recall, is there an evidentiary retention issue to be addressed?

- c. *Facility and Assets:* It's wishful thinking to expect that law enforcement and other regulatory agencies will be reasonable in regard to the business and its assets, including facilities. They are in the business of protecting the public, and your business is considered a threat to the public until the investigation is completed and you are cleared. As discussed in the leadership section above, for the sake of your business, you must maintain control of your assets as long as you can. If you cannot maintain control of all of it, battle to compartmentalize their control so you can minimize the assets you lose to the authorities. Cooperate with the authorities, but immediately initiate a response. Without push-back the business will lose it all and delay the recovery process substantially.
- d. *Legal:* As distasteful as it may sound, you need to begin preparing for the possible legal proceedings. Remain as involved in the investigation as the authorities will allow. The most important aspect of recovery from a legal standpoint is to document everything: activities, phone calls, conversations, releases....everything.
- e. *Industry Support:* In an intentional attack on the food supply, we are all in this together, government and industry. Don't hesitate to reach out to your local chamber, the associations, and the government regulators. The sooner we realize that this is an attack not on a single company but an entire industry and our food supply, the sooner the cavalry will arrive. We are all in this together.

(Case Study – See References)

Perrier Benzene Contamination (1990)

- 4. **Financial:** Cash is the name of the game. All the planning for communications and operations recovery is for naught when you can't fuel the business financially. But it's not as simple as keeping the company's head above water. There are issues that your employees, as well as the ownership and the government, are facing.

- a. *Company*: Your CFO or accountant can pull together the financial contingency planning. There are countless considerations such as cash on hand, pension funds, equity, etc. Do you have access to these funds? What are your accounts payable and accounts receivable? Will creditors provide the leverage to maneuver funds? Cutting costs? How, how much, where, and when? Is bankruptcy an option? Is there an opportunity to sell the business or to partner with another business through the crisis? Does the ownership have additional assets to carry the business through the crisis?

- b. *Employees*: How do you take care of your team while the building is burning? You don't want to lose them to a competitor or another job, but if you don't have a job for them you need to let them get on with their lives. Support them all you can. Help in lining them up with the state unemployment office. You may also use this incident to reassign staff and create a new team for the recovered business. The employees of the business are the foundation of a successful organization. We need to use this incident to demonstrate our commitment and further instantiate the business family.

- c. *Outside financial assets*: We would all like to believe that our bank, insurance company, and the government will come to our financial aid in a time of crisis, but you can't count on it. Be aggressive and upfront. Much like the media approach above, be factual and truthful. We need their help through the crisis. It is in their best interest to support us and keep us operationally solvent and generating jobs, orders, revenue, and tax base. We need to have established a close working relationship with these players before the incident. The time to be exchanging business cards is not over the bodies of the victims or the remnants of the business. The time is now.

(Case Study – See References)

Chi-Chi's Hepatitis Outbreak (2003)

In summary, if your stomach turned reading this, good. We accomplished our mission. You need to have that risk adverse frame of mind to prepare and respond effectively to such an incident. I am thankful to say that in ten years of duty as a ship's officer with the U.S. Navy in the 70s, I never lost a sailor. Why? Because I was constantly scared to death. I prepared for the worst, and trained my team to handle it. When it did—and they did—we were ready. In the food

business, we should also prepare for the worst. This means embracing the crisis management process of planning, prevention, response, and recovery.

Most of what we have discussed in this article applies to the large well-heeled businesses. I have a number of close friends and relatives in the food business. Like the majority of the food businesses in our country, they are running “mom and pop” establishments. They are successful. Should they be hit with a crisis the depth of which we discuss in our workshops and exercises, they are out of business. There is no recovery. The only hope they have is government support. The government can only do so much. It is my view that we are all in this together and what impacts the smaller companies will impact the large multi-nationals as well. With the government credibility on the line and the tax base threatened, one can be certain that we are all in this together. Recovery is everybody’s business.

“Think about it. A major disruption of the food supply would be more devastating than an oil embargo and it would be totally unexpected and unprecedented. Americans are so used to finding supermarket shelves stocked with food that they wouldn’t know what to do if our corn, wheat and soybean crops were destroyed. These commodities are used in so many food products, and to feed livestock, that there wouldn’t be much to eat without them.”²

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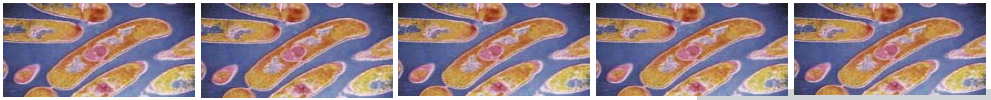
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This article was originally developed as a lecture for the National Food Safety and Toxicology Center at Michigan State University as the Business Recovery module for their on-line Graduate Food Security Course.

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Intervention Strategies for the Control of *Listeria Monocytogenes*

October 4, 2005

Holiday Inn Inner Harbor
Baltimore, Maryland

According to the Centers for Disease Control (CDC), more than 2,000 people in the United States report serious illness from Listeriosis each year. Of these, 25% will tragically die from the disease. The bacterium responsible for this illness - - *Listeria monocytogenes* — has become one of the most pertinent food safety issues of our time. During the past year, the Association of Food and Drug Officials (AFDO) has worked very closely with the United States Department of Agriculture's Food Safety and Inspection Service (FSIS), the U.S. Food and Drug Administration (FDA), our industry partners, and academia to develop intervention strategies for dealing with this organism. AFDO, through Cooperative Agreements with the FSIS, established work groups to evaluate State Food Safety Surveillance on *Listeria monocytogenes* and to develop education and training materials. Now, AFDO is offering this training program for the purpose of providing new insight into current and suggested strategies for eliminating or controlling *Listeria monocytogenes*. Attendees to this full-day program will receive:



An Instructional Videotape and an Educational Booklet on Controlling *Listeria* at Retail



An Educational Booklet on How to Address *Listeria* in Small Meat or Poultry Facilities



The AFDO Document "AFDO Cured, Salted, and Smoked Fish Model GMP" Containing the *Listeria* Control Manual Developed by the Smoked Seafood Working Group of the Food Processors Association (FPA) and National Fisheries Institute (NFI)



WHO SHOULD PLAN TO ATTEND:

FOOD SAFETY CONSULTANTS

GOVERNMENT OFFICIALS
(FEDERAL, STATE, & LOCAL)

REGULATED INDUSTRY
(MANUFACTURING & RETAIL)

QUALITY ASSURANCE
(TECHNICAL & SAFETY)

MANUFACTURING PLANT
OPERATORS & MANAGERS

GENERAL MANAGERS

CORPORATE
REGULATORY
AFFAIRS STAFF

LEGAL
(CORPORATE &
OUTSIDE COUNSEL)

CUSTOMER & PUBLIC
RELATIONS STAFF

ACADEMIA
(PROFESSORS &
INSTRUCTORS)

CONSUMER ADVOCATES



DON'T MISS YOUR OPPORTUNITY TO...

Learn New Technology and Help Your Company Identify Useful Strategies to Combat *Listeria Monocytogenes*

Dialogue with Top U.S. Food Safety Officials

Participate in a Collaborative Learning Experience with Government, Industry, and Consumers

Learn What Responsibilities Retail vs. Manufacturers Have in Regard to the Issue



**WHO SHOULD
PLAN TO ATTEND:**

GOVERNMENT OFFICIALS
(FEDERAL, STATE, & LOCAL)

REGULATED INDUSTRY
(MANUFACTURING, RETAIL,
DISTRIBUTORS & IMPORTERS)

QUALITY ASSURANCE
(TECHNICAL & SAFETY)

MANUFACTURING PLANT
OPERATORS & MANAGERS

GENERAL MANAGERS

CORPORATE
REGULATORY
AFFAIRS STAFF

LEGAL
(CORPORATE &
OUTSIDE COUNSEL)

LOGISTICS & DISTRIBUTION

ACADEMIA
(PROFESSORS &
INSTRUCTORS)

CONSUMER ADVOCATES

MARKETING PERSONNEL
(CUSTOMER/PUBLIC
RELATIONS STAFF)

INTERACTIVE, "HANDS-ON" TRAINING

Product Recall Workshop

October 5-6, 2005

Holiday Inn Inner Harbor
Baltimore, Maryland

Now is the time to discuss product recalls in light of possible bioterrorist events. In the five years following 9/11, The Association of Food and Drug Officials (AFDO) has been working very closely in conjunction with the U.S. Food and Drug Administration (FDA), the United States Department of Agriculture's Food Safety and Inspection Service (FSIS), and with regulated industry and academia to develop a comprehensive Product Recall Manual. This information will be presented as part of a day-and-a-half Product Recall Workshop that combines informative speaker sessions with a series of "hands-on" event simulation exercises.

DON'T MISS YOUR OPPORTUNITY TO...



Help your Organization Understand what Actions They Need to Take to Minimize the Overall Impact of a Product Recall



Learn New Advances in the Area of Recalls and New Responsibilities since 9/11



Assist your Company in Strengthening Your Internal Recall Strategy by Identifying Potential Areas of Weakness



Dialogue with Top U.S. Recall Officials and Participate in a Collaborative Learning Experience with Government, Industry, and Consumers



Learn What Responsibilities Retail vs. Manufacturers Have in Regard to the Issue

www.afdo.org



ADDITIONAL DETAILS AND REGISTRATION INFORMATION WILL BE AVAILABLE SHORTLY.
VISIT WWW.AFDO.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.

CATEGORIES OF MEMBERSHIP

The Association of Food and Drug Officials

New Membership Dues Structure:

- **Individual membership** is designed for singular memberships. All individual members may choose to receive the quarterly journal on-line or by mail.
- **Group memberships** are designed for those agencies/organizations that would like reduced rates to enroll several members. One quarterly journal is provided for each group by mail; other group members may access the journal on-line.*
- **Contributing memberships** are designed for those agencies/organizations that would like to support the ongoing activities of the Association of Food and Drug Officials through an “increased” level of contribution. Contributing members receive the quarterly newsletter and may choose to receive the quarterly journal via mail or on-line.*

**Organization, group and contributing memberships must be received together and processed as a group.*

JOURNAL OF THE ASSOCIATION OF FOOD AND DRUG OFFICIALS

Inquiries: For editorial matters, contact the Editor: Thomas (Bill) Brooks, PO Box 11280 Columbia, SC 29211-1280; Phone (803) 737-9700; Fax (803) 737-9703. For all other matters contact AFDO’s office: 2550 Kingston Road, Suite 311, York, PA 17402; phone (717) 757-2888; fax (717) 755-8089; email afdo@afdo.org.

Subscription Rates For Non-Members: United States and Canada: \$80; other countries: \$90 (includes airmail); single issues: \$20.

Responsibility: The opinions and statements presented in the contents of this *Journal* are those of the contributors, and the Association assumes no responsibility.

Manuscripts: The *Journal* solicits papers related to its objectives and reserves the right to determine if a submitted work is publishable. Letters, viewpoints, formal papers and other notes of interest will be considered for publication.

Reprints and References: Reprints of articles may be obtained at standard rates. Most materials published in the *Journal* do not have references.

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MEMBERSHIP INFORMATION:

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 Title _____
 Organization _____
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 Telephone _____ Fax _____
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1. Individual Membership:

Individual Members	On-line Journal	Journal
Alumni/Students	<input type="checkbox"/> \$50	<input type="checkbox"/> \$65
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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.*

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

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

Contributing Member Classifications	Government # of Memberships	Non-Government # of Memberships
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.)

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ASSOCIATION OF FOOD AND DRUG OFFICIALS

COMMITTEE PREFERENCE FORM

Please use this form if you wish to serve on an AFDO committee

PART A: Member Information

Name: _____

Title: _____

Agency or Firm: _____

Telephone: _____ FAX: _____

Email: _____

Became an AFDO member in what year? _____

Principal field of endeavor or interest _____

PART B: Member's Preference for Assignment to Committees

Note: Every effort will be made to assign you to the committee(s) in which you have expressed an interest. Committees are the backbone of AFDO, and your active participation and input are important! Please sign up only for those committees that you feel you will have time to actively serve on. Thank you!

- | | |
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| <input type="checkbox"/> Awards Committee | <input type="checkbox"/> Media and Public Affairs Committee |
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| <input type="checkbox"/> Field Committee | <input type="checkbox"/> Resolutions Committee |
| <input type="checkbox"/> Food Committee | <input type="checkbox"/> Retail Food Committee |
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| <input type="checkbox"/> Int'l. & Government Affairs | |

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 - Other: _____

When completed return this form to:
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AFDO COMMITTEES WHO THEY ARE AND WHAT THEY DO

Administration Committee: Reviews the Association's constitution, by-laws, procedures, and policies; proposed recommended changes, additions, or deletions in an annual report; and identifies potential impacts to the Association.

Alumni Committee: Assists the AFDO Board and the President of AFDO in identifying and implementing meaningful opportunities for alumni to participate in the life and business of AFDO.

Associate Committee: Serves AFDO membership by providing a link between regulatory and industry members. Associates provide input to the President through serving as associate advisors to committees and assist in identifying topics and speakers for the Annual Conference.

Awards Committee: Administers and oversees the awarding of the five AFDO awards and the AFDO Scholarship awards.

Drugs, Devices and Cosmetics Committee: Assists AFDO membership in establishing policies, posture and opinions related to Drug, Device and Cosmetic Safety Issues.

Education and Training Committee: Promotes and strengthens the technical and professional development of the members, which ultimately results in the development and enforcement of uniform food, drug, and consumer protection laws.

Field Committee: Involves food and drug safety professionals at the field level in assisting AFDO to develop policies and identify educational needs that can benefit field level employees.

Food Committee: Assist AFDO membership in establishing policies, postures, and opinions related to food safety issues.

Food Protection & Defense Committee: A forum for discussion on food security issues, and to coordinate member food security activities, as well as find a proactive role for the committee in protecting the food and agricultural sector critical infrastructure.

International & Government Relations Committee: Achieves a mutual working relationship between the Association and federal, state, and local governments in accomplishing the goals and objectives of AFDO in relation to consumer protection in the food, drug, and product safety fields.

Laboratory, Science and Technology Committee: Determines needs of laboratories supporting regulatory function and recommend the means of meeting those needs, provides information to regulatory and enforcement personnel to enhance knowledge and understanding of the changing and frequently complex scientific nature involved in regulatory work, promotes communications, coordination, and the mutual assistance of federal, state, and local government laboratories and industrial

laboratories, and provides consulting and special project services to AFDO and regulatory agencies.

Laws and Regulations Committee: This Committee is responsible for the continuous review, up-dating, and development of model laws and regulations so that the AFDO goal of uniform food, drug and other consumer protection laws is achieved.

Meat and Poultry Committee: Assist AFDO with the development of policies and positions specific to meat and poultry safety issues. Additionally, the committee provides technical assistance and expertise in the development and delivery of meat and poultry training initiatives, in conjunction with other AFDO Committees.

Media and Public Affairs Committee: Assists in reviewing and developing marketing materials, develops and executes a media plan for conferences with press releases, scheduled interviews, etc., publicizes AFDO, develops recruitment materials to increase membership, develops special programs for new members, works with committees to help develop marketing strategies, and serves as consultants on public affairs issues.

Membership Committee: This committee will work to conserve membership levels and obtain new members. Emphasis is placed on coordinating membership efforts to incorporate affiliate and national initiatives.

Nominations and Elections Committee: Comprised of six regular members, one from each affiliate association, plus a chairperson, is responsible for submitting the name of three regular members, when qualifying candidates are available and willing to serve, as nominees to fill the expiring term of each director elected at large, the office of Vice-President and the Secretary-Treasurer of the Association.

Resolutions Committee: Serves AFDO membership by gathering together proposed resolutions pertinent to current issues and presenting these to the AFDO membership for a vote.

Retail Food Committee: Assists AFDO with food related issues specific to the retail environment. Assists with the development of retail food-related policies and positions, and contributes expertise to the improvement of the uniformity of retail food regulations, policies and procedures. Liaison to the Conference for Food Protection providing input to identify and develop proposed changes to the FDA's retail Food Code.

Seafood Committee: This committee focuses on issues related specifically to seafood and assists AFDO with developing seafood related policies and positions and the development and delivery of seafood training programs.

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

2006

June 17–21, 2006

Crowne Plaza Hotel Albany City Center
Albany, NY

2007

June 16–20, 2007

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2008

June 7–11, 2008

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JOURNAL

Association of Food and Drug Officials

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**2006 ANNUAL CONFERENCE
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