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CONTENTS OF THIS ISSUE

FROM THE EDITOR	1
AFDO JOURNAL EDITORIAL BOARD	2
ABOUT THE AUTHORS	3
AFDO POSITION STATEMENT - USDA AND HHS AGENCIES WORK TOGETHER TO EXAMINE THE JURISDICTION OF CERTAIN FOOD CATEGORIES Marion Aller	6
POST-PROCESSING TREATMENTS FOR READY-TO-EAT MEATS: HIGH PRESSURE AND SURFACE THERMAL PROCESSING Paul L. Dawson.....	9
“VITAMIN D MILK” - A DIETITIAN’S PETITION TO THE FDA Tina Amato	22
TRAINING THE LOCAL COMMUNITY IN FOOD SECURITY AWARENESS Jerry Gillespie	26
ARE THERE KATRINA LESSONS FOR THE FOOD AND AGRICULTURE SECTOR? Gordon Meriwether	29
AFDO MISSION STATEMENT.....	33
AFDO MEMBERSHIP APPLICATION.....	35
AFDO CONFERENCE SCHEDULE.....	36

ASSOCIATION OF FOOD AND DRUG OFFICIALS

Mission Statement

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

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

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FROM THE EDITOR

As the year draws to a close, the editorial staff of our Journal continues to struggle with recruiting papers that would be of interest to our regulatory and industry membership. Our AFDO office staff and the Editorial Board devote much time and effort to turning out a Journal that is useful to our audience, practically all of whom have a significant stake in the works of the food and drug industries. I have to confess it is a tough job to accomplish with a small group of people, none of whom have a lot of time away from their regular responsibilities. I would like to appeal to our readers in government and industry to help in seeking out material suitable for publication in our Journal. If you come across material that might be of interest to our membership, please let our Editorial Board members or York office staff know about it. This would be a real service to the entire membership of AFDO and a most welcome assist to your Editor and the office staff who work so hard to give us a journal worthy of the important professional work we do. I can assure you that I and our Journal workers would be most grateful for the assistance.

This issue of JAFDO will be the last to be published in a print edition. Beginning in 2006, AFDO will be debuting a new “on-line reading room”. All prior articles, as well as new articles, will be archived/posted in this new area of the website. We know some who always elected to receive the print edition with their membership dues, myself included, may be disappointed at no longer having the print edition to save for their journal libraries. While we may hate to say goodbye to the Journal as we currently know it, please be assured that I and our office staff will do all we can to maintain the usefulness and accessibility of “on-line” journal articles for both our readers and our contributors.

We hope you will continue to use the Journal in the online format and provide the assistance we need from AFDO members in turning out a product that is useful to and worthy of our organization.

Thomas W. Brooks, Editor

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ABOUT THE AUTHORS

Tina Amato is a registered dietitian and manager of the Chronic Disease Program at the Allentown Health Bureau. She oversees programs funded through the Pennsylvania Department of Health addressing heart disease, diabetes, osteoporosis, nutrition, physical activity and tobacco.

Amato received her master's degree in Applied Human Nutrition from Rutgers University and has been very involved in community-based nutrition and physical activity strategies that address prevention of chronic diseases.

Paul L. Dawson was born in Salisbury, MD and graduated from Salisbury University in 1979. During the early 1980's, Paul worked as the Poultry Products Research Laboratory coordinator for Perdue Inc. He received a Master's Degree from the University of Florida in 1984 and a Ph.D. in Food Science from North Carolina State University in 1989. After two years of post-doctorate study at NCSU, Dr. Dawson accepted his present position at Clemson in 1991, receiving tenure and promotion to Associate Professor in 1997 and promotion to professor in 2000. His research has focused on studying the shelf life of food, especially poultry and meat products, as affected by packaging and processing. He has published over 90 abstracts, 60 journal articles/proceedings, 30 technical articles, and written 10 book chapters. Paul's research covers the efficacy of active packaging films, the use of biopolymers for food packaging films, oxidation in meat systems, and the in-package pasteurization of processed meats. Paul served as Section Editor for the *Poultry Science Research Journal*, reviewer for the *Journal of Food Science* and *Journal of Agricultural and Food Chemistry*, is a member of the World Food Logistics Organization Scientific Advisory Committee, is technical coordinator of the Food Safety Research Program at Clemson University and is past-chair of the Dixie Section of the Institute of Food Technologists. Research foci have included processing effects on poultry meat quality, aqueous removal of pigments and oxidation of poultry meat, aseptic processing of poultry meat, modified atmosphere meat packaging, and active packaging for meats. A major focus of research for the past 10 years has been the development of antimicrobial and antioxidant packaging for meat products.

Jerry R. Gillespie, the first director of the Western Institute for Food Safety and Security, brings to his task expertise in several fields of veterinary medicine along with experience in building effective research teams and enduring interest in food safety on and around the farm.

Dr. Gillespie earned his Doctor of Veterinary Medicine degree from Oklahoma State University in 1961, spent one year in veterinary practice, and completed his doctorate in comparative pathology at the University of California, Davis, in 1965. After a postdoctoral fellowship with the Cardiovascular Research Institute

at the UC San Francisco Medical Center, he joined the faculty of the UC Davis Schools of Veterinary Medicine and Medicine. Dr. Gillespie remained in Davis from 1966 until 1985, becoming known for his applications of heart-lung physiology to the developing field of equine anesthesiology. He has published more than 100 original scientific publications contributing internationally to a fuller understanding of respiratory disease, equine exercise physiology and food safety.

In 1985, Dr. Gillespie moved to Kansas State University, College of Veterinary Medicine, to become Head of the Veterinary Teaching Hospital and Department of Clinical Sciences. While at the college, Dr. Gillespie observed the strong links between the state and its food agriculture industry and began to promote research on food animals and food safety. He helped found the Kansas State University Food Animal Health and Management Center in 1994. The center's findings on the ecology of food-borne pathogens, the role of wildlife-livestock interaction in spreading disease to people, and other food-related matters have led to new recommendations for food safety strategies on the farm.

Dr. Gillespie served as first Executive Director of the Joint Institute for Food Safety Research, U.S. Department of Agriculture and U.S. Department of Health and Human Services. From 2000 through 2002, he and the Institute brought together 20 federal agencies conducting food safety research and laid the groundwork for further collaborations with state agencies, private industry groups and international partners.

Professional service contributions made by Dr. Gillespie encompass several national and international organizations including the American Veterinary Medical Association, the Academy of Veterinary Cardiology, the American College of Veterinary Anesthesiologists, Wellcome Trust and numerous equine groups. He has also led numerous professional committees and task forces related to food safety and veterinary education.

Dr. Gillespie's goals for the Western Institute for Food Safety and Security include fostering timely food safety research; applying new knowledge to both plant- and animal-based food products; developing port awareness tabletop exercises; responding to the public and food industries; promoting scientific scrutiny of issues throughout the food-production continuum—from the farm environment to the consumer—that will assure the highest international standards of food safety and quality.

Dr. Gillespie was awarded a DHS-ODP Training Grant in the amount of \$4.7 million titled, “Training to Enhance Prevention, Deterrence, Response and Recovery from WMD Incidents in California Dairy and Processed Produce Systems.” The grant trains front-line responders.

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.

THE ASSOCIATION OF FOOD & DRUG OFFICIALS [AFDO]

OFFICIAL COMMENTS TO:

United States Department of Agriculture;
Food Safety & Inspection Service [FSIS]

AND

United States Department of Health and Human Services;
Food & Drug Administration [FDA]

December 15, 2005

[Docket No. 05-013N]

USDA and HHS Agencies Work Together to Examine the Jurisdiction of Certain Food Categories

On behalf of the Association of Food & Drug Officials [AFDO], it is my pleasure to offer the organization's comments on FSIS' and FDA's plans to address the longstanding confusion over which agency has jurisdiction when certain food products contain meat or poultry. AFDO represents state and local food safety regulatory officials and is a close working partner to both FSIS and FDA on food safety and defense matters. Furthermore, AFDO has long supported the concept of a nationally integrated food safety system and has promoted numerous projects, in place today, that advance this concept. We believe the examination beginning here today into the jurisdiction of certain food categories can further strengthen the regulatory process, will better employ limited available resources, and will resolve a number of longstanding criticisms of the Federal food safety agencies. AFDO strongly supports this process and the approach taken by the FSIS/FDA working group for the following reasons:

1] **It will strengthen our national food safety system.** As a result of our close working relationships with FSIS and FDA, it is our belief that food safety agencies at all levels must operate in concert to protect public health. Problems which exist for the Federal agencies are also problems for the state and local agencies. Clarifying and rationalizing what Federal agency has jurisdiction over foods like pizza and sandwiches will result in more efficient and effective government regulation, benefiting all parties.

2] It permits a risk-based allocation of regulatory resources. We believe this effort is a logical cost-saving step for better applying inspection

resources to regulated industries. It is also a much improved way for addressing inspection jurisdictions for lower-risk vs. higher-risk food products.

3] **It is a logical and more easily understandable approach to distinguishing products.** We fully support the FSIS/FDA workgroup's rationale for determining what agency shall be awarded jurisdiction. Food products that primarily contain meat and poultry ingredients should be covered by resident type of inspection under FSIS, while food products that contain meat and poultry ingredients for accentuating flavor only should be assigned to FDA. This rationale is best illustrated, in our opinion, with sandwiches which pose a potential *Listeria monocytogenes* hazard to consumers, whether or not the sandwich is closed- or open-faced.

While AFDO recognizes the need for and importance of the jurisdictional examination, we note that the changes being considered will have an impact on state and local food safety programs. We urge that these impacts be considered during the decision-making process.

1] It is likely that some establishments that would be affected by the change are currently licensed and inspected by state and/or local regulatory agencies. Should these establishments become Federally-inspected plants under FSIS, would state laws be preempted and state programs lose licensing fees? What might FSIS do to ameliorate this impact?

2] AFDO has long supported the use of HACCP by all food manufacturers and wonders what will happen to current FSIS establishments operating under a HACCP plan that are then transferred to FDA jurisdiction where this requirement does not exist. It would seem inappropriate that a HACCP system, which has been mandated to and put into effect by a firm, might no longer be required. AFDO requests clarification of this matter.

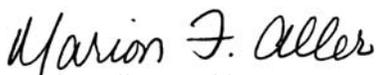
3] It would follow that rule changes for firms that are placed under a new Federal jurisdiction will be impacted as well. Establishments complying with state-required date coding, record-keeping or processing schedules different from those required by FSIS, would have to make substantial changes.

4] A number of affected firms may be currently inspected by state authorities under FDA contracts. Transferring these firms to FSIS jurisdiction will impact such contracts.

5] A number of states have taken major enforcement actions due to *Listeria monocytogenes* contamination against sandwich manufacturers currently under FDA's jurisdiction. These state actions include food seizures or embargoes, recalls, and license revocations. State programs report that some of these actions have led to requirements for "hold and test" programs and environmental plant testing. The potential for *Listeria* contamination in sandwich manufacturing facilities is of great concern to state and local food safety programs, and we believe the more intensive, resident-type inspection program of FSIS is warranted for such products. AFDO does ask FSIS to review with state programs any sandwich manufacturer under current state or local government authority where *Listeria monocytogenes* problems have existed.

This initiative could be an opportunity to look at new cooperative approaches to regulating food establishments subject to multiple jurisdictions. Food establishments where meat or poultry and non-meat or poultry products are produced in the same plant have always presented an awkward situation for regulators. Many of these plants are high-risk types such as low-acid canned food manufacturers, acidified food plants, and processors that cure, salt, or smoke various types of food products. Goals might be to prevent duplication of efforts and minimize the number of government food safety agencies with which small businesses must contend. At a minimum, where the states are not preempted entirely and continue to have a role in regulating multiple-product manufacturing establishments, the Federal agencies should provide a mechanism for consulting with the states on the coordination of Federal and state regulatory activities, including compliance efforts with retail food establishments.

AFDO is pleased to offer these comments to our Federal partners and applaud any decision that will result in a better utilization, coordination, and integration of the limited, yet very critical resources devoted to food safety.



Marion Aller; President
Association of Food & Drug Officials

**POST-PROCESSING TREATMENTS FOR READY-TO-EAT MEATS:
HIGH PRESSURE AND SURFACE THERMAL PROCESSING**

Paul L. Dawson, Ph.D.

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Ready-to-eat (RTE) meat recalls due to bacterial contamination costs the meat industry millions of dollars each year despite accounting for less than 0.1% of the total meat produced and imported annually. RTE meat recalls are often caused by *Listeria monocytogenes*, for which the USDA-FSIS has implemented a zero tolerance. To address this problem, various post-processing treatments for ready-to-eat meats have been investigated. Various systems to deliver heat to the meat surface after processing are effective and efficient and in most cases achieve the goal of bacterial inactivation. Equipment that combines heat, antimicrobials and packaging has also been proposed that resembles modified aseptic processing/packaging systems. Post-processing treatments to reduce *Listeria* ssp. on ready-to-eat meats have been strongly encouraged by the USDA-FSIS and are accompanied with incentives for less stringent microbiological testing for processors implementing one or more of the post-processing alternatives. These incentives will likely increase the use of post-processing treatments for RTE meats.

Introduction

Less than 0.1% of the total amount of meat produced and imported annually in the U.S. is recalled; however, recalls cost the RTE meat industry millions of dollars. From 1997 through 2002 there has been at least one meat/poultry recall greater than ten million pounds; five involved *Listeria monocytogenes* (*Lm*) and two involved *Escherichia coli* O157:H7. *Listeria monocytogenes* and *Escherichia coli* O157:H7 were the most frequently causative biological recall agent, despite *Salmonella* spp. and *Campylobacter jejuni/coli* causing many more foodborne illnesses (Table 1).

Table 1. Reasons for meat and poultry recalls in the US (from USDA-FSIS)

Year	Number of recalls						
	Listeria	E. coli	Salmonella	Other bacteria	Chemical/physical	Undeclared ingredients	Under-processed
1994	17	3	0	3	16	1	7
1995	11	5	2	2	13	1	7
1996	6	2	1	1	5	3	6
1997	3	6	1	5	8	4	0
1998	7	13	2	2	11	4	5
1999	30	10	6	0	3	8	4
2000	36	20	4	0	5	9	2
2001	25	26	2	0	11	24	6
2002	40	24	4	0	4	36	4

Since the size of the recall can vary from a few hundred to several million pounds, just focusing on the number of recalls can be misleading. The recalls, in pounds, for 0-10,000; 10,000-100,000; 100,000-1,000,000; and greater than 1,000,000 accounted for 55, 24, 17, and 4% of the total recalls, respectively, over the nine-year period between 1994 through 2002. Thus, while accounting for only 4% of the recalls, the over 1,000,000 pound category was likely to be the most costly to the industry. Recall costs are sometimes difficult to track since various factors will affect total cost, including the depth of the recall. Depth refers to the notification levels which, for the previous periods, were divided into notification of direct consumers (37%), foodservice users (33%), retail stores (25%), and wholesalers (5%).

TABLE 2. Prevalence (%) of *L. monocytogenes* in RTE meat and poultry products, 1990-2000 (from USDA-FSIS)

Year	Cooked, Roast, Corned Beef	Sliced Ham & Luncheon Meats	Small Cooked Sausages	Large Cooked Sausages	Jerky	Cooked Poultry Products	Salads/ Spreads/ Pâtés	Fermented Sausages
1990	6.38	7.69	4.21	5.32	0.00	2.79	5.48	N/A
1991	4.02	5.48	7.24	4.60	0.00	2.62	3.17	N/A
1992	3.86	7.89	6.03	0.42	0.00	2.01	3.32	N/A
1993	3.04	8.05	5.30	2.13	0.00	1.91	2.19	N/A
1994	2.09	5.46	4.81	1.14	2.22	2.37	2.41	N/A
1995	2.68	5.00	4.09	1.14	0.00	2.25	4.69	N/A
1996	3.35	7.69	3.74	0.95	0.00	3.17	2.17	N/A
1997	2.08	4.20	2.74	1.62	0.00	0.95	2.43	9.26
1998	2.15	4.18	3.49	1.19	1.56	2.22	3.11	2.87
1999	2.71	4.58	1.76	0.43	0.00	1.44	1.15	2.09
2000	2.24	3.05	1.26	0.51	0.75	1.24	0.98	1.49
Cumulative	2.95	4.47	2.97	1.09	0.58	1.97	2.83	2.67

Two large outbreaks of listeriosis in which deli turkey products were implicated resulted in 17 and 2 million pounds of product recalls and caused 17 deaths and 72 illnesses before the recall was implemented.

USDA-FSIS Rulings

To address these outbreaks and frequency of *Lm* detection in ready-to-eat (RTE) products (Table 2), the USDA-FSIS has proposed more stringent testing standards. *Listeria monocytogenes* presence in RTE meats has been a major concern of the USDA-FSIS, and this agency has provided incentives for processors to implement additional steps to reduce the presence of *Lm*. Processors were “encouraged” to determine if *Listeria* “was likely to occur” in a processing environment. This was accompanied with the categorization of products as “high, medium, or low risk.” Implementation of post-processing interventions then could place a high- or medium-risk product into the low-risk category. The USDA-FSIS issued an interim rule in October of 2003 for RTE meat processing. This interim rule established three alternatives that have accompanying testing requirements. Alternative 1 employs both a post-lethal treatment (such as heat, high pressure) and a growth inhibitor (such as an organic

12 Association of Food and Drug Officials

acid, antimicrobial agent, fermentation, drying, or freezing). A post-lethal treatment is a “bacterial kill” step placed after the RTE meat has been thermally processed and preferably after packaging. Alternative 2 employs either a post-lethal treatment or a growth inhibitor. Alternative 3 maintains a processing sanitation program with no additional post-lethal treatments or growth inhibitors. There are expected levels of *Listeria* spp. log reduction for the post-lethal treatment and level of reduced outgrowth for the growth inhibitor that will further dictate the number and frequency of microbiological testing. The post-lethal treatment must reduce Lm by greater than 1 log, while the growth inhibitor must prevent outgrowth from being greater than 1 log during the storage life of the product (Table 3).

Table 3. Levels of reduction or inhibition expected in *Listeria monocytogenes* (*Lm*) by post-lethal treatments and antimicrobial agents (growth inhibitors) (from USDA-FSIS).

	(Log ₁₀ reduction/inhibition of <i>Lm</i>)	
	Higher level	Lower level
Post-lethality treatment	>>2	<2(>1)
AM agent or process	<1	>1 (<2)

From a USDA-FSIS regulatory standpoint, the incentive for processors to employ the added post-lethal treatments and/or growth inhibitors is reduced frequency and types of testing (Table 4).

Table 4. Increasing levels of testing required with USDA-FSIS alternatives 1, 2, and 3. AM represents antimicrobial or growth inhibitor, and post-lethal represents a post-lethal treatment (adapted from USDA-FSIS).

REQUIREMENTS	Increasing risk levels & verification testing→				
	Alternative 1	Alternative 2		Alternative 3	
	Post-lethal & AM	Post-lethal	AM	Non-deli	Deli or hotdog
Validate post-lethality treatment	X	X			
Document AM agent/process	X		X		
SANITATION PROGRAM			X	X	X
Test FCS/ state frequency			X	X	X
ID size/location of tests			X	X	X
Explain test sufficiency			X	X	X
Additional Sanitation REQ					X
Verification test on FCS					X
Hold if 2nd FCS is (+)					X
Hold and test product lots					X

For instance, while food contact surface (FCS) testing is still required for all alternatives, the frequency of testing is about 2 times per year for alternative 1, 4 times per year for alternative 2, and from 1 to 4 times per month under alternative 3. Greater testing and verification/validation of treatments is required for deli meats and frankfurters based on a higher risk factor. There are several post-processing interventions possible that include irradiation. This paper will discuss post-processing options other than irradiation, including high-pressure processing, in-package pasteurization and antimicrobial packaging. Other treatments include chemical treatments, electrolyzed water and “aseptic” processing/packaging. Commercial post-processing systems for RTE meats are under development; Unitherm™ has such a system that has a hot-water AM rinse for frankfurters, while Alkar Rapid-Pak™ is showing a system that blows steam for 15 seconds

into hot dog pouches, after which the pouch is immediately sealed. Gande and Muriana (2003) reported a 1 log reduction in *L. monocytogenes* on unpackaged ham or roast beef in a radiant heat system after 60 seconds or 30 seconds of exposure, respectively. The radiant heat treatment was applied before packaging. Meat surface temperature for these radiant heat tests ranged from 59-98° C during the process. Foong et al. (2004) reported that irradiation to reduce *Lm* on frankfurters, ham, roast beef, bologna and smoked turkey required from 1.5 to 2.0 KGy and 2.0 to 4.0 KGy to attain 3 and 5 log reductions, respectively. Various post-processing interventions are being studied; however, high-pressure processing and in-package thermal processing will be discussed in this paper in more detail.

High-Pressure Processing

An emerging process for RTE meats is high-pressure processing (HPP), which kills bacteria with little or no change in meat quality. Pressure is often applied hydrostatically using a water-filled vessel surrounding the packaged product. This method applies pressure equally to all sides of the packaged product, which can temporarily reduce the package volume up to 15%. The package must be able to withstand this 15% volume change, after which the package will return to its original volume. During HPP, food products are usually packaged then placed in a high-pressure vessel, after which the vessel is sealed and filled with water. The pressure is raised to a set point by pumping water into the sealed vessel; then the pressure is held constant for a certain amount of time. Pressures used for foods range from about 100 MPa (14,700 lbs.in²) to 1000 MPa (147,000 lbs/in²) while typical pressures for meat are in the 300-700 MPa range. Atmospheric pressure is about 1 kg/cm² or 14.7 PSI; therefore 100 MPa is equivalent to about 14,500 PSI or 1000 Xs atmospheric pressure, and 1000 MPA is about 145,000 PSI or 10,000 Xs atmospheric pressure. Some of the capabilities of HPP are:

1. bacterial inactivation
2. spore germination or inactivation
3. enzyme denaturation
4. meat marination

Current products marketed using HPP include applesauce, apple juice, beef, chicken, orange juice, hams and RTE packaged meals. One reported advantage of HPP is that the process destroys bacteria by damaging the membrane but has little or no effect on food color, texture, flavor or nutritional quality. This is not the case with thermal processing, which damages covalent bonds; a property not affected by HPP. Furthermore, in hydrostatic HPP, pressure is applied uniformly on all sides of the product so food and package damage is minimal. There is a slight (~3°C) increase in product temperature for every 100 MPa pressure applied. There are several studies showing inactivation of *Lm* with HPP (Hayman et al., 2004; Aymerich et al., 2005) with other reports on the inactivation of *Clostridium*

botulinum spores in crab meat (Reddy-Solomon and Rhodehamel, 2003) and scrapie (as a BSE surrogate) in frankfurters (Mitchell, 2004). Hayman et al. (2004) reported a 4-log reduction for *Lm* for pastrami, beef and sausage using 600 MPa for 3 minutes. These researchers also found a large variation in *Lm* resistance to HPP due to strain type, making targeting a log reduction using HPP more difficult. High-pressure processing has been tested for inactivation of *Lm* (Simpson and Gilmour, 1997; Wei et al., 1991), *Salmonella* spp. (Wei et al., 1991; Metrick et al., 1989) and *Clostridium sporogenes* (Crawford et al., 1996). Avure Technologies reported over 5 log reductions in *L. monocytogenes* in minced chicken processed at 600 MPa (Figure 1).

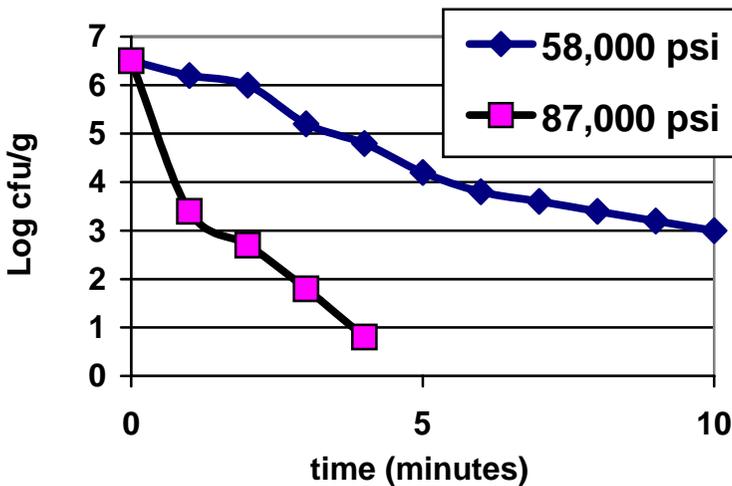


Figure 1. Inactivation of *Listeria monocytogenes* in HPP-treated minced chicken meat (From Avure Technologies, Vasteras, Sweden/S.S.I C.A. Parma, Italy).

In-Package Pasteurization

Thermal processing of the RTE meat product after packaging has been tested as a method to reduce *Lm*. Some factors affecting the rate of surface heating include meat surface roughness, product composition, packaging film, and product size (thickness). For example Murphy et al., (2003a) reported that the “roughness” of RTE turkey breast surfaces (varying in depth by >15 mm) increased the time to kill *Lm* on that surface during turkey breast in-package pasteurization. Package film thicknesses ranging from 0.08 to 0.33 mm had a significant effect on the heating rate of vacuum-packaged turkey breast (Murphy et al., 2003a, Murphy et al., 2002).

Type of heating medium also has an effect on surface pasteurization. For instance, Murphy et al. (2005a) reported that using 131°C pressurized steam on bologna required 10 seconds to attain a 2 log reduction in *Lm* while a 100°C post-

packaging steam treatment took 2.5 minutes for the same effect. Also, Murphy and Berrang (2002) reported that 227 g and 454 g packages of chicken strips packaged in 0.2 mm thick films required 20 min and 34 min hold times in an 88°C water bath, respectively. Fully cooked chicken leg quarters (160 to 300 g) vacuum-packaged in 0.08-mm-thick films and then pasteurized at 96°C in a steam cooker (heat transfer coefficient of 760 W/m² K) required 22 minutes to achieve a 7 log₁₀ (cfu/g) reduction of *Lm* (Murphy et al., 2003b). Muriana et al (2004) found that prepackage radiant pasteurization provided 2.0 to 2.8 and 2.8 to 3.8 log reductions in *Lm* on deli turkey meat when processed for 60 s and 75 s, respectively. An improved radiant oven provided 3.53 (60 s) and 4.76 (75 s) log reductions. These same researchers reported that submersed water in-package pasteurization provided 1.95 to 3.0 log reductions when processed for 2, 3, 4 or 5 min at 93.3°C, and combinations of prepackage and in-package treatments gave 3.0 to 4.0 log reductions of *Lm* using 60 + 60 s or 60 + 90 s for the prepackage and postpackage pasteurization processes, respectively. Product type effect on thermal processing was illustrated in the variation in *Lm* D values for chicken breast, turkey breast, and roast duck (Murphy et al., 2003c). These researchers reported D values of 151.5 to 0.1 min at 55 to 70 °C and z values of 4.9 to 7.0 °C for these three RTE products. For in-package pasteurized whole chicken fillets and chicken strips, Murphy et al. (2003d) found no difference in *Lm* death rate when either 100°C steam or hot water was used as the heating medium. Approximately 5, 25 and 35 min exposure times were required to attain a 7 log₁₀ reduction of *Lm* in single packed fillets, 227 g packs of strips and 454 g packs of strips, respectively. McCormick et al. (2003) found the D values for single packed slices of turkey bologna submerged in a heated water bath were 16.2 and 124 s at 65 and 61°C, respectively.

Post-process pasteurization of RTE meat is a surface pasteurization; therefore product thickness or size might be expected to have a minimal effect on surface heating rate. Based on the large range of D values for *Lm* on RTE meat (Table 5) and from discussions with industrial equipment representatives, product thickness effects on surface heating rate were investigated (Mangalassary et al., 2004). In this study, the surface heating rates were determined for 1, 3 and 5 bologna slices representing 4-, 12-, and 20-cm-thick samples. Mangalassary et al. (2004) reported surface heating rates were significantly slower for 12 compared to 4-cm-thick and slower for 20- compared to 12-cm-thick bologna stacks (Figure 2).

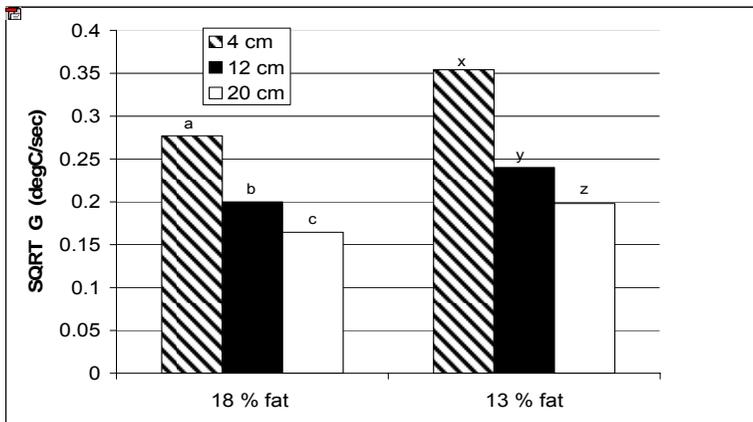


Figure 2. Surface heating rates for different thicknesses and for two types of bologna.

Table 5. Selected *Listeria* spp. decimal reduction times (D values) at various temperatures and ready-to-eat meat products.

T (C)	D (min)	Product type	Heating medium	Reference
96	2.33	4 kg turkey breast	steam	Murphy et al (2003a)
93	0.5	1.8-5.9 kg ham	radiant	Gande and Muriana (2003)
93	0.16	0.9 kg bologna chubs	radiant	Gande and Muriana (2003)
62.8	6.9	2-5 kg whole-formed turkey	water	Muriana et al. (2002)
65.6	1.23	2-5 kg whole-formed turkey	water	Muriana et al. (2002)
68.3	0.42	2-5 kg whole-formed turkey	water	Muriana et al. (2002)
71	0.16	2-5 kg whole-formed turkey	water	Muriana et al. (2002)
62.8	1.12	2-5 kg ham	water	Muriana et al. (2002)
65.6	0.5	2-5 kg ham	water	Muriana et al. (2002)
68.3	0.25	2-5 kg ham	water	Muriana et al. (2002)
71	0.08	2-5 kg ham	water	Muriana et al. (2002)
88	2.86	227 g packs of chicken strips	water	Murphy and Berrang (2002)
88	4.14	454 g packs of chicken strips	water	Murphy and Berrang (2002)

T (C)	D (min)	Product type	Heating medium	Reference
96	3.14	160-300 g chicken quarters	steam	Murphy et al. (2003b)
93.3	.6 - 9	Deli turkey meat	water	Muriana et al. (2004)
65	.38 (12.5s)	Bologna slices	water	McCormick et al. (2003)
61	2.0	Bologna slices	water	McCormick et al. (2003)
131	0.16 (5s)	Bologna slices	steam	Murphy et al. (2005a)
100	1.25	Bologna slices	steam	Murphy et al. (2005a)

To compare how meat thickness might affect thermal process times, Mangalassary et al. (2004) computed the time required in a 70°C water bath to yield a 5-log reduction of *Lm* on packed bologna surfaces to be 1.5, 5.4 and 9.5 min for 4-, 12-, and 20-cm-thick samples, respectively. For a surface 5-log reduction in *Lm* on packaged bologna in a 80°C water bath 0.72, 2.56 and 4.12 minutes would be needed for 4-, 12-, and 20-cm-thick samples, respectively. Thus, small changes in meat product thickness has a significant effect on surface heating rates and the related thermal inactivation of bacteria. Bologna proximate composition also significantly affected surface heating rate, with the lower fat and higher moisture meat heating faster on the surface than higher fat, lower moisture-containing meat (Figure 2).

Frankfurters present a slightly different challenge for postprocess thermal treatment due to their size, shape and traditional packaging style. One approach is to inject steam into the package just before sealing. Frankfurters (2.54 cm diameter by 15.24 cm length) inoculated to contain 6 log cfu/cm² then treated with 121°C steam for 1.5 s in an arrangement of 6 franks per packaging chamber followed by immediate vacuum sealing of the top films of food packages yielded a 3-log cfu/cm² reduction of *Lm* (Murphy et al., 2005b). The pasteurization depth in this study was 1.27 mm below the surfaces of the franks and it was suggested that this process provides a commercially applicable means of ensuring food safety by effectively eradicating *Lm* from frankfurters. Frankfurters surface-inoculated with *Lm* then treated with steam (100°C, 1.5 s) and/or liquid smoke (0.2 ml/frank) were reduced by approximately 1 and 2 log₁₀ *Lm* cfu/cm², respectively (Murphy et al., 2005c). In this same study, when some steam and liquid were combined, it resulted in 3 log cfu/cm² reductions. Thermal inactivation values of *Escherichia coli* O157:H7 at 55°C to 70°C were 21.36 to 0.031 min in raw frankfurters and 24.91 to 0.038 min in fully cooked frankfurters with similar z values for raw (5.07°C) and fully cooked frankfurters (5.08°C) (Murphy et al., 2004). These D and z values were used to calculate the process

lethality for both the cooking (process lethality = 254 min) and post-cook pasteurization (process lethality = 39 min) to achieve a 7D reduction of *E. coli* O157:H7 during cooking and post-cook pasteurization.

Conclusion

The presence and human health impact of *Lm* has prompted the passage of regulations to reduce *Lm* in RTE meats. The contamination by *Lm* in RTE meats is problematic at the point in the process between cooking and packaging. Therefore, post-cooking and, preferably, post-packaging interventions have been suggested as effective measures to eliminate or reduce *Lm* in these products. Two such interventions are high-pressure processing and in-package pasteurization, both of which can be performed on a packaged product. The problem in RTE meats is primarily a surface issue since the internal portion of the meat is cooked. Variables that must be addressed when implementing a post-process intervention include package material used, package thickness, product size and product composition. The final decision on whether to implement a post-process intervention and which one to use depends upon the confidence the processor has that *Lm* will not be present in the product and the cost-benefit of the intervention utilized. The processor must keep in mind the large cost associated with a product recall and subsequent loss of sales due to poor public image.

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**“VITAMIN D MILK”
A DIETITIAN’S PETITION TO THE FDA**

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Abstract

According to the Dietary Guidelines for Americans 2005, milk is among the top three contributors of saturated fat in the American diet (1) and sixty-seven percent of all milk sales remain whole and 2% (2). As a healthful part of a balanced diet, nutritionists and public health advocates recommend the daily intake of milk, but because of the impact of saturated fat consumption on chronic disease risk, and particularly in light of the obesity crisis, all people over the age of two are advised to consume low fat or fat-free milk (3). In fact, milk fat has been identified as the most important food to target to lower total and saturated fat intakes (4). Professional observation, anecdotal evidence and consumer surveys point to the name “Vitamin D Milk,” the most common name appearing on containers of whole milk across the United States, as misleading consumers in believing that “Vitamin D Milk” is nutritionally superior to lower fat milk types. To eliminate confusion caused by using the name “Vitamin D Milk” for whole milk, and to improve consistency and uniformity of labeling between milk varieties, a petition to the FDA was submitted to amend or issue regulations which would effectively end the name “Vitamin D Milk”.

Overview

“Vitamin D Milk”, the most common name for whole milk nationwide, remains the preeminent “right” choice in the minds of consumers. Sixty-seven percent of all milk sales remain whole and 2% milk (2) in spite of public health efforts to decrease saturated fat and calories in the American diet. Perhaps protected in its niche as number one in sales by the industry-wide practice of using that bold and simple name, “Vitamin D Milk,” it is what consumers reach for in the milk aisle despite the other, more healthful, options. It is therefore not surprising that, nationally, 65% of dairies use the name “Vitamin D Milk” on their whole milk labels according to a survey conducted by the Allentown Health Bureau in 2003.

What many consumers do not realize is that lower-fat milks are nutritionally equivalent to full-fat milk except that they contain less calories and less fat. Somehow the belief persists that the original “Vitamin D Milk” is best and anything else is less.

Background

The manager and staff of the Chronic Disease Program at a local health department in Allentown, Pennsylvania, piloted a low-fat milk campaign in 1997. Allentown is the third largest city in Pennsylvania, with a total population of 106,000, including a large Latino population. The low-fat milk campaign was later implemented statewide by other county and municipal health departments funded by the Pennsylvania Department of Health. As the staff interacted with consumers during the campaign, a pattern of confusion emerged in that the consumers were convinced that “Vitamin D,” as they often referred to it, was more nutritious than lower fat milks. This association between “**Vitamin D Milk**” and nutritional superiority kept consumers from making the low-fat switch. Professional and consumer surveys supported this observation:

- In 2002, the Allentown Health Bureau conducted a consumer survey investigating how consumers understand the nutritional content of the milk varieties. Using a sample size of 100, a survey developed by a local university found that 75% of the consumers used whole milk and 71% of those either believed or were unsure whether whole milk is the only type of milk that contains vitamin D.
- Studies conducted by Roper Starch Worldwide reported that “less than half [of surveyed adults] realize that skim milk contains the same nutrients [as whole milk] and with just the fat removed” (5).
- In 2003, sixty-six percent of registered dietitians responding from across the nation to an e-mail listserv question from the Allentown Health Bureau agreed that the name “Vitamin D Milk” should be changed because, in their experience, consumers mistakenly believe in the nutritional superiority of whole milk.
- Public health professionals throughout the state of Pennsylvania who implemented the low-fat milk campaign from 1997–2001, entitled the “1% or Less” Milk Campaign, also found that low-income/non-English-speaking consumers consistently look for and choose “Vitamin D Milk” because they believe it to be better than/superior to the other varieties. These consumers would not switch to low-fat milks even though they were repeatedly assured of the nutritional equality of the low-fat varieties. Those who implemented the 1% or Less Campaign in different geographic and demographic areas perceived the practice of calling whole milk “Vitamin D milk” as a barrier to the success of the campaign.

Based on these findings, a petition to the FDA was submitted to amend or issue regulations that would effectively end the name “Vitamin D Milk” (6).. The

changes requested in this petition will be particularly helpful to low-income/non-English-speaking consumers: Experts note that the belief that reduced-fat milk contains less calcium/vitamin D than whole milk is particularly prevalent among Spanish-speaking Hispanics (5).

In November 1996, FDA took an important step toward helping consumers choose lower fat milk products by making the definitions of “low fat” and “reduced fat” milk consistent with the new nutrition labeling regulations (61 Fed. Reg. 58991 (1996)). That action cleared up the confusion created by inconsistent definitions of “low fat.” This petition seeks to eliminate the lingering confusion caused by use of the term “Vitamin D Milk” for whole milk. The revisions to FDA rules that we are requesting would improve the consistency and uniformity of labeling not just with other low fat products but between different milk varieties. Our goal is to facilitate, through clearer labeling, healthier choices by consumers when they are purchasing milk.

If granted by FDA, dairies would be required to:

1. Put the vitamin/enrichment content **after** the milk’s name.
2. Use the word **added** along with the name of the vitamin.
3. Keep any letters describing the vitamin content less than (not greater than) half the height of the letters in the milk title.

Conclusion

The survey data discussed above clearly demonstrate that allowing whole milk to be labeled “Vitamin D Milk” continues to mislead consumers about the nutrition content of whole compared with 2%, 1% and fat-free milk. As a result, consumers are failing to switch to lower-fat milk products that have the same vitamin fortification but far less saturated fat. By granting the action requested in this petition, FDA would be taking one small but important step toward reducing saturated fat consumption and thereby help to lower the risk of heart disease and other chronic, diet-related diseases.

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TRAINING THE LOCAL COMMUNITY IN FOOD SECURITY AWARENESS

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In 2002, The Western Institute for Food Safety and Security (WIFSS) was established by a partnership with the California Department of Food and Agriculture, California Department of Health Services, the University of California, Davis and private industry. The purpose of the Institute is to help ensure the safety of the food supply with a focus on food systems in western United States. Sixty percent (60%) of the nation's fruit, nuts and vegetables are grown in California and 20% of all milk and dairy products are produced in California. Consumers across the nation and in foreign markets expect these products to be safe, abundant and affordable. This industry has tremendous economic importance to the state and nation. In addition to providing the majority of the foods on American tables, California leads the nation in import and export of food. Sustaining these systems is a major focus of the Institute.

The safety and security of our food has traditionally been a local responsibility. Evolving terrorist threats have only reinforced the importance of this local responsibility. To help communities prepare for food system disasters and potential agroterrorism attack, WIFSS has been designated a US Department of Homeland Security (DHS) Training Partner. WIFSS has developed an Agroterrorism Preparedness Curriculum that includes a series of courses sequentially presented in communities designed to strengthen the needed skills of frontline responders:

√ Performance Benchmarking Exercises (assessment)

- Awareness, "*Understanding the Dangers of Agroterrorism*"
- Preparedness, "*Understanding the Threats, Team Preparation and Prevention*"
- National Incident Management System (NIMS) and Risk Communication Course
- Detection and Investigation – Strategies and Technologies
- Response – Built around NIMS and Local, State, Federal and Industry Partnerships
- Recovery
- Electives (e.g., Food Processing Threats, Agroterrorism Agents, Team Building)

√ Performance Testing Exercises (certification)

Prior to the initiation of the classroom portion of this training curriculum, WIFSS will conduct a *Performance Benchmarking Exercise* designed to assess the existing level of preparedness of the community. This exercise will result in a set of measurable recommendations for improvement in food security preparedness within the community and link them directly to the training curriculum for analysis, action and resolution.

As a final component, the overall curriculum will include guided exercises (√ above) to assess preparedness of local communities and regions throughout California. These exercises will involve several different modalities including field testing, table top exercises and Web-based testing, emphasizing team building and team testing. Teams that satisfactorily complete the exercise will be certified. The WIFSS Agroterrorism Preparedness Curriculum will deliver DHS/ODP-*certified* courses in a *certified* curriculum delivered by *certified* instructors. Ultimately, the goal is to prepare California Office of Homeland Security-*certified* agroterrorism local response teams in communities throughout California, the western United States and the nation.

The participants in this training are all of the community elements needed to respond to a food system disaster or attack. Those participating in the training include:

1. Local community farmers, ranchers, and their workers who can produce effective and preventative training curriculums establishing awareness throughout the community and emphasizing training at various levels of participant education, language proficiency and responsibilities.
2. Local emergency teams and others who must respond to agroterrorism events in an effective and coordinated manner with state and federal response teams (e.g., public health officials, veterinarians, law enforcement, community leaders — in short, everyone who needs to be a part of an effective response).

In California, as in much of the nation, the workforce in the food systems is dominated by a diverse and non-English-speaking population with varied educational levels and often a transient lifestyle. The WIFSS team, in partnership with the California Department of Health Services, is developing a training curriculum that is specifically designed for the farm and food-processing facilities workers. The “Farm Workers Awareness Course” emphasizes development of food defense preparedness at the worker level and is designed to be delivered in short bursts of information and discussion. The farm worker courses are given in collaboration with the farm owner/manager, who is invited to attend the sessions. Pilot sessions have been conducted with the new worker-training program.

Response from the dairy operators and the farm workers has been extremely positive. There is considerable demand for expanding the curriculum to include other commodities and for training of workers in other segments of the food system.

As part of our outreach, WIFSS is partnering with various local communities, states, universities and businesses to provide these materials for educating the agricultural workforce in basic food security preparedness.

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**ARE THERE KATRINA LESSONS FOR THE FOOD
AND AGRICULTURE SECTOR?**

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We all sat in utter disbelief as New Orleans suddenly began to drown on that Tuesday morning. Growing up in lower Alabama, I have been well indoctrinated in the ways of the Hurricane, but in this case, to survive the blow and lose anyway was quite astounding. The aftermath was and continues to be a shock to our national nervous system. The city's infrastructure collapsed before our very eyes. The flood and ensuing breach of the levees may have been the cause, but the result was so much more devastating with the collapse of the City's critical infrastructure — not just the housing, law enforcement, communications, business, and transportation, but the demise of everything.

The food and water infrastructure also collapsed under the weight of a city drowning. As disturbing as that scene was, we need to ask ourselves, could a “Katrina-like” collapse happen in the food supply system — with or without the hurricane as a catalyst? As an industry, the food community carries more than enough vulnerabilities on a day-to-day basis to provide ample opportunity for a similar catastrophe.

You don't have to delve too deeply into the chaos of Katrina to see similarities that could easily repeat themselves in food and agriculture. In the Reality-Based Exercises (RBXs)sm we have conducted over the past 24 months with the food regulators and industry across the nation, we have found that four key elements surface as each simulated crisis unfolds.

Leadership

In New Orleans, the decision-making model broke and became fragmented. In spite of “tabletop exercises” and countless simulations, the leadership fragmented the instant the unexpected flowed through the levees. In the food world, we are already fragmented. At each level of government (national, state, and local) there exist agendas, protocols, and policies that, in their own stand-alone environments, are well-meaning and effective. But pushed together in an uncertain and ill-defined crisis, the conflicts will kindle not only within federal, state, and local agencies, but also between the federal, state and local agencies. Combined with the competitive atmosphere of the food industry, the environment can only lead to confusion, desperation, and anarchy. With chaos ruling in New Orleans, the business infrastructure was forced to step forward and play a larger role than planned. In spite of the good press that Wal-mart and Home Depot received for their efforts, by and large, the community was not ready and was caught just as “flat-footed” as their government. In hindsight, I can guarantee you that business

played a minimal role if any at all in the aforementioned exercises. The lesson: ***All food and agriculture stakeholders — including industry — must be at the preparedness table together, before the crisis unfolds.***

Operations

According to press reports, when the industry did step forward after the storm, their supply chain was impeded, if not blocked completely by well-meaning, if ill-informed, government agents who followed established and documented procedures and protocols. And to the discredit of industry, they followed directions even when it made no sense. Our operational effectiveness as a community in rapidly growing, processing, and distributing our products across the country and the globe provide a formidable strength and a devastating weakness. Our nation is so efficient that we only have 7 days of food available at any one time. The impact of a rapid widespread contamination will have enormous economic and health implications. The resulting shortages will instill panic, confusion, and a lack of confidence in our industry and government. Our food supply chain would most probably collapse from security concerns or lack of product. The storages of available products for the general public would result in general unrest, widespread looting, and hoarding of food. The supply chain is the backbone of the food and agriculture community. Without it our cities starve, our industries collapse, and our nation teeters on the brink of chaos. The lesson: ***In the absence of order, chaos will proliferate. The community must accept the potential chaos and be prepared to manage through it as a nation and an industry.***

Communications

Communications in our industry is stove-piped much like we saw in governments of New Orleans. Should a major food crisis unfold, would we be able to effectively communicate with industry, government, and the public? Will we be able to reach across boundaries of tradition (both internal and external) to communicate as a team? We hear a lot about the inability to communicate during 911, and after four years Katrina proved that not much has changed. Before we climb the podium to denounce these inefficiencies, reflect on how we as a local government and industry would fare. Most of us would look to that chaotic fragmented government network to provide that communications bridge whether it be tactical or public information. That won't cut it. The government should provide this connectivity, but based on the major crises of the recent past, that is unlikely. Industry partners must be ready to talk with each other, not through the channels in Washington, but directly face-to-face and on the local scene. **We are all in this together.** We must learn to rapidly respond as a team, not as adversaries or competitors. Exercises and workshops to establish protocols and channels for this eventuality are currently ongoing across the country, but our experience is that few incorporate the needs or the capabilities of industry. Industry is treated as a victim not an asset. In a crisis of this magnitude, the walls must come down

and come down quickly. Our communities are depending on it. The lesson: ***Industry must be ready to provide the communication links and protocols to support the government response and recovery to a crisis. These protocols must be installed, tested, and exercised by all stakeholders before a crisis.***

Financial

As proven by Katrina, the financial response and recovery is not just an industry issue. The prospect of not generating revenue or collecting a paycheck or paying bills has economic impacts that are far-reaching, well beyond the Mississippi Delta. Again this is a basic demonstration of the need for a public-private partnership. No matter how committed the government remains to sustain the business infrastructure, the bail-out is just too large. Initially, businesses will be left to fend for themselves while the government looks after the public welfare. The most important asset, the working citizen, is also the most vulnerable. Paychecks dry up, families move, and the business is further and further from recovery. Tax revenues dry up, services decline, schools are closed, and the community disappears. As we have seen demonstrated, insurance may or may not be dependable, no matter the language of the policy. The financial assets of the community, many of which are linked to investment funds, may or may not be available. Industry and government must have the ability to step forward to support each other and sustain the impacted communities and businesses at least during the short-term response and initial recovery phase. The lesson: ***These financing protocols must be established and in place prior to an incident. During chaos is not the time to be shopping for financial stability.***

In summary, growing up in the Deep South, the legacy of the hunger of the Civil War has been passed from generation to generation. My ancestral grandmother faced the war as a widow with 11 children to feed. She worked the kids to collect enough food to survive. Any available food went to one army or another, with communities desperately hoarding food for and from each other. In my lifetime, neither I, nor anyone I know, has ever faced that kind of hunger. The prospect of not being able to feed my children would, in all likelihood, drive me to hoard and even loot. Of course, my initial targets would be the readily accessible retail establishments, but soon I would also direct my attention to producers and processors. Sound eerily familiar? Are you ready?

The bottom line is we need each other. We need the government to pull with all its energy in a crisis to play out the role of guardian that only the government can play. The lessons of our major crises in recent times teach us that the food industry needs to be ready to step up with government partners to take care of our communities. What we have is an opportunity: an opportunity to create a new model of public-private partnership that is not only important to the complex food and agriculture sector, but also throughout government and industry. Let's not let the lesson of Katrina die in the history books, to be relearned with the next crisis.

We are all in this together...

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AFDO MISSION STATEMENT

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

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

AFDO Accomplishes Its Mission by:

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

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The Association of Food and Drug Officials

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JOURNAL OF THE ASSOCIATION OF FOOD AND DRUG OFFICIALS

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2008

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