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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.

FROM THE EDITOR

The new year is under way and practically all of us wonder what it will bring. Budget problems continue to plague most states but early signs of an improving national economy indicate that better times are ahead. The problems of dealing with the threat of terrorist attacks on our country occupy all of us in one way or another as we attempt to fully implement the Bioterrorism Act of 2002. Food security now almost equals food safety as a subject of ongoing concern for us all. We hope this Journal becomes a useful forum for us to keep up a healthy level of food safety and security awareness among all of us charged with the task of protecting our food supply. Like it or not, our regulatory agencies and private industry will be working to prepare us to deal with the threats posed by terrorism in today's world. AFDO will be in the forefront on these critically important matters, and we hope our Journal will be a significant contributor to the effort.

Thomas W. Brooks,
Editor

AFDO JOURNAL EDITORIAL BOARD

ABOUT THE AUTHORS

Dell Allen graduated with a BS in Agriculture from Kansas State University in 1961, an MS in Agriculture from the University of Idaho in 1963, and a PhD in Animal Husbandry from Michigan State University in 1966.

He then served on the faculty at Kansas State University for 22 years, where he had a teaching and research appointment. While at KSU, he directed the KSU Meat Laboratory, coached the meat judging team for 13 years, which provided him with the opportunity to visit meat plants extensively. In 1977 and 1978, he was contracted by the U.S. General Accounting Office to do a nationwide study on the uniformity of beef carcass grading across the nation. In 1980, he took a leave of absence from KSU to work at the Chicago Mercantile Exchange in the Law & Compliance Department.

In 1988, he joined Excel Corporation, rising through various levels to serve as its Vice President of Technical Services and Food Safety where he was responsible for the company's food safety and quality standards for 20 plants with over 25,000 employees. His leadership in food safety issues, including serving on the USDA's Meat & Poultry Advisory Committee and the industry sponsored Beef Industry Food Safety Council, have put Excel, now known as Cargill Meat Solutions, in the forefront of systems to improve food safety.

While at Cargill/Excel, Dr. Allen reached out to consumer advocacy groups, conducting facility tours of Excel plants for several of them and for elected officials and their staff that have been critical of the industry. He has spoken at many major food safety conferences, and collaborated in many high–profile efforts to work with the Department, the broader industry from the farm to the fork, and with consumer advocates. He has been recognized with awards by many groups, most recently having received the Scientific Achievement Award from the American Meat Institute, the E. Floyd Forbes Award from the National Meat Association, and the Howard Baughman Food Safety Award from the FSIS-USDA.

Dr. Allen retired from Cargill/Excel as Vice President of Technical Services and Food Safety in April of 2004. He resides with his wife Joyce in Derby, Kansas. Since retirement, he has worked as a consultant and serves as Editor at Large for Meat Marketing and Technology magazine.

Patricia Baxter graduated from Georgia Southern University in 1994 with a BS in Biology. She was then hired by ABC Research Corporation in Gainesville, Florida, as manager of the Research Microbiology Department. She worked for ABC until June 2003. She is currently employed by the Food Laboratory at the Florida Department of Agriculture and Consumer Services as a Biological Scientist III. In addition, she is a member of the International Association for Food Protection and a Board member of the Florida Association for Food Protection.

Ricardo Carvajal holds a J.D. from Northwestern University School of Law and an M.S. in Biology from University of Michigan. He is Associate Chief Counsel in the Food and Drug Division of the Office of General Counsel (OGC) of the Department of Health and Human Services (DHHS). This article was written in the author's private capacity; no official support or endorsement by the DHHS OGC is intended or should be inferred.

Larry Eils is the Senior Director of Technical Services for the National Automatic Merchandising Association (NAMA) located in Chicago. NAMA is the trade association representing the food and beverage vending, office coffee service, and food management industries.

Since 1985 he has been responsible for informing and educating vending operators, machine manufacturers, suppliers and regulatory officials on matters of health, safety and technical issues relating to food and beverage vending. Larry also oversees the NAMA Vending Machine Evaluation program, the Technician Training program, the NAMA Vending Technology Standards Committee and the Route Driver Certification program.

A graduate of Carroll College, Waukesha, Wisconsin, Larry entered the field of public health in 1964. Upon obtaining his Master's Degree from the University of Michigan School of Public Health, he joined the National Sanitation Foundation as their Regional Manager of Services. In 1974 Larry returned to public health as the Director of the Oak Park Health Department in Illinois; prior to joining NAMA, he was the Health Officer for the Rock County Health Department in Janesville, Wisconsin.

Larry is a Registered Sanitarian both in Illinois and with the National Environmental Health Association and a Certified Structural Pest Control Operator and Food Service Manager in Illinois. In addition he is active in a number of professional organizations, such as NEHA, IFPA, and AFDO.

Larry was given the Food Industry Sanitarian award in 1991 by the National Environmental Health Association and the Sanitarian of the Year award by the Illinois Environmental Health Association in 1993. In 2003 Larry received the Walter S. Mangold Award, the highest honor that the National Environmental Health Association can bestow on one of its members.

Shelley Feist was appointed Executive Director of the Partnership for Food Safety Education (PFSE) in October 2003. Ms. Feist comes to the Partnership with fifteen years experience advancing issues related to non-profit associations.

Prior to joining the Partnership, Ms. Feist worked for the Pew Charitable Trusts , a private philanthropic foundation based in Philadelphia, PA, where her work included an effort to assess and strengthen the policy development capacity of state-based organizations.

Ms. Feist has worked in the U.S. Senate on appropriations and domestic policy issues, and served as Director of Government Liaison for the John F. Kennedy Center for the Performing Arts under Chairman James D. Wolfensohn.

Travis Goodman is currently a Public Health Administrator and Food Security Specialist in the Division of Food Protection at the Indiana State Department of Health, where he has worked since June of 2000. He was employed by the Hamilton County General Health District in Cincinnati, Ohio, from 1992 to 2000, where he was a Food Safety Inspector, Water Quality Supervisor, and finally Director of Water Quality and Waste Management. Mr. Goodman holds a BS in Environmental Health Science from Indiana State University and has done graduate studies in Public Administration.

Mr. Goodman currently chairs the Food Security Committee of the Association of Food and Drug Officials; other affiliations include the National and Indiana Environmental Health Associations.

Jeff Lawrence is a graduate of Colorado State University with a B.S major in microbiology and environmental health. Currently he is the Retail Food Program Manager for the Consumer Protection Division of the Colorado Department of Public Health and Environment, where he has worked for twelve years Duties include administering statewide technical direction to Consumer Protection Division staff, local health agencies, industry representatives and the public regarding the Retail Food Program and the statutes and regulations that govern them.

Claus Mygind is a graduate of the University of Illinois where he majored in History and Secondary Education. Claus worked as a Sanitarian and Manager for 30 years in the DuPage County Health Department in Illinois. He participated on the management team that prepared and won the Crumbine Award (given for excellence in environmental health) for that County. Before becoming the Public Health Consultant for NAMA, he served four years on the Automatic Health and Industry Council helping develop vending machine construction standards. Claus has been a member of both the National Environmental and the Illinois Environmental Health Associations since 1974. He has also been a member of the American Backflow Prevention Association.

Therese Pilonetti-Hall , a graduate of Colorado State University, is currently the Institutional Environmental Health and Local Assistance Program Manager for the Consumer Protection Division of the Colorado Department of Public & Health Environment, where she has worked for nearly 5 years. Therese is currently the President Elect and Education Chair for the Colorado Environmental Health Association.

CONNECTING FOOD SAFETY AND FOOD SECURITY

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In this post-9/11 environment, we have become painfully aware of the physical, psychological, and economic toll that terrorism can exact upon our society. The possibility of terrorist attacks on our nation's food supply is real, and must not be ignored. America's food and agriculture infrastructure is, in many ways, vulnerable and helpless in deterring or responding to an intentional act of contamination. The focus must be to minimize the risk of an attack by implementing reasonable food security prevention measures and to be prepared to effectively respond to such an incident if it occurs. Connecting food safety and food security to facilitate the development of a comprehensive food defense strategy should be one of our first goals.

For those of us who have worked in food safety, the rapidly evolving field of food security is something new and interesting, but may not be fully understood. Effective food safety programs have existed for years, and have been instrumental in ensuring that our food supply has been arguably the safest in the world. While food security continues working its way into our respective programs in each state, there are many questions about how it relates to food safety and what types of food security efforts should be implemented.

Different programs and connections from food safety efforts can help in developing new food security efforts. Connecting food safety with food security will help us develop new initiatives to raise the awareness of industry and convince companies to become stakeholders in this process and protect themselves against the constant threat of intentional food contamination. One must break down "the old regulator-versus-regulated" mentality and work together to formulate a reasonable food security strategy. It is imperative that industry, academia, and government enter into a partnership to assess vulnerabilities and make progress over time to secure our food supply.

Currently, there are many food security efforts underway but there has been little coordination at any level. Although the Department of Homeland Security (DHS) has been established as the lead in food security efforts, there are many other federal agencies involved, including: the Food and Drug Administration (FDA), United States Department of Agriculture (USDA), and the Environ-mental Protection Agency (EPA). The Association of Food and Drug Officials (AFDO) has formed a Food Security Committee to address many of the current food security issues and try to coordinate efforts among government, academia, and industry to develop a reasonable food security strategy for the future.

In order to connect food safety and security we need to discuss their similarities and differences. They are similar because they are both food protection efforts and they have a common goal, which is eliminating/reducing food contamination. The key difference between food safety and food security is the way we try to prevent food from being contaminated or, simply put, intentional versus unintentional contamination.

Food safety efforts strive to eliminate/reduce **unintentional** food contamination by the enforcement of rules or regulations to deter or minimize violations such as bad sanitation practices, improper holding temperatures, bare hand contact with ready-to-eat foods, etc. We even focus on reducing risks through prevention efforts like the Hazard Analysis Critical Control Point (HACCP) program. There are already established food safety response plans in place to address unintentional foodborne illnesses. These same approaches are analogous to new food security efforts and can be applied when developing prevention and response programs.

Food security efforts strive to eliminate/reduce **intentional** contamination of food. This would include any type of intentional contamination. There are three major groups to consider when planning to protect food from intentional contamination: transnational terrorists, such as the al Qaeda network; domestic terrorists who usually belong to some type of radical activist group, such as the Animal Liberation Front; and disgruntled or psychologically imbalanced employees, which together account for the majority of incidences involving the intentional contamination of food.

Food security efforts involve a different thought process than food safety since there are no mandated rules or regulations requiring food security prevention or response measures. Farm operations, food processors, retail food operations, or food transporters must be looked at in a different way. One must think like someone with the diabolical intent to deliberately contaminate food—"think like a terrorist." By doing this the vulnerabilities in the food supply will be identified, and reasonable vulnerability-reduction plans, food shields, and/or mitigation strategies can be implemented.

An incident involving the intentional contamination of food would create many problems, putting the spotlight squarely on public health officials and the industries involved. An incident of any magnitude would create mass panic in the general public. Even people who are not directly affected by the incident would be overwhelming hospital emergency rooms like in the anthrax incidents, easily putting the industry involved out of business, if they are unprepared. It may undermine public faith in the safety and security of the food supply.

Although food security efforts have been gaining momentum since 9/11, there has been little or no training offered to local and state officials or industry. This is partly due to the fact that this is such a new area that few experts exist. Experts in food security are primarily working in private industry developing food security plans or offering training that is rather expensive to attend. There has been a perceived vacuum of leadership in this area and we are all looking to the federal food safety and security agencies as well as DHS for further guidance and training opportunities.

There are some excellent guidance documents on preventive measures for food security out there that may be used by public health officials or industry in developing some format for assessing vulnerabilities, developing and implementing preventive measures, and educating staff/employees on food security. These preventive measures were developed by federal food safety and security agencies and many industry trade organizations. Some of these guidance documents are available at the following websites:

http://www.cfsan.fda.gov/~dms/guidance.html#sec

http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?navid=SEARCH&q=food+security&Go_button.x=12&Go_button.y=9

http://www.nfpa-food.org/upload/pdfs/Publications_D-F.pdf

http://www.fmi.org/foodsafety/bio_security.htm

Awareness must be raised in industry concerning why it is important for companies to protect themselves against intentional contamination. This is particularly so for small- to medium-sized food industries that have very little time and money to put forth on food security efforts. A lot can be accomplished by educating them about preventive measures for food security and using a practical, common-sense approach to spending money on these efforts. The old adage: “Light it, Lock it, and Limit Access,” is still a good basis to build upon.

In looking at the preventive measures for food security, you will see many areas where food safety and security overlap or complement each other. The Management is responsible for food security as well as food safety. These efforts must be led from the top down or they will not work. Since they know their operations better than we ever will, industry management is responsible for assessing vulnerabilities and implementing the appropriate food security preventive measures for their own operations. They must make sure their employees are properly screened and provided with food security training that is applicable to their particular operation.

Other examples of areas where food safety and security overlap include: checking the physical characteristics of food—such as color, smell, texture, signs of package tampering; unusual substance on food; storage of hazardous materials; securing food directly upon delivery; suspicious behavior; employee illness; restricting personal items; assigning responsibility at all times for food operations; effective recall strategies; securing doors; and investigating suspicious foods.

Preventive measures for food security also help with loss prevention, such as: installing cameras or motion sensors when necessary, adding additional lighting, and limiting access to vulnerable areas of the facilities operation. The more we work with the food industry on food security issues, the more examples we have, and knowledge is gained on a daily basis.

Recently, there has been a change in terminology regarding food security efforts. Several federal agencies as well as other states and industry organizations are calling food security efforts "food defense." This is an appropriate terminology for encompassing all food security efforts. Overall, "food defense" would include all prevention, preparedness, response and recovery efforts. So, food protection and defense is a way to say food safety and security with every angle considered.

Another area that is being addressed is developing response plans for an incident involving the intentional contamination of food. There are many food safety response plans in place, but they do not account for dealing with the criminal aspects of an incident involving a weapon of mass destruction, such as a biological or chemical agent added to food. There is an effort underway by the National Association of State Departments of Agriculture (NASDA) to collect and develop the best format for responding to an incident involving the intentional contamination of food or agriculture. This is a cooperative agreement between NASDA, DHS, FDA, and USDA.

Food and agriculture is one of thirteen critical infrastructures to be protected through homeland security efforts. This is reinforced through Homeland Security Presidential Directive 9 (HSPD-9), which addresses protecting the food supply. Since there is an established relationship between food safety agencies and the food industry we are a natural fit to protect food and agriculture. However, we must establish a national strategy through a coordinated effort among all the stakeholders in food and agriculture. This will eliminate duplication of efforts and wasting tax dollars that could be spent directly on protecting the food and agriculture infrastructure. Since protecting our critical infrastructures is a national priority we must find a consistent source of funding for these food security efforts, or the directives established in HSPD-9 will not be accomplished.

The time is now for us to connect and coordinate our food safety and security prevention and response efforts. Intelligence documenting threats against the

food supply have been received, so we know that terrorists have considered this type of bioterrorism attack. A coordinated national effort must be developed to address this threat and move forward with a sense of urgency to protect the food supply. Here are some reasons why we must establish a national food security strategy and forge ahead together:

- An attack on the food supply could occur any day
- Food and agriculture protection is a national priority and we must move forward now while we have the momentum
- We will be less likely to shore up any type of federal/industry funding to support food security efforts the farther we get from 9/11
- This is the right thing to do to protect our food supply.

It might mean some extra work, but if we can prevent an incident or effectively respond to one because we are prepared, we will be able to say we did all we could, not only as public health officials, but as Americans.

NEW FOOD LABELING REQUIREMENTS ON THE HORIZON: THE FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT OF 2004

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The need to protect food-allergic consumers through the use of accurate and informative labeling has long been recognized by Congress. Congress first acted specifically to protect the health of food-allergic consumers in 1938, with the inclusion of section 403(i) in the Federal Food, Drug, and Cosmetic Act (FDCA). Prior to 1938, there was no requirement that food products be labeled to disclose their ingredients. As a consequence, allergic consumers had no way of knowing whether a food product was safe for them to eat. Section 403(i) was designed, in part, to address this problem by requiring that a food product label declare all ingredients (except colors, flavors, and spices) by their common or usual name.[i]

By the turn of the century, it was becoming clear that section 403(i) no longer adequately served one of its intended functions. The common or usual names of many of the ingredients currently in use are not recognized by consumers—especially children—as bearing any relationship to an allergenic food. Also, flavors and colors not subject to certification under section 721(c) may be derived from allergenic foods, but are not required to be individually declared on labels. To address these problems, Congress recently passed the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).[ii] The FALCPA amends the FDCA to require that a food product be labeled to disclose, in a manner comprehensible to consumers, whether that product contains a major food allergen.

What Are Food Allergens and How Are They Harmful?

Food allergens typically are naturally occurring proteins in certain foods. Ingestion of food allergens by food-allergic individuals can trigger an abnormal immune response that can result in expression of a wide range of symptoms. The most severe of these is anaphylactic shock, which involves multiple systems in the body and can rapidly result in respiratory and/or cardiovascular collapse, leading to death. There is no cure for food allergy, so avoidance of food allergens is critically important.

The prevalence of food allergy is estimated to be higher among children than adults. According to section 202 of the FALCPA, food allergies afflict approximately five percent of infants and young children and two percent of

adults in the United States. The most recent estimates of prevalence in the scientific literature are somewhat higher, and there is evidence that the prevalence of some food allergies may be on the rise.[iii]

What Is a Major Food Allergen?

The FALCPA adds several new sections to the FDCA. The first of these—section 201(qq)—defines a major food allergen as either 1) one of the so-called "major eight" (milk, egg, peanut, tree nut, soy, wheat, fish, and Crustacean shellfish), or 2) an ingredient that contains protein derived from one of the "major eight." The first part of the definition focuses on the "major eight" because those eight foods are estimated to account for 90% of food allergies. The second part of the definition focuses on protein because this is typically the component of food that elicits an allergic response. Specifically excepted from section 201(qq)'s definition of a major food allergen are highly refined oils and ingredients derived from those oils. The Senate Report notes that, for purposes of the FALCPA, "highly refined oils" are refined, bleached, deodorized oils.[iv] Studies have demonstrated that protein is not detectable in highly refined peanut oil.[v] Other food ingredients may be excepted from section 201(qq)'s definition of a major food allergen via petition or notification processes, as discussed further below.

What Are the New Labeling Requirements?

New section 403(w) of the FDCA sets out the labeling requirements. Subsection 403(w)(l) requires that the source of a major food allergen be disclosed in plain English, so that allergic consumers will no longer wonder whether an ingredient with a name that is unfamiliar to them is safe to eat. Specifically, under subsection 403(w)(l), a food that is not a raw agricultural commodity is misbranded if it bears or contains a major food allergen and does not disclose that fact in one of two ways: 1) by listing the name of the food from which the allergen is derived in a "contains" statement immediately after or adjacent to the list of ingredients (e.g., a label that lists whey as an ingredient also would state that it "contains milk"), or 2) by listing the name of the food from which the allergen is derived in parentheses immediately following the common or usual name of the allergen (e.g., "whey [milk]"). In the case of tree nuts, the specific type of nut must be revealed because some consumers may be allergic to one type of tree nut but not others. Similarly, in the case of fish and shellfish, the species of fish or shellfish must be revealed. Notably, colors, flavors, and incidental additives that are, bear, or contain a major food allergen must conform to FDCA subsection 403(w)(1).

Subsection 403(w)(l) recognizes the potential for redundant label declaration in cases where a product contains an ingredient that already reveals its source in its common or usual name (e.g., "pine nuts"). In those instances, the name of the source need not be restated. There are also cases where a product contains several

ingredients derived from the same source (e.g., a product that contains casein and whey, which are both derived from milk). In those instances, the name of the source need be stated only once, with one caveat: if the name of the source is stated only in the name of an ingredient that is not a major food allergen (e.g., peanut oil), then the name of the source must be restated elsewhere. This helps ensure that food allergic consumers will not mistakenly conclude that the food product is safe for them to eat.

Exemptions Through Petition or Notification

Some ingredients derived from the "major eight" may not be allergenic. For those ingredients, the petition process provided for in subsection 403(w)(6) provides one way of gaining an exemption from the labeling requirements of subsection 403(w)(l). A petitioner who seeks such an exemption bears the burden of providing scientific evidence demonstrating that the ingredient—as derived by the method specified in the petition—does not cause an allergic response that poses a risk to human health. A petitioner also must provide the analytical method used to produce the scientific evidence on which the petition relies. The Food and Drug Administration (FDA) then has 180 days to approve or deny the petition, or the petition is deemed denied unless both parties agree to an extension. A determination on a petition constitutes final agency action.

Another way of gaining an exemption from the labeling requirements of subsection 403(w)(l) is through the notification process provided for in subsection 403(w)(7). A notification must contain either 1) scientific evidence that demonstrates that the food ingredient, as derived by the method specified in the notification, does not contain allergenic protein, or 2) a determination by FDA under a premarket approval or notification program under FDCA section 409 that the food ingredient does not cause an allergic response that poses a risk to human health. The first of these elements recognizes that if the food ingredient does not contain allergenic protein, then there is little reason to suspect that it will cause an allergic response. The second element recognizes that there is no need to require the filing of a petition under subsection 403(w)(6) if FDA already has determined—in the course of evaluating a food additive petition or food contact notification—that the food ingredient does not cause an allergic response that poses a risk to human health.

Unless FDA determines within 90 days of its receipt of a notification that the notification is incomplete, or that there is insufficient scientific evidence to determine that the food ingredient does not contain an allergenic protein or does not cause an allergic response that poses a risk to human health, the food ingredient will be exempt from the labeling requirements of subsection 403(w)(1).

When Do the New Requirements Take Effect?

All foods labeled on or after January 1, 2006, must conform to the new requirements. Conversely, foods labeled prior to that date need not conform to the new requirements, although manufacturers are encouraged to adopt the new requirements as soon as practicable. With respect to products labeled prior to January 1, 2006, that do not conform to the new requirements, the legislative history of the FALCPA makes it clear that Congress did not intend for those products to be pulled from grocery store shelves. Thus, as a practical matter, consumers are likely to encounter some products with nonconforming labels well after January 1, 2006.

As the result of voluntary action on the part of industry, many food products already may conform to the new allergen labeling requirements. In 2001, a group of food trade associations and other interested organizations called the Food Allergy Issues Alliance published voluntary food allergy labeling guidelines that recommend food allergen disclosure in one or more of several formats.[vi] Two of the recommended formats essentially are the same as those prescribed by subsection 403(w)(1).

What about Other Food Allergens?

The FALCPA also adds new section 403(x) to the FDCA. Section 403(x) grants FDA the authority to require by regulation the declaration of any spice, flavoring, coloring, or incidental additive that is, or that bears or contains, a food allergen other than a major food allergen. In addition, section 203(b) of the FALCPA makes it clear that the FALCPA's labeling requirements for major food allergens do not alter FDA's existing authority to require labeling for other food allergens.

What about Celiac Disease?

Celiac disease is a genetic, immune-mediated disease that renders the body incapable of tolerating a protein component of the gluten found in wheat, barley, rye, and oats. Ingestion of gluten from one of these food sources can result in damage to the intestinal tract and other organs. As with food allergies, there is no cure for celiac disease, so avoidance is critically important. In order to help consumers with celiac disease avoid products that contain gluten, section 206 of the FALCPA requires FDA to issue a proposed rule to define—and permit the use of—the term "gluten-free" in food labeling. The proposed rule must be issued by August 2, 2006, and a final rule must be issued by August 2, 2008.

Food Allergy Is Likely to Remain a Topic of Interest

In addition to imposing new labeling requirements, the FALCPA is likely to focus the attention of public health officials and industry on food allergy for some time to come. Section 204 requires FDA to submit a report to Congress by February 2, 2006, that addresses the issues of contamination with food allergens during manufacture and the use of advisory labeling by food producers (e.g., labeling that states "may contain __"). Section 205 requires FDA to conduct inspections relating to food allergens. Under Section 207, the Centers for Disease Control must improve the collection of national data on prevalence, incidence, and treatment of food allergies, and to publish that information as it becomes available. Section 208 requires the National Institutes of Health to convene nationally recognized experts to review current food allergy research efforts, and to make recommendations by August 2, 2005, for enhancing and coordinating research. Finally, section 209 requires FDA to pursue revision of the Food Code to provide guidelines for the preparation of allergen-free foods in school cafeterias, restaurants, grocery stores, and other food establishments. These measures can be expected to reduce the incidence of food-allergic reactions, and perhaps eventually expand the range of food choices available to food-allergic consumers.

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[i] S. Rep. NO. 493 (Mar. 15, 1934).

[ii] Pub. L. No. 108-282, 118 Stat. 891 (2004). The President signed the FALCPA into law on Aug. 2, 2004.

[iii] Hugh A. Sampson, *Update on Food Allergy*, 113 J. Allergy Clin. Immunol. 805, 806 (2004).

[iv] S. Rep. NO.108-226 (Feb. 12, 2004).

[v] Jonathan O.'B. Hourihane, Simon J. Bedwani, Taraneh P. Dean & John O. Warner, *Randomised, Double-Blind, Crossover Challenge Study of Allergenicity of Peanut Oils in Subjects Allergic to Peanuts*, 314 Brit. Med. J. 1084 (1997).

[vi] GMA News, Food Allergy Issues Alliance Labeling Guidelines (May 31, 2001), *available at* http://www.gmabrands.com/news/docs/Testimony.cfm?docid=768& (last visited Nov. 4, 2004).

HAVE YOU HEARD OF ENTEROBACTER SAKAZAKII?

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When you attend food safety meetings, one of the new topics of discussion is *Enterobacter sakazakii*. I assure you that this emerging, opportunistic pathogen will be on the agendas of many meetings you attend this coming year. IAFP (the International Association of Food Protection) held an entire afternoon session dedicated to this subject at their 2004 annual meeting in Arizona. You may be asking what it is, where it came from, and why we are just now talking about it. Hopefully this short article will help answer some of these questions.

E. sakazakii was originally classified as a motile, non-spore forming, gram-negative rod within the family of *Enterobacteraceae*. It was referred to as the "yellow-pigmented" phenotypic form of *Enterobacter cloacae*. Based on DNA relatedness, pigment production and biochemical reactions, in 1980 it was reclassified as a unique species named *Enterobacter sakazakii*.

Its recognition has come about because of the devastating and, more often than not, fatal outcome it has on premature or immunocompromised infants. *E. sakazakii* has been found in the environment and has been linked to dry powdered milk infant formula. When this formula is consumed by infants it may cause meningitis, septicemia and necrotizing enterocolitis. Though *E. sakazakii* infections remain rare, in the past 40 years, >60 cases have been reported. Up to 80% of the infants do not survive, 50% of those die within one week of diagnosis. The infants that do survive can be left with severe neurological problems. To date, among older infants and full-term babies, only those with depressed immune systems have fallen victim to *E. sakazakii* meningitis.

In March of 2002, a number of outbreaks in American hospitals provoked the Center for Communicable Diseases to issue an advisory to hospitals and health professionals warning of the potential hazard in dry-powdered infant formula. A month later the makers of a brand of infant formula manufactured in Georgia issued a recall because *E. sakazakii* was found in the plant.

It is known that *E. sakazakii* is destroyed by pasteurization; however, it seems to be resistant to drying. Powdered infant formula is heat-treated but unlike pasteurized liquids it is not subjected to high temperatures for a sufficient time to make it sterile. To reduce the risk of infection it has been suggested that hospitals prepare the formula using high-temperature water; however, this has not been recommended since the high temperature would then destroy many of the nutritional components derived from the formula, rendering it unacceptable for

consumption. Other recommendations have been made such as limiting the time between preparation and consumption of formula, as well as ensuring that all utensils and appliances such as blenders have been properly sanitized prior to formula preparation. Such steps should help reduce the risk of an infection.

To further investigate the presence of *E. sakazakii* in the environment, Chantel Kandhai from Wageningen University in the Netherlands led a group of researchers who collected environmental samples from eight food processing manufacturers and sixteen households. The samples were collected from facilities that manufactured milk powder, chocolate, cereal, potato, flour, pasta, and spices. Samples that were collected from households included dust from vacuum cleaner bags. Aside from the spice factory, scientists found *E. sakazakii* in all the food processing facilities as well as five of the sixteen homes.

This research shows that *E. sakazakii* is not just related to powdered infant formula, and that it is more widespread in the environment than previously thought. There are so many more questions than answers regarding the bug and more research is needed. Complete risk assessments, routes of infection and virulence factors are still unknown. In addition, antimicrobial resistance has yet to be investigated. One thing is known: *E. sakazakii* is widespread throughout the environment and is no longer linked just to dry powdered infant formula.

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THE RELATIONSHIP BETWEEN BEEF RAW MATERIAL SURFACE CONTAMINANTS AND HIDE CONTAMINANTS IN BEEF CATTLE

Dr. Dell M. Allen

Introduction: The principle source of microbial contamination on the surface of beef carcasses comes from the animal's hide and is transferred to the carcass during the dehiding process. A significant relationship was reported between aerobic plate and *Enterobacteriaceae* (EB) counts on the beef carcass surface immediately after hide removal and the respective levels on the corresponding hides of the animals being dehided, i.e., the carcasses of animals whose hides carried higher numbers of bacteria were more likely to carry higher numbers of bacteria. Similar results have been reported in other studies as well [2,3,4].

In addition, the hide has been identified as the major source of *E. coli* O157:H7 on beef carcasses[1,5]. This would indicate that, in order to minimize surface contamination on beef carcasses and resulting beef trim, attention must be focused on hide removal during the slaughter and dressing process in addition to any treatments that will minimize the microbial contamination on the hides of incoming animals. Thus, it is critical to understand the factors that influence microbial load on the hides of beef animals being slaughtered. Season of the year and region of the country are two factors that will cause differences in total microbial load. In addition, there seem to be year-to-year differences that contribute to variation in load. There also appears to be feedlot-to-feedlot variation within the same region of the country. All of these need further study so that we can understand the magnitude of these differences.

Regional difference study: This study was designed and conducted cooperatively by Excel Corporation and USDA-ARS personnel from the Meat Animal Research Center, Clay Center, Nebraska, to determine if there were regional differences in the prevalence of *E. coli* O157:H7. The study was conducted at two fed beef plants, one in the high plains region of the U.S. (plant 1), the other located in the corn-belt region of the U.S. (plant 2). Samples were collected during three separate trips to each plant, one trip per week from mid-September through the first week of November of 2002. Forty-eight samples were collected from each of five sample sites during each trip, for a total of 288 samples per site.

Sampling was done with wetted sponges at five locations on the slaughter line: location 1, hide; location 2, immediately following dehiding and prior to the pre-evisceration acid rinse; location 3, post-evisceration; location 4, post-interventions but pre-chilling; and location 5, 29 hours post-chilling. Individual animals were tagged and tracked throughout the process. Two carcasses were sampled, with the first being sampled at hide (1), pre-evisceration (2), and post-evisceration (3)

processing points. The second carcass, immediately following the other, was sampled at the post- intervention (4) and chilled (5) processing points.

The microbial interventions used in each of these plants in the slaughtering process were identical and very similar in their placement. They included pre-evisceration acid rinses, steam vacuums, carcass washes, steam pasteurization cabinets and a post-evisceration acid rinse.

USDA personnel collected all samples. The hide sample was collected from a 100 cm^2 area over the plate region of the animal's hide. Each of the four carcass sampling sites included two 4,000-cm^2 areas that were then co-mingled as one sample site. The carcass sampling sites were in the areas of the carcass called the "pattern" area, which is that part of the carcass where the hide is opened up during the removal process and which is the area most apt to be contaminated by hide contaminants. Large areas were sampled because carcass contamination is not uniform in any one area. The intent was to improve the probability of finding pathogen contamination if it occurred. All samples were immediately transported back to the Meat Animal Research Laboratory and analyzed for total aerobic plate count (APC), EB counts, and for the presence of *E. coli* O157:H7. All APC and EB data were log-transformed before analysis of variance (ANOVA).

Results and Discussion: The prevalence of *E. coli* O157:H7 on the hides of the animals sampled was 75.7% (218 of 288) with a range of 50 to 93.8% on the various sampling trips. The data on hide contamination is shown in Table 1. It is seen in this table that plant 2 had a significantly greater contamination rate than did plant 1. This indicates a potential regional difference in the prevalence of this pathogen that may be a result of differences in climate, feedlot and pen maintenance, and possibly other factors not totally understood. Table 1 also shows the prevalence of *E. coli* O157:H7 on the carcass immediately after the hide was removed and prior to any interventions. Essentially twice as many carcasses in plant 2 were found to be contaminated with *E. coli* O157:H7 compared to that found in plant 1. This would indicate that the greater the presence of this pathogen on the animal's hide when introduced to the slaughter floor, the greater will be the transfer from the hide to the carcass during the dehiding process. Table 2 shows the log levels of APC found at each plant during each sampling trip. As in the *E. coli* O157:H7 sampling, plant 2 was found to have greater levels of APC on the hides of the animals being slaughtered than did plant 1. Log levels of *Enterobacteriacae* showed similar relationships to log levels of APC and thus will not be discussed in this paper.

Microbial transfer to carcasses during dehiding: Another interesting result of this study, as seen in figure 1, shows that animals with higher log levels of APC on the hide coming into the slaughter floor also had greater APC log levels on the carcass immediately after hide removal plotted for each sampling trip. The

resulting correlation was 0.99. It should also be noted that these two plants were run by the same company, had slaughter floors that were very similar and operated with identical standard operating procedures for equipment and personnel. When dividing the log levels of APC found on the carcass prior to pre-evisceration by the total log levels of APC found on the animals' hides, on a percentage basis, plant 1 transferred 44.87% of the APC on the hide to the carcass, and plant 2 transferred 45.87%. This despite the fact that, in both plants, the carcasses appeared visually clean and passed routine FSIS inspection for carcass cleanliness. In studying this same number across multiple plants with no hide-on interventions, this ranges from a low transfer number of approximately 40% to plants that transfer as much as 65% of the APC count found on the hide from the carcass during dehiding. This indicates that, under the best of circumstances, 40% of the bacteria found on a beef animal's hide will be transferred to the animal's carcass and will have to be reduced by interventions beyond that point. Thus, if an animal comes into the facility with 10 logs of APC on its hide, 4 logs will be present on the carcass under the best conditions or 6.5 logs in poorer performing plants. Figure 2 shows a correlation of 0.62 between the prevalence of *E. coli* O157:H7 on the animal's hide and the prevalence of that same pathogen found on the carcass surface after dehiding, as plotted for each sampling trip.

Relationships between APC levels and the incidence of *E. coli* O157:H7 on carcasses: Other researchers have reported that total bacterial levels as measured by APC are not correlated with levels of pathogens and thus cannot be used as indicators of possible pathogen contamination. In the author's opinion, these researchers have studied these relationships in finished products where the levels of pathogens and the indicator organisms are typically so low that relationships are difficult to determine. In this study, when grouped into classes, the relationship between APC and *E. coli* O157:H7 was significant ($P<0.05$)(table 3). It should be noted that this relationship is between the total count on the animal's hide and the prevalence of *E. coli* O157:H7 transferred to the carcass surface after dehiding and does not translate to sampling of the finished product. While APC cannot be used to determine the direct presence or absence of *E. coli* O157:H7, this would indicate that APCs could be used as a guideline as a process control mechanism for minimizing *E. coli* O157:H7 contamination of carcasses on the slaughter floor. This should translate into less *E. coli* O157:H7 contamination in finished products made from the carcasses produced on slaughter floors by using a process control model to minimize APCs.

Microbial interventions: Since USDA made *E. coli* O157:H7 an adulterant, microbial interventions have been added to slaughter floors in beef plants for treating carcasses after the hide is removed. Thus, when animals with extremely high levels of bacteria on their hides were introduced into the slaughter floor, or when worker performance is not at its maximum, levels of bacteria on the carcass

can be so high as to overwhelm the capacity of the interventions used on the carcass. This points out that anything that can be done to minimize the levels of bacteria, both APC and pathogens, on the animal's hide prior to beginning the dehiding process will improve the levels found on resulting carcasses after hide removal. This understanding caused Cargill Meat Solutions (Excel Corporation) to develop hide-on wash cabinets and install them in their fed beef facilities as an added microbial intervention.

Hide-on cabinet wash effectiveness: The development of hide-on carcass wash cabinets was carried out by Cargill Meat Solutions and Chad Company, of Kansas City, Mo. This intervention was added to the slaughter lines in all Cargill Meat Solutions fed beef facilities and positioned after the stick and bleeding operation and prior to the opening of the hide during hide removal. The cabinet is built with three sections or regions. The initial part of the cabinet where the hide-on beef animal enters applies warm water with soap. This allows a breakdown of the grime and grit carried on the animal's hide, allowing the caustic applied during the second region to act more effectively on the bacterial population present. After the application of the caustic, the animal is rinsed with clear water to remove any residual caustic and soapy water. Applications in all regions of the cabinet are done under high pressure between 700 and 900 psi. Upon leaving the cabinet, the pattern areas of the animal (where the hide is opened) are vacuumed with high-volume steam to remove as much excess water from the animal's hide as possible prior to commencing with hide opening. Table 4 shows the effectiveness of the hide-on cabinet in reducing *E. coli* O157:H7 prevalence on the beef animal's hide prior to the hide opening along with the resulting lower levels present on carcasses immediately after hide removal. It is obvious from this data that, when the prevalence of *E. coli* O157:H7 and also APCs are lowered on the animal's hide prior to opening and removing that hide, contamination levels on the carcass surface after hide removal are lessened. Table 5 shows the log levels of APC on the hide and on the carcass after hide removal for plants with and without a hide wash cabinet for an identical 4-month time period. All ground beef and carcass trim produced in these plants were also sampled for the presence of *E. coli* O157:H7 during this same time period. Table 5 also shows the percentage of ground beef found to be positive in the plants with hide wash cabinets (0.08%) and in those without hide wash cabinets (0.55%). Each plant included in this data produced between 250,000 and 500,000 lbs. of ground beef per day, so the resulting differences in the amount of positive product were significant from a statistical as well as an economic perspective. This data would indicate that plants with a hide wash cabinet were capable of producing carcasses with less than 3 logs APC (2.77) on the carcass surface after dehiding. Conversely, plants without a hide wash cabinet produced carcasses with greater than 4 logs APC (4.54) surface contamination after hide removal. The hide wash cabinet plants saw almost 7 times fewer positives in the ground beef than did the plants without cabinets.

Summary: The data presented here suggest that the difference in hide-on and hide-off APC log counts as a critical slaughter floor performance measure for plants wanting to minimize product contamination of both APCs and *E. coli* O157:H7. The data indicate that, in plants where APC log counts on the carcass surface are maintained below 3 logs immediately after hide removal, the presence of *E. coli* O157:H7 is minimized compared to plants where the APC levels are above 4 logs. Since, under the best conditions, the process of hide removal in modern plants transfers 40% of the microbial load found on the animal's hide to the carcass surface, and in the worst cases, 65% of that load, it is critical that the levels of initial contamination on the hide prior to opening is minimized. The hide-on wash cabinets discussed in this paper have the capability of achieving this reduction in initial load, thus allowing plants with these cabinets installed to meet the goal of less than 3 logs APC on the carcass surface after hide removal. A process control model using APC measurement of hide contamination and carcass surface contamination after hide removal is strongly recommended as a means of measuring plant performance and to minimize *E. coli* O157:H7 contamination of carcasses and the subsequent finished products.

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Table 1. Percentage prevalence of *E. coli* O157:H7 found on hides and carcasses immediately after hide removal by trip in two fed beef plants.

	Plant 1				Plant 2				
Sample Site	Trip 1	Trip 2	Trip 3	Plant Av	Trip 1	Trip 2	Trip 3	Plant Av	Overall
Hide	50.0	50.0	89.6	63.2	83.3	87.5	93.8	88.2	75.7
Pre-Evisceration	6.5	2.1	18.8	9.2	25.0	10.4	25.0	20.1	14.7

Table 2. APC log levels found on hides and at pre-evisceration by plant and by sampling trip.

	Plant 1				Plant 2				
Sample Site	Trip 1	Trip 2	Trip 3	Plant Av.	Trip 1	Trip 2	Trip 3	Plant Av.	Overall Av.
Hides, Log cfu/100 cm^2	7.2	7.3	7.4	7.3	9.0	8.1	8.0	8.3	7.8
Pre-Evisceration, Log cfu/100 cm^2	3.0	3.2	3.3	3.2	4.2	3.6	3.7	3.8	3.5

Figure 1. The relationship of APC hide counts and APC carcass surface counts at pre-evisceration

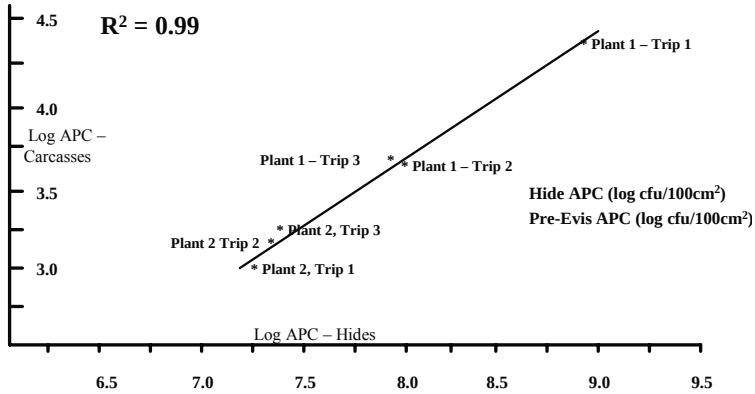

Figure 2. The relationship of *E. coli* O157:H& prevalence on hides and prevalence on the carcass surface at pre-evisceration

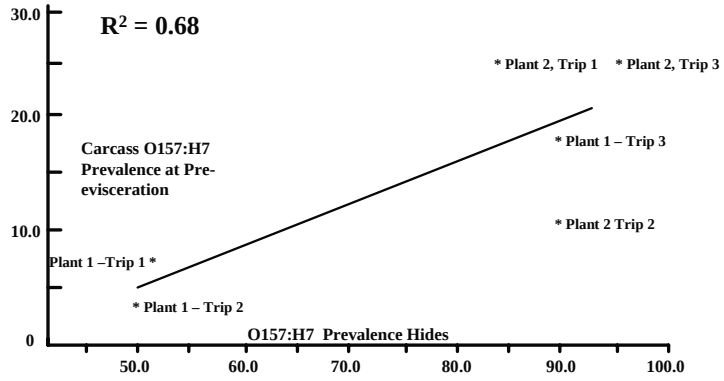

Table 3. Grouped class relationships between APC counts and prevalence of *E. coli* O157:H7 on carcass surfaces immediately after hide removal.

APC Log CFU/100cm^2	*N*	No. of *E. coli* O157:H7 Positives	% *E. coli* O157:H7 Positives
> 4	59	14	24%
< 4	227	28	12%

Table 4. Hide on cabinet wash effectiveness in reducing *E. coli* O157:H7 presence on the hide and carcass surface at pre-evisceration.

Treatment	*n*	No. of *E. coli* O157:H7 Positives	Percent of *E. coli* O157:H7 Positives
Hide, Before wash	83	50	60%
Hide, After wash	92	15	16%
Hide, Controls	98	86	88%
Carcass, Controls	251	41	16%
Carcass, Post-hide wash	262	3	1%

Table 5. APC log reductions and prevalence of *E. coli* O157:H7 positive lots of ground beef in plants with and without hide wash cabinets.

Measurement	Plants with Hide Wash Cabinets	Plants without Hide Wash Cabinets
Hide-on APC (log cfu/100 cm^2)	7.54	7.71
Pre-evisceration APC (log cfu/100 cm^2)	2.77	4.54
Av. APC Log Reduction (Hide-on to hide-off)	-4.48 (59.4%)	-3.17 (41.1%)
% Positive Lots Ground Beef	0.08%	0.55%

FDA'S NEWEST BIOTERRORISM REGULATION: ESTABLISHMENT AND MAINTENANCE OF RECORDS

The Bioterrorism Act provides the Secretary of Health and Human Services with new authorities to protect the nation's food supply against the threat of intentional contamination and other food-related emergencies. FDA is responsible for implementing these provisions. These new authorities improve FDA's ability to act quickly in responding to a threatened or actual terrorist attack, as well as other food-related emergencies. Since this legislation was signed into law, FDA has been working hard to implement it effectively and efficiently.

Section 306 of the Bioterrorism Act authorizes FDA to have access to certain records when the Agency has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. It authorizes the Secretary to publish regulations regarding the establishment and maintenance of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. For these regulations, the term "persons" includes individuals, partnerships, corporations, and associations. On December 9, 2004 the final rule on recordkeeping was issued, enhancing FDA's ability to trace food back to the source of contamination and forward to remove the adulterated food products from the food supply.

All businesses covered by this rule must comply by December 9, 2005, except small and very small businesses. Small businesses (11–499 full-time equivalent employees [FTEs]) must comply by June 9, 2006, and very small businesses (10 or fewer FTEs) have to comply by December 11, 2006.

The records required by the rule must be retained from six months to two years (depending on the shelf life of the food) at the establishment where the activities covered in the records occurred or at a reasonably accessible location. To minimize the burden on food companies affected by the final rule, companies may keep the required information in any format, paper or electronic.

The records that must be established and maintained are dependent upon whether a person is a transporter or non-transporter of food. For non-transporters, i.e., persons who own food or who hold, manufacture, process, pack, import, receive, or distribute food for purposes other than transportation, the records have to:

1. Identify the immediate non-transporter's previous sources, whether foreign or domestic, of all foods received, including the firm's contact information; type of food, brand name and specific variety (e.g., Brand X Cheddar Cheese, not just cheese; romaine lettuce, not just lettuce); date received; quantity and type of packaging (e.g., 12 oz. bottles); and identify the immediate transporter's previous sources including names

and all contact information. Persons who manufacture, process or pack food also must include lot or code number or other identifier if the information exists.

2. Identify the immediate non-transporter's subsequent recipients of all foods released, including the name the firm's contact information; type of food, brand name and specific variety; date released; quantity and type of packaging; and identify the immediate transporter's subsequent recipients, including the contact information. Persons who manufacture, process or pack food also must include lot or code number or other identifier if the information exists. The records must include information that is reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product.

Transporters include persons who have possession, custody, or control of food in the United States for the sole purpose of transporting the food and foreign persons who transport food in the U.S., regardless of whether they have possession, custody, or control of food. Records to be established and maintained include names of the transporter's immediate previous source and immediate subsequent recipient, origin and destination points, date shipment received and date released, number of packages, description of freight, route of movement during the time the food was transported, and transfer point(s) through which the shipment moved. Transporters have additional options for meeting the requirements of the final rule depending on the mode of transportation.

When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records or other information to which FDA has access must be available for inspection and copying as soon as possible, not to exceed 24 hours from time of receipt of the official request. The records access authority applies both to records required to be established and maintained by the final rule, or any other records a covered entity may keep to comply with federal, state, or local law or as a matter of business practice. Recipes (not ingredients) and data relating to finances, pricing, personnel, research, and sales are excluded from these requirements.

A draft guidance to clarify the circumstances under which FDA may access and copy records under the Bioterrorism Act and to describe the procedure that FDA intends to follow to exercise its authority to inspect these records is available at the following website: http://www.cfsan.fda.gov/%7Edms/secgui12.html. This guidance document is being distributed for comment purposes only and, when finalized, will represent FDA's current thinking on this topic. Very strict internal procedures will be followed in situations when it is necessary to access records, and FDA personnel will comply with all applicable protections, procedures, and legal requirements against the unauthorized disclosure of non-public information.

Failure to establish and maintain the required records or make them available to FDA upon request is a prohibited act. The Federal government can bring a civil action to enjoin or a criminal action to prosecute persons who commit a prohibited act.

The main benefits from the recordkeeping rule are enhanced food safety and enhanced food security. With the records required by this rule, the agency will be able to quickly investigate food that is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. Investigations will not be terminated due to poor or nonexistent records. Faster investigations will enable the Agency to respond without delay and take the necessary actions required to protect the public health.

For the text of the final rule on record keeping:
http://www.cfsan.fda.gov/~dms/frrecord.html

For additional information on the bioterrorism regulations:
http://www.fda.gov/oc/bioterrorism/bioact.html

PUBLIC HEALTH MEASURES USED TO MAXIMIZE RESOURCES

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The Consumer Protection Division (CPD) continually monitors work processes and identifies methods to enhance efficiencies within all program areas. Recently, CPD moved two additional programs, Retail Food and Child Care, to a risk-based inspectional methodology. While the methodologies for calculating inspectional frequencies differ for these two programs, the desired results are the same–more efficient processes that appropriately direct resources toward higher-risk establishments so that greater public health protection can be achieved.

The Division has developed and implemented the methodology to determine risk in retail food establishments. The protocol assigns a risk factor to an establishment based on four parameters: 1) foods served, 2) operations, 3) meal volume, and 4) inspectional history. New established frequencies range from once every two years to three times a year. Additionally, in lieu of an on-site inspection, the investigator can substitute one of three interventions types; an on-site training, a formal Hazard Analysis Critical Control Point (HACCP) study, or a consultative review. These interventions can be utilized to focus on the compliance assistance needed by an individual establishment. When inspectional frequencies were compared for fiscal year 2004 to 2005 utilizing the traditional once or twice per year inspectional approach, after implementing the risk-based protocol, a 14.2% reduction in inspections was realized. More importantly, resources are being reallocated to establishments with the highest potential link to foodborne illness. CPD has also redirected the resources saved to provide additional training for retail food inspectors at local health agencies.

The risk-based calculation for child care centers is calculated by accessing the risk value for each facility based on three parameters: 1) child's exposure or time in the center, 2) the age of children in care, and 3) the number of children in care. The children's exposure is broken into three risk indices: partial-day care, full-day care, and greater–than-24-hour care. The risk index for age is weighted more heavily than the other two indices. Therefore, a child's age is considered the most significant measure of risk due to the needs and vulnerabilities of very young children. Before the application of risk assessment, all childcare facilities in CPD's direct service jurisdiction were inspected once a year. Applying risk assessment, one of the three risk-based inspectional frequencies is assigned to each childcare facility based on each facility's risk calculation and risk category. Facilities in the highest risk category are inspected twice a year, moderate-risk facilities are inspected once a year, and low-risk facilities are inspected once every other year.

As a result of the risk analysis calculation, the total number of childcare inspections scheduled for the current year was similar to the total number that had been scheduled for previous years. Regulatory resources, however, are now directed, proportionally, to operations that have the greatest likelihood of having a detrimental impact upon the health of children attending their facility. This approach provides for more opportunity to identify deficiencies and greater resources to obtain compliance of critical issues, which are linked to illnesses in children.

CPD worked collaboratively with Information Technology Services to design a feature in CPD's database that automatically, with a simple click of a button, recalculates the risk for each retail food establishment. This recalculation is done annually. While not yet automated, the risk for childcare centers is also recalculated annually, and will soon be integrated into the database.

The resulting effect of moving these programs to a risk-based approach is a refocusing of CPD resources and improved measures for our inspection efforts. By basing these risk-based frequencies on the factors previously described, we can ensure that we continue to focus on the outcomes of reducing foodborne illness risk factors in retail food establishments and increasing overall compliance rates in the childcare setting.

BOTTLED WATER QUALITY FROM A VENDING MACHINE

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Larry Eils, Senior Director, Technical Services
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Today's water vending machines deliver quality water to a customer on par with bottled water at a fraction of the cost, generally costing in the range of 25 to 50 cents per gallon of treated water.

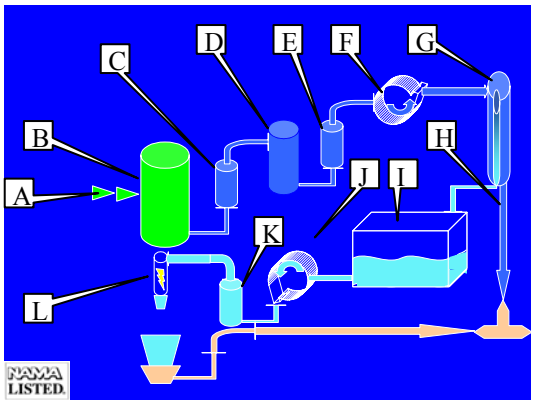
When using a typical water vending machine a customer brings his or her own bottle; this helps reduce the cost of the water to the customer. At many locations where the machine is installed in a controlled location, such as inside a store, water bottles are available for a one-time purchase at the machine, which the customer can then reuse for future purchases.

Water Vending machines always use water from a federally regulated municipal water source. Through a combination of water filtration and treatment technologies the machine removes many of the undesirable elements—as seen by the public—left in the municipal water.

The U.S. Environmental Protection Agency regulates public water supplies through the National Drinking Water Act. Within the Act, Primary Drinking Water Standards have been set covering microorganisms, disinfection byproducts, disinfectants, inorganic chemicals and organic chemicals. These standards protect public health by limiting the levels of contaminants in drinking water. Compliance with these standards are mandatory and must be met by the water supplier.

The Act also contains Secondary Drinking Water Standards relating to items that may cause cosmetic effects (tooth discoloration) and aesthetic effects (such as taste, odor or color) in drinking water. These standards are recommended, the water suppliers are not required to comply. The following chart shows how a water vending machine does its work to produce great-tasting drinking water.

Here is what happens in a water vending machine:



A. The vending machine is protected by an approved back-flow preventor.
B. If the incoming water is of really poor quality, the manu-facturer will install a water softener to help the filters and reverse osmosis (RO) membrane last longer.
C. The first sedimentation filter removes larger particles.
D. The activated carbon filter removes organic chemicals and chlorine. It is important that the chlorine is removed here or it will destroy the RO membrane.
E. A secondary polishing filter removes finer particles.
F. The booster pump creates enough pressure to force the water through the reverse osmosis unit
G. Here the Total Dissolved Solids (TDS) are removed, such as the inorganic chemicals.
H. About half of the water goes through the membrane. The other half goes to waste. The water going to waste flushes the concentrated TDS off the membrane.
I. The RO does not produce water very quickly, so the water is stored in a tank until vended.
J. A delivery pump is activated when the customer presses a button to fill the bottle.
K. The water goes through a final filter.
L. As a last step the water is disinfected by UV light.

Current trends in water vending manufacturing include items like:

- Bottle rinse cycles
- Ozonization of stored water until vended
- High-tech monitoring for TDS- and UV-intensity output
- Remote telemetry monitoring
- Varied payment methods

While some of these trends enhance the water vending experience others can lead to problems or claims of false advertising. Let us look at each of these trends and some other concerns in water vending.

Bottle rinsing is one of the hottest trends in water vending but also one that can lead to many problems. Customers should always be advised to bring a clean and sanitized bottle when obtaining vended water. The bottle rinse feature, at the very least, encourages customers to bring bottles that may not be clean. Rinsing the bottle is not a substitute for properly cleaning the bottle. Also of concern is the spray pattern on the rinse nozzle. Often the rinse nozzle does not provide adequate spray to reach all parts of the bottle. The manufacturers like to install the rinse nozzle so the bottle is rinsed in the inverted position, allowing the water to drain from the bottle as it is being sprayed into the bottle. This presents a potential cross-connection problem. Many times the nozzle is below the overflow rim of the sink in which it is located. Negative pressure on the water line to the rinse nozzle could lead to backsiphonage of contaminated water. At the very least bottle rinse lines should be separated from other internal plumbing with an approved backflow preventor.

Ozonization of stored water is another new trend. To improve maintenance of the machine as well as the product, water manufacturers are using ozone in conjunction with UV light. Sometimes ozone is injected at the vending nozzle or at the vending stage. This ozone-enriched water helps to prevent algae growth in the vending stage and presents a cleaner machine to the customer. Now some manufacturers are incorporating re-circulation of the stored water with ozone injection. This helps maintain the quality of the already treated water and as a byproduct also provides an ongoing sanitizing process of the water storage tank.

Electronics is starting to play a big part in water vending. Some machines now incorporate both ongoing TDS- and UV-intensity monitoring, helping to ensure both the quality and safety of the water vended. When it comes to UV monitoring these new devices can range from simple day counters reminding the service technician how many days remain until the UV lamp needs to be changed to actually monitoring the intensity output of the lamp and shutting down the machine when the water is no longer being adequately disinfected.

Electronics also allow vending machine operators to remotely monitor many aspects of the vending operation from their office. Items like the amount of money in the machine, number of gallons vended, performance or status of the machine, and which filters need to be changed can now be determined before making a service call. Service technicians now know what to bring along on their daily service rounds to maintain the machines before leaving the office.

Different payment options are now being explored. In addition to the standard coin acceptors and bill validators tokens are being used. This encourages the customers to return to the same machine. When tokens are purchased the customer often receives a discount, making for repeat business. Sometimes the water vending machine is located with an array of other vending machines. To make purchasing easier a debit card payment system can be installed where the customer purchases a pre-paid card that can be used on all the machines in that

location. This eliminates the need for the customer to carry lots of coins or use the change machine in order to use different vending machines. The customer simply uses a debit card in all the machines. In very busy locations some machines will now accept credit cards for payment.

In addition to the current trends in water vending there are some hidden dangers in water vending machines pertaining to improperly constructed machines. The diagram depicts a common cross-connection that exists in many machines, that is between the RO reject water and the machine's internal sump. The internal sump collects spilled water from the vending stage spill tray. When the sump pump runs, it could force the contaminated water back up the RO membrane and even back to the incoming water supply. This could cause contaminated water to not only destroy the RO membrane but also force the same wastewater into the municipal supply. Thus, the installation of an approved backflow preventor is required.

In order to assure consumers and public health officials that water vending machines meet government regulations, the National Automatic Merchandising Association (NAMA) added construction and performance requirements for water vending machines to its "Standard for the Sanitary Design and Construction of Food and Beverage Vending Machines" (Construction Standard) in 1983. NAMA is a leader in water vending machine certification. States like Ohio, Minnesota, Pennsylvania, and California only accept machines that carry a third-party Certification Mark such as the NAMA Service Mark shown here. To see the current Listing of Certified vending machines please visit www.vending.org/evaluation.

NAMA has been evaluating food and beverage vending machines since 1957. The Automatic Merchandising Health and Industry Council (AMHIC) is a NAMA advisory group overseeing the NAMA Vending Machine Evaluation Program. Its members represent federal, state and local regulatory agencies, three branches of the Armed Forces and vending industry representatives from manufacturers, operators and suppliers. This Council helps to ensure the NAMA Construction Standard is current with the latest edition of the FDA Food Code requirements pertaining to food and beverage machines. AMHIC also advises NAMA concerning other health and safety matters.

Should you have specific questions about the NAMA Vending Machine Evaluation Program, please contact either of the authors:

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PARTNERSHIP FOR FOOD SAFETY EDUCATION: STEPPED-UP MEMBER ENGAGEMENT A PRIORITY IN 2005

Shelley Feist
Executive Director, Partnership for Food Safety Education

The Partnership for Food Safety Education has begun an aggressive effort to step-up national dissemination of the FightBAC!® campaign's basic four safe food handling messages through the member networks of professional health and nutrition organizations and food industry associations.

In 2005 the Partnership plans to launch focused cooperative outreach with three leading national organizations — all existing members of the Partnership: The Association of Food and Drug Officials (AFDO), The American Dietetic Association (ADA), and the School Nutrition Association (SNA). Members of these organizations have traditionally been users of the FightBAC!® safe food-handling campaign originally launched in 1998.

The Partnership's Outreach Working Group, led by Kathy Means of the Produce Marketing Association, is in the process of developing specific engagement strategies for discussion with AFDO, ADA and SNA. The aim is to make sure the Partnership is providing the kinds of tools, in appropriate formats, that will 1) help AFDO, ADA and SNA members carry out their work in food safety, and 2) to explore ways in which to maximize dissemination of the basic four food safety messages of COOK, CLEAN, CHILL and SEPARATE in the coming year. The Partnership is interested in engaging members of these organizations as BACFighters!—providing them with food safety education news and tools and, in turn, inviting them to individually weigh in on improving delivery mechanisms and formats for FightBAC! campaign messages and materials.

AFDO and ADA have been active with the Partnership since its beginnings in 1997. In that year a Memorandum of Understanding signed by federal agencies, industry associations and health and consumer non-profits set out a framework for cooperation among the parties. They recognized that "a unifying theme and basic set of simple, common and meaningful messages [was] needed to raise consumers' consciousness and motivate them to pay attention and improve their food handling behavior." The School Nutrition Association joined the Partnership in February 2005.

The October 2003 hiring of the Partnership's first full-time executive director has made possible a strengthening of the organization's administrative budget through recruitment of eight new members and a 100% retention rate for existing members in 2004. Membership revenue in 2004 was 60 percent higher than 2003 levels, and the Partnership relies on membership income for its basic annual operations.

FightBAC! program development and dissemination is made possible through a combination of private underwriting, in-kind member and aligned organization efforts, and federal grants.

At its annual strategic planning meeting February 3 in Washington, the Partnership identified *Member and Aligned Organization Engagement* as a priority for 2005. Members and federal liaison representatives discussed the power of the "credible coalition" that retains public, private, consumer, and health professional involvement as members as well as in the program development and dissemination work of the Partnership.

In 2005 the Partnership will engage member and other aligned organizations in a high-visibility initiative tentatively titled "Project CHILL". The initiative is aimed at helping to support the goal of the Federal agency partners— the USDA, FDA and CDC—to reduce the incidence of foodborne *listeriosis* fifty percent by the end of 2005.

Project CHILL will raise awareness among consumers of the importance of keeping the home refrigerator at 40º F or below and of utilizing a thermometer to monitor refrigerator temperature. The Partnership will produce consumer-tested messages and materials, creatively and broadly disseminated through its member networks (including national retail grocery stores and restaurants, professional dieticians, and school food service), through USDA and FDA food safety education activities and communications vehicles, state agencies and paid and earned media.

AFDO members will get an update on the Partnership's 2005 program priorities in the near future.

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.

ASSOCIATION OF FOOD AND DRUG OFFICIALS
MEMBERSHIP APPLICATION

MEMBERSHIP INFORMATION:

Name_____

Title_____

Organization_____

Address_____

City _____ State_____ Zip_____

Telephone_____ Fax_____

Email_____

1. Individual Membership:

Individual Members	On-line Journal	Journal
Alumni/Students	☐ $50	☐ $65
Regulatory	☐ $50	☐ $85
Consumers/Educational	☐ $50	☐ $85
Small Business/Consultants	☐ $225	☐ $275
Associate Industry	☐ $325	☐ $375

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

# of Group Members	Government	Non-Government
5-10	☐ $46 each	☐ $300 each ☐
11-20	☐ $44 each	☐ $285 each ☐
21-50	☐ $42 each	☐ $270 each ☐
Greater than 50	☐ $40 each	☐ $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 CONFERENCE SCHEDULE

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

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

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

What Will You Learn at The AFDO 2005 Annual Educational Conference?

Food Safety & Security

- Innovative Food Security Initiatives—A session will focus on the highlights of several current initiatives in the areas of food security and emergency preparedness.

- Demystifying Food Defense—Representatives from the National Center for Food Protection and Defense will discuss the past, present and future of the food system relative to 1) Preparedness and Prevention; 2) Response and Recovery; 3) Risk Communication; and 4) Education, as well as applied science for food protection and defense.

- The National Incident Management System—Its evolution, importance and necessity from the food and agriculture perspectives.

- Food and Agriculture Security: Are They on the Radar Screens of Our State Homeland Security Directors? There will be an interactive panel discussion on food and agriculture security and the critical significance of maintaining these issues.

Drugs & Devices

- MethWatch Program—Learn about the Consumer Healthcare Product Association's program developed to assist retailers in identifying and preventing theft of products used to manufacture methamphetamines.

- Illegal Methamphetamine Production and Pseudoephedrine Sales

  - The Kansas Experience – Kansas has instituted the MethWatch program, but they also have pending legislation on stricter controls for pseudoephedrine.

  - Oklahoma is the only state so far to place pseudoephedrine-containing over-the-counter drugs into Schedule V of their state's controlled substances list.

For more information on AFDO's Annual Conference, visit AFDO's website at www.afdo.com.

JOURNAL

Association of Food and Drug Officials

2550 Kingston Road, Suite 311, York, PA 17402

2005 ANNUAL CONFERENCE
Kansas City, MO
June 4–8, 2005