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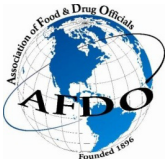

Journal
of the
Association of Food and Drug Officials

Serving the regulatory community since January 1937

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2550 Kingston Road, Suite 311 ◆ York, PA 17402
Phone 717-757-2888 ◆ Fax 717-650-3650 ◆ www.afdo.org

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Phone 717-757-2888 ◆ Fax 717-650-3650 ◆ www.afdo.org

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49 W. Michigan Avenue, Suite 300 ◆ Battle Creek, Michigan 49017
Phone 269-441-2995 ◆ Fax 269-441-2996 ◆ www.ifpti.org

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Reaping the Rewards of the Fellowship Program

Joseph Corby, AFDO Executive Director

Some have suggested that it's a great succession plan, and others have said it's a foundation for producing tomorrow's food safety leaders. Everyone agrees, however, that the Fellowship for Food Protection program was the right thing to do and the right time to do it. It will produce benefits to AFDO for many years to come.

This year's Fellows have produced some very important and instrumental projects to report on at our Annual Conference in Providence, Rhode Island. Once again, this Special Edition of the AFDO Journal is dedicated to these future leaders and their project reports. This year a number of the research projects have resulted in some very useful and positive food protection efforts. One research project relating to the Food Safety Modernization Act has already been shared with the Food Safety Preventive Controls Alliance, as it validates the critical need to conduct outreach and training to affected businesses. Three other research projects were so revealing that they resulted in AFDO resolutions to be voted on at this year's conference. There were another three research projects involving cottage foods which offered very strong support to our recently published guidance document on the same topic. We even provided these three individuals the opportunity to present their projects during the general session of our conference. Other projects concerning raw milk, local health agency inspection data, and Indian Health inspections provide important informative lessons for the food protection community as well. AFDO could not be happier with the effects the Fellowship program and research projects have had on our organization. Once again, we offer our congratulations and sincere gratitude to all the Fellows from Cohort #2.

We should not forget those who went before them, however. We are pleased that nine of the 10 Fellows from Cohort #1 are planning to attend this year's Annual AFDO Conference. A few of these individuals will be speaking during our general session on food safety prevention efforts. Several of these individuals have become very active in AFDO Committees and Affiliate activities. They will be the future leaders of AFDO and the food safety program they represent.

Yesterday we seemed to ask the same people to perform the same functions for the many activities this organization is asked to lead or participate in. Today, because of IFPTI and the Fellowship for Food Protection program, our ranks have become larger, and more and more food safety officials hunger to participate.

AFDO has always found a way to lead. Look no further than the current integration effort that exists in this country. We have always succeeded because of the wealth of individuals in this organization who are true and natural leaders. How great it is to now expand the number of these individuals that have fallen upon us through the Fellowship for Food Protection program.

We are very fortunate, and we are very grateful.

About the Fellowship in Food Protection

Gerald Wojtala, Executive Director of IFPTI

Last year's Special Edition of the AFDO journal articulated the need, in light of the 2011 enactment of The Food Safety Modernization Act (FSMA), for a program such as the *Applied Science, Law, and Policy: Fellowship in Food Protection* program developed by the International Food Protection Training Institute (IFPTI), a division of the Global Food Protection Institute (GFPI). The aim of the Fellowship program is to help shape future leaders by training the Fellows in competencies called for in a national integrated food safety system and in an increasingly global food system.

Federal, state, local, tribal, and territorial food safety regulators who have worked in the food safety field for several years and who have completed the ORAU Level I curriculum as well as the AFDO/FDA *Application of the Basics of Inspection and Investigation* course (or equivalent training) submit applications that are formally evaluated by the Fellowship applicant review committee, comprised of experienced leaders in food protection. Once selected, Fellows are matched with mentors (who also serve as subject matter experts and instructors) from professionally and geographically diverse backgrounds. In addition to a good mix of state and local food safety professionals, Cohort II included a Federal food safety professional from the Indian Health Services.

In addition to teaching the courses conducted during three week-long, seminar-style sessions held in Battle Creek (Michigan) over a year-long period, mentors also work closely with the Fellows to guide the future leaders in the topic/issue selection, creation of research project proposal, project development and implementation, analysis of research data, and submittal of research projects in the form of journal-quality articles (as printed in this Special Edition of the AFDO journal), PowerPoint presentations (as delivered by the Fellows to committee meetings at the AFDO Annual Educational Conference), and educational posters (as displayed at the AFDO conference).

The Fellowship Program is comprised of six courses covering content areas that complement the research project: 1) Food Law; 2) Compliance; 3) Policies, Strategies, and Tools; 4) The Impact of Science; 5) Food System Control Applications; and 6) Prevention, Intervention, and Response. Each week-long session delivers two courses, for a total of three week-long seminar-style sessions in Battle Creek, Michigan. The year-long program is capped off by Fellows' attendance at the AFDO Annual Educational Conference where the graduating participants deliver research project presentations in committee meetings, answer questions about their posters, and continue to add to the network of skilled professionals that the Fellows have been building during their participation in the Fellowship program.

Throughout the duration of the first year of the Fellowship program, assessment tools and evaluation mechanisms were implemented to ensure continual improvement in the program. Input and feedback were sought from Fellows, instructors, IFPTI staff members, and external stakeholders; as a result, the following modifications were made (among others) for cohort II of the Fellowship program:

1. Three instructor-mentors were added to the original group of Fellowship instructor-mentors to broaden the breadth and depth of expertise available to the Fellows and to the program.

2. The research project process was moved up in the timeline for cohort II to allow the Fellows adequate time to propose, research, and present their topics of study.

3. Fellows were required to deliver PowerPoint presentations about their projects during each week-long seminar session in Battle Creek, Michigan to demonstrate their progress on their projects; provide the instructors, Fellows, and IFPTI support staff an opportunity to provide feedback; and to provide opportunities to sharpen their presentation skills prior to final research project presentations at the AFDO Annual Educational Conference.

4. Brown Bag Webinars were added to the curriculum to support the Fellows and their mentors in the progressive development of the Fellows' research projects. The webinars were developed and delivered over the course of the year by Acting Director of Evaluation and Assessment, Dr. Kieran Fogarty.

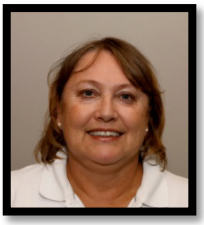
5. A learning management system (LMS) was implemented to facilitate posting of curriculum materials (reading lists, articles, templates, cohort I Fellows' articles, etc.), as well as administration of pre- and post-course assessments, course evaluations, pre- and post-course conceptual framework assessments, and post-program evaluations.

6. Modules were reviewed and updated, as needed, to target higher levels within Bloom's taxonomy of educational objectives (i.e., mid-range levels, such as Application and Analysis, rather than lower-range levels, such as Knowledge and Comprehension). Modules were also reviewed and modified to provide for greater interactivity with the intention of successfully engaging the adult participants.

7. As part of the Fellowship program, Fellows complete a pre- and post-program conceptual framework assessment that focuses on the six core competencies that are foundational to the program. Based on an internal review of the conceptual framework assessment results from cohort I, and comparison of the Fellows' assessment results against benchmark results obtained from leaders in the food safety regulatory field, the following curriculum changes were made: Food Law and Food Labeling Law were combined into one course, Applied Law; Compliance was added to replace the dropped course; and modules were added, deleted, combined or separated out to strengthen the program and better address the needs of future leaders in the food safety regulatory community, based on recommendations from the subject matter experts.

With the Fellowship approaching its third year, the staff at IFPTI is proud to have attracted so many talented individuals from across the country. This Fellowship program will encourage and support the Fellows as they develop into the next generation of regulatory officials dedicated to leading the protection of the U.S. food supply.

The Fellowship program's instructors and mentors are professionals with extensive food protection experience. Responsible for teaching the seminars, providing experienced insight, and guiding Fellows in their individual research projects throughout the year, IFPTI's experienced instructors are the crux of the Fellowship program. Additional instructors and guest lecturers also provide experience and insight into specific areas of study. Below are the Fellowship's official program instructors and mentors.

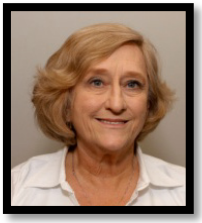


Dr. Joanne M. Brown has over 38 years of experience in food safety, animal disease, public health, and emergency preparedness. She graduated from the University of Minnesota's College of Veterinary Medicine, has a master's degree in veterinary microbiology from Texas A&M University, and is a Diplomat in the American College of Veterinary Preventive Medicine and a Distinguished Practitioner of the National Academies of Practice (retired). She spent over 26 years in the Army Veterinary Corps and retired with the rank of Colonel. Her last two Army assignments were Chief, Department of Veterinary Sciences, Army Medical Center and School, where she was responsible for basic and advanced training of enlisted soldiers and officers in the US Army Veterinary Services and Director of the Department of Defense Veterinary Laboratories. As Director she had oversight of food microbiology, food chemistry, and animal diagnostic testing for laboratories in the US, Panama, and Germany.

Dr. Brown joined the Florida Department of Agriculture and Consumer Services in 1999 as the Chief, Bureau of Food and Chemical Residue Laboratories. During her tenure as chief she initiated the process to attain the American Association of Laboratory Accreditation and renovation of the food laboratory into a bio-safety level 3 laboratory. In 2002 she was appointed as Director of the newly-created Office of Bio and Food Security Preparedness (now Office of Agriculture Emergency Preparedness), which had oversight for emergency preparedness and was the liaison with the State Domestic Security Task Force.

In 2004, Dr. Brown became the Deputy Commissioner for Food Safety with oversight for the Divisions of Food Safety, Dairy Industry, and Agricultural Environmental Services and served until her retirement in January 2011. She has worked in positions of leadership in food safety, food defense, domestic security preparedness, state food safety policy planning, and public health. As the agriculture representative on the executive board of the State Working Group for Domestic Security, she helped secure federal domestic security funding for the department. She was the Chair, Florida Food Safety and Food Defense Advisory Council from 2004 – 2005 and remained the agriculture representative until her retirement.

Dr. Brown is a member of AFDO and the Chair of the Awards Committee from 2007 to 2011. She is a past president and lifetime member of AFDOSS and remains active in the organization.



Charlene Bruce recently retired after serving for thirty years with the Mississippi State Department of Health. For the past twenty years she has served as the Director of the Food Protection Program for the state-wide Food Retail and Food Processing Programs. Prior to becoming the Director of the Food Program, she served as an FDA Rating Officer for both the Milk and Food Programs. Under her leadership, the Food Program became one of the first in the nation to develop and implement a risk-based inspection program, to require manager certification in all food facilities, and to enroll in and begin implementation of the FDA Voluntary National Retail Food Regulatory Program Standards and to incorporate HACCP principles into the routine inspectional program. Mississippi State Department was one of the first programs to adopt the original FDA Food Code in 1993 and to lead the country as the first state program to adopt the 2009 Food Code.

As a commissioned officer with FDA, Charlene coordinated numerous joint investigations with the FDA Southeast Region and New Orleans District. As a result, Charlene's Agency was the recipient of the FDA's Commissioner's Special Citation Award and the Hammer Award. The food program in Mississippi is actively involved in the implementation of the FDA Manufacturing Food Program Standards.

Charlene served as President of the Association of Food and Drug Officials (AFDO) and currently serves as President of the Association of Food and Drug Officials of the Southern States (AFDOSS). She was awarded the Eugene H. Holeman Award for outstanding service to AFDOSS. The Mississippi State Department of Health awarded her the Public Health Environmentalist of the Year award. She has served on numerous AFDO and AFDOSS committees and is presently the Chair of the Education and Training Committee. Following Hurricane Katrina, USDA presented Charlene with the Gulf Relief/Supporting our Neighboring Communities medal.

Charlene has been involved in training and advisory positions with the Conference for Food Protection (CFP), the National Environmental Health Association (NEHA), the National Association of County and City Health Officials (NACCHO), and the Food and Drug Administration (FDA) Training Branch. Charlene received her B.S. Degree from The University of Southern Mississippi and her M.S. Degree in Food and Dairy Science from Mississippi State University.

J. Joseph Corby is the Executive Director, Association of Food and Drug Officials, following a 37½-year career with the New York State Department of Agriculture and Markets, Division of Food Safety and Inspection. After receiving his Environmental Health degree in 1970, Mr. Corby became a Food Inspector with the Department in the Syracuse, NY, area. Following promotions to Senior Food Inspector in Buffalo, NY, in 1975, Supervising Inspector in Albany, NY, in 1984, Director of Field Operations in 1989, and Assistant Director in 1994, he was appointed Director of the Division of Food Safety & Inspection in 1999 until he retired in May of 2008. His service with the Department included the development of numerous food safety training programs for regulators and industry, the design of the Division's risk-based inspection system, and authoring the state's smoked fish

regulations. He was nominated four consecutive years for the Governor's Productivity Award.

Mr. Corby was an FDA Commissioned Officer and a Cornell University Certified Instructor for Human Resources Development. He also served as Faculty Advisor for Food Processing Technology at SUNY Morrisville and was a member of Cornell University's Institute of Food Science Advisory Council. He was a frequent lecturer for the FDA's State Training Branch, where he spoke on Seafood Safety, Vacuum Packaging, Meat and Poultry Processing, and Retail Food Protection issues.

Mr. Corby has been a member of the Central Atlantic States Association (CASA) of Food and Drug Officials since 1975 and has served as the Niagara Frontier Conference President, North East New York Conference Executive Board Representative, and CASA President. He was awarded the coveted CASA Award in 1991, CASA Service Recognition Award in 1992, and CASA Lifetime Achievement Award in 2008. The New York State Association of Food Protection awarded him the prestigious William V. Hickey Award in 1995 for outstanding service in the field of food sanitation and the Emmitt Gauhn Award, which is the New York State Association's highest award.

A member of AFDO since 1985, Mr. Corby was the Chairperson for the Food Committee, where he spearheaded the development of several model codes, food processing guidelines for industry and government regulators, training programs, AFDO's Food Code Pocket Guide, and official AFDO comments to national food safety issues. In addition to the Food Committee, he continues to serve on AFDO's Seafood Committee, International and Government Relations Committee, Meat and Poultry Committee, and FoodSHIELD Steering Committee. He was awarded AFDO's Distinguished Service Award in 1995 and 2000 and became President of AFDO in June of 1998. He has also received the prestigious Harvey W. Wiley Award on June 19, 2001, and AFDO's Lifetime Achievement Award on June 16, 2008.

Mr. Corby continues to work on a part-time basis for FDA's State Training Branch. He is also a member of the University of Florida's Food Science & Human Nutrition Advisory Council.

Neal Fortin has more than 20 years of experience in the area of food and drug law and agricultural regulatory law. He has considerable experience advising firms on related regulatory matters, such as labeling, licensing and registration, GMP compliance, regulatory agency enforcement actions, product claim substantiation, product recalls, and analysis of regulatory changes. Mr. Fortin also has extensive experience providing educational services to firms on these regulatory issues. Mr. Fortin is a professor at Michigan State University's College of Agriculture and Natural Resources and lead instructor for the internet course, "Food Regulation in the United States," for the Institute of Food Laws & Regulations. He is also an adjunct professor at Michigan State University's College of Law, where he teaches Food and Drug Law.

Mr. Fortin earned his Juris Doctor degree Summa Cum Laude from Michigan State University's College of Law. He is licensed as an attorney in Michigan. He is a member of

the Food and Drug Law Institute, the Institute of Food Technologists, and the State Bar of Michigan.

Jim Sevchik retired from the New York State Department of Agriculture and Markets after 33 years of public service. He served for 18 years as Chief Inspector for the Division of Food Safety and Inspection where his duties included the supervision of field inspection activities for the Upstate District, with field offices in Buffalo, Rochester, and Syracuse, New York.

As a commissioned officer with FDA, Mr. Sevchik coordinated numerous joint investigations with this agency. He is the recipient of three Commissioner's Special Citation Awards from FDA and the Hammer Award from Vice President Al Gore for developing a national training program on imported foods. Mr. Sevchik frequently presented courses for FDA's Office of Human Resource Development on food labeling, vacuum packaging, and potentially hazardous foods.

Mr. Sevchik is a Past-President of AFDO and the Central Atlantic States Association (CASA) of Drug Officials. He was awarded the Harvey W. Wiley Award and CASA Award from these associations. He also served as Chair of the Food Committee for the New York State Association of Food Protection and was presented with the William Hickey Award for his work on food safety.

After retiring from New York, Mr. Sevchik served as Training Director for AFDO. During his tenure, he designed and managed national training programs that addressed regulatory concerns for food safety, dietary supplements, imports, drugs, medical devices, and body art safety. Mr. Sevchik received his B.S. degree from State University of New York at Buffalo.

Cameron Smoak joined the Georgia Department of Agriculture in 1976, serving in various positions within the agency over a period of 30 plus years. He served as the Assistant Commissioner of the Georgia Department of Agriculture's Consumer Protection Division from 1995 until his retirement on January 31, 2007. In that capacity, he managed the field inspection forces responsible for the enforcement of rules and regulations relating to food processing, retail food sales, and fuel and measures designed to protect Georgia consumers. He supervised a staff of over 230 inspectors, specialists, and support personnel. Additionally, he served as a member of the Agriculture Department's legislative liaison team for over 28 years.

Mr. Smoak served for many years as the Department of Agriculture's liaison to the Georgia Emergency Management Agency and has extensive experience in crisis management. His emergency work included coordinating relief efforts relating to livestock welfare, food and water wholesomeness, and sanitation when Georgia was impacted by tornadoes, hurricanes, and other disasters, including the 1994 flood–one of the state's most extensive and costly disasters. He worked with local and federal counterparts in coordinating food safety efforts for two international events hosted in Georgia–the 1996 Olympics and the G8 Summit held in 2004.

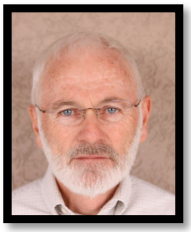
Mr. Smoak has served as a member of the Georgia Homeland Security's Agriculture and Food Defense subcommittee. He is a Past-President of AFDO and the Association of Food and Drug Officials of the Southern States (AFDOSS). He was AFDO's first representative to the Food and Agriculture Sector Government Coordinating Council (GCC) led by the U.S. Department of Homeland Security, USDA, and the FDA. In addition, he has been a member of AFDO's Seafood HACCP Training Program Certification Committee and Chairman of the Association's Rules and Regulations Committee.

Mr. Smoak currently works as a consultant in the area of food safety, food defense, and crisis management. His consultancy projects include work with WinWam Software Inc.; Uriah Group; USAID; the Georgia Department of Agriculture; CRA, Inc.; the University of California-Davis' Western Institution for Food Safety & Security; the University of Tennessee's Center for Agriculture and Food Security and Preparedness; and the Louisiana State University National Center for Biomedical Research and Training. The USAID project involved foreign travel to Egypt as part of a project to establish a new single food safety agency. The purpose of the new food safety agency is to help improve Egypt's domestic food safety and to enhance their international reputation for the safety of food products processed and exported by Egyptian businesses. He served as the expatriate consultant on the Inspection Work Group responsible for setting up the new field inspectional sector of the food safety agency.

Dan Sowards recently retired as the Food and Drug Safety Officer for the Texas Department of State Health Services, after having worked for the agency for 36 years in the area of food and drug protection. He has served in every capacity related to this field, including Division Director for Manufactured Foods and for the Drugs and Medical Devices Division. During these years, he has been responsible for the inspection of more than 18,000 food, drug, and medical device manufacturers and wholesale distributors in Texas and, in the early 1990s, developed the first risk-based inspection program among the states. In 2002, he took a short leave from his position to develop an in-house process and decision tree for dealing with intentional contamination of the food and drug supply.

Mr. Sowards is a Past-President of AFDO and was the recipient of the Harvey Wiley Award, the highest honor bestowed by that organization. He is an active member of four AFDO committees, the AFDO training coordinator, and previous chair of the Resolutions Committee. Dan was twice President of the AFDO regional affiliate organization, the Mid-Continental Association of Food and Drug Officials (MCAFDO).

During his many years of service, Mr. Sowards has spoken at national settings on many occasions, and written for such publications as the New York Bar Association, the Food and Drug Law Institute's FDLI Update, and the Journal for Food Protection. He has participated in numerous forums for FDLI, Food Update, and for the FDA. Mr. Sowards was a Work Group Chair for the National Food Safety Initiative under President Clinton and has provided many comments to the FDA on various food safety issues, including the development of the original FDA Food Code. Mr. Sowards is also a Fellow in the Texas Environmental Health Association and a member of the Central Texas Counter-Terrorism Work Group chaired by the FBI.



Steve Steinhoff worked as a food safety professional in the Division of Food Safety at the Wisconsin Department of Agriculture, Trade and Consumer Protection for 36 years; for more than 18 of those years as the division's administrator. As Administrator of the Division of Food Safety, he managed all facets of state-wide programs in the areas of manufactured food, retail food, meat inspection, dairy manufacturing, and dairy production. In this managerial role, he was responsible for management of the division's budget and personnel functions as well as liaison and active collaboration with other divisions, the Office of the Secretary, other state and federal agencies, and the legislature.

Mr. Steinhoff was an active member of the federal-state team that authored the FDA's Manufactured Food Regulatory Program Standards. He also was a member of an FDA cadre that delivered training to both federal and state food safety regulatory personnel on auditing state manufactured food regulatory programs. Currently, Mr. Steinhoff is employed by AFDO on a contract basis and managed the initial development of the International Food Protection Training Institute. Mr. Steinhoff also is employed by the National Center for Biomedical Research and Training (NCBRT) as a trainer for its course entitled, "A Coordinated Response to Food Emergencies: Practice and Execution."

Professionally, Mr. Steinhoff is a Past-President of AFDO, as well as its regional affiliate, the North Central Association of Food and Drug Officials (NCAFDO). He continues to remain active in AFDO projects and committees.

Shana Davis is from Birmingham, AL, and currently resides in Lexington, KY. She received her Bachelor's Degree in Environmental Health Science from Eastern Kentucky University in 2005. She is currently working on her Master's Degree in Public Health from the University of Kentucky, with a projected graduation date of May 2012. After working at the University of Kentucky as a Radiation Safety Specialist, she accepted a position with the Lexington-Fayette County Health Department (LFCHD) in 2006. Shana is currently a Senior Environmental Health Specialist with the LFCHD, and specializes in their Food Safety Program. She is a Primary Responder for the LFCHD, and is also the Health and Medical Coordinator for the Lexington-Fayette County Emergency Operations Center. **Mentor: Joe Corby**

Kristin M. DeMarco Shaw has served as the Health Inspector for Portsmouth, NH, since 2006. Prior to joining the City's Public Health Department, she worked as a research scientist and supervisor in both academic and clinical laboratories. She has presented her research at international science conferences and has also been published in the journal Glycobiology. Kristin has extensive experience in the retail food environment, having worked in food and beverage service for 18 years. She received her Bachelor's Degree in English from Saint Anselm College, a second Bachelor's Degree in Biology from the University of Southern Maine, and is completing her Master's Degree in Applied Immunology/Molecular Biology at the University of Southern Maine. She has also completed extensive graduate course work at the University of New Hampshire in the Public Health Ecology program. She is an active member of the New Hampshire Health Officers Association, the Northern New England Environmental Health Association, the Massachusetts Environmental Health Association, NEHA and AFDO, as well as the American Biorecovery Association. **Mentor: Jim Sevchik**

Jennifer L. Godwin is the Food and Feed Administrator for the North Carolina Department of Agriculture and Consumer Services, Food and Drug Protection Division. Jennifer has been with NCDA&CS for seven years. Jennifer serves several regulatory roles within the Food and Drug Protection Division. She served two years as the Feed Compliance Officer. She has held the role of the Feed Administrator for five years and expanded her role and responsibilities to become the Food and Feed Administrator in 2010. Currently her responsibilities include the oversight and resolution of technical and regulatory issues in both the food and feed programs and managing federal grants and cooperative programs that enhance Food and Feed Safety and Defense program and initiatives within North Carolina.

In addition to her daily duties, Jennifer dedicates herself to extensive outreach programs. The programs include, but are not limited to, the promotion of the Food Safety and Defense program. She provides assistance through the development and management of educational activities such as Food and Feed Safety outreach at events such as the North Carolina State Fair and Got to Be NC Festival. Jennifer has actively participated as a member of the Association of American Feed Control Officials for the past six years. She has assisted in the assembly of the AAFCO Feed Administrator's Seminar and AAFCO Basic Inspector Training Seminar.

Jennifer is from Eastern North Carolina and is a graduate of North Carolina State University. She received her B.S. Degree in Animal Science in 1998 and obtained both her M.S. and Ph. D. in Nutrition in 2002 and 2009, respectively.
Mentor: Cameron Smoak

Roxanne Hill is currently a Food Inspector 2/Supervising Food Inspector with the New York State Department of Agriculture and Markets. She joined the department in December 1997, was promoted to senior food inspector in 2001, and to her current title in 2004. She has received awards from the department in recognition of outstanding performance. Except for a three-year stint as a clerk typist/secretary for Army Community Services and the Veterans Health Administration, most of her career has been associated with food. She worked for fast food restaurants and a supermarket during high school and later for a food shopping/delivery company. Immediately following graduation from high school, Roxanne joined the United States Army as a 91R Food Inspection Specialist. While affiliated with the Army, Roxanne attended the University of South Carolina, City College of Chicago and Trinity University. She is a member of professional associations such as the Central Atlantic States Association (CASA), New York State Association of Food Protection, and Association of Food and Drug Officials (AFDO). **Mentor: Dan Sowards**

Karla Ann Horne completed her Master's of Science Degree in Biology at Stephen F. Austin State University in Nacogdoches, TX, in 2000. The first step in her career was as an Environmental Investigator for the Texas Commission on Environmental Quality regulating public water systems. Karla Ann then proceeded to the U.S. Environmental Protection Agency as an Environmental Scientist for the U.S. Environmental Protection Agency where she was charged with evaluating State Air Quality Implementation Plans to ensure consistency with the Clean Air Act. After moving to Michigan in 2005, she became a Registered Environmental Health Specialist while working for a local health department in rural northern Michigan. Currently, Karla Ann works for the Michigan Department of Agriculture and Rural Development as a Food Safety Field Scientist in Northwest Michigan. She is a member of the National Environmental Health Association, Michigan Environmental Health Association, and Great Lakes Conference on Food Protection. She has been in the Food Safety Field since January 2009 and looks forward to a long and fulfilling career caring for the safety of our state and national food systems. **Mentor: Steve Steinhoff**

LT Aaron McNeill, RPES, is currently an Environmental Health Officer for the Oklahoma City Area Indian Health Service Division of Environmental Health Services. He attended East Central University where he received a Bachelor's of Science Degree in Environmental Health Science in 2006. Aaron recently completed his fourth year with the United States Public Health Service as a Commissioned Corps Environmental Health Officer. He provides food safety services to eleven tribes located in north central and northeastern Oklahoma. Aaron is a Registered Professional Sanitarian with the State of Oklahoma and a member of the Oklahoma Society of Environmental Health Professionals and Oklahoma Food Safety Task Force. He also serves as the FDA Food Program Inspection and Training Officer for the Oklahoma City Area Indian Health Service. **Mentor: Cameron Smoak**

Brenda Morris is an Environmental Administrator for the Florida Department of Agriculture and Consumer Services (FDACS) Food Safety Division. She oversees a staff of 145 field inspectors and supervisors which inspect, permit, and regulate over 48,000 food manufacturing/processing, distribution and retail firms each year. The Food Safety Division conducts over 80,000 inspections each year.

Brenda is a graduate of the University of Georgia with a degree in Environmental Health. Her career in regulatory food safety as an inspector has included the Houston County (Georgia) Health Department, the Lubbock (Texas) City Health Department and the Polk County (Florida) Department of Health. As an Environmental Specialist with the Polk County (Florida) Environmental Engineering Division, she designed and approved systems for the Onsite Sewage Disposal System and Water Quality program. She was the Southeast Regional Food Safety Manager for Sears Holdings covering 6 states, PR and the Virgin Islands. In 2005 she came to FDACS as a Food Safety Specialist inspecting retail and manufacturing facilities in Lakeland, Florida. Brenda is a member of AFDO.
Mentor: Jim Sevchik

Craig Nielsen was raised in the metro-Atlanta area and graduated with a Bachelor of Science Degree in Biology from North Georgia College and State University. In 2001, he began working for the Food Safety Division of the Georgia Department of Agriculture as an Agriculture Sanitarian. After five years of being a field inspector, Craig was promoted to Agriculture Manager over Complaints, Recalls, and Label/Blueprint Reviews. Shortly thereafter, he began working as the Food Safety Division's Operations Analyst, where he oversaw the implementation of computerized inspection software. In 2008, Craig was selected to be the Market Manager of the Atlanta State Farmers' Market. He returned to the Food Safety Division in April of 2011, where he currently serves as the Food Safety Manager over Retail Operations. **Mentor: Joe Corby**

Courtney Rheinhart is the Tidewater Regional Manager for the Virginia Department of Agriculture and Consumer Services (VDACS). In this position she provides first line supervision to Food Safety Specialists; reviews and classifies inspections, investigations, and sample analysis reports from field inspectors; recommends regulatory action; and serves as part of the Program's management team. Courtney has worked with VDACS since July 2007. Prior to that she attended college at Virginia Tech where she earned her Bachelor of Science Degree in Biology. She went on to earn her Master of Science Degree in Food Science (Food Microbiology) from Virginia Tech as well. She conducted her graduate research on Clostridium botulinum toxin development in refrigerated reduced oxygen packaged Croaker fillets. Courtney currently serves as a board member for the Virginia Conference of the Central Atlantic State Association of Food and Drug Officials (CASA). She is also a member of the Association of Food and Drug Officials (AFDO) and Association of the Food and Drug Officials of the Southern States (AFDOSS). **Mentor: Dan Sowards**

Alice Robison graduated from Eastern Washington University with a Bachelor of Science Degree in Biology with a minor in Chemistry. She began her career in food protection as an Environmental Health Specialist with Northeast Tri County Health District in Colville, Washington. Alice conducts food safety inspections at permanent and temporary food establishments in three rural counties. She also conducts foodborne illness investigations and provides education on food safety and regulatory requirements. Alice has been employed with Northeast Tri County Health District for nine years and is now the Food Safety Program Lead.
Mentor: Steve Steinhoff

Jodi Taylor graduated from the Ohio State University, earning a Bachelor's Degree in Agriculture, with a focus in Animal Science. Upon graduation, she work as a pharmaceutical research technician for a large animal veterinarian and then for Battelle Memorial Institute in Columbus, Ohio. Jodi's career in food safety began in 1998, when she accepted a position with the Ohio Department of Agriculture, Division of Meat Inspection, as a Meat Inspector. She moved into the Division's Central Office in 2000 to become part of the support staff, and in June, 2010, was promoted to an Agriculture Inspection Manager. Jodi is responsible for policy development and implementation, and manages the division's sampling and training programs. **Mentor: Dr. Joanne Brown**

Shane Thompson graduated with a Bachelor of Science Degree in Animal and Veterinary Sciences with an Option in Meat Science and Food Technology from the University of Wyoming in May, 2003. After graduating from UW, he managed the Meat Laboratory at the University of Wyoming for five years. While managing this facility, he trained student workers in all facets of the meat industry, including HACCP principles and food safety from slaughter to sales. Also as manager of the facility, Shane helped train health inspectors from the State of Wyoming in Food Safety Regulatory Essentials. He also served as staff supervisor to the Food Science Club, where he educated students in food safety during catering activities. In June, 2008, he began as a supervisor trainee with Cargill Meat Solutions in Fort Morgan, CO. While supervising employees on the slaughter floor, he quickly learned that food safety was an integral part of daily operations, even in the largest of facilities. In February, 2009, he moved back to Wyoming after accepting a position with the Wyoming Department of Agriculture as HACCP Coordinator, where he is still employed today. In his current role, he leads the Consumer Health Services Division's food safety training for both staff and for Wyoming's food and meat establishments in HACCP principles and sanitation SOPs. Shane is a supervisor to two inspection specialists that inspect all types of food establishments from restaurants to meat plants, as well as pools, spas, and daycares. He also reviews and audits all HAACP food safety plans for all meat plants, food processing plants, and retail food establishments in Wyoming. He also conducts Food Safety Assessments at official meat establishments around the state. He has received his CPFS credential and plans to take the REHS exam in June of 2011. He is a member of NEHA (National Environmental Health Association) and WEHA (Wyoming Environmental Health Association). He is a former member of the Institute of Food Technologists, as well as the American Meat Science Association, where he was elected to the Student Board of Directors. While at the University of Wyoming, he was involved with several research experiments, publications, posters, and presentations. **Mentor: Charlene Bruce**

Jennine Wolf is an Environmental Health Specialist for the Environmental Health Department in Washington County, Iowa. In 2006, she became credentialed as a Certified Professional-Food Safety (CP-FS) and credentialed as a Certified Environmental Health Technician (CEHT) through the National Environmental Health Association. She has also become a Certified ServSafe Instructor and Registered ServSafe Examination Proctor through the National Restaurant Association. In 2005, she became standardized as a food inspector through the Iowa Department of Inspection and Appeals. From 2003 to 2007, Ms. Wolf wrote for and received grants through the Iowa Department of Public Health totaling $42,000 to pay for ServSafe classes for segments of the population that serves food to the public but does not require a license. She has also written for and received grants totaling $7,500 from empowerment to pay for ServSafe classes for daycare facilities in Washington County.

In 2005, 2010, and 2011, Ms. Wolf was asked to be a speaker at the Iowa Public Health Conference about the results of her grants and continuing progress with getting food safety education available for daycares. In 2008, she received the Galen Robertson Award given by the Iowa Environmental Association. In 2010, she was asked to be a speaker at the IEHA conference about the results of her grants. In 2011, she received a Fellowship from the International Food Protection Training Institute for her project of food safety education for daycare providers in Iowa. Ms. Wolf is a member of the Iowa Environmental Health Association, Iowa Wastewater Association, Iowa Environmental Health Registry, and the National Environmental Health Association. **Mentor: Cameron Smoak**

Operational Differences That Influence Inspection Scores of Corporate-Owned Versus Privately Owned Restaurants

Shana Davis
Senior Environmental Health Specialist
Lexington-Fayette County Health Department

Abstract
The objective of this study was to compare the differences of corporate-owned restaurants to those of privately owned restaurants, to determine if there is a difference between inspection scores at these establishments in Lexington, Kentucky. The 400 restaurants used for this study were randomly selected from a database developed at the Lexington-Fayette County Health Department (LFCHD), Division of Environmental Health and Protection. Restaurants were determined to be "corporate-owned" or "privately owned" through an assessment of their owner information records. The number of follow-up inspections that were required after a routine inspection was recorded for both types of establishments, with corporate-owned restaurants requiring 61 follow-up inspections and privately owned restaurants requiring 59 follow-up inspections. It was also determined that violations #15 and #17 were more frequently marked during routine inspections at both types of establishments. The "Food Equipment and Utensils" category of the inspection was marked most often during routine inspections at both types of establishments. Large facilities had the highest rate of follow-up inspections among privately owned establishments, while medium-sized facilities had the highest failure rate among corporate-owned establishments. These results suggest that the differences between corporate-owned and privately owned establishments may affect how each type of establishment scores on inspections with the LFCHD.

Background
In Lexington, Kentucky, there are more than 1,200 food service establishments. These food service establishments include places such as sit-down restaurants, carry-out restaurants, and drive-through, fast-food restaurants. Any facility that serves food to the public is required to have two routine inspections conducted by the Lexington-Fayette County Health Department (LFCHD) every year. Additional inspections are also conducted if the LFCHD receives any complaints about illnesses suspected to have resulted from people eating at a particular establishment. Employees at food service establishments are required to uphold certain standards regarding cleanliness and maintenance of equipment, personal hygiene, and food safety practices. These standards are defined under the Kentucky Food, Drug and Cosmetic Act (KRS 217.005 to 217.215, 217.992) and the Kentucky Food Establishment Act and State Retail Food Code (902 KAR 45.005) (Kentucky Department of Public Health, 2011). The LFCHD also enforces the Lexington-Fayette Urban County Board of Health's Regulation 19, which includes additional local food safety requirements for food service establishments, such as Food Manager Certification requirements. Certified food managers are required to be present at food service facilities during all hours of preparation and service to help guide employees toward proper food safety practices and ensure that all state and local regulations are being followed within the facility.

Corporate-owned facilities are identified with corporate brands, whereas privately owned facilities are owned by individuals who do not identify their facility with a corporate brand. There are many differences between the procedures of corporate-owned restaurants and privately owned restaurants, including available resources and training, different types of monitoring programs, and the size of the facility. These differences may have an effect on how each type of establishment operates.

Corporate-owned restaurants typically have many resources within their company from which they can draw guidance on a daily basis. They have guidelines and procedures outlining every process they follow during production and service at their individual facilities to increase the likelihood that they are operating in a safe and approved way (Gapud, 2010). Guidelines and procedures used at corporate-owned restaurants are often developed through corporate-funded research and testing facilities. Many corporations also conduct internal audits to verify that procedures are being followed in accordance with corporate guidelines and food regulations, or they contract with a third-party company to conduct audits of their facilities (Gapud, 2010; Stier, 2009). Audits can be a useful tool to provide an establishment with insight into how to improve facility and ultimately the quality of the food being produced (Powitz, 2009).

Privately owned restaurants typically do not have these types of guidelines or resources, so they must follow the guidance of supervisory individuals employed at their facilities. This lack of defined guidelines has the potential to create inconsistencies between different shifts and employees. Many small, privately owned restaurants cannot afford to conduct internal audits or contract with a third-party company to conduct them (Nagy-Nero, 2007).

One of the most important aspects of running a safe restaurant is having knowledgeable staff. Ideally, corporate-owned and privately owned restaurants would only employ individuals who have completed training on proper personal hygiene and food-handling procedures (Gapud, 2010; Marriott, 1999; Morgan, 2003; Percy, 2009). The LFCHD requires all food service establishments to have a certified food manager present during all hours of preparation and service, and for all other food handlers to possess a LFCHD-issued Food Handler Card (Lexington-Fayette County Health Department [LFCHD], 2011). For the Food Manager Certification, food service workers can choose to obtain either a local or nationally recognized Food Manager Certification. Food handler and food manager certifications are offered through the LFCHD for $10 and $55, respectively. This price is low enough so that employees, even without corporate funding, can afford to attend training courses. Nationally recognized educational organizations, such as ServSafe and the National Registry of Food Safety Professionals, offer classes that cost between $50 and $125 (ServSafe, 2011; National Registry of Food Safety Professionals, 2011). Higher fees could prevent many employees at privately owned restaurants from attending these courses (Gapud, 2010).

Food service establishments can enact monitoring plans as a way to avoid unsafe food practices (Marriott, 1999; Morgan, 2003). These monitoring plans could include completion of food temperature logs, date-marking of potentially hazardous foods, dish-washing temperature logs, and sanitizer concentration logs. Keeping these types of records can greatly decrease or eliminate the presence of health hazards that could potentially harm people that eat at a particular restaurant.

Monitoring plans are widely used in the food service industry, especially among corporate-owned establishments that require each of their franchises to participate in standardized monitoring and tracking practices. Most privately owned facilities, however, either do not have monitoring and tracking plans in place or they do not use them consistently. The lack of required plans at privately owned facilities could be due to a smaller staff that may not have the time to monitor food frequently or to a lack of educational resources the restaurant has to offer staff. The absence of monitoring plans may potentially lead to the use of unsafe practices in the kitchen.

The size of a restaurant could also be a factor in whether an establishment passes inspection. Within a larger facility, for example, there could be a higher demand for large quantities of food, which means more activity in the kitchen. In addition, a larger facility might have more equipment to keep clean and in good repair. There may not be enough employees at a larger establishment to complete all necessary tasks. The effects of size on an establishment could apply to both corporate-owned and privately owned establishments.

If there are violations deemed to be health hazards by the LFCHD during an inspection, the facility must take the proper corrective actions as soon as possible. There are certain violations that require immediate actions to be taken by the manager or owner of a facility. These violations are called "critical violations" and can include, but are not limited to, the following: holding foods at harmful temperatures, employees not using proper hygienic practices, and not properly sanitizing dishes and utensils. If critical violations cannot be corrected immediately, a follow-up inspection must be conducted after 10 days so that the facility can demonstrate to the inspector that the violations have been sufficiently corrected. If the problems have not been corrected by the time the follow-up inspection is conducted, a conference must be held between health department officials and the manager(s) and/or owner(s) of the facility to discuss corrective actions. Closure of the facility and permit suspension are also possible steps for a health department regulator to pursue (Lexington-Fayette County Health Department [LFCHD], 2011).

Problem Statement

The operational differences that exist between corporate-owned and privately owned food service establishments may impact the inspection scores received from the LFCHD. Determining whether there are differences in the scores of corporate-owned and privately owned restaurants and what areas of the inspection are being most affected can help the LFCHD adjust food service training to better fit the needs of the restaurant community.

Research Questions

1. Do privately owned restaurants require more follow-up inspections than corporate-owned restaurants?

2. Are certain violations more commonly marked than others during routine restaurant inspections?

3. Does the size of a restaurant affect the score it receives during a routine inspection?

Methodology

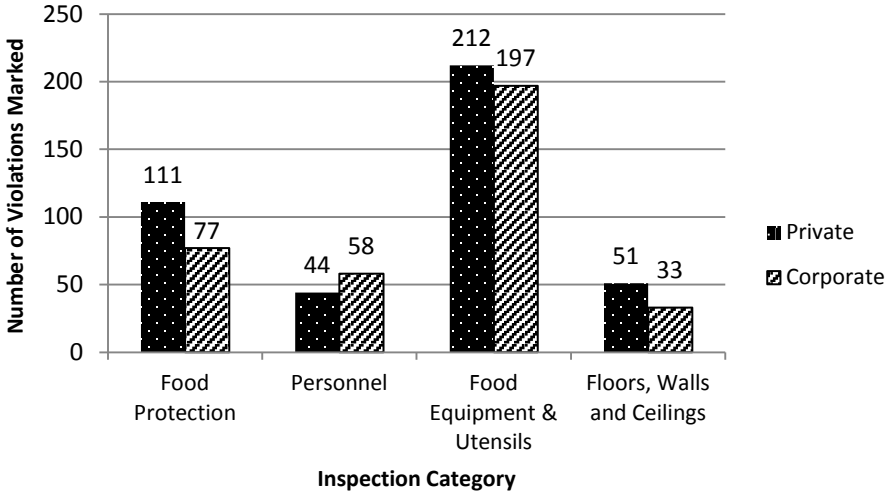
A secondary data analysis was conducted of data obtained from the LFCHD's Division of Environmental Health and Protection regarding the most recent restaurant inspection data from 2011. The inspection details for food service establishments are recorded in a LFCHD database. A random sample of 400 establishments was obtained from this database. The classification of the establishment ("corporate-owned" or "privately owned") was determined by looking at the ownership information for each restaurant. The list was differentiated into 200 corporate-owned restaurants and 200 privately owned restaurants. The information from each restaurant was recorded in a spreadsheet. Whether each establishment required a follow-up inspection after the routine inspection was recorded to determine if corporate-owned or privately-owned restaurants required more follow-up inspections. If a restaurant received a score of 85 or higher without any critical violations on a routine inspection, a follow-up inspection was not needed. If a restaurant received any critical violations, or a score of 84 or lower without any critical violations, a follow-up inspection was required. Next, violations marked during the routine inspection were recorded. This process was used to determine if there were common violations marked among both corporate-owned and privately owned restaurants. Finally, the amount of seating that was registered for each establishment was recorded to see if there was a relationship between inspection scores and the size of the establishment.

Results

Analysis of the inspection data revealed that privately owned restaurants received fewer follow-up inspections than corporate-owned restaurants. Fifty-nine privately owned establishments required follow-up inspections, and 61 corporate-owned establishments required follow-up inspections. A total of 543 violations were marked during routine inspections at privately owned establishments, including 86 critical violations. A total of 452 violations were marked at corporate-owned establishments, including 82 critical violations.

The inspection form used by the LFCHD during inspections consists of 17 categories comprising single or multiple violations (Kentucky Food Service Inspection Form, Appendix A). These 17 categories cover the most important food protection and sanitation principles. Four of the 17 categories contained 783 of the total 995 violations marked during routine inspections at both types of facilities. These four categories were as follows: "Food Protection," "Personnel," "Food Equipment & Utensils," and "Floors, Walls, and Ceilings." Figure 1 displays the number of violations marked during routine inspections at both types of establishments within these four categories.

FIGURE 1: Most Frequent Violation Categories Marked During Routine Inspections



The noncritical and critical violations that were most frequently marked during routine inspections can be found in the "Food Equipment and Utensils" category of the inspection form. The most frequently marked noncritical violation at both corporate-owned and privately owned facilities was #15. The requirements for this part of the inspection are as follows: "Equipment and utensils shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions (FDA, 2005)." Violation #17 was the most frequently marked critical violation at both corporate-owned and privately owned facilities. This section defines proper sanitization levels and requires that "utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning (FDA, 2005)."

The establishments were divided into three size categories: small (0- 100 seats), medium (101- 200 seats), and large (more than 200 seats). Among all establishments, medium- and large-sized facilities required the most follow-up inspections. Among privately owned establishments, 41.7% of the large facilities required a follow-up inspection, while at corporate-owned establishments, 38.5% of the medium-sized facilities required a follow-up inspection. Figure 2 displays the percentage of corporate-owned establishments (divided up by size) that required a follow-up inspection after their most recent routine inspection. Figure 3 displays the percentage of privately owned establishments (divided up by size) that required a follow-up inspection after their most recent routine inspection.

FIGURE 2: Percentage of Corporate-Owned Establishments That Required a Follow-Up Inspection

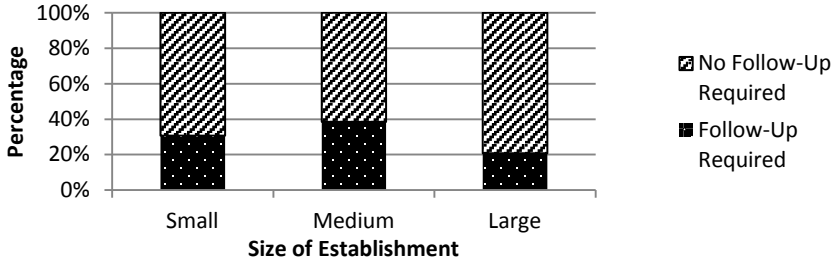
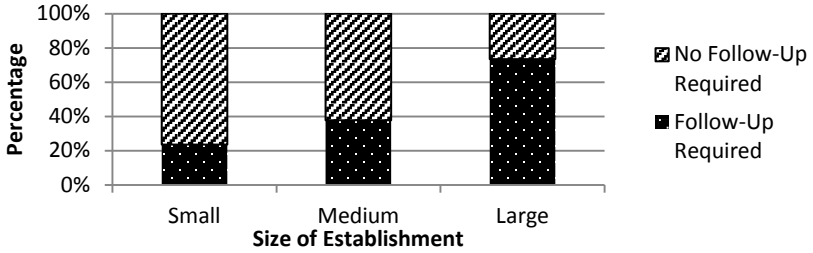


FIGURE 3: Percentage of Privately-Owned Establishments That Required a Follow-Up Inspection



Conclusions

While there were 59 follow-up inspections conducted at privately owned establishments compared with 61 follow-up inspections at corporate-owned establishments, there were 91 more violations marked at privately owned establishments than at corporate-owned establishments. The difference in the number of violations being marked at each type of establishment could be due to the educational and operational differences between corporate-owned and privately owned facilities. The lack of guidelines and corporate requirements for each worker to follow could be a contributing factor for any inconsistencies that arise at a particular privately owned establishment. Having guidelines for employees to follow can aide with consistency from one shift to another.

The most frequently marked noncritical violation (#15) and critical violation (#17) is a direct result of employees not maintaining proper equipment and utensil standards. Ensuring the proper maintenance, cleanliness, and sanitization of equipment and utensils can help reduce the possibility of cross-contamination and the unnecessary spread of harmful microbes and bacteria. Requiring Food Handler Cards and Food Manager Certifications can help the LFCHD ensure that employees are being provided with the proper food handling and sanitation education.

The four most commonly marked violation categories were "Food Protection," "Personnel," "Food Equipment and Utensils," and "Floors, Walls, and Ceilings." Of these four categories, the "Personnel" category was the only one in which corporate-owned establishments were marked more often for violations than privately owned establishments. The "Personnel" category focuses mainly on employees within the restaurant demonstrating proper hygiene practices. A lack of proper hygiene practices could be a result of corporate-owned establishments experiencing issues with high employee turnover rates. If employees are inexperienced in the food service industry, they may not have the appropriate food safety and personal hygiene knowledge that is needed to work in a restaurant.

An examination of the number of violations marked at all 400 establishments in this study suggests that the size of an establishment could be a factor in inspection scores during a regular inspection. The lowest failure rate was observed among the small-sized establishments in both categories. These establishments include facilities with less equipment that requires proper cleaning and sanitization and regular maintenance. Larger facilities, while they have more employees, will most likely have more equipment to clean and sanitize, and will produce larger volumes of food.

Recommendations

The recommendation for the LFCHD, which offers food handler and food manager certification courses, is to modify food safety education courses to add more focus on the violations most frequently marked during routine inspections. The LFCHD should put more emphasis on proper food protection, proper personal hygiene, maintenance and cleanliness of equipment and utensils, and overall facility maintenance and cleanliness. Additions to the LFCHD food safety courses can include diagrams outlining the proper storage of food in coolers, freezers, and storage areas and the proper cleaning and sanitizing of food and nonfood contact surfaces. These diagrams can be distributed during LFCHD food safety courses and during routine inspections for employees to reference while in the kitchen.

Acknowledgements

I would first like to thank my mentor, Joe Corby, for his endless support and expertise throughout this entire process. I extend thanks to everyone, including the other Fellows, at the International Food Protection Training Institute for providing me with a worthwhile experience in the 2011-2012 Fellowship in Food Protection. I would like to say a special thanks to Courtney Rheinhart, Virginia Department of Agriculture and Consumer Services, for her constant encouragement and uplifting words throughout our Fellowship experience. I would also like to thank the Lexington-Fayette County Health Department for allowing me the opportunity to participate in this program. I must thank Dr. David Mannino at the University of Kentucky, College of Public Health, for his guidance throughout this project. Lastly, I would like to thank my family and Ben for their support and patience. Thank you all.

Corresponding Author

Shana Davis, Lexington-Fayette County Health Department (Kentucky)
Email: Shana_Davis76@hotmail.com

APPENDIX A

DFS - 206 (Rev. 01/10)

COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH
FOOD ESTABLISHMENT INSPECTION REPORT

Permit No. | Sanitarian Code

DATE:

Program Code: Food / Retail

Time: Arrival / Depart

Owner | Establishment Name

Address | Zip | Phone

E-mail

Regular 1 Follow-up 2 Complaint 3 Survey 4 Other 5

		FS1	R2
	FOOD SOURCES		
*01	SOURCE, RECORDS, CONDITION, SPOILAGE, ADULTERATED	4	4
02	Container, properly labeled	1	1
	FOOD PROTECTION		
*03	POTENTIALLY HAZARDOUS FOOD - SAFE TEMP.	5	5
04	Facilities to maintain product temp.	2	2
05	Thermometers provided and conspicuous	2	2
06	Potentially hazardous food properly thawed	2	2
*07	POT. HAZARDOUS FOOD NOT RE-SERVED	4	4
08	Food Protection - storage, prep, display, service, transp.	2	2
09	Handling of food (ice) minimized. Dispensing utensils properly stored during use	2	2
	PERSONNEL		
*10	PERSONNEL WITH INFECTIONS RESTRICTED & PROPER REPORTING	5	5
*11	HANDS WASHED AND CLEAN, HYGIENIC PRACTICES PREVENTING CONTAMINATION FROM HANDS	5	5
12	Clean clothes, hair restraints	2	2
*13	SUPERVISION: PERSON IN CHARGE PRESENT AND DEMONSTRATES KNOWLEDGE OF FOOD SAFETY PRINCIPLES	3	3
	FOOD EQUIPMENT & UTENSILS		
*14	FOOD (ICE) CONTACT SURFACES DESIGNED, CONSTRUCTED, MAINTAINED, INSTALLED	3	3
15	Food/Non-food contact surfaces designed, constructed, maintained, installed	1	1
16	Dishwashing facilities, designed, constructed, maintained, installed, located, operated Accurate therm., chem. test kits, gauge	2	2
*17	SANITIZATION RINSE, TEMP., CONCE., EXP. TIME, EQUIP. UTENSILS, SANITIZED	4	4
18	Wiping cloths clean, use restricted	1	1
19	Food/Non-food contact surfaces of equip/utensils clean	1	1
20	Storage, handling of clean equipment/utensils/single service articles	1	1
	WATER		
*21	WATER SOURCE, SAFE, HOT & COLD	5	5
	SEWAGE		
*22	SEWAGE AND WASTE DISPOSAL	4	4
	PLUMBING		
23	Installed, maintained	1	1

		FS1	R2
*24	CROSS-CONNECTION, BACK SIPHONAGE, BACKFLOW	4	4
	TOILET & HANDWASHING FACILITIES		
*25	NO., CONV., DESIGNED, INSTALLED	4	4
26	Toilet rooms enclosed, self-closing doors, fixtures, good repair, clean, tissue, hand cleansers, sanitary towels/hand-drying devices provided, proper waste receptacles	2	2
	GARBAGE DISPOSAL		
27	Containers or receptacles, covered, adequate number, insect/rodent proof, frequency, clean. Outside storage area enclosures property constructed, clean, controlled incineration	2	2
	INSECT, RODENT, ANIMAL CONTROL		
*28	INSECTS/RODENTS - NO BIRDS, TURTLES, OTHER ANIMALS	4	4
	OUTER OPENINGS		
29	Outer openings protected	2	2
	FLOORS, WALLS, CEILINGS & VENTILATION		
30	Floors constructed, drained, clean, good repair, covering installation, easily cleanable	1	1
31	Walls, ceiling, attached equipment constructed, good repair, clean surfaces, easily cleanable Rooms and equipment vented as required	1	1
	LIGHTING		
32	Lighting provided as required, fixtures shielded	1	1
	OTHER OPERATIONS		
*33	TOXIC ITEMS PROPERLY STORED, LABELED, USED	4	4
34	Premises main, free of litter, misc. arbcles, cleaning/ maint. equip. properly stored. Authorized personnel rooms clean, lockers provided, located, used	2	2
35	Separation from living/sleeping quarters. Laundry, clean or soiled linen properly stored	1	1
	CONFORMANCE WITH APPROVED PROCEDURES		
*36	COMPLIANCE WITH VARIANCE, SPECIALIZED PROCESS, AND HACCP PLAN	3	3
	HIGHLY SUSCEPTIBLE POPULATIONS		
*37	PASTEURIZED FOODS USED; PROHIBITED FOODS NOT OFFERED	4	4
	CONSUMER ADVISORY		
*38	CONSUMER ADVISORY PROVIDED FOR RAW OR UNDERCOOKED FOOD	3	3

CHOKE SAVING TECHNIQUES POSTED AS REQUIRED BY KRS 217.285 ☐ YES ☐ NO

REMARKS:

Based on an inspection this day, the items circled above identify the violations found in the operation of your establishment, in accordance with the Kentucky Food, Drug and Cosmetic Act and applicable regulations pursuant there to: the violations must be corrected ☐ by the next routine inspection, or within ☐ _____ days (Circle) 1 Food Service and/or 2 Retail Food. Failure to comply with any time limits for corrections may result in suspension of your permit. An opportunity for an appeal from any notice or inspection findings, will be provided if you file a written request for a conference with the department within the period of time established by the applicable regulation.

RATING SCORE		FOLLOW-UP REQUIRED
1		Y
2		Y

Received By: Name _____
Title _____
Inspected By: _____
_____ HEALTH DEPARTMENT
☐ DEPARTMENT FOR PUBLIC HEALTH

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Food Safety Compliance: A Comparison of New Hampshire Restaurants Based on Ethnic Cuisine Categorization

Kristin M. DeMarco Shaw
Health Inspector
Public Health Department/City of Portsmouth, NH

Abstract
The diversification of the nation continues to evolve, and the population changes in New Hampshire mirror trends taking place across the United States. Although the state's population growth rate is slower than that of the nation, New Hampshire's growth is driven by increases in minority populations (Moore, 2011). The U.S. food service industry employs the highest percentage of foreign-born workers compared with other U.S. industries and this percentage is projected to steadily increase in the next decade (Mauer et al., 2006, National Restaurant Association, 2012). Restaurants are often identified as the source of confirmed foodborne illness-related outbreaks, and the Centers for Disease Control and Prevention reported in 2004 that outbreaks associated with ethnic foods were on the rise (Simonne, 2004). The ethnic food market in New Hampshire continues to grow. This study was designed to identify consistencies in violations cited on inspection of full-service restaurants across New Hampshire and to determine if compliance with the Food Code differs by ethnic cuisine categorization. An analysis of statewide inspection data indicates that the most common violations cited in ethnic restaurants in New Hampshire are for failure to prevent food contamination, poor personal hygiene, and improper temperature control of potentially hazardous foods. However, the results also indicated that issues with hand washing and other good hygienic practices are widespread in the entire food industry, demonstrating a lack of knowledge of safe food handling practices across all restaurant types.

Background
The U.S. Census Bureau has projected that minorities, who currently make up roughly one-third of the U.S. population, will become the majority in 2042 (Bernstein and Edwards, 2008). This increase in ethnic and racial diversity in America is best illustrated by the food service industry, which employs the highest proportion of foreign-born workers within U.S. industries (Mauer et al., 2006). According to the National Restaurant Association (NRA), foreign-born workers account for approximately 25% of food service manager positions and fill approximately 25% of employee positions in food-based occupations. Growth within the restaurant industry is following a similar trend; and 1.4 million jobs are expected to be added to the food industry by 2022 (National Restaurant Association, 2012).

The restaurant industry continues to be an integral part of daily life in the U.S., with over 70 billion meal and snack options served to consumers in 2010 (National Restaurant Association, 2011). A report published by the NRA indicates that "an average of one out of five meals consumed by Americans—4.2 meals per week—is prepared in a commercial setting" (Ebbin, 2000). In 2008, 52% of confirmed foodborne illness-related outbreaks reported to the Centers for Disease Control and Prevention (CDC) were caused by food consumed in a restaurant or deli (Gould et al., 2011).

Separate studies conducted by FoodNet indicated an association between foods consumed outside of the home and "an increased risk for specific foodborne illnesses" (Hedburg et al., 2006). The CDC also reported that foodborne illness outbreaks associated with ethnic foods increased 7% between 1990 and 2000. Most of these outbreaks were linked to Mexican, Italian, and Asian foods, and 43% of all of the outbreaks were attributed to food served in a restaurant (Simonne, 2004). Safe food-handling practices in restaurants are critical to the prevention of foodborne disease transmission and protection of public health.

During the last decade, certain ethnic cuisines have become so popular that they are now considered mainstream. This interest in ethnic foods has led to growth in the number of culturally-focused food establishments, markets, and products. U.S. census data for 2010 indicate that ethnic populations in New Hampshire have increased 2.1% since 2000. First-generation owners and operators of ethnic stores and restaurants tend to lack knowledge of safe food practices (Po, L. G., Bourguin, Occeea, and Po, E. C., 2011). Several studies have been conducted to examine food-handling practices in ethnic restaurants. Mauer et al. (2006) identified improper food temperature control, cross-contamination, and poor hygiene as the most common violations cited in ethnic restaurant operations. Studies by Kwon, Roberts, Shanklin, Liu, and Yen (2010) and Roberts, Kwon, Shanklin, Liu, and Yen (2011) supported these findings and reported that ethnic restaurants were cited for more violations of the Food Code, both critical and non-critical, than non-ethnic restaurants, and experienced a greater frequency of inspection. Both studies stressed the need for food safety training programs that focus on behaviors that could lead to foodborne illness outbreaks in these restaurants.

The CDC surveillance report for 1993-1997 identified food preparation practices and employee behaviors as the most frequently reported contributing factors to foodborne illness (Olsen, 2000). The U.S. Food and Drug Administration (FDA) further defined five of the categories that directly relate to food safety within retail food establishments as "foodborne illness risk factors." These five categories are as follows: Food from Unsafe Sources, Inadequate Cooking, Improper Holding Temperatures, Contaminated Equipment, and Poor Personal Hygiene. These categories are composed of many of the 44 standards (Food Code requirements) that are used by regulatory agencies to monitor food safety compliance within food service establishments.

Problem Statement

Restaurants that serve ethnic cuisine are increasing in New Hampshire, and identification of specific behaviors and practices that are most often out of compliance with Food Code requirements will allow food safety professionals to improve the safety of foods prepared and sold at these establishments. This study is designed to identify consistencies in violations found during inspections of full-service restaurants across New Hampshire and to determine if compliance with the Food Code differs among restaurant types.

Research Questions

1. What violations are most often cited in full-service restaurants in New Hampshire?

2. Do differences in compliance with the Food Code exist among restaurant types?

3. How do the cited violations correlate with the CDC-identified foodborne illness risk factors?

Methodology

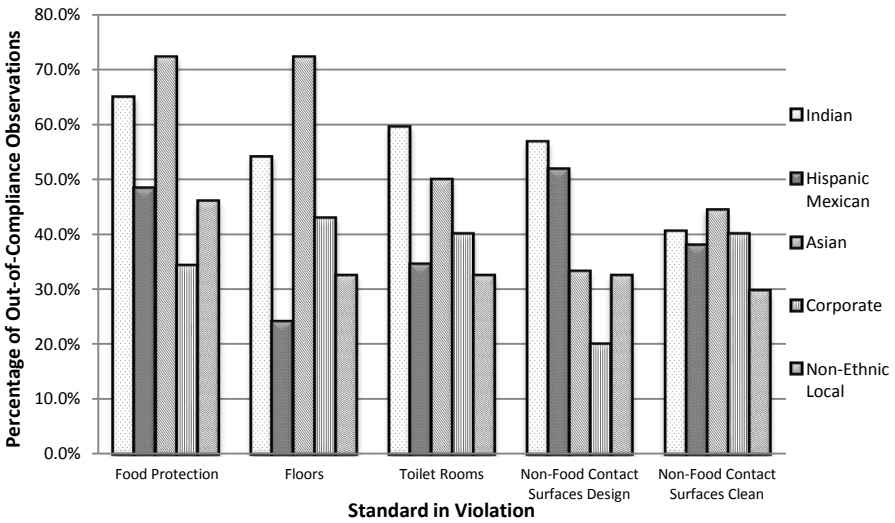
The study population was defined as full-service restaurants in New Hampshire that prepare and serve potentially hazardous food and drinks on premises and that may also offer takeout and/or delivery service. The restaurant types were classified in one of the following categories: Indian, Hispanic/Mexican, Asian (Chinese and Japanese only), corporate, or non-ethnic local. Areas of the state with greater population densities were identified, and restaurants that met the study criteria were randomly selected from these jurisdictions. A secondary data analysis was conducted using statewide restaurant inspection data collected from January 2009 through December 2010. All routine inspections during this period were included in the analysis. Inspections were performed by New Hampshire Food Protection Section Food Safety Coordinators or by local health department employees (depending on jurisdiction) in accordance with rules set forth in the New Hampshire Rules for the Sanitary Production and Distribution of Food (He-P2300).

Inspectors used standardized forms that included 44 items (standards); 13 items were designated as "critical." Critical items are violations "which [are] more likely than other violations to contribute to food contamination, illness, or environmental health hazard[s]" (He-P2300). Inspection reports also contained data such as specific violations cited, facility name and address, and overall score. For comparison purposes, a sample of 174 inspections from 35 restaurants (seven restaurants per food type) that met the study population criteria was analyzed. Data were entered into a spreadsheet and analyzed with Microsoft Excel.

Results

Analysis of the routine inspection reports indicated that the most commonly cited violations for all restaurant types were for failure to protect food from contamination during storage, preparation, display, service and/or transportation (53.5%, n = 93), followed by floors that were unclean, improperly constructed, and/or in poor repair (45.9%, n = 80). Neither of these violations is designated as a critical item violation. Figure 1 illustrates the five most frequently cited non-critical violations observed over the study period for each restaurant category identified.

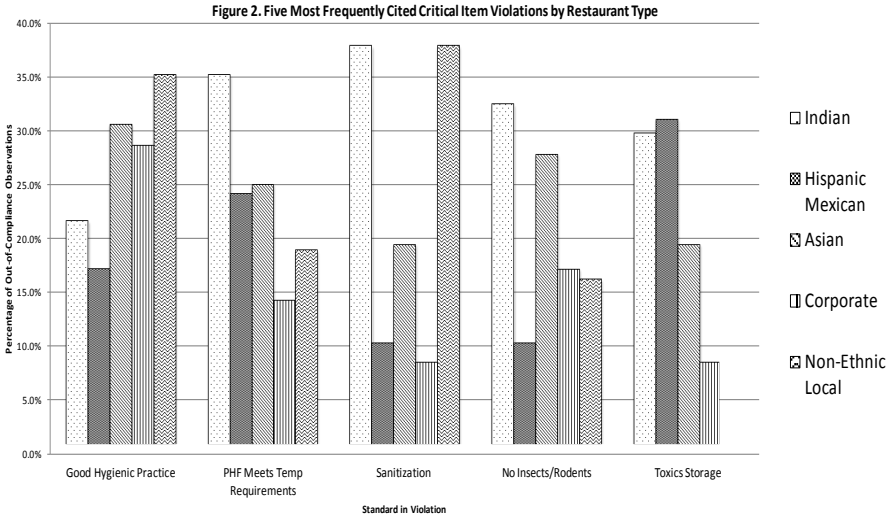
FIGURE 1: Five Most Frequently Cited Non-Critical Violations by Restaurant Type



As Figure 1 illustrates, Asian restaurants were cited most frequently for lack of compliance with three of the five standards: food protection from contamination (72.2%), maintenance of floors (72.2%), and cleanliness of non-food contact surfaces of equipment and utensils (44.4%), while Indian restaurants were cited most frequently for lack of compliance with the remaining two standards: issues with toilet rooms (59.5%) and the design, construction, or maintenance of non-food contact surfaces (56.8%). Violations for food protection, unclean/unstocked toilet rooms, and unclean non-food contact surfaces of equipment and utensils are violations that contribute to several of the foodborne illness risk factors described by the FDA. Issues with floor design and cleanliness or the misuse or poor design of non-food contact equipment and utensils are indicators of weaknesses in Good Retail Practices (GRPs) that could result in conditions that may lead to foodborne illness (FDA Food Code, Annex 5, 2009).

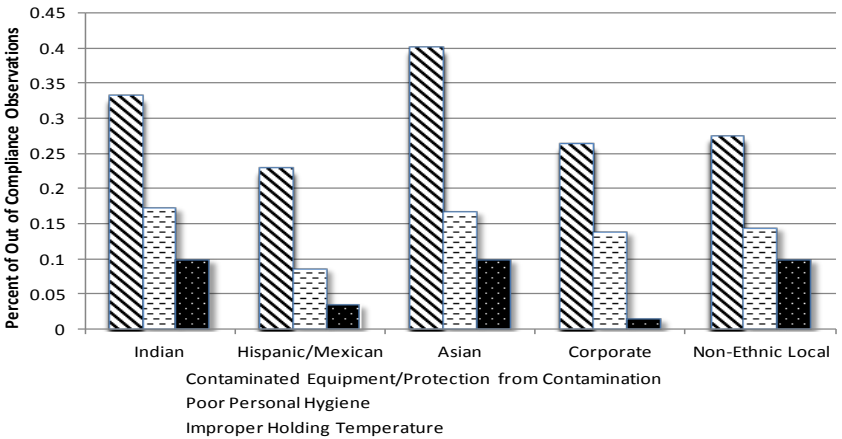
Lack of hand washing and other good hygienic practice was the most frequently cited critical item violation overall (27.01%, n = 47). Figure 2 illustrates the five critical item violations most frequently cited for each restaurant type. Although good hygienic practice was cited most frequently overall, issues with sanitization were cited most often with equal frequency (37.8%) in Indian and non-ethnic local restaurants when the violation is considered by restaurant type. Indian restaurants were also cited most often for temperature abuse of potentially hazardous foods (PHF) (35.1%) and issues with pest control and abatement (32.4%). Non-ethnic local restaurants violated the standard for good hygienic practices most often (35.1%), while Hispanic/Mexican restaurants were cited most frequently for problems with toxic storage and labeling (31.0%).

FIGURE 2: Five Most Frequently Cited Critical Item Violations by Restaurant Type



Six of the 10 violations illustrated in Figures 1 and 2 can be categorized under three of the foodborne illness risk factors. Violations for food protection, issues with sanitization, and unclean non-food contact surfaces of equipment contribute to the "Contaminated Equipment" risk factor. The "Poor Personal Hygiene" risk factor includes violations for adequate hand washing and good hygienic practices as well as hand-washing facility functionality. And the "Improper Holding" risk factor represents potentially hazardous foods that are kept out of temperature.

Figure 3. Foodborne Illness Risk Factors by Restaurant Type



Conclusions

The results of this study illustrate that the most common violations cited in ethnic restaurants in New Hampshire mirror those previously reported by Mauer et al. and Kwon et al.: failure to protect food from contamination, poor personal hygiene, and improper temperature control of potentially hazardous foods. Ethnic restaurants also seem to be more frequently cited for violations that affect the overall operational and sanitization conditions within their establishments. Problems with pest control, equipment maintenance, and poorly maintained physical facilities are factors that can derail a successful food safety management system.

However, this study also indicates that lack of hand washing and other good hygienic practices are problematic across all restaurant types, and when broken down by ethnic cuisine category, non-ethnic local restaurants are cited for non-compliance more often than any other restaurant type. Issues with proper sanitization were observed with equal frequency in Indian and non-ethnic local facilities as well. When the violations are correlated with the FDA-defined foodborne illness risk factors, contamination issues are cited with greater frequency across all restaurant types, regardless of ethnic cuisine category. These contamination issues may reflect a general lack of knowledge regarding the importance of prevention of cross-contamination and transmission of foodborne pathogens in safe food practices.

Recommendations

Although food safety training and certification are not required for food service employees in New Hampshire, food service workers must be encouraged to attend food safety education workshops whenever possible. Lack of resources is often cited as a barrier to adequate food safety training. However, food safety training workshops that focus on the importance of good hygienic practices and controlling for contamination and temperature are offered free of charge to food facilities in New Hampshire by the Cooperative Extension Services. Food safety training resources in languages other than English should be made available on a statewide level to regulatory agents and food service workers.

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Corresponding Author

Kristin DeMarco Shaw, Public Health Department, City of Portsmouth, New Hampshire
Email: kmshaw@cityofportsmouth.com

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Aflatoxin: Occurrence, Prevention, and Gaps in Both Food and Feed Safety in North Carolina

Jennifer L. Godwin
Food and Feed Administrator
North Carolina Department of Agriculture & Consumer Services

Abstract
Aflatoxin is a naturally occurring toxic metabolite produced by mold infestations affecting as much as one-quarter of global food and feed crop output. This toxin has been associated with various diseases, such as aflatoxicosis, in livestock, domestic animals, and humans (Dohlman, 2003). To ensure food and feed safety, many countries have adopted regulations to limit exposure to aflatoxin. The primary purpose of this study was to evaluate the industry's knowledge of aflatoxin in food and feed safety. An online survey was submitted to certain industries in North Carolina to determine their knowledge about the occurrence and possible health effects of aflatoxin, as well as strategies to prevent exposure to this toxin. Less than 50% of respondents knew there was an action level established by the U.S. Food and Drug Administration (FDA) for aflatoxin present in food and feed in order to protect human and animal health. The results showed that 56% of respondents knew that aflatoxin was a toxin, and among those respondents, 73% knew that it affected commodities such as corn and peanuts. The majority of aflatoxin testing, conducted by the industry, is only on the incoming ingredient (48%), and it is conducted primarily by the use of a black light (27%) or commercial test kits (22%). The conclusion of this study is that a majority of the respondents are aware of what aflatoxin is and know about effects on commodities. However, regulation and preventive testing may not be an integral part of industry standards. Ultimately, continuing education on the occurrence of aflatoxin and strategies to prevent exposure to it would help continue to bridge the gap in food and feed safety in North Carolina.

Background
In 1960, an acute hepatotoxic disease in turkeys termed "Turkey X disease" focused the attention of many scientific laboratories on a common problem affecting animals in many areas of the world (Blount, 1961; Lancaster, Jenkins, and Philip, 1961). The dramatic outbreak of the disease, which initially killed more than 100,000 turkeys and was subsequently linked to heavy mortality in ducklings and young pheasants, was shown to be associated with peanut meal in the feed (Asplin and Carnaghan, 1961). An investigation determined that the peanut meal was highly toxic with aflatoxin, a naturally occurring toxic metabolite produced by mold infestations, which demonstrated the seriousness of the problem facing the animal food industry. This case ultimately led to the recognition that aflatoxin is both an economic and a public health problem in many areas of the world (Eaton and Groopman, 1994).

Aflatoxin is a mycotoxin produced by fungi, identified as *Aspergillus flavus*, which contaminates many commodities, such as corn and corn products, peanuts and peanut products, milk, and tree nuts, which are ingredients used in both food and feed products. The occurrence of aflatoxin contamination is influenced by a wide range of environmental factors, including geography; agricultural/agronomic practices; and the susceptibility of the commodity to the fungi during harvest, storage, and/or processing

periods (Environment, Health and Safety Online, 2012). Water stress, high-temperature stress, and insect damage of the host plant are major determining factors in mold infestation and toxin production (Cornell University Department of Animal Science, 2009). The geographical location of North Carolina provides aflatoxin with favorable conditions, such as high moisture and high temperature.

The Food and Agriculture Organization (FAO) of the United Nations estimates that 25 to 50% of the world's food crops are affected by mycotoxins, with aflatoxin being the most prominent (Boutrif and Canet, 1998). Many countries try to limit exposure by regulating and monitoring aflatoxin presence in commodities intended for use as food and feed. Mycotoxins are considered unavoidable contaminants of food and feed. Therefore, to help prevent aflatoxin ingestion, the U.S. Food and Drug Administration (FDA) has established action levels for poisonous/deleterious substances to control levels of contaminants in human food and animal feed in the document *Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed* (U.S. Food and Drug Administration, 2000). Action levels are established based on the unavoidability of the poisonous/deleterious substance and represent limits at or above which the FDA will take legal action to remove products from the market. The action level for aflatoxin in food and milk is 20 ppb and 0.5 ppb, respectively, and up to 300 ppb in animal feed.

Several methods are currently being used to test for the presence of aflatoxin, such as analytical laboratories, commercial test kits, and black light tests (Iowa State University, 2009). Analytical laboratories are highly accurate and quantitative and use one of several procedures, such as thin-layer chromatography, gas chromatography, or mass spectroscopy, to determine aflatoxin levels. Commercial test kits using immunoassay or ELISA techniques, which are based on the detection of specific proteins found in aflatoxins using antibodies, are available for on-site tests for aflatoxin. The black light (also called ultraviolet light) test is a visual inspection for the presence of a greenish-gold fluorescence under light at a wavelength of 365 nm (nanometers). Because aflatoxin does not occur uniformly through a commodity and is usually localized in a small area, the best approach is to make a composite sample consisting of subsamples from every part of a load, bin, or unit of corn. The North Carolina Department of Agriculture and Consumer Services (NCDACS) requires testing for aflatoxin in corn products prior to use in products for human consumption, as described in the North Carolina Administrative Code (NCAC) (02 NCAC 09J. 0101). However, food products that are deemed adulterated by industry or regulation may be allowable as a feed product and therefore diverted into feed products. These products may then be consumed by pets and livestock.

Exposure to aflatoxin is difficult to avoid, since fungal growth in commodities is not easy to prevent. Aflatoxin has been associated with various diseases, such as aflatoxicosis (a hepatic disease) in livestock, domestic animals, and humans. Susceptibility to aflatoxicosis varies depending on age, sex, and nutrition of both humans and animals. In developed countries, food and feed products contaminated with specific levels of aflatoxin are not permitted. However, concern still remains regarding the possible adverse affects from long-term exposure to low levels of aflatoxins in the food supply. In July 2011, there were two Class II recalls due to elevated levels of aflatoxin in peanut butter (U.S. Food and Drug Administration, 2011). In 2001 and 2009, the FDA cited a

company for shipping peanuts contaminated with aflatoxin (U.S. Food and Drug Administration, 2001; U.S. Food and Drug Administration, 2009).

In animals, aflatoxin can cause liver damage, decreased milk and egg production, gastrointestinal dysfunction, reduced reproductivity, and reduced feed utilization and efficiency. According to the FDA Recall List, there were pet food recalls due to aflatoxin in 2005 and 2010, and, most recently, there were five recalls in December 2011 (U.S. Food and Drug Administration, 2011). In 2005, more than 100 canine deaths and at least one feline fatality were linked to pet food contaminated with aflatoxin, according to Cornell University veterinarians (Cornell University, 2006).

Aflatoxin is a particular problem in underdeveloped countries, which can cause concern over imported products. According to the FDA, melon seeds from the Sudan have been on "Detention Without Physical Examination" since 1982 due to violative levels of aflatoxin. Shipments continue to be offered for entry and refused due to the presence of aflatoxin (U.S. Food and Drug Administration, 2011). As the ethnic population in the United States continues to grow, so does the popularity of imported products. According to the International Dairy Deli Bakery Association (IDDBA), the ethnic food segment continues to grow due to a combination of factors, such as an increase in immigrants, more international travel, and a rising interest in cooking and cooking shows that inspire cooking of traditional and nontraditional recipes (International Dairy Deli Bakery Association, 2012).

Aflatoxin is considered an unavoidable contaminant of food and feed. For this reason, action levels were established at which the FDA will take legal action to remove products from the market. Aflatoxin contamination of food and feed poses both human and animal health concerns. The geographical location of North Carolina provides aflatoxin with favorable growing conditions, such as high moisture and high temperature. Therefore, people who may use susceptible commodities need to understand the occurrence of aflatoxin, its possible health effects, and strategies to prevent exposure to it through food and feed.

Problem Statement

The presence of aflatoxin in significant quantities can cause illnesses in both humans and animals. Ingredients and finished feed deemed adulterated with aflatoxin by one industry group or by regulation may potentially enter another industry group. Regulatory agencies lack information pertaining to industries' knowledge of the cause and effect of aflatoxin in common agricultural products and the strategies that industries employ to prevent aflatoxin contamination.

Research Questions

This study examined industries' knowledge of aflatoxin in common ingredients, such as corn and peanuts, used in North Carolina food and feed manufacturing.

1. What is the level of aflatoxin knowledge in the industry of the causes and effects of aflatoxin contamination in the food and feed supply?

2. What is the industry doing to help prevent aflatoxin contamination of food and feed?

Methodology

A 20-question online survey was submitted to the North Carolina food and feed industry, including farmers, to collect information concerning the industry's knowledge of aflatoxin and strategies to prevent exposure to this toxin. The survey was sent to approximately 200 North Carolina firms selected from the NCDACS, Food and Drug Protection Division, Food and Feed firms database based on industry codes that identify (?) the firm type. Firm types, such as bakeries, flour mills, dairy farms, peanut processors, cereal/breakfast food manufacturers, and animal feed manufacturers, were selected based on their potential use of commodities that are susceptible to aflatoxin contamination in food and feed manufacturing. The survey identified the establishment size and primary purpose of the firms (human food manufacturer, animal feed manufacturer, or crop farmer). Next, questions about the identity of aflatoxin, i occurrence, regulation, and possible effects on human and animal health were used to help gather information on the firms' knowledge of aflatoxin. Finally, the survey explored the firms' policy on testing for aflatoxin in susceptible commodities.

Results

The survey was designed to capture information regarding each firm's establishment size and purpose, knowledge of aflatoxin occurrence, policy on aflatoxin testing, and opinion of aflatoxin testing. Of the respondents, 48% identified their primary purpose as animal feed manufacturers, 32% as human food manufacturers, and 10% or less as farmers for human or animal consumption and other types of firms that handle commodities.

The results showed that 56% of those who responded knew that aflatoxin was a toxin, and among those respondents, 73% knew that aflatoxin affected commodities such as corn and peanuts. Approximately 50% knew that the FDA has established an action level for aflatoxin present in food and feed in order to protect human and animal health. The survey identified each firm's policy on testing for aflatoxin in susceptible commodities as well as in the finished product. Of those who responded, 48% tested aflatoxin on incoming ingredients only, and no more than 21% conducted aflatoxin testing on the finished product. The results showed that the primary means of testing for aflatoxin were a form of the immunoassay technique (22%) and the use of an ultraviolet lamp or black light (27%). A black light is often used as an initial screen to detect aflatoxin contamination. However, this method is strictly a presumptive test and does not confirm the presence of aflatoxin; only a chemical analysis can verify the presence of aflatoxin (Woloshuk and Wise, 2011). The U.S. Department of Agriculture Grain Inspection, Packers and Stockyards Administration (GIPSA) under Directive 9181.2 has implemented a program to verify the performance of rapid commercial tests for mycotoxins in grains (U.S. Department of Agriculture, 2011). According to the GIPSA *Aflatoxin Handbook*, there are several approved commercial methods for testing aflatoxin (U.S. Department of Agriculture, 2002).

Conclusions

These research findings suggest that gaps exist in North Carolina's food and feed industry regarding the occurrence of aflatoxin, possible health effects, regulation, and strategies to prevent exposure. This project found that the industry has awareness of aflatoxin. However, aflatoxin testing is conducted on a limited basis throughout the industry. The testing of ingredients and finished products for aflatoxin contamination is

an area of great concern. The survey results showed that a popular testing method is the use of a black light, which is strictly a presumptive test and does not confirm the presence of aflatoxin. Only a chemical analysis can verify the presence of aflatoxin. If ingredients are not monitored, there is the risk of aflatoxin contamination in our food and feed supply, which could lead to potential health issues for both animals and humans. These issues lead to emotional distress, loss of consumer confidence, economic loss, and even death. Risk, such as aflatoxin contamination, is an everyday possibility in business. Those companies that take a proactive approach to risk management often put themselves in a better position to succeed.

Recommendations

As the U.S. strives to build an integrated food and feed safety system, the importance of educational outreach is imperative. One method to help reduce potential health risks and economic losses associated with aflatoxin is to increase awareness among food and feed producers of practices that would minimize aflatoxin contamination and to encourage the adoption of process-based guidelines, such as good agricultural practices (GAPs) and good manufacturing practices (GMPs) (Dohlman, 2003). A Codex Committee on Food Additives and Contaminants (CCFAC) report recommended that GAPs and GMPs be used to establish formal hazard analysis and critical control point (HACCP) food safety systems to identify, monitor, and control mycotoxin risks along the entire food production chain (Codex Alimentarius Commission, 2002). Park et al. (1999) suggested steps to lower mycotoxin contamination that can be taken at the following four stages of food production: preharvest, harvest, postharvest (storage and processing/manufacturing), and animal feeding. For example, at the postharvest processing/manufacturing stage, all susceptible ingredients for aflatoxin should be tested. Incoming ingredient and finished product testing helps ensure that food and feed safety controls are in place. Education and outreach about the identity, occurrence, regulation, and effects of aflatoxin on human and animal health are necessary to promote awareness of this common—but potentially deadly—substance.

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Corresponding Author

Jennifer Godwin, North Carolina Department of Agriculture & Consumer Services
Email: jennifer.godwin@ncagr.gov

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Food Safety Laws and Regulations Related to Home-Based Food Businesses: Perceptions of Regulatory Staff, Food Processors, and the Home-Based Food Industry in New York State

Roxanne Hill
Supervising Food Inspector
New York State Department of Agriculture and Markets

Abstract
The primary goal of this project was to determine if sufficient regulation exists concerning enforcement of food safety laws with home-based food processors. New York State Department of Agriculture and Markets offices field a number of calls each week from individuals interested in developing a home-based business preparing foods for sale to the general public. Home-based food processors are exempt from the licensing provisions of the Agriculture & Markets Law, Article 20-C (see A&ML section 251-z-4, 1NYCRR section 276.4[b]) and are not subject to inspection by any of the health departments. A review of literature and online videos indicated that information regarding home-based food processor licensing is varied and unreliable. The review also revealed variances between states regarding legal requirements for home-based food processors. New York state regulators, commercial food manufacturers, and home-based food processors were surveyed using the Internet, telephone, and mailings. Survey results suggested that both regulators and manufacturers are concerned about the lack of training for and routine inspection of home-based food processors.

Introduction
New York state laws require commercial food manufacturers to be licensed and routinely inspected. On the other hand, NYS 281, Declaration of Legislative Findings and Intent, encourages farms and food product producers within the state to sell directly to consumers on a state, regional, or local basis at wholesale and retail. The home-based food processor exemption policy thus allowed an extension of the business for farmers, which helped the farmers use excess crops. New York State Department of Agriculture and Markets (NYSDAM) Circular 933, Rules and Regulations Relating to Human Foods: Current Good Manufacturing Practices (GMPs), is for firms that are not regulated by licensing, such as home food processors. The policy of NYSDAM is to perform a one-time, announced, curtailed inspection of each home kitchen shortly before the firm is registered and to follow up only when a complaint is received.

In 1993, there were 490 registered home-based food processors in the state of New York. By 2011, that number grew to 2,039, and as of February 2012, there were 2,100 registered home-based food processors (Archived and Active NYSDAM records). Although there is no record of foodborne illness outbreaks associated with home-based food processors in New York state, food sources for home-based food processors are not routinely monitored to ensure the delivery of wholesome products. Consequently, the potential exists for distribution of contaminated foods to the public in New York.

Further, concern over food security has grown tremendously in recent years, as evidenced by new federal laws addressing the issue. The FDA Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4, 2011. The Act aims to ensure that the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing contamination. "We know that we need to prevent and to use our modern understanding of where hazards come from and how they can be minimized to reduce the risk of illness," said Michael R. Taylor, Deputy Commissioner for Foods, U.S. Food and Drug Administration (2012, Bottemiller).

The current compliance enforcement methods for commercial businesses include inspections, re-inspections, fines and penalties, industry conferences, and food safety education classes and seminars. NYSDAM also utilizes seizure authority, administrative hearings, preliminary injunctions by court order, orders of contempt, arrest warrants, temporary restraining orders, summary suspensions, inspection warrants, and warning letters for enforcement against commercial businesses. These authorities are not fully used for enforcement purposes with home-based food processors. Products from an unregistered home-based food processor are classified as coming from an unapproved source. Potentially hazardous products made by a home-based food processor are considered violative. Both types of products are seized and destroyed under signed waiver where found. The other enforcement actions are not used with home-based food processors.

Background

Unregistered home-based food processors usually become known after they have been reported, they are seen on TV, a website is stumbled upon, or homemade food products are found in a store during an inspection or investigation. Occasionally, a home-based food processor (or potential processor) will call NYSDAM because the person learned about NYSDAM from the Internet, from a cooperative extension, or from farmers' market management, or because "someone" told the person to call. Due to the current state of the economy and the perception that homemade food products are fresher, safer, or more nutritious, interest in preparing foods at home for sale to the public has grown tremendously (2011, Haupt). The Brooklyn regional NYSDAM office fielded 30 calls during one week in 2011. During initial conversations with inspectors, many unregistered home-based food processors say they plan to produce cakes, cookies, or other non-potentially hazardous foods. However, in subsequent conversations, some home-based food processors admit to making products not permitted by New York state law, such as fermented red yeast rice, meat dishes, dips and sauces, layer/filled cakes, wedding cakes, banana breads, zucchini breads, and tarts. Some home-based food processors sell only to stores, while others sell directly to the public at flea markets and farmers markets. A new NYSDAM home-based food processors policy allows use of the Internet for communication or promotional purposes.

Problem Statement

In the state of New York, food safety laws and regulations require training for all commercial food preparers. These New York state laws and regulations do not require routine inspections for people processing food from a home kitchen. The lack of routine inspections for home-based food processors could lead to habitual deviations from GMPs and allow the continued presence of unrecognized food safety hazards.

Research Question
What are the perceptions regarding food safety laws for home-based food businesses among various stakeholders, specifically regulatory staff, licensed manufacturers, and home-based food processors?

Methodology
A mixed-method approach, in the form of quantitative and qualitative analyses of data obtained from surveys of commercial food manufacturers, home-based food processors, and New York state regulators, was used. The Brooklyn regional NYSDAM office staff used a phone questionnaire to survey non-registered home-based food processors as they called in. The callers were asked questions about food safety training, types of products, sales venue, and advertising. Surveys that included the same set of questions were mailed to the current list of registered home-based food processors from NSYDAM's intranet database.

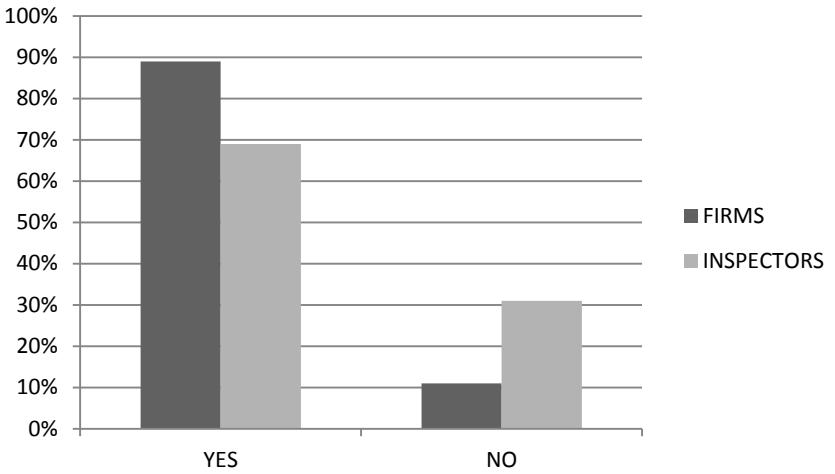
The NYSDAM regulators' survey was administered by SurveyMonkey. Regulators were asked questions relating to the safety of homemade foods, minimum food safety requirements for home-based food processors, adequacy of current enforcement, and limiting of sales venues. Mail surveys were sent to commercial food manufacturers found in NYSDAM's database. Manufacturers were asked about their knowledge of home food processing, safety of home-processed foods, training, education, and routine inspections.

To conduct a more focused and manageable study, the survey population was limited to Region 3 of NYSDAM. The survey responses from manufactures and regulators were compared for similarities.

Results
The majority of manufacturers and regulators who participated in the surveys believe that home-processed foods are unsafe. Foods considered to be unsafe are meat, poultry, seafood, dairy products, pickled products, and canned goods. Responses to questions about minimum food safety requirements for home-based food processors were tallied by the number of mentions and grouped into the following categories: Training, Inspections, Good Manufacturing Practices/Sanitation Standard Operating Procedures (GMPs/SSOPs), and Other. GMPs/SSOPs responses included being insect- and vermin-free, having clean kitchens, and practicing good hygiene. The following is one of the responses in the "Other" category: "Homemade foods should be sold locally for easy trace back; limit to small venues where enforcement could be easier."

The following chart (Figure 1) shows that manufacturers and inspectors believe training should be mandatory.

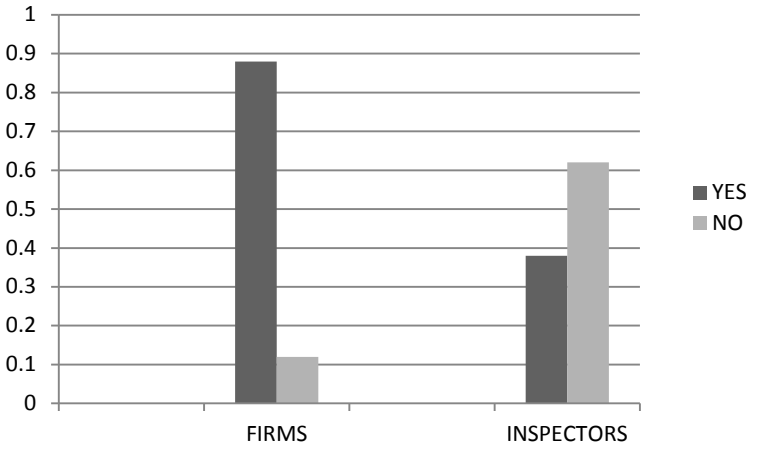
FIGURE 1: Should Training be Mandatory?



Inspectors believe home-based food processors should be restricted to producing small batches of food; allowed only limited distribution, subjected to random product sampling, and required to keep household ingredients separate from processing ingredients.

Manufacturers and inspectors also agree that home-based food processors should be subject to routine inspection (Figure 2).

FIGURE 2: Should Home-Based Food Processors be Subject to Mandatory Routine Inspections?



Conclusions

Some form of training should be required for home-based food processors in order to educate them about safe food handling practices, food-related hygiene/health concerns, approved food sources, etc. Routine inspections should be conducted in home kitchens to verify continued good manufacturing practices. Manufacturers and inspectors are in favor of training and routine inspections being required for home-based food processors. Potentially hazardous foods should remain restricted. Regulators and manufacturers agree that potentially hazardous foods, such as meats, seafood, salads, and dairy products, should not be home-processed.

Recommendations

The survey results suggest that the NYSDAM's home-based food processor policy should be modified to require routine inspections for home-based food processors and mandatory training before a home-based food processor can begin making products to sell to the public. In addition, the policy should be amended to require home-based food processor product labels to indicate that a food is home-processed.

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Being granted the Fellowship at IFPTI was a tremendous honor and privilege. I could not have met the challenge and completed the project without the assistance of several people. Much thanks to my mentor, Dan Sowards, for his guidance and insights. I would also like to thank Joseph Corby for his support, Dr. Kieran Fogarty for his evaluations and comments, and all the IFPTI instructors for their subject matter expertise. I am grateful to Richard Olson, Chief Region 3; Erin Sawyer, Field Director; John Luker, Assistant Director; and Stephen Stich, Director, Food Safety and Inspection Services of NYSDAM for allowing me to participate in the Fellowship. My sincere appreciation is extended to the regulators, manufacturers, and home-based food processors who participated in the surveys that generated results for the project.

Corresponding Author

Roxanne Hill, New York State Department of Agriculture & Markets
Email: Roxanne.Hill@agriculture.ny.gov

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The Food Safety Modernization Act: What Do Processors Know About the Hazard Analysis and Food Safety Plan Requirements, and Where Do They Anticipate Finding Assistance?

Karla Ann Horne
Food Safety Scientist
Michigan Department of Agriculture and Rural Development

Abstract
The 2011 Food Safety Modernization Act (FSMA), Section 103, requires food processors to develop a hazard analysis and preventive controls plan for all of their processes. The U.S. Food and Drug Administration (FDA) plans to publish rules implementing these FSMA requirements in 2012. An electronic survey was sent to food processors in Michigan to determine a baseline knowledge regarding these new requirements. The survey also asked where the processors would seek assistance, if needed, in complying with the upcoming requirements. The results of this survey indicate a significant disparity in the knowledge base between processors grossing greater than $10 million a year and processors grossing less than $499,999 a year. The results also show that firms expect the primary source of assistance in complying with the FSMA requirements to be the Michigan Department of Agriculture and Rural Development (MDARD).

Background
In March 2009, President Obama established a working group to focus on food safety in the United States. This working group included representatives from the U.S. Food and Drug Administration (FDA), the Food Safety and Inspection Service (FSIS), the Centers for Disease Control and Prevention (CDC), the Department of Homeland Security (DHS), the Department of Commerce, the Department of State, the U.S. Environmental Protection Agency (EPA), and several other agencies. In July 2009, the Food Safety Working Group recommended three core food safety principles to guide a more focused public health-based approach to developing a food safety system (Food Safety Working Group, 2009): (1) Preventing harm to consumers, (2) Improving the effectiveness of inspections, enforcement, and data analysis, and (3) Improving response and recovery to foodborne illness outbreaks. Many of this working group's recommendations are included in the Food Safety Modernization Act (FSMA), which was signed into law in January 2011. Among the many provisions, this law requires food businesses that hold, package, process, or manufacture foods to develop a food hazard analysis and preventive controls plan. A hazard analysis requires firms to identify and evaluate hazards associated with food facilities, food processing or handling practices, and the foods or food products. This analysis must consider biological, chemical, physical, radiological, and other hazards. Once the hazards have been identified and documented, the firm must develop and implement a plan to control for, or significantly minimize, these hazards within the facility at each point where these potential food safety risks may occur (Food Safety Modernization Act of 2011). Functionally, the FSMA-required food safety plan is similar to a Hazard Analysis Critical Control Point (HACCP) Plan. However, at this time, only firms that process juice, seafood, or low-acid canned foods are formally required to develop and operate using a HACCP plan. In May 2011, the FDA issued a Notice of Request for Comments for "Preventive Controls for Registered Human

Food and Animal Food/Feed Facilities" to gather information from interested parties and stakeholders regarding the development of the forthcoming regulations and guidance on hazard analysis and preventive control plans for human food and animal feed facilities (Preventive Controls for Registered Human Food and Animal Food/Feed Facilities, 2011).

As the federal government moves forward in addressing the need for food safety plans to help ensure a safer food supply, there may be a substantial impact on businesses that historically have not been required to have these plans. Each plan will be unique, and tailored to each firm's specific food safety needs and risks. Regulators are currently unclear how informed processors are regarding the requirements of FSMA and where processors anticipate finding assistance in developing their hazard analysis and food safety plans.

If firms are ignorant of the food safety rules, regulations, and legislative requirements that govern their business or they do not see the value in the regulations, the firms will not be motivated to comply (Yap and Fairman, 2006). For example, a study conducted in 2004 in the United Kingdom found that food establishment operators believe that the enforcing officer (i.e., regulatory staff), rather than the firm, is responsible for the analysis of the firm's potential food safety hazards. This study also determined that small and medium-sized food businesses had significant barriers to compliance with regulations. The primary reasons noted in the study were lack of knowledge, lack of awareness, lack of motivation, and lack of a management system. Additionally, the general level of knowledge about hazard analysis was poor, with about 25% of the firms surveyed having no knowledge. The authors of the study concluded that firms that are well-informed and invested in their planning and process controls will more likely comply with regulations (Yap and Fairman, 2006).

Problem Statement

The general knowledge level of food processors in Michigan regarding the FSMA requirements for food manufacturers to perform a hazard analysis and develop a preventive control food safety plan is unknown. If processors lack the foundational knowledge to develop and implement a hazard analysis and food safety plan, regulators are unclear where Michigan processors intend to secure assistance and resource information. Regulators assume, but do not know, if there are differences in knowledge levels based upon a processor's size.

Research Questions

1. Is there a lack of knowledge among Michigan food processors about FSMA requirements concerning food safety hazard analysis?

2. Is there a lack of knowledge among Michigan food processors about FSMA requirements concerning preventive controls (food safety plans)?

3. Where will businesses in need seek assistance in understanding and complying with FSMA requirements?

Methodology

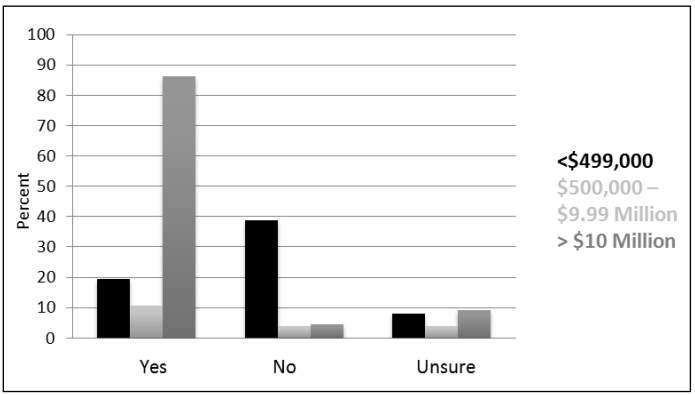
An electronic survey was administered to a representative sample of Michigan food processors using a Web-based survey program. The 10-question survey was designed to determine respondents' baseline awareness of the FSMA hazard analysis and food safety plan requirements. The survey also requested information about where respondents planned to secure assistance, if needed, to comply with the FSMA. Additionally, the survey collected basic information about the firms' size, geographic location, and general processing type.

The survey was sent to 401 licensed processors in the state of Michigan who have provided e-mail addresses to the Michigan Department of Agriculture and Rural Development as part of the licensure process. Survey recipients had approximately three weeks to complete and return the survey. Forty-nine percent of these processors (198) responded to the survey. Responses to the survey were blind, so that no individual processor could be identified. Responses were analyzed to determine if Michigan food processors are knowledgeable of the FSMA requirements to develop a hazard analysis and a food safety plan, and where processors plan to acquire assistance, if necessary, in meeting the requirements. The responses were also studied to discover whether differences in knowledge exist across general industry types and industry sizes. Of the 198 respondents, 23% (46), were excluded from this analysis because their production is already regulated under existing HACCP regulations for juice or seafood or they did not properly complete the survey. All data analysis was based on the responses provided by the remaining 152 respondents who properly completed the survey and are not currently regulated under an existing HACCP regulation.

Results

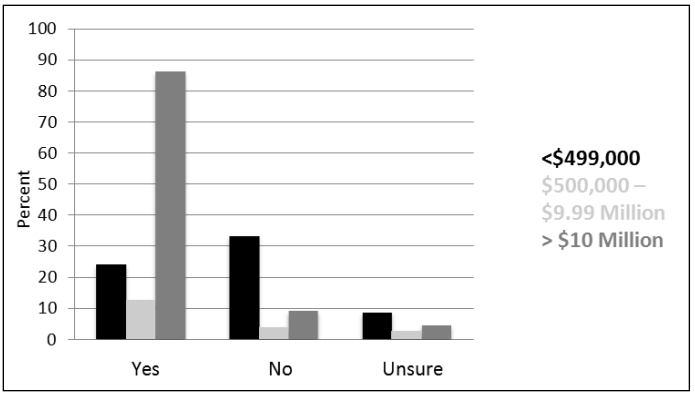
Approximately 42% of processors were aware of the FSMA requirement to perform a written hazard analysis, and 50% of processors were aware of the FSMA requirement to develop and implement a preventive control plan (food safety plan). When the data were analyzed to compare processor knowledge based on processor size, a disparity in knowledge was revealed. Eighty-six percent of firms grossing greater than $10 million a year are aware of the FSMA requirements for written hazard analysis and food safety plans (see Figure 1).

FIGURE 1: Processor Knowledge of Hazard Analysis



Nineteen percent of establishments grossing less than $499,999 a year reported having knowledge of the hazard analysis requirement, and only 24% of those establishments reported having an understanding of the food safety plan requirements (see Figure 2). A significant majority of respondents, 79%, are processors of non-potentially hazardous foods (such as baked goods, jams/jellies, coffee roasters, etc.); therefore a statistical comparison of knowledge between types of processors was not feasible.

FIGURE 2: Processor Knowledge of Preventive Controls



When processing establishments were asked to rank where they would seek assistance in meeting the FSMA Hazard Analysis and Food Safety Plan requirements, respondents ranked the Michigan Department of Agriculture and Rural Development (MDARD) first. Respondents ranked MDARD first 1.6 times more frequently than the Michigan State University Extension Service, twice as often as industry or trade groups, and three times more frequently than the FDA, private consultants, or internal programs.

Conclusions

When the data are aggregated and analyzed for the Michigan food processing industry as a whole, the results indicate that the food processing industry is relatively aware of the new hazard analysis and food safety plan requirements set forth in the FSMA. However, when the data are segmented and analyzed based on predefined categories for establishment size, a different picture emerges. As the establishment size decreases, the knowledge level about the upcoming FSMA requirements for a hazard analysis and a preventive control plan decreases. When knowledge level is compared based on gross dollar volume, the largest establishments (>$10 million gross per year) fare far better, with 86% report being aware of the requirements. Only 19% of the smallest firms (<$499,999 gross per year) reports being aware of the hazard analysis requirement, and 24% reports being aware of the FSMA requirement that preventive controls be developed and implemented.

With the lack of knowledge regarding hazard analysis and food safety plans, particularly among smaller food processing companies, these businesses will need significant assistance in complying with the FSMA requirements. Michigan food processors anticipate their primary source for assistance to be the MDARD. However, at this time neither, the MDARD nor the FDA appears to have any mechanisms in place for establishments to secure their identified need for training or consultative assistance.

Recommendations

As discussed previously, establishments that are knowledgeable about regulations governing their business and invested in the development of this new hazard analysis and food safety plan will be more likely to be successful in complying with food safety regulations (Yapp and Fairman, 2006). A strong, targeted public outreach and training program is needed. The MDARD lacks the resources and personnel to perform this type of outreach. Likewise, as a result of budget cuts and loss of extension grants, Michigan's land grant universities are unable to meet all of the industries' needs for high-value, low-cost training.

Although neither MDARD nor the land grant universities can provide this critical training alone, perhaps MDARD can develop other public and private partnerships that can accomplish this training goal by working cooperatively. A training curriculum could be developed cooperatively and delivered at local community colleges throughout the state. Community colleges are already offering a large variety of technical courses targeted at continuing education and training. Community college staff members are skilled educators. Community colleges are conveniently located throughout the state and could provide the training in a cost-effective manner once a curriculum was developed (Marguerite Cotto, Vice President of Life Long Learning, Northwest Michigan College, personal communication, December 20, 2011). Strategically located and knowledgeable MDARD Food Division staff could supplement and enhance training by serving as subject matter experts.

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Corresponding Author

Karla Ann Horne, Michigan Department of Agriculture and Rural Development
Email: hornek@michigan.gov

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Food Safety Compliance Levels Among Tribal Nations in the Oklahoma City Area Indian Health Service

LT Aaron McNeill
Environmental Health Officer
Oklahoma City Area Indian Health Service—Division of Environmental Health Services

Abstract
This research paper will focus on how the adoption or implementation of a food code affects the compliance levels, food safety risk factors, and critical violations of American Indian food service operations within the Oklahoma City Area Indian Health Service (OCAIHS) region. In the OCAIHS region, 28 tribal nations prepare food for the general public. The majority of these tribes have neither adopted nor formally implemented the U.S. Food and Drug Administration's model Food Code, the Oklahoma State Food Sanitation Code, or a tribal food code as a tool to address food safety principles.

This research focused on tribal food service operations located in the Pawnee and Miami Service Units of the OCAIHS. In 2010, a total of 3,566,315 meals were served from the food service operations located within these two Service Units.

Completion of the data analysis revealed that there was an increase in the level of compliance and reduction in risk factors and critical violations in food establishments that have adopted or implemented a model of the U.S. Food and Drug Administration's model Food Code.

Background
According to a report from the Centers for Disease Control and Prevention (CDC), 1 in 6 Americans (or 48 million people) gets foodborne illness each year, 128,000 are hospitalized for these diseases, and 3,000 die of these illnesses (Centers for Disease Control and Prevention, 2011).

Twenty-eight American Indian tribes within the Oklahoma City Area Indian Health Service (OCAIHS) region prepare food for tribal citizens and the general public. The tribes receive direct environmental health services, including food sanitation, by professional environmental health officers of the OCAIHS. One objective of the OCAIHS's Division of Environmental Health Services (DEHS) is to prevent and control foodborne illness risk factors among the American Indian population and among the general public. The DEHS staff fulfills this objective by conducting routine food sanitation surveys and food handler training for tribal food establishment personnel. The majority of tribes served by the OCAIHS have not adopted the U.S. Food and Drug Administration (FDA) model Food Code, the State of Oklahoma Food Sanitation Code, or a tribal food code.

The tribes served by the OCAIHS are not subject to food safety laws, standards, or policies established by a local or state government due to tribes' independent sovereign nation status recognized by the United States government. The tribes and the federal government function according to a government-to-government relationship. This unique relationship gives tribes sovereignty and sole authority to enact their own laws and policies regarding their government, citizens, programs, and business entities within

their jurisdictional boundaries. Several tribal programs, such as Head Start, Office of Child Care, and Elderly Nutrition Title VI programs, receive federal funding. For this reason, these programs may be required to follow federal mandates that address food safety in order to receive or maintain funding.

Federally recognized tribal nations in the OCAIHS are treated as sovereign nations by the United States government and are not subject to state food safety laws unless they choose to be subject to them through tribal government resolution, law, or policy. On the other hand, there are instances in which a tribal program, such as a tribal Head Start Center, may receive federal funding or a grant and may be required to adhere to federal mandates addressing food safety in order to receive or maintain the federal funding. Tribal gaming operations receive federal oversight by the National Indian Gaming Commission (NIGC) and its Environmental, Public Health, and Safety (EPHS) standards. The EPHS standards are designed to ensure that Indian gaming facilities have tribal ordinances, laws, or regulations to protect the environment and the s public health and safety, including food safety.

On October 17, 1988, Congress enacted the Indian Gaming Regulatory Act, 25 U.S.C. 2701-21, which created the NIGC. The NIGC was granted oversight and enforcement authority to monitor tribal gaming operations. This oversight and enforcement authority included establishing EPHS standards designed to ensure that Indian gaming facilities have tribal ordinances, laws, or regulations to protect the environment and the public health and safety. Pursuant to Chapter 25 of the Code of Federal Regulations (CFR), CFR 502.22 and 559.5, tribal gaming operations must identify the existing laws, resolutions, codes, policies, standards, or procedures and certify compliance with and enforcement of those laws, resolutions, codes, policies, standards, or procedures inherent to the EPHS standards. Tribal gaming operations identifying and certifying compliance with and enforcement of the model FDA Food Code would be an example of meeting the CFR requirement indicated above. If an ordinance, law, or regulation is found to be in noncompliance, the NIGC has authorization to undertake enforcement actions, including citing violations, assessing civil fines, and/or issuing closure orders.
The National Environmental Health Association (NEHA) position paper titled “Retail food protection on the local, state, and tribal levels: Left out of the new federal food protection initiatives?” discusses steps that are needed to develop a successful national retail food protection system. According to the NEHA Food Safety Committee, nationwide adoption of the latest FDA Food Code is required for uniformity of standards among the ranks.

The model FDA Food Code establishes practical, science-based guidance and enforceable provisions for mitigating risk factors known to cause foodborne illness. Adoption and implementation of the model FDA Food Code supports achieving uniform national food safety standards and enhances the efficiency and effectiveness of the food safety system (2009 Food Code). Tribal governments have the autonomy to support the framework of the uniformity of national food standards by choosing to adopt or develop food code standards based on the most recent FDA Food Code. The uniformity of standards within all tribal food service operations would be strengthened and create more consistency within themselves and with neighboring nontribal food service establishments.

Problem Statement

Eight percent of tribal nations with foodservice operations located within the OCAIHS service area have adopted or developed food code standards based on the Model FDA Food Code. The implementation of a food code modeled after the most recent FDA Food Code could lead to uniformity in national food safety standards and increase the effectiveness of a food safety system. This research project compared food safety risk factor violations in food service establishments having an adopted food code to violations in establishments that have not implemented any form of the model FDA Food Code.

Research Questions

1. Does the adoption of an approved food code increase or decrease the level of compliance in addressing FDA foodborne illness risk factors?

2. How do critical violations compare between food establishments with a food code to those having no food code?

Methodology

Research was conducted via a Web-based environmental health reporting system called WebEHRS. The WebEHRS database is a program designed by the Indian Health Service to input and track environmental health-related activities. WebEHRS allows users to set filters to produce various reports from the data that are entered into the system. For food service surveys, WebEHRS uses the 2001 FDA Food Code. The data generated from WebEHRS involved tribes in two different service units and were entered by two different environmental health officers who have been standardized in the FDA food inspection protocol.

The reporting filters used in this research included tribal nation, establishment type, and risk factor violations from January 2010 through October 2011. Four tribal nations were selected for comparison. Two of the four tribes had adopted the model FDA Food Code. All four tribes had a comparable number of food establishments. The two tribes that had adopted the model FDA Food Code had 16 food service operations, while the two tribes with no food code had 19 food service operations. Additional factors for comparing the tribes and facilities were based on near equivalency in the total number of food service operations within a gaming facility and nongaming food service operations.

Facility Types 47 and 80 were selected. Facility Type 47 refers to a stand-alone café/restaurant or a food establishment located within a tribal gaming facility. Facility Type 80 refers to a food service operation that provides meals to clientele of a tribal program or nongaming facility. Facility Type 80 operations include kitchens located in Head Start centers, day care centers, senior centers, and community buildings.

Regarding food safety and associated foodborne illness concerns, the model FDA Food Code lists the leading food safety risk factors associated with foodborne illness as improper holding temperatures, inadequate cooking, contaminated equipment, food from unsafe sources, and poor personal hygiene. A critical violation refers to a provision of the FDA Food Code that, if in noncompliance, would more likely than other violations contribute to food contamination, illness, or an environmental health hazard.

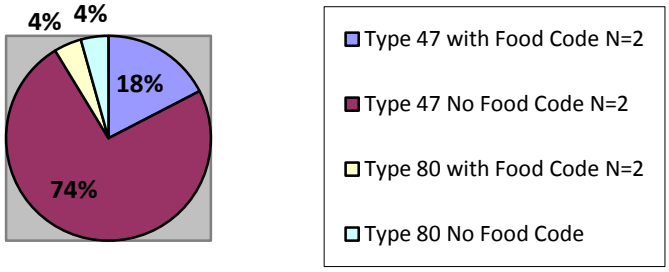
Results

From January 2010 through October 2011, a total of 46 FDA Food Code risk factor violations were documented for four tribes with Facility Types 47 and 80. The risk factor violations occurred at both gaming and nongaming food service operations. The risk factor with the highest percentage of violations was improper holding temperatures. Improper holding temperatures contributed to 47% of the total violations documented during calendar year 2010. Over the course of the year, food from unsafe sources and inadequate cooking temperatures had the fewest documented violations for all facility types and groups.

The data compiled from the WebEHRS report revealed interesting results when comparing tribes with an adopted food code to those without one. The total number of violations in the WebEHRS report for the two tribes without an adopted food code with Facility Type 47 and Facility Type 80 food service operations totaled 36. The majority of the risk factor violations were found within the Facility Type 47 operations, because there were more facilities of that type than Facility Type 80 operations.

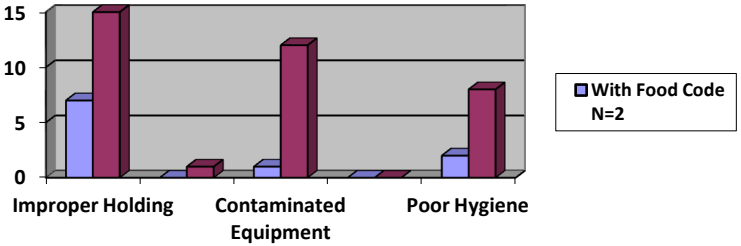
Figure 1 illustrates that food service operations that utilize the model FDA Food Code had a lower percentage (21%) of risk factor violations than did those without a food code (79%).

FIGURE 1: Percent Comparison of Risk Factor Violations of Food Service Operations with an Adopted FDA Food Code and Those without an Adopted FDA Food Code



Although foodservice establishments which are operated by a tribal nation with an adopted food code had fewer risk factor violations in comparison to those without an adopted food code, Figure 2 shows little difference in the areas of inadequate cooking and food from unsafe sources. The foodservice establishments operated by a tribal nation without an adopted food code had a higher number of violations of improper holding temperatures, contaminated equipment, and poor personal hygiene.

FIGURE 2: Number of Foodborne Illness Rick Factor Violations of Tribal Food



Operations with and without an adopted model FDA Food Code

Conclusions

Among the tribal food service operations evaluated in the OCAIHS region, the data demonstrated that a greater number of documented food safety risk factor violations occurred in foodservice establishments operated by tribal nations without an adopted model FDA Food Code than in those with an adopted model FDA Food Code. The data supports the adoption and implementation of the model FDA Food Code as a tool to reduce food safety risk factors associated with foodborne illness. The adoption and implementation of the model FDA Food Code by all food safety agencies at the federal, state, local, and tribal levels establishes a sound regulatory foundation and legal framework for uniformity in achieving a reduction of these risk factors (U.S. Food and Drug Administration, 2011, p. 2).

Recommendations

Additional research by other Indian Health Service (IHS) areas would be required to determine if the data results are similar across the country. This information could help provide the data that IHS and environmental health officers need to assess whether there is a correlation between the increase of food safety risk factor violations and possible foodborne illness cases within tribal food service operations that have not adopted a model of the FDA Food Code. If further studies of this type are conducted and such a correlation is found, it could be a factor in support for the adoption of the model FDA Food Code by all food safety agencies at the federal, state, local, and tribal levels. Adoption and implementation would allow for a national retail food system with uniform food code standards to achieve a reduction of food safety risk factors.

As sovereign entities, Indian tribes have a unique opportunity to empower themselves in their initiatives to promote and protect the health and safety of their citizens. An ongoing study of this topic could provide valuable data and documentation that could be presented to tribal councils and tribal leaders to help persuade them to adopt tribal food codes based on the model FDA Food Code.

In the meantime, steps can be taken to reduce the number of food safety risk factor violations. Food safety education, technical assistance, and food handler training should continue to be provided to tribal food service operations. Attention should be focused on reducing the leading FDA risk factors having the highest percentage of violations and encouraging safeguards that will lead to a decrease in risk factor violations that cause foodborne illness.

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Corresponding Author
Aaron McNeill, Oklahoma City Area Indian Health Service—Division of Environmental Health Services
Email: aaron.mcneill@ihs.gov

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Assessment of FDA Rapid Response Team's Implementation

Brenda D. Morris
Environmental Administrator
Florida Department of Agriculture and Consumer Services, Division of Food Safety

Abstract
The promulgation of federal initiatives and directives after the September 11, 2001, terrorists' attacks on the United States provided resources to various federal agencies to improve our nation's response to and preparedness for emergencies. In 2008, the U.S. Food and Drug Administration (FDA) announced the Food Protection Rapid Response Team (RRT) and Program Infrastructure Improvement Prototype Project (U18), which provided significant funding for nine pilot states to develop and identify components that would strengthen and implement a rapid response to food- and feed- related emergencies (U.S. Food and Drug Administration RFA FD08 007, 2008). The three- to five-year FDA cooperative agreement provided milestones and expected accomplishments that would require documentation and reporting to substantiate progress, regulatory compliance, and corrective action supporting the FDA project. The compiled information would be used to corroborate continued and sustainable funding necessary for the success and continued implementation of the FDA program. States need assurance of continued sustainable funding from the federal government to provide for long-term planning and continued development of a feed/food emergency response plan to assure a safe food supply for the nation. Such funding would also allow for the pilot states' completion of the RRT Best Practices Manual to be used by other states or entities that want to develop a rapid response to food/feed incidences. This research study was designed to evaluate the progress made by states on the deliverables of the cooperative agreement. The results demonstrate achievements as well as challenges of implementing and sustaining a Rapid Response Team.

Background
The attacks of September 11, 2001, forever changed the United States. The reality of an intentional attack on the nation's food supply became an immediate national security concern and priority. The federal government began evaluating the vulnerability of the U.S. food and feed supply and enacted the Bioterrorism Act of 2002 (U.S. Department of Health and Human Services, 2002). The Homeland Security Presidential Directive empowered the federal government to fund and develop programs to protect the nation's food supply (U.S. Food and Drug Administration RFA-FD 08-007, 2008). In 2008, the Office of Regulatory Affairs (ORA) introduced a program through the FDA Division of Federal-State Relations (DFSR) to provide guidance to help states identify and implement means to strengthen food safety programs and develop a rapid response to food- and feed-related incidents. The project became known as the Rapid Response Team (RRT). Initially, the project funded six states (California, Florida, Massachusetts, Michigan, Minnesota, and North Carolina) to participate in the pilot program, and in 2009, selected three additional states (Texas, Virginia, and Washington) to participate. The nine states selected had evidence of an existing or a potential response plan.

The pilot states' representatives submitted documentation of their infrastructure and response capabilities to the Western Institute for Food Safety and Security (WIFSS) through an onsite face-to-face meeting. WIFSS developed a written assessment of the states' current preparedness using the documentation provided. The states would were required to develop their programs based on their individual state government structures, existing emergency response plans, and the numbers and types of food emergencies that have occurred in the past. The RRT pilot program, funded for three to five years, required states to plan and document how to improve, strengthen, and integrate the program components into their state plans. The initial deliverables of the pilot program included:

- Conduct exercises emulating intentional food contamination and prepare an After Action Report (AAR) that provided an overview of strengths and weaknesses of the teams' performance during the emergency;
- Implement an Incident Command System (ICS);
- Develop and foster multi-agency relationships;
- Implement Manufactured Food Regulatory Program Standards (MFRPS) as enacted by the Food Safety Modernization Act (FSMA);
- Develop and specialize in rapid response capabilities;
- Conduct annual self-assessments;
- Provide an MFRPS Program Assessment Validation Audit;
- Participate in the development of an RRT Playbook; and
- Send state officials to annual face-to-face meetings with FDA officials.

Problem Statement

Since the inception of the RRT pilot program in 2008, states have worked to develop and implement the components required in the cooperative agreement. States have been allowed to define and structure their RRT based on their unique structure, organization, needs, and assets. Because of the diversity of each state program, comparing specific details and assessing progress equally is difficult. Pilot RRTs may not have an understanding of the collective unforeseen challenges and achievements resulting from implementation, as well as the advancements that have been accomplished throughout the pilot project.

Research Questions

To evaluate the progress of the states' implementation of the RRT cooperative agreement, this study was designed to answer the following research questions:

1. What progress has been made by the pilot RRT programs since the original WIFSS assessment?

2. What are the challenges of the state RRT programs?

3. What are the achievements resulting from implementing the RRT programs?

Methodology

The research data for this project were collected in two ways. First, all of the nine pilot state RRT project managers were asked to submit a copy of their WIFSS assessment, which provided baseline data for each state. The contract with the WIFSS included assessment of the response plan, identification of training needs, evaluation of the level of preparedness, and interaction among agencies. The information gathered at the inception of the RRT pilot project was used to design and implement the RRT program.

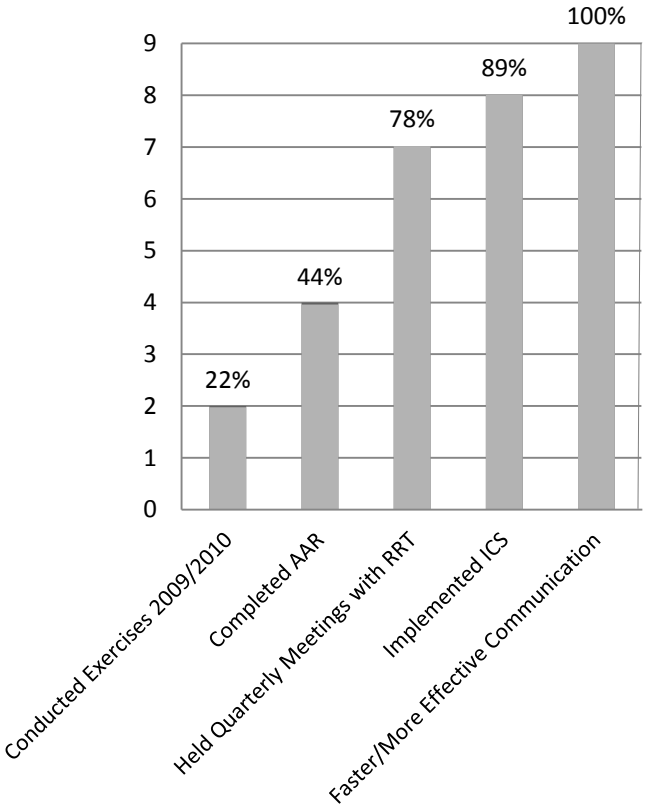
The second component of this research study involved phone interviews with the designated RRT program manager in each of the nine states. Eleven questions were developed based on discussions with subject matter experts, methodologists, and experts in the DFSR. Some of the information gathered was charted to show the progress and completion of components of the grant.

Results

All nine RRT pilot states participated in this research study and supplied answers to the interview questions, which provided details of their progress. These interviews revealed that all nine states have designed and initiated the implementation of a written program to meet the requirements of the Food Protection RRT and Program Infrastructure Improvement Prototype Project (U18).

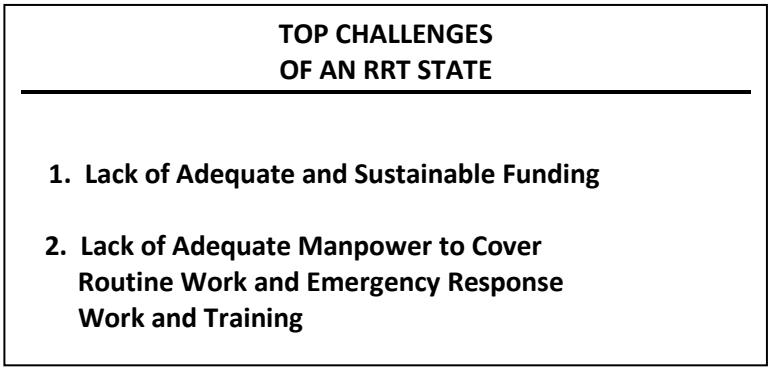
Seven states held at least one concept exercise since inception. However, as illustrated in Figure 1, in 2010 and 2011, only two of the nine states (22%) met the requirement of holding an annual concept exercise. Four states (44%) completed AARs from annual concept exercises, which identified corrective actions needed to improve multi-agency performance. Seven states' RRTs (78%) met quarterly with the FDA and other core partners, either via conference call or in face-to-face meetings, to foster communication, build relationships, better define and reevaluate roles and responsibilities, and maintain infrastructure of the team. Eight states (89%) indicated they implemented an ICS to provide an effective framework of communication and coordination if an actual emergency occurred. Nine states (100%) reported that faster and more effective communication was developed and fostered between all RRT agencies and the FDA.

FIGURE 1: Accomplishments of the RRT States



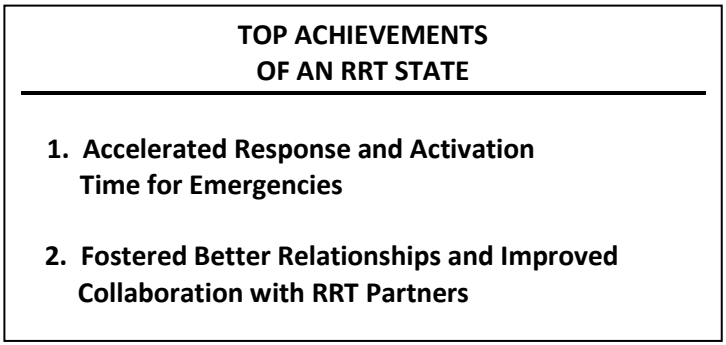
The project managers were asked to identify the top two challenges facing their RRT. Figure 2 shows that lack of adequate and sustainable funding was the major challenge and lack of manpower to perform both the core mission of their department and to incorporate necessary training and exercises was the second challenge.

FIGURE 2: Top Challenges of an RRT State



The last question asked the project managers to identify the top two achievements resulting from the implementation of an RRT. As seen in Figure 3, seven states saw an increase in speed and transparency in responding and in implementing control measures resulting from an incident, and the movement to response mode from reaction mode improved considerably. Six states indicated that the working relationships developed through the RRT program had greatly impacted their ability to respond faster, communicate more clearly, and coordinate action faster during exercises and actual events requiring coordination of efforts.

FIGURE 3: Top Achievements of an RRT State



Conclusions

The findings of this research demonstrate the dedication and commitment of the RRT pilot states. States have made significant progress in training and development for preparedness and investigations. Without sustainable funding, states will be unable to continue planning, developing, and implementing the necessary components of an effective integrated food safety system. States will continue to be cautious and guarded with financial resources and responsibilities without the assuredness that funds will be available to expand and advance the project. States have primarily focused on required deliverables as their program priorities and have viewed recommendations for the project as secondary objectives. As a result, key objectives of the RRT pilot program, such as annual exercises, were delayed as states prioritized requirements based on deliverables rather than focusing on the project as a whole. The diverse frameworks within states have presented challenges in developing a model plan to execute, but states have collaborated to overcome these issues. This work has significantly benefited the agencies and their food and feed programs that would serve as key participants in the event of an emergency. Written plans and strategies have increased, resulting in improved readiness and the ability to respond quickly. States can continue to strengthen their RRT through trial and error with real-world food emergencies and AARs. Protocols and procedures are now the norm in the chain of events that will occur at the report of a possible emergency. Additional components of the RRT pilot program not evaluated in this research were discussed during the interview and further demonstrate that states are taking remarkable steps to implement RRT program requirements.

Recommendations

States need assurance of sustainable funding from the federal government to provide for long-term planning and development of an RRT. Included in the RRT program are multiple layers of requirements and components for national programs leading towards the objectives of FSMA, including the MFRPS. The need for a nationwide, integrated food and feed emergency response plan is critical—now more than ever—for the security of the United States. Failure to allocate and continue funding would be a tremendous setback in the strides taken by the government to protect the food supply. Funding is also crucial for both the designated state program manager and RRT coordinator, who should focus primarily on the development and advancement of the states' food safety emergency response team. People involved in overseeing the core mission of their state's food safety organization and managing the RRT are challenged to provide the direction and oversight needed for a successful program.

All program components expected of states should be required deliverables, rather than recommendations. When milestones are expected, but not required as an annual milestone, they become secondary in importance. Many program recommendations are key to completing effective deliverables. Additional face-to-face meetings with the auditors regarding self-assessments to stay on track with the deliverables would be beneficial.

Actual RRT food emergencies should count as training events when an AAR is conducted and reviewed with the team. States are already involved in actual incidents of varying degrees and have constraints regarding manpower. This approach would allow for a more thorough review of the incidences in order to discuss possible challenges and

issues. These actual emergencies, the lessons learned, and the AARs could be used as learning tools for other states.

The project manager should plan and schedule quarterly meetings one year in advance and require a minimum of one face-to-face meeting per year. This advance scheduling would allow direct interaction with those people who are key players in the RRT program agencies. More frequent and scheduled assessment reviews would allow states to continue to stay focused and on track to implement the goals and objectives of the program.

The continued development of an RRT Best Practices Manual (previously known as the RRT Playbook) is the foundation of a model program. Adding a chapter titled "Getting Started: The Basics," in which to share groundwork laid and initial lessons learned, would benefit other states wanting to develop a rapid response plan to food and feed emergencies. This additional chapter would increase efficiency during the development stages and would help states avoid challenges initially experienced by the pilot program states.

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Corresponding Author
Brenda Morris, Florida Department of Agriculture and Consumer Services, Division of Food Safety
Email: Brenda.Morris@freshfromflorida.com

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Cottage Food Industry: Lessons Learned from the Southeastern States

Craig Nielsen
Food Safety Manager
Food Safety Division/Georgia Department of Agriculture

Abstract
The cottage food industry, in which foods are produced at private residences, is an emerging issue for public health agencies. The Georgia Department of Agriculture (GDA) has received inquiries from community leaders and a state legislator advocating to allow cottage food operations in Georgia. If the GDA is going to adopt cottage food regulations, the lessons learned from experiences in other states that have established such regulations would be very beneficial. In an effort to understand other regulatory agencies' perspectives on the cottage food industry, state food safety program managers within the Association of Food and Drug Officials of the Southern States (AFDOSS) region were surveyed and asked to evaluate their state's cottage food program. The results of the qualitative analysis of the survey data indicated that funding for a cottage food program is a fundamental issue to be considered, and that the more control an agency exerts over cottage food operators, the more resources the agency must spend on the cottage food program. When asked to identify strengths of their cottage food programs, program managers cited public relations and the control that the regulatory agencies have over the types of products produced and the limited locations where these products can be sold. Weaknesses identified include the personal safety of employees having to enter private residences, the lack of food safety training, inadequate resources, and the possibility of future exemptions to food safety regulations. If funding is one of the primary challenges to having a cottage food program, educational programs and certified food safety training can provide the best "bang for the buck." Another recommendation would have cottage food operators register annually and be permitted by the regulatory agency. The final recommendation is for regulatory agencies to reevaluate their cottage food programs.

Background
Currently, 37 states have cottage food regulations, and some of these states are looking to expand their cottage food industry. There are even "food freedom" movements that would like to see food safety disregarded and all regulations that impede personal liberties removed, regardless of the public health consequences. New Hampshire is the latest state to take this stance with the introduction of the New Hampshire Food Freedom Act, which was introduced during the 2012 session (HB 1650-FN).

In times of economic hardship, people begin to explore other sources of income, and many consider selling food they prepare at home. In the state of Georgia, which currently has a jobless rate of 9.2% (Georgia Department of Labor), home-produced foods may be sold at nonprofit events, but there are some restrictions. Organic foods, dairy products produced under the Pasteurized Milk Ordinance, meat products covered by the Meat Inspection Act, and acidified/low-acid foods are examples of food products that are not exempt from the licensing requirements, and, therefore, cannot be sold at nonprofit events unless the manufacturer has obtained a license from the Georgia Department of Agriculture (GDA).

Even before the recent economic troubles, local farmers markets began popping up as there became an increased demand for "locally grown" products. Since the economic downturn, however, these local markets have become an outlet for many new home food producers who are out of work and are trying to generate income. The popularity of local markets is increasing, and the city of Atlanta is adding zoning regulations for farmers markets. The new regulations require at least 75% of the products sold at a farmers market to be produce or "value-added farm products," such as jams, baked goods, meats, and cheeses (Wood 2011). Value-added farm products, cheeses, and meats sold at nonprofit events are not exempt from Georgia licensing requirements.

Problem Statement

While Georgia currently does not have cottage food regulations, the GDA has received inquiries from community leaders and a state legislator advocating to allow cottage food operations. If the GDA is going to adopt cottage food regulations, the agency needs a better understanding of the potential immediate and long-term effects of those regulations.

Research Questions

1. If the state of Georgia is going to adopt cottage food regulations, what lessons can be learned from other states that have established such regulations?

2. What would these other states have done differently?

3. What are the strengths of these other states' programs?

4. What are the weaknesses of these other states' programs?

Methodology

In an effort to understand other regulatory agencies' experiences with the cottage food industry, a survey was developed for program managers to evaluate their state cottage food programs. The survey was reviewed by International Food Protection Training Institute (IFPTI) subject matter experts and program managers within GDA. After review, the revised survey was administered to program managers within the Association of Food and Drug Officials of the Southern States (AFDOSS) region. AFDOSS is an affiliate of the Association of Food and Drug Officials (AFDO), which consists of 11 southern states (including Georgia) and one territory (Puerto Rico). While many differences exist from state to state in the way that the cottage food industry is regulated, regionally, states tend to handle issues in similar ways.

Using the survey, a qualitative study was conducted consisting of face-to-face interviews with the program managers from eight states at the AFDOSS Fall Conference in Gatlinburg, Tennessee, in September 2011. Another interview was conducted via phone, and the last was sent via e-mail. Program managers were encouraged to speak candidly about their programs, and all responses were used and discussed anonymously.

The first part of the survey contained 11 questions about the agencies' cottage food programs, aimed at enhancing dialogue about program attributes. This information

gained through these questions was used to determine if the agencies allow cottage food, and the manner in which cottage foods are regulated.

The last part of the survey consisted of 12 questions regarding the implementation of cottage food programs in each state.

Results

Answers to the research question pertaining to what program managers would have done differently when implementing the cottage food programs are summarized in Table 1.

Table 1

State	What Would the Program Directors Have Done Differently?
1, 2, 3, 4, 9, 10	Nothing.
5	Implement better controls—for example: limit the sales and where cottage food products can be sold.
6	N/A
7	Get the legislature involved on the front side. Secure resources if required by law.
8	Charge a fee for the registration. Require food safety training.

Responses to the research questions pertaining to the strengths and weaknesses of the cottage food programs are summarized in Table 2.

Table 2

State	What is the Greatest Strength of the State's Cottage Food Program?	What is a Weakness of the State's Cottage Food Program?
1	In-depth review of the cottage food operator's process and effective controls, before allowing operations to commence.	Hard to catch them when they're processing— requires you to call and schedule an inspection. Employee safety of inspectors going into peoples' homes.
2	Educational instead of regulatory. Makes friends instead of creating enemies.	Variability that takes place makes it impossible to regulate. Cost prohibitive to inspect.
3	Tight definition of what can be produced.	Outreach to home processors is through the agency's webpage. Communication goes in one direction.
4	Low volume allowed to be produced. Labeling requirements. Broad authority granted by the statute for those who violate the regulations.	Reactive strategy. Cottage food operators doing things that they're not aware of. No training required. No record keeping.

Table 2 (continued)		
State	**What is the Greatest Strength of the State's Cottage Food Program?**	**What is a Weakness of the State's Cottage Food Program?**
5	Requires separate facilities. Regular inspections.	Unclear delineation of inspectional authority with other state/local agencies.
6	N/A	N/A
7	Supports small business. Another source of food for consumers.	Educate the public on food safety issues that prohibit potentially hazardous foods from being allowed.
8	Good public relations. Labeled as "farm-friendly." Forced partnerships with other agencies and organizations, which spread food safety knowledge. Seen as "small business advocates."	Legislatively mandated to allow low-acid foods to be produced.
9	Permitting and registration allows you to know what is being done. Gives cottage food operators an avenue to be legitimate, and to test the marketplace.	Don't have adequate personnel. Can't police the whole state.
10	Lack of registration/inspection of cottage food operations means regulatory agencies do not have to spend resources on cottage food.	Allowing cottage food operations by exemption may "open Pandora's box." Future possibility of additional products to be allowed and expansion of permissible sales locations.

Conclusions

The study has some limitations. Three of the program managers interviewed were from states that have recently adopted cottage food regulations. These states' regulatory agencies may not have had enough time with the regulations to offer a meaningful critique of the states' cottage food programs. In addition, one of the states surveyed does not have a cottage food program. The responses for that state are listed in Tables 1 and 2 as "N/A."

While the majority of the program managers surveyed did not indicate they would have done anything differently when implementing the cottage food programs, two of the three elaborative responses concerned money and program resources. Most agencies have seen a reduction to their budgets, since tax revenues have declined during the recession. Food safety agencies have to evaluate how much of their resources can be devoted to a cottage food program. An agency must first decide what degree of oversight to use, and then fund the program accordingly. Two of the program managers suggested that the funding issue could be addressed by charging a fee for the permit or by getting the state legislature involved. The legislature can appropriate additional staffing and resources required to oversee cottage food operations. While involving the legislature does not guarantee funding or ensure passage of a law that is amenable to a food safety program, the possibility exists that the regulatory agency will have some input into the process.

There were a multitude of answers given when the program managers were asked to give the greatest strength of the state's cottage food program. A common theme involves public relations. Cottage food programs have allowed some agencies to be characterized as "farm-friendly," "small business advocates," and "making friends instead of creating enemies." The cottage food industry has allowed small businesses to flourish and provide locally grown foods. For agencies with a marketing division, cottage food is a tool to advocate for farmers, sustainable agriculture, and farm-to-fork initiatives that are gaining in popularity.

The other perceived strengths of the cottage food programs stem from the control that the regulatory agencies have over the types of products produced and the limited locations where those products can be sold. The program managers who participated in this study all valued the degrees of oversight afforded to cottage food programs in their states. Avenues of oversight identified through this study include; the ability to conduct an in-depth review of the operators' products; licensing/permitting/inspection of cottage food operations; the low volume of foods allowed; labeling requirements; and regulatory foundation that allows an agency to fine operators that do not comply with food safety rules and regulations.

When asked to describe the weaknesses of the state's cottage food program, one agency cited the lack of food safety education required for the cottage food operators. Another cited the safety of the agency's employees having to enter private residences. Visiting private residences was also decried as counterproductive, since the inspectors frequently have to call ahead to see if the operator is processing. One of the agencies was legislatively mandated to allow production of low-acid foods, which the majority of agencies surveyed do not allow. Other program managers identified as a weakness the lack of resources and staffing required to regulate cottage food operations. The last weakness involves creating exemptions to the laws and regulations. Allowing exemptions creates the "slippery slope" leading to less control and the increased likelihood of foodborne illness outbreaks.

Recommendations

The first recommendation is to require food safety training of operators as a prerequisite to cottage food operations. If funding to implement and maintain a cottage food program is a primary challenge for agencies, educational programs and certified food safety training are two cost-effective strategies agencies can adopt. The cost of educational materials is relatively small compared with the costs of funding positions and purchasing equipment. Educational materials can be disseminated online, thanks to the availability of Web access and the increasing use of social media. Agencies that administer food safety exams can charge a registration fee to cover the costs associated with providing the training. Education generally does not pose a significant burden to budget-strapped food safety programs, and this strategy guarantees that operators had some measure of food safety knowledge at one point.

The second recommendation is to require cottage food operators to register annually and receive a permit from the regulatory agency. A preoperational inspection would be required, and the operator would be subject to consumer complaint or foodborne illness outbreak investigations. Registration fees can be used to offset the cost of issuing permits and preoperational inspection. Issuing permits to cottage food operators allows the regulatory authority to reap the benefits of positive public relations, and could help create a level playing field. Policing an entire state is not possible, according to some of the program managers. Requiring cottage food permits could help consumers make more informed decisions, and also could force unpermitted operators to register.

The final recommendation is for regulatory agencies to reevaluate their cottage food programs. Surveying states in the AFDOSS region has shown a fair amount of variability in how cottage foods are handled from state to state. The AFDO has drafted a Regulatory Guidance for Cottage Foods that provides valuable information on the best practices and limitations that should be placed on cottage food operations. As state agencies strive for consistency in regulatory programs, agencies should also strive for consistency between states in how cottage food programs are developed and implemented. The slippery slope exists. Every time a regulatory program relinquishes control, states that do not have cottage food regulations will have a more difficult task, when attempting to establish such regulations.

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Corresponding Author
Craig Nielsen, Food Safety Division/Georgia Department of Agriculture
Email: Craig.Nielsen@agr.georgia.gov

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An Analysis of Regulatory Schemes Used Throughout the U.S. for Home-Based Food Businesses: Options Available to Enhance Food Safety

Courtney Rheinhart
Tidewater Regional Manager
Virginia Department of Agriculture and Consumer Services

Abstract
As economic growth has slowed and job loss has risen, many people are turning to the cottage food industry as a way to supplement their income. Increasing support for local foods has also caused individuals to aspire to start home-based food businesses. Regulators, however, have concerns that allowing foods to be produced in the home kitchen may lead to unsafe food and/or foodborne illnesses. The purpose of this study was to explore regulatory schemes currently being used by state agencies in regards to home-based food businesses. Further analyses were completed to compare the efforts of the Virginia Department of Agriculture and Consumer Services to various other states' regulatory actions regarding home-based food businesses. This study showed that there is little uniformity between state agencies when it comes to regulating food products produced in the home kitchen. This research suggests that state agencies need guidance to help them be more uniform regarding home-based food business regulations. This project also indicates that in Virginia, support of the cottage food industry has led to multiple inspection exemptions and policies that have negatively impacted the state's regulatory authority over these home-based types of businesses to a greater degree than in other states.

Background
As the economy has weakened and unemployment has risen, the public has begun to look for ways to supplement their income. Many people are turning to the cottage industry as a way to make extra revenue. The term "cottage industry" is applied to an industry in which at least part of the manufacturing takes place in the home (Sutton, 2009). Requests from the public to regulatory agencies to manufacture food products in private homes are on the rise in Virginia as well as in other states. The "Buy Fresh- Buy Local" movement also supports small, home-based businesses. This movement encourages people to buy local food products and support local businesses and farmers. However, regulators fear that allowing food to be produced in the home and sold to the public with little or no oversight exposes consumers to dangers from foodborne illnesses and possibly from intentional food contamination (Wolfson, 2009).

Foodborne illness outbreaks and recalls of a food product can be catastrophic to a food manufacturer. In the case of a recall, the manufacturer often must pay to have the recalled product shipped and destroyed. Recalls can also have damaging effects on the public's perception of the firm, and food safety regulation in general. Manufacturers may have to spend additional revenue to regain consumers' trust and repair their damaged reputation. Such potential negative impacts are why the majority of large, non-home-based food manufacturers believe that investing ample resources into food safety will benefit their company.

Mainstream food manufacturers often rely on third-party audits to ensure that their processes, personnel, equipment, and establishment conform to food safety regulations and other standards (Hall, 2009). Manufacturers typically hire a quality assurance manager, someone with extensive food safety knowledge, to oversee day-to-day production and assure that the company is conforming to food safety guidelines implemented by regulators and/or the company's buyers.

Large food manufacturers invest in equipment that not only creates a more efficient process, but that also allows the plant to implement effective cleaning practices. Many of the pieces of equipment found in food processing plants are designed so that crevices and other small openings where physical, chemical, or microbiological contaminants could collect are not present. Choosing this type of equipment helps food manufacturers to be profitable as well as provide a safeguard to reduce the potential risk of foodborne illness (Koch, 2011).

When food is produced in the home, the same standards of safety often cannot be met as those in the mainstream food processing facilities. Owners of home-based food businesses do not usually have an extensive background in food safety. They typically have not taken food safety courses and do not have a clear understanding of the regulations they must follow. In addition, they do not have the revenue to invest in third-party audits, quality assurance managers, or advanced equipment (Scott, 2003).

A review of studies from both Europe and North America showed that many cases of foodborne illness occur as a result of improper food handling by consumers in their own kitchens (Scott, 2003). In fact, a study conducted in Canada identified the home as the most common exposure location for cases of Salmonella species, Campylobacter species, and infectious E. coli. Inadequate cooking, reheating, and storage temperatures; cross contamination; and infected food handlers are the most common sources for foodborne pathogens in the home (Scott, 2003).

The home can be a multifunctional setting inhabited by residents of various ages and health conditions, which may impact food safety. Humans and animals living in the home may serve as sources of foodborne pathogens, and both can be symptomatic or asymptomatic carriers. Pets living in the home can range from typical to exotic, and foodborne illnesses can be acquired from either. Salmonella and other pathogens that cause intestinal illnesses are associated with household pets such as dogs and cats (Scott, 2003).

In Virginia, few restrictions are placed on home-based food businesses. As long as a home-based food business fills out an "Information Request Sheet for a Food Processing Operation," has approved recipes and processes, can comply with the laws and regulations, and has been inspected by VDACS, there are no laws that prohibit the sale of a particular type of food product that falls under VDACS jurisdiction. Therefore, the types of foods produced in the home can range from cookies and cakes to baby food and acidified foods. In addition, for home-based food businesses that do not fall under inspection exemption in Virginia, there are also no limitations on where these products can be sold. Home food manufacturers may sell products directly to consumers, or they may sell to retail establishments in another state.

In Virginia, certain home-based food businesses are exempt from routine inspection. Support for the cottage food industry allowed Senate Bill 272 to be enacted in 2008. This bill exempts from inspection "private homes where the resident processes and prepares candies, jams and jellies not considered to be low-acid or acidified low-acid food products and baked goods that do not require time or temperature control after preparation if such products are: (i) sold to an individual for his own consumption and not for resale; (ii) sold at the private home or at farmers markets; and (iii) labeled "NOT FOR RESALE – PROCESSED AND PREPARED WITHOUT STATE INSPECTION" (Code of Virginia, 2011). Every year, additional legislation regarding inspection exemptions for cottage foods is proposed to the General Assembly.

Although VDACS requires the majority of home-based food manufacturers to be under inspection, limited resources are available to carry out these inspections. As of January 2011, more than 12,000 food facilities were on file with VDACS, but there were only 27 inspectors throughout the state. Home food manufacturers cannot be inspected as often as they should be, usually once every two years for a low-risk company. Mainstream non-home-based food manufacturers are usually inspected at least once per year. When inspections are conducted of mainstream, non-home-based food businesses, the inspections are unannounced, allowing the inspector to determine if the manufacturer is adequately assuring that routine practices are conducted in a safe and sanitary manner. On the other hand, inspections of home-based food manufacturers are scheduled. Therefore, inspectors are unable to determine whether the conditions they observe are representative of actual conditions that would be noted during unannounced inspections.

Problem Statement

Home-based food businesses present unique food safety and defense challenges to regulatory agencies throughout the United States. Since there may be few restrictions on the types of food products that can be produced in the home and where these products can be sold, there is the potential of an increased risk of unintentional foodborne illness outbreaks, as well as intentional contamination of home-produced food products. State food regulatory agencies may not be aware of all regulatory options available or the positive impacts these options may provide. Exploring how other regulatory agencies throughout the United States regulate home-based food businesses could provide policymakers in Virginia and in other states with additional options in regards to modifying regulatory oversight of these types of businesses.

Research Questions

1. What are the commonalities of and differences between state regulatory requirements for home-based food businesses in the United States?

2. How do Virginia's regulatory requirements compare to national estimates of state regulatory requirements for home-based food businesses in the United States?

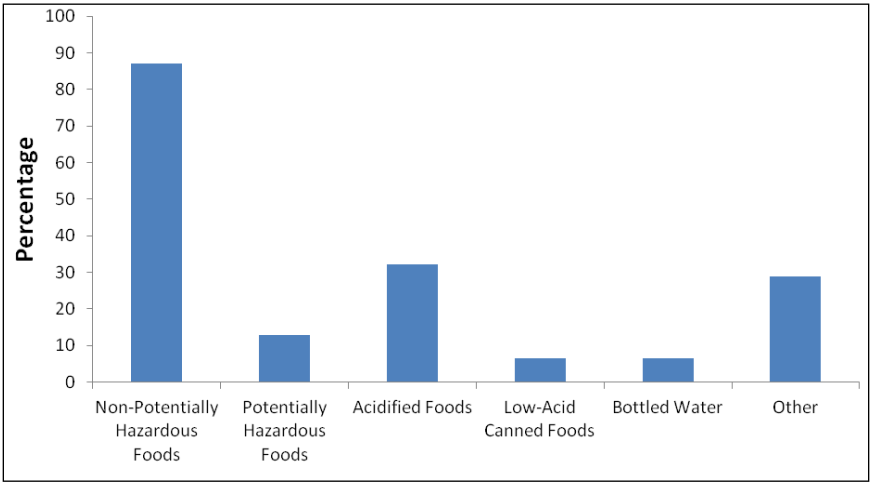
Methodology

An analysis of existing state regulatory policies and procedures for home-based food manufacturers was conducted. Key personnel from regulatory agencies in the other 49 states who were responsible for food-related regulatory programs were contacted via e-mail and asked to participate in an online survey. The survey contained 24 questions that were developed to assess regulatory schemes currently used by other state agencies. These policies and procedures were then compared to the approach currently being used by VDACS.

Results

Of the 49 state agencies polled, 40 responded to the survey. Nine (22.5%) of the survey participants indicated that their state's policies, procedures, or regulations do not permit the sale of food products manufactured in the home kitchen, while 31 (77.5%) responded that their states permit the sale of these types of food products. Of the 31 state agencies that allow the sale of food products manufactured in the home kitchen, 30 (96.8%) place restrictions on the types of food products that can be sold. Figure 1 shows the response to the second question of the survey, which asked about the types of food products manufactured in the home that may be sold. The survey asked the respondents to check all types of food products that apply.

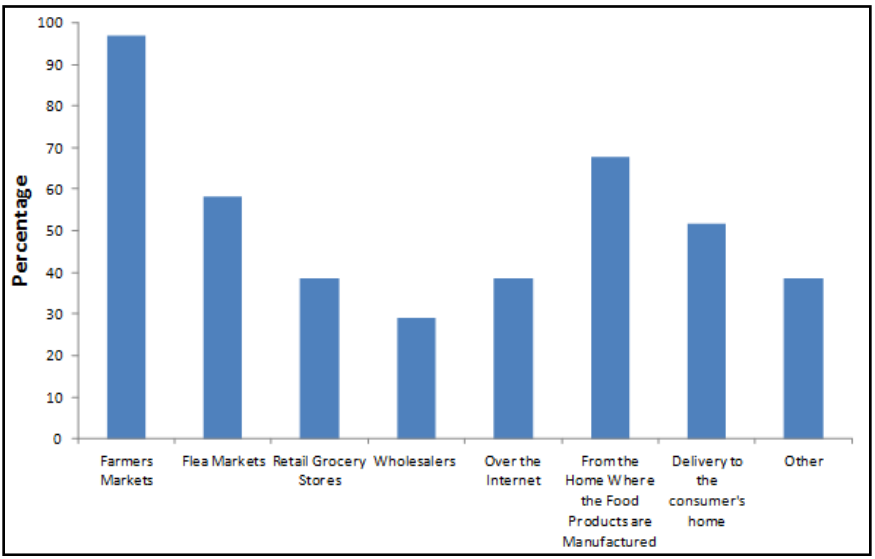
FIGURE 1: Food Products Manufactured in the Home Kitchen That Can Be Sold



Respondents did not use the "Other" section to address other types of food products, but instead used this section to provide further explanation. For example, one respondent wrote in the "Other" block that "A home food license … is limited to bakery items only."

Out of the 30 states that place restrictions on the types of food products that can be sold, 17 (56.7%) only allow the sale of non-potentially hazardous food items. Of those 17, three place even further restrictions on the specific types of non-potentially hazardous foods that can be sold. One respondent stated that only non-potentially hazardous baked goods, dried herbs, and jams and jellies are permitted. Another responded that only non-potentially hazardous products that are baked or are a confectionary good are allowed; jams, jellies, and canned/bottled products are prohibited. Finally, another respondent replied that only certain baked goods, such as cookies, bread, and buns, may be manufactured and sold from the home kitchen. Of the 31 state agencies that allow home-based food businesses, only four (12.9%) permit the sale of potentially hazardous foods. Only one allows the sale of all types of food products (non-potentially hazardous food products, such as cookies, jams, jellies, and chips; potentially hazardous food products, such as cream-filled pies/cakes, meat products, and deli salads; acidified foods, such as salsas and pickled products; low-acid canned foods, such as canned green beans; bottled water). However, during a subsequent phone discussion with an official at this state agency, the official clarified that meat products cannot be produced from the home kitchen, and that acidified or low-acid canned food producers are required to have their product/process approved by a third party. The official also stated that at this, time the agency does not know of anyone producing low-acid canned foods from the home kitchen. Of the 30 states that place restrictions on the types of food products that can be sold, 22 (73.3%) also place restrictions on where these products can be sold. Figure 2 shows the response to the third question of the survey, which asked where food products produced in the home kitchen can be sold. The survey asked respondents to check all choices that apply.

FIGURE 2: Where Food Products Manufactured in the Home Can Be Sold



Respondents from 14 (45.2%) of the 31 state agencies that allow food products to be manufactured in the home replied that their agencies license home-based businesses, while 17 (54.8%) stated that their agencies do not. Of the respondents who answered the question on whether their agency has the authority to inspect home-based food businesses, 18 (60%) stated that their agency does have the authority, while 10 (33.3%) responded that they do not. One respondent was unsure whether the agency had the authority to inspect home-based food businesses.

Of those respondents who answered the question on whether their agencies had any formal regulatory authority over home-based food manufacturers, all but two responded that they had some type of regulatory authority over these establishments. Types of regulatory authority included detention/embargo/seizure authority, authority to impose civil or administrative fines or penalties, authority to provide injunctive relief, authority to suspend or revoke a license, closure authority, and others.

When asked whether their state allows certain inspection exemptions for home-based food manufacturers, 15 (71.4%) respondents replied that their state allows exemptions, while six (28.6%) responded that their state does not. Six respondents (22.2%) indicated that operators of home-based businesses are required to attend some sort of training. Types of training varied from attending Better Process Control School to obtaining a Food Handler's Card. Twenty-seven of the 29 respondents (93.1%) who answered the question on whether their agencies required foods produced in the home kitchens to be labeled replied that they did. Of those, 14 (51.9%) responded that the label must include a caveat stating that that the food was manufactured without inspection by the state regulatory authority.

Although a majority of respondents (56.7%) indicated that their agencies only permit non-potentially hazardous food items to be produced in the home kitchen, VDACS allows both potentially hazardous and non-potentially hazardous food items to be produced in the home kitchen. While 73.3% of the other state agencies place restrictions on where these types of products can be sold, VDACS allows these products to be sold anywhere.

The data compiled from this study show that although most of the state agencies allow the sale of food products manufactured in the home kitchen, the majority place some type of restriction on these types of businesses. These restrictions may involve the types of food products that can be manufactured, where those food products can be sold, training for the operator, a certain labeling requirement, or all of the above.

Conclusions

This survey revealed that regulatory authority varies greatly among state agencies. The research showed that there is a lack of uniformity in regards to the regulations used to oversee home-based food manufacturers. Many agencies may believe that the best way to protect public health is to place restrictions on the types of products produced in the home kitchen and where these products can be sold. However, other agencies may believe that these types of operations will exist regardless of whether restrictions are in place and that therefore, the best approach is to inspect every operation and provide training and guidance to operators.

The results of this survey demonstrated that VDACS does not place as many restrictions on home-based food businesses as other states. Providing educational outreach to home-based food operators in Virginia may address the current lack of regulatory authority over these types of businesses. In addition, presenting legislators and policymakers with these survey findings may prove useful and help prevent additional inspectional exemptions from being enacted.

Recommendations

Based on the results of this survey, one recommendation is that the Association of Food and Drug Officials (AFDO) submit the Cottage Foods Regulatory Guidance document to the Conference of State Legislatures for potential adoption at the state level. State agencies should readdress their regulatory scheme regarding home-based food businesses so that the approach used matches up more closely with the AFDO guidance document. In addition, other research should be conducted to assess the training needs of home-based food business operators. In order to address any lack of regulatory oversight over these types of food businesses, state agencies should invest resources to provide training and information to operators of home-based food businesses. This information could be posted on the agency's website, or an online training program could be created to allow operators to become more familiar with food safety regulations.

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Corresponding Author

Courtney Rheinhart, Virginia Department of Agriculture and Consumer Services
Email: Courtney.Rheinhart@vdacs.virginia.gov

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Effect of a Certified Food Protection Manager on Employee Food Safety Behaviors in Rural Washington Counties

Alice Robison
Environmental Health Specialist II
Northeast Tri County Health District

Abstract
The Centers for Disease Control and Prevention (CDC) estimates that each year, roughly 1 in 6 Americans (or 48 million people) get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases (Scallan et al., 2011). The U.S. Food and Drug Administration (FDA) *Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types* (2009) found that the presence of a certified food protection manager (CFPM) correlated with higher compliance levels with food safety practices and behaviors than in establishments without a CFPM present (U.S. Food and Drug Administration [FDA], 2009). In 2010, the Conference for Food Protection (CFP) was asked to consider modifying the FDA Model Food Code to require that at least one person in charge at each food establishment is a CFPM (Julian, 2010). The CFP accepted this recommendation, and the Supplement to the 2009 FDA Model Food Code now requires food establishments to employ a CFPM (U.S. Public Health Service, 2011). The purpose of this study was to determine if a violation trend similar to the one shown in the 2009 FDA study is observed in food establishments located in northeastern Washington State. Results of food safety inspections performed in the Northeast Tri County Health District over a five-year period confirm that food establishments that employ a CFPM have significantly fewer employee-related violations of retail food safety requirements than food establishments without a CFPM.

Background
The northeast corner of Washington state, consisting of Ferry, Stevens, and Pend Oreille counties, is a rural area (United States Department of Agriculture, 2010). The population density of the tri-county area is 10.5 persons per square mile, compared with Washington state's population density of 101.2 persons per square mile (U. S. Census Bureau, 2010). Colville (population: ~5,000) is largest city in the tri-county area. (Northeast Washington Trends, 2011)

Chapter 246-215 Washington Administrative Code (WAC), Washington State Retail Food Code is a modification of the 2001 FDA model Food Code. Washington State is in the process of adopting the 2009 FDA model Food Code. The Washington State Environmental Health Directors expressed interest in modifying the 2009 FDA Food Code to require mandatory manager certification in the State of Washington. The Washington State Department of Health formed a committee to explore the issue. The committee determined the Department of Health could legally require manager certification but chose not to include mandatory manager certification in the Washington State Retail Food Code at the time of this rule revision for the following reasons.

Mandatory manager certification is not included in the 2009 FDA Model Food Code because the state delegates to the Conference for Food Protection (CFP) did not recommend that the FDA incorporate mandatory manager certification in the 2009 model retail food code (U. S. Public Health Service, 2009). Unilateral adoption would have caused confusion across governmental jurisdictions and among the retail food industry. Additionally, because not all stakeholders currently support mandatory manager certification, proposing mandatory certification may have significantly increased the time and expense of the rule revision process.

Currently, the Washington State Retail Food Code requires employees in food establishments to obtain a Food Worker Card within 14 days of beginning work. The format of the Food Worker Card training varies from county to county. Since 1992, the Northeast Tri County Health District has fulfilled this requirement by showing a 30-minute food safety video and then allowing participants to use the notes they took while watching the video to complete a multiple-choice test. A Food Worker Card is issued upon successful completion of the test. In February 2012, the Northeast Tri County Health District began offering the Food Worker Card training in an online format, as well as in-person at the Health District's office locations.

The Washington State Retail Food Code requires a "Person in Charge" (PIC) to be present during operation. The PIC is usually the manager or owner of the food establishment. The Food Code requires the PIC to demonstrate food safety knowledge. Food safety knowledge can be demonstrated by any of the following: being a certified food protection manager, correctly answering relevant food safety questions posed during an inspection, and/or by the food establishment not having any violations during an inspection. The Food Code also requires the PIC to provide food safety training to all employees and ensure that they have valid Food Worker Cards.

Currently, three food protection manager programs are accredited by the American National Standards Institute (ANSI)-Conference for Food Protection (CFP) Accreditation Program. The accredited food protection manager programs are offered by: 1) National Restaurant Association Solutions–ServSafe, 2) Environmental Health Testing, and 3) Prometric Inc. These programs provide a comprehensive training program, which educates managers on food safety issues, such as foodborne illness prevention, good personal hygiene, temperature control, cross-contamination, receiving, food storage, and facility sanitation. Managers also learn how to take active managerial control of foodborne illness risk factors and provide ongoing employee training. For this study, a manager that has been certified by an ANSI-CFP accredited certification program is considered to be a Certified Food Protection Manager (CFPM).

Problem Statement

In many food establishments, the only food safety training the manager has received is the Food Worker Card class. This class provides a baseline level of food safety education, but it does not provide specific training for managers about their role in the food safety system or how to provide food safety training to food employees. Situations arise in which managers expect that because employees have Food Worker Cards, they know how to apply what they have learned in the Food Worker Card class to the actual work situation without receiving additional, more specific training. Employees who have not received food safety training specific to their job may be more likely to make

errors in the food establishment that will increase the risk of unsafe food being served, and the resulting increased risk of foodborne illness to customers.

Research Question
Does the presence of a certified food protection manager in a food establishment result in fewer violations related to employee food safety behaviors being cited during inspections?

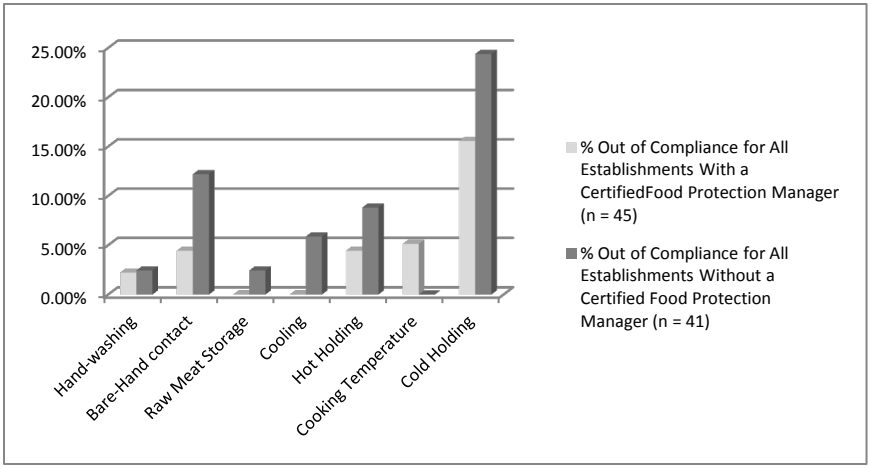
Methodology
A secondary data analysis was conducted of inspection reports for routine inspections conducted from 2006 through 2011. Inspection reports were obtained from the Northeast Tri County Health District. All inspections and inspection reports were completed by the same inspector. All food establishments that require a CFPM were included in the study. Food establishments requiring a CFPM included one full-service restaurant, three quick-serve restaurants, and one multidepartment grocery store. Forty-five inspection reports of food establishments that require CFPMs were reviewed. A matched number of food establishments that do no require a CFPM were also selected for use as the comparison group.

Establishments were selected based on their similarity to establishments requiring a CFPM using various characteristics, such as menu similarity and franchise or corporate affiliation. Food establishments not requiring a CFPM included one full-service restaurant, three quick-serve restaurants, and one multidepartment grocery store. Forty-one inspection reports of food establishments that do not require a CFPM were reviewed. Inspection report data were analyzed for violations of the following employee practices relating to retail food safety requirements:

- Hands washed as required
- Proper methods used to prevent bare-hand contact with ready-to-eat foods
- Raw meats below or away from ready-to-eat food
- Proper cooling methods
- Proper hot holding temperatures
- Proper cooking temperatures
- Proper cold holding temperatures

Results
Food establishments with a CFPM had fewer violations of all risk factors except for cooking temperature (see Figure 1).

FIGURE 1: Foodborne Illness Risk Factors out of Compliance for Establishments With a CFPM vs. Establishments Without a CFPM



The most significant differences were seen among violations related to the following risk-based requirements: The "Proper methods used to prevent bare-hand contact with ready-to-eat foods" requirement was documented as a violation on inspection reports for 4.44% of establishments with a CFPM versus 12.20% of establishments without a CFPM. Documented violation of the "Proper cooling methods used" requirement was not cited for establishments with a CFPM but was documented on 5.88% of inspection reports of establishments without a CFPM. Violation of the "Proper cold holding temperatures" requirement was documented on 15.56% of inspection reports of establishments with a CFPM versus 24.39% of establishments without a CFPM. Full-Service Restaurants had significant differences among violations related to the following risk-based requirements: The "Proper methods used to prevent bare-hand contact with ready-to-eat foods" requirement was documented as a violation on inspection reports for 9.00% of establishments with a CFPM versus 63.00% of establishments without a CFPM. Documented violation of the "Proper cooling methods used" requirement was not cited for establishments with a CFPM but was documented on 50.00% of inspection reports of establishments without a CFPM (see Table 1).

TABLE 1: Foodborne Illness Risk Factors out of Compliance for Different Types of Establishments With or Without a CFPM

Establishment Type With or without CFPM	Percent Out of Compliance						
	Hand-Washing	Bare-Hand Contact	Raw Meat Storage	Cooling	Hot Holding	Cooking Temperature	Cold Holding
Multidepartment Grocery With (n = 8)	0.00%	0.00%	0.00%	0.00%	25.00%	0.00%	12.50%
Multidepartment Grocery Without (n = 8)	0.00%	0.00%	12.50%	0.00%	37.50%	0.00%	75.00%
Quick-Serve Restaurant With (n = 26)	3.85%	3.85%	0.00%	0.00%	0.00%	7.96%	3.85%
Quick-Serve Restaurant Without (n = 25)	4.00%	8.00%	0.00%	0.00%	0.00%	0.00%	13.00%
Full-Service Restaurant With (n = 11)	0.00%	9.00%	0.00%	0.00%	0.00%	0.00%	45.00%
Full-Service Restaurant Without (n = 8)	0.00%	63.00%	0.00%	50.00%	0.00%	0.00%	13.00%

Further investigation revealed that the high incidence of cooking temperature violations in establishments having a CFPM were due to problems with a specific type of cooking equipment being used by a corporate quick-serve food establishment, as well as failure by employees to properly follow company-provided temperature-monitoring procedures for this equipment.

Conclusions

The presence of a certified food protection manager has a positive effect on the food safety behaviors of employees and results in fewer violations being observed during inspections. A limited number of food establishments in northeast Washington have CFPMs due to the limited availability of training programs. Regularly scheduled classroom training opportunities are not currently available. Online training and exams are available; however, the availability, cost, and quality of Internet service vary in rural areas. The cost of online CFPM certification ranges from $83 to $125. The cost associated with manager certification may create a competitive disadvantage between businesses willing to pay for manager certification and those that are not. Also, the economic differences between the rural Tri County area and the rest of Washington state, such as the per capita personal income ($27,931 in 2010 for Tri County area vs. $42,570 in 2010 for Washington state) and the percentage of the population living below the federal poverty rate (18.1% in 2010 for Tri County area vs. 15.3% for Washington state), may be more financially burdensome for individuals seeking manager certification (Northeast Washington Trends, 2011).

Recommendations

The Northeast Tri County Health District should explore the possibility of offering an accredited CFPM certification program locally. Because the Northeast Tri County Health District covers a large geographic area, the certification program could be offered at multiple sites to minimize the travel distance and cost for participants. A survey of local food establishment owners should be conducted to determine the following: awareness of existing manager certification programs, existing barriers to obtaining manager certification for employees, interest in manager certification opportunities offered

locally for employees and the costs that food establishments would be willing to incur for manager certification. The data generated by the survey could help the Northeast Tri County Health District determine if offering a manager certification program locally would be a viable option.

Further research should be conducted in other counties in Washington, including in both urban and rural areas, to determine if food establishments with a CFPM have fewer violations related to employee behaviors than food establishments without CFPMs. If the findings of this further research confirm that employee practice violations are significantly fewer in retail food businesses with CFPMs, the Washington State Retail Food Code should be amended to require that all food establishments employ a certified food protection manager.

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Corresponding Author
Alice Robison, Northeast Tri County Health District (Washington)
Email: arobison@netchd.org

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Testing for Non-O157:H7 Shiga Toxin-Producing Escherichia coli (STEC) Serotypes in Ohio

Jodi Taylor
Agriculture Inspection Manager
Ohio Department of Agriculture, Division of Meat Inspection

Abstract
The Ohio Department of Agriculture's Division of Meat Inspection (DMI) carried out preliminary testing of ground beef samples generated at state-inspected, red meat slaughter facilities for the presence of six non-O157:H7 Shiga toxin-producing *E. coli* (STEC) organisms (known as the "Big 6"). Specifically, these serotypes include O103, O111, O26, O45, O121, and O145. This pilot study used two different screening methods: the BioGX® and the DuPont BAX® assays. The results of this project were inconclusive with regard to quantifying the level of these organisms in state-inspected facilities. However, both the DMI and the Consumer Protection Laboratory (CPL) expressed the opinion that this study suggests that there is much work, including more extensive validation of the aforementioned screening kits and follow-up confirmation tests, which needs to be done prior to the use of these methods for regulatory purposes.

Background
The Ohio Department of Agriculture's Division of Meat Inspection (DMI) is a state-administered program that is responsible for the regulation and oversight of approximately 280 meat and poultry facilities throughout the state. The DMI's main objective is to ensure the safety of the meat and poultry products produced by these regulated establishments. The program has been in operation since July 1969, under the authority of the Wholesome Meat Act of 1967. Under this law, state meat-inspection programs must be maintained in a manner that is deemed "at least equal to" the federal program administered by the United States Department of Agriculture's Food Safety and Inspection Service (FSIS).

Foodborne illness is estimated to cost the U.S. over $152 billion each year (Scharff, 2010) and account for approximately 48 million illnesses, resulting in 128,000 hospitalizations and 3,000 deaths annually (Centers for Disease Control and Prevention, 2012.) One contributing culprit: pathogenic *Escherichia coli*. Pathogenic *E. coli* serotypes have been implicated in numerous outbreaks. Symptoms of *E. coli* infection include stomach cramps, bloody diarrhea, vomiting, and a low-grade fever. In the most severe cases, hemolytic uremic syndrome (HUS) and death can occur.

The DMI began testing for *E. coli,* specifically O157:H7, in ground beef in October 2002. Beef carcass testing was added in October of 2004, followed by testing of beef manufacturing trimmings and other non-trim, ground beef components in 2007. The DMI subsequently dropped carcass testing in July 2009 due to a lack of scientific data that supported the effectiveness of that program. The funds previously used for carcass testing were reallocated and used to strengthen the ground beef and beef manufacturing trimmings sampling programs. As per the current ground beef program, each inspected facility that is grinding or regrinding beef products is subject to sampling at a minimum of six submissions per year. If a positive finding is reported, that facility is

entered into an intensified sampling program consisting of eight follow-up samples taken from consecutive production lots under a "test and hold" mandate. Currently, the DMI has no testing protocol in place for any other pathogenic serotypes of *E. coli*.

Because there are few commercially available, validated, and reliable analytical methods for the identification of non-O157:H7 STEC organisms, and due to the difficulty of differentiating pathogenic non-O157:H7 strains from non-pathogenic *E. coli*, mandated testing has been slow to evolve (Eblen, 2007). However, the FSIS has recently proposed legislation mandating that six additional pathogenic strains of *E. coli*, known as the "Big 6," be defined as adulterants and thus be included in testing programs for federally regulated establishments. These "Big 6" serotypes of STEC include O103, O111, O26, O45, O121, and O145. In some countries, such as Australia, Argentina, Canada, and the European Union, illnesses associated with these serotypes are at least as prevalent-if not more so-than the better-known O157:H7 STEC (Eblen, 2007). Since 2007, the Centers for Disease Control and Prevention (CDC) has reported only three outbreaks related to non-O157:H7 STEC serotypes, none of which was traced to beef products. In 2010, an O145 outbreak in the U.S. was traced to shredded lettuce (26 confirmed cases, no deaths). In 2011, an outbreak tied to O104 (not one of the "Big 6") was associated with contaminated sprouts in Germany and France, where 852 total cases resulted in 32 deaths. In 2012, a six-state outbreak of O26 infections in the U.S. was tied to sprouts (14 cases, no deaths) (Centers for Disease Control and Prevention, 2012).

Although testing for Shiga toxin-producing *E. coli* (STEC) serotypes other than O157:H7 is not *currently* mandated by the FSIS, the DMI recognizes the potential food safety issues associated with these serotypes. For this reason, the DMI s proposing to perform preliminary testing to serve as a gauge that will aid the agency's sampling program in the months to come.

Problem Statement

The DMI has a very rigorous and well-executed sampling program for the detection and monitoring of *E. coli* O157:H7. However, the agency has yet to establish a baseline for the other "Big 6" serotypes. In addition, commercially available test kits are limited, and validation of these kits on field samples has not been well documented. This study will allow the DMI to determine the next steps in addressing this emerging food safety concern, such as the development of an additional testing program or perhaps conducting additional follow-up baseline studies of a broader magnitude.

Research Questions

1. Have the analytical methods been validated enough to produce accurate results?

2. Is the DMI able to regulate for these additional *E. coli* serotypes?

3. Can these assays be used to determine if non-O157:H7 STEC is present in DMI-inspected beef slaughter facilities?

Methodology

This study focused on the analysis of one hundred 325-gram ground beef samples randomly collected each day of operation, Monday through Thursday, from beef slaughter operations under the jurisdiction of the DMI. All samples were analyzed by the Ohio Department of Agriculture's Consumer Protection Laboratory (CPL), an ISO 17025 accredited laboratory. Sample collection began on Monday, August 22, 2011, and ended Thursday, September 29, 2011. The management of all participating facilities and the inspectors assigned to those facilities were briefed with the details of the research.

The beef slaughter establishments selected each month for the DMI's random *E. coli* O157:H7 ground beef program were further tested for non-O157:H7 STEC. Although samples came to the CPL with the identification of the establishment (as required by the current O157:H7 sampling program), for the non-O157:H7 portion of the testing, the CPL assigned an internal number to the sample which was not associated with the establishment. Therefore, the non-O157H7 STEC portion of the study was conducted blind. The DMI decided that there would be no regulatory ramifications to any participating establishment based on confirmed positive findings for non-O157:H7 STEC during this study.

Each of the 100 ground beef samples were analyzed within 24 hours of collection by the CPL. Any samples in transit for greater than 24 hours were rejected upon receipt by the CPL. Incoming sample conditions that rendered samples unsuitable for testing were noted and added to the "Comments" section of the Laboratory Information Management System (LIMS).

Initially, all samples were prepped by adding 25 grams of the ground beef to 225 mL of mTSB+N (Modified Trypticase Soy broth plus 20 mg/L novobiocin) following the USDA Microbiology Laboratory Guidebook (MLG) chapter 5, original version "Detection and Isolation of Non O157 Shiga Toxin producing *E. coli* from Meat Products" guidelines. The resulting enrichment was incubated. Following incubation, DNA was extracted from the sample. Any unused enrichment was refrigerated until the analysis was complete.

The initial run used the commercially available STEC screening assay from BioGX®. Each sample of DNA was analyzed on this assay following the parameters detailed in the MICRO-MDPEN-METH-007, Real Time polymerase chain reaction (PCR) detection of Shiga toxin *E. coli* utilizing the Cepheid Smart Cycler II platform. This screening assay detects the presence of the encoding Shiga toxin 1 and/or Shiga toxin 2gene (*stx*1 and *stx*2, respectively) and/or the uidA gene mutation. If negative for all three gene targets, the sample was reported as "None Deteced." If the sample was positive for any one of the three gene targets, the DNA was further analyzed using the two BioGX® STEC "Big 6" panels. Each panel is set up to screen for three of the "Big 6" serotypes: panel 1 for serotypes O145, O111, and O26 and panel 2 for O45, O121, and O103. If there were any positive results from panel 1 or panel 2, the CPL attempted to culturally confirm the sample.

Sixty of the original 100 DNA samples were also screened utilizing the DuPont BAX® STEC screening assay (40 samples were inadvertently discarded). The BAX® STEC screening assay screens the samples for the stx gene as well as the Intiman Gene (eae). The BAX® STEC screen assay regards a sample positive only if both the stx and eae genes are positive. If only one of the targets (stx or eae) is present, the sample is considered negative. Samples that tested positive on the BAX® STEC screening assay were then tested on the BAX® Panel 1 (*E. coli* O26, O111, and O121) and Panel 2 (*E. coli* O45, O103, and O145). If the sample is positive for the stx, eae, and wzx gene, CPL attempted to culturally confirm the sample (FSIS, 2011).

All potential positive samples for serotypes O145, O111, O26, or O103 were culturally confirmed using immunomagnetic separation (IMS) beads. Currently, the magnetic beads for serotypes O45 and O121 are not commercially available. If any samples were positive for any of the aforementioned four serotypes, the IMS was carried out on the automated Dynal Bead Retriever. Following the IMS, the samples were plated on each of the following: one Rainbow agar plate, one CHROM agar *E. coli* (CHROME), one Eosin Methylene Blue agar plate (EMB), and one Horse blood agar plate. The plates were read following the incubation period, and a total of 10 to 20 typical colonies (for *E. coli*) were selected for further analysis. The DNA was extracted from each colony and again analyzed using the PCR panels (from either the BioGX® or the BAX® kit). If both panels were negative, the analysis was stopped, and the samples were reported as "None Detected." If any panel was positive, the DNA was tested against the serotype-specific antisera. If found to be positive, the sample was analyzed using the VITEK® 2 a microbial identification system. If identified by the VITEK® 2 as an *E. coli*, the sample was reported as positive for non-O157:H7 *E. coli*.

Results

This section will summarize the results for both the BioGX® and BAX® methods as well as the limitations encountered with these testing methods. Additionally, due to the labor-intensive measures required to culturally confirm a screen positive, coupled with the high probability of not being able to locate the presumptive colony, the samples identified as potential positives via both testing methods were not culturally confirmed by CPL.

In both testing methods, the sample was enriched by adding 25 g of ground beef to 225 ml of mTSB containing 20 mg/L of novobiocin, which is an antibiotic that is used in the screening process for *E. coli* O157:H7, as it has been shown to have no effect on the growth *E. coli* O157:H7. This particular enrichment was used for enriching samples for non-O157 STEC, also following the USDA-MLG chapter 5, original version "Detection and Isolation of Non O157 Shiga Toxin producing Escherichia coli from Meat Products." As a result of this study, the CPL hypothesized that the concentration of novobiocin used was too high and could have potentially inhibited the growth of any low-level population of non-O157H7 *E. coli*. The FSIS has since decreased the amount of novobiocin used in the enrichment to 8 mg/L with reference to the current USDA-MLG version (Chapter 5B.01).

The initial BioGX® analysis revealed four potential positive samples for one of the "Big 6" serotypes: two for O26, one for O45, and one for O121. The confirmation steps outlined in the "Methodology" section were carried out, and ultimately eliminated two of the original four potential positive samples (both O26 samples were confirmed to be "None Detected"). The remaining two potential positive samples were unconfirmed for their respective serotypes (O45 and O121), since, again, the magnetic beads for serotypes O45 and O121 were not commercially available. Based on these findings, the testing process resulted in a 2% positive rate.

The main limitation of this initial BioGX® testing method is that the kit does not test for the presence of the Intiman Gene (eae), a protein essential for the intimate attachment and the formation of attaching and effacing lesions on gastrointestinal epithelial cells (Centers for Disease Control and Prevention, 2011). Because the "Big 6" serotypes must be either stx1 or stx2 positive and eae-positive, this initial testing method fell short of being able to definitively screen samples as potentials for one of the "Big 6."

In addition, the CPL experienced problems with the software used to interpret the results. Users encountered problems with the filter that accounts for other organic material present in the sample, which made distinction of a potential positive difficult.

During this research project, the DMI learned that the FSIS would not be using the BioGX®, but, rather, a customized method from DuPont. The CPL obtained several BAX® test kits from DuPont and analyzed the samples that were retained after the BioGX® testing was complete (60 samples total).

The results obtained from the BAX® method revealed a total of six potential positives. Of those, five could be classified as "true" "Big 6" potential positives. These results represent an 8.6% positive rate (based on the smaller sample size of 58). The sixth sample, although positive for stx1 or 2, was eae-negative, meaning that although the sample may be a pathogenic non-O157:H7 STEC, it isn't one of the "Big 6."

While performing the testing, the CPL experienced interference with other *E. coli* organisms, making it difficult to single out the "Big 6" organisms. The CPL also experienced difficulty with the software needed to execute the analyses, and technical support from DuPont was not readily available. Currently, the software is being modified to improve both the sensitivity and specificity.

Of the four potential positives identified with the BioGX® method, three (O121 and both O26 samples) were also identified with the BAX® method. The O45 serotype was eliminated using the BAX® method, as the serotype tested negative for the eae gene. Three additional samples were identified as potentially positive using the BAX® method (i.e., both stx1 and/or stx2 and eae-positive) that were not identified as such using the BioGX® method (in fact, all three samples tested negative for stx1 and stx2). At this point, it is not known why those four samples were missed by one method but identified by another. Both assay methods require more extensive validation in the laboratory.

Below is a table summarizing all potential positive findings by method and specific serotype:

METHOD	BIG 6 SEROTYPE						
		O145	O111	026	O45*	O121*	O103
	BioGX®			2	1	1	
	BAX®	1		2		3	
	*NO IMS BEADS AVAILABLE						

Conclusions

Based on this evaluation of the two commercially available screening methods, along with the challenge of isolating potentially positive colonies needed to culturally confirm a non-O157:H7 STEC, the DMI concludes that more work needs to be done before incorporating these assays into a regulatory sampling program to monitor non-O157:H7 STEC organisms in the meat industry. Some critical changes have been made to the official USDA-MLG method since this study was conducted (e.g., the decrease in the amount of novobiocin used in the extraction step). More validation studies need to be carried out in the laboratory to evaluate the commercial assays that are currently available in the market before the DMI can officially start testing meat samples for non-O157 STEC. The CPL is also in the process of evaluating the current USDA-MLG method (Chapter 5B.01) that uses custom-made PCR reagents (rather than a commercial kit) for detection of STEC as well as the use of "modified" cultural methods to isolate the STEC. All steps after that selection are futile if the original pathogen was missed during this selection process.

Recommendations

The DMI recommends conducting additional research and validation before these assays are used in mandatory testing programs. If the BioGX® and BAX® kits are validated either by the CPL or another official certifying, body such as AAOC International, the DMI will consider additional testing to again try to ascertain if these non-O157:H7 organisms are present in red meat slaughter facilities under DMI jurisdiction. As mentioned earlier, the CPL is also considering verifying the USDA-MLG method for use in the laboratory.

The results of this study suggest that the FSIS should consider working in conjunction with state programs to conduct validation studies in state-accredited (ISO 17025) labs to attempt to identify and address weaknesses in both the screening and confirmation steps.

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Corresponding Author
Jodi Taylor, Ohio Department of Agriculture, Division of Meat Inspection
Email: Taylor@agri.ohio.gov

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Potential Risks Associated With Raw Milk Consumption

Shane Thompson, REHS
HACCP Coordinator
Wyoming Department of Agriculture
Consumer Health Services

Abstract
Raw, unpasteurized milk products have been the confirmed source of several foodborne illnesses, outbreaks, and hospitalizations across the United States between 2005 and 2009. The purpose of this study was to determine if there was a relationship between the number of foodborne illnesses, outbreaks, and hospitalizations from raw milk products, and state regulations regarding the sale of raw milk products. Three different levels of regulation were identified, states that allow raw milk sales at retail (R); states that allow raw milk sales on the farm (F); and states that do not allow any raw milk sales for human consumption (N). There were no differences found between groups for the number of foodborne illnesses (P = 0.43), outbreaks (P = 0.89), or hospitalizations (P = 0.32) caused by raw milk products.

The Centers for Disease Control and Prevention (CDC) estimates that approximately 1 in 6 Americans (or 48 million people) get sick, 128,000 are hospitalized, and 3,000 die every year from foodborne diseases (CDC, 2011c). Many techniques have been developed for food processing, in an attempt to make the foods we consume safer from harmful bacteria. One of these techniques is pasteurization, which has long been accepted as a process, which reduces foodborne illnesses. Pasteurization is most commonly achieved by heating milk to 161º F for 20 seconds (CDC, 2011a). In recent years, people have been consuming more foods that undergo less processing because they believe those foods to be healthier. As a result, there has been an increased demand for unpasteurized milk and milk-products.

Background
Many Americans are seeking healthier lifestyles in what has become a convenience-driven, unhealthy era. According to nutritionist Cynthia Sass, MPH, RD, a national spokesperson for the American Dietetic Association, "The biggest trend I see is a back-to-the-basic approach – getting away from highly processed foods and back to whole foods" (Bouchez, 2006). Milk is no exception, and with the demand for raw milk on the rise, opponents are concerned that the risks of drinking raw milk outweigh the perceived benefits (CDC, 2011a; CDC, 2011b; Food and Drug Administration [FDA], 2011a; Raylea, Huck, Wiedmann, Boor, & Murphy, 2009).

According to the CDC, raw milk is milk from cows, goats, sheep, or other animals that has not been pasteurized. In the U.S., all milk products cause less than one percent of foodborne illnesses, and the sale of unpasteurized milk is estimated to account for less than one percent of milk sold to consumers (CDC, 2011b). On the contrary, around the turn of the 20th century, studies were conducted that linked raw milk to several disease outbreaks, and in fact, in 1938, raw milk caused 25% of all foodborne diseases in humans (Pasteurized Milk Ordinance [PMO], 2011).

Although not supported by empirical data, advocates of raw milk claim that pasteurization destroys enzymes, diminishes vitamin content, denatures fragile milk proteins, destroys vitamins C, B12, and B6, kills beneficial bacteria, promotes pathogens and is associated with allergies, increased tooth decay, colic in infants, growth problems in children, osteoporosis, arthritis, heart disease, and cancer (Realmilk.com, 2000).

The U.S. Food and Drug Administration (FDA) and other health agencies such as the CDC, and organizations such as the American Academy of Pediatrics agree that raw milk is unsafe because of the potential to contain disease-causing pathogens such as *Brucella*, *Campylobacter*, *Listeria*, *Mycobacterium bovis* (a cause of tuberculosis), *Salmonella*, Shiga toxin-producing *Escherichia coli*, *Shigella*, and *Yersinia* (CDC, 2011b; FDA, 2011a; Ralyea et al., 2009). In the past 20 years, the nature of foodborne illnesses associated with dairy products has changed. Recently, raw milk product outbreaks have been primarily associated with *Salmonella enteric, Listeria monocytogenes, Campylobacter jejuni,* and *Escherichia coli* O157:H7 (Ralyea et al., 2009).

Although interstate sales of raw milk have been prohibited since 1987 (PMO, 2011), some states have recently legalized, in varying degrees, the intrastate sale of raw milk. Other states, however, have continued to prohibit the sale and distribution of raw milk intended for human consumption within their borders.

Problem Statement

The desire to sell, purchase, and consume raw milk is on the rise. The public, however, may not know the benefits, risks, and necessary regulations to ensure the safety of raw milk for consumption. The correlation between foodborne illnesses, outbreaks, and hospitalizations from raw milk consumption and the differences between state regulations that govern raw milk sales is not well defined.

Research Question

Is there a difference in the number of raw milk related foodborne illnesses, outbreaks, and hospitalizations between states that have differing levels of regulations?

Methodology

All dairy-related, foodborne illness data for *Campylobacter* spp*., Salmonella* spp*.,* Shiga toxin-producing *Escherichia coli* (STEC), and *Listeria monocytogenes* were obtained through the National Outbreak Reporting System (NORS) from 1998 to 2009. This was the most current data available at the time of this study. Raw milk data were analyzed for the most recent five years of available data (2005-2009).

States (n=50) were divided into three different groups according to their regulations for selling raw milk. Groupings were based on a 2008 survey conducted by the National Association of State Departments of Agriculture (Beecher, 2011). Twelve states allow raw milk sales at retail (R): Arizona, California, Connecticut, Idaho, Maine, Nevada, New Hampshire, New Mexico, Pennsylvania, South Carolina, Utah, and Washington. Eighteen states allow raw milk sales on the farm (F): Arkansas, Colorado, Illinois, Kansas, Kentucky, Massachusetts, Minnesota, Mississippi, Missouri, Nebraska, New York, Oklahoma, Oregon, Rhode Island, South Dakota, Texas, Vermont, and Wisconsin. Twenty states do not allow the sale of raw milk for human consumption (N): Alabama, Alaska, Delaware, Florida, Georgia, Hawaii, Indiana, Iowa, Louisiana, Maryland,

Michigan, Montana, New Jersey, North Carolina, North Dakota, Ohio, Tennessee, Virginia, West Virginia, and Wyoming.

Arkansas, Colorado, Mississippi, Missouri, South Dakota, Vermont, and South Carolina have unique regulations that did not match the category definitions precisely, so each state was assigned to the category that most closely resembled their regulations.

Data from each group were analyzed for incidence of raw milk product outbreaks, illnesses, hospitalizations, and deaths. Because there were no deaths reported during the timeframe of this study associated with raw milk, no further analysis regarding deaths was carried out. The number of raw milk related outbreaks, illnesses, and hospitalizations for each group were calculated per 100,000 people, based on 2008 state populations (Information Please Database, 2010).

The number of raw milk associated outbreaks, illnesses, and hospitalizations caused by each of the four bacterial types (*Salmonella* spp., *E. coli* spp., *Listeria monocytogenes*, and *Campylobacter* spp.) were also individually analyzed.

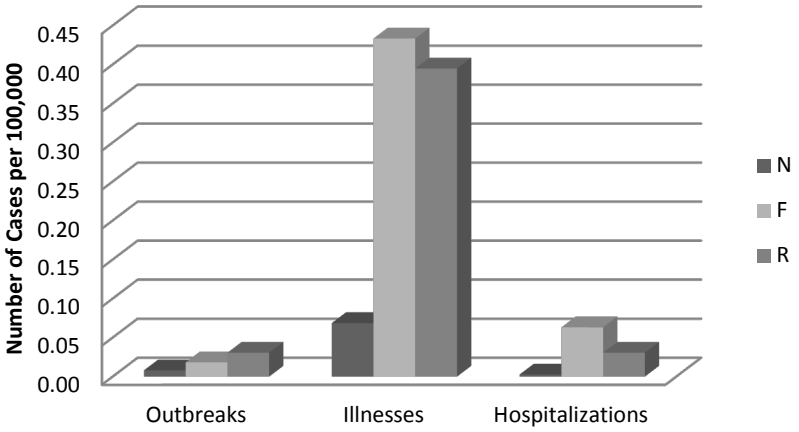
The data were analyzed using the PROC-GLM procedure in SAS, version 9.2 (SAS Institute, Cary, NC).

There was one multi-state outbreak during the timeframe of this study in which *E. coli* O157:H7 was the etiological agent. The outbreak caused 18 illnesses and 5 hospitalizations, but because the states involved were not identified, the outbreak data was not included in this study.

Results

Although there was a greater number of outbreaks from raw milk products in states that allow sales at retail (R) than states that allow sales on the farm (F), and a greater number of outbreaks from states that allow sales on the farm than states that do not allow raw milk sales (N), the differences were not statistically significant (P = 0.89). Similarly, there was a greater number of not only raw milk related illnesses, but also raw milk related hospitalizations in F than R, and R than F; however, differences were not significant between illnesses (P = 0.43) and hospitalizations (P = 0.32) among the different groups (Figure 1).

FIGURE 1: 2005-2009 Surveillance Data

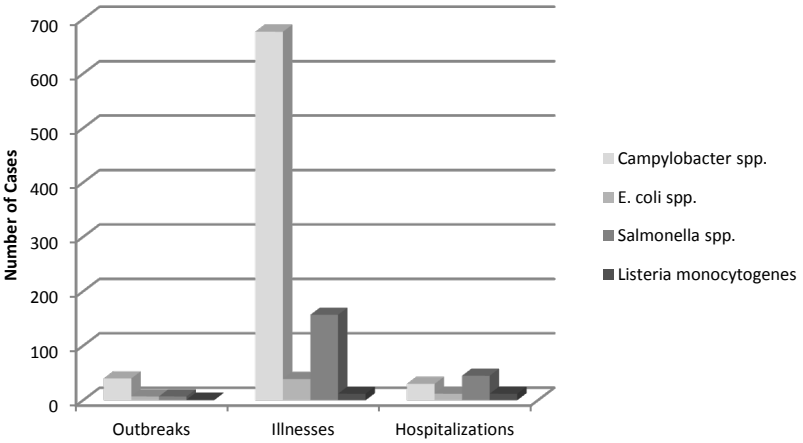


This figure illustrates the number of raw milk product outbreaks, illnesses, and hospitalizations per 100,000 people in the three study groups: states that do not allow raw milk sales (N); states that allow raw milk sales at the farm (F); and states that allow raw milk sales at retail (R).

Additionally, there were more illnesses associated with each outbreak for states that allow raw milk product sales vs. states that do not. In N, there were approximately 8.6 illnesses per outbreak associated with raw milk. In F, there were 23.7 illnesses per outbreak, and in R, there were approximately 12.9 illnesses per outbreak from raw milk products. Furthermore, there were fewer outbreaks, illnesses, and hospitalizations associated with raw milk in N than either F or R.

In addition, the data provides evidence that *Campylobacter* spp. was the most common cause of raw milk-related foodborne illness from 2005-2009, accounting for approximately 77% of all cases, followed by *Salmonella* spp*., E. coli* spp., and *Listeria monocytogenes* at 18%, 4%, and 1% respectively (Figure 2).

FIGURE 2: 2005-2009 Causative Agents



This figure shows the number of outbreaks, illnesses, and hospitalizations that have been linked to raw milk for the timeframe of this study for each of the four bacteria, *Campylobacter* spp., *E. coli* spp., *Salmonella* spp., and *Listeria monocytogenes*.

Conclusions/Recommendations

The popularity of raw milk is growing. In California alone, sales of raw milk increased 25% in 2010 (Raw-Milk-Facts.com, 2011). With the rapid expansion in sales, consumers need to understand the risks involved with consuming raw milk products, as well as the perceived benefits.

Although raw milk products make up approximately one percent of dairy production in the U.S., they account for 60 % of outbreaks caused by all dairy products, and people that consume raw milk products are 150 times more likely to contract foodborne illness than those that consume pasteurized products (CDC, 2012).

Proponents of raw milk claim that pasteurization destroys enzymes, diminishes vitamin content, denatures fragile milk proteins, destroys vitamins C, B12, and B6, kills beneficial bacteria, promotes pathogens and is associated with allergies, increased tooth decay, colic in infants, growth problems in children, osteoporosis, arthritis, heart disease, and cancer (Realmilk.com, 2000). However, both the FDA and CDC are strongly opposed to consuming raw milk, and have very different views compared to those that favor raw milk. According to the CDC (2011b), there are no health benefits from drinking raw milk that cannot be obtained from drinking pasteurized milk. The milk pasteurization process has never been found to be the cause of chronic diseases, allergies, or developmental behavioral problems (CDC, 2011b). Similarly, the FDA (2011b) states that pasteurizing milk does not cause lactose intolerance and allergic reactions. Both raw milk and pasteurized milk can cause allergic reactions in people sensitive to milk proteins (FDA, 2011b). Furthermore, pasteurization does not reduce milk's nutritional value, or make milk safe to leave out of the refrigerator for extended time, particularly after the container has been opened (FDA, 2011b).

The risks associated with consuming raw milk products are very well documented (CDC, 2011b; CDC, 2011c; FDA, 2011a; FDA, 2011b), and even though there are perceived benefits to drinking raw milk, people that choose to drink raw milk need to be aware of the risks. The results of this study are a great educational tool that can be used to inform consumers of those risks, and give them an opportunity to see how many people have gotten sick and/or hospitalized from consuming raw milk.

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Corresponding Author

Shane Thompson, Wyoming Department of Agriculture, Consumer Health Services
Email: shane.thompson@wyo.gov

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The Need to Implement Food Safety Education and Training for Child Care Providers in Iowa

Jennine Wolf
Environmental Health Specialist
Washington County Environmental Department

Abstract
In 2009, more than 40 million meals were served to Iowa children ages 5 or younger child care programs. Lack of food safety education regarding food preparation, service, and sanitation puts this vulnerable population at constant risk. In order to assess knowledge of safe food preparation and serving among child care providers, 62 child care conference attendees were surveyed using a multiple-choice tool. The results of the survey confirmed that child care providers know little about food pathogens, do not understand how food can be contaminated, fail to recognize how to prevent contamination, and lack knowledge necessary to prepare foods safely. This situation needs to change for the benefit of children in Iowa. The survey results suggest that the Iowa Department of Human Services (DHS) and Iowa Department of Public Health should require mandatory annual food safety training for child care providers. Food safety education is a continual learning process, because new food-related concerns continue to emerge as food processing technology advances.

Background
In 2009, 72% of children in Iowa ages 5 or younger had one or both parents who worked, compared with 62% nationally. This family dynamic has resulted in child care facilities serving more than 40 million meals to children 0-5 years of age (Iowa Department of Education, 2009). The protection of this high-risk population, who may consume 75 to 100% of their daily food intake in child care, is quietly falling through the cracks.

Although child care programs may be ”licensed and inspected,” many of them do not have requirements for safe food handling. There have been major transformations over the past 30 years in food technology that have led to changes in food manufacturing and, in turn, have altered the type of food the public consumes and how that food is prepared (Tauxe, RV, 1997). According to the Centers for Disease for Disease Control and Prevention (CDC), this fast and innovative progress has facilitated many new food safety issues, including the emergence of 14 previously unknown food pathogens. Unfortunately, educating the public on how to protect themselves and others against these food safety concerns has not kept up with the technological progress.

The only food-related requirement in many child care facilities is that regular meals and midmorning and mid-afternoon snacks be provided that are well-balanced, nourishing, and in appropriate amounts. Even parents who send meals with the children have no assurance that the child care provider is handling that food safely.

Problem Statement

Child care programs are increasing, and many of these providers are not up to date on current safe food handling standards. Parents have no guarantee that the food their children eat will be prepared under safe and sanitary conditions.

Research Questions

The following research questions were designed to assess if Iowa child care providers have minimum knowledge to prepare and serve food safely to the susceptible population in their care:

1. Are child care providers aware of emerging pathogens and how these pathogens contaminate the food?

2. Do child care providers understand what foods are safe to serve children and have minimum knowledge to prepare food safely?

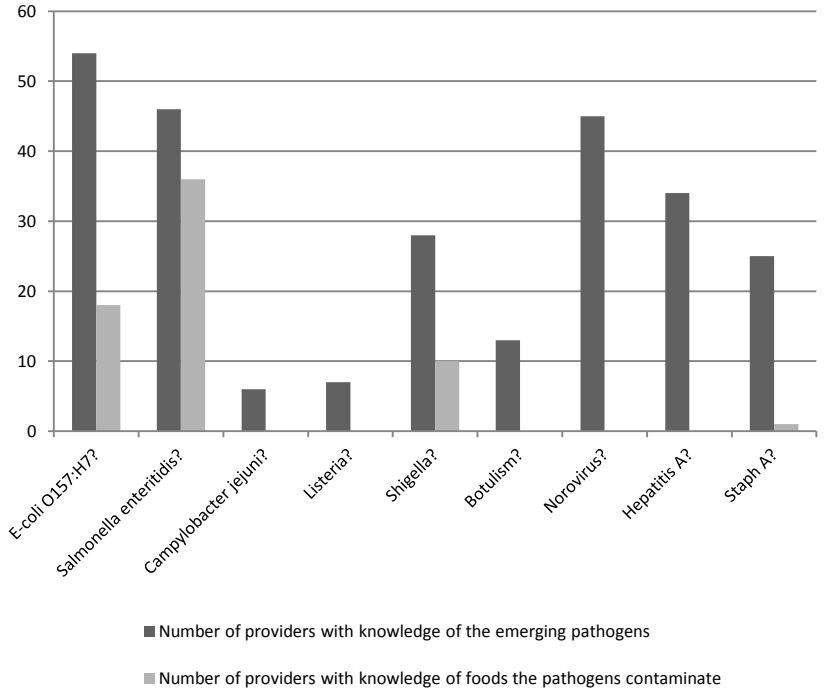
Methodology

A multiple-choice survey with 28 questions was developed to answer the two research questions. The questions were written using input from four experts in the field with extensive experience in food safety and survey administration among the targeted population. The survey was administered to child care providers who attended two conferences in October 2011: the Iowa Association for the Education of Young Children conference, held in Des Moines, Iowa, and the 4Cs Community Coordinated Child Care Fall Conference, in Iowa City, Iowa. Sixty-two child care providers participated in the survey.

Results

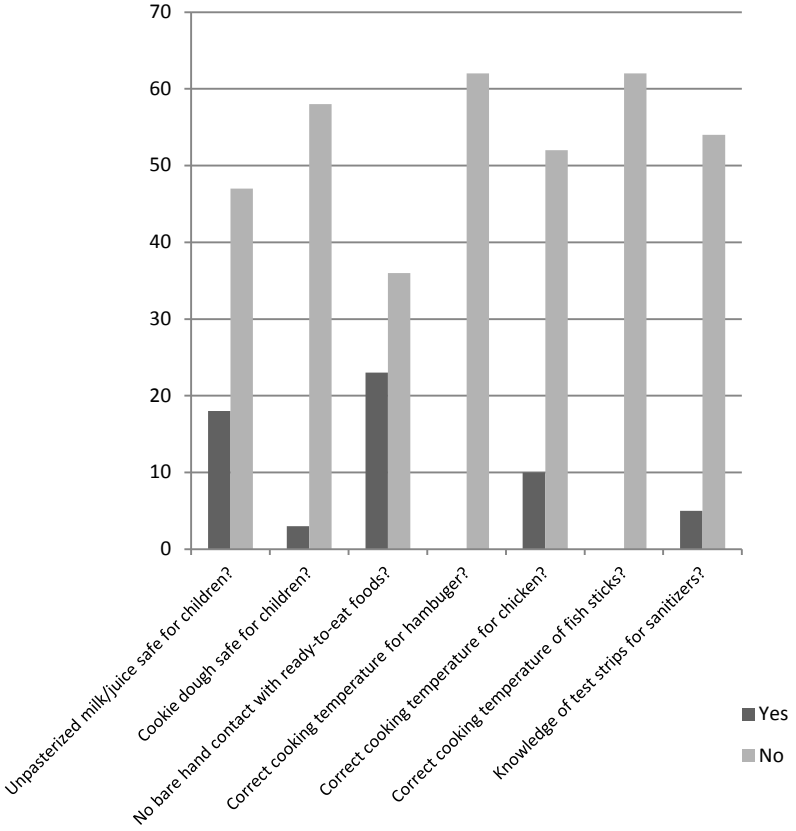
Research Q–1. Approximately 50% of survey participants had heard of some of the emerging pathogens on the survey. None of the respondents knew how *Norovirus, Hepatitis A, Listeria, Botulism*, *or Campylobacter jejuni* contaminates foods, and 90% did not know what foods *Shigella* contaminates (Figure 1).

FIGURE 1: Child Care Providers' Awareness of Foodborne Pathogens and How They Contaminate Food



Research Q–2. A total of 30 (48%) providers answered that unpasteurized milk and juice, undercooked eggs, and raw cookie dough are safe for children to consume. None of the providers knew correct cooking temperatures for hamburger or fish sticks, and 90% did not know the correct cooking temperature for chicken. More than 90% did not know the correct parts per million (ppm) for sanitizer for use on food contact surfaces (Figure 2).

FIGURE 2: Child Care Providers' Awareness of Safe Foods and Preparing Foods Safely



Conclusion

The survey results demonstrate that child care providers who participated in the survey do not possess minimum food safety knowledge to prepare and serve food to a high-risk population. Knowledge of the emerging food temperature pathogens and how they contaminate foods is critical to buying, preparing, and serving safe food, especially to a high-risk population. A large number of menus in child care facilities include ready-to-eat foods, which will increase with the current emphasis to add more fresh fruits and vegetables. Eliminating bare hand contact with ready-to-eat foods is the only way to prevent the contamination these foods by *Norovirus, Shigella* and *Hepatitis A.* Unpasteurized milk and juice and undercooked eggs are foods that should never be given to children. The results of this survey support the need for child care providers to possess at least minimum food safety knowledge to provide the safest food possible to the vulnerable population in their care.

Recommendations

The Iowa Department of Human Services (DHS) must add food safety education to the list of mandatory requirements for Iowa child care providers. Updated information for safe purchasing, storing, handling, preparing, and serving of food should be incorporated annually into existing continuing education resources. Safe food handling procedures should be included in the DHS regulations for child care centers and home-based programs. In addition, the CDC, the U.S. Department of Agriculture, and other organizations that provide food safety information the general public should put more emphasis on food safety for children in child care settings. All child care providers should be able to easily access this important information.

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Corresponding Author

Jennine Wolf, Washington County Environmental Department (Iowa)
Email: jwolf@co.washington.ia.us

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