



Journal of the Association of Food and Drug Officials

Serving the regulatory community since January 1937

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AFDO Welcomes Cohort VI

Joseph Corby, AFDO Executive Director

It's a little difficult to write an introduction to the AFDO Journal Fellowship Edition without thinking of Dan Sowards.

AFDO, IFPTI, and the Fellowship for Food Protection program lost a true friend this year in Dan Sowards. Dan had a great food safety career with the Texas State Department of Health and within AFDO, but I think it was his work and dedication with the IFPTI Fellowship program that revealed one of his greatest features – his willingness to share his knowledge and experience with young state and local officials destined to become tomorrow's food safety leaders. Dan probably could have worked most anywhere following his retirement from state service, but he chose rather to work on perfecting our profession by helping young and energetic individuals succeed and enhance their careers through the IFPTI Fellowship program.

Dan was an original designer of the Fellowship curriculum and was one of the more colorful Instructors and Mentors as well. It was always clear to us all that Dan very much enjoyed the Fellowship program and how it improved career opportunities for the Fellows. He was always interacting with the Fellows, listening to their career hopes, and helping them build confidence. He was inspirational and motivating – and yes, a great deal of fun when classes concluded. His influence was well recognized as he empowered others through his wisdom and skills.

Thank you Dan for helping to usher in the Fellowship program and thank you for sharing your knowledge. We are all going to miss you for sure.

About the Fellowship in Food Protection

Gerald Wojtala, Executive Director

This special edition of the AFDO journal highlights the research conducted by Cohort VI of the Applied Science, Law, and Policy: Fellowship in Food Protection. The Fellowship Program was created in 2011 in order to help foster the integrated food safety system in the U.S., as called for by the Food Safety Modernization Act in 2011.

The Fellowship Program is open to individuals who 1) perform food protection regulatory functions at the federal, state, local, tribal, or territorial level; 2) have at least four years of experience in the food regulatory field; and 3) have completed the FDA ORAU Level 1 retail or manufactured foods curriculum. Prospective Fellows undergo a rigorous application process and are evaluated closely before being accepted into the program. Cohort VI represented a good mix of 12 food safety professionals from state and local regulatory agencies.

The Fellowship Program comprises three week-long, seminar-style courses, held during a one-year period and taught by recognized leaders in food protection. The courses cover topics such as Food Law, Compliance, Food System Control Applications, and the Impact of Science.

Along with this coursework, Fellows also develop and conduct – in collaboration with their mentors – a research project designed to advance a specific topic related to food safety. After conducting their research, Fellows write a journal-quality article (published in this issue) and create a poster and PowerPoint presentation specifically for the AFDO Annual Educational Conference. Fellows are often asked to additionally present their work at other conferences and meetings. Some projects also influence policy and are adopted for further investigation. Resolutions for agency action often arise from Fellows' projects and this year is no exception.

Throughout the history of the Fellowship Program, assessment tools and evaluation mechanisms have been implemented to ensure continuous improvement to the program. Input and feedback is obtained from the Fellows, the instructors, and other external stakeholders. Modifications and improvements to the Fellowship Program over the years have included the addition of instructor-mentors, increasing the opportunities for the Fellows to deliver oral presentations to their peers, the addition of brown bag webinars, the implementation of assessments and resources using a learning management system, and updates to course modules.

In 2017, the Fellowship program is undergoing a major redevelopment. This redevelopment is based on a competency framework that was developed specifically for this audience. Mainly, the seminar component will be replaced with problem-solving activities and exercises designed to increase the knowledge and skills of the Fellows. We are really looking forward to the new and improved program!

All of us at IFPTI are very proud of the success of the Cohort VI Fellows, and we look forward to seeing how their hard work will impact the integrated food safety system.

Meet the Mentors



Charlene Bruce retired in 2011 after serving for thirty years with the Mississippi State Department of Health. For the past twenty years, she 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 Protection Program, she also served as an FDA Rating Officer for both the Milk and Food Programs.

Under her leadership, the Food Protection Program became one of the first in the nation to develop and implement a risk-based inspection program. Additionally, under her direction this program initiated a manager certification requirement in all food facilities, enrolled in and began implementation of the FDA Voluntary National Retail Food Regulatory Program Standards, and incorporated HACCP principles into the routine inspectional program.

While serving as Director, the Food Protection Program of the Mississippi State Department of Health became one of the first programs nationwide 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. The Mississippi State Department of Health awarded her the Public Health Environmentalist of the Year award.

While a commissioned officer with FDA, Ms. Bruce coordinated numerous joint investigations with the FDA Southeast Region and New Orleans District. As a result, the Food Protection Program was the recipient of the FDA's Commissioner's Special Citation Award and the Hammer Award. Following her directive, the Food Protection Program in Mississippi continues to be actively involved in the implementation of the FDA Manufacturing Food Program Standards.

Following Hurricane Katrina, USDA presented Ms. Bruce with the Gulf Relief/Supporting our Neighboring Communities medal. She 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.

Ms. Bruce served as President of AFDO and currently serves as President of AFDOSS. She was awarded the Eugene H. Holeman Award for outstanding service to AFDOSS. She has served on numerous AFDO and AFDOSS committees and is presently Chair of the Education and Training Committee. Charlene was awarded the Harvey W. Wiley Award at the 119th AFDO Annual Educational Conference on June 23, 2015. The Harvey W. Wiley Award is AFDO's most prestigious award. It is presented to a regular or honorary member for exceptional service to the state or nation in the performance of duties and responsibilities in the administration and enforcement of food and drug law and/or consumer protection laws and demonstrated promotion of the objectives of the Association.

Ms. Bruce 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. **Mentor to Jessica Egan, Renita Stroupe, and JoAnn Xiong-Mercado**



Joseph Corby is the Executive Director, Association of Food and Drug Officials (AFDO), following a 37 ½ 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 of Food and Drug Officials (CASA) 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.

Mentor to Kyle Shannon and Skya Murphy



Dr. Paul Dezendorf teaches in the Master of Health Sciences program at Western Carolina University in the University of North Carolina system, along with serving as a Research Subject Matter Expert for the IFPTI Fellowship program. At the University of South Carolina, he earned a Ph.D. in Public Health, a Graduate Certificate in Gerontology and a Master of Social Work in Community Development as well as a Master of Business Administration from Rutgers University. He also received a doctoral fellowship at the Centers for Disease Control and a Fulbright Scholar award for teaching and research in Russia. He has taught in several universities including UNC-Greensboro, East Carolina University, and Winthrop University in South Carolina. Prior to his academic career, he held management and regulatory positions in the cable television industry. Research Subject Matter Expert



Cameron Smoak joined the Georgia Department of Agriculture in 1976. Mr. Smoak served 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 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 and 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 costliest 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 past president of AFDO and 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, United States Department of Agriculture and the FDA. In addition, he has been a member of the AFDO's Seafood HACCP Training Program Certification Committee and chairman of the AFDO'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 Center for Agriculture and Security and Preparedness, and the Louisiana State University National Center for Biomedical Research & 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. **Mentor to Matthew Coleman and Autumn Schuck**



Dan Sowards (Deceased March 29, 2017) Retired in 2010 as the Food and Drug Safety Officer for Texas, and was employed for 37 years in food and drug safety by the Texas Department of State Health Services. He served in many different capacities during those years, including director of the Manufactured Foods Division (MFD), and acting director for the Drugs and Medical Devices Division between 1995 and 2010. Dan was responsible for the inspection and regulation of more than 20,000 manufacturers and wholesale distributors throughout Texas. Under his direction, in 1995 the MFD developed the first complete risk assessment module for food manufacturers in the U.S., which was requested and used by the FDA as a basis for future risk assessments for FDA's inventory of manufacturers. In 2002 Mr. Sowards took a brief leave of absence from his director position to develop an in-house decision tree and training for dealing with intentional contamination of the food supply and was a member of a national industry/government group dealing with the same issue.

Dan was a past president of the Association of Food and Drug Officials (AFDO) and a recipient of the Harvey W. Wiley Award, the highest honor bestowed by that organization. He was an active member of two AFDO working committees, the past training director for AFDO, and the training liaison for the development of AFDO training workshops sponsored by IFPTI. He was also a past president (twice) of the Midcontinent Association of Food and Drug Officials regional affiliate of AFDO.

During his many years of service, Mr. Sowards addressed numerous national settings and written for such publications as the Journal of the New York Bar Association, the Food and Drug Law Institute's FDLI Update, and the Journal for Food Protection. Dan participated as a presenter at numerous forums for the FDLI, Food Update, and for the FDA, and in the early nineties worked directly with FDA in the development of the food labeling regulations following the passage of the Nutrition Labeling and Education Act. He also worked directly with the Federal Trade Commission's Consumer Protection Division on a number of food labeling and misbranding issues. Dan was a Work Group Chair for the original Food Safety System initiative under President Clinton, and has provided numerous comments over the years, both for Texas and for AFDO, to the FDA on various food safety-related issues, including the original FDA Food Code. Dan was also the only State person on the FDA's original Food Advisory Committee established in 1991, which developed FDA's policy on reviewing genetically modified foods and the approval of the use of Recombinant Bovine Somatotropin Hormone (rbST) for use in dairy cattle.

Mr. Sowards was one of the original instructors for the IFPTI Fellowship beginning with Cohort I in 2010 and was always a strong supporter of the Fellowship program and each of the Fellows. He will be greatly missed. **Mentor to Odeisa Hichez and Kyle Shannon**



Steve Steinhoff worked as a food safety professional at the Wisconsin Department of Agriculture, Trade and Consumer Protection for 36 years. For more than 18 of those years Mr. Steinhoff was the administrator of the Department's Division of Food Safety. As Administrator of a division comprised of approximately 200 food protection professionals and support staff, he led statewide programs in the areas of manufactured food, retail food, meat inspection, dairy manufacturing, and dairy production. In this leadership role, he also was responsible for management of the division's budget and personnel functions as well as liaison and collaboration with other divisions, the Office of the Secretary, other state and federal agencies, and the state 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 on a contract basis as a course developer and instructor by the International Food Protection Training Institute (IFPTI) and the National Center for Biomedical Research and Training (NCBRT) at Louisiana State University (LSU).

Professionally, Mr. Steinhoff is a Past-President of AFDO, and its regional affiliate, the North Central Association of Food and Drug Officials (NCAFDFO). **Mentor to JoAnna Beck, Odeisa Hichez, and Sherri Sigwarth**

About the Fellows



JoAnna Beck is currently employed by the Indiana State Department of Health as a Food Safety Farm Consultant. She earned a Bachelor's of Science in Agriculture Business from Northwest Missouri State University and is currently pursuing a Master of Public Administration from the University of Southern Indiana. JoAnna has extensive knowledge and experience in fresh produce from working in the private sector for a large produce firm and currently she consults with and educates produce growers in Indiana on the best food safety practices for their operation. She enjoys cycling and spending time with her husband and two children. **Mentor: Steve Steinhoff**



Matthew Coleman is working as an Environmental Manager in the Manufactured Food Program, Division of Food Safety with the Florida Department of Agriculture and Consumer Services (FDACS). He obtained his Bachelor of Science in Environmental Studies in December 1998. In July 2005, he earned his Registered Sanitarian(RS) and continues to maintain this credential through National Environmental Health Association (NEHA). In 2016, Matthew, earned his Certified Professional in Food Safety (CP-FS) through NEHA.

In May of 1999, Matthew found his passion for Public Health after he began his career with the Florida Department of Health (FDOH) working as a field inspector in multiple programmatic areas: food, onsite wastewater(septic), group care, public pools and bathing area, rabies prevention, healthy beaches, tanning, mobile home and RV parks, and onsite drinking water. In 2004, Matthew became an Environmental Supervisor managing both programs and field personnel in multiple Public Health programs. In 2005, while working for FDOH, Matthew began working with the Centers for Disease Control and Prevention (CDC) to create and present presentations for the Environmental Health Training in Emergency Response (ETHER) courses. Matthew presented the Wastewater module at: CDC, Department of Homeland Security (DHS), National Aeronautics and Space Administration (NASA), 2007 NEHA conference, and several Florida County Health Departments. Matthew continued this partnership work until 2012 and coming aboard with FDACS. For his 18-year Public Health career, Matthew has over 700 Continuing Education training hours in Public Health.

In his current role with the Division of Food Safety, Matthew is responsible for the recruiting, hiring and training of field inspectors to work in our now further specialized Manufactured Food Program. During program maintenance, he is continually advising and further developing the senior inspectors that are the "boots on the ground" trainers for new Manufactured Food trainees and inspectors. Matthew acts as both a manager and, due to his broad Public Health knowledge and experience, a technical advisor to industry, field inspectors, supervisors, other managers and administration.

Matthew has developed and maintained networks with sister agencies, other state and federal agencies, and industry. He continues to prove himself as a leader in Public Health and eagerly seeks out increased responsibility and training. **Mentor: Cameron Smoak**



Jessica Egan is a Research Scientist in the Food Protection section of the Bureau of Community Environmental Health and Food Protection (BCEHFP) at the New York State Department of Health (NYSDOH). Jessica received her Master of Public Health (MPH) in Epidemiology at the University at Albany State University of New York in 2008.

While completing her MPH, Jessica served as a consultant with the Hospice and Palliative Care Association of New York State to write the Pandemic Flu plan for hospice programs across the state.

In 2007, Jessica began her career with the NYSDOH, working under the Centers for Disease Control and Prevention (CDC) Environmental Health Specialists (EHS-Net) grant on special studies to identify environmental factors that contribute to foodborne illness. In 2012, Jessica shifted to her current position as a food safety regulator. Jessica coordinates the NYSDOH Food Service Inspection Officer (FSIO) training program, which provides standardization training to food service inspectors across the state. She works closely with the NYS Education Department on food safety aspects of the childhood summer feeding program, and is working on the NYS adoption of the FDA Model Food Code. Jessica maintains and analyzes environmental health program data, and has worked on several projects to implement Lean Management practices into the area of food safety. Jessica also continues to participate in foodborne disease outbreak investigations. Jessica is a member of the Central Atlantic States Association of Food and Drug Officials (CASA) and the Northeast Food and Drug Officials Association (NEFD OA). **Mentor: Charlene Bruce**



Odeisa Hichez was born and raised in the Dominican Republic, where she also graduated with a Bachelor of Science in Psychology in 1993. In that same year, Odeisa moved to the U.S. and pursued a second Bachelor of Science in Biology, minoring in Chemistry, from The City University of New York (CUNY) Hunter College.

In March 2002, Odeisa began working for the New York State Department of Agriculture and Markets (NYSDAM) as a Food Inspector 1. During her 15-year career as a food inspector for NYS, Odeisa has conducted numerous inspections at retail and wholesale level, including Seafood and Juice Hazard Analysis Critical Control Points (HACCP), Low-Acid Canned Foods (LACF), acidified, U.S. Food and Drug Administration (FDA) contract, United States Department of Agriculture (USDA) contract, and live poultry custom slaughterhouses. Additionally, she has been involved in traceback of several class one recalls, which were performed jointly with other agencies. Along with these achievements, Odeisa has received several outstanding performance awards at the department's annual inspector's update.

Odeisa is an active member of Central Atlantic States Association of Food and Drug Officials (CASA) where she is currently Jr. Vice-President of the New York chapter. In addition to her duties as a Food Inspector, Ms. Hichez enjoys time with her family, photography, and hiking the New York/New Jersey area. **Mentors: Steve Steinhoff and Dan Sowards (Deceased March 29, 2017)**



Skya Murphy is a Program and Policy Analyst and Manufactured Food Regulatory Program Standards Coordinator for the Wisconsin Department of Agriculture, Trade and Consumer Protection (WDATCP) where she has worked since 2011. Her background is in policy analysis, food service, small scale-agriculture, and tropical ecology. Skya earned Bachelor of Art degrees in Spanish and Biological Aspects of Conservation from the University of Wisconsin, Madison in 1999, and a Master of Science in Environmental Science from Florida International University, Miami, in 2005.

As a certified project manager, Skya coordinates all aspects of implementation, evaluation and reporting for the FDA's Manufactured Food Regulatory Program Standards in Wisconsin. She is currently working with the Minneapolis District of the FDA to incorporate mutual reliance activities such as inspections planning and avoidance of duplication into WDATCP's routine practices. Skya routinely uses program data to evaluate the effectiveness of Wisconsin's regulatory approach and makes recommendations to improve the way WDATCP accomplishes its mission. She has been a member of the Association of Food and Drug Officials (AFDO) since 2012. Ms. Murphy is a world traveler looking forward to a trip to Spain this summer, who also enjoys kayaking, hiking, camping, and literature.

Mentor: Joe Corby



Autumn Schuck is the Inspection Manager for the Food Safety and Lodging Division within the Kansas Department of Agriculture, a position she has held since January 2016. She earned her Bachelor of Science in Hotel and Restaurant Management from Kansas State University in 2000.

Earlier in her food safety career, she has held positions within the Food Safety Division as an inspector, Field Supervisor, and Contract Supervisor. She also has experience as a third-party auditor. In her role as the Inspection Manager, Autumn serves as a resource to field staff and field supervisors throughout the state. As an extension of her Fellowship project, Ms. Schuck is collaborating with the Confucius Institute on a Culinary Class project focused on proper food safety practices during Chinese cuisine food preparation. After this pilot project, she is hoping to extend the project into different cuisines to provide outreach and improve food safety.

Mentor: Cameron Smoak



Kyle Shannon joined the Maryland Department of Health and Mental Hygiene (MDHMH) in June 2013, and serves as the Rapid Response Team (RRT) Coordinator. Kyle earned a Bachelor of Science in Biology from the University of Maryland Baltimore County in 1999 and became a Board Certified Licensed Environmental Health Specialist in the State of Maryland in 2003. Prior to coming to MDHMH, Kyle was employed by the Anne Arundel County Department of Health (AACDH). With AACDH, he worked in the Housing and Food Protection Services Program and then as a specialist in the control of Zoonotic and Vector-borne Diseases and was the primary AACDH Emergency Operations Center Representative.

As the MDHMH RRT Coordinator, Kyle is the primary point of contact for the FDA Baltimore District Office Emergency Response Coordinator, and is responsible for coordinating responses to foodborne disease outbreaks, food recalls, and other food emergencies within the Office of Food Protection (OFP) at MDHMH. In addition, he develops and provides training for Maryland RRT members in emergency response and food emergencies, and is

an active member of the MDHMH Emergency Management Team which acts as Liaisons for the Maryland Emergency Management Agency (MEMA) during all-hazards emergencies. In addition, to completing the Fellowship, as the MDHMH RRT Coordinator, Kyle is preparing to submit a continuation application for the RRT Cooperative Agreement with FDA and will continue to work with MDHMH Center for Food Processing for compliance with the Manufactured Food Regulatory Program Standard, particularly Standard 5, Food-related Illness, Outbreak, and Hazards Response. **Mentors: Joe Corby and Dan Sowards (Deceased March 29, 2017)**



Sherri Sigwarth is a Food Safety Specialist for the Iowa Department of Inspections and Appeals, Food and Consumer Safety Bureau, where she has served since 2013. She graduated with an Associate of Science degree (AS) in Dental Hygiene and is pursuing a Bachelor of Science in Health Care Leadership Administration at the University of Dubuque. After graduating with her AS, Sherri worked in the dental field for nineteen years. She also has worked in the restaurant industry for twenty-five years in a high-volume, multi-faceted, full-service restaurant.

Currently, Sherri performs retail food inspections in five counties in Northeast Iowa. She is a member of the Association of Food and Drug Officials (AFDO) and the National Environmental Health Association (NEHA). Ms. Sigwarth loves being involved in her hometown of Balltown, Iowa where she is the current mayor and lives with her husband and two children. **Mentor: Steve Steinhoff**



Renita Stroupe is the Health Educator for the DeKalb County Board of Health—Georgia Department of Public Health. She has served as the Health Educator for three years and served as an Environmental Health Specialist for five years prior to her current position. Renita has a Bachelor of Science in Neuroscience and Behavioral Biology from Emory University. She has been a Registered Environmental Health Specialist since 2014, and a Certified Pool/Spa Inspector, Certified Food Safety Instructor and Proctor (ServSafe and Prometrics), and Certified in Mosquito Larval Identification.

In her current position, Renita seeks to increase the agency's outreach within the local community, especially to those where English is a second language. She has created and translated educational guides and flyers for distribution and is currently working with other community organizations to provide training information in other languages, including Farsi, Arabic, and Chinese. Renita is a member of Georgia Environmental Health Association and Georgia Board of Registered Environmental Health Professionals (GBREHP). She is a State of Georgia Standardized and Re-Standardized Food Inspector and is currently becoming a member of the Association of Food and Drug Officials of the Southern States (AFDOSS). She is involved in DeKalb County Board of Health Wellness Committee to promote healthy changes at work to improve the health of employees as well as the community.

Renita's current project is to find more ways to incorporate food safety into culinary arts and engage in making food safety a primary focus instead of secondary to food quality within establishments of all cultural backgrounds. She is working with academic organizations, food manufacturers, and other regulators to find a common, integrated approach to talking about food safety and promote variety of foods that people enjoy and can continue to enjoy safely. Renita enjoys working with the youth in community organizations and in her church, because they have a fresh approach to life, yearn to know more, and can teach us without even trying. **Mentor: Charlene Bruce**



JoAnn Xiong-Mercado is the Food Safety Education & Outreach Specialist with the Marion County Public Health Department (MCPHD) where she has worked for the last six years. In 2007, JoAnn interned with Columbus Public Health in Columbus, Ohio, working in each of the environmental health departments throughout her internship. In 2008, JoAnn earned her Bachelor of Science in Public Health from Indiana University-Purdue University Indianapolis, and then she earned an Associate of Science in Culinary from Ivy Tech

Community College, in 2014.

In May 2011, JoAnn began working at MCPHD, in Mosquito Control. Later, in September 2011, she transferred to the Food & Consumer Safety Department as an Environmental Health Specialist. Finally, in February 2017, JoAnn was promoted to her current role as the Food Safety Education & Outreach Specialist. In this role, JoAnn provides food safety classes for the public and internal training for new hires. Additionally, she performs retail food inspections and works toward bringing about standardization. JoAnn is also an adjunct instructor of Sanitation for Ivy Tech's Culinary Program, the Vice President of the Indiana Environmental Health Association, Education Chair for the American Culinary Federation, Greater Indianapolis Chapter, and a kitchen volunteer at Second Helpings, a food rescue organization. **Mentor: Charlene Bruce**

Indiana Food Safety Regulator Enumeration

JoAnna Beck

Food Safety Farm Consultant

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Abstract

The purpose of this study was to determine the number, titles, and types of food safety regulatory personnel in Indiana. The objective of this study is to build a model approach that may be used to gather information about the collective capacity and diversity of the food protection system nationwide. Surveys via telephone and email were conducted with eight agencies across all levels of government including: United States Food and Drug Administration, United States Department of Agriculture Food Safety and Inspection Service, Indiana State Department of Health Food Protection Division, Indiana State Department of Health Long Term and Acute Care, Indiana Board of Animal Health, Indiana State Egg Board, and each local county health department in Indiana. Federal and state agencies provided 100% response to the survey questions posed, while, local health agencies had a response rate of 49%. Recommendations include: ensuring correct contact information for regulatory agencies, utilizing professional organizations to obtain a higher response rate, and being prepared to employ various strategies or tactics for initiating response from a dispersed audience.

Indiana Food Safety Regulator Enumeration

Background

At present, there is no comprehensive description of the food safety regulator workforce including the number and types of food safety regulators in Indiana. This lack of an overall picture comes at a time when food safety has been a rising concern in Indiana as well as throughout the country leading to the enactment of the Food Safety Modernization Act in 2011. There is an importance for Indiana to have an understanding of the number of food safety regulators in regards to the amount and types of training needed, as well as the number of establishments that require inspections vs. the amount of full time equivalent (FTE) employees are available to complete the work. The lack of a comprehensive description of the workforce has led to a belief among some food safety regulators that there are insufficient regulators to meet public health needs.

Regulatory food agencies with food protection staff located in Indiana include: The United States Department of Agriculture Food Safety and Inspection Service (USDA FSIS), and the Food and Drug Administration (FDA). Indiana State Department of Health-Food Protection, Indiana State Egg Board, Indiana Board of Animal Health, Indiana State Department of Health Acute and long Term Care Division, and 92 local county health departments.

USDA FSIS and FDA are responsible for regulating food that crosses state lines or enters into interstate commerce. USDA FSIS regulates meat, poultry and processed egg products

that enter into interstate commerce, while the FDA regulates all other food products that enter into interstate commerce.

The Indiana State Department of Health (ISDH) Food Protection is responsible for regulating wholesale food establishments, retail food establishments on state property, and temporary food establishments that are on state property. Local Indiana county health departments are responsible for regulating retail food establishments in their counties.

The Indiana State Egg Board regulates raw shell eggs of domesticated chickens in Indiana. The Indiana State Egg Board adopted the U.S. Standards, Grades, and Weight Classes for shell eggs promulgated by the USDA.

The Indiana Board of Animal Health (BOAH) consists of two divisions: meat and poultry inspections and dairy inspections. BOAH is responsible for inspecting instate meat and poultry production of amenable species that is only sold in intrastate commerce. In addition, BOAH is responsible for inspecting milk, cheese, and other dairy production that may cross state lines under the agency's participation in the National Conference on Interstate Milk Shipments (NCIMS).

Indiana State Department of Health (ISDH) Acute and Long Term Care Divisions are responsible for inspecting food in nursing homes, prisons, and state inspected daycare facilities.

Local county health departments in Indiana are responsible for regulating retail food establishments. Besides regulating retail food establishments (not on state property) local county health departments also regulate tattoo parlors, public swimming pool regulations, and onsite septic and wastewater regulations in retail settings. Local health departments in the State of Indiana are all autonomous as Indiana is a "home rule" state. Local health departments serve as agents to ISDH Food Protection and may act on its behalf. ISDH Food Protection provides guidance, consultation and training to local health departments.

Problem Statement

Currently there is no comprehensive inventory of the number, job classifications, and organizational affiliations of Indiana food safety regulators.

Research Questions

1. Which state and local agencies employ food safety regulators?
2. What job classifications exist for food safety regulators?
3. How many food safety regulators are employed in each job classification?
4. How many food safety regulators are employed in each agency?
5. How many Full Time Equivalent (FTE) collectively, are devoted to food protection in Indiana?

Methodology

This study began with identifying all food safety regulators within the ISDH Food Protection Division. Interviews both in-person and by phone were conducted with supervisory staff within ISDH Food Protection to obtain a list of additional state level and federal agencies including contact information with food regulatory authority in Indiana. Utilizing the information obtained through the interviews with ISDH Food Protection staff, email interviews were conducted with the following agencies: Indiana BOAH, Indiana State Egg Board, ISDH acute and long term care divisions, USDA FSIS, and FDA. A list of Indiana's 92 counties was obtained from ISDH Food Protection including contact information.

A survey was sent by email to all 92 counties in Indiana. Email survey questions for each agency included:

1. What are the position titles for your agency?
2. What food program is each position working under?
3. Type of position?
4. Does the position work in the field or office or a combination of both?
5. Please provide a summary of each position.
6. How many positions for each job title are authorized by the agency?
7. What percent of time is allocated for food regulatory work for each position?

An interview was conducted with the director of ISDH Food Protection that asked the same questions as the email survey. An email survey was not deemed necessary for this agency, as communication was more easily obtained by an interview.

Results

Federal and state agencies provided a complete set of responses to questions posed in the survey. The responses indicated that the job titles and regulatory responsibility vary greatly between the agencies. A summary of job titles and employee count for local health departments can be seen in Table 1.1. Federal and state agency data is summarized in Table 1.2.

Table 1.1

Local Health Departments

Agency	Job title	Total positions	% regulatory food work	Food regulatory FTE
Local Health	Environmental Health Specialist	87	52%	45.24
	Food Inspection Officer	2	100%	2
	Food Inspector	1	50%	0.5
	Food Service Inspector	1	20%	0.2
	Specialist	1	95%	0.95
	Supervisor	5	50%	2.5
	Support Staff	7	50%	3.5
Total		2	50%	1
Total		106		55.89

Table 1.2

State and Federal Agencies

Agency	Job Title	Total Positions	% Food Regulatory Effort	Food Regulatory FTE
FDA	Consumer Safety Officer	6	100%	6
USDA FSIS	Food Inspector	150	100%	150
ISDH Food Protection	Food Scientist	12	100%	12
	Supervisor	4	100%	4
ISDH Acute Care	Inspector	4	5%	0.2
ISDH Long Term Care	Surveyor	100	6%	6
	Supervisor	8	100%	8
BOAH	Inspector	33	100%	33
	Auditor	4	100%	4
Egg Board	Inspector	4	80%	3.2
	Supervisor	1	80%	0.8
Total		326		227.2

Out of 92 counties in Indiana, 45 (49%) replied to the survey questions. Commonalities among job titles were noted with the local health departments as the title “environmental health specialist” was noted in 80% of the enumerated responses. One result to note is that 45 percent of the local health departments reported having employees who spent more than 50% of their time and effort on food regulatory work. The remainder of the time was spent on various regulatory work in areas other than food such as: swimming pool inspections, sewer and septic work, and inspecting tattoo parlors.

100% response rate was obtained from the federal and state agencies that were polled for the survey. There are currently 326 food safety regulator positions across federal and state agencies with a FTE value of 227.2 employees.

Conclusions

Because this was an enumeration study, the target response rate was 100%. One of the keys to successful completion of this research was identifying which agencies regulated food, and then finding correct contact information for each agency. Once state food regulatory agencies and federal food agencies with personnel working in Indiana were identified, getting a 100% response rate and complete information from these respondents was a relatively easy task.

Conversely, polling local health departments proved difficult. There was no accurate, comprehensive contact information for local health departments in Indiana and getting all or nearly all of the local health departments to respond to the survey was problematic due to the short time frame available and using the methodology employed in this study. Even after repeated e-mail contacts and follow up phone calls, the response rate for local health departments was 49%.

Recommendations:

1. Prior to initiating data collection, ensure correct contact information for each regulatory agency to be surveyed.
2. The use of professional organizations where large portions of the target survey audience are members could prove to be beneficial in gaining a higher response rate from local or municipal health departments where other communication attempts have failed. Organizations could include the state wide environmental health association.
3. Researchers should be prepared to employ various tactics to initiate responses from audiences where all forms of communication have failed. This approach would prove to be beneficial to rely on those who have responded to encourage the response rate for those who have failed to respond.
4. When developing a larger survey, researchers should utilize the titles identified in his study as check boxes to begin standardizing responses.

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First, I would like to acknowledge Krista Click and George Jones of the ISDH for supporting me throughout and allowing me the time to complete this fellowship. Additionally, I would like to thank all of the participants that responded to the survey conducted as part of this research.

I would also like to thank IFPTI for providing the opportunity to participate in the fellowship, and the IFPTI educators, subject matter expert, Paul Dezendorf, and my mentor, Steve Steinhoff, for guidance throughout the project. Lastly, I would like to thank each of the fellow Cohort 6 members in making the Fellowship such a rewarding experience.

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Use of Critical Control Points (CCPs) In Florida Seafood HACCP Plans

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Abstract

The Critical Control Points (CCPs) in Fish and Fishery Products Hazard Analysis and Critical Control Point (Seafood HACCP) plans from 158 Florida wholesale seafood establishments were evaluated for food hazard significance, probability, and likelihood to occur within the food establishment's process, end product, and intended consumer use. The plans were obtained from onsite, rated inspections during the period October 1, 2014, to September 30, 2016, carried out by the Florida Department of Agriculture and Consumer Services (FDACS) under FDA contract.

The study found that a substantial percentage of the CCPs, 105 of 440 or 23.9%, were not significant, probable, or reasonably foreseeable food hazards within that given process and/or end product nor were they required by 21 CFR Part 123. These CCPs, termed "negligible elements" in the study, were found in 63 of the 158 plans (39.9%); in fact, 9 of those 63 plans (14.3%) did not include a single valid CCP. The study also found that these negligible elements were distributed among small, medium, and large firms in proportion to the number of firms in those categories.

The study recommends further studies to determine whether the conclusions of this study might apply beyond Florida; whether negligible elements might be controlled by other means; the potential extent and cost of HACCP report bias due to negligible elements; opportunities to overcome the negligible element problem by training or outreach; and whether the problems found in Seafood HACCP plans might also occur in Preventive Controls for Human Food and food safety plans.

Key words; Seafood Hazard Analysis and Critical Control Points (HACCP) plans; Critical Control Points (CCPs); 21 CFR Part 123; Fish and Fishery Products Hazards and Controls Guidance (4th edition).

Background

Mandatory Fish and Fishery Products Hazard Analysis and Critical Control Point (HACCP) (hereinafter referred to as Seafood HACCP) preventive measures have been in place for nearly 20 years in Florida. During this period, some seafood processors appear to have incorporated elements as Critical Control Points (CCPs) that may not be significant, reasonably foreseeable and/or probable food hazards within the specific process and/or end product, termed "negligible elements" in this study. For example, anecdotal evidence

suggests that some seafood establishments may be using their Seafood HACCP plan as a repository for a broad range of company, program and/or customer-specific rules that are only related in a minor way, if at all, to food safety in regard to the given process and end product. In other cases, differing end products and processes are included into one single HACCP plan, thus unnecessarily applying CCP(s), monitoring, and verification steps to an end product and/or a process where a food hazard may not be significant, reasonably foreseeable and/or likely. The continuing and perhaps growing use of seafood HACCP plans as a “catch all” location for company, customer and/or third party specific information by creating negligible elements has the potential to cloud the purpose of Seafood HACCP plans to the seafood establishment operator.

For regulators, the inclusion of negligible elements appears to have the potential to undermine the statistical validity of the Seafood HACCP system. For example, an unlikely food safety element as a CCP in a HACCP plan, an element not required by 21 CFR Part 123, may be found in violation and thus count toward a HACCP violation but have nothing to do with HACCP. The continued use of these negligible elements may misstate the actual situation regarding Seafood HACCP violations in the State of Florida and as a result divert resources from other food safety regulatory areas.

As a result of these concerns, the Florida Department of Agriculture and Consumer Services (FDACS), Division of Food Safety authorized the time for the author to pursue his concerns about Florida Seafood HACCP reporting.

Problem Statement

The extent to which negligible elements are incorporated as Critical Control Points (CCPs) in Florida Seafood HACCP plans is unknown.

Research Questions

1. What is the distribution of required CCPs and negligible elements in seafood establishment HACCP plans?
2. What is the percentage of negligible elements incorporated into seafood HACCP plans?
3. What percentage of food establishments incorporate negligible elements as CCPs that could be monitored as SSOPs?
4. Is there any correlation between the inclusion of negligible elements in Seafood HACCP plans and the food establishment size?

Methodology

A total of 158 seafood HACCP plans acquired during rated inspections, under FDA contract, of seafood wholesale establishments from October 1, 2014, to September 30, 2016, were used as a sample for this project. Those plans were evaluated for biological, chemical, and physical potential hazards in relation to one end product and process using the information obtained at time of inspection (including inspector flow charts, inspector hazard analysis, and the seafood establishment’s HACCP plan) and 21 CFR Part 123, and the Fish and Fishery Products Hazards and Controls Guidance (4th edition). Each CCP was then scored in regard to a food hazard that was reasonably foreseeable, significant, and probable or as a negligible element within the specific process, end product and intended consumer use. The evaluation of these CCPs considered the specific end product package (air package or modified air packaging), process steps and time, product holding state (frozen or refrigerated) and the intended end consumer use (raw, cooked or further processed).

In order to test for the relationship between the inclusion of negligible elements and the size of the seafood establishment, the seafood establishments were assigned to one of ten categories based on annual gross sales estimated by the seafood establishment at the time of rated onsite inspection. Those ten categories were then broken into three groups: Small (\$0 to \$499,999), Medium (\$500,000 to \$9,999,999) and Large (\$10,000,000 and up). The size categorization was used to test whether a firm’s size was associated with the likelihood of use of negligible elements.

Results

A total of 440 individual CCPs were identified and reviewed in the 158 HACCP plans evaluated. A total of 335 out of the 440 CCPs reviewed (76%) were reasonably foreseeable, significant, and probable food hazards within the specific process, end product and/or intended customer use. However, 105 out of the 440 CCPs reviewed (23.9%) appeared to be negligible elements, that is not required to be CCPs, in regard to the applicable process and end product.

These 105 negligible element CCPs, not required by 21 CFR Part 123, were found in 63 of the 158 HACCP plans (39%) evaluated. The percentage of CCPs not required in a HACCP plan ranged from 12.5% to 100% of the total CCPs in the food establishment’s plan. Table 1 presents the relationship between the percentage of negligible CCPs and the number of plans.

Table 1

Relationship Between Number Plans and the Percentage of Negligible CCPs

Number of plans	Negligible CCP%	Number of negligible CCPs in plan(s)
1	12.5%	1 of 8 CCPs in 1 plan
1	14%	1 of 7 CCPs in 1 plan
2	20%	1 of 5 CCPs in 2 plans
7	25%	1 of 4 CCPs in 7 plans
20	33%	1 of 3 CCPs in 18 plans
		2 of 6 CCPs in 1 plan
		3 of 9 CCPs in 1 plan
1	43%	3 of 7 CCPs in 1 plan
12	50%	1 of 2 CCPs in 4 plans
		2 of 4 CCPs in 6 plans
		3 of 6 CCPs in 2 plans
1	60%	3 of 5 CCPs in 1 plan
6	67%	2 of 3 CCPs in 6 plans
1	71%	5 of 7 CCPs in 1 plan
1	75%	3 of 4 CCPs in 1 plan
1	83%	5 of 6 CCPs in 1 plan
9	100%	1 of 1 CCPs in 4 plans
		2 of 2 CCPs in 3 plans
		3 of 3 CCPs in 1 plan
		5 of 5 CCPs in 1 plan

All the CCPs in nine of the 63 plans (14.3%) were negligible elements. In most of these cases, the seafood establishment (secondary receiver) received frozen product, did not further process or re-label, and shipped back out the frozen product, e.g. box-in, box-out products. In other words, the probability of significant food hazards occurring while in an unchanged frozen state is not reasonably foreseeable and thus any CCP is a negligible element.

Some of examples of negligible elements included as CCPs in the HACCP plans reviewed:

- Metal inclusion – knives used with manual cutting of fish
- Cooling – rapidly cooled cooked seafood to safe temperatures within 2 hours
- Allergen labeling – within a single ingredient fish end product
- Storage – product held in a frozen state
- Clostridium botulinum – for an end product air packed
- Receiving – incoming product received in a frozen state
- Processing – histamine time control with brief processing steps

Small seafood establishments made up 20% of the 158 plans examined in the study; medium size seafood establishments comprised 57%; and 23% were large. Table 2 further illustrates percentage of HACCP plans by food establishment size.

Table 2

HACCP Plans by Food Establishment Size

<u>Food establishments by size</u>	<u>% of whole (N=HACCP plans)</u>
35 large	23% (158)
90 medium	57% (158)
33 small	20% (158)

The size distribution was then applied to only those 63 seafood establishments with negligible elements, i.e. CCPs not required by CFR123. Table 3 shows HACCP plans grouped by food establishment size. These results were close to the size distribution of all 158 Seafood establishments. There appears to be no correlation of seafood establishment size and the subsuming of negligible elements as CCPs into HACCP plans.

Table 3

HACCP Plans with Negligible Elements by Food Establishment Size

<u>Food establishments by size</u>	<u>% of whole (N=HACCP plans)</u>
12 large	19% (63)
38 medium	60% (63)
13 small	21% (63)

Conclusions

There were a substantial number of negligible elements subsumed as CCPs in the sample of HACCP plans reviewed in this study. In fact, a total of 105 out of the 440 CCPs (23.9%) reviewed appear to be negligible element and 39% of the food establishment HACCP plans evaluated contained at least one negligible element included as a CCP in their HACCP plan but not required by 21 CFR Part 123.

Further research is required in order to determine how the 105 negligible element CCPs could be better controlled by other means than inclusion in a Seafood HACCP plan.

In conclusion, there does not appear to be a correlation of food establishment size and the inclusion of negligible elements as CCPs into HACCP plans. In other words, seafood establishments from the smallest to the largest appear to be including negligible elements as CCPs into their HACCP plans.

Recommendations

1. A similar study should be carried out in one or more states with a large seafood industry in order to identify whether the conclusions here are particular only to Florida or may indicate a national pattern of including negligible elements into Seafood HACCP plans.
2. Future research should examine how negligible elements in Seafood HACCP plans might be better controlled by other means.
3. Further research should examine to what extent the inclusion of negligible elements biases inspection reports based on Seafood HACCP plans as well as estimating the potential costs of that bias in terms of industry and regulatory resources. The relationship between steps unnecessarily incorporated as CCPs as compared with addressing these lesser food elements by other means needs further in-depth research. In doing so, such research might assess the potential detraction from the qualitative statistical approach of HACCP as well as unnecessary use of industry and regulatory resources when these lesser elements steps are incorporated as CCPs.
4. Further research should examine opportunities to either identify existing Seafood HACCP training methods and focused outreach initiatives or develop methods and initiatives that might address the issues identified in this study.
5. Further research also should examine whether the problem of negligible elements in Seafood HACCP might well be a problem in the future in Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food in order to incorporate changes into training methodology for industry and regulators.

The intention is to apply some of the above recommendations and take action in Florida. Specifically, focused outreach activities to those seafood processors that were identified during this research to have incorporated negligible elements as CCPs within their HACCP plans. Additionally, outreach initiatives to broach this subject with various seafood industry associations is already in the making.

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Making the Grade: Do Current Restaurant Grading Systems Fulfill Stakeholder Expectations?

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Abstract

A restaurant grading system is a program in which food service establishments are assigned a score reflective of the sanitary conditions of the facility. These scores take a variety of formats ranging from letters to numbers to colors. Most restaurant grading systems are based on similar grading system elements. A 2012 National Association of County & City Health Officials (NACCHO) survey of local food regulatory programs found that 38% of respondents reported that their jurisdiction had a restaurant grading system in place. (NACCHO, 2016)

These systems are not fully supported as they are frequently criticized as being only reflective of a 'snapshot' in time. (Baer, 2015) From December 2016, to January 2017, this study gathered 2,370 responses from restaurant grading system stakeholders (food safety regulators, food safety academics, members of the food industry, and consumers) regarding the elements they believe restaurant grading systems should be based on; what other elements, if any, they believe should be factored into a restaurant's overall grade; and, their perceptions as to the meaning behind certain grades.

Survey results show that 70% of respondents believe that a restaurant's grade should be based on the results of more than one inspection; 70% of respondents believe that non-critical violations are very or somewhat representative of the level of food safety at a restaurant, while at the same time, 82% of respondents believe that restaurant grades should be based on the results of inspections done by inspectors who have attended a risk-based inspection training program; and across all survey groups, one quarter of respondents were unsure what color grades represented in terms of the level of food safety at a restaurant. These results indicate that a gap exists between stakeholder expectations regarding restaurant grading system elements and the basis of most existing restaurant grading systems. When considering a restaurant grading system, jurisdictions should take into account stakeholder expectations and perceptions in order to implement the ideal grading system.

Background

As consumers continue to demand access to information about the sanitary conditions at their local restaurants, more jurisdictions across the country have adopted restaurant grading systems. The intent of these grading systems is to interpret the results of a facility's most recent inspection in a quick and easily understandable manner so that the public can use this information when making decisions about dining out. Existing restaurant grading systems use a color, number, letter or combination thereof to represent the restaurant's assigned grade. The challenge for food safety regulators is to develop a grading system that accurately reflects the overall level of food safety at a facility. The challenge for the restaurant industry is to adhere to food safety regulations to provide safe food for their customers, and to maintain a positive public image as reflected in the grade they are assigned.

While consumers and some food safety programs are in favor of restaurant grading systems, many regulatory and industry stakeholders have long been opposed to the systems because they feel that grading systems are inconsistent, economically detrimental, and only representative of the conditions at the facility during the brief time of last inspection (National Restaurant Association, 2012). Though some states and municipalities, such as Boston, Massachusetts, have recently adopted restaurant grading systems, others, such as the state of Colorado, have restricted them (Food Safety News, 2016).

Problem Statement

Stakeholder perceptions and expectations regarding restaurant grading system elements are largely unknown.

Research Questions

The objective of this project was to answer the following questions:

1. What are the common elements of existing restaurant grading systems?
2. To what extent do stakeholders think that these elements reflect the level of food safety at restaurants?
3. Are there any other elements that stakeholders believe should be included in a grading system?
4. How do stakeholders perceive the meaning of different types of restaurant grades?

Methodology

This research project surveyed food safety regulators, academics in food safety, members of the restaurant industry, and consumers to determine if the basis of restaurant grading systems met the expectations of the different stakeholder groups. The groups included in the survey were those believed to have an interest or concern in restaurant grading systems, thereby making them stakeholders in the issue.

This research project began with an extensive literature review to identify existing restaurant grading systems and the elements on which the grades are based. One limitation of this study was the lack of a dataset identifying existing restaurant grading systems. For the purpose of this research project, restaurant grading systems were identified using a state by state internet search, as well as various news articles referencing grading systems. As a result, all restaurant grading systems may not have been identified.

A survey was developed using Survey Monkey, and was sent to individual stakeholders. The survey primarily consisted of four sections asking respondents to rank the following:

- How representative different grading system elements are of the level of food safety at a restaurant
- How many inspections should be factored into a restaurant’s grade to best represent the level of food safety at the facility
- The level of agreement related to other statements about restaurant grading systems
- The respondent’s understanding of the different restaurant grades most often used today.

After ranking each of the items in the four sections, an open-ended comments box was provided for additional information respondents may wish to provide. By asking stakeholders their opinion on how reflective restaurant grading system elements are of the level of food safety at a restaurant, this project attempted to identify the most valuable components on which a restaurant grading system should be based.

An email introducing this research project was sent to members of Association of Food and Drug Officials (AFDO), the Conference for Food Protection (CFP), and the Center for Science in the Public Interest (CSPI). Included in the email was the link to the survey. Recipients were given two-weeks to complete the survey. The survey asked respondents to self-identify as a member of one of the following groups: Regulatory – local government, Regulatory – state government, Regulatory – federal government, Academia, Industry, Consumer, or Other.

Prior to being sent to stakeholder groups, the survey was pilot tested by sanitarians and research scientists at the New York State Department of Health to identify and address any problems such as formatting issues and spelling errors. SAS statistical software version 9.4 was used to analyze survey results and identify similarities and differences among the four groups of respondents.

Results

Of the 109 existing restaurant grading systems identified by this research, the majority are based on a numeric score assigned at the most recent inspection. These scores are generally calculated by assigning each restaurant a score of 100 before the inspection begins, and deducting points for each violation identified during inspection.

There were 2,370 responses to the survey. The majority (70.93%) of respondents self-identified as consumers, followed by local regulators (9.37%), academics (6.84%), state regulators (6.29%), industry members (5.15%), and federal regulators (1.43%) (see Table 1).

Table 1

Survey Respondent Affiliation

<u>Group Affiliation</u>	<u>Percent</u>	<u>Number</u>
Consumer	70.93	1681
Regulatory (local)	9.37	222
Academia	6.84	162
Regulatory (state)	6.29	149
Industry	5.15	122
Regulatory (federal)	1.43	34

While the results of each survey question were thought-provoking, three findings were selected for further discussion.

The majority of respondents (70%) believe that restaurant grades should be based on the results of more than one inspection (see Figure 1).

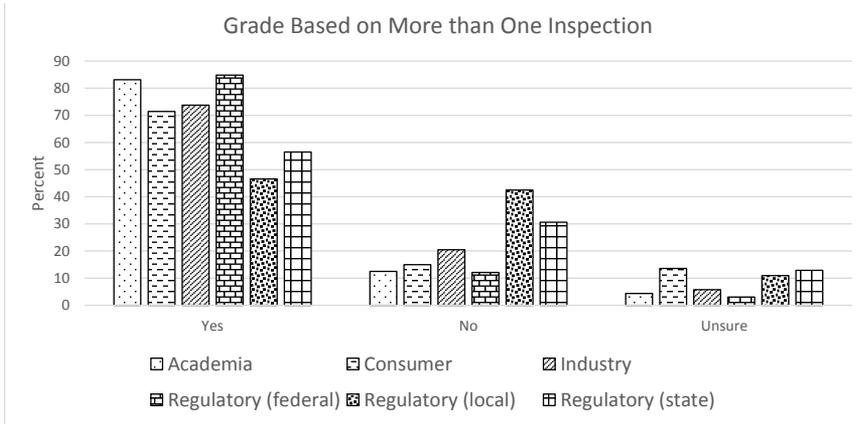


Figure 1. Restaurant Grade Based on More than One Inspection.

Overall, 70% of respondents believe that non-critical violations are very or somewhat representative of the level of food safety at a restaurant. While at the same time, 82% of respondents believe that restaurant grades should be based on the results of inspections done by inspectors who have attended a risk-based inspection training (see Figures 2 and 3). For the purposes of this research project, risk-based inspection training was defined for respondents as a training that teaches inspectors to focus on the conditions most likely to cause foodborne illness.

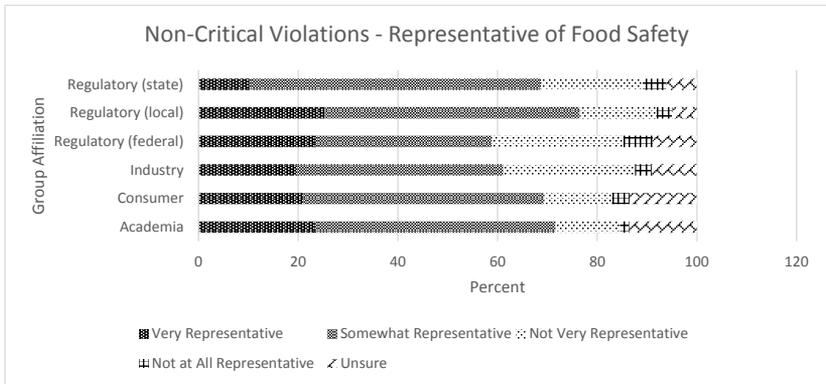


Figure 2. Non-Critical Violations – Representative of Food Safety.

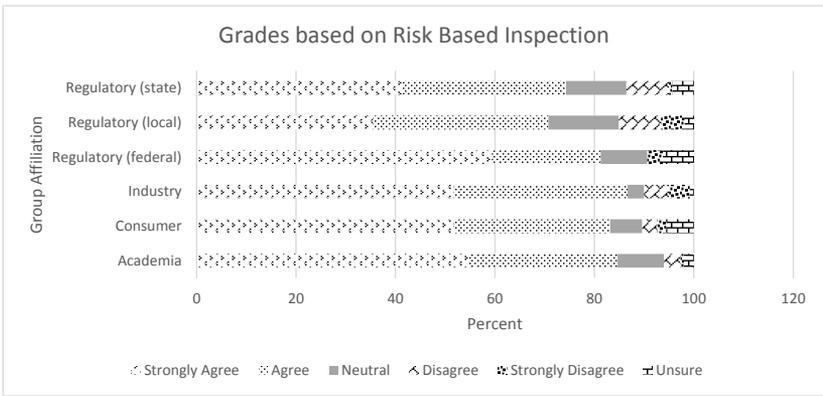


Figure 3. Restaurant Grade Based on Risk Based Inspection.

Across all survey groups, one quarter of respondents were unsure what color grades represented in terms of the level of food safety at a restaurant (see Table 2).

Table 2

Stakeholder perception of the level of food safety represented by color grades, by respondent group

Perceived Level of Food Safety by Color Grade	Percent of Respondents, by Group					
	Academia	Consumer	Industry	Regulatory (federal)	Regulatory (local)	Regulatory (state)
Green						
High	68	70	70	76	58	63
Fair	5	4	8	7	9	6
Low	3	2	4	3	1	1
Unsure	23	24	18	14	32	31
Yellow						
High	1	1	3	0	2	1
Fair	64	66	64	72	54	58
Low	10	8	14	7	14	10
Unsure	24	25	20	21	30	30
Red						
High	5	2	4	3	2	1
Fair	0	1	0	0	0	1
Low	74	76	77	76	67	70
Unsure	22	22	19	21	31	27

Conclusions

The results of this survey show that the majority of stakeholders believe that restaurant grades should be based on the outcome of more than one inspection. This concept is in direct contrast to the way that most restaurant grading systems currently operate, as most restaurant grading systems currently in place assign a grade based solely on the results of the most recent single inspection.

The majority of stakeholders believe that non-critical violations are very or somewhat representative of the level of food safety at a restaurant. These violations focus primarily on the general sanitation or maintenance of a restaurant, and have not been shown to directly cause foodborne illness. At the same time, most stakeholders believe that restaurant grades should be based on inspections done by inspectors who have attended a risk-based inspection training program. Risk-based inspection training teaches inspectors

to focus on conditions that have been shown to cause foodborne illness. The premise for this question was that an inspector who attended risk-based inspection training would apply risk-based inspection principles while conducting restaurant inspections. That is to say, inspectors trained in conducting a risk-based inspection would focus on the violations most likely to cause foodborne illness, rather than the general sanitation violations that make up non-critical violations.

On average, one quarter of all stakeholder groups surveyed were unsure of the meaning of color restaurant grades; in particular, the colors red and green. While some restaurant grading systems use color as all or part of the representation of their grades, most do not use color alone. The results of this survey indicate that color alone may be confusing to some stakeholders.

Recommendations

1. When designing a grading system, jurisdictions should consider incorporating more than one inspection score into a restaurant's overall grade. While there are existing restaurant grading systems, such as that in Lincoln-Lancaster County, Nebraska, that utilize a statistical model to calculate restaurant grades from the results of multiple inspections, the majority of existing systems base a restaurant's grade on results of only one inspection.
2. Risk-based inspection training should be increased. This survey identifies a contradiction in that stakeholders see non-critical violations as indicative of the level of food safety at a restaurant, but at the same time believe that the inspections used to calculate a restaurant's grade should be done by inspectors trained to conduct risk-based inspections. This contradiction highlights the need for more education on the relationship between critical and non-critical violations and food safety. While the average consumer stakeholder may not fully understand how violation categories differ in terms of the implications for foodborne illness, the results of this survey show that there are some misconceptions at the food safety regulatory level as well. Additional risk-based inspection training opportunities could help strengthen the understanding of the relationship between violations and foodborne illness.
3. Grading systems should not use color alone. Informing consumers is the primary goal of restaurant grading systems, therefore information about restaurant conditions must be communicated in an easy to understand manner. Given that one quarter of stakeholders, particularly consumers, are unsure what different color grades represent, the results of this survey illustrate that color alone should not be used to represent a restaurant's grade.
4. Further research should be undertaken. It is the hope that these results will further the development of an ideal restaurant grading system to both satisfy the desire of consumers to better understand, and to accurately reflect the sanitary conditions at their local restaurants. The ideal grading system will likely incorporate the results of more than one inspection into a restaurant's grade. While this survey asked stakeholders to specify how many inspections should be factored into a restaurant's grade and over what period of time these inspections should take place, formatting issues with the survey responses prevented in-depth analysis of this data. However, preliminary data analysis showed that stakeholders believed that a minimum of two inspections should be used to determine a restaurant's grade. The amount of time over which these inspections should take place will likely depend on each jurisdiction's time frame for frequency of inspection. Future studies can delve deeper into these questions.

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State and Territory Food Safety Regulation of Leased Commercial Kitchens (LCKs)

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Abstract

This exploratory study gathered information from 80 food regulatory state agencies in all U.S. states and Guam, the Northern Mariana Islands and Puerto Rico, in order to describe the current nature and status of food safety regulation of leased commercial kitchens (LCKs) by state and territorial agencies. LCKs are leased or rented facilities providing space and equipment for food processing by multiple users. Based on the literature available (Hall, 2007; Heller et al., 2013; Wonka et al. 2016; "Culinaryincubator," n.d.), and the perceptions of the population of this study, the number of LCKs has increased significantly in the past decade. This study found that regulation of LCKs is regarded as a significant issue by a majority of respondents. The five most often cited food safety concerns by states and territories were: cross contamination risks, including allergens; lack of secured and adequate storage space; off-site production; inconsistent sanitation practices and unclear accountability of all the parties involved. Despite the general concerns about food safety risks associated with LCKs among regulators across the country, there is no uniform regulatory approach specific for kitchen owners and users. The most common regulatory approach is to apply state and territorial regulatory requirements adopted from Good Manufacturing Practices (GMPs) or the Retail Food Code (Food Code). This study concluded that LCKs are an area of increasing food safety regulatory concern. The study recommends that regulators, professional associations, and the affected industry work together to develop best practices guidelines, or a food safety model code focused on the operation and regulation of LCK owners and users.

Keywords: LCKs, LCK owners, LCK users, food safety regulations or guidance, state and territorial agencies.

Background

Leased Commercial Kitchens (LCKs) are facilities that provide space and equipment for food processing either on a short-term or long-term rental or lease basis. LCKs may be called shared kitchens, commercial kitchens, food incubators, culinary incubators, accelerator kitchens, test kitchens, community kitchens as well as combinations of these names, due in part to the varied nature of ownership and operation. Owners may be individuals, partners, companies, universities, local government, not-for profit communities or a combination thereof. While most of these kitchens serve a commercial or entrepreneurial function, there are some that serve specific groups such as low income populations, minorities,

women or immigrants. In addition, some kitchen owners provide ancillary or support services such as sources for grants, loans and investment capital, food safety training, marketing strategies, and information about regulatory requirements and expectations.

These kitchens are used by food processing operators that share the space and equipment to prepare or process food. Each processor is an individual business entity with a separate staff, business license, business insurance, and food processing permit. Uses include a variety of activities including public sales, menu reviews, taste testing, co-packing services, educational activities, product development and research. Foods processed in LCKs range from low-risk baked products such as cookies to higher risk products such as fresh baby food or a shelf stable ethnic fish-based sauce known as shito. Food processes range from assembly of salads or sandwiches to specialized acidified and low acid canned food processing. The complex nature of these kitchen operations may increase existing food safety risks or create new risks not found in conventional food processing facilities. As a result, this study sought to determine the nature of risks seen by agencies in LCKs; if those agencies are addressing the risks; how agencies are regulating these risks; and, if agency efforts are effective.

Problem Statement

The content, focus, and application of state food safety regulations or guidance for LCK owners and users on a national basis is currently unknown.

Research Questions

1. What food safety approaches are currently used by states or territories to regulate or provide guidance to owners of LCKs?
2. What food safety approaches are currently used by states or territories to regulate or provide guidance to users of LCKs?
3. What are the most common food safety issues identified by states or territories that regulate or provide food safety guidance regarding the operation of LCKs?

Methodology

This study reviewed the literature available on the subject of LCKs. In addition, the author surveyed directors or managers of state and territorial food safety programs that regulate LCKs using The Association of Food and Drug Officials (AFDO) Directory of State and Local Officials (DSLO). 88 state agencies from all 50 states, plus Guam, the Northern Mariana Islands and Puerto Rico, were contacted via email with a seven-question survey. A total of 80 agencies from 50 states, Guam and Puerto Rico responded to the survey primarily via email. Out of the 80 respondents, 62 reported having regulatory jurisdiction over LCKs. Two, and in some cases, three follow-up emails were sent to several agencies to ensure a comprehensive survey; some agencies received phone calls at their request.

Results

Of the 62 state agencies regulating LCKs, 45 responded with the numbers of kitchens under their jurisdiction. The number of LCKs varies among U.S. geographic regions. The West region has the greatest number of these facilities, and the highest rate of LCKs per million population, as shown in Table 1.

Table 1

LCKs by U.S. Census Geographic Areas and Territories

<u>Region</u>	<u>LCK Number</u>	<u>LCK rate (2)</u>
Northeast	60	1.07
Southeast	348	4.22
North Central	340	5.79
South Central	49	1.01
West	710	10.21
Territories (1)	3	0.7

Note.

1. Territories included were Puerto Rico, Guam, and the Northern Mariana Islands
2. Number of LCKs per million population, based on data from www.census.gov and www.cia.gov

Out of 62 respondents, 50 reported that the agency does not register, license, or permit LCK owners. However, kitchen owners are required to provide food processors with facilities and equipment that comply with state or territorial requirements based on the Food Code or Good Manufacturing Practices (GMPs), as well as applicable local building and plumbing regulations. All food regulatory state and territorial agencies require that food processors using these kitchens for a commercial purpose possess individual food licenses or permits. Survey results showed that only one state agency (South Carolina), and two state agencies from Georgia, in the Southeast region, have specific regulations or guidelines for LCK owners and users. The remaining 59 state and territorial agencies regulate LCKs using existing regulations adopted from GMPs or the Food Code.

This survey found the most commonly used food processing equipment were standard items such as refrigerators, freezers, stoves, ovens, and mixers. However, some LCKs provided specialized equipment such as proofers, vat pasteurizers, plate heat exchangers, or hot water vats for canning. In addition to equipment provided by the leased kitchen, some kitchen owners allow users to bring their personal food equipment, which may be potentially shared among processors.

The types of foods allowed to be processed in LCKs are limited mainly by the food processing equipment and layout available in the kitchen based on reports from 56 state and territorial agencies. A few specific restrictions were noted by 6 state agencies in the Southeast, North Central, and West regions as discussed below. The most common foods reported being processed in LCKs were baked goods, sauces, jams, and jellies. Specialty foods included fermented products such as sauerkraut, acidified pickles and condiments, juice manufacturing and bottling requiring juice HACCP, raw seafood and fish repacking requiring seafood HACCP, and canning using hot water vats.

There were a limited number of food processing restrictions for LCKs. In the Southeast, restrictions were found on animal feed, bottled water, LACF, and wholesale meats. In the North Central region, restrictions were limited to non-pressure and non-acid canned foods. In the West, restrictions were found on animal feed, marijuana infused edibles, and wholesale meat.

Numerous food safety concerns about LCKs were reported by 56 state and territorial agencies. The three most common food safety concerns were cross- contamination, storage issues, and off-site production. Sanitation, accountability of owners and users,

and physical layout of the kitchen followed. Other concerns such as labeling of foods and transportation were specific to one particular region. Table 2 shows all reported concerns per geographic region, and the total number of states and territories sharing the concerns, in decreasing order.

Table 2

Food Safety Concerns About LCKs by Geographic Areas and Territories

Concerns	Total	Regions					
		NE	SE	NC	SC	WE	TE
Cross contamination (including allergens)	35	3	7	9	5	10	1
Storage issues	30	6	7	8	5	3	1
Off-site production	24	6	4	6	1	7	
Sanitation	16	2	2	6	3	3	
Accountability owners and users	12	1	4	3	1	3	
Physical layout of the kitchen	10	3	1	1	2	3	
Number processors at same time	9	1	1	1	3	3	
Lack of unannounced inspections	9	2	2	3		2	
Traceability of kitchen users	6	1	1	2	1	1	
Poor personal hygiene	5		1	1		3	
Lack of food safety knowledge by kitchen users	4	2			1	1	
Food security	4		1	1		2	
Proper cooking and cooling methods	4		2		1	1	
Recalls and traceability	2		1		1		
Record keeping	2			1		1	
Turn over of kitchen users	2		1	1			
Cold and hot holding	2	1					1
Having requirements met (scheduled processes)	2	1					1
Labeling of foods	1		1				
Number of kitchens available	1				1		
Process and product testing	1		1				
Testing after packaging	1					1	
Transportation	1	1					

Concerns	Total	Regions					
		NE	SE	NC	SC	WE	TE
Foods for susceptible population	1		1				

Note. NE=Northeast, SE=Southeast, NC=North Central, SC=South Central, WE=West, TE=Territories.

State and territorial agencies were particularly concerned about the increased risk of cross contamination between ready-to-eat and raw foods, and cross contact with foods containing allergens, because the same equipment and space is shared by different food processors. Regulatory agencies reported difficulty monitoring proper cleaning of food equipment between uses because there is not clear accountability between kitchen owners and users. The storage issues identified by respondents were lack of secured and sufficient storage space. Kitchens lack secured storage, which increases the risk of cross contamination and protection of foods from accidental or intentional adulteration. Respondents reported the lack of sufficient storage space caused kitchen users to use off-site non-regulated locations for storage of raw, in process or finished foods. Similarly, but in an even larger context, regulatory agencies stated that processors may identify the LCK physical address as their processing address, but have been found to be processing in their homes or other non-permitted facilities. LCK users generate contracts with the kitchens and list their addresses as the processing locations. However, after a while, these processors stop going to the kitchens. Instead, processors end up processing from locations that are not regulated, causing foods, including high risk foods like acidified sauces, to be produced without any food safety regulatory supervision.

Conclusions

Parts of state and territorial regulatory agencies do not know the actual number of LCKs under their jurisdictions due to the lack of requirements from these agencies for kitchen owners to register or to be licensed. LCKs are not considered food processing facilities; only kitchen users are treated as food processing entities by state and territorial agencies. This approach leaves out one part of the food safety regulatory equation: the function of LCKs entails both kitchen owners and users.

The lack of recognition by state regulatory agencies of LCKs as a unique business model might be the reason why most state agencies do not impose restrictions specific to LCKs. Agencies use kitchen layout and food processing equipment available as the main factors to limit the type of food being processed on site. This perspective potentially fails to identify and address specialized processes that might be taking place in the kitchens as some LCK users bring their own equipment, which might not be on site at the time of an inspection.

The most commonly noted food safety issues related to LCKs were shared among U.S. geographical regions and territories, indicating the presence of a general problem.

Agencies appeared highly concerned about certain food safety risks being increased or created by the unique communal operating nature of LCKs. However, 95% of state and territorial agencies have not drafted specific guidelines or regulations for kitchen owners and users.

The current approach of the Food Code or GMPs by state and territorial agencies to regulate or provide guidance to kitchen owners and users fails to address the unique circumstances under which these facilities operate.

Recommendations

A national uniform food regulatory model or guideline specific to LCKs should be developed that includes: a formal definition of LCKs, owners, and users; requirements for licensing of LCK owners; defined responsibilities of LCK owners and users; requirements for LCK layout, including storage; requirements for equipment and restrictions on the type of food that can be processed on site.

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Corrections after FDA and Wisconsin Manufactured Food Inspections Show Comparable Compliance Rates

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Abstract

Comparable regulatory inspections are a critical component of establishing an Integrated Food Safety System (IFSS) in the state of Wisconsin. Compliance effects of inspections performed by U.S. Food and Drug Administration (FDA) and Wisconsin Department of Agriculture, Trade and Consumer Protection (WDATCP) at manufactured food plants in Wisconsin were compared by analyzing rates of correction of violations between inspections. Inspectional outcomes documented in FDA and WDATCP reports compared with the subsequent inspection reports showed comparable regulatory outcomes. The average rate of correction of violations following a routine inspection was not significantly different between WDATCP and FDA. Analysis of uncorrected violations shows room for improvement in following up on the violations noted by the other agency, agencies' coordinating timing of inspections, and methods used to achieve compliance. The results of this study are evidence of integration and show continued mutual reliance on each other's inspections is warranted.

Corrections after FDA and Wisconsin Manufactured Food Inspections Show Comparable Compliance Rates

Background

An Integrated Food Safety System (IFSS) can address the hazards of foodborne illness and injury more effectively than independently operating regulatory agencies with similar goals (National Food Safety System Project Outbreak Coordination and Investigation Workgroup, 2001; Partnership for Food Protection, 2013; Partnership for Food Protection, 2014). The IFSS concept asserts that by adopting the same best practices, using the same quality standards, and conducting ongoing quality assurance and quality improvement, federal and state manufactured food regulatory programs should be able to rely on each other to effectively and efficiently achieve compliance outcomes and protect public health. The Wisconsin Department of Agriculture, Trade and Consumer Protection (WDATCP) was formally recognized for adopting regulatory best practices and quality assurance procedures in 2014, when the U.S. Food and Drug Administration (FDA) Office of Operations Audit Staff found WDATCP in full conformance with the Manufactured Food Regulatory Program Standards (FDA, 2016). Also in 2014, WDATCP recognized FDA as achieving comparable

regulatory outcomes when WDATCP began counting FDA manufactured food inspections towards the WDATCP workload. Mutual agreement of comparable regulatory effect forms the basis for the Minneapolis District FDA and WDATCP's current joint implementation of the Partnership for Food Protection's (PFP) best practices for Local Federal/State Planning and Coordination of Field Operations and Training (PFP, 2013) as part of a Pilot Mutual Reliance Project in the state of Wisconsin. WDATCP has been inspecting on behalf of the FDA under contract for over 30 years, and WDATCP manufactured food inspections are conducted by sanitarians that have received at least 40 hours of FDA classroom training. WDATCP sanitarians are regularly audited to FDA performance standards while performing inspections. However, the agencies' programs vary, thus a direct comparison of inspectional findings' effects on firms acting to address violations is warranted to confirm or refute comparability in firms' future compliance with the law.

Inspections and compliance strategies of the two agencies are similar but distinct. When violations are observed during a routine inspection, both agencies verbally communicate violative findings, or inspectional observations about objectionable conditions to the establishment during an interview with the most responsible person onsite and require that the establishment come into compliance. After an establishment is inspected by WDATCP or FDA and found to have significant or critical violations, the firm is subject to a series of progressively more stringent compliance activities. Both agencies provide written summaries of significant objectionable conditions, which could trigger further compliance. FDA notes and communicates inspectional observations to the firm differently (FDA Investigations Operations Manual, 2016) and does not rely as heavily on re-inspections as WDATCP (personal observation). FDA observations not considered as significant are described narratively in the establishment inspection report and discussed verbally with management upon conclusion of the onsite inspection. When more significant observations, which may result in a compliance action (warning letter), are found, they are communicated to the firm using an FDA 483 form, the notice of inspection observations; the FDA 483 form is given to the firm at the conclusion of the inspection (FDA Investigations Operations Manual, 2016). Firms are encouraged to submit a written response detailing corrections to the observations contained in the 483 form. The WDATCP strategy is also to combine a discussion of inspectional findings at the conclusion of the inspection with written warnings, but WDATCP does not routinely suggest that the firm prepare a written response documenting corrections (WDATCP Inspection Procedures). Another difference with FDA is that WDATCP procedure is to provide the all violative observations in written form whether or not further compliance is warranted.

If further compliance is warranted, in the case of WDATCP, compliance may entail an onsite follow-up or re-inspection, a warning letter, and the payment of a fee for another inspection to ascertain the correction of violations observed. Sanitarians that observe critical, significant, numerous or repeat violations warn establishments of ensuing re-inspections upon conclusion of their violative routine inspection, and a follow-up visit to the firm is a near certainty given critical violations at a firm. In contrast, the FDA investigator does not determine by the end of the inspection that a repeat site visit, accompanied by a re-inspection fee, will follow (FDA Investigations Operations Manual, 2016). FDA inspections generally involve longer time spent in the establishment, and may involve a longer delay between the conclusion of the inspection and the receipt of written inspectional findings in narrative form. WDATCP provides complete written findings in narrative format to the firm within one week of concluding the inspection, whether violations were found or not.

Table 1 summarizes some of the differences and similarities in inspectional procedures and first steps to following up violative routine inspections. The differences in the inspectional and compliance approaches between the two agencies validates the question, are WDATCP

and FDA equally effective in achieving their desired effect of inspected establishments correcting the violations their inspection staff observes and communicates during routine inspections?

Table 1

Summary of FDA (FDA 2016) and WDATCP Inspectional Procedures (WDATCP 2007-2016) for Firms with Violative Inspectional Findings Found During Routine Inspections

<u>Inspection Procedures</u>	<u>FDA</u>	<u>WDATCP</u>
Violations verbally discussed with management	Yes	Yes
Expectation that all violative conditions will be corrected	Yes	Yes
Follow up on previous inspection findings	Yes	Yes
Lack of correction of previous violations grounds for further compliance actions	Yes	Yes
Additional establishment visit to verify correction of significant violations (re-inspections and follow-up inspections)	No / Rarely	Yes-Usually within 60 days of violative inspection
Inspections are equal duration	No, inspections range from 1-many days depending on violative status	No, usually 1 day or less; complex inspections may be 2 or more days
Terminology for violations is the same	No, FDA uses the terms "objectionable conditions," "items discussed with management" and "inspectional observations"	No, WDATCP uses the term "violation"
Written inspectional observations are provided to firm	Yes-significant violations provided on the FDA 483, all other observations described in the establishment inspection report	Yes-all significant and minor violations and observations provided in the inspection report
Timeframe for firm receipt of establishment inspection report is variable	Yes- varies according to violative status	No, it is always within 1 week of inspection

Problem Statement

The effect of a regulatory inspection on a firm’s future compliance with the law may be different depending on whether FDA or WDATCP does the inspection.

Research Question

1. Is the compliance rate of violations corrected following manufactured food inspections in Wisconsin affected by which agency did the inspection?

Methodology

The rate of correction of violations following FDA and WDATCP inspections was used to measure the effectiveness of the inspection in encouraging future compliance. This rate was defined as the percentage of violations corrected between inspections, as documented in inspection reports from manufactured food firms inspected by FDA and WDATCP

since 2014, where at least one violation of 21 CFR 101, 110, 113, 114, 120, or 123, (GPO e-CFR 2017) or equivalent WDATCP provision, was noted. The number of violations that went uncorrected between inspections was also tabulated and analyzed. Time between inspections and compliance follow up activities was recorded for each set of inspection reports analyzed.

To control for two additional factors that may affect degree of compliance—low risk categorization, and Grade A status—manufactured food establishments categorized as low-risk by both agencies (i.e., warehouses), and those that are subject to more frequent “Grade A” dairy plant inspections, were excluded from this analysis.

To calculate degree of corrections, at least one violation must have been noted, and there must have been a subsequent inspection with which to compare. Thus, once the Grade A inspections and low-risk inspections had been eliminated, initial inspections for analysis were selected from those inspections conducted in 2014 or 2015 for which there was at least one violation, and which had received a subsequent routine inspection.

In order to generate a valid interagency comparison, the average degree of compliance that WDATCP achieves between routine inspections of manufactured food facilities, without an intervening FDA inspection was estimated. Estimation was done by analyzing 40 randomly-selected pairs of consecutive WDATCP routine inspections of manufactured food facilities. For the comparison with the FDA, 40 FDA establishment inspection reports from establishments that had received a subsequent routine inspection were randomly chosen and included in the sample if at least one violation was noted. In each case, a random number generator (random.org) was used to select 80 reports such that if an inspection report randomly selected did not qualify for the sample, the report could be replaced by another randomly selected report until 40 initial inspections completed by the FDA were selected and paired with 40 subsequent inspections. Thirty-nine of the subsequent inspections were completed by WDATCP, and one was completed by FDA.

Violations in each report were counted according to the initial report author’s grouping or itemization of violations. Whether or not the report author of the subsequent inspection report made reference to the prior report used in this analysis, violations were counted as corrected as long as they were not listed as observations or violations in the subsequent report. Variables measured in this analysis are listed in Table 2.

Table 2

Comparison of Means, Confidence Intervals, and Proportions of Further Compliance of FDA Followed by WDATCP (FDA) and WDATCP Followed by WDATCP (WDATCP) Routine Inspections

<u>Variable Measured</u>	<u>Initial Inspection Agency</u>	
	<u>FDA</u>	<u>WDATCP</u>
Compliance rate	0.82 ± .08	0.86±.08
Days between inspections	272.1 ± 49.34	471.5 ± 51.84
% of initial inspections that resulted in a FDA form 483 or WDATCP re-inspection	30%	20%
Total number of violations--initial inspection	4.5 ± 0.82	4.15 ± 1.32
Number of corrected violations as per subsequent inspection report	3.65±2.33	3.65±4.00
Uncorrected violations, as per subsequent inspection report	0.85±1.17	0.5±0.75
Percentage of firms with new violations detected at subsequent inspection	85%	85%
Number of new violations	4.43±1.5	4±1.5

Results

Comparison of the rate of compliance achieved as number of corrected violations divided by total number of observed violations revealed no significant difference in compliance rate between the two agencies. The mean rate for compliance after an FDA inspection was $0.82 \pm .08$, and the rate after a WDATCP inspection was $0.86 \pm .08$ (margin of error at 95% confidence). A paired t-test comparison showed no significant difference in the means (two-tailed $p < 0.47$). Further examination of the average number of violations per establishment, and the percentage of FDA-inspected firms that received a notice of adverse inspectional observations (483 form) or a followed-inspection or re-inspection reveal striking similarities (Table 2). One of the more prominent differences between the two sets of inspections was the average number of days elapsed between inspections. The minimum days between the initial FDA inspection and the subsequent WDATCP inspection was seven, with a range of 682 days between inspections, while the minimum interval between an initial WDATCP inspection and later WDATCP inspection was 128, with a range of 634 days. There were 54 total uncorrected violations, 34 were initially detected by FDA and 20 were initially detected by WDATCP.

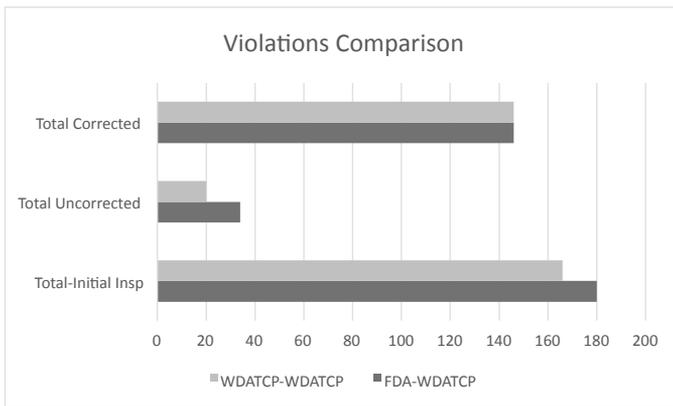


Figure 1. Comparison of total numbers of violations detected and corrected.

Three hundred violations were found and communicated to firms during the initial inspections (146 during 40 inspections by FDA, and 154 during 40 inspections by WDATCP). The subsequent inspections of these firms found a total of 329 new violations (328 during 79 inspections by WDATCP and one during one FDA inspection). Thus, though 82-86% of violations were corrected between inspections, caution should be used in concluding that this compliance rate demonstrated full compliance was achieved in the establishments that corrected all previous violations.

Conclusions

The results of this study show comparable compliance outcomes following routine inspections done by the FDA and WDATCP. There was no significant difference in the average compliance rates achieved by the two agencies. This finding supports the validity of mutual reliance on each other's inspections, demonstrates regulatory equivalency, and documents the emerging Integrated Food Safety System in Wisconsin.

The chief interagency similarity in communicating inspectional findings and expectation of corrections with a firm's management is the exit interview. This study's findings serve to emphasize the importance of the exit interview.

The majority of reports analyzed did not explicitly reference the other agency's report even the other agency's inspection was the most recently-conducted routine inspection. Only

six WDATCP reports made explicit reference to the preceding FDA report, and none of the FDA reports explicitly referenced the most recent routine WDATCP inspection unless the inspection was completed under FDA contract.

Recommendations

The results of this study support four recommendations.

1. First, and most broadly, this study shows that WDATCP and FDA should continue the practices that resulted in the comparable compliance rates shown here. To maintain current levels of integration, both agencies should continue to adhere to current inspection, training, and auditing systems. In particular, the exit interview should continue to be emphasized as the primary way to convey inspection observations and required corrections.
2. The second recommendation has to do with the FDA practice of recommending that firms respond to violative findings in writing to the FDA. The efficacy of this approach is supported by the equivalent compliance rates occurring after FDA form 483 receipt and WDATCP re-inspections. The fact that comparable compliance rates were achieved by both agencies, but only WDATCP made return establishment visits to verify corrections, suggests that perhaps adopting this FDA strategy could improve efficiency of WDATCP resource use. The FDA recommends firms submit written proof of corrective action, in response to violations listed on the FDA form 483. Using this method of documenting compliance could allow WDATCP to reduce the resources WDATCP uses conducting re-inspections while achieving similar compliance rates. In order to save resources and lessen inspection fees charged to the establishments that qualify for re-inspection, WDATCP could implement a requirement that firms submit a written response to WDATCP warnings advising of further compliance action. If the response is satisfactory, WDATCP could forestall re-inspection and save inspectional resources.
3. Third, in order to increase integration and increase compliance rates, FDA and WDATCP should read and refer to the most recent inspection conducted, regardless of which agency conducted the last inspection. To truly inspect as one program, each agency would follow up on the other agency's findings. More consistently referring to the other agency's inspection findings and explicitly addressing a firm's correction of the violations described therein could help detect and more adequately address chronic violations such as roof leaks and equipment repair issues that go uncorrected for two, three, or more regulatory inspections. A way of identifying these violations as "chronic" in reports could help flag accelerated compliance and trigger re-inspections by WDATCP.
4. The fourth recommendation is to continue to improve interagency inspection scheduling. Our Mutual Reliance goal is to space routine inspections by WDATCP and FDA at least five months apart. The occurrence of short intervals between routine inspections demonstrates room for improvement in the agencies' mutual reliance goal of minimizing duplication of work. Efforts to communicate ongoing updates to work planning should continue; if FDA routinely requested the most recent routine inspection in preparation for their inspections, this could give WDATCP more advanced notice of ad hoc inspections while also improving compliance rates by facilitating following up on recent violations.

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Inspector Use of Chinese Language Retail Food Safety Training Tools

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Abstract

The Kansas Department of Agriculture (KDA) inspects and regulates over 15,000 food establishments in the state of Kansas with the purpose of preventing foodborne illness. Of those facilities, 12,500 are restaurants and grocery stores (KDA USA Food Safety, 2017). Some of those establishments are owned and operated by individuals who speak English as a second language or do not speak English at all.

Communication involving a language barrier can be difficult between the operator and the inspector. A review of literature was conducted to identify effective training tools and top food safety concerns in ethnic restaurant operations. This study gathered data on which training tools are used nationwide by regulators when delivering food safety training in the Chinese language while conducting inspections. A survey was sent to State and Local Officials nationally to determine training tools used in other jurisdictions and recommendations are presented based on these results.

Inspector Use of Chinese Language Retail Food Safety Training Tools

Background

Agriculture accounts for 42.8% of the Kansas economy. This industry is vital to the growth of the economy. The Kansas Department of Agriculture (KDA) promotes public health and safety and works to support a safe food supply by providing food safety education and inspections to the food industry. KDA has progressive compliance actions that consistently and fairly apply in situations involving noncompliance with the law.

The KDA Food Safety & Lodging Division has many levels of compliance enforcement. Compliance data and research have shown that Kansas has a history of elevated progressive enforcement involving Chinese restaurants. In 2016, additional elevated compliance inspections occurred 34% of the time in comparison to 18% of elevated compliance inspections occurring in other industry segments as a whole (KDA Food Safety database, 2017).

The KDA tries to improve overall compliance in restaurants with handouts and on-site trainings. Current regulations, educational handouts, and trainings developed by KDA

have generally not been translated into different languages, thus potentially impacting compliance levels in some facilities.

Research on effective training tools has been conducted. Liu and Kwon (2013) conducted phone interviews with 50 Chinese restaurants from various municipalities and regions across the U.S. and found that Chinese restaurateurs preferred the use of food safety training materials in Chinese over other methods. One type of training tool being used is video. Visual-based food safety training increased attitudes and knowledge among independently owned Chinese restaurants in Iowa (Li, 2015).

There is a need for increased food safety training, specifically for time and temperature control and handwashing (Kwon, Roberts, Shanklin, Liu, & Yen, 2010). Mauer et al. (2006) found that improper food temperatures, cross contamination, and employee hygiene were among the top concerns for food safety professionals when dealing with ethnic restaurant operations. When developing training tools for ethnic restaurants, these food safety concerns should be focused on first.

Problem Statement

The extent and effectiveness of Chinese language food safety training tools for retail food establishment employees in the United States is unknown.

Research Questions

1. What tools nationally do regulatory agencies currently use to train Chinese-speaking employees in food establishments?
2. What tools would agencies use to train Chinese-speaking employees in food establishments if they were given a choice?

Methodology

An electronic survey was distributed through Survey Monkey™ to 50 individuals based on the Directory of State and Local Officials from the Association of Food and Drug Officials (AFDO) website. A survey link was also disseminated directly by AFDO to the Food Safety Program managers in their database. Direct emails with the link to the survey were sent to 90 recipients. The survey sample consisted of state regulatory officials nationwide.

The survey contained five questions. The questions consisted of multiple choice, ranking, and open-ended question styles. The survey was designed to gather data on what specific food safety training tools each jurisdiction commonly uses. The survey also collected answers on what level of difficulty the inspectors experience with compliance involving food establishments that have Chinese-speaking employees. A question was asked on the survey what compliance issues are commonly reported on inspections, the tools used, and tools preferred. At the conclusion of the survey, a question posed an opportunity to indicate what type of tools the regulatory official would like to utilize if they were able to choose.

Results

Of the 140 survey links that were distributed, 64 surveys were completed, with a response rate of 45.7%. The survey results showed that just under 80% indicated experiencing moderate difficulty or high difficulty with compliance in Chinese and non-English speaking restaurants, as shown in Figure 1. Only 4.7 % experience no difficulty with compliance.

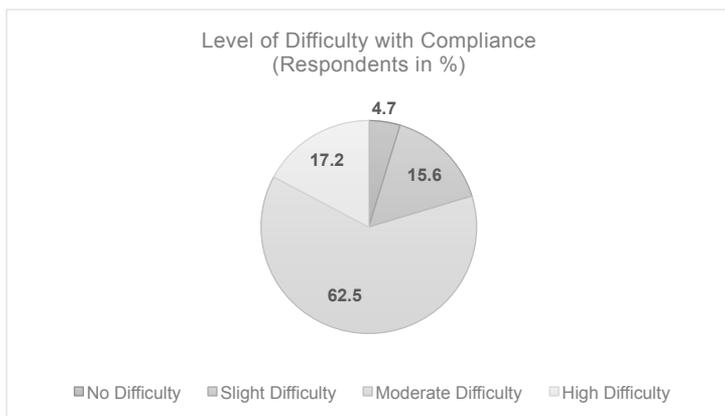


Figure 1. Level of difficulty with compliance.

The most common violations found were hot and cold holding (80.65%). This issue was also stated in a previous study that found similar results in Kwon, et al. (2010). Improper cooling (74.19%) and improper handwashing (66.13%) were other common compliance issues found.

Figure 2 represents preferred food safety training tools by regulatory officials as indicated in survey responses. The preferred method of training is the use of translated handouts, followed by Chinese translated video and finally online food safety training in the Chinese language.



Figure 2. Chinese training tool preferred in order of interest.

Figure 3 represents food safety training tools used as indicated in survey responses. The most common tool used in training food service workers is Chinese translated handouts. The tool used least was video in Chinese or English with only 16% and 12%, respectively. An interpreter is used as a training tool in Chinese operated food establishments 45% of the time as indicated from those who responded to the survey. Three respondents reported an interpreter call service was used. The training tool indicated as “other” represents a variety of responses including, but not limited to, the use of bilingual inspectors, community meetings with owners and operators, and a full-time liaison.



Figure 3. Food Safety Training Tools Used.

The majority of those experiencing moderate difficulty with compliance reported utilizing at least one Chinese educational training tool (80%). Those experiencing moderate difficulty with compliance have most often used Chinese handouts as a tool (65%). The majority of those experiencing high difficulty with compliance reported utilizing at least one Chinese educational training tool (70%). Those experiencing high difficulty with compliance have most often used a Chinese online class (70%).

When asked an open-ended question on the survey of additional suggestions to gain compliance, responses included encouraging involvement of industry associations, educational visits with the use of an interpreter and limiting the teaching to one topic at a time so that the operator doesn't feel overwhelmed. An understanding of cultural differences by inspection staff was also suggested as a way to improve compliance.

Conclusions

After the distribution of the survey, the responses show that there are training tools available at all local, state, and federal levels. Although tools are available, there is a lack of organization and a centralized library to obtain these tools. Perhaps not all food safety topics are available to all jurisdictions, limiting widespread use. The majority of the respondents use translated handouts for training food service workers; however, over 60% continue to experience moderate difficulty with achieving compliance. Although, the level of success when using these tools could vary dependent on the quality of the content or the delivery method. Previous study from Liu and Kwon (2013) stated that video was the preferred method of food safety training by Chinese-speaking restaurant owners, although the use of English or Chinese video for training was reported to be used least. When choosing a training tool, this study shows that video may be an effective type.

The issue of non-compliance results from more than an absence of handouts and videos. An understanding of cultural differences by the inspector was also suggested as a way to gain compliance. Knowing these differences can impact the operator's actions based on interactions with their inspector.

Recommendations

1. Development of a focused video/tools training by entities with the background and expertise to properly address the need for this type of training.
2. Provide a central clearing house for the short food safety training videos to allow for broad access to the tools. There are jurisdictions that already use translated video for training. The food safety work force could increase consistency and speak with one unifying voice. All jurisdictions would have access to the same tools for training.
3. Additional research is also recommended to establish ways of connecting cultures to improve relationships and food safety awareness.
4. Additional research to evaluate the effectiveness of the specific training tools would be beneficial.

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Spice Lead Levels and Blood Lead Levels in Maryland Children

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Abstract

This retrospective study examines the relationship between spice lead levels and blood lead levels in Maryland children based on case investigations conducted by the Maryland Department of the Environment (MDE) from January 1, 2013, through December 31, 2016. These cases were reviewed to determine the environmental antecedents associated with the elevated blood lead levels (EBLL). In 52 of 534 cases, spices were identified as an environmental antecedent. In the 42 cases in which spice samples were collected, 47% had detectable levels of lead. The study also found lead levels above the Food and Drug Administration's (FDA) guidance level for lead in candy in over 62% of spice samples collected by the Maryland Department of Health and Mental Hygiene (MDHMH) between January 7, 2014, and May 5, 2016, and in over 71% collected by the New York State Department of Agriculture and Markets (NYS DAM) between February 15, 2011, and August 15, 2016. The study recommends: (1) evaluating and recording the consumption levels of spices if there is a suspect lead risk found during a childhood lead investigation; (2) creating a national regulatory or guidance level for lead in spices; (3) increasing educational outreach regarding "non-tradition sources" of lead exposure; (4) that Laboratories conducting analytical testing of lead in food use a method appropriate for solid matrices with a low "limit of detection" (LOD) and; (5) conducting a follow-on study to identify a baseline and further evaluate whether spices present a lead hazard.

Spice Lead Levels and Blood Lead Levels in Maryland Children

Background

Lead is a naturally occurring element found in all parts of the environment such as in the air, soil, and water. Additional lead can enter the environment due to the release of lead by human activities such as past use of leaded gasoline and lead based paint; lead and lead compounds also have been used in household products such as ceramics, plumbing pipes and materials, batteries, ammunition, and cosmetics. The most common sources of exposure among children with blood lead levels above the Centers for Disease Control and Prevention (CDC) reference value of 5 ug/dL of blood are lead hazards in and around older housing, including deteriorated lead-based paint, lead-contaminated dust, and accessible lead contaminated soil (CDC, 2012). The main target for lead toxicity is the nervous system, both in adults and children. At high levels of exposure, lead can severely damage the brain and kidneys in adults or children and ultimately cause death. In pregnant women, high levels of exposure to lead may cause miscarriage. (Department of Health

& Human Services [DHHS], 2007). Chronic exposure, particularly in children is associated with impaired cognitive function (CDC, 2012).

Dietary exposure to lead has received less attention than the traditional environmental antecedents such as deteriorated lead-based paint and lead contaminated dust. Only two federal regulatory limits for lead exist at present. The Environmental Protection Agency (EPA) has a limit of 0.015 ppm in drinking water (National Primary Drinking Water Regulations, 2010) and the FDA has a guidance level of 0.1 ppm in candy. (FDA, 2006). Contamination of food animals and crops does occur due to contaminated soil, heavy pesticide use, and industrial processes near food production areas.

Although there are few regulatory limits for lead in products, the FDA has set a Provisional Tolerable Total Intake Level (PTTIL) of 6 micrograms of lead per day for children 6 years of age and under. (FDA, 2006). The PTTIL is the total daily intake from all sources that provides a reasonable margin of protection against the known adverse effects of lead. When considering the PTTIL, other sources of lead must be considered as well.

However, there is still currently no recognized safe level of lead in products (CDC, 2007) nor is there a safe level of lead found in the blood (CDC, 2007). The CDC has set a “level of concern” for lead in blood of children under 6 years of age at 10ug/dL. In 2012, CDC recommended lowering this level to a “reference level” of 5 ug/dL. (CDC, 2012). The elimination of elevated blood lead levels (EBLL) (level of 10 ug/dL) in children age 6 and under also continues to be a national goal of the Healthy People 2020 initiative.

The Maryland Department of the Environment (MDE) carries out environmental investigations associated with cases where children are found to have EBLL, i.e. exceeding the CDC “level of concern.” Recent MDE investigation results suggested that EBLL in some cases may be associated with the consumption of certain spices. These investigations included a review of environmental antecedents such as household conditions including lead paint, spice, and other foods. As a result, in November 2013, MDE initiated a collaborative partnership with the Maryland Department of Health and Mental Hygiene (MDHMH) to conduct surveillance on lead levels found in spices purchased in Maryland retail facilities. This research project was designed to examine the strength of the relationship between elevated blood lead levels and consumption of certain spices by Maryland children as well as other potential sources of lead exposure.

Problem Statement

The relationship between childhood EBLL and consumption of spices in Maryland is unknown.

Research Questions

1. What are the common lead contaminants found during Maryland Department of the Environment (MDE) lead Investigations?
2. What are the lead levels found in certain spices consumed by children in Maryland?
3. What is the relationship between dietary intake of certain spices by Maryland children and elevated blood lead levels?

Methodology

Data was collected during a review of MDE case investigations from January 1, 2013, through December 31, 2016. Because some data within the files were considered to be protected health information, the study methodology and data collection and analysis plan were required to be reviewed and approved by the MDHMH Institutional Review Board. Specific data of interest in the review were environmental antecedents that were

discovered during the investigation, including traditional antecedents such as lead paint exposure and non-traditional exposures, particularly spices. Cases of interest were those in which MDE identified spices as a hazard, particularly those in which spices recovered from the home were tested and found to have detectable limits of lead and those in which no other antecedents were found during the investigation. For the cases in which MDE listed lead as a hazard, the files were reviewed in detail to examine whether cultural and dietary practices increased the likelihood of exposure; gather data regarding environmental sampling results particularly spices; and identify the blood lead concentrations of the children associated with these investigations. Data was also collected from spice surveillance activities performed by MDHMH between January 7, 2014, and May 5, 2016, and by New York State Department of Agriculture & Markets (NYSDAM) between February 15, 2011, and August 15, 2016, in order to examine the potential for lead in spice risks more broadly.

Four different methods were reported for the analysis based on the analytical laboratory, the reported methods were: EPA Method 6020, EPA Method 200.8, FDA Elemental Analysis Manual (EAM) Method 4.7 and NYSDAM Food Laboratory Division Method CHEM-MTH-428. The limit of detection (LOD) was reported for each spice analysis for the MDE samples using EPA Method 6020. (EPA, 2014). To allow statistical analysis of all the MDE data available, values that were reported as non-detects or below the limit of detection were reported as half the LOD. A limit of detection was provided for all MDHMH spice analysis using EPA Method 200.8 (EPA 2012) and FDA EAM Method 4.7 (FDA, 2015). A single LOD was reported for the NYSDAM Method. (NYSDAM, 2016). Values reported as less than the LOD were assigned a numeric value of half the LOD for statistical purposes. Mean lead levels were calculated for each of the sample sources. The interquartile range (IQR) was calculated to determine outliers.

Results

From January 1, 2013, through December 31, 2016, MDE conducted 534 Lead Poisoned Child Investigations. Spices were considered possible contributing factors in 52 (9.7%) of those cases by MDE investigators. In seven (1.3%) of the 534 cases only spices were found to be an antecedent during the MDE investigation after ruling out other potential sources such as lead based paint, household dust and other environmental sources.

Table 1 provides an overall summary of results by sample source. For all sample sources, the range, mean lead levels, IQR, and number of outliers were determined. The mean lead levels for all sample sources were above the FDA guidance level for lead in candy. Although the outliers were omitted in determining the mean, it is important to note the number of outliers since the lead levels in a number of the outliers were significant.

Table 1

Comparison of Spice Sample Analysis Results (in ppm) by Sample Source

Sample Source	No. of Samples	Minimum Lead Level	*Mean Lead Level	Interquartile Range (IQR)	No. of Outliers (Range of Outliers)	Maximum Lead Level
MDE	202	0.1	0.548	1.103	23	2000
MDHMH	45	0.0072	0.176	0.201	4	3.14
NYSDAM	253	0.0188	0.229	0.394	37	146

*Values that were outliers were removed when calculating the Mean

The study found that the laboratories conducting the analysis are using different methods to detect lead, which made comparing results from the various sources problematic. Reporting values depends on the method and specificity of the individual analysis.

Although many samples in this study were reported as non-detects, the non-detects were assigned values of one-half of the LOD to allow statistical analysis of the data. When assigning replacement values for all “non-detects” and samples less than the LOD, all MDE data exceeded the 0.1ppm FDA guidance level. Of the MDHMH and NYSDAM values, 62%, and 71% exceeded 0.1ppm, respectively.

There appears to be a cultural component to this potential link of EBLL and spices. Of the 52 cases where MDE found spices as a potential antecedent, 39 identified a Country of Origin (CoO) of the child. Twelve different CoO were identified. Although the dataset was small, India was identified as the CoO in 14 cases which was 35.9% of the cases in which the CoO was identified. Seven cases had Pakistan identified as the CoO and five cases had Afghanistan identified as the CoO. Three cases had each Nepal and El Salvador identified as the CoO. Each of the following countries had one case: Zimbabwe, the U.S., the Republic of Congo, Uganda, Saudi Arabia, Liberia, and Iran.

Of the 202 spice samples collected by MDE investigators there were 52 different types of spices identified in which 53% of those spices were purchased in the U.S. As shown in Table 2, the ten most observed spice types and the mean lead levels associated with the spice. The table also shows the percentage of those spices that were purchased in the U.S. according to the case files.

Table 2

Mean Lead Levels of the Ten Most Commonly Observed Spices and Percentage of Those Purchased in the U.S.

<u>Spice</u>	<u>Mean Lead Level</u>	<u>No. of samples</u>	<u>Purchased in U.S. (%)</u>
Turmeric	1.064	28	64.3
Spice Mix	0.794	22	63.6
Cumin	0.165	20	60
Masala	0.501	18	50
Chili Powder	0.807	17	62.5
Coriander	0.291	10	80.0
Cardamom	0.189	6	33.3
Cinnamon	0.479	6	66.7
Fenugreek	0.785	6	66.7
Mustard Seed	0.636	6	66.7

* The above comparison was done on spices collected during MDE Investigations

In lieu of specific dietary intake and consumption data from the cases, when comparing the mean lead level of spices collected by MDE investigators of 0.548 ppm with FDA PTTIL of 6 micrograms per day, the estimated amount of spices needed to be consumed to reach the PTTIL is approximately ¼ of a Tablespoon.

Conclusions

The case reviews conducted as part of this research project found that there were 52 cases in which spices were identified as potential environmental antecedents. This study found that a large proportion of the samples collected as a direct result of the MDE case investigations as well as surveillance samples collected in Maryland and New York showed detectable levels of lead. For all of the samples collected in response to these cases, more than half had detectable limits of lead and for those samples with detectable lead levels the mean lead level was 0.549 ppm, when removing the larger outliers, which is significantly above the 0.1ppm guidance level in candy.

Recommendations

1. Investigators should evaluate and record the consumption levels of spices if there is a suspect lead risk found during a childhood lead investigation.
2. A national regulatory or guidance level for lead in spices should be created due to the percentage of products in which a detectable level of lead was found.
3. Educational outreach to populations at a greater risk should be expanded by the CDC, FDA, and State lead prevention programs.
4. Laboratories that conduct analytical testing of lead in food should use a method appropriate for solid matrices with a lower LOD allowing for comparison of results to the FDA guidance level in candy in lieu of a specific limit for lead in other foods.
5. The methodology used in this study should be applied in a follow-up study by the MDE at some point in the future.

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Community Size and Retail Risk Factors in Iowa Retail Food Establishments

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Abstract

This study evaluated the perception that rural retail food establishments pose a higher food safety risk than urban establishments; a perception shared by the author and other food safety inspectors employed by the Iowa Department of Inspections and Appeals (DIA), Food and Consumer Safety Bureau. The study analyzed food safety risk violations found in urban, urban cluster, and rural establishment inspections in Iowa as well as risk factor patterns associated with the type of ownership, length of ownership, and presence of a Certified Food Protection Manager (CFPM). The U.S. Census Bureau categorizes communities based on population: urban $\geq 50,000$, urban cluster $\geq 2,500$ and $\leq 50,000$, and rural $\leq 2,500$. The study found that there was not a significant difference in the type or rate of specific CDC risk factor violations among retail food establishments based on the size of the community. However, this study found a slight difference in the rate of food safety risk violations related to ownership type, with sole proprietorship showing a relatively higher violation rate in risk factors than franchise and corporate ownership. The study concluded that increased reliance on statistical analysis by food safety inspectors would tend to offset erroneous impressions regarding rural food establishments. The study recommended that an annual food safety risk factor statistical report be prepared and made available to all food safety regulators in Iowa.

Community Size and Retail Risk Factors in Iowa Retail Food Establishments

Background

After initially being trained to perform retail food inspections in an area of the state composed primarily of communities categorized as urban or urban cluster, I was assigned to an area comprised primarily of rural communities. My impression was that there was a significant difference in the prevalence in one type of risk-based violation. There were some retail food establishments in this newly assigned rural area that appeared to have more risk factor violations associated with food from unapproved sources. My perception was that there is a relationship between this type of risk factor violation and the size of the community where the retail food establishment is located.

Further investigation revealed that the perception that rural retail food establishments were associated with a higher number of foodborne illness risks was more widespread.

When DIA's Regulatory Food Safety Specialists were asked about their perceptions of the level of food safety knowledge associated with the food establishment's location, their responses revealed that the perception of the level of food safety knowledge and practice is lower in retail food businesses located in rural communities. This perception appeared to be based on anecdotal information rather than evidence-based. Whether there is a significant difference in the level of food safety knowledge or practice among retail food establishment operators in rural, urban cluster, and urban communities is unknown. Further, whether there is a difference in food safety knowledge or practice related to other factors, such as type or length of ownership, risk level associated with product or process, or employment of a Certified Food Protection Manager (CFPM) is unknown.

Problem Statement

The differences in the type and number of foodborne illness risk factor violations among urban, urban cluster, and rural area food establishments in Iowa is unknown.

Research Questions

1. Are there differences in the prevalence of specific retail risk factors among Iowa retail food establishments in urban, urban cluster, and rural communities?
2. Are there differences in violation rates for specific retail risk factors among Iowa retail food establishments located in urban, urban cluster, and rural communities?
3. Are observed differences in the specific risk factors or the rate of violations observed for specific risk factors related to other non-population related factors tracked in the Iowa Department of Inspections and Appeals U.S. Food Safety?

Methodology

As a preliminary step, 20 of DIA's regulatory Food Safety Specialists, all of whom have experience in inspecting in all of the geographical locations, were polled to determine if they knew or perceived that there are differences in the type and number of retail risk factors among food establishments located in urban, urban cluster, and rural areas. The questions asked were:

- Do you run across stereotypes or myths related to urban, urban cluster, or rural food establishments?
- In your experience, does the restaurant-going public tend to see chain/urban/urban cluster and independent/rural food establishments differing in some way related to food safety?

18 of the 20 regulatory Food Safety Specialists stated that they perceived that rural food establishments have less food safety knowledge than food establishments in urban or urban cluster areas.

Data from the two most recent routine inspections of 100 Iowa retail food establishments in each urban, urban cluster, and rural population categories was examined. A total of 600 inspection reports, completed by standardized food inspectors throughout Iowa were examined and the data gathered included the establishment's name, location, population category (urban, urban cluster, or rural), type and number of foodborne illness risk factor violations, type of ownership, agency assigned risk level (complexity), and whether the food establishment had a CFPM onsite. This data was entered into an Excel spreadsheet for data analysis.

Data showing length of ownership was also compiled, but preliminary examination of this data set found the length of ownership to be incomplete and inaccurate. For this reason, this data was not analyzed further.

Results

Table 1 compares the percentages of specific risk factor violations among food establishments in the three defined population categories. There is a slight difference in the prevalence of the risk factor food from unsafe source between rural food establishments (12%) and urban (7%) or urban cluster (7%) food establishments. There is also a slight difference in the prevalence of the risk factor improper holding/time and temperature between urban (18%) or urban cluster (21%) and rural food establishments (11%).

Table 1

Comparison of Risk Factor Violations Among Different Sized Communities

<u>Risk Factors</u>	<u>Rural %</u>	<u>Urban Cluster %</u>	<u>Urban %</u>
Food from Unsafe Source	12	7	7
Contaminated Equipment/Protection from Contamination	38	38	42
Improper Holding/Time and Temperature	11	21	18
Improper Cooking Temperature	1	3	3
Poor Personal Hygiene	3	3	7

Table 2 compares the percentage of observed risk factor violations among ownership types: sole proprietor, corporate LLC, and corporate franchise. This data shows that sole proprietors have a higher level of risk factor violations in the risk categories: food from an unsafe source, contaminated equipment, and improper holding temperature.

Table 2

Comparison of Risk Factor Violations Among Ownership Types

<u>Risk Factor Violations</u>	<u>Sole Proprietor %</u>	<u>Corporate LLC %</u>	<u>Corporate Franchise %</u>
Poor Personal Hygiene	3	3	1
Unsafe Source	10	5	.5
Contaminated Equipment	34	20	7
Inadequate Cooking	2	2	.2
Improper Holding Temperatures	16	8	4

Figure 1 compares the percentage of specific risk factor violations in food establishments with and without a CFPM on staff. The data shows that retail food establishments with a CFPM have a significantly lower violation rate for the risk factor contaminated equipment and a slightly lower rate for the other risk factors. Establishments with a CFPM on staff had a violation rate of 31% while food establishments without a CFPM on staff had a violation rate of 50%.

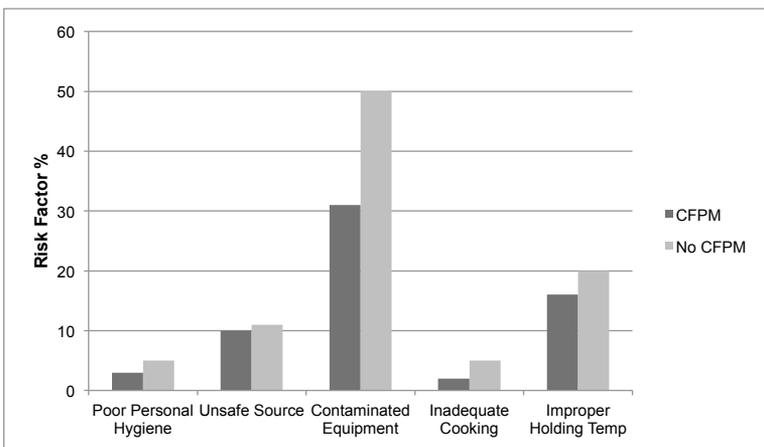


Figure 1. Comparison of risk factor violations in food establishments with and without CFPM.

Conclusion

The study concluded that the differences in foodborne illness risk factor violations found in Iowa's retail food establishments among rural, urban cluster, and urban areas are minor and that in fact rural areas are not less safe in terms of foodborne illness risks. Examination of the risk factors and their association of one of the non-population related parameters, ownership type, revealed that retail food establishments that are operated by sole proprietors have more documented risk factor violations than retail food establishments operated under franchise or corporate ownership for 3 categories of risk factors. Though this study did not explore the reason(s) for this relatively higher level of risk factor violations, the data suggests that retail food establishments operated by sole proprietors may have, and apply, less food safety knowledge in the operation of their retail food business.

The study also compared the prevalence between foodborne illness risk factors and having a CFPM on staff. The association between the presence of a CFPM and the prevalence or rate of risk factor violations had a significant difference in the risk factor category contaminated equipment; otherwise it was slightly lower in the other risk factor categories. Establishments with a CFPM on staff had a risk factor violation rate of 31% while food establishments without a CFPM on staff had a risk factor violation rate of 50%.

Recommendations

1. Data concerning risk factor violations should be collected and analyzed annually. This report would evaluate and compare sets of variables similar to those evaluated in this study.
2. The results of this analysis should be shared with DIA staff and local county contracts that perform inspections of retail food establishments on DIA's behalf. Results would be used to target education and regulatory efforts based on data rather than perception or anecdotal information.
3. Design and conduct research to determine the cause of the relatively higher level of risk factor violations associated with sole proprietorship. Based on the results of this study, develop a strategy to assist sole proprietor-owned food establishments in improving their food safety knowledge and practice.
4. Design and conduct more focused research about the effect of the presence of a CFPM on the prevalence and rate of risk factor violations now and again after the effective date for Iowa's requirement to employ a CFPM (January 1, 2018).

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Control of Behavior-Centric Risk Factors Between Two Management Groups

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Abstract

Per the Boston Consulting Group, millennials eat out 3.4 times per week, the largest amount in American history. With more people eating out, the significant number of foodborne illness outbreaks associated with consumption from restaurants within the U.S. should be noted. To reduce the frequency of foodborne illness outbreaks associated with these establishments, many states now stipulate that foodservice establishments have some form of an accredited food protection manager. The purpose of this study was to observe the utility of a Certified Food Protection Manager (CFPM) with the implementation of a Food Safety Management system in controlling the occurrence of CDC risk factors within a specific metro-area in Georgia. This study focused on behavior-centric risks; poor personal hygiene/employee health; and protection from contamination/contaminated equipment. Data was collected at 26 establishments to accurately assess the controls in place for each risk factor and determine if there was any relationship between the occurrence of risk factor violations, the presence of a CFPM, and the CFPM implementation of a Food Safety Management System (FSMS). Results indicate that the presence of a CFPM with the implementation of an FSMS reduced the incidence of contaminated equipment and poor personal hygiene/employee health significantly as compared to facilities that do not have a management system. The results also indicate that a CFPM alone has less effect on the reduction of these two risk factors than previously indicated in FDA Retail Food Risk factor study. The study recommends continued educational outreach to food establishment operators using the study results as well as continuing the study's methodology to analyze after one year those establishments who hired a CFPM and instituted a FSMS.

Control of Behavior-Centric Risk Factors Between Two Management Groups

Background

The Centers for Disease Control and Prevention (CDC) has identified the top five risk factors typically responsible for foodborne illness outbreaks. To observe the occurrence of these risk factors within retail foodservice the Food and Drug Administration (FDA) conducts a risk factor study every ten years. The results of studies have contributed to the development of recommendations and requirements to improve food safety practices in foodservice as well as other areas such as manufacturing. One of the results from these studies has been the recommendation to employ trained and knowledgeable Certified Food Protection Managers (CFPMs) to reduce the incidents of CDC risk factor items.

Another result of these studies has been the adoption of regulations by many states requiring a CFPM. FDA has found the requirement is improving the overall practices within

industry. Data from a 2008 study indicate improvement in four categories (excluding proper cooking) when establishments complied with CFPM (FDA, 2009). Research has been utilized to monitor the effects of utilizing a CFPM and the five risk factors identified by the CDC. However, few studies have evaluated how the management system has been formed or created for active managerial control of stated risk factors. The project sought to evaluate if there is a relationship between the lack of CFPM, presence of CFPM, and the implementation of food safety management system in addition to employment of Food Protection Manager on the occurrence of behavior centric risk factor violations; personal health and hygiene and contamination.

Problem Statement

The degree to which employing a CFPM in comparison to utilizing a food safety management system under the direction of CFPM to reduce incidents of two behavior-centric risk factor violations; poor personal health/hygiene and contaminated equipment/protection from contamination within DeKalb County is unknown.

Research Questions

1. Does having a CFPM affect risky behavior; specifically, personal health and hygiene and protection from contamination of food and equipment?
2. Does implementing a management system impact the number of behavior-centric CDC risk factor violations observed in DeKalb County, GA?
3. Are the CFPMs within DeKalb County implementing a management system that reduces the number of CDC risk factor violations observed?

Methodology

Methodology in the study mimicked the method utilized by FDA Risk Factor Study 2008 and 2016. A geographical information system (GIS) database containing a listing of businesses throughout the county was used as the establishment inventory for the data collection. Establishments were randomly selected to participate in the study from among all eligible establishments located within boundaries of DeKalb County, Georgia. To further determine the pool of establishments eligible for selection, an assessment was made to exclude operations that handle only pre-packaged food items.

A sample size of 2% of permitted establishments within DeKalb County, Georgia was selected, however only 1.2% were used due to exclusion criteria ($s=26$ establishments, $n=2209$ permitted establishments as of August 30, 2016). In addition to being a permitted facility, establishments must have been in existence for at least 1 year. This time frame was selected to coincide with the requirement for a certified food protection manager within 90 days of permit issuance and to have a record of at least 2 inspections for which violation history can be established. In addition, facilities with limited preparation were excluded. Establishments for which cooking or cooling could not be observed were excluded.

Each data collection visit was unannounced, to observe the operation in its normal mode. Upon arrival to the establishment, the Environmental Health Specialist (Specialist) explained the purpose of the visit. If entry into the selected establishment was denied by the person in charge, the Specialist did not conduct a data collection. The Specialist then selected a new establishment from the substitute establishment list provided by random number generator for 23 additional facilities. The primary purpose of the data collection was to observe food safety practices and employee behaviors that are associated with the control of foodborne illness risk factors. After discussing the purpose of the data collection, the Specialist conducted a quick walk-through of the establishment's kitchen. The goal was to identify the critical food preparation processes being conducted at the time of the assessment, so that priorities can be determined. For each critical activity observed during

the walk-through, the Specialist determined whether the activity is static (one that will likely be the same over the specified visit) or dynamic (one that will likely be completed soon or will change quickly during the assessment). Based on the walk-through and responses provided by the operator about the specific activities being conducted at the operation specific areas were monitored by the Specialist. The establishment’s menu was reviewed and utilized by the Specialist prior to data collection at the facility as guidance on processes that were to be observed during the assessment.

The focus of the data collection was observation of two critical foodborne illness risk factors listed on the data collection form; contaminated equipment and personal hygiene. To assess the food safety management system in place the managerial control data collection form utilized in the FDA Retail Food Risk Factor study collected four elements of each establishments management system (FDA, 2009). The management system elements included whether the establishment had procedures, training, and monitoring in place for these risk factors, as well as if a violation was observed during the data collection visit. The operator was asked to provide any documentation utilized for standard procedures, training, or monitoring of employee health and hygiene including handwashing, hygienic practices, exclusion and restriction criteria, and prevention of contamination by hands.

Determination of CFPM was assessed using the Conference for Food Protection (CFP) accreditation program. Establishments with a person in charge that currently holds an American National Standards Institute-Conference Food Protection (ANSI-CFP) recognized certificate with verifiable proof were recognized, for this study, as having an CFPM employed. Furthermore, if that person was present during the site visit that individual was identified as the person in charge and was expected to convey all necessary information, procedures, documents, as required for the assessment.

Results

Out of the 26 establishments evaluated, 13 facilities had an FSMS implemented. Three additional facilities were removed from the study because of lack of proof of CFPM employment or failure to employ a CFPM at the establishment during the site visit, see Table 1.

Table 1

Employment of Certified Food Protection Manager (CFPM)

<u>CFPM</u>	<u>CFPM (N=29)</u>	<u>%</u>
1-Proof available	26	89.66%
2-No proof available	1	3.45%
3-No CFPM	2	6.90%

Note. Establishments that could not produce evidence of employment of a CFPM were excluded for this study, the findings at these sites were not included in the data.

Out of the 26 facilities with a CFPM, 13 had documentation of FSMS in place in addition to CFPM. Of these facilities, only 4% had contamination violations compared to 46% facilities with CFPM without a management system and 35% of all establishments (with a CFPM and CFPM with FSMS). Additionally, personal hygiene and health had 4% in facilities that had a CFPM but utilized no food safety management system. All facilities utilizing a FSMS had significantly fewer personal health-hygiene and contamination violations all around, see Table 2 and Figures 1 and 2.

Table 2

Percentage of Risk Factor Violations No CFPM, CFPM, CFPM with Management System

Observed Violations	CFPM (n=26)	CFPM with management system (n=13)	CFPM without management system (n=13)
Employee Health	35%	8%	46%
Employee Hygiene	27%	12%	38%
Contaminated Equipment	27%	4%	46%
Protection from Contamination	23%	4%	38%

Note. Employee personal health/hygiene risk factor showed statistically significant improvement in establishments utilizing a CFPM with a food safety management system compared to those that employ a CFPM only. Contaminated equipment/protection from contamination showed statistically significant improvement compared to CFPM only.

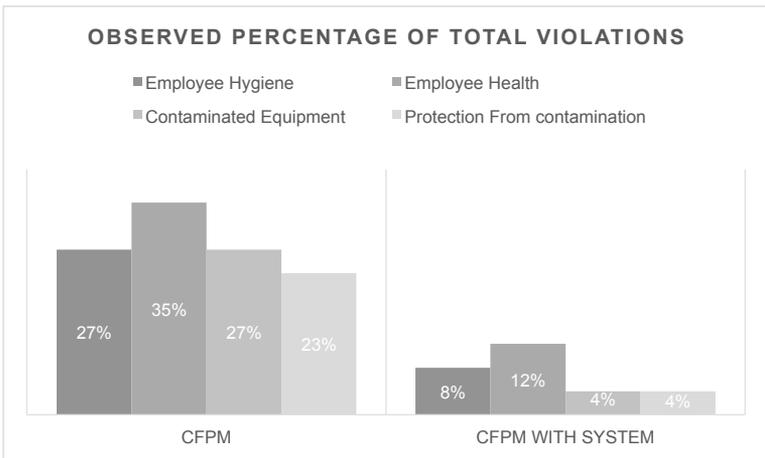


Figure 1. Observed Violations Between Two Management Groups.

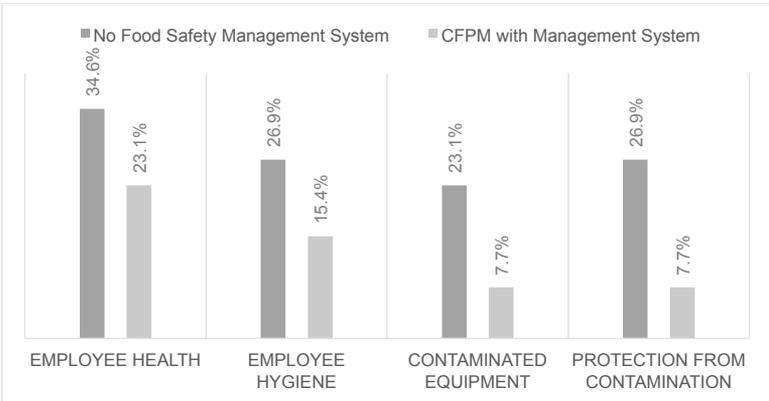


Figure 2. Observed Violations within Management System.

To assess FSMS, the managerial control data collection form utilized in the FDA Retail Food Risk Factor study was used to collect elements of each establishments management system (FDA, 2009). Not all facilities had a management system that encompassed all elements; procedures, training, and monitoring in place for these risk factors, see Table 3.

Table 3

Components of Food Safety Management System

<u>Management System Component</u>	<u>Present (n=13)</u>	
	<u>Yes</u>	<u>No</u>
Contaminated Equipment/Protection from Contamination Violation Observed	1	12
Contaminated Equipment procedures	12	1
Contaminated Equipment training	12	1
Contaminated Equipment monitoring	1	12
Personal Health/Hygiene Violation Observed	2	11
Personal hygiene procedures	13	0
Personal hygiene training	8	5
Personal hygiene monitoring	2	11

Note. Food safety management system was assessed for each risk factor; contaminated equipment/protection from contamination and personal health/hygiene. Although, 13 facilities had a food safety management system, majority of establishments were lacking protocols for monitoring these behaviors to assess whether risks were being effectively controlled.

The person in charge was asked to provide any documentation utilized for standard procedures, training, or monitoring of employee health and hygiene including handwashing, hygienic practices, exclusion and restriction criteria, and prevention of contamination by hands. The person in charge was also asked to provide documentation for standard procedures, training, and monitoring of cleaning and sanitizing food equipment, separation of raw animal foods, and protection from environmental contamination.

In one case, from inspection history and file review, it was established the facility did have a FSMS, however, the person in charge was not able to produce the written documentation until after the site visit. Monitoring was an element that was lacking in majority of FSMS for both risk factors (Table 3). Only 1 facility had procedures for monitoring protection from contamination controls and 2 establishments had monitoring procedures for personal health and hygiene. Of the 2 establishments that had the personal health/hygiene monitoring protocols, none had observed personal health/hygiene violations. There were not enough facilities with monitoring procedures in place to state statistical significance.

Conclusion

The results suggest there is a relationship between the CFPM and the CFPM utilizing a written FSMS and incidence of two behavior-centric risk factors; personal health/hygiene and protection from contamination/contaminated equipment.

Evidence does suggest that a relationship exists between the presence of CFPM and occurrence of employee health/hygiene and protection from contamination risk factor observations. Facilities utilizing a food safety management system; utilizing written procedures, training, and monitoring demonstrated fewer incidents except for employee health. In facilities that had a CFPM and facilities utilizing a Food Safety Management

system this risk factor was still observed at least 23% of the time. The data also suggests that the regulation for requiring a food protection manager still leaves a gap in controlling employee behavior. As employee health risk factors were still prevalent approximately one-third of the time. Protection from contamination and preventing contamination of equipment were better controlled by CFPM but the procedures, training and monitoring utilized in FSMS saw fewer incidence of these violations. The integrated strategy of utilizing the CFPM to promote a management system to proactively and continuously prevent, reduce, and eliminate hazards could close this gap.

Recommendations

1. Food establishments should be encouraged to use a FSMS as the best integrated approach to maintaining the safety and integrity of foods in foodservice establishment.
2. Agencies should use data, such as in this study in their educational outreach to operators regarding the benefits of a CFPM and a FSMS.
3. A further study using this methodology should be carried out on an annual basis examining the impact of adopting a CFPM and a FSMS on those food service establishments that currently do not have any preventative control measures or food safety system. The study should also examine food service establishments one year after employing a CFPM and adoption of a FSMS.

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Estimating Risk by Measuring Coliform on Common Touch Surfaces

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Abstract

This exploratory study surveyed five percent of Marion County, Indiana restaurants by sampling dining room common touch locations for the presence of coliform bacteria. Coliforms, although not often a direct cause of foodborne illness, were chosen as indicator organisms due to their common association with soil and feces. Testing was limited to full-service, sit-down restaurants with ten or more employees. Four environmental samples were collected at each restaurant; no food samples or food contact surfaces were sampled as a part of the study. Full, routine inspections were not performed. Restaurants that were selected were given no advance warning. All samples were submitted to the Marion County Public Health Department laboratory for analysis. The study concluded that IDEXX Colilert-18[®] is an effective method for establishing the presence of coliforms on non-food contact surfaces within food establishments and thus identifying the possible need for improved routine cleanings. The study also explored a number of methodological issues in testing common touch surfaces. The study recommends the increased use of collecting common touch surface samples, improvements in cleaning regimens for food establishments, reconsidering dining room design, and the development of criteria for evaluating acceptable levels of coliform contamination on common touch surfaces.

Estimating Risk by Measuring Coliform on Common Touch Surfaces

Background

Pathogens, such as viruses and bacteria, can remain and survive on surfaces for extended periods of time and those surfaces, in turn, may become temporary environmental reservoirs that facilitate the spread of illness (Scott, 2013). Studies of currency, menus, home kitchens, and common items found in hospital settings established the risk of these items serving as illness vectors (Michaels, 2002; Choi et al, 2014; Donofrio et al, 2012).

Total spending on food away-from-home increased by 66.4%, when measured as a percentage of total consumer spending, between 1970 and 2012 (USDA, 2016); 53% of foodborne illness outbreaks are attributed to sit-down restaurants (CDC, 2014).

Standard environmental assessments conducted after outbreaks require food sampling,

trace backs, employee health reporting and interviews. A lack of contaminated food available for sampling and asymptomatic food workers may be barriers in locating the source of foodborne illness. However, environmental sampling in dining areas may provide clues in cases where traditional means of information gathering fall short, e.g. environmental sampling for Norovirus after outbreaks on cruise ships has proven valuable (Park, 2015).

Problem Statement

Common touch surfaces in restaurant dining areas may serve as pathogenic reservoirs but the extent of the risk is largely unknown.

Research Question

Can environmental sampling in restaurant dining areas help illuminate risks associated with common touch surfaces and offer value as an investigative tool for regulators?

Methodology

Although they rarely directly cause foodborne illnesses, coliform bacteria were selected as indicator organisms as a means of establishing contamination. According to the CDC, the presence of coliforms generally indicates contamination by soil or feces. This study conducted environmental sampling for coliforms in the dining areas of selected restaurants. A randomized list of 879 full-service, sit-down restaurants with 10 or more employees in Marion County, Indiana was generated. The first 44 restaurants on that list were selected. Sampling was conducted during unannounced visits; no inspections were performed at the time of sampling. All samples were tested at the Environmental Microbiology Lab (EML) at the Marion County Public Health Department (MCPHD).

A hierarchical list of possible common touch sampling locations was created using subjective assumptions that certain items/locations may be overlooked in the course of normal cleaning regiments as a result of their ubiquity. The hierarchy of sampling locations, in order, included: laminated menus, high chairs, soda guns/soda self-service touch screens, women's restroom inner doorknobs, salt and pepper shakers, ketchup and mustard bottles, the undersides of chairs, and the undersides of tables. Each item on the hierarchy was given a higher priority for sampling than the ones beneath that item in order to ensure that the sampler was not biased towards items that "looked dirty" to the sampler.

Four samples were collected from each of the 44 restaurants for a total of 176 samples. At least 4 of the 8 sampling locations included in the hierarchy were available at every sampling location. All of the samples for the study were taken with 3M Hydrated Sponges and transferred to 3M Petrifilm Coliform Count (CC) Plates.

The 3M Hydrated Sponge is pre-hydrated with a Lethen broth solution to retain viable coliforms. Efforts were made to take samples in a consistent manner with roughly equivalent amounts of surface area sampled in each instance. Due to inconsistent sizes and shapes, consistent sampling area sizes were not always possible to achieve for items such as door knobs. The ideal surface area to sample per sample was set at 187 in²--or the equivalent of two standard sheets of paper. Additionally, some items, such as soda guns, were consistently too small to meet the 187 in² standard and thus some caution should be made when comparing results across sample types.

Additionally, a one mL serial dilution at 10⁻⁷ of *E. coli* was used to establish a control. The same quantity was routinely plated and counted on a Petrifilm plate to ensure that no irregularities in sampling or incubation caused inaccurate results. Taking the same quantity, plating and recounting the bacteria on the plate after incubation each time other samples

were done yielded colony counts between 35 and 106 for the control in each instance. A secondary control demonstrated that sponge-based capture resulted in a 1000-fold reduction in colony forming units (CFU) counted. For every bacterium on the plate, 999 remained in the sponge or on the surface that was sampled.

Samples were plated on the same day or refrigerated at 1°C - 5°C (34°-41°F) until plated. After 24 hours, the 3M Petrifilm CC Plate® was counted for the total number of visible colony units with gas production per the Interpretation Guide provided by 3M. Colony units without gas production were also noted; however, these colony units are not indicative of coliforms and were not included in coliform colony count.

Additionally, each sample was further tested against an enzyme substrate coliform test known as Colilert-18® as a secondary means of coliform detection. The 3M Hydrated Sponge® was submerged in single-strength Trypticase Soy Broth (SS TSB), incubated and visually inspected for any growth, cloudiness or particulate matter. Cloudiness indicated bacterial growth and prompted a Colilert test. In 100% of the samples, the SS TSB contained cloudiness and particulates and thus 100% of samples were subjected to the Colilert test.

Colilert is a coliform sampling test whose efficacy for testing water of all types is long-established and well-documented. Colilert's use with regards to food sampling is rare but not unique to this study; a 2014 field study tested its efficacy for food sampling with good results (Rodrigues, 2014).

When Colilert is added to a liquid sample, an enzymatic reaction occurs causing the liquid to turn yellow in the presence of coliforms and fluoresce in the presence of *E. coli* specifically. The enzymatic reaction remains consistent if the quantities of enzyme and liquid being tested are maintained at an appropriate ratio. Accordingly, the test can be scaled down and a single test kit can be used to conduct dozens of tests in individual test tubes—making Colilert very cost-effective within this context. A provided “Quantitray” can also allow Colilert to quantify the number of coliforms per sample; however, the quantitray will not work if the test is performed without the standard amount of liquid per sample.

In instances where a positive Colilert result was noted when <1 CFU/mL had been counted on the plates, RapID was used as the final layer of testing to potentially validate the Colilert positive reading. Due to the costs associated with the RapID test, 9 out of the 67 potential false-positives were randomly selected for further testing. Another three samples with more than one visible colony and one with no visible colonies and a negative Colilert test were also run through RapID.

Due to a limited number of RapID test kits available, all RapID samples were given an oxidase test to ensure that the bacteria they contained were oxidase-negative. One additional sample “failed” the oxidase test by indicating the presence of oxidase-positive bacteria and was not tested. The oxidase-positive sample had been a non-typical (not clear or yellow) negative Colilert sample. Additionally, two other samples fluoresced indicating the presence of a β -glucuronidase positive bacteria and were plated on an Eosin Methylene Blue (EMB) plate in order to isolate suspected *E. coli* instead.

RapID testing requires a pure isolate in order to identify a species. To obtain an isolate from a broth sample, MacConkey Agar (MAC) plates were used to separate bacteria by type. The agar in a MAC plate contains food mediums to support various bacteria and a dye which is pH sensitive. Coloration changes in the agar caused by bacterial activity allow the plate to sort bacteria into three groups. If the bacteria present metabolize lactose by fermenting it into acid, the pH of the plate will lower causing the dye to turn purple. If peptone is metabolized instead, ammonia is produced causing the dye color to fade or turn white.

Otherwise, the sample retains the default yellow color. Most coliforms ferment lactose and so purple colonies were selected for RapID testing.

In one instance, no color changes were observed on a MAC plate containing a sample that had generated as Colilert positive reading. This sample was tested via RapID anyways and was identified as *Enterobacter* (a coliform). This strain of *Enterobacter* possibly had a mutation that allowed the strain to survive by some means other than fermenting lactose.

Of the ten Colilert positives to undergo secondary testing, 5 were positively identified as coliforms (including *E. coli*, *Klebsiella*, and *Citrobacter*). The five that were not positively confirmed as coliforms could indicate a false-positive by the Colilert test, however a false positive is unlikely given that the MAC plates confirm that they were indeed lactose-fermenting bacteria and the RapID database only contains the coliform species considered to have “clinical significance”. Thus, in effect, RapID validates Colilert in at least 5 of 10 instances, and its inability to validate the positive Colilert test in the other 5 cases does not mean RapID disputes those results. Given that the MAC plates consistently supported the Colilert positive results and the RapID “unknown” result do not necessarily dispute those results, those results are assumed to be mostly valid. Therefore, in instances where Coliert was positive but no colony units were visible on the Petrifilm, it is most likely that coliforms were indeed present at rates <1 CFU/mL.

Results

The 3M Petrifilm CC Plate Interpretation Guideline was used to count gas producing colonies likely to be coliforms. Instances where no colonies are observed but secondary testing still indicates the presence of coliforms are also noted. Table 1 shows the results.

Table 1

Distribution of Colony Forming Units Across Samples

Colony counts	Counts	% of samples with one CFU or more
No Colonies and Colilert Negative	82	46.59
Colilert Positives (<1 Colony)	67	38.07
1-20 Colonies	21	11.93
21-100 Colonies	4	2.27
101+ Colonies	2	1.14

Note: The two counts with 101+ colonies were a soda gun and a ketchup and mustard bottle.

Table 2 shows how many samples of each type were taken (based on the pre-established priority list) and how many tested positive for Colilert.

Table 2

<i>Colilert Results by Sampling Location</i>					
Priority list	Sampling location	Total sampled	% of total	Total positive	% of Sampled
1	Laminated menus	20	11.36	13	65.00
2	High chairs	40	23.73	37	92.50
3	Soda gun/self-service soda touch screen	26	14.77	14	53.85
4	Women's restroom doorknob (inside)	36	20.45	10	27.78
5	Salt and pepper shakers	34	19.32	10	29.41
6	Ketchup and mustard bottles	4	2.27	3	75.00
7	Under chairs	10	5.68	4	40.00
8	Under tables	6	3.41	3	50.00

Thirteen samples were tested and were identified with RapID testing including 4 *Klebsiella*, 2 *Enterobacter*, 1 *Citrobacter*, and another two fluoresced indicating *E. coli*. The two *E. coli* results were isolated on an Eosin methylene blue (EMB) plate. EMB plates were used after a positive Colilert test with fluorescence, a characteristic for *E. coli* that can detect β -glucuronidase positive bacteria. The two *E. coli* positive samples came from the underside of a chair and a laminated menu.

One Petrifilm with a colony without a gas bubble was tested and positively identified as *Acinetobacter*. There were 36 other 3M CC Petrifilm plates with the same characteristics (colonies with no gas production). *Acinetobacter* is not a coliform and is the probable bacteria in those 36 instances as well. However, anaerogenic (non-gas producing) coliforms, or other anaerogenic bacteria, cannot be ruled out without further testing.

Conclusions

This study verifies the efficacy of Colilert as an effective testing method for establishing the presence of coliforms on non-food contact surfaces within food establishments. Plate counts enumerate the extent of coliform, but current guidelines for evaluating the safety profile of those counts do not exist for common touch environmental samples. Safe levels of coliform contamination on common-touch surfaces, if any, are unknown. The "Guidelines for the microbiological quality of some ready-to-eat foods sampled at the point of sale" suggest that anything under 100 CFU's per gram of food is acceptable, but translating these guidelines to apply to one milliliter of liquid from a sample taken by swabbing a 187² inch surface area is difficult. Furthermore, the lack of food substrate on common-touch surfaces will naturally suppress bacterial populations while no such limitations exist for food samples. Accordingly, the thresholds established for bacteriological contamination on food may be too high to be comparable even if the challenges in establishing a comparable sampling technique could be conquered.

The large gap between contamination found between high chairs and women's restroom inside-door knobs implies a link between the Colilert positive detections and cleaning regimens. Many restaurateurs believe consumers view restroom cleanliness as a strong indicator of overall sanitation and so discovering that an item sampled inside a restroom was cleaner than everything sampled within the dining room is not exceptionally surprising.

The results of the study suggest that there are surfaces, particularly high chairs, to which restaurants need to pay more attention in their normal routine cleanings. While the risks associated with various levels of coliform contamination for common touch objects within restaurants may be hard to quantify, the risks for some pathogens are well-known. For instance, Norovirus, also associated with fecal contamination, is notorious for being infectious even at comparatively low levels of surface contamination and the role of surface contamination in facilitating outbreaks has been documented (Wu, et al 2005)—therein lies the value of an indicator organism.

Recommendations

Based on the conclusions of this study, the following recommendations are offered for the consideration of interested parties:

1. Regulators should consider using routine environmental sampling to uncover risk factors for outbreaks or as an investigative tool when other methods fail or when otherwise indicated (such as cleaning verification after an outbreak has occurred).
2. Regulatory agencies should adopt a standardized method for common surface sampling so as to better compare results and risk factor implications
3. Restaurant operators should examine their cleaning practices regarding areas which are frequently touched but may not be frequently cleaned such as high chairs, soda guns, laminated menus and condiment bottles.
4. Restaurant operators should consider food safety as a part of dining room design and material selection as they do kitchens. For instance, many kitchen items are made of metals such as steel or copper. Such metals are naturally biocidal due to a process known as oligodynamic effect in which positive charged metal ions interact with negative ions in living cells leading to cell death.
5. Increased guidance regarding common surface cleaning for retail food establishments should be offered by regulatory authorities.
6. Establishments should focus on cleaning high chairs with relation to high risk population.

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