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"More Leaders are on the Way"
Joseph Corby, AFDO Executive Director

AFDO is pleased to welcome Cohort III to the AFDO Annual Conference. The Fellowship for Food Protection program has once again produced the leaders of tomorrow that will guide our profession and association through the continuing challenges we face.

This year's Fellows have produced some very important and instrumental projects to report on at our Annual Conference in Louisville, Kentucky. And once again, this Special Edition of the AFDO Journal is dedicated to Cohort III and their project reports. This year, three of the projects have resulted in AFDO Resolutions to be voted on at this year's conference. I hope everyone is able to see the project presentations at our Committee meetings and have the opportunity to visit with the Fellows during the Tuesday afternoon Poster Session we have planned. AFDO is once again extremely happy with the effects the Fellowship program and research projects have had on our organization. We offer our congratulations and sincere gratitude to all the Fellows from Cohort III.

I want to take this opportunity to thank the AFDO Endowment Foundation for their generous contribution to the Fellows by providing travel funding so they may attend the Annual Conference.

Many believe our food safety system today is over-managed and under-led. AFDO believes our profession is so important that we cannot wait for leaders to come along. IFPTI continues to seek out individuals with leadership potential and expose them to career experiences that are designed to develop that potential. The Fellowship Program not only builds leaders, but it builds AFDO as well.

More leaders on the way – that's great news for AFDO.

About the Fellowship in Food Protection

Gerald Wojtala, Executive Director of IFPTI

In 2012-13, IFPTI's Applied Science, Law, and Policy: Fellowship in Food Protection welcomed its third Cohort, which comprised of twelve future food protection leaders at the federal, state, and local levels from eleven states across the US, including New York, Texas, and Alaska.

The Fellowship was created by IFPTI in response to the Food Safety Modernization Act (FSMA), which supports a national, integrated food safety system. The Fellowship provides future leaders with an intense professional development experience focused on critical thinking, problem-solving and decision-making skills, within the framework of food regulatory science, law, and policy.

The Fellowship is offered to federal, state, local, tribal, and territorial food regulatory professionals with 2 to 10 years of experience and who desire to pursue a long-term food protection career. As a prerequisite, Fellows are required to complete the ORAU online courses identified in Standard 2 of both the retail and manufactured foods program standards as well as the AFDO/FDA Application of the Basics of Inspection and Investigation course (or equivalent).

During the year-long program, the Fellows: 1) participated in three week-long seminar-style sessions at the IFPTI global headquarters in Battle Creek, MI; 2) designed and developed an original research project under the supervision of an IFPTI mentor and IFPTI senior staff; and 3) presented their research findings (via a PowerPoint presentation and an educational poster) at the 117th AFDO Annual Conference in Louisville, KY.

IFPTI strives to improve the Fellowship program from year to year, based on input and feedback from Fellows, instructors, IFPTI staff and external stakeholders, along with various 'live' assessment tools and evaluation mechanisms.

After Cohort I, modifications to the program included: 1) removal of the Labeling course; 2) realignment of the Policies and Strategies course; and 3) the addition of a course on Compliance.

After Cohort II, changes to the Fellowship included: 1) adding FSMA to the content of the Food Law course and removing the Food Labeling module; and 2) changes to various modules contained in the Food System Control Applications course.

We seek ideas from anyone – especially industry – for food safety or regulatory research projects that can be offered to the Fellows at the beginning of each cycle. In fact, this year an industry award was given to the most innovative retail-related project. All of us at IFPTI would like to thank the Cohort III Fellows, and wish them the best as they assume leadership roles in the food protection arena and take full advantage of a network of Fellows and mentors. We also look forward to Cohort IV of the Fellowship, slated to begin in August, 2013.

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

Dr. Joanne M. Brown has over 40 years of experience in food safety, animal disease, public health, and emergency preparedness. She graduated from the University of Minnesota's College of Veterinary Medicine, has a master's degree in veterinary microbiology from Texas A&M University, and is a Diplomat in the American College of Veterinary Preventive Medicine and a Distinguished Practitioner of the National Academies of Practice (retired). She spent over 26 years in the Army Veterinary Corps and retired with the rank of Colonel. Her last two Army assignments were Chief, Department of Veterinary Sciences, Army Medical Center and School, where she was responsible for basic and advanced training of enlisted soldiers and officers in the US Army Veterinary Services and Director of the Department of Defense Veterinary Laboratories. As Director she had oversight of food microbiology, food chemistry, and animal diagnostic testing for laboratories in the US, Panama, and Germany.

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

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

She has been an adjunct professor at Florida State University for food safety since 2012.

Dr. Brown is a member of AFDO and the Chair of the Awards Committee from 2007 to 2011. She is a past president and lifetime member of AFDOSS and the 2012 recipient of the Eugene H. Holeman Award.

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

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

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

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

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

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

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

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

A member of AFDO since 1985, Mr. Corby was the Chairperson for the Food Committee, where he spearheaded the development of several model codes, food processing guidelines for industry and government regulators, training programs, AFDO's Food Code Pocket Guide, and official AFDO comments to national food safety issues. In addition to the Food Committee, he continues to serve on AFDO's Food Committee, Administration Committee, Seafood Committee, and International and Government Relations 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 IFPTI, The University of Tennessee, and Louisiana State University. He is also a member of the University of Florida's Food Science & Human Nutrition Advisory Council, and he serves on the Board of Directors for IFPTI and the Partnership for Food Safety Education.

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

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

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

After retiring from New York, Mr. Sevchik served as Training Director for AFDO. During his tenure, he designed and managed national training programs that addressed regulatory concerns for food safety, dietary supplements, imports, drugs, medical devices, and body art safety. In addition to serving as an instructor in the Fellowship Program, Jim is an Adjunct Instructor for LSU's Academy of Counter Terrorist Education and the University of Tennessee Center for Agriculture and Food Security Preparedness. Mr. Sevchik received his B.S. degree from State University of New York at Buffalo.

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

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

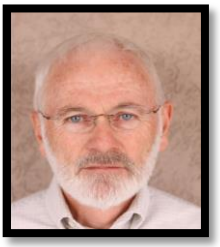
Mr. Smoak has served as a member of the Georgia Homeland Security's Agriculture and Food Defense subcommittee. He is a Past-President of AFDO and the Association of Food and Drug Officials of the Southern States (AFDOSS). He was AFDO's first representative to the Food and Agriculture Sector Government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

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

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

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

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



Steve Steinhoff worked as a food safety professional 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. Mr. Steinhoff retired from state service in 2008.

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 (NCAFDO). He continues to remain active in AFDO projects and committees.

Anthony P. Anderson recently graduated with a M.B.A. and is actively pursuing a second Master degree in Occupational Health and Safety with an emphasis on Environmental Management. He has been with the Milwaukee Health Department-Consumer Environmental Health Division for six years, where he serves as an Environmental Health Specialist. Anthony is a Certified Food Manager with the Wisconsin Department of Health Services and a Certified Professional in Food Safety with the National Environmental Health Association. **Mentor: Joanne Brown**

Erik Bungo graduated from Juniata College (Pennsylvania) with a B.S. in the field of physics and math. Currently, he is a Food Safety Field Supervisor for the Virginia Department of Agriculture & Consumer Services (VDACS) Food Safety & Security Program. He has served in this intermediate supervisory role for four years as a point of immediate guidance for field personnel in the Northern Virginia region. Erik is the Jr. Vice -President and Program Chair of the Central Atlantic States Association of Food and Drug Officials (CASA) and serves as the Virginia conference representative to the CASA Executive Board. Recently, he was honored as the 2009 AFDO Achievement Award winner and for his leadership as the Local Arrangements Committee Chair for the 2010 AFDO Annual Conference. **Mentor: Joanne Brown**

Karla Clendenin received her B.S. in Legal Studies from the University of Central Florida and began her career with the State of Florida in 2006. She regularly conducts regulatory food safety inspections and also is a staff trainer and auditor. Karla is on The Special Inspection Team and the Florida Integrated Rapid Response Team. Her most recent professional endeavors include participation on a panel led by the Institute of Food Technologists' that produced the Product Tracing Pilots Report as well as conducting the food safety inspections at the 2012 Republican National Convention. **Mentor: Charlene Bruce**

Scott Daly graduated from Illinois State University with a B.S. in Environmental Health. He interned with the Indian Health Service in Phoenix, Arizona, which led to his current position as a commissioned officer with the U.S. Public Health Service working for the Indian Health Service in Rhinelander, Wisconsin. Scott, a Registered Environmental Health Specialist, provides environmental health and safety services to the federally recognized Indian tribes in Wisconsin and Michigan. **Mentor: Charlene Bruce**

Valerie Gamble has a B.A. in Biology and Geology and a M.S. in Geological Sciences. Currently, she is an Agricultural Consultant with the Minnesota Department of Agriculture Dairy and Food Inspection Division. Previously, Valerie spent several years working on organic farms in northern California and with the University of California Agricultural Extension–Davis. In addition to manufacturing and retail food establishment inspection duties, Valerie provides information and educational outreach to local Twin Cities' organizations. Recently, she was appointed the Coordinator for liaisons working with local health agencies under delegation agreements. Valerie has assisted with the Minnesota Retail Food Code Rule revision and, in 2012, was a member of the Minnesota Wild Mushroom Retail Food Code Workgroup. **Mentor: Joe Corby**

Adam Inman received a B.S. in Biology from Kansas State University and, since 2009, has served as the Assistant Program Manager for the Kansas Department of Agriculture (KDA) Food Safety and Lodging program. Early in his career, he was a Food Protection Investigator for the Kansas Department of Health and Environment-Bureau of Consumer Health. Between 2004 and 2006, Adam was the Food Safety Technical Specialist for KDA's Food Safety Program. Prior to his current position, he spent three years as a Case Review Officer with KDA's Pesticide and Fertilizer Program. **Mentor: Joe Corby**

Davonna Koebrick, a graduate of Victoria College (Texas), also earned a B.S. from the University of Texas-Pan American and a M.S.W. at the University of Houston. Currently, she is a Sanitarian II with the Texas Department of State Health Services (TDSHS) Environmental and Consumer Safety Section, Food and Drug Branch, South Group Food Inspections Unit. Davonna serves as a technical resource to inspector and managers as well as web-based maintenance of Inspections Unit project spaces on Traction TeamPage and maintenance of the Procedures Manual. She serves on the Dietary Supplement Task Force and is a Traction TeamPage subject matter expert for the Texas Rapid Response Team. Davonna is a Texas Registered Professional Sanitarian. **Mentor: Jim Sevchik**

Melissa Lombardi earned her B.S. in Biology through the University of North Carolina-Wilmington. She was employed for five years as an Environmental Health Specialist for New Hanover County, Wilmington, North Carolina, and currently serves in the same capacity in Brunswick County, Bolivia, North Carolina. As a general Environmental Health Specialist, Melissa conducts restaurant and other retail food establishment inspections. Additionally, she inspects swimming pools, lodging facilities, hospitals, and childcare facilities. **Mentor: Cameron Smoak**

Allen L. Mozek received a B.S. in Community Health Education from Montclair State College (New Jersey) and a M.P.H. from the University of Medicine and Dentistry of New Jersey-Rutgers Medical School. Currently, he serves as the Supervising Food Inspector for 11 counties from the Rochester Office of the New York State Department of Agriculture and Markets-Division of Food Safety and Inspection. Previously, Allen was employed with Wakefern Food Corporation Quality Assurance in Elizabeth, New Jersey. He also served as Health Administrator, Sanitarian, and Health Educator for the East Hanover Township Health Department in East Hanover, New Jersey. Allen was active in the New York State Pest Control Association, having operated a private pest control company for twelve years and was also a sales associate with Orkin Pest Control. Allen was Chair of the Food Committee for the New York State Association of Food Protection in 2012 and 2013. **Mentor: Jim Sevchik**

Morgan Poloni holds a M.S. in Environmental Science from the University of Idaho. Her food safety career began in Tillamook County, Oregon, where her varied duties included food inspection to investigation of animal bite incidents. Currently, Morgan is an Environmental Health Officer III with the Alaska Department of Environmental Conservation. She is responsible for developing and monitoring audit measures and performance indicators to determine program compliance with established policies, procedures and directives including compliance with the FDA Voluntary National Retail Food Regulatory Program Standards and Manufactured Food Regulatory Program Standards. Morgan is a Registered Environmental Health Specialist. **Mentor: Cameron Smoak**

Sarah Robbin earned her B.S. and M.S. in Botany from Iowa State University. Currently, she is a Lead Registered Environmental Health Specialist with El Paso County Public Health in Colorado Springs, Colorado. She has worked in many of the programs including Food Safety, Onsite Waste Water, Body Art, and Non-Community Ground Water. In 2012, she was promoted to one of the newly created Lead positions. These positions are the point people for certain teams and are partly responsible for specialist training. Sarah is involved with the Foodborne Illness-HACCP and Plan Review teams. She is a Registered Environmental Health Specialist and a member of the National Environmental Health Association. **Mentor: Dan Sowards**

Laura Van Wagenen-Birdsill received her B.S. in Biology and Physics from the University of Colorado. She is the Program Coordinator for Manufactured Foods and Food Recalls at the Colorado Department of Public Health and Environment (CDPHE). Previously, she served two and a half years on the Gulf Coast in Biloxi, Mississippi with the Mississippi State Department of Health and returned to Colorado as a field investigator with CDPHE-Division of Environmental Health and Sustainability. Laura is an integral part of the Manufactured Food Regulatory Program Standards team and a cornerstone of Colorado's Food Defense Program in industry outreach and partnership. She is an active member of the AFDO, the Rocky Mountain Food Safety Committee, and the Western Association of Food and Drug Officials. **Mentor: Steve Steinhoff**

Food Safety Inspection Officers' Awareness of Reduced Oxygen Packaging (ROP) Requirements in Wisconsin

Anthony Anderson
Environmental Health Specialist
Milwaukee Health Department

Abstract
Reduced oxygen packaging (ROP) is the reduction of the amount of oxygen in a package by removing, displacing, or replacing oxygen with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (US FDA, 2013). As the ROP process creates an anaerobic environment, foods in reduced oxygen packages are more susceptible to the growth of both anaerobic pathogenic bacteria such as *Clostridium botulinum* and facultative psychotropic bacteria such as *Listeria monocytogenes*. Food Safety Inspection Officers (FSIO) must understand ROP processes and food code requirements in order to adequately address the associated hazards. This paper examines Wisconsin FSIO awareness of ROP processes in addition to current and proposed food code requirements in relation to ROP. A thirteen-question survey was developed to capture Wisconsin FSIO awareness with ROP practices and code requirements, and to identify opportunities for ROP training. A key finding was that participants were not familiar with proposed code changes in relation to ROP. In addition, many respondents stated more training in ROP would be beneficial.

Background
As more retail food establishment operators utilize specialized processes to maximize production, improve food flavors and extend shelf life, there is an increased need for Food Safety Inspection Officers (FSIOs) to understand these processes and any associated risks (Rodgers, 2002). The national trend of implementing specialized processes is being experienced first-hand by Milwaukee FSIOs, who are discovering on their inspections an increasing number of restaurateurs and chefs who are utilizing or inquiring about complex food processes such as Reduced Oxygen Packaging (ROP). For example, a newly opened Milwaukee restaurant is the second establishment using an ROP process within a one-block radius (Lazarski, 2012).

Two distinct methods of ROP being encountered throughout the U.S. and within some of Wisconsin's retail food establishments are Cook-Chill (CC) and Sous Vide (SV) processes. CC is an ROP procedure of placing a fully cooked hot food item into an impermeable bag and rapidly cooling the food product to a safe cold-holding temperature. SV is an ROP procedure of placing a partially cooked or raw food product into an impermeable bag, removing the oxygen, and cooking and serving or cold-storing until customer service. This paper will explore the familiarity of Wisconsin's Food Safety Inspection Officers (FSIOs) with code requirements as they relate to retail ROP processes including CC and SV.

Wisconsin FSIOs currently enforce food safety regulations under the 2006 Wisconsin Food Code (WFC), which is a modification of the FDA 2001 Model Food Code. This regulatory document has requirements that address controls for *Clostridium botulinum* (*C. botulinum*) during ROP practices. However, the 2006 WFC may be limited regarding ROP in Wisconsin's retail food establishments. The WFC is not based upon the most

current scientifically-based 2009 FDA Model Food Code which, in comparison to previous versions, offers in-depth information on the control of *Listeria monocytogenes* (*L. monocytogenes*) in addition to *C. botulinum* for retail ROP practices. These controls are important because ROP creates an ideal anaerobic growth environment for psychotropic pathogens such as *L. monocytogenes*.

The Food Code is the FSIOs' core reference tool for protecting public health and preventing foodborne illnesses. The Food Code addresses the 5 major risk factors associated with foodborne illnesses as identified by the CDC: food from unsafe sources; inadequate cooking; improper holding temperatures; contaminated equipment; and poor personal hygiene (National Advisory Committee on Microbiological Criteria for Foods, 1998).

In 2010, Wisconsin proposed adopting FDA's 2009 Food Code with modifications. Adoption of an updated regulation will strengthen the ability of Wisconsin FSIOs to protect consumers from foodborne illnesses in addition to strengthening Wisconsin's ROP requirements.

As Wisconsin is operating under a modified 2001 FDA Model Food Code, there is an education and enforcement gap regarding the control of *L. monocytogenes* in ROP. The conversion to a modified 2009 FDA Food Code within the state of Wisconsin will result in the need for increased education and sanitation requirements for retail establishments performing ROP procedures.

Problem Statement

Wisconsin's Department of Agriculture Trade and Consumer Protection and Department of Health Services (DHS) are slated to adopt a food code based on the 2009 FDA Model Food Code, which contains the most current science-based provisions for ROP processes. The 2009 Code contains significant changes related to ROP, yet FSIOs may not be familiar with these provisions. As a result of this potential knowledge gap, FSIOs may not be educating retail food service operators appropriately, nor enforcing the ROP provisions in the current Wisconsin Food Code appropriately.

Research Question

The three primary research questions are:

- What is Wisconsin FSIOs' awareness of ROP?
- What is FSIOs' awareness of Wisconsin's proposed food code requirements in relation to retail ROP?
- What are the training needs for Wisconsin FSIOs in ROP?

Methodology

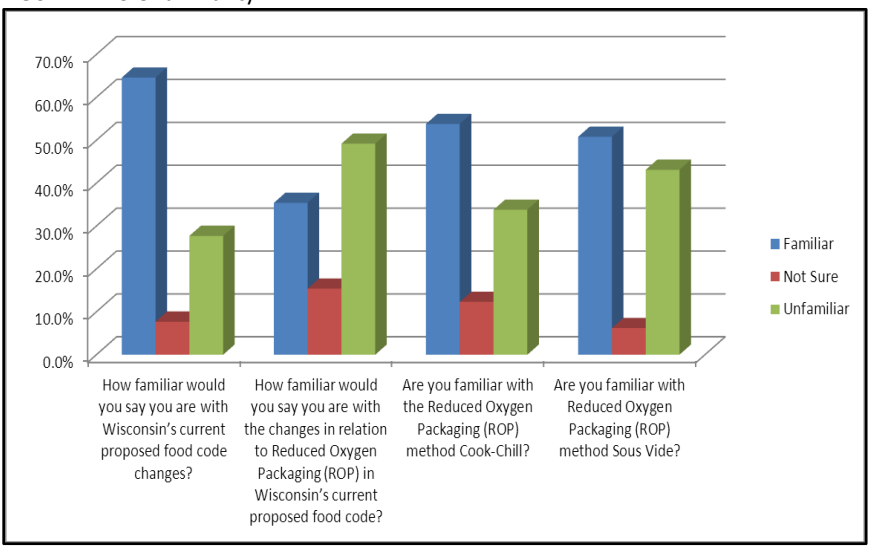
A thirteen-question electronic survey was developed to gather information about Wisconsin FSIO awareness of ROP processes, Wisconsin's current and proposed ROP food code changes, and ROP training needs. The Wisconsin DHS Food Safety Program Manager was asked to forward a survey email invitation to a constituent list of Wisconsin FSIOs. The email included information about the study, an invitation to participate, and the link to the online survey. The survey was also distributed by International Food Protection Training Institute staff to Wisconsin FSIOs using the AFDO Directory of State and Local Officials. A total of 105 potential participants were

solicited. Data for the research project was collected online via Survey Monkey™ and analyzed by the study author.

Results

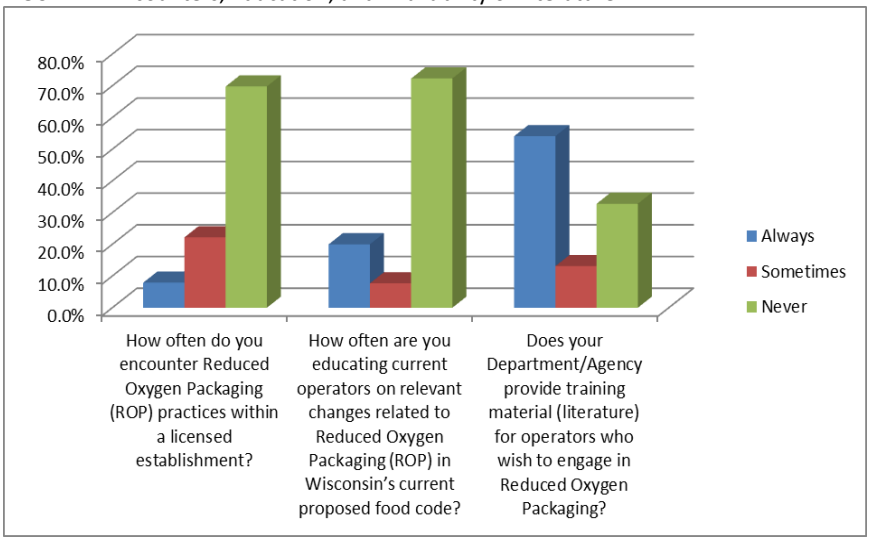
Sixty five participants responded to the survey within a two-week time frame (61.9% response rate). Four questions from the survey were determined to be not formatted correctly and therefore were omitted from results. Forty-five of the respondents (69.2%) were familiar with Wisconsin's proposed Food Code change; however, thirty-two (49.2%) of the respondents were not familiar with changes in relation to ROP. Thirty-five of the respondents (53.8%) were familiar with Cook-Chill, and thirty-three of the respondents (50.7%) were familiar with Sous Vide (Figure 1).

FIGURE 1. FSIO familiarity.



More than two-thirds (67.6%) of the respondents reported never encountering ROP practices within licensed establishments. Similarly, 72.3% of the respondents reported having no experience educating operators on relevant changes related to ROP in Wisconsin's proposed food code. Approximately half (33/65) of the respondents stated their Department/Agencies provide training material (literature) for operators engaged in ROP and that their Department/Agency is familiar with ROP (32/65) (Figure 2). The overwhelming majority (54/65) of the respondents indicated that they would benefit from additional training in ROP.

FIGURE 2. Encounters, Education, and Availability of Literature.



Conclusions

This research assessed Wisconsin FSIOs' awareness of ROP processes, awareness of proposed food code changes, and training needs regarding ROP. From analysis of the data three main conclusions emerged:

1. One-third of FSIOs were unfamiliar with proposed food code changes. Therefore, education and outreach is needed to assure all FSIOs are aware of the ROP changes in the code, specifically in addressing *Listeria monocytogenes* concerns.
2. Experience with ROP is limited. A system must be set up to provide FSIOs opportunities to observe specialized processes and become truly prepared to deal with the processes when encountered in the field.
3. Though FSIOs reported having knowledge of ROP, the vast majority indicated they could benefit from additional training, which indicates that the level of proficiency with ROP is low and training should be made widely available.

Recommendations

Adoption of the 2009 WFC, statewide training and review of the state variance and/or Hazard Analysis & Critical Control Points (HACCP) requirements for ROP may strengthen FSIOs' enforcement and knowledge base. Even though a majority of FSIOs within Wisconsin are familiar with ROP practices, there is still an added benefit to education related to ROP practices. A statewide training session for Wisconsin FSIOs on ROP practices and equipment would aid in addressing ROP practices that are becoming more prevalent in retail food establishments.

Acknowledgments
This educational journey was made possible by the care of International Food Protection Training Institute (IFPTI) and their affiliates, IFPTI support staff and their passion for an integrated food safety system; the leadership of my mentor, Dr. Joanne Brown, support from Angela Hagy (Director of Consumer & Environmental Health, Milwaukee Health Department); and the guidance of Julie Hults (Environmental Health Coordinator, Milwaukee Health Department). I also would like to extend my gratitude to Wisconsin's AHJs and FSIOs for your survey responses and for holding the frontline on food safety daily.

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References

Lazarski, T. (2012, July 11). *First Impressions*. Retrieved from http://www.avclub.com/milwaukee/articles/c-1880,82288/

National Advisory Committee on Microbiological Criteria for Foods. (1998). Hazard Analysis and Critical Control Point Principles and Application Guidelines. *Journal of Food Protection*, pp. 1246-1259.

Rodgers, S. (2002). Survival of Clostridium botulinum in Hot-Fill Meals. *Food Service Technology*, pp. 69-79.

US FDA. (2013, February 28). *FDA Food Code 2009: Chapter 1- Purpose and Definitions*. Retrieved from http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/ucm186464.htm

A Survey of Regulatory Practices Regarding Non-Amenable Species: Slaughter, Processing and Sale for Human Consumption

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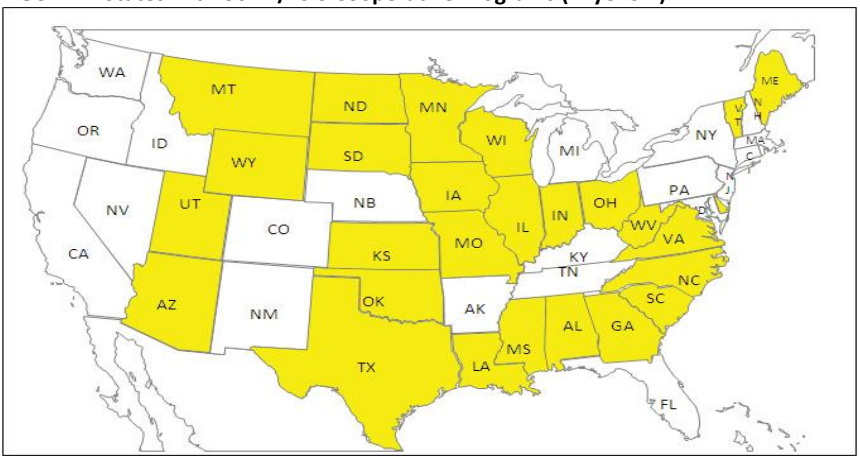
Abstract

This study explores protocols that state government agencies with animal health jurisdiction in the United States are implementing in response to the growth of the game animal industry and the slaughter and processing of non-amenable species of animals (Klein, 2004). The Federal Meat Inspection Act (FMIA) defines the species of animals that must be slaughtered and processed under United States Department of Agriculture Food Safety and Inspection Service (USDA/FSIS) oversight. Animals mentioned under the FMIA are amenable; animals not mentioned are non-amenable (not covered) under the FMIA and these animals are exempt from USDA/FSIS requirements. Non-amenable species may be a vector for agents of public health concern because deficient slaughter and preparation could cause human disease. Demand for food products from non-amenable species has increased pressure on policymakers and regulators to evaluate a range of regulatory options that may not be uniform or that may not effectively address public health concerns. Online survey results suggest that demand for non-amenable species products is a growing concern and more uniform regulatory action is needed to protect public health. A review of literature and analysis of current government policies indicate that inadequate regulatory oversight may be provided for these products intended for human consumption due to inconsistent application of varying regulations amongst the states. Recommendations based on current best practices are presented to provide insight to policymakers in other states.

Background

The United States Department of Agriculture Food Safety and Inspection Service (USDA/FSIS) regulates meat and poultry products in interstate commerce and foreign export under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA). The United States Food and Drug Administration (FDA) regulates food in interstate commerce and has agreements with the states for regulation of food in intrastate commerce. Interstate movement of state-inspected or voluntary FSIS-inspected non-amenable species and products is dictated by FDA and state laws and regulations. The FMIA permits the states to enter into cooperative agreements with the USDA/FSIS, whereby states may impose and enforce mandatory inspection programs equal to that of federal standards; this arrangement limits state-inspected amenable species to intrastate commerce only. There are currently 27 states with state-federal FMIA cooperative agreements according to the FSIS (Figure 1).

FIGURE 1: States with USDA/FSIS Cooperative Programs (in yellow)



(www.alpacameatcouncil.com)

In Virginia, the Office of Meat and Poultry Services (OMPS) within the Virginia Department of Agriculture & Consumer Services (VDACS) ensures the production of safe, wholesome, and truthfully-labeled meat and poultry products, as well as the humane treatment of livestock. OMPS also provides inspection services to individuals and companies that slaughter and/or process meat and poultry products. The USDA/FSIS and OMPS both exempt non-amenable species from the inspection process and offer voluntary inspection for farm-raised game animals. The Agricultural Marketing Act (AMA) of 1946 allows FSIS to inspect non-amenable species under a voluntary inspection program that does not require Hazard Analysis & Critical Control Points (HACCP) or Standard Sanitary Operating Procedures (SSOPs).

The producer must pay for the voluntary inspection, which includes an hourly fee and travel cost associated with this service. Mandatory inspection, however, is funded by tax dollars. When a processor does not produce meat products under FSIS/OMPS voluntary inspection, the processor is subject to FDA inspection under the Food, Drug & Cosmetic Act (FD&C Act). General sanitation inspections of the facilities utilizing 21 CFR 110 (Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food) and the FD&C Act could unintentionally allow an unsafe food product to enter into commerce, since animal health considerations are not prescribed in these rules to the extent they are in the FMIA.

The primary concern regarding game animals according to Annex 3 of the FDA Food Code relates to animals not commercially raised but obtained in the wild. Specifically, wild game animals may be available as a source of food only if a regulatory inspection program is in place to ensure that these animal products are safe for human consumption. This inspection is important because wild animals may be carriers of organisms or parasites that cause human illness. Non-amenable species appear to present health risks similar to those associated with poultry and meat products already subject to mandatory inspection (NACMPI, 1999). In addition to the risk posed to consumers, there is a risk to the people who harvest, process and prepare wild game.

Wild game species that can be legally hunted under federal or state regulatory authority can be harvested for personal consumption; however, they cannot be sold for food in Virginia according to the Virginia Department of Game and Inland Fisheries (VDGIF) even though there is an exception in the VA Retail Food Establishment Regulations administered by VDACS.

Farm-raised game animals must be cleared through VDGIF and if approved, the producer must obtain a permit. However, the species that are farm-raised cannot be native to Virginia. A game animal may not be received for sale or service if the species is listed in 50 CFR Part 17, Endangered and Threatened Wildlife. The PPIA was expanded in 2001 to include rhea, ostrich, and emu because the USDA determined that the food safety hazards are essentially the same as those posed by species already included within the Act.

The 2010 Retail Food Establishment Regulations for the Enforcement of the Virginia Food Laws state that game animals received for sale or service at a retail establishment must either be inspected by VDACS OMPS under their voluntary inspection program or inspected by the Food Safety and Security Program utilizing OMPS laws and/or regulations. Although Food Safety Specialists (FSS) in VDACS have expertise in a wide variety of food processing operations, they do not have expertise in the slaughter of animals.

Addressing the slaughter of animals requires specialized knowledge including the ability to identify zoonotic diseases and concerns relative to both ante-mortem and post-mortem examinations. FSIS regulations require ante-mortem and post-mortem inspections of each animal and daily inspection of the processing facility. FSIS/OMPS inspectors examine each animal before and after slaughter for visible defects that can affect the safety and quality of meat and poultry products. This examination is not the case with FDA regulations, as only the source and sanitary process, not the ante-mortem and post-mortem inspection of the animal itself, must be evaluated.

Anecdotally, there is increasing inquiry in Virginia about the slaughter and processing of non-amenable species of animals for sale to the public. The growing demand for non-amenable species food products has created some concern within VDACS, as there are significant issues in providing sufficient regulatory oversight. Exploring how other regulatory agencies throughout the United States regulate non-amenable species processors could provide policymakers in Virginia and in other states with additional options in regards to modifying regulatory oversight of these types of businesses.

Problem Statement

VDACS is unaware of how other states regulate the slaughter and processing of non-amenable species. This information could be useful to VDACS and other states to help make good regulatory policy decisions about how to ensure public health.

Research Question

How are state programs ensuring food safety and public health with regard to food products derived from non-amenable species?

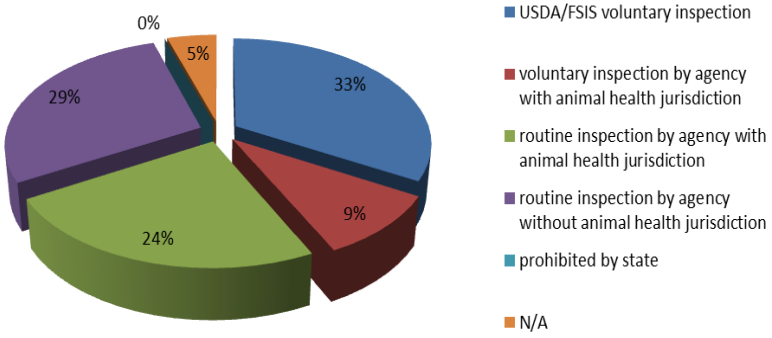
Methodology

This study examined how state agencies with animal health jurisdiction and routine inspection programs are enforcing section 3-201.17 of the FDA Food Code related to the processing and sale of wild game animals and non-amenable species at the retail level and what challenges they are encountering. Program Managers and Directors from regulatory agencies with animal health jurisdiction in all 50 states were identified utilizing the AFDO Directory of State and Local Officials. One key individual from each state, identified as the person most responsible for regulations governing non-amenable species, was contacted via email and invited to participate in an online survey developed through SurveyMonkey®. The fourteen-question multiple-choice survey was written to identify procedures and strategies used by other states to help determine the best course of action for VDACS. The email briefly explained the IFPTI Fellowship Program, the research project and included a link to the online survey. The survey was administered with response anonymity and the states could not be identified by the submissions. Data from the survey was exported from SurveyMonkey® and entered into an Excel spreadsheet. A tabulation of survey results and trends was used to capture the comparative overall application of federal/state oversight relative to the slaughter and processing of non-amenable species. An analysis comparing differences in regulatory approaches was conducted to determine several recommendations.

Results

This analysis is based on 17 responses from 50 state programs surveyed, for a 34% response rate. Thirty-three percent (33%) of respondents indicated inspection of non-amenable species processors was accomplished using USDA/FSIS voluntary inspection and 9% indicated voluntary inspection was performed by the state agency with animal health jurisdiction. Fifty-three percent (53%) of respondents indicated that only routine, sanitary inspection by the state agency with/without animal health jurisdiction is conducted and the remaining 5% indicated this was not applicable to their state program (Figure 2).

FIGURE 2: Programs that Provide Regulatory Oversight for the Slaughter and Processing of Non-Amenable Species



However, 29% of respondents indicated that they attempt to arrange for voluntary inspection of prospective processors through their state's respective meat inspection program, while 53% do not. Eighteen percent (18%) indicated that voluntary inspection does not apply to their state program. Another 41% indicated that the state food safety program is attempting to arrange for inspection of these prospective processors. Fifty-three percent (53%) of respondents indicated that state inspectors do not perform ante- and post-mortem examinations of the animals, and only 6% indicated that a trained veterinarian is present with the inspector during the inspection. Twenty-nine percent (29%) of respondents indicated that a guidance document for the inspector/processor has been developed by the state program with regulatory authority while 53% indicated that a guidance document does not exist. Seventy-one percent (71%) of respondents indicated that there are currently 25 or fewer establishments processing non-amenable species on file in their jurisdiction. Deer, rabbit, elk, bison, buffalo, pheasant and quail were reported as the most commonly slaughtered and processed non-amenable species and some comments from the survey indicated minor interest in processing other types of animals.

Conclusions

The processing and sale of non-amenable species may present unique challenges to state regulatory agencies as survey results indicated varying approaches used by the states represented by the respondents.

The high number of states that rely only on sanitary inspection as their regulatory policy, in addition to the low number of respondents indicating use of veterinarians on inspections, calls for further study of the reasons why the USDA/FSIS approach (voluntary inspection) is not used consistently. The low number of estimated establishments processing non-amenable species (<25 in 71% of responses) could indicate a low potential for exposure for the general U.S. population. However, there is elevated food safety risk for consumers of non-amenable species food products due to the inconsistency of approaches to regulatory oversight. A uniform approach is needed and agencies must collaborate and communicate to ensure public health.

Results indicated that cost has been prohibitive for start-up processors. Construction of new facilities must meet certain minimum requirements and hourly voluntary inspection fees range from $29 for state inspection to $60 for USDA/FSIS inspection. Limited government resources within state programs place the burden on the processor to come under voluntary USDA/FSIS inspection as state regulatory options may not be available.

Recommendations

State agencies need more guidance and studies should be done to determine the most cost-effective approach to this emerging issue of regulatory oversight of non-amenable species. Several recommendations based on the study data are outlined below:

- A risk assessment should be conducted on the consumption of commercially processed non-amenable species.

- Further study should be conducted to identify uniform regulatory approaches and associated costs.

- State agencies should collaborate in a more comprehensive survey of nationwide practices, findings and approaches.

- Processors should be encouraged to participate in a voluntary state inspection program through incentives such as certification and consideration as an approved source that can sell anywhere intrastate (farmer's markets, retailers, restaurants).

- Firms not under voluntary inspection by FSIS or a state-federal cooperative program should be required to meet more stringent requirements such as keeping written, up-to-date Good Manufacturing Practices (GMPs), SSOPs, and HACCP plans including hazard analyses.

- To aid in outbreak investigations, non-amenable species slaughter logs detailing dates and numbers should be required. Processors should also provide, and keep a copy of, an invoice that includes the business name, address, date, identity and quantity of product sold to every customer.

- Processors not under voluntary inspection by OMPS should label their products with a statement indicating that slaughter and processing took place without the benefit of state/federal ante-mortem and post-mortem inspection.

- FSS in VDACS could inspect slaughtering operations using OMPS laws and regulations. This concept could be applied to other states where one state agency is either trained in another agency's expertise or is given shared regulatory authority between agencies.

- FSS in VDACS could be allowed to inspect the post-slaughter portion of non-amenable species processing under current food safety laws and regulations where OMPS provides inspectional assistance relative to the slaughter portion of the operation.

- As an alternative, FSS in VDACS could inspect slaughter and processing operations under current food safety laws and regulations utilizing a comprehensive guidance document developed by OMPS.

- The Association of Food and Drug Officials (AFDO) could assist in promoting guidance for state agencies.

- The guidance document titled "Guidelines for Exempt Slaughter and Processing Operations" developed by AFDO is available for reference to help meet the regulatory needs of various states. These guidelines are intended to provide a national standard for the regulation of slaughter and processing operations not subject to mandatory inspection under federal laws (AFDO, 2011).

Other considerations may include establishing priorities with respect to levels of coverage to determine the most effective use of resources when there are already additional food safety responsibilities that demand attention. Other states are currently considering options similar to those suggested based on public health rationale and relative food safety risks presented by different animal foods.

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References

2 VAC5 Chapter 585. (2010). Retail Food Establishment Regulations for the Enforcement of the Virginia Food Laws. Retrieved from: http://www.vdacs.virginia.gov/fdsafety/pdf/retailfoodregs.pdf

9 CFR Part 301. (1970, October 3). Subchapter A – Mandatory Meat Inspection. Part 301 Definitions. Retrieved from: http://www.gpo.gov/fdsys/pkg/CFR-1998-title9-vol2/pdf/CFR-1998-title9-vol2-part301.pdf

9 CFR Part 321. (1970, October 3). Part 321 Cooperation with States and Territories. Retrieved from: http://www.gpo.gov/fdsys/pkg/CFR-2006-title9-vol2/pdf/CFR-2006-title9-vol2-part321.pdf

9 CFR Part 352. (1985, October 16). Part 352 Exotic Animals and Horses; Voluntary Inspection. Retrieved from: http://www.gpo.gov/fdsys/pkg/CFR-2011-title9-vol2/pdf/CFR-2011-title9-vol2-part352.pdf

Association of Food and Drug Officials. (2011, June). Guidelines for Exempt Slaughter and Processing Operations. Retrieved from: http://www.afdo.org/Default.aspx?pageId=1279485

Federal Meat Inspection Act. (2011, April 28). Retrieved from: http://www.fsis.usda.gov/regulations/federal_meat_inspection_act/index.asp

FIGURE 1: States with USDA/FSIS Cooperative Programs. (2012). Retrieved from: http://alpacameatcouncil.com/resources/

FSIS Directive 5720.2 Revision 3. (2004, November 16). Retrieved from: http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5720-2Rev3.pdf

Klein, Patrice N. (2004, December). Game Meat: A Complex Food Safety and Animal Health Issue. *Food Safety Magazine*. Retrieved from: http://www.foodsafetymagazine.com/magazine-archive1/december-2004january-2005/game-meat-a-complex-food-safety-and-animal-health-issue/

National Advisory Committee on Meat and Poultry Inspection (NACMPI). (2000, May). Mandatory Inspection of Non-Amenable (Exotic) Species. Retrieved from: http://www.fsis.usda.gov/OPPDE/NACMPI/May2000/Amenability.html

National Advisory Committee on Meat and Poultry Inspection (NACMPI). (1999, October). Concept Paper on Extending USDA's Inspection Program to Additional Species. Retrieved from: http://www.fsis.usda.gov/OPPDE/NACMPI/May2000/Concept_Paper_Attch1.html

Poultry Products Inspection Act (PPIA). (2011, May 2). Retrieved from: http://www.fsis.usda.gov/regulations/Poultry_Products_Inspection_Act/index.asp

U.S. Public Health Service. (2009) FDA Food Code 2009: Annex 3, Pages 377, 378. Retrieved from: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/ucm189211.htm

Common Regulatory Critical Violations of Establishments in Florida with Adulterated Food Samples

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Abstract
The Florida Department of Agriculture and Consumer Services (Florida) collects and analyzes approximately 1400 food samples each year. Samples are collected for various reasons including routine surveillance, discretionary sampling, and by contract with the United States Food and Drug Administration (FDA). When samples are found to be adulterated, the processor is notified and follow-up samples are subsequently collected and analyzed. This study was designed to identify trends found in Florida's routine inspections that led to adulterated foods. Florida's inspection data results indicated the lack of food protection to be the leading violative food safety practice cited in inspections of facilities that produced adulterated foods. The data also recognized the presence of pests, inadequate toilet and hand-washing facilities, maintenance of toxins, and plumbing issues as significant contributors.

Background
There is a shift in food regulation to be more prevention-oriented with the enactment of The Food Safety Modernization Act (FSMA). When fully implemented, FSMA will require a written food safety plan to be implemented by food facilities that would include:

1. Evaluating hazards that could affect food safety;
2. Specifying what preventive steps, or controls, will be put in place to significantly minimize or prevent the hazards;
3. Specifying how the facility will monitor these controls;
4. Maintaining routine record of the monitoring; and
5. Specifying what action the facility will take to correct problems that arise.

Furthermore, FDA has established prevention-oriented standards and rules for seafood, juice, and eggs, as has the U.S. Department of Agriculture for meat and poultry, and many in the food industry have pioneered "best practices" for prevention (Hamburg, 2011). This proactive shift in paradigm requires a great deal more foresight by both the regulated and the regulator.

Six state agencies share the responsibility of inspecting food facilities in Florida. Retail establishments, including convenience stores and grocery markets, comprise the bulk of the inspections conducted under the jurisdiction of the Florida Department of Agriculture and Consumer Services' Division of Food Safety. Manufacturers, processors, packers, and warehousing operations make up the remaining inspections.

Food inspection reports typically provide a snapshot of violative food safety practices taking place at the time of the inspection. Food samples are routinely collected as part of the inspection process and analyzed in Florida's food laboratories. The International Standards Organization (ISO) has accredited the Florida Department of Agriculture and Consumer Services food laboratories. ISO accreditation is a recognized independent evaluation of a laboratory's competence to perform to international standards. When laboratory analyses indicate foods are adulterated in Florida, a protocol to remove the product from commerce is initiated in addition to addressing the sources of contamination.

Consumers demand a safe food supply and government is responding by requiring proactive food safety practices. In this prevention-oriented atmosphere, noting violations on inspection reports is no longer an adequate response. Rather, the inspection report and the analyses of the collected samples are verification that the proactive food safety practices are effective.

Government regulators and the regulated industry have a common goal to avoid a possible food safety crisis. If more emphasis can be placed on the cooperative approach to prevention during inspections, a reduction in violative food safety practices may be achieved. Partnering with industry may serve as a platform for collaborative process improvements in food safety as long as the relationship does not compromise the public interest (Sparrow, 2000).

Problem Statement

Compliance strategies are broadly reactive when adulterated food is discovered through laboratory analysis. This study is designed to identify trends found in Florida's routine inspections that preceded the discovery of contamination. By utilizing this trend data, regulators may initiate intervention techniques and outreach efforts in a proactive and collaborative approach with the regulated industry, thereby reducing the factors that are historically shown to lead to contamination.

Research Questions

1. Within Florida, what are the adulterants most frequently detected through laboratory analysis?

2. What are the violations with a critical component most frequently documented during routine inspections prior to a laboratory finding of an adulterated sample?

Methodology

Secondary data analysis was conducted on inspection and laboratory reports for food facilities that, under the regulatory authority of Florida's Division of Food Safety, produced adulterated food samples in 2010 and 2011. Sample data was collected from Florida's Bureau of Food Laboratories and inspectional data was collected from Florida's Division of Food Safety. Incidents of laboratory detection of contamination at a facility were cross-referenced with the three inspection reports for that facility prior to the detection of contamination. Violations noted on inspection reports were analyzed using a spreadsheet computer program to determine if common violations were found.

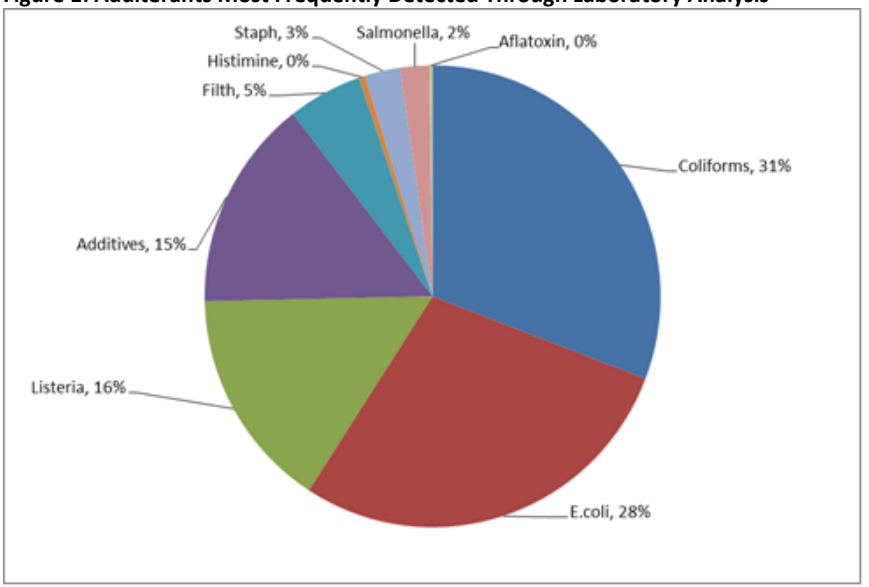
Violations are categorized in Florida as critical and non-critical; only the broad categories of violations that had a critical component were included in the results. For

the purposes of this study, the term "adulterated" is used to describe samples that include either recognized illegal contaminants or indicators of contamination such as the presence of high levels of coliform bacteria or *E. coli*.

Results

In the two-year period studied, Florida's Bureau of Food Laboratories identified 438 samples as adulterated. Multiple samples from the same facility and follow-up samples are treated individually in the results. Laboratory reports indicated unsafe levels of coliforms, including fecal coliforms, were present in 31% of the adulterated samples. *E. coli* and *Listeria* were found in 28% and 16% of the samples, respectively. Undeclared or harmful ingredients were present in 15% of the samples. The remaining 10% of the adulteration was due to filth, staphylococcus, salmonella, histamine formation, and aflatoxin.

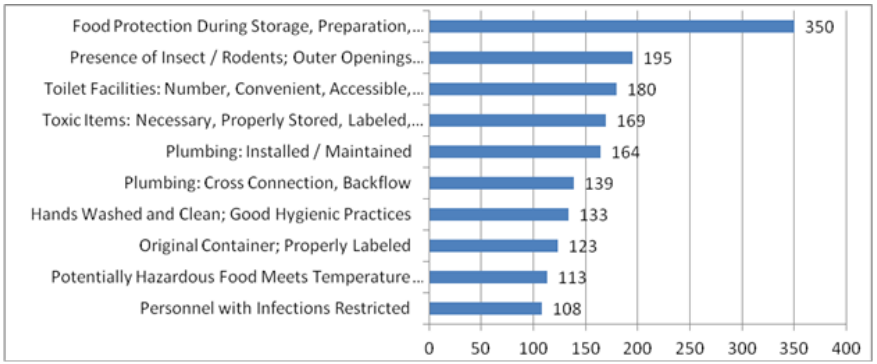
Figure 1: Adulterants Most Frequently Detected Through Laboratory Analysis



Of the 428 adulterated samples, 257 samples were eliminated from this study as the samples were manufacturer-packaged foods. Since the foods were not exposed at this step in the supply chain, the adulteration occurred at a previous distribution step. The remaining 171 adulterated samples were exposed and possibly contaminated while under the control of the inspected facility. For each adulterated sample, the three (3) routine inspection reports that preceded each adulterated sample were analyzed to identify common violations. Five adulterated samples did not have three previous inspections to review, as the facilities were too new to have a history of at least three inspections. Additionally, inspectors cited violations during an unrated industry visit (while delivering lab results) 16 times. An industry visit should not contain violations, but inspections do. These visits were included in the analysis as a fourth inspection of the facility.

Florida's Bureau of Food Safety inspection records indicated the violation Lack of Food Protection was noted in over 67% of the 513 inspections (Figure 2). The data also recognized the presence of pests, inadequate toilet and hand-washing facilities, maintenance of toxins, and plumbing issues as significant contributors. The top ten violations with a critical component cited in the food facilities that processed an adulterated food sample are shown in Figure 2.

FIGURE 2: 2010 and 2011 Top Ten Most Frequently Documented Violations with a Critical Component



The Lack of Food Protection was cited 350 times during the 513 inspections that preceded an adulterated food sample. This violation may be (and occasionally was) cited more than once on each inspection. For example, an inspector may have cited the violation (Lack of Food Protection) in the warehouse and also in the processing room for different commodities or processes.

Conclusions

In the study data, Lack of Food Protection was the violation with a critical component most frequently documented on inspection reports prior to laboratory finding of an adulterated food sample. As such, the documentation of Lack of Food Protection on routine inspection reports may be an indicator of food adulteration in an establishment. The presence of *Listeria* in 16% of the samples is cause for concern since *Listeria* can be a chronic environmental contaminant in exposed food settings – thus placing importance on Lack of Food Protection.

Recommendations

The Lack of Food Protection violation and **all** of the "canned text embellishments" should be critical violations. The eight "canned text embellishments" that can be added by the inspector are:

- Improper and or no date-marking on ready-to-eat food held for more than 24 hours.
- Barriers are not in place to control *C. botulinum* toxin formation when using reduced-oxygen packaging.
- Food is not protected from contamination during preparation.

- Food is not protected from contamination during transportation.
- Food is stored or displayed in a location subject to contamination.
- Food is stored or displayed on the floor.
- Food is stored or displayed on unclean surfaces.
- Food is stored or displayed uncovered and exposed to contamination.

In Florida, critical sanitation violations are required to be addressed immediately. Only the first two "canned text embellishments" are critical sanitation violations: date-marking and controls for reduced-oxygen packaging. The other six embellishments are non-critical violations.

When assigning a performance-based variable inspection frequency, critical violations should be a factor rather than the overall rating, as is the current policy. Food establishments in Florida are subject to a variable inspection frequency based on performance (Florida Administrative Code, 2011). A food establishment may require a higher frequency when deemed necessary or reduced frequency with continual compliance. Together the most vulnerable food facilities will be inspected more frequently.

Florida should then utilize food surveillance sampling data and historical inspections as a tool to identify the factors and behaviors that lead to adulterated food. Relevant and timely data can be a powerful tool that can be shared on a collaborative platform for process improvement.

Inspectors can focus on the Lack of Food Protection during their inspections, which could be considered as a leading risk factor for food contamination in Florida. Food contamination may be averted by more communication during routine inspections, with added emphasis on this risk factor. Intervention strategies, risk-control plans, and other outreach efforts may pioneer a best practice for prevention.

Additional research should be conducted to investigate the relationship between the notation of the top ten most documented violations with a critical component and the laboratory finding of an adulterated sample. If it can be determined that inspection report violations can be predictors of a laboratory finding of an adulterated sample, then inspections could provide a point of intervention for immediate as well as long-term corrective measures to prevent adulteration.

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I would like to express my sincere gratitude to The International Food Protection Training Institute (IFPTI) and Vice President Dr. Craig Kaml for providing such a rich platform through the 2012-2013 Fellowship in Food Protection program with unprecedented access to subject matter experts; my career path will forever be changed. This project could not have been completed without the wise guidance of my mentor Charlene Bruce, Dr. Preston Hicks, and Gerald Wojtala; they were instrumental in honing in on the message. The re-creation of the wheel was often averted with the guidance and open access from Sanitation and Safety Administrator Dr. Myriam Perdomo-Pabon, Environmental Administrator Brenda Morris, and Bureau Chief Dr. John Fruin at The Florida Department of Agriculture and Consumer Services.

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References

FDA Retail Food Steering Committee. (2000, August 10). *Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors.* Retrieved from http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm123544.htm

Florida Administrative Code. (2011, May 19). Chapter 5K-4.020. *Inspection Frequency Based on Risk*.

Hamburg, M. A. (2011, January 6). *Food Safety Modernization Act: Putting the Focus on Prevention*. Retrieved from http://www.crfsc.org/news/22-food-safety-modernization-act-hr-2751

Sparrow, M. K. (2000). *The Regulatory Craft.* Washington, D.C.: Brookings Institution Press.

Food Code Adoption and Food Safety Training within the Bemidji Area Indian Health Service

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Abstract
This paper explores food code adoption and food safety training within the Bemidji Area Indian Health Service (BAIHS). The BAIHS serves 34 federally-recognized tribes in the states of Minnesota, Wisconsin, Michigan, and Indiana. The adoption of the FDA Food Code is not uniform among the tribes in the BAIHS, and no data exists on whether the manager and basic food handler training requirements to achieve active managerial control are being satisfied. A thirteen-question SurveyMonkey® questionnaire was sent via email to each of the 15 Environmental Health Specialists (6 federal employees and 9 tribal employees) who provide services to the 34 tribes in the BAIHS. Each of the 15 Environmental Health Specialists completed the questionnaire for a response rate of 100%. The results indicate 62% of the tribes in the BAIHS do not have a food code adopted at the tribal level based on the FDA Food Code and only 3 tribes have a food code based on the current 2009 FDA Food Code. Certified food protection manager (CFPM) training is required by 38% of the tribes but 85% of the tribes provide CFPM training as best practice. Basic food handler training is required by 26% of the tribes but 79% of the tribes provide basic food handler training as best practice. CFPM training and basic food handler training is a critical component of active managerial control. The survey results identify a significant gap in terms of achieving an integrated food safety system. Priority should be given to adopting or updating the tribal food codes within the BAIHS and to developing a standardized operating procedure to prioritize CFPM and basic food handler training among food service employees.

Background
The Bemidji Area Indian Health Service (BAIHS) serves 34 federally-recognized tribes in the states of Minnesota, Wisconsin, Michigan, and Indiana. Encompassing an area of 5,183 square miles and serving approximately 110,000 American Indians, the BAIHS maintains two district offices: the Minnesota District Office, which serves 11 tribal nations in Minnesota; and the Rhinelander District Office, which serves 23 tribal nations in Wisconsin, Michigan, and Indiana. Each tribe within the BAIHS has two options to receive environmental health services: either directly through the Indian Health Service (IHS) Division of Environmental Health Services (DEHS), or through their own Tribal Environmental Health Specialists. IHS DEHS employs 6 field Environmental Health Specialists to provide services to 23 tribes in the BAIHS. The remaining 11 tribes receive services from their own individual Tribal Environmental Health Specialists.

The U.S. Food and Drug Administration (FDA) publishes the Food Code to serve as a guide for state, local, territorial, and tribal jurisdictions to regulate the retail food service industry. The FDA Food Code is a framework for safeguarding the public health and ensuring food is unadulterated and honestly presented to the consumer. There have been eight Food Codes issued by the FDA since 1993; the 2009 Food Code is the most recent. The FDA Food Code establishes practical, science-based guidance and enforceable provisions for mitigating risk factors known to cause foodborne illness. The

FDA Food Code is neither federal law nor federal regulation and it is not preemptive. Rather, the Food Code represents FDA's best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and safeguarded.

The importance of food safety integration has been discussed for years by the regulatory community and is a major focus point in the Food Safety Modernization Act, which was signed into law by President Obama on January 4, 2011. The FDA identifies partnerships with retail food industry, state, local, and tribal authorities, and other government agencies as fundamentally key to the success of its Retail Food Safety Initiative (FDA, 2011). The Retail Food Safety Initiative is part of the FDA's overall shift in regulatory philosophy: moving away from a reactive approach to a proactive, prevention-based, food safety strategy to reduce foodborne illness (FDA, 2011). After a ten-year study assessing retail food establishment control of five key foodborne illness risk factors (food from unsafe sources, inadequate cooking, improper holding temperatures, contaminated equipment, poor personal hygiene), the FDA identified four action areas to address: 1) Make the presence of certified food protection managers (CFPMs) common practice; 2) Strengthen active managerial control at retail and ensure better compliance; 3) Encourage widespread, uniform, and complete adoption of the FDA Food Code; and 4) Create an enhanced local regulatory environment for retail food operations (FDA, 2011).

The 2009 FDA Food Code defines active managerial control as the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors. A prominent element of active managerial control is manager and employee food safety training. The ten-year study conducted by the FDA concluded that having a CFPM has a positive impact on food safety and should become common industry practice (FDA, 2011). Moreover, in 2010 the Conference for Food Protection (CFP) sent a request to the FDA to modify the Food Code to require that at least one "Person in Charge" in each food establishment be certified according to a CFP recognized program (CFP, 2010). The CFP request was based on a study published in the Journal of Food Protection that suggests the presence of a CFPM, defined as managers who received a certificate upon completion of a food safety training course, was the major distinguishing factor between restaurants in which foodborne illness occurred and restaurants in which foodborne illness outbreaks did not occur (Hedberg, 2006).

Federally recognized tribes are sovereign nations and are not subject to federal, state, or local laws. Tribal sovereignty allows each tribal nation to adopt and enforce their own laws, including those regarding food safety. Each tribal nation has the same authority as any state, territory, or local agency to adopt the FDA Food Code.

Problem Statement

The adoption of the FDA Food Code is not uniform among the tribes in the Bemidji Area Indian Health Service, and no data exists on whether the manager training and basic food handler training requirements to achieve active managerial control are being satisfied.

Research Questions

1. What is the current level of FDA Food Code adoption among the tribes in the Bemidji Area Indian Health Service?

2. What type of training is required for tribal food managers and food handlers in the Bemidji Area Indian Health Service?

3. What type of training is provided to tribal food managers and food handlers in the Bemidji Area Indian Health Service?

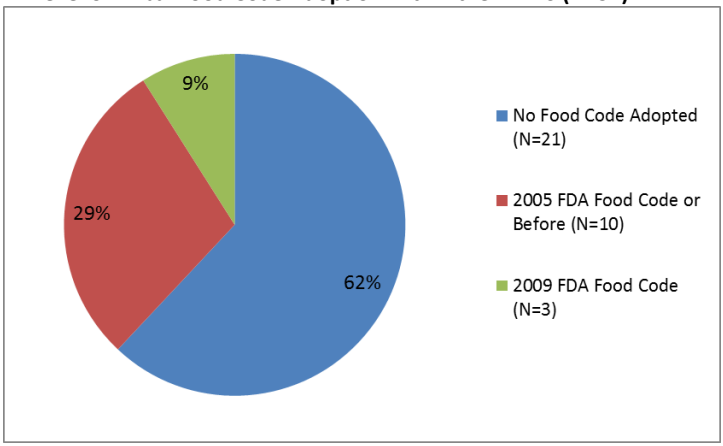
Methodology

A thirteen-question electronic questionnaire was sent via email to each of the 15 IHS DEHS and Tribal Environmental Health Specialists who provide field services for the 34 tribes in the BAIHS. The email contained a two-paragraph explanation and overview of the project and an embedded link to a SurveyMonkey® questionnaire. The questions asked about the level of FDA Food Code adoption for each tribe and what food manager and food handler training is required and/or provided by each tribe. The responses for level of FDA Food Code adoption were tiered into three groups: 1) 2009 edition adopted; 2) 2005 or earlier edition adopted; and 3) no food code adopted. Environmental Health Specialists who serve more than one tribe were asked to complete the questionnaire for each tribe with which he/she works. Participants were given a two-week timeframe to complete the questionnaire. Those participants who did not complete the questionnaire were encouraged to do so with a follow-up phone call. The questionnaire was completed by each of the 15 Environmental Health Specialists for a response rate of 100%.

Results

The results indicate 62% of tribes in the BAIHS do not have a tribal food code adopted based on the FDA Food Code. Of the 13 tribes with a food code adopted at the tribal level, only 3 are based on the most current 2009 FDA version (Figure 1).

FIGURE 1: Level of Tribal Food Code Adoption within the BAIHS (N=34)

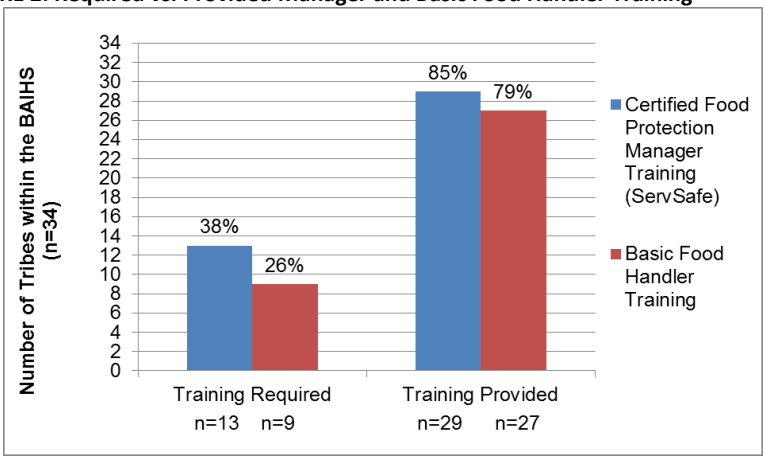


Although CFPM training is required by 38% of the tribes, 85% of the tribes provide CFPM training to their managers as a best practice. All four American National Standards Institute (ANSI)-accredited CFPM trainings were listed in the questionnaire; all respondents selected ServSafe® as the only CFPM program offered. A similar

breakdown is seen for basic food handler training for food service employees; 26% require basic food handler training while 79% provide it (Figure 2).

Five tribes do not provide CFPM training to their managers, four of which are served by a Tribal Environmental Health Specialist. Seven tribes do not provide basic food handler training to food services employees, four of which are served by an IHS DEHS employee. A total of 3 tribes in the BAIHS do not provide any food handler training to managers or food service employees.

FIGURE 2: Required vs. Provided Manager and Basic Food Handler Training



Conclusions

Uniform adoption of the FDA Food Code is a critical component of achieving an integrated food safety system and active managerial control in a food establishment. Having more than half the tribes in the BAIHS without an adopted food code based on the FDA Food Code is problematic because tribal facilities are allowed to operate without rules or regulations, and there is a subsequent lack of accountability. Moreover, 77% of the tribes with an adopted food code have adopted codes that are not based on the most current (2009) FDA version, which contains recommendations based on the most up-to-date science.

Certified food protection manager and basic food handler training is a critical component of active managerial control. The survey results indicate a gap between tribal regulations and food safety training. Although the percentage of tribes that voluntarily provide both CFPM training to their managers and basic food handler training to their food service employees, respectively, is high, 15% of the tribes are not receiving CFPM training and 21% are not receiving any type of basic food handler training. There are 3 tribes in the BAIHS not receiving any type of food safety training. These numbers identify a significant gap in terms of achieving an integrated food safety system.

The level and type of training differs between tribes that receive their environmental health services from IHS DEHS employees versus Tribal Environmental Health Specialists. Four of the five tribes not providing CFPM training to their food service managers

receive their environmental health services from Tribal Environmental Health Specialists. This disparity could be due to a lack of resources for someone to become a certified instructor and proctor for an ANSI-accredited course such as ServSafe®. Four of the seven tribes not providing basic food handler training to their food service employees receive their environmental health services from IHS DEHS employees. This disparity could be explained by the fact that IHS DEHS employees serve multiple tribes over a large geographical region, whereas Tribal Environmental Health Specialists only serve one tribe.

Recommendations

Priority should be given to adopting or updating the tribal food codes within the BAIHS. The adoption and enforcement of a tribal food code based on the FDA Food Code will put added emphases on active managerial control and subsequently the training required to achieve active managerial control, especially as active managerial control is given more emphasis in upcoming versions of the FDA Food Code. The tribes should also be encouraged to ensure the tribal food codes automatically update when a new version of the FDA Food Code is issued. This approach will ensure the tribal food code is based on the most current and up-to-date science.

All tribal food service employees should be receiving the same type and quality of training throughout the BAIHS. Since a majority of the tribes not providing CFPM training to their food service managers are served by Tribal Environmental Health Specialists, IHS DEHS employees can assist them with building their capacity to provide CFPM training such as ServSafe®. IHS DEHS employees, who are all ServSafe® Instructor and Proctor certified, can help Tribal Environmental Health Specialists to become ServSafe® certified instructors and proctors. This approach would allow food service managers to be trained onsite, reducing the cost associated with course and instructor fees for off-site training.

Since IHS DEHS employees are responsible for providing environmental health services to several tribes over a large geographical area, time is a valuable resource and time spent on training should be as efficient as possible. ServSafe® consumes valuable employee time teaching and preparing for the course. The BAIHS can establish a standard operating procedure (SOP) to improve the efficacy of CFPM and basic food handler training provided to tribes. The SOP would prioritize which employees should receive which type of training to improve efficiency. Since ServSafe® is designed for food service "managers," the SOP would recommend ServSafe® be offered only to managers, sous chefs, shift leaders, and other people in charge identified by management. All other food service employees would receive basic food handler training. This strategy would reduce the amount of time spent preparing and teaching ServSafe® to food service employees who do not need manager-level training.

A standardized training module and assessment tool could be developed for the basic food handler course, which would ensure all food handlers in the BAIHS receive the same level of training. The training module and SOP would be distributed to all 15 IHS DEHS employees and Tribal Environmental Health Specialists serving the 34 tribes in the BAIHS to help achieve food safety integration. The BAIHS should also consider developing an online food handler course to alleviate the burden placed on staff to provide basic food handler trainings over a large geographical region. An online course

may increase the number of food handlers trained by making the training more convenient for tribal employees.

The basic food handler training would be developed by Registered Environmental Health Specialists and would be based on the latest science and information from the FDA and Centers for Disease Control and Prevention. Subsequent research can evaluate the effectiveness of basic food handler training.

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References
Conference for Food Protection. (2010) Issue Form II-021. Retrieved From: http://www.foodprotect.org/biennial-meeting/issues/2010Packet/issues/II_021.html

Hedberg C, Smith J, Kirkland E, Radke V, Jones T, et al. (2006). Systematic Evaluations to Identify Differences Between Outbreak and Nonoutbreak Restaurants. Journal of Food Protection, 69(11), 2697-2702.

U.S. Food and Drug Administration. (2009). FDA Model Food Code. Retrieved From: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/

U.S. Food and Drug Administration. (2011). Retail Food Safety Initiative Action Plan. Retrieved From: http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/UCM272982.pdf

Attitudes on Imported Food Regulation in Minnesota's West African Communities

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Abstract
A mixed method study was conducted to explore attitudes and behaviors of West African food business owner-operators in Minnesota regarding the inspection of illegally imported foods. Minnesota Department of Agriculture regulatory data collected from January 2007 until June 2012 documented enforcement action taken against imported West African foods, specifically smoked, uneviscerated fish that is currently illegal in the United States. A focus group conducted in October of 2012 with six West African food business owner-operators highlighted smoked uneviscerated fish as the most desired yet most difficult to obtain African food product in Minnesota. The discussion indicated that the smoked uneviscerated fish is easily obtained elsewhere in the United States despite the fact that it is illegal to import and sell, pointing to unequal enforcement of regulations from state to state. The focus group also indicated that individuals were willingly procuring and commercializing illegal imported foods that pose a public health threat, causing tension between food handlers and regulatory inspectors.

Background
Food is imported from more than 150 countries and territories into the United States. These imported food products constitute 10-15% of the U.S. food supply (Office of Global Regulatory Operations and Policy, 2011). The amount of imported foods is increasing in the United States as a result of increased diversity in the population and overall demand (Brooks, Buzby & Regmi, 2009). During the last ten years in the state of New York, 71% of food recalls were associated with imported food products (Montalbano, 2011).

The United States Food and Drug Administration (FDA) electronically reviews imported food entering 329 ports of entry, targeting approximately 1-2% of items with associated higher risk for physical examination (Elder, 2010). In 2011 the FDA documented 10,439,236 food imports and physically examined 243,400 of those imports (FDA, 2012). The gap between food import volume and number of inspections conducted by the FDA poses a threat to public health (Government Accountability Office, 2009). Indeed, inspection of imported food may be one of the most visible flaws in the United States food safety system.

Fishery and seafood products in particular can be problematic as 80% of seafood consumed in the United States is imported. During 1998 and 2004, fishery and seafood products had the second highest number of import refusals due to adulteration or misbranding, with 11,016 shipments out of 49,448 total shipments refused. Seafood products also had the highest number of total pathogen adulteration violations recorded compared to other food categories, at 53% (Buzby, Unnevehr & Roberts, 2008). The new authorities granted to the FDA under the Food Safety Modernization Act (FSMA) address the larger problem of illegal imported food entering the United

States (FDA, 2013). However, the sections of FSMA covering imports will take time to implement and the challenges facing regulators today still need to be addressed.

Imported food is in demand by the general population and especially by growing immigrant communities in the United States (Brooks, Buzby & Regmi, 2009). Minnesota has well-established immigrant populations including groups from Asia, Latin America, and more recently, Africa (Owen, 2010). Minnesota is a designated U.S. refugee resettlement area and is currently home to both the largest Somali and Liberian communities in the United States (Fennelly, 2012). African immigrants, approximately 76,335 people, are now the third largest group in Minnesota behind those of Asian and Latin American origins (Migration Policy Institute, 2012). The percentage of ethnic businesses, including food facilities, is increasing in Minnesota, with over 31,000 ethnic firms in 2007, a 43% increase from 2002 (Corrie, 2007).

As the African immigrant population in Minnesota increases, anecdotal evidence from food regulatory agency observations suggests an increase in the commercialization of African food products. The majority of African ethnic foods in Minnesota is not imported directly into the state, but is shipped interstate. These products include imported traditional West African food such as smoked fish that is often processed and marketed uneviscerated. There is strong demand in the West African community for this product, even though the sale of uneviscerated fish is illegal in the United States. Routine inspections of both retail and wholesale West African food business owner-operators indicate that an underground commercial market exists in Minnesota, as shown by the owner-operators obtaining, handling, and distributing illegal and potentially dangerous imported food products including uneviscerated, smoked fish. According to Section 540.650 of the FDA Compliance Policy Guide, smoked, uneviscerated fish is dangerous and is an adulterated food due to the potential for botulism toxin development in the viscera of the fish.

The botulism risk makes the smoked, uneviscerated fish a prime target for regulatory action. A challenge facing Minnesota regulators with this fish and other imported foods is the determination of product source. Many African imports come with minimal records or chain-of-custody paperwork and often products are brought to Minnesota without any identifying information on the shipping boxes or packaging. The current system of downstream control for food regulation in the United States relies on the previous supplier being inspected and regulated to ensure continuous food safety. Without documentation or source information, products are assumed to be suspect and potentially adulterated. Any suspect foods encountered are investigated and subsequently voluntarily discarded, embargoed and sampled, or destroyed on site following condemnation.

Clandestine sale of illegal food products is difficult for Minnesota regulatory agencies to address with traditional inspection resources because of challenges associated with community perception of regulatory action. Minnesota inspectors enter West African food firms and often encounter new products, unlabeled products, and very different food handling practices. While West African food business owner-operators understand the law in Minnesota, they may not understand why certain foods are considered dangerous. Compliance actions such as embargos, condemnations and recalls take more time to complete than regular inspection activities due to additional required documentation, product disposal and repeat visits to facilities. The additional time

demand created by these compliance actions potentially limits the number of inspections and routine checks accomplished.

Regulatory actions alone are not preventing the availability of products such as smoked, uneviscerated fish. Community engagement has the potential to encourage self-regulation in the recent African immigrant communities and allow for education of both regulators and African business owners. The New York State Department of Agriculture and Markets has had success with community engagement and education for immigrant populations in the past, as demonstrated by outreach coordinated with the Cornell University Department of Food Science for the Chinese and Russian food business communities in New York City. This effort resulted in an improved awareness of illegal imported foods, the responsibilities of food businesses, and steps businesses could take to protect themselves from liability for possessing illegal imported food products (J. Corby, personal communication, 2012).

Problem Statement

Conventional inspection and enforcement practices with Minnesota's West African food business owner-operators selling illegal imported foods may not be an optimally effective regulatory approach to public health protection.

Research Questions

1. What is the nature of regulatory action taken in Minnesota on African food products from June 2007 to June 2012?

2. What is the demand for illegal imported food products in Minnesota's West African community?

3. How can training, education, and community engagement of West African food business owner-operators by regulators impact the demand for illegal importation of food products?

Methodology

To explore attitudes and behaviors of West African food business owner-operators in Minnesota regarding illegally imported foods, relevant documents were reviewed, and a focus group was conducted.

Tracking data from the Minnesota Department of Agriculture documenting inspections, surveillance, and sampling were used to answer the first research question regarding the nature of regulatory action taken in Minnesota on African food products from June 2007 to June 2012. These data were used to determine, through a primary analysis, the number of regulatory actions taken on food from unapproved sources, including imported food items. The data were organized using Microsoft Excel by type of action taken: Product Embargo, Condemnation, or Voluntary Removal. Thirteen categories were developed for classifying the reasons for action taken (including the presence of adulterated, smoked, uneviscerated fish). The voluntary removal data was not included in the final analysis due to the size of the dataset.

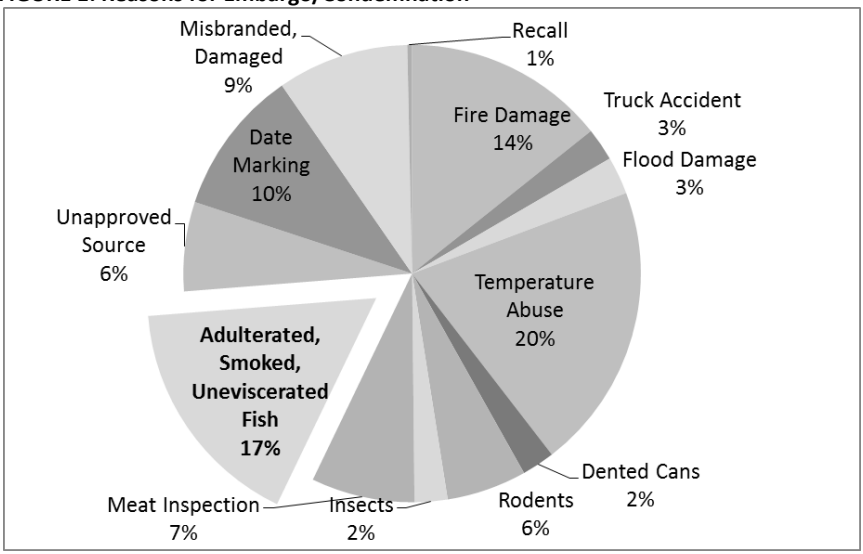
A focus group was conducted to answer the second research question regarding the demand for illegal imported food products in Minnesota's West African community. A single category design focus group with one target audience was conducted with an assistant moderator on October 27, 2012 at Brooklyn Park City Hall with six West African

food business owner-operators from Coon Rapids, Brooklyn Park, and Brooklyn Center, Minnesota. Data were collected with written notes and a short participant check occurred at the end of the focus group. A debriefing with the assistant moderator was also conducted immediately following the discussion to confirm themes and ideas presented by the participants. The focus group data were analyzed for general content and trends using factors such as the frequency of mentioning each topic, the specificity of the discussion on different topics, emotional expression, and the extensiveness or depth of the discussion (Krueger & Casey, 2000).

Results

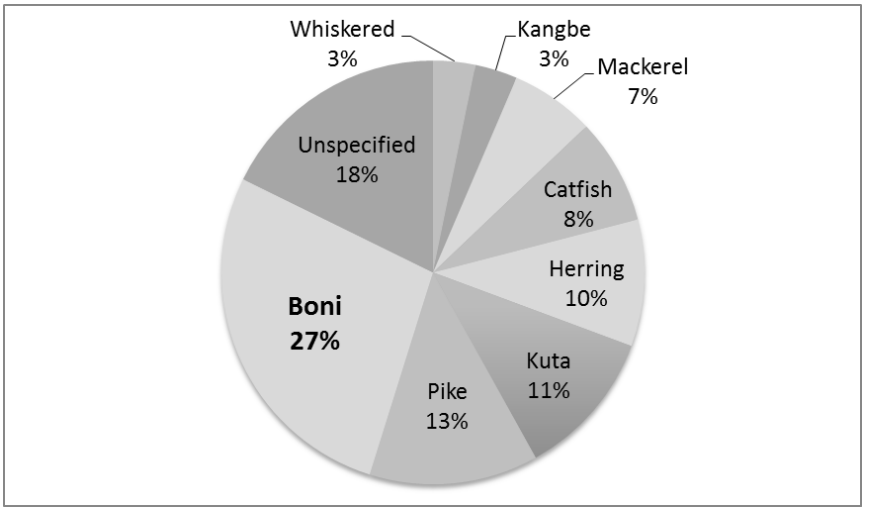
Inspection tracking data collected by the Minnesota Department of Agriculture from January 2007 to June 2012 indicate that the second most common reason for embargoing or condemning food, at 17% of the total number of actions taken, was the presence of adulterated, smoked, uneviscerated fish (Figure 1).

FIGURE 1: Reasons for Embargo/Condemnation



From 2007 to 2012, 93% (64 products) of embargos and condemnations placed on products from unapproved sources involved imported food items considered potentially adulterated because of unknown storage and handling conditions. Of the 64 imports, 78% were different types of adulterated, smoked, uneviscerated fish. Regulatory action was taken on smoked, uneviscerated fish 62 times, with the most common fish being Boni and the least common being Whiskered and Kangbe (Figure 2).

FIGURE 2: Different Types of Smoked, Uneviscerated Fish by Percentage



Sixty-three of the 64 imports were from either African food establishments or Asian stores selling African food products, and the amount of product onsite ranged from 1 pound to 1880 pounds.

Emerging from the focus group were four major themes:

1. There is a high demand for smoked, uneviscerated fish despite its illegal status in the United States.

2. West African food business owner-operators in Minnesota identified significant non-uniformity in regulatory practices and enforcement in the United States.

3. West African food business owner-operators hold beliefs that differ from those suggested by food safety regulations about the safety and handling of smoked, uneviscerated fish.

4. Minnesota's West African food business owner-operators would be receptive to education and training outreach as part of a solution.

Regarding the first theme, all participants stated that smoked, uneviscerated fish was the product they wanted that was difficult to obtain in Minnesota. Multiple fish types were mentioned during the focus group including Boni, Kangbe and Kuta. With respect to the second theme, the participants strongly believed that Minnesota is enforcing food safety regulations differently from the rest of the country, especially with regard to smoked, uneviscerated fish. Focus group participants expressed frustration multiple times that the fish sold and purchased illegally in Minnesota is easily obtained in stores and wholesale establishments elsewhere in the country. This enforcement in Minnesota was seen as a barrier to the community getting the food that they want and have been eating for many decades. The problem, as one person stated, was not that uneviscerated fish is not getting into the United States; the problem is buying and selling the fish in Minnesota. With regard to the third theme, the participants were not concerned about the safety of the smoked, uneviscerated fish. Rather, they felt that the

product was perfectly safe and had been eaten for hundreds of years the same way smoked, uneviscerated fish is prepared today. One participant explained that the fish were boiled for at least fifteen minutes in stews and soups, often for several hours, and then either eaten in the soup or taken out.

Regarding the fourth theme, the participants were interested in the concept of educational outreach but would like regulators to learn more about traditional West African foods. They did not think that training for community members in general would be helpful because the community wants the fish, whether obtained illegally or legally. The comments were very passionate regarding United States food law, and once this sentiment was stated everyone in the room appeared to agree with the idea that regulation was unfair for African food products. They suggested that inequity was due to lack of understanding of the food products, how they are prepared, and where they come from.

Conclusions

The tracking data indicated that sale of imported smoked, uneviscerated fish is a significant regulatory issue in Minnesota. The focus group data indicated that West African food business owner-operators in Minnesota are aware of state and federal regulations governing imported food sources, but the demand for traditional, familiar food products encourages commercialization of illegal imports. The data also indicated that there is a perception of non-uniformity between states in regulation of illegal imported foods. In addition, traditional embargo and condemnation-oriented regulatory actions do not appear to limit the sales of imported foods from unapproved sources or illegal foods such as smoked, uneviscerated fish.

Recommendations

The prevalence of smoked, uneviscerated fish in Minnesota, and the United States in general, suggests a need for action. The implementation of the import rule developed following the passage of FSMA will address illegal imports entering the United States. However, even with new regulation, the FDA will not be able to physically inspect all imported foods. The import and inspection gap, combined with the desire for traditional foods, will allow some illegal imported foods into the U.S. and Minnesota, continuing the current problem of the commercialization of illegal food products. The FDA and state and local agencies must identify intervention strategies to effectively halt the underground traffic of uneviscerated fish using the proposed import rules and subsequent regulation.

The perceived lack of uniformity in addressing imported food products among state regulatory agencies should also be investigated and addressed. Greater collaboration and communication between states (domestic inspections) and FDA (import operations) could potentially remove illegal imported food from the market. More specifically with regard to the smoked, uneviscerated fish, providing training and factsheets on the FDA Compliance Policy Guide Sec. 540.650 could be helpful in increasing national awareness. Local and national community engagement through joint development of educational programs, training and outreach activities utilizing existing organizations may be an effective way to address the regulatory challenges because the local organizations already have the trust of and connections with the community (Egerstrom, 2011).

Without the engagement of the West African community, conventional regulatory activity will continue to be an ineffective way of controlling the sale and consumption of illegal imported smoked, uneviscerated fish. Additional focus groups in Minnesota and at the national level should be conducted to build on the findings presented here and continue building a base for community engagement. Community engagement and education can be a major component of intervention and future regulation strategies to decrease or eliminate the underground market for illegal imported food products including smoked, uneviscerated fish.

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References

Brooks, N., Buzby, J.C., & Regmi, A. (2009). Globalization and Evolving Preferences Drive U.S. Food Import Growth. Journal of Food Distribution Research, 40(1), 39.

Buzby, J. C., Unnevehr, L. J., & Roberts, D. (2008) Food Safety and Imports: An Analysis of FDA-Food Related Import Refusal Reports. Economic Information Bulletin Number 39.

Corrie, B. (2007). Latest Data on Minority Firms in Minnesota. Retrieved from http://www.ethniccapital.com/uploads/1/2/2/9/12297431/latest_data_on_minority_firms_in_minnesota_2007.pdf.

Egerstrom, L. (2011). Made in Minnesota 2011: Fertile Ground for Minority Opportunity. Minnesota 2020. Retrieved from http://www.mn2020.org/assets/uploads/article/Fertile_Ground_web.pdf.

Elder, D. (2010). Ensuring the Safety of Imported Products. Retrieved from http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM229925.pdf.

Fennelly, K. (2012). Minnesota Summary Report. Midwest Coalition on Immigration and the Region's Future: Data compiled by Katherine Fennelly and Graduate Students at the University of Minnesota. Retrieved from http://immigrationtaskforce.hhh.umn.edu/Minnesota.

Krueger, R.A. and Casey, M.A. (2000). Focus Groups 3rd Edition: A Practical Guide for Applied Research. Thousand Oaks, CA: Sage Publications Inc.

Migration Policy Institute. (2012). Minnesota: Social and Demographic Characteristics. MPI Data Hub: Migration Facts, Stats, and Maps. Retrieved from http://www.migrationinformation.org/datahub/acscensus.cfm#.

Montalbano, A. (2011). Targeted Enforcement Surveillance of Imported Foods in New York State. Journal of the Association of Food and Drug Officials, 71(1), 62-69.

Office of Global Regulatory Operations and Policy (2011). U.S. Food and Drug Administration Special Report, Pathway to Global Product Safety and Quality. Retrieved from http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobal RegulatoryOperationsandPolicy/GlobalProductPathway/default.htm.

Owen, G. (2010). A New Age of Immigrants: Making Immigration Work for Minnesota. Summary of Key Findings, August 2010. The Minneapolis Foundation. Retrieved from http://www.mncompass.org/_pdfs/Immigration_Report_Summary_web.pdf

U.S. Food and Drug Administration. (2012). Annual Report to Congress on Food Facilities, Food Imports, and FDA Foreign Offices Provisions of the FDA Food Safety and Modernization Act. Retrieved from http://www.fda.gov/Food/

FoodSafety/FSMA/ucm315486.htm.

U.S. Food and Drug Administration. (2013). Making Certain Imported Foods Meet U.S. Standards under FDA Food Safety Modernization Act. Retrieved from http://www.fda.gov/Food/FoodSafety/FSMA/ucm257980.htm

U.S. Government Accountability Office. (2009). Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food. GAO-09-873.

Kansas Legislators' Opinions about Food Safety Regulation of Hunger Relief Organizations

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Abstract
There are many organizations and individuals in the United States dedicated to addressing the concern of food insecurity. The volume and complexity of food handled by hunger relief organizations and individuals presents a risk to public health. The regulation of these organizations is an important component of maintaining food safety. This study explored the opinions of Kansas State Legislators from the Agriculture and Health and Human Services Committees about food safety regulation of food donations. A survey of these legislators was administered and analyzed. Although legislators expressed concern about food safety, the respondents did not seem to be aware of the potential health risks associated with food handling practices of hunger relief organizations.

Background
An estimated 50.1 million people in the United States, including 16.7 million children, suffer from *food insecurity*, i.e., not enough access to food and/or nutrition. In 2011, 14.9 percent of U.S. households experienced food insecurity during part of the year (Coleman-Jensen, Nord, Andrews, & Carlson, 2012).

There are many hunger relief organizations in the United States that are supported by tens of thousands of volunteers annually. For example, one hunger relief organization, the Society of St. Andrew, reported 30,779 volunteers in 2011 (Gross & Hickock, 2011). In addition, efforts to alleviate food insecurity are taken up by many other volunteers who operate independently of any formal organization. Hunger relief organizations receive food donations from all parts of the food supply system including food processors, food distributors, food retailers, restaurants, and private citizens.

Another example of a hunger relief organization is Feeding America, a national charity with 202 member regional food banks. These food banks distribute food to thousands of agencies that provide food to the food insecure. In 2010, Feeding America served 37 million people annually and 5.7 million people in any given week (Mabli, Cohen, Potter, & Zhao, 2010).

In 2011, 14.5% of Kansas households experienced food insecurity during part of the year (Coleman-Jenson et al., 2012). Kansas has a variety of hunger relief organizations ranging from warehouses to operations that provide groceries or serve meals directly to the recipient.

Hunger relief organizations face the same food safety challenges as any other component of the food system. However, there may be additional steps in the supply chain that add risk. For example, some organizations accept donations of leftover food from restaurants, caterers, food processors, and even private citizens. Many people do not understand the food safety risks associated with food preparation. Cody and Hogue (2003) found that consumers generally do not associate foodborne illness with home preparation. However, according to Redmond and Griffith (2003), foods consumed at home contributed to approximately 87% of reported foodborne outbreaks, and restaurants and other group dining facilities contributed approximately 28%. Consumers may prepare food in their homes and donate the food to hunger relief organizations.

Understanding the risks to the food donation segment of the food system is complicated by a lack of data. Only a small proportion of foodborne illnesses are diagnosed and reported (Scallan, et al., 2011). The U.S. Centers for Disease Control and Prevention (CDC) collects information about gastrointestinal illnesses in the National Outbreak Reporting System using form CDC 52.13. This CDC form does not does not include hunger relief organizations as potential locations of exposure, which limits the usefulness of the CDC's Foodborne Outbreak Online Database to determine the numbers of foodborne illnesses associated with hunger relief organizations.

While there have been no reports of a foodborne illness outbreak associated with a hunger relief organization in Kansas, nationally there were at least two such outbreaks reported in the media in the past three years. In October 2010, 26 people were diagnosed with food poisoning after eating at the Chattanooga, Tennessee Community Kitchen (Staff, 2010), and in July 2012, about 60 people were hospitalized with a suspected foodborne illness after eating at a Denver rescue mission. Many of the victims were believed to be homeless, leaving them to deal with their illnesses in the alleys and streets of the city (Denver Post, 2012).

Multiple factors influence the enforcement of food safety regulations in hunger relief organizations, including public opinion. An example of the effect of public opinion is a case involving two hunger relief organizations in Kansas. The first hunger relief organization (Organization A) serves, on average, 183.5 meals daily to food insecure people including families, the homeless, the physically or mentally disabled, and low-income individuals. Meals are prepared in private residences and brought to the service location. In 2003, another hunger relief organization (Organization B) complained that, unlike Organization B, Organization A did not have a food safety license and did not receive food safety inspections. In response to the complaint, the Kansas Department of Health and Environment (KDHE) inspected Organization A. The inspection cited food from unapproved sources, specifically food prepared in private homes. The inspection report was met with strong resistance from the public and KDHE "quickly reversed course" according to the media (Lawrence Journal World, 2003). This incident also highlighted inconsistencies in licensing and inspection of hunger relief organizations.

Another factor influencing the enforcement of food safety regulations in hunger relief organizations is legislative activity. In 2008, legislation modified the Kansas Food Service and Lodging Act to exempt from food safety licensure food service establishments that are operated to raise funds for certain organizations or purposes, including humanitarian purposes. One effect of the change was that fundraising activities involving food service to support soup kitchens and food pantries would not require a food safety license. However, soup kitchens and food pantries would still be required to have a food safety license. In other words, the soup kitchen would be licensed and inspected, but the "chili feed" held to raise funds to support the soup kitchen would not.

In 2012, based on perceptions of public, media, and legislative opinions, and in response to the 2008 law change, the Kansas Department of Agriculture (KDA) created a statutory exemption from food safety licensure for hunger relief organizations, defined as "organizations that offer, without charge, food to the food insecure." The exemption from food safety licensing effectively ended food safety inspections of these operations. However, hunger relief organizations that provide food for further distribution are still required to have a food safety license.

Problem Statement

Given the volume and complexity of foods managed and handled by hunger relief organizations, food safety regulations pertaining to such organizations must be appropriate and effective. The opinions of legislators who create the laws that impact food safety regulation of hunger relief organizations are not well documented.

Research Questions

1. What is the self-reported knowledge level of key Kansas legislators about the risks of foodborne illness associated with donated food?

2. How do these key Kansas legislators support regulatory food safety activities related to food donations in Kansas?

3. How do these key Kansas legislators support using tax dollars to fund regulatory food safety activities for food donations in Kansas?

Methodology

A five-item electronic survey was designed for this study using SurveyMonkey®. Each survey item had a comment field. The invitation to participate in the survey, including a link to the survey, was sent by email to the 57 legislators on the respective Kansas House and Senate Agriculture and Health and Human Services Committees. The legislators' email addresses were obtained from public directories. These legislators were selected because they play a significant role in advancing legislation that impacts regulatory activity regarding hunger relief organizations.

The survey results were compiled using nominal data-reporting frequencies.

Results

- Eleven (11) of 57 legislators completed the survey, which is a response rate of 19.3%.

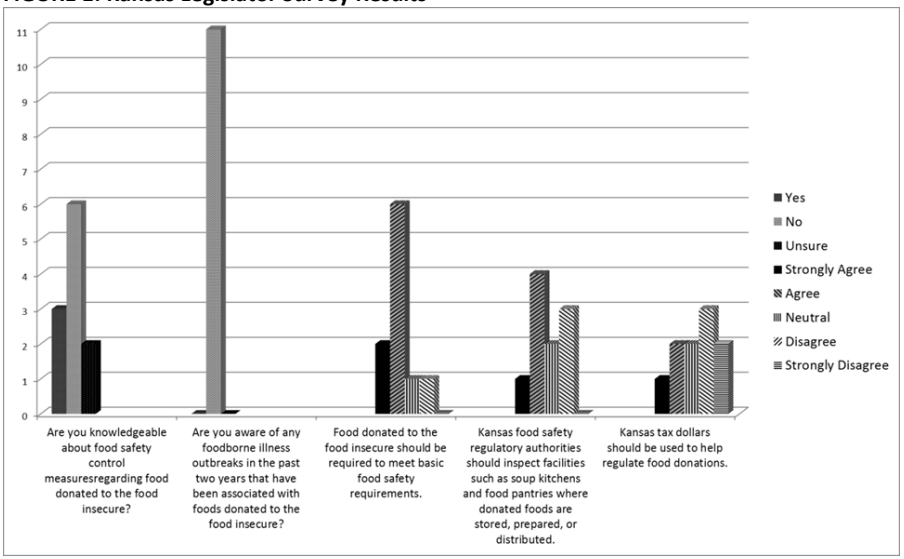
- A majority (54.5%) of the respondents felt that they were not knowledgeable about food safety control measures regarding donated food. The only written comment provided for question one was, "do know about the 'good samaritan' state law [sic]".
- None of the respondents were aware of any occurrence of foodborne illness outbreaks in the past two years associated with food donations to the food insecure.

- Seventy-two percent (72.3%) of the respondents agreed or strongly agreed that food donated to the food insecure should meet basic food safety requirements.

- Forty-five percent (45.5%) of the respondents agreed or strongly agreed that Kansas food safety regulatory authorities should inspect facilities such as soup kitchens and food pantries where donated foods are stored, prepared, or distributed, while 18.2% were neutral and 27.2% disagreed. Two comments were provided for question four. First, "State inspectors are more interested in 'finding' problems and preserving their positions than safety." Second, "soup kitchens and food pantries should follow basic food safety measures."

- Twenty-seven percent (27.2%) of the respondents agreed or strongly agreed that Kansas tax dollars should be used to help regulate food donations, while 18.2% were neutral and 45.5% disagreed or strongly disagreed.

FIGURE 1: Kansas Legislator Survey Results



Conclusions

Although the respondents indicated that food safety is generally important, the responses imply a lack of understanding of the risks associated with food donations. While 45.5% of respondents agreed that government food safety inspections should occur, they did not want to use tax dollars to fund the inspections. The lack of a funding mechanism for food safety regulatory activities pertaining to donated foods creates a dilemma for agencies in setting policy and using constrained resources to support food safety work – thereby creating a risk for consumers involving donated foods.

Respondents were divided about whether food safety regulatory interventions are necessary or have an impact on food safety.

Recommendations

Based on the results of the survey, there is an opportunity to provide outreach to the Kansas Legislature about food safety in general and specifically pertaining to food donations to the food insecure. The KDA should consider scheduling a series of seminars with key legislative leaders, including discussions to explore the best way to fund food safety efforts related to hunger relief organizations.

The Association of Food and Drug Officials (AFDO) should consider developing a position statement supporting efforts of state regulatory officials to protect food insecure persons from unsafe donations, and distribute this position statement to organizations of state legislatures. Additionally, AFDO should also consider partnering with national organizations such as Feeding America to establish best practices for food donations.

CDC should consider adding a category entitled "Hunger Relief Organization (soup kitchen, food pantry, etc.)" as a location of exposure in the National Outbreak Reporting System form CDC 52.13 to allow data capture for the Foodborne Outbreak Online Database.

Finally, further research about the extent of food safety risks of donated foods should be conducted.

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References

Cody, M. M., & Hogue, M. A. (2003). Results of the Home Food Safety-It's in Your Hands 2002 survey:comparisons to the 1999 benchmark survey and the Healthy People 2010 food safety behaviors objective. Journal of the American Dietetic Association, 103:1115-25.

Coleman-Jensen, A., Nord, M., Andrews, M., & Carlson, S. (2012). Household Food Security in the United States in 2011. United States Department of Agriculture Economic Research Service.

Denver Post. (2012, July 24). Denver health investigators probing tainted meal that sickened 60. Retrieved from: http://www.denverpost.com/news/ci_21141863/denver-health-investigators-probing-tainted-meal-that-sickened

Denver Post. (2012, August 3). Staph-related toxin made Rescue Mission clients sick, probe says. Retrieved from: http://www.denverpost.com/breakingnews/ci_21228274/staph-related-toxin-made-rescue-mission-clients-sick

Gross, M., & Hickock, M. (2011). Society of St. Andrew 2011 Annual Report. Retrieved from: http://www.endhunger.org/news_room/Financial/AnnualReport.pdf

Lawrence Journal World. (2003, September 27). Retrieved from: http://www2.ljworld.com/news/2003/sep/27/link_has_close/?print

Mabli, J., Cohen, R., Potter, F., & Zhao, Z. (2010). Hunger In America 2010. Mathematica Policy Research, Inc.

Redmond, E. C., & Griffith, C. J. (2003). Consumer food handling in the home: A review of food safety studies. Journal of Food Protection, 66:130-61.

Scallan, E., Hoekstra, R. M., Angulo, F. J., Tauxe, R. V., Widdowson, M. A., Roy, S. L., Griffin, P. M. (2011). Foodborne Illness Acquired in the United States—Major Pathogens. Emerging Infectious Diseases.

Staff. (2010, 10 14). 26 get food poisoning from Community Kitchen. Retrieved from WRCBtv.com: http://www.wrcbtv.com/Global/story.asp?S=13322471

WhyHunger. (2013, March 15). Community Food Projects (CFP) Database. Retrieved from http://www.whyhunger.org/search?name=&city=&state=&country=&zip=&orderBy=0&onlyCfp=1&year=&focusArea=&orgGov=0&optionIds=&page=1

Impact of FDA Core Courses on Texas Manufactured Food Inspector Written Observations

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Abstract

Texas Department of State Health Services (TDSHS) Manufactured Food Inspectors attended U. S. Food and Drug Administration (FDA) Core Courses FD150: Food Good Manufacturing Practices, FD151: Food Inspection Techniques and Evidence Development, and FD152: Food Processing and Technology in groups beginning September 24, 2009 through April 27, 2012 as part of TDSHS Manufactured Food Regulatory Program (MFRP) Standard Two: Training Program. This study assessed whether there was a difference in the reported critical and noncritical observations documented in TDSHS routine inspection reports after FDA training as compared to inspection reports prior to FDA training. The results of the study were inconclusive given the inability to control for all of the possible variables that could have contributed to any variances. Despite the outcome, three challenges to evaluating and comparing written observations were identified as needing to be considered by regulatory programs implementing the MFRP Standards, particularly Standard 4: Inspection Audit Program. This standard requires the state program to conduct quality assurance reviews to evaluate the effectiveness of the inspections program and recognize trends in inspectional coverage (U.S. Food and Drug Administration, 2010). The challenges included lack of detailed written observations, lack of written guidance to determine the appropriate regulation(s) the observation violates, and lack of written guidance to determine when an observation is critical versus noncritical.

Background

The Texas Department of State Health Services (TDSHS) began implementing the Manufactured Food Regulatory Program Standards (MFRP Standards) in 2009 as a requirement of the U. S. Food and Drug Administration (FDA) Food Protection Rapid Response Team (RRT) and Program Infrastructure Improvement Prototype Project. The MFRP Standards were developed by a committee of FDA and state regulatory officials in response to a June 2000 U. S. Office of Inspector General (OIG) report that made several recommendations to FDA to address shortcomings identified in FDA's oversight of state food firm inspections. The report highlighted the need for equivalency among federal and state food safety standards, inspection programs, and enforcement practices (U. S. Office of Inspector General, 2000). The MFRP Standards Committee identified ten areas crucial to a high-quality regulatory program charged with protecting the public from foodborne illness, including Regulatory Foundation, Training Program, Inspection Program, Inspection Audit Program, Food-related Illness and Outbreaks and Response, Compliance and Enforcement Program, Industry and Community Relations, Program Resources, Program Assessment, and Laboratory Support (U. S. Food and Drug Administration, 2010).

The MFRP Standards for Training Program, Inspection Program and Inspection Audit Program help ensure that food protection agencies have competent inspectors and consistent inspections. The Training Program standard defines coursework and field training at the basic and advanced level for a person conducting food inspections. The Inspection Program standard describes how an effective program, through written policy and procedures, requires an inspector to recognize significant violative conditions or practices, record findings, and distinguish between significant and insignificant observations, and isolated incidents versus trends. The Audit Program standard describes the basic quality assurance reviews necessary to: (1) evaluate the effectiveness of the inspection program, (2) recognize trends in inspectional coverage, and (3) identify best practices used to achieve quality inspections and sample collections. This standard uses Field Inspection Audits, Inspection Report Audits and Sample Report Audits to assess the effectiveness of the inspection program. In particular, the Field Inspection Audit and Inspection Report Audit evaluate inspectors against criteria such as the ability to recognize significant violative conditions or practices, and whether inspectors are able to distinguish between significant and insignificant violative conditions (U.S. Food and Drug Administration, 2010).

TDSHS selected FDA's Level 1 Manufactured Foods Curriculum to meet the Training Program standard. The curriculum includes a combination of online and three face-to-face core courses: Food Good Manufacturing Practices (FD150), Food Inspection Techniques and Evidence Development (FD151), and Food Processing and Technology (FD152). TDSHS inspectors that had not completed FD150, FD151 and FD152 began attending the courses in large groups in September 2010 and most had completed the courses by April 30, 2012.

The TDSHS Manufactured Foods program inspects wholesale and retail food manufacturers operating in Texas. Retail food establishments that manufacture food are inspected under 25 Texas Administrative Code (TAC) Chapter 229, Good Manufacturing Practice and Good Warehousing Practice in Manufacturing, Packing, or Holding Human Food that closely follows, with state-specific modifications, 21 Code of Federal Regulations (CFR) Part 110 Current Good Manufacturing Practice (GMP) in Manufacturing, Packing, or Holding Human Food. Violative conditions observed by inspectors during an inspection are called "observations" and are recorded on Form E-14 issued to the food manufacturer at the conclusion of the inspection.

Problem Statement

The impact of FDA Food Core courses FD150, FD151 and FD152 on TDSHS inspector reporting of significant violative conditions or practices during routine GMP inspections of food manufacturers in Texas is unknown.

Research Question

Did attending FDA Food Core courses FD150, FD151 and FD152 have an impact on inspector reporting of significant violative observations during routine GMP inspections of Texas food manufacturers?

Methodology

To assess whether completion of the FDA courses impacted reported written observations, and because there was no control group available, inspection reports from before and after course completion were selected for review. In order to be included in the study, the inspection report was required to meet the following conditions: The inspection report had to be conducted during the same time periods in 2010 and 2012; the report had to be a routine GMP inspection of a food manufacturer that processes food; the inspector must have completed all three FDA courses during the same time period; and the inspector must have conducted inspections prior to and after the courses. Additionally, the ratio of retail manufacturers to wholesale manufacturers was kept the same for both sets of reports reviewed.

The last FDA course completed by groups of inspectors was FD151 on April 27, 2012. Post-course inspection reports were collected from May 1, 2012 through July 31, 2012 due to availability and the onset of the IFPTI Cohort III Fellowship in July 2012. To control for seasonal variability, pre-course reports were collected from the same time period of May 1 through July 31 in 2010 prior to inspectors attending the FDA courses which began in September 2010. In addition to the course completion requirements, only inspectors that conducted manufactured food inspections prior to and after completing the courses were included.

Inspection reports selected were limited to routine GMP inspections of food manufacturers because FD150, FD151 and FD152 cover basic GMP inspections. FDA provides other courses that cover specialized processing such as acidified foods and low acid canned foods. Although companies that conduct specialized processing must also comply with GMPs, this study was conducted to assess the impact of the courses on basic food manufacturing operations. To ensure that all categories under the GMPs and product labeling were applicable for review during the inspection, focused inspections such as sampling, recalls, and some field investigations were excluded from the study, as well as private label manufacturers and warehouses that do not process food.

The 2010 inspection list generated by the TDSHS Regulatory Programs Regulatory Automation System (RAS) Portal database resulted in 127 inspections that fit the study parameters involving 41 wholesale manufacturers and 86 retail manufacturers. The 2012 inspection reports were randomly selected until 41 wholesale manufacturers and 86 retail manufacturers were identified that fit the study parameters. Reports for routine inspections resulting in regulatory action such as warning letters were only available for review in person while reports for routine inspections that did not result in regulatory action were available remotely on the TDSHS server. If a “review in person” report was selected, that report place was maintained. If the “review in person” report was unavailable, the report was replaced with another “review in person” report that resulted in regulatory action.

Written observations of the inspection report were entered into a Microsoft-Excel spreadsheet with columns for the inspection report number, inspection date, inspector number, the food product code, food risk, study observation classification, 2009 Food Code observation classification, Texas law citation, and the Food Code citation. Pre-defined cell drop boxes were used to utilize the spreadsheet filtering features and to assist with observation categorization consistency.

Observations were categorized as follows: personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, production and process controls, labeling, unable to determine, and other. The "other" category included licensing and non-applicable observations such as expired over-the-counter drugs. The "unable to determine" category was used for observations that were not written clearly.

Within each category, the observation was subcategorized as "critical" or "noncritical" using 2009 Food Code risk designations Priority, Priority Foundation and Core; FDA's FD320 State Food Contract Auditing manual (U.S. Food and Drug Administration, 2011); and International Food Protection Training Institute (IFPTI) Fellowship "Evaluating Violations" exercise (8/15/2012) as guidance. In the "Labeling" category, undeclared allergens or no manufacturer name and location was designated as "critical." Similar reported observations in an inspection report that were numbered separately on the E-14 were grouped into one observation in the spreadsheet. For example, if five separate foods with the same labeling violation were numbered 1 through 5 on the E-14, they were entered as one observation in the spreadsheet. For consistency, unclean food contact surface observations were categorized in the Production and Process Controls category even though they can also be categorized under Sanitary Operations [21 CFR 110.35(d)] in the GMP regulations.

The frequency rates of all 2010 and 2012 reported observation categories and sub-categories were calculated. The frequency rates from 2010 and 2012 were then compared for each category and sub-category using chi-square distribution with one degree of freedom ($\alpha = 0.05$, $X^2 = 3.84$) (Lipschutz & Lipson, 2011) (Robson, Shannon, Goldenhar, & Hale, 2001).

Results

Inspection reports from 24 TDSHS manufactured food inspectors met the study parameters. Of the 127 inspection reports from 2010 that met the study criteria, nineteen did not list any critical or noncritical observations on the E-14. Ten of the 127 inspections from 2010 resulted in warning letters. Of the 127 randomly selected reports for 2012, thirty-eight inspections did not list any critical or noncritical observations on the E-14, and twelve of the remaining reports resulted in warning letters. The increase from 19 inspection reports without observations in 2010 to 38 reports without observations in 2012 was a statistically significant change ($X^2 = 6.33$).

Excluding the inspection reports without observations, a total of 449 reported observations were entered into the spreadsheet for 2010 from the remaining 108 reports. A total of 425 reported observations were entered for 2012 from the remaining 89 reports.

Overall the percentage of total critical observations and noncritical observations in all categories did not change significantly between the 2010 and 2012 inspections, with 34.30% critical in 2010 and 34.59% in 2012 [See Section A of Table 1]. Likewise, the "unable to determine" category did not show a significant change. The ratio of total critical to noncritical observations was 0.586 and 0.588 respectively for 2010 and 2012 also indicating no significant change [See Section F of Table 1].

TABLE 1: 2010 and 2012 Reported Observation Comparison Results

	2010		2012		Chi-Square Value
A. Total Number of Written Observations	449		425		
Total Critical Observations	34.3 %	n= 154	34.6 %	n= 147	0.005
Total Noncritical Observations	58.6 %	n= 263	58.8 %	n= 250	0.002
"Unable to Determine"	1.6 %	n= 7	1.0 %	n= 4	0.662
"Not Applicable" (Licensing, other rules, etc.)	5.6 %	n= 25	5.7 %	n= 24	0.002
B. Percentage of Total Critical + Noncritical Observations by Category					
110.10 Personnel (employee hygiene and health, handwashing)	3.1 %	n= 14	4.5 %	n= 19	1.058
110.20 Plant & Grounds	11.8 %	n= 53	8.5 %	n= 36	2.383
110.35 Sanitary Operations (chemicals, pests)	27.0 %	n= 121	24.2 %	n= 103	0.627
110.37 Sanitary Facilities & Controls (water, sinks, plumbing)	14.7 %	n= 66	8.2 %	n= 35	**7.895***
110.40 Equipment & Utensils	9.4 %	n= 42	11.8 %	n= 50	1.205
110.80 Production & Process Controls	14.7 %	n= 66	20.2 %	n= 86	**3.848***
Labeling (allergens, name & location)	12.3 %	n= 55	16.0 %	n= 68	2.182
C. Percentage of Critical Observations per Category Total in Section B Above					
110.10 Personnel	7.1 %	n= 1	0.0 %	n= 0	1.357
110.20 Plant & Grounds	5.7 %	n= 3	5.6 %	n= 2	0.0004
110.35 Sanitary Operations	24.0 %	n= 29	28.2 %	n= 29	0.377
110.37 Sanitary Facilities & Controls	69.7 %	n= 46	71.4 %	n= 25	0.010
110.40 Equipment & Utensils	31.0 %	n= 13	16.0 %	n= 8	2.236
110.80 Production & Process Controls	44.0 %	n= 29	38.5 %	n= 39	0.017
Labeling	60.0 %	n= 33	64.7 %	n= 44	0.108
D. Percentage of Critical Observations per Total Year Observations by Category (2010=449 Total; 2012=425 Total)					
110.10 Personnel	0.2 %	n= 1	0.0 %	n= 0	0.947
110.20 Plant & Grounds	0.7 %	n= 3	0.5 %	n= 2	0.149
110.35 Sanitary Operations	6.5 %	n= 29	6.8 %	n= 29	0.044
110.37 Sanitary Facilities & Controls	10.3%	n= 46	5.9 %	n= 25	**5.115***
110.40 Equipment & Utensils	2.9 %	n= 13	1.9 %	n= 8	0.932
110.80 Production & Process Controls	6.5 %	n= 29	9.2 %	n= 39	2.073
Labeling	7.4 %	n= 33	10.4 %	n= 44	2.235
E. Critical to Noncritical Observations Ratio by Category					
110.10 Personnel	0.077	1:13	0.000	0:19	1.462
110.20 Plant & Grounds	0.060	3:50	0.059	2:34	0.001
110.35 Sanitary Operations	0.315	29:92	0.392	29:74	0.690
110.37 Sanitary Facilities & Controls	2.300	46:20	2.500	25:10	0.113
110.40 Equipment & Utensils	0.448	13:29	0.190	8:42	**3.855***
110.80 Production & Process Controls	0.784	29:37	0.830	39:47	0.054
Labeling	1.500	33:22	1.833	44:24	0.762
F. Combined Critical to Noncritical Ratio	**0.586**	154:263	**0.588**	147:250	0.001

*Statistical Significance using Chi-square one degree of freedom $\alpha = 0.05$, $X^2 = 3.84$

When total critical and noncritical observations are organized by the six GMP and Labeling categories [See Section B of Table 1], there is a significant change in the Sanitary Facilities and Controls and the Production and Process Controls categories. The total in Sanitary Facilities and Controls decreased from 66 observations in 2010 to 35 in 2012 ($x^2 = 7.895$). The two areas within this category with the largest decreases were plumbing, from 19 total observations to 11, and handwashing facilities, from 32 total observations to 15. The total observations in Production Processes and Controls increased from 66 to 86 ($x^2 = 3.848$). The area of raw material and ingredient handling increased by 19 observations and maintenance of equipment, utensils and finished food containers in acceptable condition increased by 13 observations.

There were no significant changes when the percentage of critical observations to total observations within each category was compared [See Section C of Table 1]. However, when the percentage of critical observations per total observations in the year [See Section D of Table 1] was reviewed for each category, there was a significant change in Sanitary Facilities and Controls, with 10.2% in 2010 decreasing to 5.9% in 2012 ($x^2 = 5.115$).

When the ratio of critical to noncritical observations within each category was compared [See Section E of Table 1], only Equipment and Utensils changed significantly from a ratio of 0.448 in 2010 to 0.190. In 2010, for every one critical observation there were 2.2 noncritical observations, and in 2012, for every critical observation there were 5.3 noncritical observations. The largest increase within the category was in the construction and maintenance of equipment and utensils, from 26 total observations (84.6% noncritical) to 40 total observations (90.0% noncritical).

Conclusions

There are too many uncontrolled variables in the study to conclude that the FDA courses did or did not impact TDSHS food manufacturer inspector reporting of critical violations. However, there were findings within the data that warrant additional exploration. First, the fact that there was no change between the ratio of critical to noncritical observations between the 2010 reports and the 2012 reports could indicate that TDSHS food manufacturer inspectors view all observations as equally valid because the observation is out of compliance with a specific regulation, as opposed to viewing the level of risk that an observation could result in the adulteration of the manufactured food. Second, out of 254 inspection reports and 874 observations reviewed, none of the observations were for failing to wash hands even though there was a total of 47 pre- and post-training observations regarding the adequacy of facility handwashing sinks. Third, there was a reduction in the number of observations regarding unshielded lights from 19 in 2010 to 10 in 2012. However, the written observations still did not adequately describe how food was exposed under the unshielded lights even though this regulation [21 CFR 110.20(b)(5)] was covered in the FD150 course along with the other GMP regulations.

Three challenges were encountered in this study that may also have a direct impact on an inspection program's ability to evaluate training and inspection program effectiveness and to identify trends in inspectional coverage as required under the MFRP Audit Standard. The first challenge was lack of detailed written observations. Some observations reviewed were classified as noncritical because of a lack of information, e.g. equipment observed to be unclean without describing whether the unclean area was a food-contact surface. An observation could have been further strengthened if a description of the food being processed was included, particularly if the food was ready-to-eat and/or potentially hazardous. The FD151 course included a section on how to write a good observation.

A second challenge was determining the appropriate regulation for the observed violative condition. While some observations are easy to match with the applicable regulation, some violative conditions appear to fall under more than one rule e.g., unclean food contact surfaces fall under Sanitary Operations [21 CFR 110.35(d)] and Production and Process Controls [21 CFR 110.80(b)(1)].

The third challenge was determining whether a violative condition is critical or noncritical. While the FDA 2009 Food Code for retail food establishments provides guidance as to whether a rule is a Priority or Priority Foundation issue based on CDC's causes of food-borne illness, comparable risk-based guidance is not available for food manufacturing establishments.

Recommendations

Additional inspector guidance and training is needed to enable TDSHS inspectors to consistently compose written E-14 observations that are clear, complete and applicable and to consistently identify and distinguish high-risk critical violations from low-risk observations.

Moreover, inspectors need to receive timely, regular feedback and clarifications on actual written observations from inspections. The Inspection Report audit component of the MFRP Audit standard may need to include a detailed review of written observations in such a way that feedback can be provided to inspectors where specific rules may need to be clarified or reminders given regarding the components of a well-written and actionable observation.

In-depth analysis of category data collected in this study can be used to identify areas where clarification may be needed as to the applicable regulation and the correct interpretation of the regulation. The 2009 Food Code Priority, Priority Foundation and Core food-borne illness contributing factor risk levels, which were used during this study to classify reported observations of food manufacturing establishments, could be used as a starting point to develop a guidance document for inspectors to use during inspections, and for field and report auditors to use when evaluating individual inspector performance.

Regulatory programs implementing the MFRP Standards should consider assessing training effectiveness to ensure that selected courses impart the knowledge and job skills against which manufactured food inspector performance is measured. A valid and reliable evaluation tool outside of the accompanying end of course assessment may need to be developed to ensure the classroom course meets the needs of a food inspection program.

Acknowledgments

I would like to sincerely thank all of my colleagues in the Texas Department of State Health Services (TDSHS) Environmental and Consumer Safety Inspections Unit-Foods and the Policy, Standards and Quality Assurance (PSQA) Foods Group for everything you all do on a daily basis to protect the public. Thank you PSQA for pulling all those inspection reports for me and answering all my questions about the work you do. I would especially like to thank Frank Borden, TDSHS Food and Drug Branch Manager, and my supervisor, David Sueltenfuss, South Group Manager, for your support in my participation in the International Food Protection Training Institute (IFPTI) Fellowship. A special thanks to my mentor, Jim Sevchik, and Dan Sowards, my temporary mentor, for your invaluable patience, support and feedback on this project. To all of the IFPTI staff, IFPTI Fellowship subject matter experts, and IFPTI fellows, it has been an honor to be in your company, and I feel blessed to have had the opportunity to share this time with you and learn from you. Most of all, thank you to my husband, Paul, and daughter, Bailey, who always believe in me and are my number one fans.

References

U. S. Food and Drug Administration. (September 2011). *State Food Contract Auditing FD320*. Kansas City, Missouri.

U. S. Food and Drug Administration. (September 2010). *Manufactured Food Regulatory Program Standards (MFRPS)*. Retrieved from http://www.fda.gov/ForFederalStateandLocalOfficials/PartnershipsContracts/Overview/default.htm

Lipschutz, S., & Lipson, M. (2011). *Probability*. New York: McGraw-Hill Companies.

Robson, L. S., Shannon, H. S., Goldenhar, L. M., & Hale, A. R. (2001). *Guide to Evaluating the Effectiveness of Strategies for Preventing Work Injuries: How to Show Whether a Safety Intervention Really Works*. Cincinnati: National Institute for Occupational Safety and Health.

U. S. Office of Inspector General. (2000). *FDA Oversight of State Food Firm Inspections: A Call for Greater Accountability* OEI-01-98-00400.

Regulator Perceptions and Treatment of Temporary Food Establishments

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Abstract
Temporary food establishments (TFEs) are venues for the handling, preparation, distribution, and consumption of foods for a period of no more than 14 days in conjunction with a single event or celebration (U.S. Food and Drug Administration, 2009). Food safety implicating characteristics of TFEs include limited space, sanitation facilities, and regulatory uniformity. Thus, there is a potential for an increased likelihood of a rapid, efficient spread of foodborne and water-borne outbreaks of infectious diseases from these parameters (Abubakar, 2012). This research explored retail food program managers' perceptions of TFEs through a national survey (including Puerto Rico) mailed to members of the Association of Food and Drug Officials (AFDO). The survey inquired about: 1) TFE types, 2) application of regulatory oversight to TFEs, and 3) using the five Centers for Disease Control and Prevention (CDC) risk factors to rank the perception of those risk factors at TFEs. The most noted CDC risk factor across all TFEs was improper hot/cold holding temperature. Recommendations are provided to improve inconsistencies and inadequate regulations.

Background
Temporary Food Establishments (TFE) were mentioned in the first edition of the U. S. Food and Drug Administration's (FDA) 1993 Model Food Code. The 2009 Food Code defines a TFE as a food establishment that operates for a period of no more than 14 days in conjunction with a single event or celebration (Food and Drug Administration, 2009).

Foodborne and water-borne outbreaks of infectious diseases have the potential to spread efficiently and rapidly on a large scale (Abubakar, 2012). According to the CDC 2008 Outbreak Morbidity and Mortality Weekly Report, there were 356 outbreaks associated with known locations of fairs and festivals (CDC, 2008). The 1998-2010 CDC Foodborne Outbreak Online Database (FOOD) indicates there were 4,634 foodborne outbreaks that occurred in the United States at a fair, festival, or temporary mobile service (CDC, 2012). Although there have been limited studies on outbreaks associated with TFEs, the CDC reports, most foodborne infections go undiagnosed and unreported (CDC, 2012). Catering at large outdoor events is considered to be of greater risk than catering in other settings due to the large numbers of people, the temporary nature of the accommodation, the frequent use of temporary staff, reduced storage facilities, a frequent lack of access to an approved water source and potential exposure to extreme weather conditions (Willis, 2012).

TFE regulations and practices vary by jurisdiction. Regulatory practice may consist of a plan review, permit, and an inspection. TFE plan reviews ensure regulatory requirements are met by identifying potential food-safety code violations associated with construction or renovations. Plan review guidance documents by FDA advise that all TFEs submit an application, a plan review, and menu options for each event. The

regulatory authorities review the application and plans to determine if all the specifications and requirements are met.

A TFE permit, according to the 2009 Model Food Code, refers to the document issued by the regulatory authority that authorizes a person to operate a food establishment (Food and Drug Administration 2009). Regulatory authorities may issue a permit for the facility to operate based on an approved plan review and an inspection of the facility.

TFE regulatory inspections involve a process that is guided by each establishment's menu, potential hazards related to menu ingredients, and control measures to mitigate those hazards (CDC, 2011). Control measures and hazards are reflective of laws and regulations for each jurisdiction's food safety regulatory programs. Types of inspections vary from risk-based inspections to inspections that just note violations of regulatory requirements. In 2011, the Conference for Food Protection released a guidance document suggesting inspection and plan review forms for states to follow.

Problem Statement

Little empirical evidence exists regarding regulatory treatments of TFEs or regulator perceptions of the extent to which TFEs expose the public to the risk of foodborne illnesses.

Research Questions

1. What types of regulations are implemented for TFEs?

2. What types of TFEs receive a pre-operational plan review?

3. What are regulator perceptions of TFEs based on the five CDC risk factors?

Methodology

For the purpose of this study, TFEs consisted of fairs, festivals, farmers' markets, and non-profit events. These settings are normally high-risk food operations as operators prepare, store, serve, and dispose of foods often having limited physical space and sanitary facilities (Food and Drug Administration, 2000). A survey was created using a PDF-fillable form and sent to all retail food program managers on the Association of Food and Drug Officials (AFDO) electronic distribution list, which contained representatives of all 50 states and Puerto Rico. AFDO is an international non-profit organization that is at the forefront of streamlining and simplifying regulations by drafting regulatory rules or commenting on government proposals. AFDO's membership is comprised of high level regulatory officials, industry, and trade and consumer organizations (AFDO, 2013).

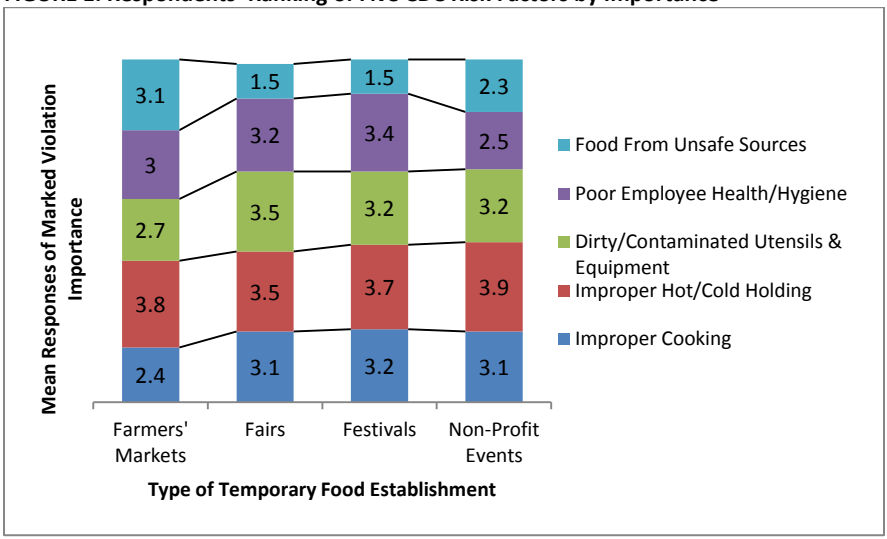
Participants were directed to forward complete surveys to the email address of the principal investigator. Two weeks following the initial distribution of surveys a reminder email was sent by AFDO to the distribution list. One week later the survey participation period closed.

For the states of Utah, New Hampshire, Illinois, and Arizona, which each have multiple regulations in different jurisdictions, the state directors supplied lists of the individual jurisdiction representatives for the state, and the representatives on these lists were emailed with the same survey. Four states had multiple respondents; their responses were averaged by state to provide one representative response per state. Excel was used to conduct an analysis of mean responses, job titles, departments, and states.

Results

Participants from 24 states (there were no responses from Puerto Rico) responded to the first questions on types of regulation and plan reviews conducted. Eleven states responded to the risk perception ranking of CDC risk factors. The survey respondents' titles included State Directors of Environmental Health, Program Managers of local jurisdictions, Lead Environmental Health Specialists, and General Environmental Health Officers. For all types of events, eleven (11) out of 24 states perceived the highest CDC risk factor, ranked by importance on a scale of 1 to 5, to be improper cold/hot holding temperature, with an overall average of 3.7. Respondents ranked dirty/contaminated utensils and equipment equally high in the same category for TFEs found at fairs with an average ranking of 3.5. For festivals, the second ranked risk factor by importance was poor employee health and hygiene with an average ranking of 3.4. For farmers' markets, the second ranked risk factor was food from unsafe sources with an average ranking of 3.1. At non-profit events, the second ranked risk factor was dirty/contaminated utensils and equipment, ranked at 3.2, followed closely by improper cooking at 3.1 (Figure 1).

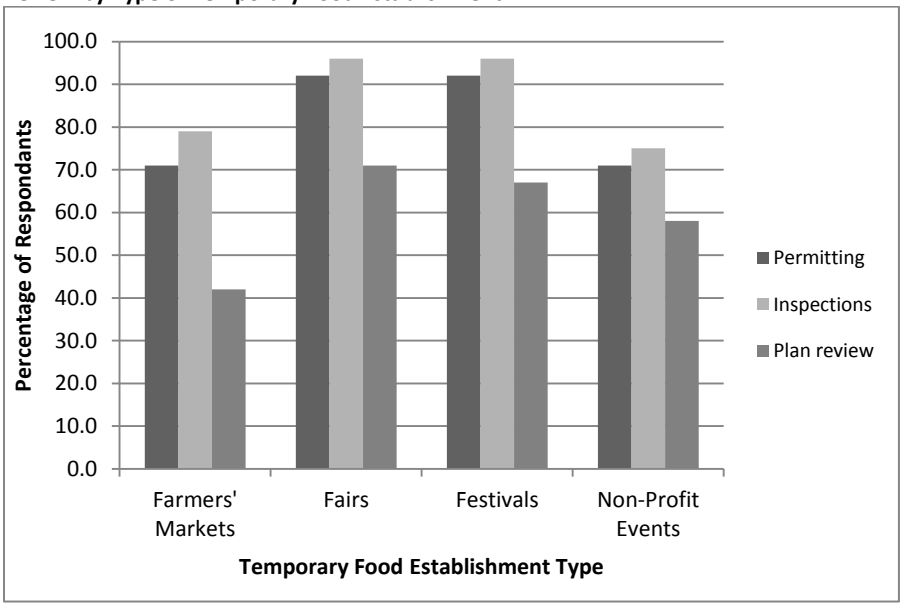
FIGURE 1. Respondents' Ranking of Five CDC Risk Factors by Importance



Ninety-two percent (92%) of participants indicated that their states issue permits to TFEs at fairs and festivals, and 96% of respondents indicated that their states inspect TFEs at fairs and festivals (Figure 2). TFEs at farmers markets and non-profits are permitted by 71% of the states represented. Seventy-nine percent (79%) of respondents indicated that TFEs at their state farmers' markets are inspected and seventy-five percent (75%) of respondents indicated that their states inspect non-

profits. A pre-operational plan review is conducted for TFEs at farmers' markets by 42%, at fairs by 71%, at festivals by 67%, and for non-profits by 58% of the states represented by respondents (Figure 2).

FIGURE 2. Percentage of States that Permit, Inspect, and Conduct Pre-Operational Plan Review by Type of Temporary Food Establishment



Conclusions

While most states responding to the survey permit and inspect all types of TFEs, there were notable gaps in regulatory approaches used for TFEs at different venues. TFEs at farmers' markets and non-profit events appear to receive less regulatory control than those found at fairs and festivals. Overall, less than half of the responding states conduct a pre-operational plan review for all types of TFEs--an integral part of foodservice review and regulation. Improper hot/cold temperature was ranked as the most important risk factor according to the survey, suggesting it is one of the most difficult types of risk factors to control at this type of establishment.

The second most important risk factor was different for three of the four event types. This interesting finding could be explored further in future studies as it may indicate TFE characteristics unique to event types or common regulatory concerns in these different settings. It is concerning that not all respondents indicated at least one of the three regulatory interventions were used in 100% of the cases.

Limitations

Limitations of this study include: 1) lack of definition; 2) lack of uniform respondent authority; 3) lack of consistency among event types; and 4) combining of responses to represent a state.

The first limitation in the study was not providing definitions of the different types of TFEs for survey recipients. For example, there may have been confusion among respondents between the definition of a "fair" and a "festival." The second limitation to the study was the lack of uniformity of the levels of authority that responded to the survey, which may have had a role in the ranking of the variables.

Inconsistency between types of TFEs may be another limitation. For example, fairs are a type of TFE held at a designated fair ground at a set time of year, while festivals are a celebration or event set up at any location and may not occur at a set time each year.

Another limiting factor of the study was the averaging of data for four states due to the fact that there were multiple respondents represented within each of these states. Certain jurisdictions and state laws and regulations limit the authority of these jurisdictions and states to permit and inspect certain types of TFEs.

Recommendations

States would benefit from: 1) applying the recommendations from the FDA and Conference for Food Protection 2011 Temporary Food Establishment Guidelines when updating TFE rules and regulations for both plan review and inspections; 2) using a pre-operational plan review as a requirement prior to operation, permitting, and inspecting of TFEs; 3) adopting the FDA Model Food Code which would require the same type of regulations for all food establishments including TFEs; and 4) studying the regulation of non-profit organizations. Future studies should allow for clear determination of the types of TFEs, identify jurisdictions with regulatory authority, and allow an opportunity for the respondent to list additional types of TFEs allowed in their jurisdiction.

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References

Abubakar I, et al. (2012). Global perspectives for prevention of infectious diseases associated with mass gatherings. The Lancet Infectious Diseases, 12, 66-74.

Association of Food and Drug Officials (2013). About. Retrieved from http://www.afdo.org/about.

Center for Disease Control and Pervention. Surveillance for foodborne-disease outbreaks--United States, 1998-2002. In Surveillance Summaries, MMWR 2006; 55 (No. SS-10).

Center for Disease Control and Prevention (2008). Number of reported foodborne disease outbreaks and outbreak - associated illnesses, by etiology and place where food was eaten*- United States, 2008. Retrieved from: http://www.cdc.gov/outbreaknet/pdf/2008MMWR-Table3.pdf.

Center for Disease Control and Prevention. (2011). Food safety and environmental assessments. Retrieved from: http://www.cdc.gov/nceh/ehs/eLearn/EA_FIO/food-safety-environmental-assessment.htm.

Center for Disease Control and Prevention (2012). Foodborne Outbreak Online Database. Retrived from http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx.

Center for Disease Control and Prevention. (2012). Foodborne Illness, Foodborne Disease, (sometimes called "Food Poisoning"). Retrieved from http://www.cdc.gov/foodsafety/facts.html.

U. S. Food and Drug Administration. 2009. Food Code 2009. Retrieved from http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/default.htm

U. S. Food and Drug Administration. 2000. Pre-operational Guide for Temporary Food Establishments – 2000 Food and Drug Administration and Conference for Food Protection. Retrieved from http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ComplianceEnforcement/ucm095200.htm

Willis C, Elviss N, Aird H, Fenelon D, McLauchlin J. (2012). Evaluation of hygiene practices in catering premises at large-scale events in the UK: Identifying risks for the Olympics. *Public Health*, doi:10.1016/j.puhe.2012.04.q\007.

U.S. Food Regulators' Perceptions of Areca Nut as Food and Religious Exemption

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Abstract
This study examines U.S. food regulators' perceptions of areca nut as food and religious exemption of adulterated food. Areca nut is the processed edible seed kernel of the *Areca catechu* fruiting palm tree. Areca nut is the fourth most commonly used addictive psychoactive substance in the world after tobacco, alcohol, and caffeine-containing beverages (IARC, 2004). Areca nut itself has been classified as a Group 1 carcinogen (carcinogenic to humans) by the International Agency for Research on Cancer (IARC, 2004). Areca nut consumption causes an *unconventional chronic foodborne disease* called oral submucous fibrosis (OSF) and other precancerous lesions and conditions. Ancient areca nut chewing culture is practiced by 600 million people on the Indian subcontinent and in Southeast Asia (Gupta & Warnakulasuriya, 2002; Sullivan & Hagen, 2002). The number of U.S. immigrants and refugees from these regions has increased from 2000 to 2010 faster than the general population (U.S Census, 2010). Asian immigrants and refugees have access to areca nut in South Asian and Southeast Asian food stores and restaurants in New York City (Changrani et al, 2006) and other U.S. metro areas with large Asian populations. An electronic survey was conducted of 19 food regulators to gauge perception of areca (betel) nut and paan as food and as a religious exemption. Survey results revealed a lack of awareness and uncertainty among the regulators. Additional studies are warranted, especially in metro areas with large Asian populations.

Background
The sale and use (chewing and consumption) of areca nut, which is a definitive cause of oral submucous fibrosis (OSF) (Aziz, 2010), is not regulated as either a food or drug in the United States; however, the availability of areca nut is increasing due to demand from growing Asian immigrant and refugee populations. The use of areca nut and common food combinations called paan (betel quid) can be defined by four main categories: social acceptability, religious beliefs, perceived health benefits, and addiction (IARC, 2004).

Areca nut is commonly and incorrectly referred to as 'betel nut' through association with the betel leaf (*Piper betel*). *Areca catechu* fruit is akin to stone fruits such as peaches, apricots, and cherries. The mature fruit is the size of a mango and is a mottled orange in appearance. Areca fruit is usually listed as an edible fruit and is, therefore, normally sold as a food, although the food value is uncertain (IARC, 2004). The areca fruit is most valuable for the seed kernel or "nut," which is processed overseas by de-husking, boiling, sun drying, roasting, and fermenting. The result is a very hard nut, the size of a small egg, with a tan exterior and a mottled whitish or reddish colored interior.

Asian immigrants and refugees in the United States and other Western countries retain areca nut chewing culture (Auluck et al., 2009). Asian immigrant populations that practice areca nut chewing culture are increasing in the U.S. faster than the general population. The Asian Indian population grew 24.6% between 2000 and 2010 in New York State, and 12.5% in New York City during the same period (U.S. Census, 2010). According to the 2010 Census, there are 3.2 million Asian Indians in the U.S. OSF is predominantly affecting Asian Indians.

There is a concern that the habit of spitting out some of the contents of paan (betel quid) has changed and, as a result, more of the contents are now being swallowed in Western countries. This change in habit may increase the risk of hypopharyngeal and esophageal cancer (Nandakumar et al., 1996). South Asian communities are generally not aware that areca nut chewing can cause oral cancer and that ceasing its use would reduce the likelihood of developing oral cancer. Reports also suggest that many shopkeepers selling these chewing products are not aware of any health risks (IARC, 2004).

Dry areca nut imported into the U.S. is a processed, ready-to-eat food and not a raw agricultural commodity. The nut is imported whole, sliced, crushed, or shredded and has been reported as adulterated and misbranded by the U.S. Food and Drug Administration (FDA) and the New York State Department of Agriculture. Areca nut is offered for sale in New York State and New York City via Asian Indian restaurants and South Asian food stores in the form of freshly prepared paan (betel quid) and bulk packages of sliced areca nut. Many Asian Indian restaurants and Asian Indian video stores in New York City prepare fresh paan for sale for about one U.S. dollar (Stanley, 2010; Changrani et al, 2006).

The areca nut contains natural alkaloid toxins, principally arecoline, which are similar to other toxic plant alkaloids. Mushroom poisoning is an example of a natural plant poison and foodborne disease. Areca nut consumption is the definitive cause of oral submucous fibrosis (OSF) (Aziz, 2010) – an unconventional chronic foodborne disease. OSF is a chronic disorder characterized by fibrosis of the lining mucosa of the upper digestive tract involving the oral cavity, oro-and hypopharynx and the upper third of the esophagus. The fibrosis involves the lamina propria mucosa and the submucosa and may often extend into the underlying musculature, resulting in the deposition of dense fibrous bands. These bands give rise to the limited mouth opening called trismus, which is a hallmark of this disorder (IARC, 2004).

The United States Federal Food, Drug, and Cosmetic Act defines “food” as (1) articles used as food or drink for man or other animals; (2) chewing gum; and (3) articles used for components of any such articles. Areca nut is a component of paan (betel quid) which, in turn, contains conventional foods. Tobacco ingredient in conventional foods is not considered generally recognized as safe (GRAS) by the FDA. The addition of tobacco to conventional foods in the U.S. deems those foods adulterated.

Areca nut is considered an adulterated food under Sections 402 and 801 of the U.S. Federal Food, Drug, and Cosmetic (FD&C) Act according to the FDA and the New York State Department of Agriculture (Stanley, 2010). In fact, the FDA provided Congressional testimony in 2000 opposing a measure (HR.2462) to exempt betel nuts from being considered adulterated under the FD&C Act. The FDA testimony claimed

that exempting an unsafe food, like betel nuts, undermined the important public health provisions of the FD&C Act.

Problem Statement

South Asian and South East Asian immigrant and refugee populations practicing areca nut chewing culture have an increased risk of OSF and oral cancer due to consuming areca nut. The level of U.S. regulatory food safety professionals' knowledge of areca (betel) nut and paan (betel quid) and their perception of either as a food is unknown. Additionally, regulatory food safety professionals' perception of a religious exemption for non-food use of an adulterated food is also unknown.

Research Questions

1. What are U.S. regulatory food safety professionals' perceptions of areca (betel) nut and paan (betel quid) as food?

2. What are regulatory food safety professionals' perceptions of a religious exemption for an adulterated food if labeled: For Religious Purposes Only – Not for Human Consumption?

Methodology

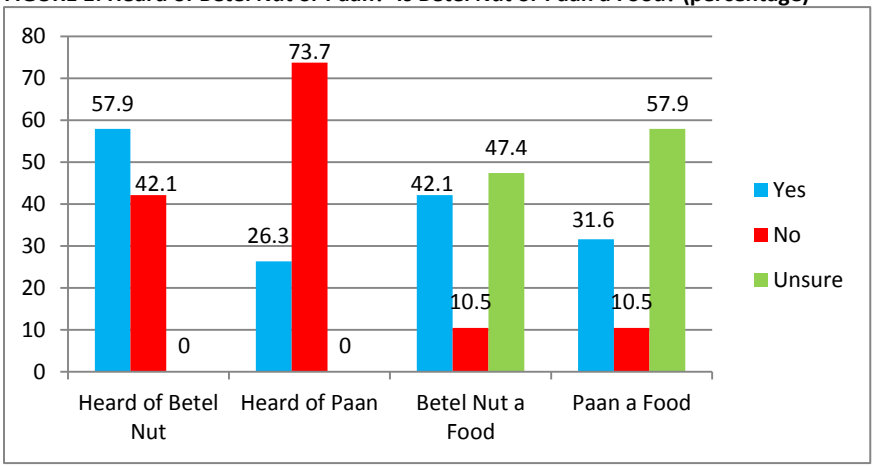
A survey was conducted of 108 food regulators in 22 states via email (using SurveyMonkey®). The email addresses were obtained from the Association of Food and Drug Officials (AFDO) - Directory of State and Local Officials (DSLO). The states were chosen that correspond to the top 5 Asian Groups in 20 Metro Areas with the largest Asian populations per the 2010 U.S. Census. Regulatory food safety professionals from Health Departments, Departments of Agriculture, and State Epidemiologists were surveyed. No background explanation was provided for the questions. The questions were:

1. Have you heard of betel nut (areca nut)?
2. Have you heard of paan (betel quid)?
3. Do you consider betel nut a food (betel nut is a processed edible seed kernel that is chewed)?
4. Do you consider paan a food (paan is betel nut with edible limestone paste wrapped in a betel leaf with optional condiments that is chewed)?
5. Would you consider a religious exemption for an adulterated food if labeled: For Religious Purposes Only – Not for Human Consumption?

Results

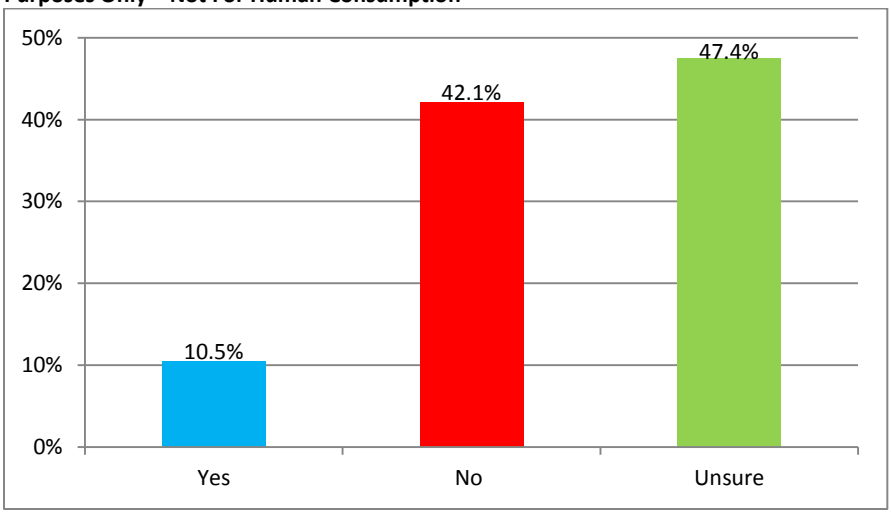
Nineteen of 108 regulators responded to the survey (17.6%). Figure 1 shows the percentage of respondents who had heard of betel nut or paan and considered betel nut or paan a food. Approximately fifty-eight percent (57.9 %) of respondents had heard of betel nut, and a little over twenty-six percent (26.3%) of respondents had heard of paan. Approximately forty-two percent (42.1%) considered betel nut a food, 10.5% did not consider betel nut a food, and 47.4% were unsure. Just over thirty-one percent (31.6%) considered paan a food, 10.5% did not consider paan a food, and 57.9% were unsure (Figure 1).

FIGURE 1: Heard of Betel Nut or Paan? Is Betel Nut or Paan a Food? (percentage)



Approximately ten percent (10.5%) of respondents would consider a religious exemption for an adulterated food if labeled: For Religious Purposes Only – Not for Human Consumption; 42.1% would not consider a religious exemption, and 47.4% were unsure (Figure 2).

FIGURE 2: Religious Exemption for an Adulterated Food if Labeled: For Religious Purposes Only – Not For Human Consumption



Conclusions

This survey reveals a lack of awareness amongst the respondents of both areca (betel) nut and paan (betel quid), and uncertainty as to whether betel nut or paan are food. The results also reveal uncertainty as to whether a religious exemption applies to an adulterated food if labeled: For Religious Purposes Only – Not For Human Consumption. The exclusive use of this product by Asian immigrants and refugees and the foreign cultural practice of chewing, consumption, and religious worship may account for the lack of investigation, enforcement, and awareness. The small sample size of respondents may reflect the reluctance of the respondents to comment about a subject they are not familiar with. Additional studies are warranted regarding areca nut and paan (betel quid) use patterns in metro areas with large Asian populations. Research should be conducted involving health care providers (especially oral surgeons and dentists) serving at-risk populations (people who practice areca nut chewing culture) regarding the prevalence of diagnosing OSF and oral cancer in relation to the general population.

Recommendations

- Provide U.S regulatory food safety professionals with evidence of the serious harm caused by areca nut and betel quid consumption.
- Examine oral sub mucous fibrosis (OSF) as an unconventional chronic food borne disease caused by consumption of areca nut.
- Educate immigrants and refugees concerning the health effects from consuming areca nut products.
- Inform health providers serving at risk populations about the likelihood of diagnosing oral sub mucous fibrosis (OSF) and other precancerous lesions and conditions.
- Regulate areca nut as an adulterated food.
- Exempt whole areca nut for religious worship when packaged and labeled: Not for Human Consumption – Religious Purposes Only.
- Build collaborations between medical centers, academia, health providers, and food regulatory agencies in the U.S. and India regarding education and measured enforcement based on thoughtful regulatory policy.
- Re-examine regulatory policy when areca nut is combined, in any formulation, with tobacco.

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References

Auluck A, Hislop G, Poh C, Zhang L, Rosin MP. (2009). Areca nut and betel quid chewing among South Asian immigrants to Western countries and its implications for oral cancer screening. Rural Remote Health. 9,1118–1125.

Awang, MN. (1986). Estimation of arecoline contents in commercial areca (betel) nuts and its relation to oral precancerous lesions. Singapore Medical Journal, 27, 317-320.

Aziz, SR. (2010). Coming to America: Betel nut and oral submucous fibrosis. Journal of the American Dental Association 141(4), 423-428.

Bunning V.K., Lindsay J.A., Archer D.L. (1997) Rapport Trimestrial de Statistiques Mondiales. World Health Statistics Quarterly, 50(1-2), 51-56.

Changrani J, Gany FM, Cruz G, Kerr R Katz R. (2006) Paan and Gutka Use in the United States: A Pilot Study in Bangladeshi and Indian-Gujarati Immigrants in New York City. Journal of Immigrant & Refugee Studies 4(1), 99-109.

Gupta MK, Mhaske S, Ragavendra, Raja, Imtiyaz. (2008). Oral submucous fibrosis – Current Concepts in Etiopathogensis. People's Journal of Scientific Research, 1, 39-44.

Gupta PC & Warnakulasuriya S. (2002). Global epidemiology of areca nut usage. Addiction Biology 7, 77-83.

Gupta, PC, Ray CS. (2004).Epidemiology of Betel Quid Usage. Academy of Medicine Singapore; 33(Supplement), 31S-36S.

International Agency for Research on Cancer. (2004). Betel-quid and areca-nut chewing and some areca nut related nitrosamines. IARC Monographs 85, 1-334.

Lindsay JA. (1997) Chronic Sequelae of Foodborne Disease. Emerging Infectious Diseases, 3(4), 443-452.

Murti PR, Bhonsle RB, Gupta PC, Daftary DK,Pindborg JJ, Metha FS. (1995). Aetiology of oral submucous fibrosis with special reference to the role of areca nut chewing. Journal of Oral Pathology & Medicine, 24, 145–152.

Nandakumar A, Thimmasetty KT, Sreeramareddy NM, Venugopal TC, Rajanna, Vinutha AT, Srinivas, Bhargava MK. (1990). A population-based case-control investigation on cancers of the oral cavity in Bangalore, India. British Journal of Cancer, 62(5), 847–851.

Pickwell SM, Schimelpfening S, Palinkas LA. (1994) 'Betelmania'. Betel quid chewing by Cambodian women in the United States and its potential health effects. Western Journal of Medicine, 160, 326–330.

Shah N, Sharma PP. (1998). Role of chewing and smoking habits in the aetiology of oral submucous fibrosis (OSF): a case control study. Journal of Oral Pathology & Medicine, 27, 475-479.

Stanley J. (2010). Confessions of a White, Middle-Aged Paan Eater. Retrieved from: http://nypress.com/confessions-of-a-white-middle-aged-paan-eater/.

Sullivan RJ & Hagen EH. (2002) Psychotropic substance-seeking: Evolutionary pathology or adaptation? Addiction 97, 389-400.

U.S. Census Bureau. (2012). The Asian Population: 2010. Retrieved from: http://www.census.gov/prod/cen2010/briefs/c2010br-11.pdf.

The Impact of Desk Audits on the Consistency of Retail Food Inspection Reports in Alaska: A Trend Analysis

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Abstract
The State of Alaska Food Safety and Sanitation Program has 25 full-time Environmental Health Officers (EHOs) located throughout the state that regulate 9,300 permitted facilities. Many EHOs are located in remote offices throughout the state. As a consequence, there may not have been consistent reinforcement of program protocols or Food Code interpretation necessary to ensure uniformity and consistency among staff. To address this concern, the State of Alaska Food Safety and Sanitation Program implemented the General Food Desk Audit outlined in the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) and recorded progress over the course of a year. This study explored the effectiveness of desk audits through a trend analysis. Results showed an improvement in staff consistency over the course of one year.

Background
Alaska has 25 full-time Environmental Health Officers (EHOs) responsible for regulating, primarily through permitting and inspection, 9,300 food establishments and public facilities. Many EHOs are located in remote locations where they are expected to work independently, and direct oversight is not practical. As a consequence, there may not have been consistent reinforcement of program protocols or Alaska Food Code interpretations necessary to ensure uniformity and consistency among staff.

Inconsistent communication has resulted in many offices developing their own inspection styles and methods within the culture of their community. These varying styles and methods include independent filing systems, interpretations on permitting, and interpretations of how to address violations found in food establishments. The inconsistency was identified as a problem by the State of Alaska Food Safety and Sanitation (FSS) Program Managers.

The State of Alaska Food Safety and Sanitation Program enrolled in the FDA's Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) in 2006. The VNRFRPS provide an outline for food safety programs to follow to become uniform and consistent. The desk audit tool provides a list of 11 key factors that should be verified during each inspection and then documented on the corresponding inspection report. Using the desk audit outlined in VNRFRPS Standard 4, the FSS Program began to assess inspection reports beginning in January 2012.

Training on the Desk Audit process and procedures began in December, 2011, which appeared to create apprehension among the EHOs. Many EHOs had not received feedback on their inspection reports since their initial training, which, for some staff, was as long as 10 years.

Problem Statement
Varying interpretation of Alaska's Food Code and program policies does not provide uniform and consistent application of inspections and enforcement, which may pose a threat to public health.

Research Question
What is the effectiveness of feedback to Environmental Health Officers using the desk audit form outlined in the VNRFRPS over the course of one year?

Methodology
Using the desk audit as a tool, seven inspections per month were randomly selected and assessed from January 1st, 2012 through December 31st, 2012. The results of the desk audit were first given to the EHO's supervisor to be reviewed with the EHO. After that, the results were entered into a database, averaged monthly, and then plotted on a graph over the course of the year.

The General Food Desk Audit addressed 11 key factors, 10 of which were observable and were chosen for the purposes of this study. The key factors that were used verified that the EHOs did the following on each inspection report:

1. Verified that the establishment was in the proper risk category;

2. Inspected the establishment at the required inspection frequency;

3. Reviewed past inspection findings and acted on repeated or unresolved violations;

4. Conducted a risk-focused inspection. This was determined by documenting the compliance status of each risk factor and intervention--through observation and investigation;

5. Provided an inspection report that is clear, legible, concise, and accurately recorded observations and discussions with establishment management;

6. Cited the proper Alaska Food Code provisions for foodborne illness risk factors and public health interventions;

7. Obtained and documented on-site short-term and long-term corrective action for out-of-control risk factors during the inspection as appropriate to the type of violation;

8. Documented discussion with establishment managers of options for the long-term control of risk factors when the same out-of-control risk factor occurred on the previous inspection;

9. Followed through with compliance and enforcement; and

10. Cited Good Retail Practices correctly.

Results

The results of the one-year trend analysis show a rise in percent compliance on the 10 key factors addressed by the Desk Audit Form (Figure 1). A decrease was observed over late spring/early summer before increasing again (Figure 2). Figure 1 and Figure 2 were calculated by taking an average of the 10 key items each month and plotting them over the course of one year.

Figure 2 - Effectiveness of Desk Audits through 2012 by Month

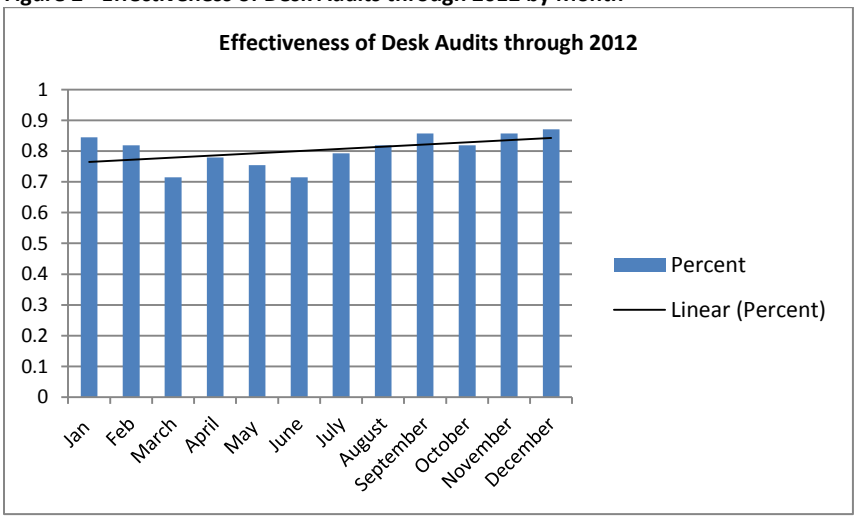
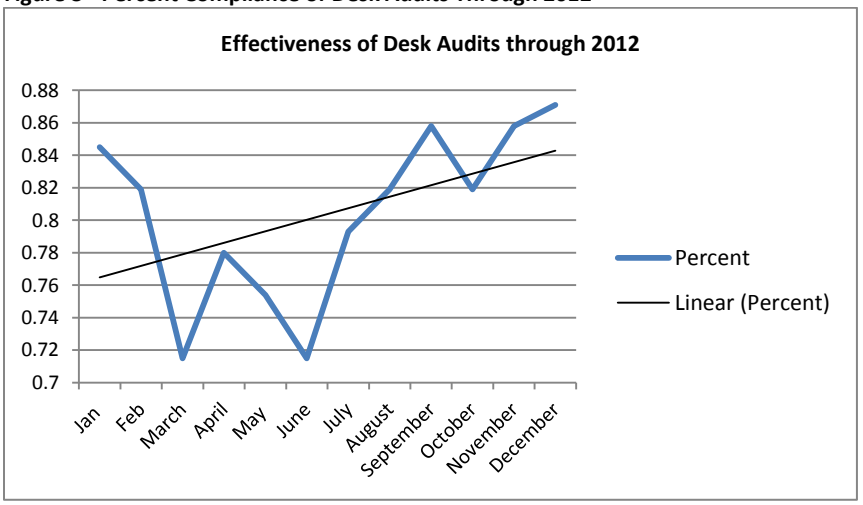


Figure 3 - Percent Compliance of Desk Audits Through 2012



Conclusions

There is a distinct upward trend in compliance, which indicates that staff reports were becoming more uniform and consistent across the state after EHOs received feedback. The dip in percentage calculated may be attributed to the hiring of five new field staff in the spring of 2012. The rise may correlate to the new EHOs learning as they are trained in the field and then released to do independent inspections.

In addition, variation within the graph may be attributed to the fact that seven random inspections were pulled each month. Within the confines of this study, every EHO did not receive feedback monthly, and feedback was dependent on the EHO's activity in the field. Since the program has 25 full-time field staff, and if a different EHO was selected for each desk audit, it would take four months for all staff members to receive feedback. Due to the random selection process, this did not happen and, as a result, some EHOs did not receive any feedback until later during the study period.

Recommendations

There were three recommendations noted during the course of this study. First, supervisors need to understand that timely review with EHOs is important to the success of the desk audits. Initially, not all supervisors were reviewing the desk audit information with staff in a timely manner (within 15 days of receiving the desk audit results). The lack of timely feedback decreased the immediate effectiveness of the desk audits in the first six months.

Second, a thorough review of the inspection protocol and marking instructions should happen before beginning the Desk Audits. Although Alaska's FSS Program staff members were trained in the protocols and marking instructions, the information was not reviewed right before starting the Desk Audits

The third recommendation would be to document all key questions pertaining to the desk audit, food code, or program policies and review them with all staff. Consistent review and uniform communication reinforces the training to EHOs that have had feedback through the desk audits and provides information to the EHOs who haven't.

Acknowledgments

I would like to thank the International Food Protection Training Institute for the opportunity to participate in the Fellowship Program. I would also like to thank the International Food Protection Training Institute instructors and staff, and my mentor Cameron Smoak. In addition, I would like to thank the State of Alaska, Department of Environmental Conservation – Food Safety and Sanitation Program Staff and my supervisor, Kimberly Stryker.

Behavior Change Inspection Model: A Tool for Improving Food Safety

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Abstract
This study explored the impact of a behavior change inspectional model adopted from the Health Belief Model (HBM) on food safety at the retail level in El Paso County (EPC), Colorado. The study focused on the U.S. Food and Drug Administration (FDA) Risk Factor Violations (RFVs) cited during routine regulatory inspections. The RFVs, determined by the Centers for Disease Control (CDC) and adopted by the FDA, identify conditions known to cause foodborne illnesses. To observe the impact of this behavior change model, inspection data and foodborne illness outbreak data from EPC was collected and analyzed prior to and following the implementation of the behavior change inspection model. Additionally, input from EPC food safety specialists was collected and analyzed along with inspection routine time data. The study found a reduction in the frequency of reported FDA RFVs during routine inspections, a reduction in the incidence of food borne illness outbreaks, and a slight decrease in the time inspectors spent in a facility during routine inspections after implementation of the behavior change model.

Background
The goal of all regulatory inspections is compliance with food safety regulations. Long-term compliance in a retail food facility indicates that a facility is serving safe food. If a facility cannot achieve compliance, a food safety specialist must perform numerous follow-up inspections that can lead to warning letters, letters of non-compliance, monetary civil penalties, hearings, and license/permit revocation proceedings. These methods are collectively known as enforcement and may not necessarily lead to long-term compliance. Monetary civil penalties, which may come about during enforcement, may adversely impact relationships and may discourage future compliance with food safety regulations (Verlee 2012).

The more serious food safety violations are labeled as the U.S. Food and Drug Administration (FDA) Foodborne Illness Risk Factor Violations (RFVs). FDA RFVs are conditions known to lead to foodborne illness (U.S. Food and Drug Administration, 2006). Examples of FDA RFVs include using food from unapproved sources, cross contamination between raw animal products and ready-to-eat foods, lack of adequate hand washing (facilities and the act of), poor personal hygiene, employees working while they are ill with norovirus, bare hand contact with ready-to-eat foods, smoking/eating/drinking in food preparation areas, food temperature violations (holding temperatures as well as cooling and reheating), lack of an approved water source, and lack of proper sewage disposal.

A Colorado State Task Force has outlined “winnable battles” for the state; one of those battles centers on providing safe food for the citizens of Colorado. For the calendar year of 2011, 14.3% of all regular retail food inspections in Colorado cited three or more of the FDA RFVs (Colorado Department of Public Health and Environment, 2011). The goal is to decrease by 5% the number of inspection reports with three or more FDA RFVs

cited by 2016. The question for achieving this goal is: What strategy or strategies can food safety regulatory agencies employ to reduce the prevalence of risk factor violative conditions in retail establishments?

To help state and local agencies improve their retail food programs, the FDA has introduced the Voluntary National Retail Food Regulatory Program Standards. One of the anticipated goals of implementing the Standards is a reduction of the FDA RFVs cited during regular inspections (U.S. Food and Drug Administration, 2009). The Standards require departments to complete a self-assessment of ten different areas within their program, identify the gaps, and work toward filling in the gaps. A combination of three of these self-assessment areas (staff training and competency, industry outreach, and inspectional reviews) may help achieve the goal of reducing the prevalence of risk factor violative conditions in retail establishments.

In June 2011, along with traditional enforcement methods, the El Paso County Public Health Environmental Health Division (EPC) implemented a behavior change model for inspections. The behavior change model was implemented to address new challenges and continual non-compliance with the FDA RFVs by retail facilities. An additional issue that needed to be addressed was the lack of communication EPC had with the local industry and the other specialists.

The behavior change model employed by the EPC stems from the Health Belief Model (HBM) first introduced in the 1950s by social psychologists Hochbaum, Rosenstock, and Kegels (Glanz, Rimer, Lewis 2002, and T. Gonzales, personal communication, September 2012). The concept posits that a person will perform the necessary healthful actions if he or she believes that a negative health condition may be avoided by taking a recommended action (T. Gonzales, personal communication, September 2012). The application of the EPC model focused on the way inspections are performed.

The goal of the EPC model is to increase compliance with food safety regulations and thereby increase the safety of food being served in the retail food facilities. In this model, food safety specialists work with the owners and operators in a proactive partnership to ensure safe food is being served. The specialists conduct inspections to assess compliance with food safety regulations, note any violations, and discuss the necessity of corrective action with the owner and/or operator. The specialists explain possible outcomes of not correcting the violation, and discuss how the owner and/or operator may be able to correct the violation. Food safety specialists can provide guidance; however, they cannot specify how a violation must be corrected. After conferring with the owner and/or operator, specialists either schedule a follow-up inspection or ask for documentation to be sent to the inspector describing how the violation was corrected.

As an industry outreach strategy, EPC developed a series of colorful, one-topic handouts to aid facilities with violation corrections and remind staff how to serve safe food. Monthly staff meetings were used to discuss inspectional reviews and conduct in-service training on proper marking of the FDA RFVs, striving for consistency among specialists.
Environmental health specialists may be involved in multiple programs such as food safety, septic systems, drinking water, pools, air quality, body art, and school safety. The workload of each of these programs requires a certain number of inspections to be accomplished each day. For example, for food safety, Colorado requires two regular

inspections per facility per calendar year (Colorado Retail Food Establishment Rules and Regulations, 2006). In EPC, this requirement equates to approximately 5,000 inspections a year, or approximately 19 inspections per day by the 14 EPC food safety specialists, for food facilities. A potential benefit of the EPC model is the need for fewer follow-up inspections, which may allow inspectors to meet the workload.

Problem Statement

Regulatory agencies strive for long-term compliance with food safety regulations through the use of routine regulatory inspections. A behavior change model was implemented in El Paso County, Colorado to reduce the prevalence of violative food safety conditions in food establishments; however, no data exists regarding the impact of this model.

Research Questions

1. How did the implementation of the behavior change inspection model impact the prevalence of the FDA RFVs noted during routine regulatory inspections?

2. What is the correlation between foodborne illness outbreaks and the implementation of the behavior change inspection model?

3. How did the implementation of the behavior change inspection model impact the time spent in a food service facility?

Methodology

To address question number one (1), routine inspectional violation data was gathered for 15 months before and 15 months after implementation of the model by EPC using the Garrison Software System (an environmental health data management system used by EPC) and EPC's data analyst Christopher Wright. The data was analyzed for FDA RFVs cited per routine inspection. Quarterly averages occurring before and after implementation of the behavior change inspection model were graphed and averaged over all inspections. Statistical analysis was performed to determine significance between the averages.

To address question number two (2), foodborne illness outbreak data was gathered using the El Paso County Public Health Communicable Disease Division Database. The same time frame was utilized along with the Centers for Disease Control (CDC) definition of outbreak, defined as two or more people getting the same illness from the same contaminated food or drink. The outbreaks were graphed showing the number of incidences before and after implementation of the behavior change inspection model.

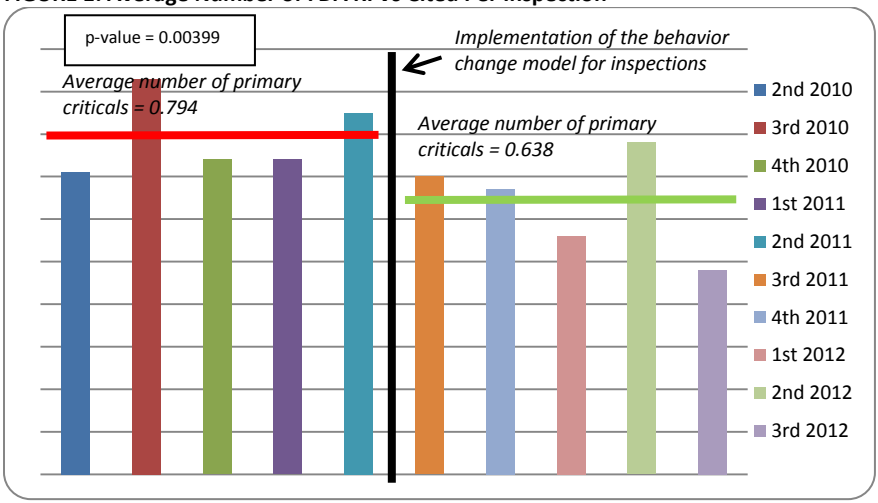
To address question number (3), data regarding the amount of time inspectors spent conducting inspections was manually gathered through a random sampling of inspectional time stamps. The Garrison Software System was used to analyze the time data from inspection reports from the time frame of 15 months before and 15 months after implementation of the behavior change model. One hundred facilities were chosen at random, from the group of facilities that had routine inspections before and after implementation of the behavior change model, and whose inspection reports contained time data. The data was analyzed and graphed. Additionally, a 5-item survey was developed and sent to food safety specialists within EPC to gather time and violation information. This information was compared with the data base results.

Results

Data analysis of the routine inspectional violations revealed an average of less than one FDA RFV citation (.794 or 79 citations within 100 inspection reports) per inspection within El Paso County, Colorado, prior to the implementation of the behavior change model. Figure 1 displays the average number of FDA RFVs per inspection (out of 100) per quarter over the 15 months prior to, and after the implementation of the behavior change model, as well as the average number of FDA RFVs over each time period. The average number of inspections with one or more FDA RFVs shows a decrease from approximately 79 per 100 inspections prior to implementing the behavior change model to approximately 64 per 100 inspections after implementation.

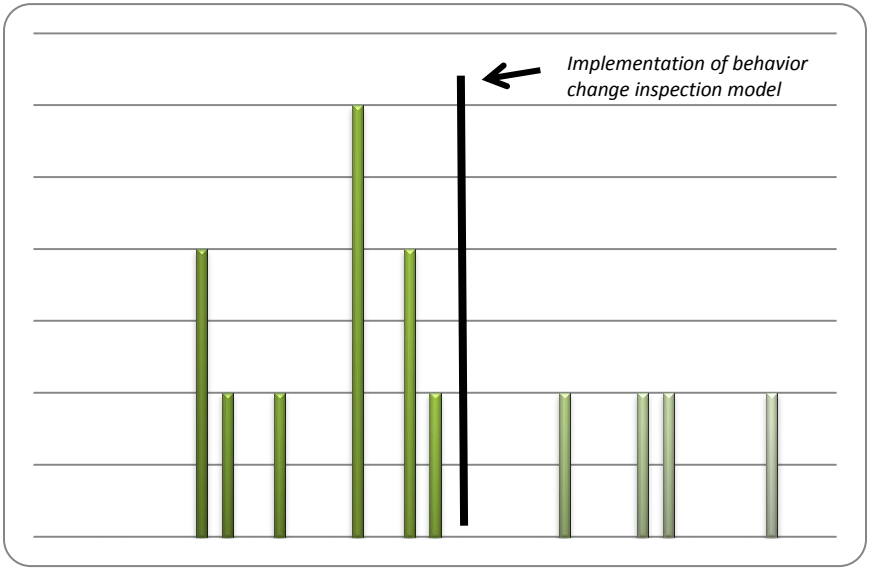
A two-tailed t-test was conducted on the monthly average number of FDA RFVs per regular inspection to see if the difference was significant. The p-value was 0.00399 for these two data sets; a p-value of less than 0.05 is significant. The reduction in number of times FDA RFVs were cited is, therefore, statistically significant.

FIGURE 1: Average Number of FDA RFVs Cited Per Inspection



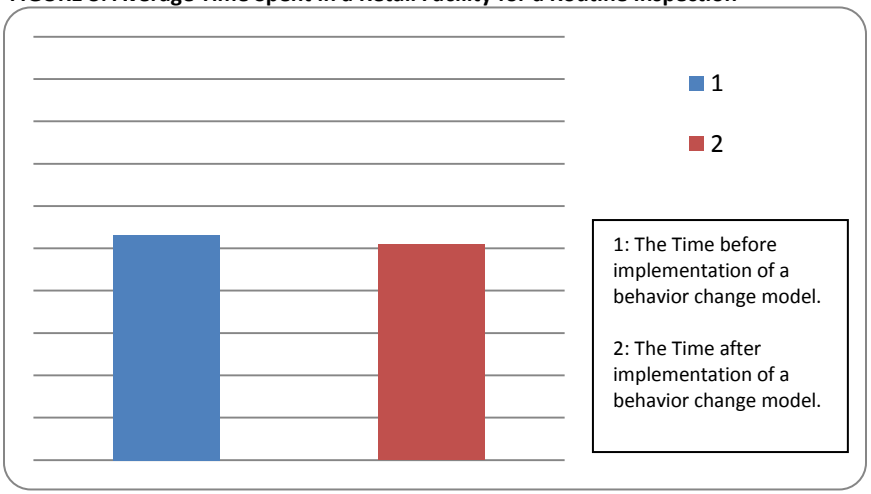
The number of foodborne illness outbreaks within El Paso County, Colorado also shows a decline. A total of 10 outbreaks occurred before implementing the behavior change model. After the implementation, 4 outbreaks occurred in a similar time frame (Figure 2). A two-tailed t-test was conducted on the number of outbreaks to see if the difference was significant. The p-value was 0.12688 for these two data sets and, therefore, not significant.

FIGURE 2: Foodborne Illness Outbreak Data



Analysis of the amount of time spent performing routine inspections revealed a change from an average of 53 to 50.82 minutes, an average of a 2.18 minute difference (Figure 3). Two minutes is not statistically significant (p-value= 0.559). Food Safety Specialists did not perceive that there was an increase in time spent in a facility and the data gathered confirms this.

FIGURE 3: Average Time Spent in a Retail Facility for a Routine Inspection



Conclusions

The results of this study indicate that there may be real value in using the Health Belief Model in the form of a behavior change model for the EPC retail food inspection program. After EPC implemented a behavior change model there were fewer FDA RFVs cited per routine inspection within the 15 months after implementation, as compared to the same time period prior to implementation. Within the same time period, EPC had fewer reported foodborne illness outbreaks. However, implementation of the behavior change model did not significantly decrease the amount of time a specialist spent in a facility. The lack of a time change may be due to the specialist spending more time focusing on the FDA RFVs and educating the operators on the importance of correcting and keeping these violations corrected (El Paso County Specialists, personal communication, October 2012).

Recommendations

Based on the results of this study, state and local departments with a retail food inspection program should consider adopting the Health Belief Model, and implementing a behavior change model for routine inspections. Implementation of a behavior change inspection model could shift the focus of a routine inspection to the FDA RFVs and educating the owner and/or operator on the possible outcomes of not correcting violations. Food safety specialists should have meetings (once or twice a month) to discuss trends of violations and to focus on consistency in citing violations. Lastly, a high level of importance should be placed on having handouts for operators to convey basic food safety concepts. The handouts should be easy to read, convey only one topic, and be colorful to attract attention. The handouts should be in the major languages of the jurisdiction. Departments that currently have materials should share those materials and other successful program elements to help other departments achieve successful results.

Future areas for study should focus on whether implementing a behavior change inspection model results in fewer follow-up inspections and fewer compliance activities. Another area of future study would be to see if the trend in reduction of FDA RFVs cited continues over the next 3 to 5 years or levels off. Lastly, a relationship between high turnover in management and violations, regardless of how much time a specialist spends on educating the operator, may exist and may require further study.

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References

Colorado Retail Food Establishment Rules and Regulations. (May, 2006). Section 11-201 A.

Colorado Department of Public Health and Environment. (July, 2011). Colorado's 10 Winnable Battles. Retrieved from http://www.colorado.gov/cs/Satellite/CDPHE-Main/CBON/1251628821910

Glanz, K., Rimer, B. K., Lewis, F. M. (Eds.). (2002). *Health Behavior and Health Education.* (3rd ed.). San Francisco, CA: Jossey-Bass.

U.S. Food and Drug Administration. (November, 2006). Reducing Foodborne Illness Risk Factors in Food Service and Retail Establishments. Retrieved from http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/ucm106205.htm

U.S. Food and Drug Administration. (April, 2009). Voluntary National Retail Food Regulatory Program Standards. Retrieved from http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ProgramStandards/ucm180269.htm

Verlee, M. (2012, July 16). Restaurants Fines Leave Bad Taste. Colorado Public Radio. Retrieved from http://www.cpr.org/#load_article/Restaurants_Fines_Leave_Bad_Taste

Colorado Industry Perception of Manufactured Food Regulatory Program Standards

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Abstract
The Manufactured Food Regulatory Program Standards (MFRPS) are a set of standards developed by the FDA, in collaboration with state food agencies, as a guide for continuous improvement for state regulatory food manufacturing programs. The Colorado Department of Public Health and Environment (CDPHE) elected to enroll in the MFRPS in 2008. The initial program assessment occurred in December 2011. One of the gaps identified was in the area of regulatory foundation. Initial assessment determined that some of Colorado's laws, regulations, and authorities are not equivalent to those of the FDA. This research explores Colorado food manufacturers' perceptions about CDPHE inspection uniformity and equivalency as well as the agency's participation in the MFRPS, and any impact on industry outreach and education activities.

Background
The United States Food and Drug Administration (FDA) partnered with state food agencies to develop the Manufactured Foods Regulatory Program Standards (MFRPS). MFRPS establishes a single, uniform, equivalent, risk-based state and federal manufactured regulatory food safety system. The MFRPS is comprised of ten component standards for the critical elements of a viable manufactured foods regulatory program. Key requirements of MFRPS are that states perform an initial assessment to identify any gaps with the MFRPS and use this information to articulate and implement program improvement plans, which are monitored and audited by the FDA.

The Colorado Department of Public Health and Environment (CDPHE) enrolled in the MFRPS in 2008. FDA completed Colorado's 18-month Program Assessment Verification Audit (PAVA) in December 2011. CDPHE's self- assessment of Colorado's manufactured foods regulatory program identified gaps and inconsistencies with Standard 1, Regulatory Foundation, equivalence with Federal laws and regulations.

Based on Colorado's PAVA, Colorado's current wholesale food regulations are not equivalent to all parts of 21 Code of Federal Regulations (21 CFR) governing food manufacturing. Colorado currently incorporates by reference nearly all of 21 CFR, Part 110, Current Good Manufacturing Practices in Manufacturing, Packaging, and Holding Human Food. However, Colorado adopted requirements referenced in the 1998 edition of 21 CFR, Part 110 which are, therefore, significantly out of date. Additionally, Colorado's wholesale food regulatory program does not have the direct statutory authority to enforce sections of 21 CFR governing thermally processed, low acid canned foods, acidified foods, hazard analysis critical control point (HACCP) systems, or seafood (21 CFR Parts 113, 114, 120, 123). Colorado regulatory staff may enforce these provisions only when acting as a commissioned agent under the state food contract with the FDA.

As a result of the program assessment findings, Colorado has made a commitment to the FDA to work to improve Colorado's regulatory foundation to achieve equivalency and alignment with the most current parts of 21 CFR pertaining to manufacturing, packing, and holding human food. In order for Colorado to make these improvements, the Colorado Wholesale Food Regulations Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food must be updated. Colorado's state statute requires stakeholder involvement for such regulatory changes.

Problem Statement

Colorado's wholesale food regulations are not equivalent to all parts of 21 CFR governing food manufacturing. There is expressed concern from CDPHE managers that non-equivalency and non-uniformity may adversely impact the quality of inspections. In addition, current education and outreach to Colorado food manufacturers may be inadequate and/or ineffective.

Research Questions

1. What are the perceptions of representatives of food manufacturing companies registered in Colorado regarding the uniformity of regulatory inspections conducted in Colorado?

2. What are the perceptions of representatives of food manufacturing companies registered in Colorado regarding the equivalency of regulatory inspections conducted by Colorado Department of Public Health and Environment to inspections conducted by the United Stated Food and Drug Administration?

3. What are the perceptions of representatives of food manufacturing companies registered in Colorado regarding the impacts of Colorado Department of Public Health and Environment participation in the MFRPS on industry outreach and education?

Methodology

A ten-item electronic survey was administered to a representative sample of Colorado food manufacturing companies using a web-based survey program. The purpose of the survey was to gauge food manufacturing company representatives' perceptions about the uniformity and equivalence of Colorado's regulatory inspections among Colorado wholesale food inspection staff as well as inspections of similar types of food manufacturers performed by FDA. The survey also gauged food manufacturing company representatives' perceptions of the impacts Colorado's enrollment in the MFRPS could have on outreach and education. Additionally, the survey collected basic information about the size of the firm, baseline awareness of the MFRPS, and participation in industry organizations.

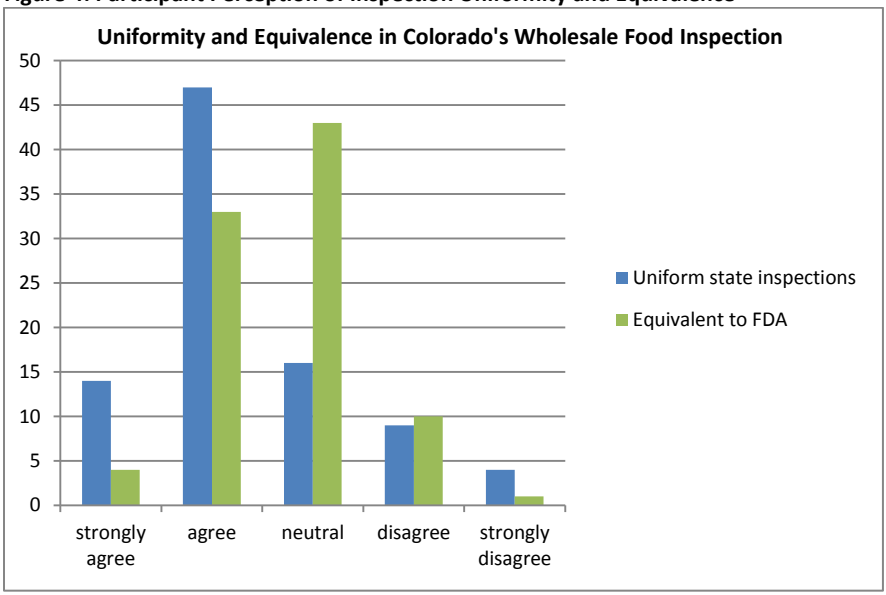
The survey was sent to 711 wholesale manufacturers in the State of Colorado registered with CDPHE. Survey recipients had approximately two weeks to complete and submit the electronic survey. Responses to the survey were blind, so that no individual firm could be identified.

Results

Ninety-one surveys were completed, for a response rate of 12.8%. The following demographic information was collected in survey question number one: Firm size based on gross annual sales: Very Small ($0-15,000); Small ($15,001-50,000); Medium ($50,001-150,000); and Large (over 150,001). The Colorado Revised Statute for wholesale food defines these categories for firm registration requirements. The survey respondent break down was as such: 34 Very Small; 14 Small; 14 Medium; and 29 Large.

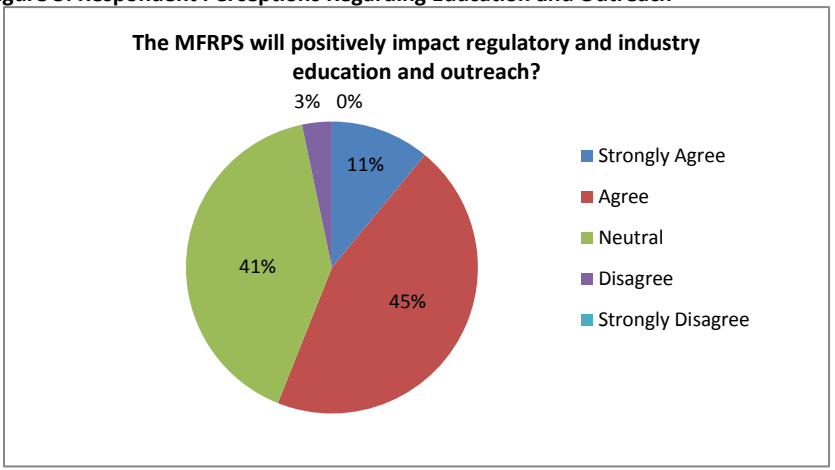
Approximately 68% of the 91 respondents agreed or strongly agreed that inspections by Colorado inspectors were uniformly conducted. When data was analyzed to compare Colorado inspection equivalency to FDA inspections, approximately 41% of industry agreed or strongly agreed (Figure 1).

Figure 4: Participant Perception of Inspection Uniformity and Equivalence



Approximately 56% of the 91 respondents agreed or strongly agreed that state involvement in the MFRPS would have a positive impact on education and outreach to stakeholders (Figure 2). Approximately 30% of the respondents that agreed or strongly agreed were registered as small and very small manufacturing operations.

Figure 5: Respondent Perceptions Regarding Education and Outreach



Conclusions

The results of this study indicate that the survey respondents, representing food manufacturing companies registered in Colorado, perceive regulatory inspections by CDPHE to be uniform. Results of the data indicate that the respondents may perceive equivalence in inspections conducted by Colorado state inspectors and those conducted by FDA. However, further study on this topic may be needed.

The study showed that the survey respondents, representing food manufacturing companies registered in Colorado perceive a positive impact on outreach and education due to their companies' involvement in the MFRPS.

Recommendations

Improving Colorado's regulatory foundation to comply with standard 1 of the MFRPS regulatory foundation may significantly change the specific content of Colorado's laws, regulations and authorities as well as the application by Colorado inspection staff. For these reasons, the perceptions of food manufacturing company representatives about regulatory expectations, uniformity, and equivalent application of food safety requirements, may need to be reassessed after full implementation of improvement plans to achieve conformance with the standards has been completed. Additionally, Colorado should develop and implement a plan to actively engage a larger representation of the food manufacturing industry leadership and management in Colorado through education and outreach.

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