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AFDO Welcomes Cohort V

Joseph Corby, AFDO Executive Director

AFDO is pleased to welcome Cohort V to the AFDO Annual Conference, and we invite you to review the research projects they have completed. The Fellowship for Food Protection program has once again produced the food safety leaders of tomorrow who will help to guide our profession and association through the continuing challenges we all face.

This year's Fellows have produced some very important and instrumental projects, and they will provide a report on these projects at our Annual Conference in Pittsburgh, Pennsylvania. And once again, a Special Edition of the AFDO Journal is being dedicated to Cohort V and their project reports. I hope everyone is able to hear the Fellows provide their project presentations at our Committee meetings and that you have the opportunity to visit with the Fellows during the Monday afternoon Poster Session we have planned. AFDO is once again extremely happy with the impact the Fellowship program and research projects have had on our organization. We offer our congratulations and sincere gratitude to all the Fellows from Cohort V.

I also 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.

The International Food Protection Training Institute [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. For this we are very thankful.

About the Fellowship in Food Protection

Gerald Wojtala, Executive Director of IFPTI

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

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

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

Along with this coursework, Fellows also develop and conduct – in collaboration with their mentors – a research project designed to advance a specific topic related to food safety. After conducting their research, Fellows write a journal-quality article (published in this issue) and create a poster and PowerPoint presentation specifically for the AFDO Annual Educational Conference. Fellows are often asked to additionally present their work at other conferences and meetings. Some projects also influence policy and are adopted for further investigation. Resolutions for agency action often arise from Fellows' projects.

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

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

Meet the Instructors and Mentors

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

Charlene Bruce retired in 2011 after serving for thirty years with the Mississippi State Department of Health. For the past twenty years she served as the Director of the Food Protection Program for the state-wide Food Retail and Food Processing Programs. Prior to becoming the Director of the Food Protection Program, she served as an FDA Rating Officer for both the Milk and Food Programs.

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

While serving as Director, the Food Protection Program of the Mississippi State Department of Health became one of the first programs nationwide to adopt the original FDA Food Code in 1993 and to lead the country as the first state program to adopt the 2009 Food Code. The Mississippi State Department of Health awarded her the Public Health Environmentalist of the Year award.

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

Following Hurricane Katrina, USDA presented Ms. Bruce with the Gulf Relief/Supporting our Neighboring Communities medal. She has been involved in training and advisory positions with the Conference for Food Protection (CFP), the National Environmental Health Association (NEHA), the National Association of County and City Health Officials (NACCHO), and the Food and Drug Administration (FDA) Training Branch.

Ms. Bruce served as President of AFDO and AFDOSS. She was awarded the Eugene H. Holeman Award for outstanding service to AFDOSS. She has served on numerous AFDO and AFDOSS committees. Charlene was awarded the Harvey W. Wiley Award at the 119th AFDO Annual Educational Conference on June 23, 2015.

The Harvey W. Wiley Award is AFDO's most prestigious award. It is presented to a regular or honorary member for exceptional service to the state or nation in the performance of duties and responsibilities in the administration and enforcement of food and drug law and/or consumer protection laws and demonstrated promotion of the objectives of the Association.

Ms. Bruce received her B.S. Degree from The University of Southern Mississippi and her M.S. Degree in Food and Dairy Science from Mississippi State University. Mentor to Norman Arroyo-Llantin, Brandon Morrill, and Priya Nair.

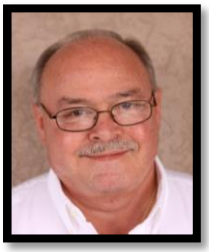
Cameron Smoak joined the Georgia Department of Agriculture in 1976. Mr. Smoak served in various positions within the agency over a period of 30 plus years. He served as the Assistant Commissioner of the Georgia Department of Agriculture's Consumer Protection Division from 1995 until his retirement January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

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

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

Mr. Smoak currently works as a consultant in the area of food safety, food defense, and crisis management. His consultancy projects include work with WinWam Software Inc., Uriah Group, USAID, the Georgia Department of Agriculture, CRA, Inc., The University of California Davis Western Institution for Food Safety & Security, the University of Tennessee Center for Agriculture and Security and Preparedness, and the Louisiana State University National Center for Biomedical Research & Training.

The USAID project involved foreign travel to Egypt as part of a project to establish a new single Food Safety Agency. The purpose of the new food safety agency is to help improve Egypt's domestic food safety and to enhance their international reputation for the safety of food products processed and exported by Egyptian businesses. He served as the expatriate consultant on the Inspection Work Group responsible for setting up the new field inspectional sector of the Food Safety Agency. Mentor to Jason Guzman and Adam Lewis

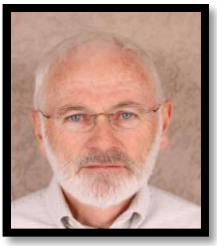


Dan Sowards retired in 2010 as the Food and Drug Safety Officer for Texas, and was employed for 37 years in food and drug safety by the Texas Department of State Health Services. He served in many different capacities during those years, including director of the Manufactured Foods Division (MFD), and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

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

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

which developed FDA's policy on reviewing genetically modified foods and the approval of the use of Recombinant Bovine SomatoTropin Harmone (RBST) for use in dairy cattle. Mr. Sowards is one of the original instructors for the IFPTI Fellowship beginning with Cohort I in 2010. Mentor to Gemedi Geleto.



Steve Steinhoff worked as a food safety professional at the Wisconsin Department of Agriculture, Trade and Consumer Protection for 36 years. For more than 18 of those years Mr. Steinhoff was the administrator of the Department's Division of Food Safety. As Administrator of a division comprised of approximately 200 food protection professionals and support staff, he led statewide programs in the areas of manufactured food, retail food, meat inspection, dairy manufacturing, and dairy production. In this leadership role, he also was responsible for management of the division's budget and personnel functions as well as liaison and collaboration with other divisions, the Office of the Secretary, other state and federal agencies, and the state legislature.

Mr. Steinhoff was an active member of the federal-state team that authored the FDA's Manufactured Food Regulatory Program Standards. He also was a member of an FDA cadre that delivered training to both federal and state food safety regulatory personnel on auditing state manufactured food regulatory programs.

Currently, Mr. Steinhoff is employed on a contract basis as a course developer and instructor by the International Food Protection Training Institute (IFPTI) and the National Center for Biomedical Research and Training (NCBRT) at Louisiana State University (LSU).

Professionally, Mr. Steinhoff is a Past-President of AFDO, and its regional affiliate, the North Central Association of Food and Drug Officials (NCAFDO). Mentor to Brendon Gibbs, Kirsten Knopff, and Nikeya Thomas

Dr. Norman Arroyo-Llantin was born in Puerto Rico and grew up with a passion for agriculture and innovative technologies (inherited from his grandparents), which led him to obtaining a bachelor's degree in agricultural engineering from the University of Puerto Rico. Through a fermentation course, he discovered food science and technology, which matched the two fields he enjoyed most: agriculture sciences and technology. This discovery led him to pursue a master's degree in food science and technology with a concentration in food microbiology from the University of Puerto Rico. He then completed a doctoral degree at Mississippi State University, Department of Food Science, Nutrition, and Health Promotion. After completing his studies, he worked for the Mississippi State Department of health on a national food safety initiative to coordinate and implement the food safety Rapid Response Team and the Manufactured Food Regulatory Program Standards (MFRPS). Currently, he serves as an Environmental Manager at the Florida Department of Agriculture and Consumer Services, Division of Food Safety, managing the quality assurance program, assisting in the implementation of the MFRPS, developing guidance documents, assisting in foodborne illness investigations, and providing scientific knowledge to the bureau. **Mentor: Charlene Bruce**

Gemedi Geleto graduated from Oregon State University with a degree in microbiology in 2004, then began his career as an Environmental Health Specialist with the Washington County (Oregon) Department of Health & Human Services. He served in different programs within the department for over a decade, conducting inspections of retail food establishments, daycare centers, and swimming pools, and investigations of foodborne illness outbreaks and consumer complaints. As a State Standardized Training Officer, Gemedi trained local food safety regulators to properly interpret and apply the Oregon Food Code. Prior to joining Washington County Oregon, Gemedi worked as a Lab Assistant in the Biochemistry and Biophysics Department at Oregon State University from 2003 to 2004. **Mentor: Dan Sowards**

Brendon Gibb earned a B.S. in medical studies from Our Lady of the Elms College and is currently pursuing a graduate degree in epidemiology. He is an Environmental Health Specialist for Carson City Health and Human Services in the Department of Disease Prevention and Control. He started his career in his hometown at the Chicopee Health Department where he conducted routine inspections in retail food facilities and tattoo parlors, conducted mosquito surveillance, and coordinated temporary events. Currently he performs regulatory inspections at retail and manufacturing food establishments, reviews plan approvals, and leads the vector-borne disease program in Carson City. Brendon is also an integral part of the Retail Food Regulatory Program Standards team. **Mentor: Steve Steinhoff**

Jason Guzman is a Training and Standardization Officer for the Texas Department of State Health Services in the Public Sanitation and Retail Food Safety Group. In this role, he trains and standardizes state and local health department inspectors to conduct risk-based inspections on retail food establishments to facilitate compliance with federal code, state rules, and the FDA Voluntary National Retail Food Regulatory Program Standards. Additional functions include presenting educational and training programs at workshops, seminars, professional associations, and for the general public. Working in the Policy Standards and Quality Assurance Department also allows him to collaborate on the development and revision of the Texas Food Establishment Rules, which are the minimum food safety rules for the State of Texas. Prior to this position, he worked in public health performing retail food safety, environmental, and air quality inspections with the City of San Antonio Metro Health Department. He earned his undergraduate degree from St. Mary's University in San Antonio, Texas, majoring in biology with a minor in chemistry. **Mentor: Cameron Smoak**

Kirsten Knopff is the Business and Quality Management Supervisor for the Minnesota Department of Agriculture – Food and Feed Safety Division (FFSD) in Saint Paul, Minnesota. Prior to her current position, she was the Regulatory Standards, Training, and Outreach Coordinator for FFSD and also worked for a food ingredient company in Chicago as a Regulatory Coordinator. Kirsten earned a B.S. in Food Science from the University of Wisconsin – Madison and then completed an MBA from the University of St. Thomas with a focus in management and leadership. Kirsten is currently the President of the North Central Association of Food and Drug Officials (NCAFDO). **Mentor: Steve Steinhoff**

Adam Lewis received his Bachelor of Science in Nutrition & Dietetics from the University of Minnesota. He is currently employed by the State of Minnesota Department of Agriculture (MDA), working as an Agricultural Consultant. Adam was hired as an Agricultural Specialist at MDA in October of 2013. He was nominated for Emerging Inspector of the Year Award in 2014. In 2015, Adam was accepted into the IFPTI Fellowship Program. While completing the fellowship program Adam was promoted to Agricultural Consultant where he reviews HACCP plans at the retail level, is a contact point for a delegated agency, and continues to conduct field inspections. Adam is a Certified Food Protection Professional with 7 years' professional experience working and managing in food service with 2 years of experience regulating retail and manufactured food facilities in Minnesota. **Mentor: Cameron Smoak**

Brandon Morrill is a sanitarian in the food safety protection program with the Health Department of Northwest Michigan. He earned his bachelors from Albion College in Bio-Chemistry and is currently finishing a Master's Degree in Public Administration from Western Michigan University. As the district's standardized trainer, he is responsible for the training of food protection staff. In addition, he currently serves as a committee member for Michigan Association of Local Environmental Health Administrators (MALEHA). **Mentor: Charlene Bruce**

Priya Nair is the Environmental Assessment Coordinator for Georgia Department of Public Health – Environmental Health Section. In this role, she provides guidance in interpretation of the Rules and Regulations, Food Service for Georgia, manages the District Uniform Inspection Program, manages the grant related to the conformance of the Voluntary Program Retail Standards and trains Environmental Health Specialists in Environmental Assessment for foodborne outbreak investigations. Prior to this position, Priya worked as the EHS-Net Food program coordinator for Georgia where she managed all grant activities related to CDC (Center for Disease Control) funded EHS-Net program. She attended Ryerson University, in Canada – and received her Bachelor of Applied Science degree from the School of Occupational and Public Health, Canada. Priya worked as a Certified Public Health Inspector with Toronto Public Health for five years. Currently she is FDA Standardized as a Certified Inspection/Training Officer in Food Safety and is a Standardized Food Safety Inspection Officer in Georgia. She is the Co-Chair of the Georgia Food Safety & Food Defense Task force and has been instrumental in organizing and planning the meetings of the taskforce since 2009. Priya is a Registered Environmental Health Sanitarian with the National Environmental Health Association and a member of the Georgia Environmental Health Association. **Mentor: Charlene Bruce**

Nikeya Thomas is a Food Safety Specialist with the Virginia Department of Agriculture and Consumer Services. Ms. Thomas joined The Department of Agriculture in November of 2013, and most recently earned a "SPOT Award" for her outstanding work in the Sabra Hummus food safety inspection and recall. Ms. Thomas earned a Bachelor's of Science in Food Science and Nutrition from North Carolina Agriculture and Technical State University in 2012. She is currently pursuing a Master's Degree with Virginia Polytechnic Institute and State University in Biosecurity. She began working in the food industry by joining the Quality Assurance team with MOM Brands (Malt-O-Meal) in 2012 and then later working with Smithfield foods in 2013. She is a native of Tampa, Florida, and now calls Richmond, Virginia, her home. As the youngest of 4 siblings and raised in a military family, Ms. Thomas has held an appreciation for food safety since a young age by growing up around strawberry fields and orange groves. Witnessing this ignited her passion for one of life's greatest resources… food. **Mentor: Steven Steinhoff**

A Comparison of the Approach to Sampling Among Nine State Food Safety Programs

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Florida Department of Agriculture and Consumer Services

Abstract
Telephone interviews were conducted with nine state food safety program managers to examine the methods used to plan for sampling and their working relationship with the state's laboratory. The interviews revealed that while food safety programs plan their sampling, different factors were used among the programs to plan for sampling. These differences in sampling practices were dependent on the structure and mandate of the state agencies regulating different types of foods; as a result, the study found no uniformity among the states regarding the factors. The study recommends that future research focus on the relationship between planning all aspects of a food sampling program and the use of resources and associated costs. The study also recommends additional research to measure the relationship between effectiveness in planning and operating a food sampling program and food safety risks.

Keywords: food laboratories, food inspection program, food safety, food sampling, ISO 17025:2005

Background
Food sampling by food safety programs can be used as a surveillance tool to identify contaminated products, remove them from the market, and protect public health (Pehrsson et al., 2000; Lo-Fo-Wong et al., 2004). Sampling of high-risk products, fresh produce, and finished products may vary from state to state and may be used for surveillance, as a factor for foodborne illness outbreak investigations, during inspections, for recalls, for examining local products, or for any other activity pertinent to food safety.

Sampling of food products can be costly (Patil, 2002), and is often limited based on funding, resources, and laboratory capacity. Due to the wide variety of food products, some federal inspection programs have established sampling plans based on data collected from their regulated food establishments (U. S. Department of Agriculture [USDA], 2010). Federal agencies have provided general sampling guidance, but may not reflect state food safety program needs (U. S. Food and Drug Administration [FDA], 2015). To support these efforts, the FDA has provided funding through the use of cooperative agreements to assist state food safety programs and laboratories in making infrastructure improvements necessary to build an integrated food safety system. Cooperative agreements include the Retail and Manufactured Program Standards and ISO (International Organization for Standardization) 17025:2005 accreditation for laboratories (FDA, 2015). ISO is an international accreditation organization that identifies requirements for testing, calibration, and sampling (ISO, 2010). ISO 17025:2005 is used by laboratories to achieve a national integrated food safety system by preparing food-testing laboratories for quality, administrative, and technical operations. As a result, state and federal programs are strengthening their sampling efforts by strategically planning sampling to protect public health (USDA, 2013).

Federal agencies provide guidance on sampling and analysis of food products, but the guidance is only based on a national initiative and may not be reflective of state sampling needs. There may be a lack of guidance on developing and implementing sampling programs that is reflective of the state needs. Planning in advance for sampling using pre-determined factors may enable food safety programs to make efficient use of resources, time, and program funding, and prevent contaminated product from reaching the end consumer.

Problem Statement

The factors used among food safety programs regarding planning for sampling of food products are unknown.

Research Questions

1. Do state food safety programs that conduct sampling take a uniform approach to plan sampling of food products?

2. Do food safety programs that conduct sampling use pre-determined factors to plan for sampling?

Methodology

Nine food safety managers or designees of manufactured and retail food programs were interviewed via telephone. Only state food safety programs with a laboratory component as part of their inspection program were selected. The lists of state programs were found by using directories of the Association of Food and Drug Officials (AFDO), the Manufactured Food Regulatory Program Standards Alliance (MFRPA), and the Association of Public Health Laboratories (APHL). The food safety programs surveyed were from the West (n=1), Midwest (n=3), Northeast (n=1), and the South (n=4). Seven questions were developed and used to collect data and to capture general information about their sampling program. Questions used during the interview gathered information regarding 1) the sampling program; 2) whether sampling was for surveillance or complaint-based; 3) the frequency of sampling; 4) whether the program was ISO 17025:2005 accredited; 5) whether there were written sampling procedures regarding what to sample; 6) whether there was planning between inspection and laboratory programs; and 7) the factors used to determine the approach to sampling. The study population included state departments of health (n=3), a state department of environmental conservation (n=1), and state departments of agriculture (n=5). Answers to the interview questions were documented and Excel was used to analyze the data.

Results

All of the state food safety programs had written sampling procedures that included collection methods, frequencies, and number of samples. The majority (78%) of these food safety programs worked with their laboratories to plan for sampling. The remaining respondents (22%) worked without consulting their laboratory, and sampling plans were developed solely within the inspection program. Furthermore, the majority (78%) of the programs collected surveillance and complaint-based samples that included samples of finished food products and samples related to confirmed foodborne illness investigations, respectively. The remaining respondents collected samples for surveillance purposes only of finished products at retail and manufactured food facilities.

ISO 17025:2005 accreditation of the laboratories had been achieved by only 56% of the programs, with the remaining programs indicating that they were seeking ISO 17025:2005 accreditation (see Table 1).

Table 1

Food Safety Programs' Responses to Interview Questions

Food Safety Programs' Responses	% (*N* = 9)
Written procedures	100%
ISO accreditation	56%
Conduct surveillance and complaint-based sampling	78%
Collaboration between the inspection program with the laboratory	78%

Table 2 shows the number of samples that states reported collecting in the past year. The samples from the four Southern states varied from 3.93 to 34.54 samples per 100,000 population. A state in the West collected 9.75 samples per 100,000; in the Midwest, 1.97 samples per 100,000 population were collected; and in the Northeast, 106.08 samples per 100,000 population were collected. Two states did not report this information.

Table 2

Sample Collection by State Regions in the U.S.

Region	Samples Collected/year	Population Estimate*	Number of Samples/ 100,000
South 1	1,080	27,469,114	3.93
South 2	400	2,992,333	13.37
South 3	7,000	20,271,272	34.53
West	72	738,432	9.75
Northeast	21,000	19,795,791	106.08
Midwest	120	6,083,672	1.97
South 4	2,350	10,214,860	23.01

Note. *Data from U.S. Census Bureau 2015.

Factors used for determining sampling differed among the surveyed food safety programs, and appeared to be dependent on the programs' operations and needs (Table 3). Factors triggering sampling included food previously subject to recalls, high-risk foods, foods associated with foodborne illnesses, and local food products. The top factor reported was response to foodborne illness (n=4), while high-risk foods were mentioned by two of the respondents, along with recalls (n=2), seasonal sampling (n=1), and local trends (n=1).

Table 3

Food Safety Programs Factors Used for Sampling

Factors Used for Sampling	Number of Mentions	Percent (%) (*N*=9)
Recalls	2	22
High Risk	2	22
Local Trends	1	11
FBIs	4	44
Seasonal	1	11

Conclusions

The study found that food safety programs are planning in advance for sampling. Programs reported having written procedures for sampling, and the majority of programs (seven of nine) work with their laboratory to plan for their sampling. The remaining state food safety programs (n=2) planned sampling internally and did not integrate their laboratory in the planning process. Written procedures and collaboration with the laboratory appear beneficial to maximizing the use of resources, staff, and laboratory capacity. In addition, some of the laboratories are pursuing ISO 17025:2005 accreditation. The ISO 17025:2005 accreditation enables laboratories to have a system in place for uniformity and validation of their sample collection and analysis methods. The work toward accreditation indicates that laboratories are working proactively to standardize their processes, which will improve their ability to collaborate with other food safety programs and support the integrated food safety system.

The number of yearly samples collected was another area that differed among food safety programs, and may relate to differences in resources, staff, equipment, laboratory capacity, and geographical needs. These findings appear to indicate that food safety programs rely on specific factors within their state rather than food consumption, population, or geographical size. The most commonly-reported factor determining sampling was foodborne illness, as the majority of food safety programs conduct complaint-based and surveillance sampling, regardless of whether the programs are in departments of agriculture or health or not. In addition, the pattern of sampling is attributed in some jurisdictions to conducting manufactured and retail food inspections under the same agency. Furthermore, sampling practices are dependent on the structure or mandate of the state agencies, with some being centralized and others having multiple jurisdictions that regulate different types of foods.

High-risk products and recalls were the second highest sampling factor among the survey programs, which appears to indicate a common approach to plan for samplings.

Although the majority of the food safety programs are planning sampling in advance, factors for sampling appear to be dependent on regional regulatory needs, regardless of jurisdiction. This planning in advance appears to be an indication that state food safety programs are supporting an integrated food safety system. However, this research was not able to determine uniform factors used for planned sampling.

Recommendations

Future research should focus on whether planning all aspects of a food sampling program will affect the use of resources and associated costs.

Future research should also focus on measuring the effectiveness in planning and operating a food sampling program and its correlation with food safety risks. Measuring the effectiveness should be done by studying multi-year sampling surveillance data and comparing the data with current operating procedures.

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Perceptions by Regulators and Operators Regarding Retail Bare Hand Contact Prohibition in Oregon

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Abstract
This exploratory study examined the perceptions of food safety regulators and food service establishment operators regarding the prohibition of bare hand contact with ready-to-eat (RTE) foods in an area encompassing approximately 40% of Oregon's population. A nine-question survey was sent in 2015 to 142 local food regulators and over 1286 food service establishments in Deschutes, Washington, and Multnomah counties; the study received 217 responses. Study findings included low levels of belief in bare hand contact as a public health problem by operators (27%), but also by some regulators (67%); both regulators (33%) and operators (65%) were opposed to prohibiting bare hand contact; and roughly half of both groups believed that the only way to limit bare hand contact is by prohibition. Study recommendations include the adoption of a no bare hand contact provision given wide-spread evidence of risk and only limited problems in implementation; a need for improved education of operators and regulators regarding bare hand risks and risk reduction methods; and encouragement for operators to adopt alternatives to bare hand contact.

Keywords: bare hand contact prohibition, bare hand contact risks, food safety regulators, food service, Oregon Health Authority, public health

Background
Bare hand contact with food is one of the frequent contributors to foodborne illness outbreaks in the U.S. (Green et al., 2006). Sixty percent of reported foodborne illness outbreaks occurred in restaurants (Centers for Disease Control and Prevention [CDC], 2013) and 89% of these outbreaks were attributed to employee contamination (CDC, 2011a, 2011b). Contamination can increase by as much as 50% where bare hand contact with foods is not prohibited (CDC, 2013). Bare hand prohibition varies among states. A U. S. Food and Drug Administration (FDA) Regional Food Specialist, shared internal National Restaurant Association (NRA) data showing that 10 states permit bare hand contact, 12 states prohibit bare hand contact, and the other 28 states allow bare hand contact if a food service operator has a variance. The FDA defines variance as a written document issued by the regulatory authority that authorizes a modification of Model Food Code guidelines if, in the opinion of the regulatory authority, a health hazard will not result from the modification (FDA, 2009).

The Oregon Health Authority did not adopt a bare hand prohibition in 2012 during the Food Code adoption process due to industry pressure (LeTrent, 2012). Anecdotal evidence from food safety regulators suggests that Oregon food service operators do not understand that bare hand contact is a significant contributor of foodborne outbreaks (Russell, 2012, June 28). In email communications from an Oregon Health Division regulatory official and a Washington County Oregon regulatory official, unpublished Oregon outbreak database report from 2011-2014, shows that bare hand

contact was a contributing factor in 11 foodborne outbreaks involving 302 people, nine hospitalizations, and one death.

Problem Statement

The Oregon Health Authority's adoption of the 2009 FDA Food Code did not include the bare hand contact prohibition related to ready-to-eat (RTE) foods despite national evidence that bare hand contact is a contributing factor to foodborne illness outbreaks in Oregon.

Research Questions

1. Why do food service operators oppose a bare hand contact prohibition?

2. What actions can be taken to avoid bare hand contact within regulated industry without a bare hand contact prohibition rule?

3. How can regulators address industry concerns regarding a bare hand contact prohibition rule?

Methodology

A nine-item electronic survey was developed with the assistance of experienced regulators. The survey included three demographic questions followed by six questions related to bare hand contact with RTE foods in food service establishments. The questions were: 1) What does the term "bare hand contact" with RTE foods mean to you? 2) Do you think "bare hand contact" with RTE foods is a public health problem? 3) Is "bare hand contact" with RTE foods a major contributing factor in foodborne illness outbreaks? 4) Should the Health Department prohibit "bare hand contact" with RTE foods? 5) A. Would you have concern if the Health Department prohibited "bare hand contact" with RTE foods? B. What would concern you? 6) A. Are there ways to limit "bare hand contact" with RTE foods without a stringent "no bare hand contact" requirement by the Health Department? B. Please write the best ways to limit "bare hand contact" with RTE foods.

After a pilot test, the survey was sent to operators working in five types of food service establishments: fast food restaurants, sit-down restaurants, mobile food units, national chain restaurants, and regional chain restaurants. Distribution was accomplished with assistance from the Environmental Health Departments in three counties during November and December 2015: Washington County sent the survey to 526 establishments; Deschutes County sent the survey to approximately 700 establishments; and Multnomah County posted a link to the survey on its web site. These counties comprise roughly 40% of Oregon's population, a wide urban-rural mix, and a great variety of food service establishments. The survey was also sent to 142 county Environmental Health Department regulators in the entire State of Oregon who supervise or carry out inspections of food service establishments. Responses to the six questions related to bare hand contact were analyzed in order to address the research questions given above.

Results

A total of 165 operator responses were received; 98 from Washington; 52 from Deschutes; and 31 from Multnomah Counties. Sixteen of the respondents had restaurants both in Washington and Multnomah Counties. Of those 16 respondents, four were national chain restaurants. Two of the respondents in both Multnomah and Washington Counties owned regional chain restaurants. Three of the respondents operated mobile

food units in both Multnomah and Washington Counties. A total of 46 regulator responses were received representing 13 of Oregon's 36 counties. Three regulator responses came from county epidemiologists. The results are summarized below.

The survey questions began by examining the meaning of the term "no bare hand contact." For both groups, "no bare hand contact" was associated with "no glove use." The study then used two parallel questions to assess the respondents' perceptions of bare hand contact risk by asking whether "bare hand contact" is a public health problem and whether "bare hand contact" is a major contributing factor in foodborne illness outbreaks (Table 1). Regulators were positive about both (67% responded affirmatively to each question), but the majority of operators (56% and 52%) believed the opposite. However, of interest is that the national chain restaurant operators were more positive (50% and 44%) than other types of operators regarding whether bare hand contact is a public health problem. The survey then sought to determine whether the respondents believed that bare hand contact with RTE foods should be prohibited. In general, the responses indicated that barely half the regulators and less than one fourth of the operators support a prohibition.

Table 1

Perception of bare hand contact by regulators and operators

		Perception of Bare Hand Contact								
		Public health problem?			Contributor to foodborne illness?			Should be prohibited?		
Respondents	*n*	Yes (%)	No (%)	Not sure (%)	Yes (%)	No (%)	Not Sure (%)	Yes (%)	No (%)	Not Sure (%)
Regulators	43	29 (67%)	8 (19%)	6 (14%)	29 (67%)	9 (21%)	5 (12)	21 (49%)	14 (33%)	8 (18%)
Operators	165	45 (27%)	92 (56%)	27 (16%)	39 (24%)	85 (52%)	40 (24%)	35 (21%)	107 (65%)	23 (14%)
Sit-Downs	77	18 (23%)	48 (62%)	11 (14%)	14 (18%)	44 (57%)	19 (25%)	12 (15%)	54 (68%)	11 (14%)
Fast Food	44	13 (30%)	27 (61%)	4 (9%)	10 (23%)	29 (66%)	5 (11%)	13 (30%)	29 (66%)	2 (4%)
National Chain	18	9 (50%)	6 (33%)	3 (17%)	8 (44%)	9 (50%)	1 (6%)	6 (32%)	11 (58%)	1 (6%)
Regional Chain	20	2 (10%)	14 (70%)	4 (20%)	2 (10%)	12 (60%)	6 (30%)	3 (15%)	13 (65%)	4 (20%)
Mobile Units	24	6 (25%)	13 (54%)	5 (21%)	4 (17%)	12 (50%)	8 (33%)	4 (17%)	15 (62%)	5 (21%)

Note: Operators could be counted twice depending on how they answered survey questions. Some operators can identify as both sit-down and national chain restaurants, while others may identify as fast food and national chain restaurants. If we add up these responses, they would be higher than the total number (164) of operators.

The study then sought to determine if the respondents would have concerns if the Health Department prohibited bare hand contact with RTE foods. Overall, operators were more concerned (56%) about such a prohibition than regulators (28%). Both operators and regulators believed glove use would provide food workers with a false sense of security and would result in improper handwashing. Additionally, the operators cited cost and the environmental impact of glove use as concerns related to a bare hand contact prohibition more often than the regulators. When compared with other operators, regulators and national chain operators were less concerned with a bare hand contact prohibition (Table 2).

Table 2

Concerns with prohibition of bare hand contact

Respondents	*n*	Yes (%)	No (%)	Not Sure (%)	Security	Wash	Glove	Waste	Glove $
Regulators	43	12 (28%)	27 (62%)	4 (9%)	2	4	10	1	
Operators	163	91 (56%)	59 (36%)	13 (8%)	12	28	56	8	7
Sit-Downs	78	50 (64%)	24 (30%	4 (5%)	7	18	33	7	4
Fast Food	43	27 (63%)	15 (35%)	1 (2%)	6	8	19	3	1
National Chain	18	7 (39%)	10 (56%)	1 (5%)	1	3	2	0	1
Regional Chain	20	13 (65%)	4 (20%)	3 (15%)	3	3	7	0	0
Mobile Units	23	10 (44%)	9 (39%)	4 (17%)	1	1	6	1	0

Legend: “Security”: False sense of security; “Wash”: Improper handwashing; “Glove”: Improper glove use; “Waste”: Waste and environmental issues; “Glove $”: Cost of gloves.

The survey concluded with a question that asked for ways in which operators might limit bare hand contact in the absence of a state prohibition. Roughly half of the regulators and the operators thought that operators could do so (Table 3). Operators reiterated the importance of handwashing and education when asked about how to limit bare hand contact in the absence of a bare hand contact prohibition rule. While both groups mentioned handwashing and use of gloves and utensils, the operators frequently mentioned use of gloves and education while the regulators did not.

Table 3

In the absence of a state prohibition, can bare hand contact be limited, and how?

Respondents	*n*	Yes (%)	No (%)	Not Sure (%)	Wash	Tongs	Utensils	Paper	Gloves	Educa-tion
Regulators	43	24 (56%)	13 (30%)	6 (14%)	3	5	7	4	8	0
Operators	165	92 (56%)	19 (11%)	54 (33%)	26	0	30	0	27	10
Sit-down restaurants	78	50 (65%)	5 (6%)	23 (30%)	17	10	5	1	15	10
Fast food	44	18 (41%)	10 (23%)	16 (36%)	4	6	5	1	7	1
National Chain	18	8 (44.4%)	2 (11.1%)	8 (44.4%)	3	2	2	1	3	0
Regional Chain	20	13 (65%)	1 (5%)	6 (30%)	0	1	5	0	5	1
Mobile Units	24	12 (50%)	4 (17%)	8 (33%)	3	2	3	0	5	3

Legend: “Wash”: Handwashing; “Tong”: Use of tongs; “Glove”: Wear gloves; “Utensil”: Use utensils; “Education”: Increase education

Conclusion

The study concluded that there were three primary reasons for opposition to a prohibition on bare hand contact in food service establishments. First, there was a lack of acceptance that bare hand contact with RTE food is a public health problem. Second, the survey participants expressed concern that glove use would diminish handwashing by food workers and that gloves would not provide adequate public health protection. Third, the survey participants incorrectly assumed that "no bare hand contact" with RTE food meant that the Health Department was going to mandate glove use.

The study also concluded that bare hand contact can only be limited in part without a state rule. The operators believed that educating food workers on alternative methods of handling food would help limit bare hand contact. The suggested alternatives to bare hand contact included the use of wax paper, utensils, tongs, and gloves. Regulators also believed that bare hand contact could be limited by employing alternative methods. However, a significant number of operators and regulators remained opposed to glove use. The operators' perception that handwashing was adequate to protect public health, combined with their fear of food workers' false sense of protection when using gloves, led the operators to oppose glove use. The regulators were opposed to glove use for a slightly different reason: the observation of improper glove use by operators during inspection.

Recommendations

The Oregon Health Authority should adopt a "no bare hand contact" provision given the widespread evidence of foodborne illness associated with bare hand contact nationally and in Oregon, and the limited number and type of problems identified by operators in this study resulting from adoption of such a prohibition.

The Oregon Health Authority should improve the education of operators regarding the risks associated with bare hand contact, along with methods (such as glove use) to reduce those risks, especially given the limited knowledge among operators of those risks and methods found in this study.

Regulators can find ways to address concerns about glove use. Regulators can educate operators on the availability of cost effective and biodegradable gloves. In fact, the Oregon Health Authority identified cost effective gloves during the 2012 Food Code adoption process. The cost of gloves can range from one-tenth of one cent to 10 cents each depending upon the type (Fussell, 2012). Additionally, regulators can help operators understand that there are alternatives to glove use if the operators choose not to use gloves.

The Oregon Health Authority should provide training for regulators to increase their understanding of bare hand contact risks.

The Oregon Health Authority should encourage the food service industry to find and apply more alternatives to bare hand contact when handling RTE foods given the limited number of alternatives identified by respondents in this study.

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Food Safety Risk Attributed to Ionic Bond Between Quaternary Ammonium Sanitizers and Cloth Towels in Nevada

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Abstract
This study examined awareness of food safety risk due to "quat binding," which occurs when quaternary ammonium is used with a cotton or viscose cloth to sanitize surfaces. A bond is formed, preventing the sanitizer ions from making it onto food contact surfaces at the prescribed concentration, and thus inadequately deactivating all pathogens that could lead to human illness. Standardized interviews were conducted by food safety regulators at restaurants and food processing facilities in Carson City, Nevada (162) and Douglas County, Nevada (133), where 61% and 75.2% respectively use quaternary ammonium for sanitizing food contact surfaces. In Carson City, only six facilities (3.7%) surveyed were aware of the risk that quat binding presents, while in Douglas County no facilities were aware of any risk. The study concluded that knowledge of quat binding and its associated risk was almost nonexistent. Recommendations included 1) increasing the education of food safety regulators and chemical supply representatives who may instruct restaurants and food production facilities at the operational level and 2) chemical manufacturers including instructions on product labels targeting quat binding.

Keywords: cotton, food contact surfaces, food safety, ionic bonds, pathogens, quat binding, quaternary ammonium, restaurants, sanitizer, viscose

Background
Properly-sanitized food contact surfaces are critical to minimizing food safety risks associated with the growth of pathogens. According to 4-701.10 of the 2013 U. S. Food and Drug Administration (FDA) Food Code, food contact surfaces must be sanitized in order to minimize cross-contamination (U. S. Food and Drug Association [FDA], 2013). Sanitizing with chemical compounds provides a cost-effective and relatively simple approach to ensure that effectively-cleaned food contact surfaces are free of pathogens and safe for food preparation work. Three types of sanitizers are commonly used in retail food establishments: chlorine, iodine, and quaternary ammonium compounds. Chlorine—once the most prevalent sanitizer due its effectiveness and low cost—has been replaced by quaternary ammonium sanitizers, in part due to a lack of skin irritation and corrosiveness. Quaternary ammonium compounds are positively-charged ions which are highly-effective at inactivating negatively-charged pathogens such as Staphylococcus aureus, Listeria monocytogenes, and Escherichia coli (Ekhtalat, 2012).

There are essentially four factors that affect quat binding: the amount of time that the cloth spends in the sanitizer solution, the volume of the solution, the type of fabric, and the concentration of the solution (Ecolab Inc, n.d.). Researchers have discovered that the use of cotton or viscose cloths as application vehicles may cause degradation of quaternary ammonium sanitizer strength. Food establishments frequently use cotton or paper cloths to apply quaternary ammonium sanitizer solutions to food contact surfaces. Many facilities will use either a pre-mixed quaternary ammonium solution or a solution prepared according to the manufacturer's label, using water and concentrated

quaternary ammonium. A cloth is then used to transfer the solution from the bucket to a surface to be sanitized. The assumption is that the required concentration of sanitizer is applied to a surface, thus deactivating the viruses and killing the bacteria that are present. However, new research has revealed that "quat binding" decreases the concentration of quaternary ammonium chlorides and ultimately reduces the efficacy of the solution that is applied to food contact surfaces with cotton cloths. Negatively-charged surface fibers, including viscose and cotton, have been shown to bind up to 40% of the positively-charged quaternary ammonium salt, therefore limiting disinfection performance and wasting valuable amounts [of the active compound] (Condon, 2014).

To achieve disinfection, the prescribed concentration of quaternary ammonium must be applied to food contact surfaces. Quaternary ammonium chlorides, the active ingredient of quaternary ammonium sanitizers, are cationic, or have a positive charge, while the cloth fibers of the cotton cloths used to apply the quaternary ammonium sanitizer are anionic, or negatively charged. As a result, when the cloth is dipped into the sanitizer solution, the available quat chlorides form an ionic bond with the cloth, causing less of the sanitizer's active ingredient to be available to sanitize food contact or environmental surfaces. When food contact surfaces are sanitized with an ineffective level of active sanitizer, pathogens may remain. One study conducted by the U.S. Department of Agriculture (USDA) Agricultural Research Service showed that biofilms of Listeria Monocytogenes developed resistance to sanitizing agents, including quaternary ammonium, when exposed to non-microbicidal concentrations of sanitizer (Breidt, Kathariou, & Pan, 2006).

Problem Statement

The risk regarding the misuse of quaternary ammonium-based sanitizers when cleaning surfaces with a cotton cloth is unknown in restaurants and food processing facilities in Douglas County and Carson City, Nevada.

Research Questions

1. What is the level of knowledge of food workers in Carson City and Douglas County regarding the reaction that occurs between cotton cloth and quaternary ammonium-based sanitizers?

2. What methods are currently used by restaurants and food facilities in Carson City and Douglas County to reduce the risk caused by the reduction of effectiveness when using cotton cloth towels to apply quaternary ammonium sanitizers?

Methodology

Research data was collected via survey by five Environmental Health Specialists while performing their routine investigative duties at restaurants and food production facilities in Carson City and Douglas County. The survey was given to 162 out of 320 total facilities in Carson City and 133 out of 345 total facilities in Douglas County. Target facilities were those who processed, manufactured, or cooked food on-site. The five specialists collected data according to a standardized set of procedures. The data collected included the number of facilities using quaternary ammonium, the knowledge that managers and persons-in-charge had pertaining to quaternary ammonium, and their knowledge of the consequences of the ionic bond that forms when the sanitizer is applied with a cotton or viscose cloth. Data collected also included job titles of staff members interviewed;

whether the facility used quaternary ammonium in their three-basin sink, on food contact surfaces, or both; whether the person-in-charge demonstrated knowledge of 'quat binding'; whether the facility had any preventive measures in place; and the business' chemical supply company.

Results

Facilities were found to either be using bleach or quaternary ammonium for sanitizing food contact surfaces. One facility used chlorine dioxide and isopropyl alcohol in combination with quaternary ammonium-based sanitizers.

In Carson City, 99 out of 162 (61%) facilities surveyed used quaternary ammonium for sanitizing purposes. In Douglas County, 100 out of 133 (75.2%) facilities reported using quaternary ammonium as a sanitizing agent.

In Carson City, a person-in-charge at 6 out of 162 (3.7%) facilities surveyed demonstrated knowledge of quat binding. In Douglas County, there were zero out of 133 (0%) facilities where a person-in-charge was aware of quat binding. Table 1 shows that 3.7% of facilities surveyed in Carson and 0% of facilities in Douglas County were knowledgeable on the issue of quat binding.

Table 1

Use of Quat and Knowledge of Quat Binding in Carson City and Douglas County

Location	Total Facilities Using Quat	Total Aware of Quat Binding
Carson City (pop. 55,274)	99 out of 162 (61%)	6 out of 162 (3.7%)
Douglas County (pop. 46,997)	100 out of 133 (75.2%)	0 out of 133 (0%)

Of the six facilities that demonstrated knowledge of quat binding, five currently used quaternary ammonium on food contact surfaces. These five reported that they tested the quaternary ammonium concentration in the sani-buckets more frequently, and limited the amount of rags that they used with each bucket of sanitizer solution. The other facility stated they circumvented this bonding issue by using quaternary ammonium for sanitizing in the three-basin sink, but used bleach when sanitizing surfaces.

Conclusions

Knowledge of the sanitization limitations of quaternary ammonium is virtually unknown at the operational level in restaurants and food production facilities in Carson City and Douglas County, Nevada, despite the fact that the vast majority of restaurants and food production facilities use quaternary ammonium as their preferred sanitizer. With the exception of the restaurant substituting bleach for sanitizing food contact surfaces, there were no other known effective preventive measures in place. More frequent concentration testing of the sanitizer solution in the bucket prior to cloth immersion does not reveal the applied concentration of quaternary ammonium, and is not a strategy that will lead to reduction of quat binding.

While information about quat binding is available, this information is not known or understood at the operational level where preventive measures must be applied. However, when the restaurants and food production facilities were given verbal instructions concerning quat binding and its negative food safety consequences during the course of this study, the vast majority of operators asked for more information on how they could mitigate this issue and still use sanitizers to reduce the risk of foodborne illness in their establishments.

In addition, some anecdotal information from field-level chemical supply representatives encountered during data collection indicated that many did not understand quat binding and the risks this reaction presents. On two occasions, however, representatives referred the surveyor to corporate staff who demonstrated knowledge of quat binding and suggested using microfiber towels in place of cotton cloths. These instances may indicate a potential gap in knowledge within the chemical supply industry.

Similar anecdotal information suggests minimal knowledge held by inspectors in partner food safety regulatory agencies in the region covered by the study. Further research may be needed to determine level of awareness of quat binding within the chemical supply industry and food safety regulatory agencies.

Recommendations

Food safety regulators should better understand quat binding and be trained on how to educate food workers at the operational level with regard to mitigation strategies. Training may be offered in the form of classes that count for Continuing Education Units. This training should include techniques such as using a spray bottle to apply the quaternary ammonium sanitizer onto a surface and allowing the sanitizer to sit so that the active quat chlorides will bind with pathogens before being swept away with a cloth; soaking the cloth towels in sanitizer, then replacing the sanitizer solution which will push the absorption reaction past equilibrium, thus allowing more positively-charged quats to bind with negatively-charged pathogens; switching from cotton cloths or paper towels to higher polyester blends, which will reduce the effect of quat binding because polyester fiber has less of an ionic attraction (Condon, 2014); using ionized cloths or presoaked quaternary ammonium wipes that have already been balanced; and using bleach or iodine instead of quaternary ammonium if the operation would consider using other sanitizers.

Chemical supply company representatives who set up automated sanitizer processes and provide quaternary ammonium sanitizers to restaurants and food production facilities, should provide better instruction on how to use their products and avoid any of the products' limitations.

Manufacturers who produce quaternary ammonium sanitizers should add specific instructions on the chemical containers' label that address quat binding and how to avoid this limitation. Quaternary ammonium sanitizer manufacturers should address the quat binding issue by giving instructions on how to correctly use their product and whether prescribed concentrations change depending on the application process used.

Proper use and limitations of sanitizers, such as quaternary ammonium, should be covered in the new version of the FDA Food Code, which is the model for the vast majority of food safety programs and health organizations throughout the county.

Efforts to reformulate quaternary ammonium sanitizers use salts to compete with quat chlorides for position in the ionic bond with the cotton fibers. This research may lead to a more permanent solution in the future. However, in the interim, practical mitigation strategies need to be implemented at the operational level to reduce risks that result from quat binding.

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Texas Health Departments' Experiences with the Voluntary National Retail Food Regulatory Program Standards

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Abstract
This exploratory study examines influences on Texas health departments' experiences with the U. S. Food and Drug Administration's (FDA's) Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) using a ten-question email survey to 13 enrolled and 3 non-enrolled departments serving from 2,889 to 1,436,697 persons. Enrolled departments reported improvements in four areas: training standardization; improvement in policy and procedures; foodborne illness/food defense preparedness; and protocols for response to foodborne illness. The survey identified four barriers to meeting standards: lack of funding; limited staff/high turnover; lengthy and sometimes confusing auditing process; and difficulty partnering with another enrolled department to carry out standardization and audits. The study also found a similarity among enrolled departments prior to their enrollment and non-enrolled health departments. Recommendations include the creation of a dedicated website for Texas health departments to share Texas-specific information and advice regarding the Retail Program Standards; to encourage communication among the 262 local health departments regarding opportunities and overcoming barriers to implementation; to identify funding and resources for enrollees; and to provide technical information on topics such as auditing and self-assessment.

Keywords: Texas health departments, Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), retail program standards, food standards implementation, barriers to food standards implementation

Background
National uniformity among retail food protection regulatory programs has long been a subject of debate among industry representatives, regulators, and consumers; adoption of the FDA Food Code at the state, local, and tribal levels since its creation in 2001 has been a keystone in the effort to promote greater uniformity (U. S. Food and Drug Administration [FDA], 2015c). As part of that effort, the FDA's Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) were developed to identify what constitutes a highly effective and responsive retail food program in order to provide a recommended framework for food regulatory programs within which active managerial controls can best be realized (FDA, 2015c).

Texas is a "home rule" state (National League of Cities, n.d.) that allows a great degree of independence to local governments such as promulgating their own food safety ordinances. As of 2015, only 65 of 262 (25%) local governments have chosen to enroll in the Retail Program Standards since their creation in 1999 (FDA, 2015a; Texas Department of State Health Services [DSHS], 2015). In addition, these 65 enrollees are making only very limited progress toward meeting the nine Retail Program Standards (FDA, 2015b); in fact, by 2015, no department had reached compliance with all nine standards.

Problem Statement
No current published research describes the influences that bring about or hinder adoption of the Retail Program Standards by Texas local health departments.

Research Questions

1. What do Texas local health departments perceive as the benefits of enrollment in the Retail Program Standards?

2. What do Texas local health departments perceive as the barriers to entry into the Retail Program Standards?

3. What barriers have local health departments in Texas encountered after enrolling in the Retail Program Standards?

4. What are the characteristics associated with the local health departments enrolled and those not enrolled in the Retail Program Standards?

Methodology
An online survey was sent to 16 local health departments using addresses from the Texas Department of State listing of Local Public Health Organizations and the FDA's Listing of Jurisdictions Enrolled in the Retail Program Standards. The departments served populations ranging from 2,889 to 1,436,697 persons (United States Census Bureau, 2014). The survey asked why the department decided to enroll in the Retail Program Standards; which retail regulation was enforced before enrolling; which of the nine standards had been met; which of the nine standards were most challenging to meet; improvements since enrollment; the greatest areas of struggle in meeting the standards; whether there was a formal training program in place before enrolling and how the training program changed due to enrollment; the status of and issues involving the standardization officer; and a request to share their thoughts regarding the Retail Program Standards.

Results
Overall, the departments surveyed provided complete information about each of the survey questions in a prompt manner. Thirteen departments were currently enrolled in the Retail Program Standards and three were not enrolled. The departments were chosen to represent very small departments serving populations of 100,000 or less (3 respondents), medium departments serving populations between 100,000 and 200,000 (5 respondents), and large departments serving populations of 200,000 and above (5 respondents). One each of the three non-enrolled departments were in the small, medium, and large categories. Currently 26 (40%) of the 65 enrolled health departments in Texas are in the small health department category; 16 (25%) are in the medium-sized health department category; and 23 (35%) are in the large health department category.

Departments identified three reasons for enrollment: creating uniformity in inspections completed by their departments (38.5%); improving public safety policies and procedures such as creation of a foodborne outbreak framework and updating food safety policies to the most current science-based FDA Food Code (23.1%); and promoting training and establishing a criteria for training by these departments (15.4%). Two of the 13 stated that they were unsure of the original reason for enrollment.

The departments were asked which standards they have met since enrollment. Eleven of the 13 enrolled health departments have completed standards since enrollment. Two departments have completed up to seven of the nine Retail Program Standards. Large health departments tended to complete two or more standards, whereas small to medium-sized health departments seemed to have only completed one or less. Departments were also asked which of the standards after enrollment have been the most difficult for them to achieve. Five of the 13 answered Standard 2 (focused on training regulatory staff) as the most difficult; however, the results varied by department size.

Table 1 summarizes the enrolled health departments' population, standards met by 2015, and the standards that they found most difficult to meet.

Table 1

Standards completion, difficulty with standards, and department size

Health Department	Standards Completed Since Enrollment (2015)	Difficulty w/Standard	Health Department Size
Texas Department of State Health Services (DSHS)*	1, 2, 3, 4, 5, 6, 7	8	Large
City of San Antonio	1, 3, 4, 5, 6, 7, 8	2	Large
City of El Paso	1, 2, 3, 7, 8	2, 9	Large
City of Lubbock	1, 2	8	Large
Brazos County	3, 7	1, 5	Large
Williamson County	1, 2	3, 9	Large
City of Austin	2, 5	5	Large
Ector County	3	Not Answered	Medium
City of McKinney	1,2	2	Medium
City of Amarillo	0	7	Medium
City of Frisco	4	6	Medium
City of South Padre Island	1	2	Small
City of North Richland Hills	0	2	Small

*Note: "State acting as agent" where the Texas Department of State Health Services acts as the local health department for all unincorporated areas throughout Texas.

The departments were then asked about their improvements since enrolling. There were seven local health departments (53.8%) enrolled in the Retail Program Standards that had seen improvements in their training such as increased training opportunities, uniformity in their inspections, and ability to train more staff consistently. Two local health departments (15.4%) had seen improvements in development of policy and procedures including the use of a risk-based inspection frequency program for establishments conducting high-risk processes and thus increasing the frequency of inspections as

needed. Another two local health departments (15.4%) reported improvements in foodborne illness/food defense preparedness and response which encompassed improved foodborne illness outbreak investigations and the creation of systems for addressing a foodborne illness occurrence. Two local health departments (15.4%) noted no change in their organizations: one due to its recent enrollment and lack of a self-assessment and the other due to an upper-management restructuring of its retail program that led to a reduction in progress toward the Retail Program Standards.

The departments were also asked about their struggles in meeting the standards. There were seven local health departments enrolled in the Retail Program Standards (53.8%) that noted difficulty in implementing the Retail Program Standards due to lack of funding and reduced staff caused by budget cuts and employee turnover. Another barrier cited by three local health departments (23.1%) was the requirement to standardize a training officer within their departments; all three were in the large category. The departments noted this process to be lengthy, time-consuming, and difficult to achieve.

Some local health departments also noted that the requirement to conduct 25 joint inspections during training was a barrier given that the standardizing officer in larger local health departments maintains other work responsibilities and is responsible for standardization of as many as 30-40 personnel. An additional area of struggle by two (15.4%) of the enrolled health departments was the lengthy auditing process which they found confusing and the cause of delay in meeting standards. One local health department (7.7%) noted a lack of enrolled local health departments nearby that would serve to provide assistance if federal or state offices were not available (Table 2).

Table 2

Enrolled Program Improvements vs. Barriers

			Improvements				Barriers			
Health Depts. Enrolled in Retail Program Standards	Population	Health Dept. Size	Train	Policy	FBI	No Changes	Budget/ Personnel	Standard -ization Officer	Audit	Neigh-boring Juris-dictions
San Antonio	1,436,697	Large						X		
DSHS*	~1,000,000	Large	X				X			
Austin	912,791	Large							X	
El Paso	679,036	Large	X				X			
Willliamson County	489,250	Large	X		X		X			
Lubbock	243,839	Large	X			X	X			
Brazos County	209,152	Large	X				X			
Amarillo	197,254	Medium				X		X		
McKinney	156,767	Medium	X					X		
Ector County	153,904	Medium	X				X			
Frisco	145,035	Medium		X					X	
North Richland Hills	68,529	Small		X			X			
South Padre Island	2,889	Small			X					X
Results:	~5,695,143	-	53.80%	15.40%	15.40%	15.40%	53.80%	23.10%	15.40%	7.70%

*Note: "State acting as agent" where the Texas Department of State Health Services acts as the local health department for all unincorporated areas throughout Texas.

Of the non-enrolled health departments, two of the three cited a lack of budget and workforce as a barrier to enrolling in the Retail Program Standards. No other reasons were given.

The departments were also asked whether there was a formal training program in place before enrolling and how that training program may have changed after enrollment. Ten of the 13 (76.9%) enrolled local health departments had no formal training program in place for inspectors before enrolling in the Retail Program Standard but instead referred to "hands-on" and "on-the-job" training, attendance of food safety courses provided in the area, shadowing of experienced inspectors, and completing joint inspections as their training before being released into the field to complete routine inspections. The same 10 enrolled local health departments reported a change in their training programs due to completion of the standardization and training process entailed in Standard 2, including the addition of a designated training officer that carries out training and standardization of inspectors as well as attending FDA courses on risk-based inspection techniques and application of HACCP principles.

Similarly, 2 out of 3 non-enrolled health departments showed no current formal training for inspector staff. Instead they used joint inspections under the supervision of senior staff and “on-the-job” training as their approach to training new inspectors in their departments.

The departments were also asked about their standardization officer status. Ten of the 13 enrolled health departments reported having a designated training officer who completes training and standardization of staff; however, only four health departments’ standardization officers were up-to-date on training of staff.

Finally, the local health departments were asked to share their thoughts about how the DSHS might assist them regarding the Retail Program Standards. The majority of enrolled local health departments very strongly called for more assistance from the FDA and state partners including guidelines for the Training Standardization Officer. Enrolled local health departments also requested improvement in communication from the FDA and state partners; conference calls or webinars that could address specific issues and eliminate travel cost and time spent away from the office; and standard-specific courses and workshops. Other comments included a request for additional support, such as a quick reference guide regarding the requirements for standardization officers.

The non-enrolled departments did not want any involvement by the Department of State Health Services in their retail regulatory activities. They stated that they felt uniformity was not a priority to them and their current regulatory program was sufficient.

Conclusions

After enrollment, the primary benefit perceived by the surveyed local health departments was implementation of formal training programs. A limited number of departments also cited as benefits the creation of policy and procedures (two departments) and foodborne illness/food defense preparedness and response (two departments). The primary difficulties in implementation reported by enrolled departments were budget limitations; the complexity of the auditing process; and barriers to partnering with another agency to help perform the audit.

Recommendations

The study recommends that a website dedicated to the Retail Program Standards in Texas be created for the following four reasons: to share Texas-specific information and advice regarding the Retail Program Standards; to encourage communication among the 262 local health departments regarding opportunities and overcoming barriers to implementation of the Retail Program Standards; to identify funding and resources for enrollees; and to provide technical information on topics such as auditing and self-assessment. A website containing materials related to those topics is likely to address some of the problems cited by enrolled health departments in the study such as the perceived lack of guidance documents from the FDA and the State of Texas.

The website could also aid departments in addressing the barriers to entry found in the study as well as offsetting outdated information on the current FDA website. An updated contact list, easily located on a dedicated website, would encourage communication among local health departments and may solve the issue of finding similar local departments in neighboring jurisdictions that can aid in answering questions related to those specific health departments. The website would also be able to inform departments of the funding and grant opportunities available to departments that are enrolled and allow easy access to this information on the FDA website. Finally, the lengthy auditing process which caused confusion among enrolled health departments could be resolved with links and simplified guidance documents on the website that break down the process in a basic way to aid the departments that have never addressed a self-assessment and audit.

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Possible Influences of MFRPS on the Planned Adoption and Implementation of the Preventive Controls for Human Food Rule

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Abstract
The purpose of this study was to identify if state programs' level of implementation/conformance with Manufactured Food Regulatory Program Standards (MFRPS) Standard 1 – Regulatory Foundation and Standard 8 – Program Resources influence the state program's plan to adopt, and its capacity to implement the Food Safety Modernization Act (FSMA) Preventive Controls for Human Food rule (PCHF). The PCHF will have a significant impact on the way that state manufactured food regulatory programs conduct their work. Implementation by state programs of the PCHF may require legislative or rule changes, training, and additional resources. Forty-two programs are working toward implementation and conformance with MFRPS in 40 states. An online survey was conducted of the 42 programs currently enrolled in the MFRPS. State programs may be in partial or full implementation, or partial or full conformance with a Standard, depending on whether required procedures and systems are in place and working effectively. A larger relative percentage of state programs in full implementation, partial conformance, and full conformance, with Standard 1 plan to adopt the PCHF in comparison to state programs at partial implementation. There was no relationship between Standard 8 implementation/conformance and the state program's capacity for implementation of the PCHF. The author recommends training and guidance for state programs, along with investigating funding mechanisms and resources to help state programs adopt and implement the PCHF. Finally, the MFRPS should be updated to reflect the PCHF, which will require state programs to assess adoption and implementation capacity.

Keywords: Manufactured Food Regulatory Program Standards (MFRPS), Food Safety Modernization Act (FSMA), Preventive Controls for Human Food rule (PCHF), food regulatory standards, state implementation of FSMA, state adoption of FSMA

Background
The Manufactured Food Regulatory Program Standards (MFRPS) establish a uniform foundation for the design and management of state programs responsible for the regulation of food plants (U. S. Food and Drug Administration [FDA], 2013). Since 2007, state programs have enrolled in the MFRPS in different years and are at varying levels of conformance with the MFRPS due to enrollment dates, resources, and agency support. There are ten distinct standards in the MFRPS, but this study limits analysis to Standard 1 – Regulatory Foundation, and Standard 8 – Program Resources. Standard 1 describes the elements of the regulatory foundation used by a state program to regulate food plants, and Standard 8 describes the elements for assessing the resources (staff, equipment, and funding) needed to support a manufactured food regulatory program (FDA, 2013).

Forty-two programs are working toward implementation and conformance with MFRPS in 40 states. (FDA, 2016). Based on draft definitions in the 2016 version of the MFRPS and from U. S. Food and Drug Administration (FDA) audit staff, state programs are assigned a

full implementation audit status when procedures and systems are in place, but the state program is unable to demonstrate the procedures and systems are being used. An audit status of full conformance means that a state program is using and can demonstrate the use of procedures and systems required by the Standard. The FDA conducts audits of state program implementation with the Standards every 18, 36, and 60 months. During an audit of a state program, a Standard status of partial or full implementation is assigned, and conformance is determined for each Standard. If a state program is found to have fully implemented all of the standards, the auditors will evaluate the program for full conformance.

The Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4, 2011 (FDA, 2015a). Since then, the FDA proposed a number of new rules, updated these rules based on public comment, and published several of the new rules. The Final Rule for Preventive Controls for Human Food (PCHF) was published by the FDA in September 2015 in 21 CFR Part 117 (FDA, 2015b). The industry has specific timelines for compliance: between one to three years depending on size and income limits, to comply with the PCHF. During this time, state programs are examining their legal authorities to determine if they have the legal authority necessary to adopt this new rule. Assessments are also being carried out to determine the additional programmatic resources required to conduct preventive control inspections.

The MFRPS have significantly changed many manufactured food state inspection programs since the Standards require written procedures, training and evaluation documentation, and other accountabilities. However, the PCHF will change expectations of manufactured food inspection further in the next few years, due to the new requirements in the rule. Because the PCHF have not yet been implemented, there is a lack of research related to state programs' intent regarding the adoption of the PCHF rules or if state programs have the capacity to implement the new rules. If state programs do not have the legal authority, capacity, or desire to adopt the preventive control rule, state programs may have the option of using FDA credentials during FDA contract inspections to conduct inspections using the PCHF.

Problem Statement

Whether implementation of and conformance with the MFRPS Standards 1 and 8 effects a state program's plan to adopt, or the state program's capacity to implement, the PCHF is not known.

Research Questions

1. What are the state programs' current levels of implementation/conformance with MFRPS Standard 1, Regulatory Foundation, and Standard 8, Program Resources?

2. What are the state programs' plans to adopt and capacity to implement the PCHF?

3. Does a state program's level of conformance with the MFRPS Standard 1 effect the likelihood that a state program will adopt the PCHF?

4. Does a state program's level of conformance with the MFRPS Standard 8 effect state programs' capacity to implement the PCHF?

Methodology

An electronic survey was sent to manufactured food program managers and MFRPS coordinators for the 42 state programs enrolled in the MFRPS as of October 2015. Contacts for state programs were identified using the MFRPS enrollment directory as of October 29, 2015, the Manufactured Food Regulatory Program Alliance (MFRPA) attendee list from the 2015 MFRPA meeting, and the Association of Food and Drug Officials (AFDO) Directory of State and Local Officials (DSLO) as of October 29, 2015. The survey was distributed by email and responses were collected via SurveyMonkey® and/or by email attachment, based on respondent preference. The survey was conducted between October 2015 and December 2015. Survey questions captured general descriptive data for each state program, MFRPS cooperative agreement information, and data related to the state program's implementation and conformance with Standards 1 and 8 of the MFRPS.

State programs provided the designation of partial implementation, full implementation, and full conformance given during their last audit. Although not an official audit status, for this study an additional status of partial conformance was provided as a response option to identify states that felt they were partially conformant with either Standard 1 or 8. The survey also collected data regarding the state's plan to adopt the PCHF rules and the capacity of the state program to implement the PCHF. The survey tool did not provide a contextual definition of "capacity" but allowed the respondent to interpret these words based on the respondent's perception.

Results

Standard 1 Implementation/Conformance and Plan to Adopt the PCHF

Twenty-nine of the 42 state programs (69%) provided complete answers to the survey. Seventeen of the 29 state programs (59%) responded that they plan to adopt the PCHF. Twelve (41%) replied that they do not know if they will adopt the PCHF. Zero state programs responded that they do not plan to adopt the PCHF at this time. Figure 1 shows the state programs at each level of implementation and conformance with Standard 1 – Regulatory Foundation and how the level corresponds to the state programs' intent to adopt the PCHF.

State programs in full implementation, partial conformance, and full conformance with Standard 1 plan to adopt the PCHF at a higher rate 12/17 (71%) than state programs currently in partial implementation 5/12 (42%). State programs in full implementation, partial conformance, and full conformance have completed and legally reviewed MFRPS Standard 1 self-assessment, a document that assesses the state's authority in comparison to the FDA's authority, and have a written plan/procedure for an annual review to determine equivalency between state and federal regulations at the time of their last FDA MFRPS audit. State programs in partial implementation may not have completed the self-assessment or may not have a written plan for an annual review of regulations at the time of their last audit.

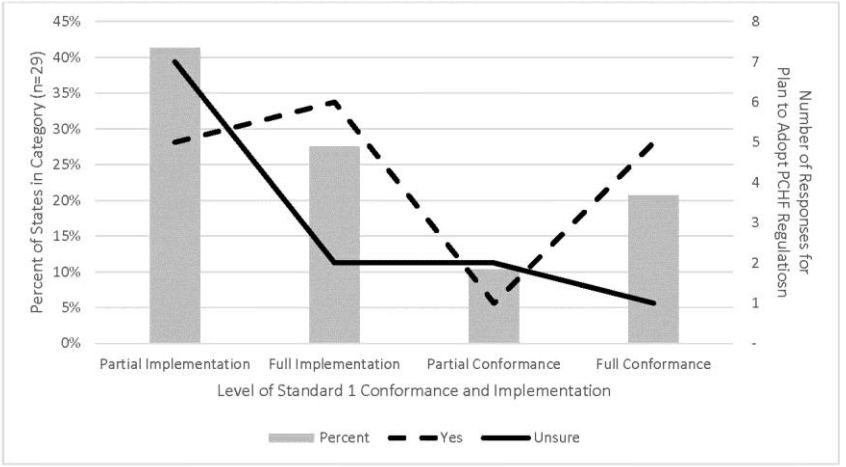

Figure 1. Standard 1: Implementation/Conformance and the Plan to Adopt the PCHF Regulations

Standard 8 Implementation/Conformance and Capability to Implement the PCHF
Nineteen of the 29 respondents (66%) intend to implement the PCHF and conduct inspections using the new rules. Nine respondents (31%) responded that they are unsure if the program will implement the PCHF and conduct inspections using the PC rules. One respondent (3%) did not answer the question.

The survey also asked respondents to consider their state program's perceived capacity to implement the PCHF. Five of the 29 (17%) respondents believed that their state programs have the capacity to implement the PCHF, 13 (45%) did not think that their state programs have the capacity, and 10 (35%) were unsure if their state programs have the capacity. One (3%) state did not answer this question.

Respondents conveyed the need for additional funding (90%), inspection staff (80%), industry partnerships (55%), equipment (38%), and office space (21%) in order to implement the PCHF. Along with specific resources required, respondents stated the availability of training (38%) and legislative/leadership support of the PCHF (28%) are other possible obstacles to implement PCHF.

Figure 2 shows state programs at each level of implementation and conformance with Standard 8 – Program Resources and how the level corresponds to the perceived capacity of the state program to implement the PCHF regulations. Standard 8 requires state programs to assess the current program resource needs and identify staff, funding, and equipment required to maintain full conformance with each Standard.

Based on survey responses, 2/2 (100%) of state programs in full conformance with Standard 8 are unsure if they have the capacity to implement the PCHF. Of those state programs in partial conformance with Standard 8, 2/7 (29%) believe their programs have adequate capacity to implement the PCHF, while 1/11 (9%) in full implementation responded that their programs have adequate capacity, and 2/9 (22%) of state programs

partially implementing Standard 8 responded that their programs have adequate capacity for implementation of the PCHF.

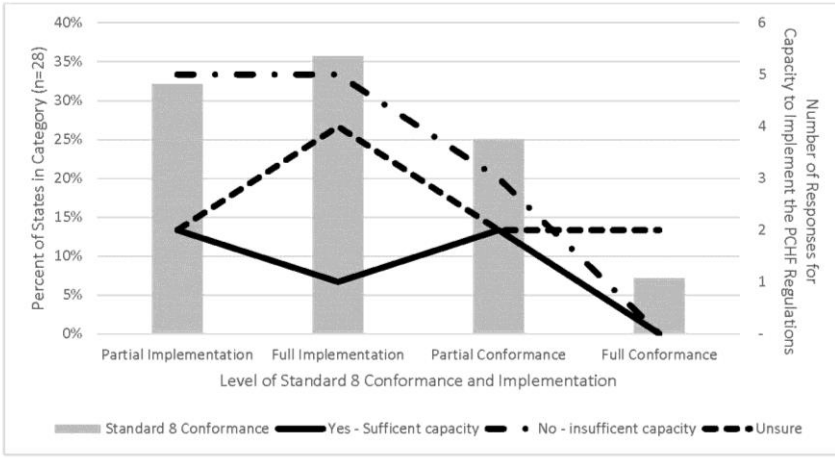

Figure 2. Standard 8: Implementation/Conformance and the Capacity to Implement the PCHF Regulations

Conclusions

The level of implementation/conformance with Standard 1 appears to be related to a state program's intention to adopt the PCHF based on the higher rate of planned adoption by state programs in full implementation, partial conformance, and full conformance in comparison to state programs in partial implementation. Further research is required to identify if there are other factors, such as enrollment date and overall awareness of requirements, which may correlate with the intent to implement the PCHF. Further research is also required to determine if the annual legal review process required for full conformance with Standard 1 may contribute to a state program's overall awareness of statutory authorities. Additionally, does the annual review process prompt strategic discussions around adoption of the PCHF in order to maintain regulatory consistency with the FDA.

The level of implementation/conformance with Standard 8 does not appear to correlate with the perceived capacity to implement PCHF. There was no Standard 8 implementation or conformance category where a majority of state programs conveyed that there was capacity for implementation of the PCHF. The variety of responses in each category suggests that most state programs recognize that additional resources will be required to implement the PCHF. State programs also identified the need for additional resources to implement the PCHF such as funding, inspection staff, industry partnerships, equipment, and office space.

Thirty-five percent of respondents replied that they are unsure if their programs have the capacity to implement PCHF, which may suggest that state programs lack an understanding of the resources needed for implementation. Throughout the survey, respondents conveyed their need for additional funding for staff, training, and equipment, along with support from the state legislatures and department heads to adopt and implement the PCHF.

Recommendations

1. Additional research should be conducted to re-examine the issues studied in this research, after the state programs have more information about PCHF adoption and implementation.
2. Outreach, training, and support should be provided related to the adoption of the PCHF such as meetings with legislators, commissioners, and other types of leadership in positions to influence the adoption process.
3. State programs and the FDA should create additional guidance such as estimated PCHF inspection times based on mock inspections, record keeping requirements by the state program, and estimated training time for inspectors to assess the resources required for state program implementation of the PCHF.
4. Funding mechanisms should be created to assist state programs in the adoption and implementation of the PCHF.
5. Resources should be provided to assist state programs in the adoption and implementation of the PCHF.
6. MFRPS should be updated to reflect the new requirements related to the PCHF to help state programs assess conformance with federal regulations and resource assessment.

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Review of U.S. State-Level Entomophagy Regulation 2015

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Abstract
This study examined state-level food safety regulatory response to the use of insects for human consumption, or "entomophagy." Interviews were conducted with state regulatory officials from the 50 states; multiple interviews were conducted in states where regulation of retail and manufacturing of food are carried out by different agencies or delegated to a local agency. The study identified states where insects are sold at retail and the number of insect manufacturers; current regulations; types of insect food products; regulatory challenges regarding manufacturing facilities; and perceived food safety risks. Twenty states either reported receiving inquiries related to beginning an entomophagy-based business within their state; had previously regulated entomophagy facilities; or currently regulate entomophagy at the manufacturing or retail level. However, while the Food and Drug Administration (FDA) has jurisdiction over food being made using insects that is wholesaled and crosses state lines, there is no clearly-defined guidance at present for state regulators from the FDA. The study concludes that present state-level food safety regulation is fragmented, inconsistent, and does not address the current widespread use of insects as food. Recommendations include increased FDA-industry collaboration in order to create an entomophagy guidance document for the successful implementation of a preventive control system in order to provide consistent regulation of entomophagy processing and manufacturing facilities.

Keywords: 50 states, approved source, crickets, food safety, Food Safety Modernization Act (FSMA), guidance document, hazards, insects as food, insects for human consumption, Preventive Controls for Human Food (PCHF)

Background
People throughout the world have been eating insects as a regular part of their diets for millennia (van Huis et al., 2013, p.1). More than 1900 species are regarded as edible, including beetles, caterpillars, bees, wasps, ants, grasshoppers, locusts, crickets, cicadas, leaf- and planthoppers, scale insects, termites, dragonflies, and flies (van Huis et al., 2013, p.1). The benefits of entomophagy include utilizing a nutrition source that is high in calcium, zinc, and iron; environmental friendliness (e.g., requiring 12 times less feed than cattle to convert feed into the same amount of protein); and economic benefit, as the cost of start-up is significantly less than traditional farm-raised animals (van Huis et al., 2013, p.2).

Insect food producers are currently regulated by the FDA using Good Manufacturing Practices (GMPs) (Halloran & Munke, 2014); however, these GMPs are subject to a variety of interpretations. The FDA has published guidance documents and provided regulations for seafood and juice processors incorporating hazard analysis and critical control point (HACCP) principles which provide industry and regulators with consistent, sound scientific evidence to ensure the product and process is safe. However, the FDA has not provided guidance for insect food processors.

The Food Safety Modernization Act (FSMA) Preventive Controls for Human Food (PCHF) rule is now final (U. S. Food and Drug Administration [FDA], 2016) and uses HACCP-based principles that food facilities must follow unless the facilities are covered by an exemption. If not, the firm has the responsibility for: conducting a hazard analysis, preventive controls, monitoring, verification, corrective actions, and making corrections. Farms are exempt from the preventive controls rule unless raw agricultural commodities (RACs) are changed into a processed food. The FDA identifies multiple activities that change an RAC to a processed food, including slaughtering of animals and freezing. Insect farms would be exempt from the new FSMA PCHF rule unless facilities are slaughtering insects, freezing them, or conducting activities that would change the product into a processed food. FDA is developing guidance documents addressing the following: hazard analysis and preventive controls, environmental monitoring, food allergen controls, and validation of process controls. However, no guidance document currently exists for insect processors despite the fact that insects are rich in nutrients and moisture, and provide a favorable environment for microbial survival and growth (van Huis et al., 2013, p.117).

Problem Statement

At present, there is no comprehensive description of the state regulation of the processing and sale of insects for human consumption.

Research Questions

1. What types of insects are most commonly being processed and consumed for human consumption?

2. What types of foods are produced using insects?

3. What are the challenges associated with the regulation of insect-processing facilities?

4. What are the food safety risks related to insect processing and consumption based on the current understanding of state food safety regulators?

Methodology

A telephone survey of state agriculture and local health officials was carried out using the Directory of State and Local Officials (Association of Food and Drug Officials [AFDO], 2015). An introductory e-mail provided the subjects with thirteen questions to be asked in the telephone survey. Eight questions focused on the subject's regulatory framework and five questions related to the regulatory process. Responses to the survey questions were analyzed to address the four research questions above.

Results

All 50 states responded to the survey. Twenty states indicated that they had either received inquiries related to beginning an entomophagy-based business within their state; had previously regulated entomophagy facilities; or currently regulate entomophagy at the manufacturing or retail level. Six of the 20 states were currently regulating crickets or cricket products using Good Manufacturing Practices (GMPs) (see Table 1). Two of the 20 states had previously regulated cricket entomophagy products using the GMPs (Louisiana and Utah); nine of the 20 states had received inquiries related to cricket entomophagy (Alaska, Idaho, Maine, Michigan, Minnesota, South Carolina,

Texas, Vermont, and Washington); and two states (Arizona and New York) reported currently regulating entomophagy at the retail level.

Several responses to the survey questions illustrate the diversity of regulatory experiences related to entomophagy. A Montana regulatory official stated, "There has been talk and phone calls about insects for human food, and we have seen insects used for human food that fall under our temporary food exemption." An Arizona regulatory official said, "The State Fair is primarily where insects for human consumption are offered for sale, and the insects used at the State Fair are primarily from California. There are also numerous retail stores selling packaged entomophagy products including novelty items such as lollipops with an edible insect such as scorpions inside of the lollipop." From Kansas, a regulatory official commented that "There was a startup for mealworm flour, and at this point the start-up operation falls under the cottage food retail exemption."

The widespread nature of entomophagy is illustrated by two manufacturers: Chapul and Exo. Chapul produces cricket bars using cricket protein powder that is dairy- and soy-free. Exo produces protein bars using cricket flour and claims that the bars are all natural, dairy-free, gluten-free, paleo-friendly, soy-free, and contain 10g of protein. These two companies distribute products to 42 of the 50 states, primarily to retail establishments (Exo, n.d.; Chapul Bars, n.d.).

All of the states using the GMPs (or a modified form of the GMPs) to regulate entomophagy facilities identified crickets as an ingredient, or sold as a whole insect as shown in Table 1.

Table 1

States Currently Regulating Entomophagy Using Good Manufacturing Practices

State	Regulating cricket product entomophagy?	Cricket used as an ingredient?	Selling whole crickets?	Regulating other insect products using GMPs?	Food products manufactured
California	Yes	Yes	No	Yes	Chocolate-dipped insects, hard candy w/insects, cricket flour
Illinois	Yes	Yes	No	No	Power bars
Massachusetts	Yes	Yes	No	No	Snack products, chips
North Carolina	Yes	Yes	No	No	Baked goods
Ohio	Yes	Yes	Yes	No	Whole crickets
Oregon	Yes	Yes	No	No	Cricket flour, instant oatmeal

The potential size and evolution of large producers is illustrated by two other manufacturers: Big Cricket Farms in Ohio and Aspire, located in Texas. According to its website, Aspire has the capacity to process up to 7 million crickets on a weekly basis (Aspire Food Group, 2016). Big Cricket Farms, whose mission statement starts with "To drive the edible insect industry forward" also raises crickets specifically for human consumption; the company bills itself on its website as "the first American insect farm to obtain food-grade certification from their state Department of Agriculture and the FDA." The firm raises Gryllodes sigillatus, a.k.a. the Tropical Banded Cricket (Big Cricket Farms, 2014). An Ohio regulatory official who has been to the facility identified jurisdiction as one of the biggest challenges in regulating insect facilities, as the Ohio Department of Agriculture does not have jurisdiction until the crickets are dead—in effect, after an important part of the manufacturing process has already taken place.

California was the lone state in the survey to regulate products other than crickets or cricket products using the GMPs. A California regulatory official identified insects in hard candies such as ants and scorpions (which are regulated under the GMPs) and chocolate-covered grasshoppers during the interview. Products found on the website of California's Hotlix Candy Store include ant wafers and whole crickets flavored with bacon and cheddar, sour cream and onion, and salt and vinegar. Worm snacks were also offered in BBQ, Mexican spice, and cheddar cheese flavors (Hotlix Candy Store, 2015).

During each interview, state representatives were asked to identify challenges related to regulating entomophagy facilities. Table 2 shows what challenges were identified for all states participating in the survey. Approved source, understanding the process, and understanding the hazards accounted for 66% of challenges identified. Of the six states indicating that entomophagy regulation was occurring and applying the GMPs in Table 1, ten responses to challenges were noted. The challenges identified (from the states listed in Table 1) included understanding the process (40%), determining approved source (20%), understanding the hazards (20%), the unknown (10%), and establishing jurisdiction (10%).

Table 2

Challenges Identified by Regulators Regarding Entomophagy

Challenges	Number of Responses	Percent of Total Responses
Approved Source	24	30%
Understanding the Process	18	23%
Understanding the Hazards	10	13%
No Response	9	11%
Training Staff	7	9%
No Specific Regulation	4	5%
No Challenges	3	4%
Establishing Jurisdiction	2	2%
No Scientific Evidence	2	2%
The Unknown	1	1%
Total	80	100%

Of the eight states that regulated entomophagy firms or had previously regulated entomophagy firms using the GMPs, none indicated that any hazards were identified during inspection work. A New York State regulatory official pointed to a 2001 incident where approximately 15 people became ill following the annual Explorers Club dinner in New York City. The primary symptom was burning mouth/throat due to the mechanical irritation caused by the urticating hairs of tarantula. A food prep review found that some of the tarantulas may not have been adequately singed to remove the hairs. The tarantula example illustrates the hazards within entomophagy which could easily be overlooked without scientific guidance provided to industry and regulators.

A Georgia regulatory official shared information received from the FDA that there is a growing body of scientific literature that people who are allergic to shellfish (shrimp, lobster, etc.) may also be allergic to insects either as food or as adulterants in foods.

The FDA has provided e-mail guidance to a Pennsylvania regulatory official that states there is no specific FDA regulation that either prohibits or condones the use of insects as food. The Food, Drug, and Cosmetic Act requires food products to be “fit for food” (FDA, 1938). In general, “fit for food” means the product is safe and wholesome and does not present a health hazard. Firms, not the FDA, must determine if this is the case and FDA’s role should be to oversee that firms meet this charge.

Conclusions

Entomophagy regulation lacks national standardization and existing regulation is fragmentary and often ad hoc. However, entomophagy is found in most states; nationally, the volume of product is increasing. States are currently regulating entomophagy manufacturers using GMPs, which is not a food process- or product-specific regulation. Insect processors may fall under the Preventive Controls for Human Food (PCHF) rules, in which case regulators would rely on industry to provide information related to hazards in

the product and process. The PCHF rules will also require manufacturers to identify hazards in their operation and validate and verify control of these hazards based on scientific data. Additionally, the FDA has not provided guidance to state regulators or to industry regarding hazards, processes, and sources. As a result, there is a current and significant need for increased guidance for consistent entomophagy regulation.

Recommendations

The FDA should work with the manufacturers of entomophagy products to provide a guidance document for entomophagy. The guide would be used as a resource for industry and regulators to provide consistent, sound, scientific evidence ensuring the product and process is safe.

An expanded study should be conducted to identify potential hazards associated with the production of insect-based foods in order to assist in the continued effort to achieve a comprehensive description of the regulation and sale of insects for human consumption.

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First National Survey of State-Level Wild Mushroom Safety Training for Retail Establishments

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Abstract
This first national survey of the food safety training and requirements regulating the use of wild foraged mushrooms in retail establishments compared 49 states to Michigan's new training and standards using telephone interviews during the fall of 2015. In 2014, the Michigan Department of Agriculture and Rural Development, in collaboration with non-profit partners, created a "mushroom broker" certification that defined "approved sources" and the training required to be a "wild mushroom expert"; this survey was designed to place the Michigan training in a national context. The survey found limited common ground regarding definitions and regulations among the states. While 26 states perceived wild mushroom foraging as an increasing food safety risk, only 28 states had formal or informal partnerships with relevant non-profits or academic institutions to address mushroom harvesting and only 4 states provided training for either inspectors or harvesters. The study concluded that current food safety regulation is rudimentary, fragmented, and lags behind the increasing use and associated risk of wild mushrooms. The study recommends adoption of an Association of Food and Drug Officials (AFDO) guidance document and increased state efforts to seek ideas and models for regulation from other states to identify possible resources within their own borders for training, such as the use of academic centers or non-profit organizations.

Keywords: wild foraged mushrooms, wild mushroom expert, AFDO, safety training, retail food

Background
Commercial mushroom production in the U.S. is increasing in terms of the value of sales, which reached $1.12 billion in 2014 (U. S. Department of Agriculture [USDA], 2014). Factors influencing food choices—such as farm- or harvest-to-fork marketing, an increase in imported food products, increased immigration, and consumer willingness to try new foods—are contributing to commercial mushroom production, which, in turn, has increased the interest in foraging and harvesting of wild mushrooms.

In response to the increased use of wild mushrooms, the U. S. Food and Drug Administration's (FDA's) 2009 Food Code in §3-201.16 Wild Mushrooms required that the product being foraged or harvested be done so by an "approved mushroom identification expert" (U. S. Food and Drug Administration [FDA], 2009). Following the adoption of the 2009 Food Code, the Conference for Food Protection (CFP) recommended that additional requirements be added—similar to shellstock tags with shellfish—so as to allow traceback in the event of a foodborne illness. The CFP also recommended creation of a national guidance document. In turn, the Association of Food and Drug Officials (AFDO) in 2014 convened an ad hoc Wild Mushroom Subcommittee in response to the perceived increase in risk. That Subcommittee was tasked with drafting a national guidance document for AFDO review by the end of 2016.

There is limited epidemiological information regarding mushroom exposures due to a lack of national surveillance data (Kintziger et al., 2011). For example, in Michigan the state Poison Control Center has tracked an average of 370 cases per year since 2004, but no data is available regarding the number of cases involved in retail sale or consumption. However, the increased demand for wild mushrooms along with the perception of increased risk led the Michigan Department of Agriculture and Rural Development (MDARD) to establish a set of standard requirements that defines a "wild mushroom expert" and to specify the species approved for sale with the help of Midwest American Mycological Information (MAMI), the Michigan Farmers Market Association (MIFMA), and the Institute for Sustainable Living, Art, and Natural Design (ISLAND). These groups also developed a training program including hands-on exercises and written examinations. Most participants to date have been mushroom brokers and market managers. The all-day class provided by MAMI costs $175. If participants pass the exam, they are recognized by MDARD as a "wild mushroom expert" for a period of five years. MDARD is in the final stages of adopting guidelines regarding the wild mushroom competency of local and state inspectors. These standards and practices will include guidance regarding the use of foraged wild mushrooms in the retail setting, both farmers markets and food service, in addition to the best practices for storing and labeling.

At the same time as Michigan was developing an approach focused on training, the FDA's 2013 Food Code was released. The 2013 Code shifted focus from mushroom identification experts to approving individual food establishments to sell wild foraged mushrooms (FDA, 2013, 2014). Given the changes in the Food Code and the increased concern with retail mushroom sales, regulators in Michigan sought to better understand how wild mushroom food safety regulation was being carried out across the nation by examining the number of foodborne illnesses related to mushrooms in a retail setting; specific mushroom training; barriers and challenges to training; resources for regulators; and statewide directives regarding wild mushroom certification.

Problem Statement

At present, there is no national overview of training for food safety regulation regarding wild mushrooms foraged for retail sale or consumption.

Research Questions

1. What wild mushroom training is available to regulatory officials?

2. What are the barriers and challenges to providing wild mushroom training to regulatory officials?

3. What are the resources available for developing wild mushroom training for regulators?

Methodology

A telephone survey was conducted with all 50 states and the District of Columbia. Respondents were identified from the Directory of State and Local Officials (DSLO) (Association of Food and Drug Officials [AFDO], 2015) whose responsibilities included retail food. The survey consisted of nine questions: the first two questions identified level of management and knowledge; the remainder of the questions quantified the respondent's experiences with wild mushrooms; training available to them or their staff; and resources available for developing and maintaining training. The survey was

conducted between November 1, 2015 and March 18, 2016. All respondents received an informed consent notice by email, along with the questions, in advance of the interview.

Results

Twenty-nine states and the District of Columbia responded to the initial telephone call (56.8%). Multiple attempts were required to obtain a complete national survey. All respondents described their position in the agency or department as supervisor, manager, or executive and all were located in state departments such as Agriculture, Health, or other agency. Most respondents had responsibility over food protection in the retail setting, and a few had policy responsibility.

The difficulty in obtaining responses from roughly half of the states was associated with a lack of familiarity with wild mushroom safety. In fact, respondents—who had responsibility in their state for retail food protection—considered their knowledge of wild mushrooms as either "basic" or "nonexistent." Only 28 respondents could identify a local association or academic organization with expertise in wild mushrooms as an actual or potential resource; only eight had an identification expert; two relied on reference books; and eight were dependent on the Internet for their knowledge. On the other hand, 26 respondents perceived wild mushroom foraging as presenting an increasing food safety risk to the public and almost every respondent stated that they would like to improve their knowledge of this area.

Another difficulty in obtaining a national picture of wild mushroom training is the lack of standardization as illustrated by Table 1. Ten states allowed wild mushroom harvesting under the 2009 and prior versions of the Food Code. Those who were using the current (2013) version of the Food Code did not allow for wild mushroom harvesting. Previous versions of the Food Code, 2009 and prior, placed the responsibility of defining "approved mushroom expert" on the State. The current Food Code (2013), §3-201.16, simply states the food establishment must be approved in order to sell wild foraged mushrooms.

Table 1

States approach to Wild Mushroom Use in Retail

Food Code	Regulation	Provide training		Total
2009/prior Food Codes	Mushroom expert required for retail	MCAFDO [IA, MO] NCAFDO [IN, MN, MI] WAFDO [WA]	AFDOSS [KY, GA] CASA [MD, WV, VA] MCAFDO [KA, AR] NCAFDO [IL, ND, WI] NEFDOA [ME, NY] WAFDO [AK, AZ, HI, ID, NV, OR, WY]	25
	No wild mushrooms allowed		AFDOSS [AL, FL, NC, LA, TN] CASA [OH, NJ] NCAFDO [SD] NEFDOA [CT, RI, NH, VT] WAFDO [UT, OR]	14
2013 Food Code	All adopted	AFDOSS [SC]	AFDOSS [MS] WAFDO [CO]	3
	Mushroom harvesting not included		AFDOSS [TX] NCAFDO[DC] CASA [DE, PA] WAFDO [MT, NM, UT]	7

Legend: The Association of Food and Drug Officials of the Southern States (AFDOSS), Central Atlantic States Association of Food and Drug Officials (CASA), Mid-Continental Association of Food and Drug Officials (MCAFDO), North Central Association of Food and Drug Officials (NCAFDO), Northeast Food and Drug Officials Association (NEFDOA), and the Western Association of Food and Drug Officials (WAFDO).

Only one state, Michigan, offered training to retail operators and only six states offered training to inspectors. In each, the training was developed in partnership with local non-profits that specialized in mushroom-related activities and with universities. The remaining states cited the lack of standardization or course availability as the main barrier to the training (eight states) and the second-most cited reason was the lack of a demand for training (seven states). Those respondents who cited no demand were located in regions unconducive to mushroom growth. The third-most cited reason (five states) was they did not view wild foraged mushrooms as an approved source of mushrooms.

Table 2

Typical Responses to Survey Questions

Is specific training available to your agency/department?	What are the barriers/challenges that are preventing training?	What other resources are available?
No (*n=42*)	Lack of standards	Local land grant university
No, not an issue	Not an approved source	Internet
Yes, non-profit group	Budget constraints	Local expert

Conclusion

The study found that training for regulatory officials regarding retail sale or consumption of wild mushrooms is extremely limited. Most states are only now becoming aware of the extent of foodborne illness risks associated with wild mushrooms.

One possible reason for the low level of knowledge and lack of resources devoted to mushroom safety is the lack of publicized mushroom poisoning incidents. For example, only two respondents could identify a foodborne illness resulting from retail sale or service of wild mushrooms. Another reason is that epidemiological tracking of mushroom incidents at retail is either limited or nonexistent throughout the country. Another possible contributing factor is a low level of senior management interest; only seven of the respondents could identify a statewide directive or memo of any type issued by senior agency officials regarding wild mushrooms.

The barriers and challenges to implementing training begin with the lack of national uniformity regarding wild mushroom regulation. Another concern in many states is potential liability related to allowing wild mushroom sales. In these states, there appears to be a "zero tolerance" approach to wild mushroom foraging. Another barrier occurs when states define "approved source" and "wild mushroom expert" in order to relieve themselves of the training requirement for regulators, which mirrors a concern brought forth by the CFP.

Most states had not sought assistance in dealing with wild mushrooms, despite the evidence of resources for designing and implementing training available from major universities, non-profits who work to educate the public on mushroom safety, and other sources.

Recommendations

States should support AFDO's effort, supported by other organizations, to create a national guidance document in order to foster a more proactive and uniform regulatory approach to wild mushroom use at retail.

States should also seek out and identify possible approaches to addressing mushroom safety by examining efforts in other states. For example, Michigan pioneered the use of a collaborative approach involving a multi-stakeholder working group. Other approaches might include a multi-state working group, an initiative based at a land-grant university, and a convening of stakeholders by the Partnership for Food Protection.

States should work with those in their AFDO region and neighboring states as climate and geography encourage growth of certain types of mushrooms in specific regions that encompass multiple states. In addition, the specialized nature of mushroom identification lends itself to those neighboring states pooling resources for training.

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National Survey of State Regulation of Wild Mushroom Foraging for Retail Sale

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Abstract
An online national survey examined the regulatory approaches of 49 states toward wild foraged mushrooms intended for retail sale. A twenty-one question survey was sent to 50 state agencies, with 49 responses (98% response rate). The results indicated six different regulatory approaches to regulating wild foraged mushrooms at retail. These approaches include not allowing sale; identification by the state of approved wild mushroom experts certified via training; licensing of wild mushroom sellers; consumer advisory in the retail food establishment; identification of mushrooms by a wild mushroom expert with state verified credentials; or variance on a case-by-case basis. Study recommendations include the development of a guidance document by the Conference for Food Protection (CFP) and the Association of Food and Drug Officials (AFDO); increased collaboration among states to develop and share approaches for certification of wild mushroom identifiers; developing a registry and common criteria to determine qualifications of wild mushroom experts; and a comprehensive national index of edible species.

Keywords: foraged wild mushrooms, regulatory approaches, wild mushroom expert, mushroom identification, mushroom guidance resources, retail food

Background
A possible result of the increasing popularity of foraging wild mushrooms has been the increase in reported cases of mushroom poisoning (Wolf-Hall, C., 2009). Most literature related to mushroom exposures and poisonings are clinical case reports, with few studies characterizing the epidemiology of exposures (Jacobs, Von Behren, & Kreutzer, 1996; Nordt, Manoguerra, & Clark, 2000; Mrvos, swanson-Biearman, & Krenzelok, 2007). Over 5,000 species of mushrooms are presumed to be found worldwide; only 20–25% have been named; and about 3% of these are poisonous (Gonmori & Yoshioka, 2003). Many of these poisonous wild mushrooms look similar in appearance to edible species of wild mushrooms. The American Association of Poison Control Centers reported 8,601 cases of mushroom poisonings in 2004 with five fatalities (Watson et al., 2005). About 80% of mushrooms involved in these cases were unidentified. An estimated guess of mushroom poisonings from foraged wild mushrooms at retail would most likely be anywhere from 10-30%, although no studies in the literature have cited any epidemiologic data. Overall, there appear to be 20-30 cultivated edible species and 15 wild edible species that are commonly collected for commercial sale and many more wild, non-commercial edibles (Kuo, 2007; Chang, 2009; Lincoff, 2010). Public health concerns related to food safety arise when commercial foragers of wild mushrooms pick toxic, “look-alikes” of edible species and offer them at retail.

Limited state and local laws exist to regulate the sale of foraged wild mushrooms. Some states have followed the guidance for regulating foraged wild mushrooms based on the U. S. Food and Drug Administration (FDA) Food Code. In Georgia, the Rules and

Regulations for Food Service (Georgia Food Code Chapter 290-5-14), which is based on the 2005 FDA Food Code, states that "mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert" (FDA, 2005; Georgia Department of Public Health [DPH], 2007). However, the codified text in Chapter 290-5-14 does not define who is an approved wild mushroom expert for the purpose of identifying safe species of foraged wild mushrooms. In addition, the Food Code does not clearly address traceability of foraged wild mushrooms from field to the consumers' plate in retail food establishments. The purpose of this study was to examine the existing regulatory approaches of the state agencies that regulate foraged wild mushrooms at retail in the U.S. and to provide recommendations to states regarding the regulation of foraged wild mushrooms offered for retail sale.

Problem Statement

There is no published research in peer-reviewed food safety literature regarding regulatory approaches used by state food safety agencies related to foraged wild mushrooms at retail in the United States.

Research Questions

1. What are the existing regulatory approaches regarding foraged wild mushrooms sold at retail in the United States?

2. What resources do state food safety agencies have available for them to identify edible mushrooms that are foraged from the wild and offered at retail in the United States?

Methodology

The Association of Food and Drug Officials (AFDO) Directory of State and Local Officials (DSLO) was used to identify contacts. Initial phone calls were made to these contacts to determine which agencies are responsible for wild mushrooms at retail. A survey was then delivered by a web-based software program to the appropriate agencies. The survey consisted of 21 questions that were reviewed and revised based on input from AFDO's Wild Mushroom Subcommittee and the International Food Protection Training Institute (IFPTI). The survey asked how foraged wild mushrooms at retail were regulated; the reasons, if appropriate, for lack of regulation; the requirements for retail operators; and resources available for identification of foraged wild mushrooms. A follow-up telephone call was made to those participants who had not responded to encourage participation.

Results

Forty-nine states responded; in nine states (18%), two food safety regulatory agencies have jurisdiction (Florida, Georgia, Louisiana, Mississippi, Montana, North Carolina, South Carolina, Utah, and Virginia) and in 18 states there is no regulation (36%). Most regulation occurs in the South (39% of the 31 regulated states), followed by the Midwest (32%), the West (16%), and the Northeast (13%). Twelve (39%) of the 31 states that do regulate identified morels and chanterelles as the most common types of foraged wild mushrooms sold at retail.

Of the states which regulate, 45% use the 2009 FDA Model Food Code. The study did not find any association with the adoption of a specific version of the Food Code by a state

and its specific regulatory approach related to foraged wild mushrooms at retail. However, this study did find six distinct approaches to regulation.

1. Three states do not allow the sale or service of foraged wild mushrooms at retail as they regard foraged mushrooms as coming from an "unapproved source": Delaware, Kentucky, and Louisiana.
2. Four states do allow the sale or service of foraged wild mushrooms at retail if the product was identified as safe by an "approved wild mushroom expert"—a person certified after training: Iowa, Michigan, North Carolina, and South Carolina. All of these states except for North Carolina had a state-recognized and approved training program e.g., in Michigan, a third party provides training and certification related to wild mushroom "experts."
3. Seven states allow the sale or service of foraged wild mushrooms at retail if the mushrooms were provided by a "licensed wild mushroom seller": Kansas, Missouri, Montana, Nebraska, Rhode Island, Washington, and Wisconsin. The "licensed wild mushroom seller" is required in these states to ensure compliance with the regulatory requirements related to foraged wild mushrooms.
4. Only one state, Alaska, relied on consumer advisories in retail food establishments for ensuring the safety of sale or service of foraged wild mushrooms at retail.
5. Seventeen states allow the sale or service of foraged wild mushrooms at retail if they are identified by an "approved wild mushroom expert" with credentials verified by the state: Alabama, Colorado, Florida, Georgia, Indiana, Kansas, Minnesota, Missouri, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Tennessee, Virginia, and West Virginia. In all of the states, persons who consider themselves to be a wild mushroom expert due to qualifications and experience may be reviewed by the state and may or may not be approved. Note that all of these states have no set standards for being a wild mushroom expert except for Colorado, Indiana, Kansas, Minnesota, Missouri, and Pennsylvania.
6. The respondent from one state, Utah, indicated that their state would allow the sale or service of foraged wild mushrooms in retail food establishments by use of a variance on a case-by-case basis.

Please refer to Table 1 for more information on the types of regulatory requirements for retail sale and service of foraged wild mushrooms among states who regulate foraged wild mushrooms at retail.

Table 1.

Types of Regulatory Requirements for Retail Sale of Foraged Wild Mushrooms Among the 31 States Who Regulate Wild Mushrooms at Retail

Regulatory Requirements	Yes (%)	No (%)
Have restrictions to limit the volume of wild mushroom species	5 (16%)	26 (84%)
Require records to be maintained by harvester of wild mushroom species	8 (26%)	23 (74%)
Maintain a list of safe wild mushroom species	7 (23%)	24 (77%)
Maintain a list of approved wild mushroom experts	7 (23%)	24 (77%)
Have criteria for approval of wild mushroom experts	10 (32%)	21 (68%)

Table 2 identifies specific regulatory criteria that operators of retail food establishments must comply with in regards to the sale and service of foraged mushrooms at retail.

Table 2.

Regulatory Requirements for Retail Operators for Sale or Service of Foraged Wild Mushrooms at Retail

Regulatory Requirements	Yes (%)	No (%)
Notify health authorities prior to selling wild mushrooms at retail	2 (6%)	29 (94%)
Inform customers of risk of consuming wild mushrooms in their establishments	2 (6%)	29 (94%)
Maintain written buyer specifications of wild mushrooms for traceability purposes	5 (16%)	26 (84%)
Purchase wild mushrooms from a permitted/licensed wild mushroom seller	5 (16%)	26 (84%)
Other	3 (10%)	28 (91%)

Note: This is among the 31 states that regulate the sale or service of foraged wild mushrooms at retail.

Only a third (10 of 31 states) reported that they have resources to identify safe and unsafe types of foraged wild mushrooms at retail in their states: Alabama, Georgia, Kansas, Michigan, Montana, North Carolina, Pennsylvania, South Carolina, Washington, and

Wisconsin. Please refer to Table 3 for more information on the different types of resources used for the identification of foraged wild mushrooms.

Table 3.

Types of Resources Used for Identification of Foraged Wild Mushrooms at Retail

Resources	Yes (%)	No (%)
Approved wild mushroom identifiers who have been certified through agency-recognized training.	3 (6%)	7 (70%)
An established committee that consists of food service personnel from industry, associations (mycological & restaurant), academia and commercial wild mushroom foragers	3 (30%)	7 (70%)
Extension service & academia	3 (30%)	7 (70%)
Other – another agency	1 (10%)	9 (90%)

Note: This is among those 10 states that have resources available for identification of foraged wild mushrooms at retail.

Nine states reported that they lack the resources to identify safe and unsafe mushrooms: Delaware, Kentucky, Louisiana, Nevada, New York, Oklahoma, Rhode Island, Virginia, and West Virginia. Three other states (Florida, Ohio, and Tennessee) did not respond to the question.

Seven states maintain a list of wild mushroom experts to serve as a reference for identification and traceability of foraged wild mushrooms: Colorado, Kansas, Indiana, Michigan, Missouri, Montana, and Pennsylvania. Nebraska reported that sanitarians must consult a certified mushroom individual. The respondent for Alaska indicated that the resource for identification of foraged wild mushrooms is non-applicable because they use the option of a Consumer Advisory as an approach for regulating wild mushrooms for sale or service at retail.

Some states maintain a list of safe edible species of foraged wild mushrooms that they permit for sale or service at retail in their state: Iowa, Michigan, Montana, Pennsylvania, South Carolina, Virginia, and Washington.

Conclusions

The study concluded that there is great variation in the regulation of foraged wild mushrooms. In addition to the differences in regulatory approach, almost a third of the states surveyed have more than one food safety agency involved in wild mushroom regulation which, in turn, may encourage this variation.

Another conclusion of the study is that the absence of state and national data regarding the production of foraged wild mushrooms significantly limits the ability to assess the

sources of risk. For example, some states have commercial foragers picking large quantities and transporting those mushrooms across state lines.

A third conclusion is that some states are in the process of revising their regulations for food service which may increase the length of time in developing standards for foraged wild mushrooms and thus influencing the regulatory approaches in those states. Another reason for the difference in regulatory approach concerns regulatory jurisdiction. Some states have jurisdictional differences for regulating food safety at retail which may account for having more than two agencies that regulate food at retail, and this may explain the difference in inspection process for foraged wild mushrooms at retail.

Finally, some states use multiple resources to identify safe species of foraged wild mushrooms, including mycological associations, academia, and the food service industry. This multiplicity of resources suggests that there may be a need to assess the adequacy of communication and collaboration among states and their food safety partners regarding foraged wild mushrooms.

Recommendations

Four recommendations are suggested below given the great variation in regulation as well as the lack of national data and generally accepted best practices.

A Conference for Food Protection (CFP) and Association of Food and Drug Officials (AFDO) guidance document should be developed regarding the regulation of foraged wild mushrooms for sale or service at retail. A guidance document is clearly the single most important step forward given the great variety in regulation and a strong national demand for wild mushrooms.

States should collaborate and partner with other states and industry to recognize certification programs for approved wild mushroom identifiers. Given that mushrooms tend to be regional in nature due to geography and climate, states are likely to achieve economies of scale due to joint action in regulation.

All states might consider developing common criteria to determine qualifications for the approval of wild mushroom experts and creating a registry of approved wild mushroom experts.

All states should maintain a list of safe edible species of foraged wild mushrooms for reference purposes. This is clearly a simple step forward and one that appears of immediate use.

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A Comparison Study of the Occurrence of Risk Factors in Retail Food Establishments Observed Nationwide and in Virginia

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Abstract
This study compared the five Centers for Disease Control (CDC) foodborne illness risk factors found in Virginia high-risk retail food establishments during the Virginia Department of Agriculture and Consumer Services (VDACS) inspections (2012 – 2013) to the number and type of these risk factors documented nationally by the U. S. Food and Drug Administration (FDA) in 2009. Nationally, the highest-occurring risk factor was improper holding/time and temperature, while in Virginia the highest occurring risk factor was contaminated equipment/protection from contamination. The study also revealed large differences in occurrence rates for the improper holding/time and temperature risk factor in Virginia in comparison to national rates. Comparison of risk factor observations of VDACS regions and the Virginia average revealed significant differences for two risk factors: food from unsafe sources and improper holding/time and temperature. Recommendations include further research to determine the reasons for differences in the rates of specific risk factor violations as well as additional research to examine whether Virginia-trained inspectors are appropriately standardized. Finally, the study recommends that regulators continue to update and reinforce the guidance that they provide to retail food establishment operators about the use of retail risk factors to actively manage their establishment's food safety system.

Keywords: FDA, food inspections, food service, retail food establishments, risk factors, time and temperature, Virginia Department of Agriculture and Consumer Services (VDACS)

Background
The Centers for Disease Control and Prevention (CDC) Surveillance Report for 1988 – 1992 identified the most significant contributing factors to foodborne illness (Centers for Disease and Prevention [CDC], 1996; U. S. Food and Drug Administration [FDA], 2009) as: Food from Unsafe Sources, Poor Personal Hygiene, Inadequate Cooking, Improper Holding/Time and Temperature, and Contaminated Equipment/Protection from Contamination. In 1996, the National Performance Review Report determined that foodborne illness caused by harmful bacteria and other pathogenic microorganisms in various food industry sectors (e.g., meat, poultry, seafood, dairy products) and a host of other foods was a significant public health problem in the U.S. (FDA, 2009). As a result, the Food and Drug Administration (FDA) conducted a study in 1998 to serve as a baseline for evaluation of future efforts to help improve food preparation practices and food employee behaviors in institutional food service establishments, restaurants, and retail food stores.

In 2009, the Virginia Department of Agriculture and Consumer Services (VDACS) began to better align its risk identification process with the CDC Surveillance Report by increasing focus on violations of the five CDC risk factors. For example, inspection report requirements were updated to reflect FDA risk categories and definitions. As a result, the

data from the new inspection reports began to capture ordinal data about foodborne illness risk factor occurrences in retail establishments. VDACS also integrated risk factors into the evaluation of other food safety-related factors including: food service processes, labeling, vulnerability to intentional contamination, employee training, and enforcement in the field.

Problem Statement

The differences between national and Virginia rates of the five risk factors found in high risk retail food establishments is unknown.

Research Questions

1. What are the differences between the rates of occurrence of CDC risk factors in Virginia and those documented in the 2009 national survey by the FDA?

2. What are the differences among the CDC risk factors in the three VDACS regions (Northern Virginia, Southwest, and Tidewater) as compared with the Virginia average?

Methodology

The protocol used to identify observable occurrences in the national survey was also used for this study. High-risk retail establishments in the VDACS database from September 1, 2012 to August 31, 2013 that were similar to the establishments used in the 2009 national survey completed by the FDA were identified, including retail food stores such as delis, meat departments, seafood departments, and produce departments. Seven hundred and seventy-four (774) inspections met the criteria. A random number simulator was used to select 390 reports (50%) that were reviewed for this study. The data was examined, sorted, and analyzed to determine the number and types of risk factor violations documented in selected retail establishments located in all three regions of Virginia (Northern Virginia, Southwest, and Tidewater). The data was then analyzed for the prevalence and distribution of risk factor violations in Virginia during the 2012-2013 time frame and compared to the trends found at the national level by the FDA; in addition, trends among the three VDACS regions were compared to trends statewide.

Results

The national study revealed that improper holding/time and temperature occurred at a rate of 50.8% and this study found that the rate in Virginia was 37% (see Table 1). The contaminated equipment/protection from contamination risk factor occurred at a rate of 67.9% in Virginia and at 18.8% in the national study. The poor personal hygiene risk factor occurred at a rate of 20.5% in the national study compared to a rate of 8.4% in Virginia.

Table 1.

Difference Between National and Virginia Out-of-Compliance Inspection Findings

Risk Factor	National	Virginia	Difference
Food from Unsafe Sources	4.30%	12.05%	+7.75%
Improper Holding/Time and Temperature	50.80%	37.09%	-13.71%
Improper Cooking	9.40%	0.76%	-8.64%
Contaminated Equipment/Protection from Contamination	18.80%	67.90%	+49.1%
Personal Hygiene	20.50%	8.46%	-12.04%

A comparison of risk factors in the three Virginia regions revealed both differences and similarities (see Table 2). Risk factors for inadequate cooking and poor personal hygiene showed a low occurrence rate of less than 10% in each region. Contaminated equipment/protection from contamination ranged from 65% to 69% in Virginia regions, which was a rate close to the Virginia average of 67.9%. Improper holding/time and temperature occurred at a rate of 52% in the Tidewater region and 31% for both Northern Virginia and Southwest regions, compared with the Virginia average of 37%. The food from unsafe sources risk factor differed among the three Virginia regions, with Tidewater at 21.4%, Southwest at 3.7%, and Northern Virginia at 11.7% which is close to the Virginia average of 12%.

Table 2.

Difference Among Virginia Regions Compared With Virginia Average

Risk Factor	Virginia Average	Northern Virginia	Southwest	Tidewater
Food from Unsafe Sources	12.05%	11.71%	3.70%	21.40%
Improper holding Time/Temperature	37.09%	31.20%	31.80%	52%
Improper Cooking	0.76%	0%	0%	2.30%
Contaminated Equipment/Protection from Contamination	67.90%	65.60%	68.80%	69.80%
Personal Hygiene	8.46%	7.03%	8.80%	9.50%

Conclusion

Virginia rates reflect similarities with observations of the national study in that improper holding/time and temperature was one of the highest-occurring risk factors regionally. However, the risk factor protection from contaminated equipment/protection from contamination occurred at the highest rate in Virginia and at an even greater rate than the frequency observed at the national level.

The observed occurrence rate for improper holding time and temperature in Virginia was 20% higher than the data observed nationally. Protection from contamination was overall one of the highest-occurring risk factors out of all five of the risk factors in Virginia. The inadequate cooking temperature and food from unsafe sources risk factors occurred at a significantly lower rate both nationally and in Virginia.

Observed risk factor violations were consistent among VDACS regions in all risk factor categories except food from unsafe sources and improper holding/time and temperature. The greatest variation among VDACS regions was the rate that the risk factor food from unsafe sources was reported as a violation. In the Southwest region, inspectors documented observations of the food from unsafe sources violation approximately 6% less often than the Virginia average, while inspectors working in the Tidewater Region documented this risk factor approximately 9% more often than the Virginia average. The sole outlier in the documentation of improper holding/time and temperature involved inspectors in the Tidewater Region, who documented this violation at a rate nearly 15% more often than the Virginia average.

A possible limitation of this study is the difference between the identification of observable occurrences and method of inspection performed by FDA during the national study and Virginia inspectors.

Recommendations

Further research needs to be completed to determine the cause of notable risk factor differences (improper holding/time and temperature, contaminated equipment/protection from contamination) in Virginia as compared with the national study. This research should include determining whether Virginia-trained inspectors are standardized to perform retail food establishment inspections based on the current Food Code requirements and associated FDA guidance related to the identification and categorization of risk factor violations.

Further research also needs to be performed to determine the cause of VDACS regional variance from the state's average observed violation rates for the food from unsafe sources and improper holding/time and temperature risk factors.

VDACS should develop approaches to ensure that foodservice and retail food store operators responsible for active managerial control of retail food establishments are systematically reminded about risk factors present in their businesses, and are provided information about updated requirements and establishment-specific guidance for application of these requirements. FDA risk-based inspection protocols and method of inspection should be studied to see if elements can be incorporated into routine inspection methods performed by Virginia inspectors.

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