



Analysis of Factors Influencing the Implementation of Risk-Based Inspections

**A Study Conducted With
Local Retail Food Regulatory Programs**

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Public Health
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NACCHO

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The National Connection for Local Public Health



Abstract

According to the U.S. Food and Drug Administration (FDA), more than 3,000 state, local, and tribal agencies have primary responsibility to regulate the retail food and food service industries in the United States.¹ With the novel coronavirus (COVID-19) pandemic upending routine public health operations and changing the way retail food establishments serve their customers, jurisdictions will need to be better prepared in an ever-changing landscape to mitigate foodborne illness outbreaks. Resource constraints such as funding, staffing, and time commitment have been known to be major impediments to advancing retail food safety before the pandemic—even contributing to unenrollment in the FDA’s Retail Program Standards²—and it is crucial that retail food safety partners and federal agencies come together to fill gaps and boost public health capacity in a post-COVID-19 era.

As the primary agency tasked with ensuring the safety of the nation’s domestically-produced and imported foods, the FDA assists state, local, tribal, and territorial (SLTT) agencies by developing and maintaining a Food Code to promote evidence-based practices with the vision of ensuring a uniform system to assist jurisdictions that regulate the retail segment of the food industry. Recognizing the importance of adopting the Food Code, while also acknowledging the challenges that SLTT programs face with adoption, the FDA developed and released the Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards). Enrollment in the Retail Program Standards is designed to, among other things, identify program areas where a regulatory program can have the greatest impact on retail food safety; promote wider application of effective risk-factor intervention strategies; and assist in identifying areas in critical need of attention. In shifting the mode from response to prevention, the Food Code and the Retail Program Standards together represent a strategically sound framework that addresses the root causes leading to foodborne illness outbreaks. Owing to this strategy, “risk-based inspections” became the new focus, and full or partial implementation of risk-based inspections allows SLTT retail food regulatory programs to effectively control the five major foodborne illness risk factors identified by the Centers for Disease Control and Prevention (CDC).

To aid the expansion of SLTT regulatory programs using risk-based inspections, the National Association of County and City Health Officials (NACCHO) and the Conference for Food Protection (CFP) conducted a study in 2021 to identify, better understand, and assess the application of risk-based inspection methods currently employed by local retail food regulatory programs while seeking to identify the overarching barriers preventing application of risk-based inspection methods.

The study identified more success factors by jurisdictions implementing risk-based inspections—such as funding, training, and leadership buy-in—than barriers. Common barriers identified included inadequate staffing and time needed to train existing staff to support implementation. Based on the study findings, actionable recommendations were derived for national retail food safety partners, federal agencies, and SLTT regulatory programs to support implementation of risk-based inspections.

Introduction

Foodborne illness poses a significant risk to public health in the United States. The CDC estimates that in the U.S. each year, 48 million people get sick, 128,000 are hospitalized, and 3,000 die from foodborne illnesses.³ The factors contributing to foodborne illness outbreaks have been grouped into five major risk factors: (1) improper holding temperatures; (2) inadequate cooking temperatures; (3) contaminated equipment; (4) food from unsafe sources; and (5) poor personal hygiene.³

As the primary agency tasked with ensuring the safety of the nation's domestically produced as well as imported foods, the FDA assists SLTT agencies by developing and maintaining a Food Code⁴ to promote evidence-based practices with the vision of ensuring a uniform system to assist jurisdictions that regulate the retail segment of the food industry. In addition to numerous funding opportunities and the Food Code, this assistance is also provided, in part, through the Voluntary National Retail Food Regulatory Program Standards (hereafter Retail Program Standards),⁵ Food Safety Modernization Act,⁶ and the New Era of Smarter Food Safety.⁷

Recognizing the importance of adopting the Food Code while also acknowledging the challenges that SLTT programs face with adoption, the FDA released the Retail Program Standards.⁵ Developed with input from federal, state, and local regulatory officials; retail food industry professionals; trade associations; academia; and consumers, the nine Retail Program Standards define a "highly effective and responsive retail food regulatory program" and serve as a framework of continuous quality improvement for SLTT retail food regulatory programs. Enrollment in the Retail Program Standards is designed to, among other things, identify program areas where a regulatory program can have the greatest impact on retail food safety; promote wider application of effective risk-factor intervention strategies; and assist in identifying areas in critical need of attention. In shifting the mode from response to prevention, the Food Code and the Retail Program Standards together represent a strategically sound framework that addresses the root causes leading to foodborne illness outbreaks (FBIOS). Owing to this strategy, 'risk-based inspections' became the new focus in the short- and long-term control of the five major risk factors contributing to FBIOS.

NACCHO and CFP partnered to conduct a study in 2021 to identify, better understand, and assess the application of risk-based inspection methods currently employed by local retail food regulatory programs as well as to identify barriers preventing application of these methods.

The National Association of County and City Health Officials and the Conference for Food Protection partnered to conduct a study in 2021 to identify, better understand, and assess the application of risk-based inspection methods currently employed by local retail food regulatory programs as well as to identify barriers preventing application of these methods.

Hazard Analysis and Critical Control Point (HACCP) is a systematic approach to the identification, evaluation, and control of food safety hazards.

[Learn more about HACCP.](#)

Standard 3	Standard 4	Standard 6
Inspection Program Based on HACCP Principles	Uniform Inspection Program	Compliance and Enforcement
Through conformance to Standard 3, the Retail Food Safety Program uses HACCP principles to identify risk factors and to obtain intermediate- and long-term corrective action(s) for recurring risk factor(s).	Through conformance to Standard 4, the Retail Food Safety Program implements a quality assurance program to ensure uniform, high-quality inspections (e.g., uniform interpretation of regulatory requirements, program policies, and compliance/enforcement procedures).	Through conformance to Standard 6, the Retail Food Safety Program has an effective compliance and enforcement program that is implemented consistently to achieve compliance with regulatory requirements.

Figure 1: Retail Program Standards 3, 4, and 6.

This study focuses on Retail Program Standards 3, 4, and 6 (see Figure 1) as they describe practices employed by a program conducting risk-based inspections. **When implemented fully or partially, these three Retail Program Standards represent the key components to conducting risk-based inspections.** Conducting a risk-based inspection requires inspectors to focus their efforts on evaluating the degree of active managerial control that operators have over foodborne illness risk factors. In addition, it is essential that the implementation of Food Code interventions also be verified during each inspection. Inspectors need to spend most of their time observing the behaviors, practices, and procedures that are likely to lead to out-of-control foodborne illness risk factors and asking management and food employees questions to supplement actual observations.

The key informant interviews generated 13 factors for success (41 comments) and 15 challenges (33 comments) to implementing risk-based inspections. The local retail food safety programs reiterated common themes around factors for success including funding sources, sufficient staff training, and buy-in from leadership and food safety staff. To address the challenges and bolster the success of local retail programs, this report concludes with recommended actions for state and local leadership, national associations, and federal partners.

Methods

NACCHO and CFP initiated the study by reviewing the FDA's list of jurisdictions that are enrolled in the Retail Program Standards.⁸ As of March 31, 2021, there were 868 SLTT retail food regulatory programs enrolled in the Retail Program Standards, including county, city, town, and district programs. Nine key informant interview participants were selected from this group and these programs were further categorized into two groups based on pre-defined "inclusion" and "exclusion" criteria related to conformance to some combination of Standards 3, 4, and 6 (e.g., met expectations through a Self-Assessment and verified through a Verification-Audit). Efforts were made to include SLTTs serving jurisdictions of different population sizes and varying degrees of urbanization. SLTTs were classified as small if they serve fewer than 50,000 people, medium if they serve between 50,000 and 500,000 and large if they serve 500,000 or more people. To ensure all relevant factors for categorization were fully considered, NACCHO and CFP routinely consulted with the Retail Food Safety Advisory Group (RFSAG), an advisory group of 15 state, local, tribal, and territorial health department professionals, academic food safety professionals, retail food industry professionals, retail food association staff, and the Retail Food Safety Regulatory Association Collaborative (hereafter known as the Collaborative).⁹

The Retail Food Safety Regulatory Association Collaborative is comprised of the following associations and agencies: the Association of Food and Drug Officials, the U.S. Centers for Disease Control and Prevention, the Conference for Food Protection, the U.S. Food and Drug Administration, the National Association of County and City Health Officials, and the National Environmental Health Association working together to reduce the incidence of foodborne illness. Our work focuses on a national strategy for the adoption of the latest editions of the Food Code, promoting and improving food safety culture, increasing enrollment and active participation and conformance with the Voluntary National Retail Food Regulatory Program Standards, improving foodborne illness outbreak investigations, improving food safety management systems at retail food facilities, and enhancing effective communications and sharing of best practices among retail food protection partners.

Category 1: SLTTs that have implemented risk-based inspections

To identify strategies for successful application of risk-based inspections, jurisdictions placed in Category 1 had conformed to **all** three Standards (3, 4, and 6). Based on conformance to the three Standards, these jurisdictions have policies and procedures in place to implement an effective risk-based inspection program. Thirty jurisdictions belonged to this category.

Category 2: SLTTs that have not implemented risk-based inspections

To identify perceived barriers for implementing and applying risk-based inspections, NACCHO and CFP intentionally included jurisdictions who have conformed to **some but not all** of Retail Program Standards 3, 4, and 6. Category 2 included 205 jurisdictions.

The final key informant interview participants were selected from Category 1 (n = 6) and Category 2 (n = 3) based on jurisdiction availability and while ensuring representation from diverse regions across the United States. See *Appendix A* for details regarding the demographics of the selected participants. Key informant interviews were conducted from February to April 2021 by NACCHO and CFP staff (see *Appendix B*). NACCHO disseminated a web-based questionnaire through Qualtrics® software followed by qualitative interviews by NACCHO and CFP staff with the nine participants using Zoom® software. The questionnaire and interview tools were the same for both categories of participants. Interviews were audio recorded with the verbal consent of participants and transcribed using an external transcription service. Following transcription, the questionnaire responses and interviews were analyzed by NACCHO using an in-vivo coding process in Excel®. Themes and subthemes were established following iterative expansion and consolidation of codes. These themes have been expanded upon in the results section of this study with both participant categories combined.

Study Limitations

This research study was limited by a sample size of nine jurisdictions, which may not completely reflect the experiences of all retail food establishments. Only those jurisdictions who were actively enrolled in the Retail Program Standards and confirmed meeting and auditing Standards 3, 4, and 6 were selected to participate. A larger sample size could provide even more insight into identified themes and factors for enrollment.

Results

Factors Contributing to Successfully Implementing Risk-Based Inspection Methods

The interview participants identified 13 factors that have helped to develop, strengthen, and ensure program success for implementing risk-based inspection methods (see *Table 1*). Collectively, 41 comments around success factors were recorded from participants, with the following success factors being frequently mentioned: funding source(s), training, and leadership buy-in. Of the jurisdictions interviewed, three stated that they implemented risk-based inspections as a directive from their state health department. These jurisdictions stated the risk-based approach was tied to a contract or the state's Food Code.

The local retail food safety programs reiterated common themes around factors for success including funding sources, sufficient staff training, and buy-in from leadership and food safety staff.

Main Themes

Funding source(s) were identified by six jurisdictions as a factor for success. Participants stated that the access to funds enabled them to purchase necessary equipment, send staff to receive trainings, and employ adequate staffing to conduct required inspections. In addition to grant funding, jurisdictions identified “permit fees” and “being self-funded” as factors that ensured adequate staffing and resources.

“NACCHO’s Mentorship Program and the Association of Food and Drug Officials (AFDO’s) Retail Grant Programs [helped]. We have been able to send staff to national-level conferences for continuing education as well.”

T **Training** was another success factor identified by six jurisdictions. Participants referenced several beneficial training opportunities for staff, including: following the requirements for Standard 2 of the Retail Program Standards; completing online courses provided by the FDA (e.g., FD215 – Managing Retail Food Safety and FD218 – Risk-Based Inspection Methods in Retail); attending professional conferences such as the Association of Food and Drug Officials’ (AFDO’s) Annual Educational Conference and the National Environmental Health Association (NEHA) Annual Educational Conference for continuing education; and having an internal standardization program already implemented.

- **In-person vs. virtual trainings:** When asked about preferred training options, six jurisdictions strongly recommended in-person trainings. Five jurisdictions stated that a web-based training would also be beneficial and noted that virtual training was a good alternative when travel funds were reduced.

- **Other helpful resources:** Four jurisdictions stated that technical assistance as well as mentorship or coaching opportunities were good resources for successfully implementing a risk-based inspection program.

Leadership buy-in, which includes support from the local Boards of Health, upper management, and elected officials, were identified by five jurisdictions as a factor contributing toward successful implementation.

Table 1. Factors that have helped to develop, strengthen, and/or ensure success of risk-based inspection programs.

Local Jurisdictions Interviewed		Category 1						Category 2			Total
		1	2	3	4	5	6	7	8	9	
Factors that have helped to develop, strengthen, and/or ensure success of risk-based inspection programs.	Leadership Buy-in	√		√	√	√	√				5
	Funding Source(s)	√	√	√		√			√	√	6
	Public buy-in	√				√	√				3
	Training	√	√		√		√		√	√	6
	Focused inspections						√				1
	Using the Retail Program Standards				√		√			√	3
	Staff buy-in			√	√		√			√	4
	Open communication		√				√				2
	High level of accountability						√				1
	Use of technology		√				√			√	3
	Partnerships		√				√			√	3
	Closure procedure						√				1
	Education of facility managers		√				√			√	3

Category 1 = met all three standards ; Category 2 = met some but not all three standards

Subthemes. **Staff buy-in** was identified by four jurisdictions as a factor for success. This included hiring people who are passionate about food safety, ensuring that experienced staff was supporting the risk-based inspection processes, and following a seasoned training program for new hires.

“We hire people that want to do food. I think in environmental health, a lot of times, food [safety] is like the kind of forgotten one. You may want to do septic, do land use. So, we’ve been very intentional about our hiring. We want to hire people who are passionate about food safety, and I think that helps build our own internal culture and really helps our programs because we hire the right people.”

Use of technology: Three jurisdictions noted this factor as important since electronic systems can allow for easy analysis of inspection data, inspection and follow-up tracking, and an inspection questionnaire can serve as a reminder to the inspector about repeat violations and long-term control of risk factors.



Partnerships and educating facility managers were identified by three jurisdictions as factors that led to success. These jurisdictions stated that having good relationships with food establishment owners or operators and restaurant associations, the FDA, and other agencies allowed them to better educate retail food establishments in addressing risk-factors.

- One jurisdiction **leveraged local restaurant association partnerships** to conduct outreach using informational handouts and log sheets.
- Another jurisdiction **utilized existing partnerships with facilities** as an opportunity to provide education to address long-term compliance to retail food safety.

Barriers to the Implementation of Risk-Based Inspection Methods

The interview participants identified 15 factors that impeded or made the implementation of risk-based inspections more challenging (see Table 2). Collectively, the nine participants recorded 33 comments around those barriers, which has been further grouped into two categories: staffing and time.

Staffing was identified as the largest barrier to successfully implementing a risk-based inspection program. This barrier was cited by six jurisdictions and includes staff buy-in, lack of employees, staff retention, and standardization of staff (e.g., standardized training for all food safety staff). Of note, some participants remarked that experienced staff were also reluctant to learn a new inspection method. Some were reluctant to take the extra time required for on-site corrective action, or to close establishments when risks were not eliminated or brought under control.

“Get buy-in from your experienced inspectors, otherwise it will be difficult to get new inspectors to buy in.”

- Four jurisdictions stated that **they do not have enough staff to complete all required inspections** and that this does not meet the FDA’s suggested ratio of inspections to Full Time Employees (FTEs) (Refer to Retail Program Standard 8 for more information on this criterion).
- Three jurisdictions stated that **staff retention was a barrier for implementation**. Low salaries and loss of experienced staff further complicated staffing issues.
- Three jurisdictions stated that **standardization was a barrier to implementing risk-based inspections due to lack of resources** required to complete the standardization process. Barriers included lack of individuals needed to perform the standardization process, and resources to ensure inspections are being conducted and standardization forms are being completed.

Time was identified as the second-largest barrier to successfully implementing a risk-based inspection program. Jurisdictions reported that re-training staff who were hired prior to implementing risk-based inspections was time-consuming. One jurisdiction stated that, “once risk-based inspections were implemented, routine inspections began taking much longer due to the documentation of the risk factors identified out of compliance.”

“...we don’t really have barriers other than time. Transition to risk-based inspections was slow because [we] had to do a lot of [the] training and education.”



Table 2. Challenges identified as a barrier to implementing risk-based inspections.

Local Jurisdictions Interviewed		Category 1					Category 2			Total	
		1	2	3	4	5	6	7	8		9
Factors that make successfully implementing risk-based inspections challenging.	Lack of staff		√	√				√	√		4
	Standardization			√	√				√		3
	Public knowledge of risk-based inspections			√							1
	Staff retention			√			√			√	3
	Leadership buy-in				√	√				√	3
	Took a long time to implement risk-based inspections	√						√			2
	Language							√			1
	Staff knowledge of risk factors		√	√							2
	Staff bias in enforcement		√								1
	Facility management turnover		√								1
	Staff buy-in	√	√		√	√		√	√		6
	Alignment of priorities between FDA, state, and local									√	1
	Facility buy-in	√				√	√				3
	Addressing one-off issues						√				1
	Time constraints								√		1

Category 1 = met all three standards ; Category 2 = met some but not all three standards

Strategies to Support Implementation of Risk Based Inspection Methods

The results of the key informant interviews were analyzed by NACCHO and CFP staff, with input from the RFSAG, the Collaborative, the FDA, and the CDC. This was followed by development of concrete recommendations for strategies and actions that SLTTs, Collaborative associations, federal partners, and regulatory agencies may take to reduce barriers faced by local jurisdictions in implementing risk-based inspection methods.

Five strategies to overcome these barriers are described below.

1 Training

Participants referenced the following success factors related to training: adhering to the requirements for Standard 2 (Trained Regulatory Staff) of the Retail Program Standards for new staff; having staff complete FD215 Managing Retail Food Safety and FD218 Risk Based Inspections at Retail; sending staff to different professional conferences such as AFDO's and NEHA's for continuing education; and implementing a standardization program.

Recommendations

- **Identify** and post available trainings necessary to implement risk-based inspection methods on the Collaborative's webpage.
- **Advocate** and post funding opportunities for staff to attend trainings.
- **Disseminate** widely and equitably the availability and importance of trainings as a foundation.
- **Require** new and existing staff to take/re-take trainings (e.g., FD215 and FD218) to integrate risk-based inspections as a culture into regulatory inspections.
- **Reinforce** concepts learned in training during internal staff meetings and updating policies when needed.

- **Utilize** Retail Program Standard 2 as a foundation or guideline to the program’s training framework.
- **Utilize** FDA’s Retail Food Specialists as a resource for providing training assistance in development of in-house workshops and trainings for staff so they can address training gaps.

2 Funding
The key informant participants described funding source(s) as a factor for success.

Recommendations

- **Identify** grants and funding, to be made available on the Collaborative’s “Funding Opportunities” webpage,⁹ Collaborative associations’ webpages, and other communications channels.
- **Make available** more funding and grants for SLTT programs to assist in implementing risk-based inspections.
- **Create** easy and/or low-barrier applications enabling more SLTTs to receive grant funding.
- **Disseminate** publications demonstrating return on investment through implementing risk-based inspections.
- **Develop and maintain** accessible education courses and material for current and future public health food safety workforces.
- **Review** how funding has been used to support the implementation of risk-based inspections to identify best practices for future funding opportunities.
- **Expand** collaborations between local and state partners and national associations to learn/share funding information and create networking opportunities. For example, creating mentorship communities of practice, Retail Program Standards focus groups or peer networks, and utilizing social media groups to meet SLTTs (e.g., LinkedIn, Facebook).
- **Identify or develop and disseminate** a comprehensive workforce development plan for SLTT staff, including recommendations to review and update regularly.

Did You Know?

External funding for retail food safety programs can be particularly beneficial to those operating within local health departments (LHDs) as there has been a 21% decrease in LHD workforce capacity over the past decade. And, while LHD budgets have slowly started to increase, 67% of LHDs have reported a stagnant or decreased budget in 2019.⁵

3 Leadership Buy-In
Leadership buy-in was identified by five of the jurisdictions as a factor for success.

Recommendations

- **Prepare** elevator pitches, fact sheets, one-pagers, and other resources that can help SLTT jurisdictions describe the benefits of risk-based inspection methods to their leadership.
- **Develop** a concise database of studies and evidence of the effectiveness of risk-based inspection methods to demonstrate results, including measures or indicators of successful implementation.
- **Provide** a statement of support for risk-based inspection methods from regulatory programs, industry organizations and members, associations, academia, and agencies around the country.
- **Disseminate** publications with cost-to-benefit data demonstrating the monetary value of implementing risk-based inspections.
- **Develop** a toolkit with sample materials to disseminate to upper-level leadership. This may include finance directors or other key stakeholders who can understand return on investment.

- **Build** strong partnerships between local, state, and federal stakeholders and elected officials to ensure the benefits of environmental health work is known locally.
- **Invite** FDA's Retail Food Specialists to local government meetings or on-site "meet and greets" with upper management to talk about the importance of risk-based inspections, risk factor studies, and to highlight the accomplishments of the jurisdiction if they are enrolled in the Retail Program Standards.
- **Include** measures as part of the local strategic planning process.
- **Examine** any outcomes, activities, or performance measures that tie to Public Health Accreditation.

4 Staffing

Staffing was identified as the largest barrier to successfully implementing a risk-based inspection program.



Recommendations

- **Prepare** factsheets or case studies of how other SLTT programs have implemented risk-based inspection methods with limited staffing or lack of staff buy-in.
- **Make available** more funding/grants for SLTT programs to hire additional staff to assist in implementing risk-based inspection methods. Encourage SLTT programs to meet the recommended ratio of inspections to full-time employees as recommended in the Retail Program Standards.
- **Provide** a statement of support for risk-based inspection methods from regulatory programs, industry organizations and members, associations, academia, and agencies around the country.
- **Develop and promote** educational opportunities for current and future workforce to ensure standardized training of all staff. This may include sample onboarding guides for new hires and making available continuous training for current staff.
- **Encourage** the hiring of interns to conduct nonfood activities (such as seasonal swimming pool inspections) so full-time staff can perform food program activities. May include sharing intern position description templates and strategies to connect with local universities.
- **Promote** and advocate staff advancement opportunities to acquire Food Safety Inspection Officer roles.
- **Explore** workforce development strategies and career paths for the retail food safety professional, including approaches to redefine the culture of the regulatory program into a public health program with a regulatory component.
- **Prepare** demonstrations to show return on investment among leadership and to advocate for increased recruitment for dedicated staff for regulatory programs.

5 Time Commitment

Time dedicated to conducting risk-based inspections was identified as the second-largest barrier to successfully implementing a risk-based inspection program.

Recommendations

- **Prepare** case studies of how other SLTT programs have implemented risk-based inspection methods with limited time, and how once SLTT programs have implemented risk-based inspection methods, the subsequent time of inspection and follow-ups decreased.
- **Make available** more funding and grants for SLTT programs to hire additional staff to assist in implementing

- risk-based inspection methods. Advocate for permit fee increases to offset additional staff salaries.
- **Create** opportunities for SLTTs to streamline processes (e.g., peer-to-peer mentorship program).
 - **Share** best practices for SLTTs to partner locally with another jurisdiction that has implemented risk-based inspection methods (e.g., building networks for ad hoc mentorship).
 - **Use** Retail Program Standard 8 to evaluate staffing level in terms of inspection to FTE ratio as a justification to request more staff.
 - **Program managers** could provide support to FSIOs for risk and performance-based inspection frequencies.

Conclusion

Despite acknowledging challenges to implementing risk-based inspections, the key informant interviewees in this study referred to more success factors (41 comments) over barriers (33 comments). Identification and utilization of funding sources, adequate training for staff, and leadership and staff buy-in were the most frequent success factors that were referred to for implementing a risk-based inspection program by local jurisdictions. These local retail food safety programs further described how the challenges of staffing and time can hinder risk-based inspections. Buy-in from leadership, facility managers, and staff also surfaced in multiple interviews as a potential challenge. In some cases, this may reflect generational differences in the approach to food safety as more and more programs are now recommending that inspectors educate and inform first then enforce with financial citations instead of proceeding with citations directly. This type of cultural shift in the approach to retail food safety practices is not uncommon in local jurisdictions.

The five strategies—and their recommendations—can serve as an actionable checklist to specifically reduce barriers and enhance success factors related to implementation of risk-based inspection methods.

This report goes beyond naming the barriers to successful implementation of risk-based inspections to highlight recommended actions for state and local leadership, national associations, and federal partners to reduce or eliminate these barriers and propel retail programs towards success. The five strategies—and their recommendations—can serve as an actionable checklist to specifically reduce barriers and enhance success factors. While the sample pool in this study is limited in size, these interviews likely highlight many popular barriers to conducting risk-based inspections and can serve as a baseline with which to measure progress, especially as these recommendations are being enacted. Further research should examine how these success factors and strategies can create a “multiplier effect” to empower sustained momentum and continued advancement towards fully implemented risk-based inspections throughout the retail food safety industry in the United States.

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APPENDICES

APPENDIX A: Key Informant Demographics

Local Jurisdiction Key Informant Interview Participant Demographics									
	1	2	3	4	5	6	7	8	9
Local Retail Food Safety Program									
Years of Experience Working on Retail Program Standards	11	7	5	9	8	15	6	6	1
Authority Derived	State	State	Local ordinance	State	State	State	State	State	State
Food Code Edition	2013	2013-Modified	2009	2017	2001 plus local ordinances	2013	2013	2013, including 2015 supplement	2013
Number of Retail Establishments	3,000	9,000	1,100	1,000	450	1,293	934	668	6,271
Number of Full-Time Equivalents (FTE) Actively Conducting Retail Food Work*	32	36	8	8	5	10	9	7	19
Size of Jurisdiction [†]	Large	Large	Large	Medium	Small	Medium	Medium	Medium	Large
Region	Southeast	Southwest	Midwest	Midwest	Northeast	Southwest	Midwest	Southeast	Southwest
Retail Program Standards Met (3, 4 and/or 6)	3, 4, 6	3, 4, 6	3, 4, 6	3, 4, 6	3, 4, 6	3, 4, 6	4, 6	3	3, 4

*FTE is determined by the number of productive hours contributed by one person working full-time for one year. This is taken from the Standard 8 Staffing Level Assessment Workbook; Instruction Guide <http://www.foodprotect.org/media/site/standard-8-staffing-level-fe-to-inspection-ratio-assessment-workbook.pdf>

[†] Jurisdiction sizes included small (<50,000), medium (50,001 – 499,999), and large (>500,000)

APPENDIX B: Key Informant Interview Questions

Key Informant Interview Questions Administered via Qualtrics or Phone Interview

Topic I: Jurisdiction Background

Qualtrics©

- How many retail food establishments (e.g., retail food stores, food service, convenience, etc.) does your agency regulate?
- How many full-time equivalents (FTEs) are assigned and actively conducting retail food field work in your agency? (Note 1: Excludes vacant FTEs. Note 2: If you have 20 people conducting retail inspections, but only 50% of their work time is assigned to the retail program, then that would be 10 FTEs. Note 3: If 10% of the Supervisor's time is spent conducting routine or follow-up retail food regulatory inspections, then that would be counted in this number.)
- How many staff members are actively conducting retail food field work for your agency? (Note: This may be different than total number of FTEs. For instance, two half-time employees would equal one FTE, but would be two distinct staff members conducting inspections.)
- What version of the FDA Food Code has your jurisdiction adopted (including any Food Code supplements)?
- Where does your agency derive its regulatory authority to conduct retail food regulatory activities (i.e., local ordinance, state)?
- When did your agency start using risk-based inspection methods? What factors influenced your agency's decision to implement risk-based inspection methods?

Phone

- How do you determine your risk categories for retail food establishments?
- How do you assign inspection frequencies based on the risk categories?
- Are you able to accomplish that schedule during non-pandemic times? If not, why?
- Do you have other types of inspections such as 'educational' inspection that aren't scored or have a food rating affect?
- How do you identify risk factors and their appropriate interventions?
- How do you determine the compliance status of each risk factor and intervention? How do you assess what is IN compliance, OUT of compliance, Not observed, or Not applicable?
- How do you document compliance and enforcement activities?
- What is your process for changing the frequency of inspection of a retail food establishment?
- How do you implement your policy for onsite corrective actions as appropriate to the type of violation?

Topic II: Inspection Program Based on HACCP Principles (Standard 3)

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- What best practices/tools/resources did your agency use to implement risk-based inspections?
- Does your inspection form(s) allow for the recording and quantifying of the compliance status of risk factors and interventions (i.e., IN compliance, OUT of Compliance, Not Observed, or Not Applicable)?
- What are your risk categories and their associated frequencies of inspections? What type of establishments fall into the different categories?
- Does your jurisdiction take into consideration whether an establishment has implemented a voluntary food safety management system like HACCP when determining the frequency of inspections at a retail food establishment?
- What factors does your jurisdiction use to justify an increase in inspection frequency?
- What is your jurisdiction's definition of an out-of-control risk factor?
- Do you follow the FDA's recommended time frames for correction?
- If not, what are you using to determine your time frames?
- What trainings or educational opportunities do you have in place for the retail food facility staff on Active Managerial Control?
 - ◊ 'Person-in-Charge' training
 - ◊ Managers Certification Course
 - ◊ ANSI-accredited course
 - ◊ Offer educational visits
 - ◊ Other (list other trainings/education opportunities)

Phone

- How do you determine your risk categories for retail food establishments?
- How do you assign inspection frequencies based on the risk categories?
- Are you able to accomplish that schedule during non-pandemic times? If not, why?
- Do you have other types of inspections such as 'educational' inspection that aren't scored or have a food rating effect?
- How do you identify risk factors and their appropriate interventions?
- How do you determine the compliance status of each risk factor and intervention? How do you assess what is IN compliance, OUT of compliance, Not observed, or Not applicable?
- How do you document compliance and enforcement activities?
- What is your process for changing the frequency of inspection of a retail food establishment?
- How do you implement your policy for onsite corrective actions as appropriate to the type of violation?
- How does your program implement and ensure inspectors are addressing issues with long-term control of risk in your retail food establishments?
- How do you ensure and document timely correction of code violations?
- How are inspectors conducting and documenting follow-up activities?
- How do you manage variance requests that are related to foodborne illness risk factors and interventions?
- How do you verify and validate of HACCP plans when the HACCP plan is required by a code?
- What inspection equipment does your jurisdiction's inspectors use to determine control of foodborne illness risk factors?
- How do your jurisdiction's inspectors evaluate and document the degree of Active Managerial Control that a food establishment has over foodborne illness risk factors?
- How do your jurisdiction's inspectors lead by example when performing inspections (e.g., hand washing, not touching ready-to-eat food with bare hands)?
- How do you ensure that your agency conducts inspections at variable times?
- What are your agency's inspection processes and how are they established (e.g., establishing an open dialogue, review previous inspection records, conduct a menu or food list review, conduct a quick walk-through)?
- What barriers/challenges did your agency encounter in implementing inspections based on HACCP Principles? For example: What barriers/challenges did your agency encounter with identifying risk factors and interventions? Establishing corrective actions that target immediate and long-term control of risk factors?
 - ◊ How has your agency overcome any barriers/challenges it encountered when implementing inspections based on HACCP Principles?

Topic III: Uniform Inspection Program (Standard 4)

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- What best practices/tools/resources does your agency use to ensure a uniform inspection program?
- What policies are in place to ensure that there is a uniform inspection program in place to conduct risk-based inspections?
- Do you have a trainer or lead staff responsible for regulatory checking inspection reports for quality assurance/quality control and following proper marking instructions?
- What training (e.g., classroom training, in-field training, standardization, continuing education) is provided to retail food regulatory staff?
- Do you require staff to take FD218 of Risk-Based Inspection Methods in Retail training? If yes, what percentage are required to take the FD218 training?
- Does your state provide training of new inspectors?
- Do you have tools to track staff data on average violations noted that compare to other staff or average violations noted?
- What procedures do you have to verify that an establishment is assigned to in the proper risk category and that the required inspection frequency is being met?
- What are the procedures for notifying a supervisor when an establishment is not in the proper risk category or when the required inspection frequency is not being met?

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- How do you ensure that your staff provide the proper identification as a regulatory official to the person in the charge and state the purpose of their visit?
- How do you ensure that your staff are using a risk-based inspection methodology to conduct the inspection?
- How does your program assess the performance of the inspection program? How does your program address deficiencies in quality or consistency identified in the uniform inspection program?
- How do you ensure that your agency has adequate resources to support a risk-based retail food safety program designed to reduce the occurrence of foodborne illness risk factors (e.g., funding, staffing, equipment)?
- How do you ensure that staff are taking regulatory actions to achieve compliance with regulations?
- How do you ensure that staff are documenting options for a long-term control of risk factors that were discussed with establishment managers when the same out of control risk factors occurs on consecutive inspections?
- What barriers/challenges did your agency encounter in implementing a uniform inspection program?
 - ◊ Did you have any challenges with obtaining adequate resources to support a risk-based retail food safety program?
 - ◊ How did your program advocate to receive adequate resources to support a risk-based retail food safety program?
 - ◊ Have there been any issues with maintaining adequate resources to continue support a risk-based retail food safety program?
 - ◊ How has your agency overcome barriers/challenges in implementing a uniform inspection program?

Topic IV: Compliance and Enforcement (Standard 6)

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- What resources/best practices/tools did your agency use to create policies for compliance and enforcement?
- What barriers/challenges did your agency encounter in implementing a compliance and enforcement program?

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- Does your program follow proper 'marking instructions' for each risk factor (based on FBI Outbreaks and interventions) violation?
- How does your program track compliance and enforcement?
- How do you work with operators to obtain voluntary corrections to achieve compliance with regulations?
- How are regulatory enforcement actions used to achieve compliance with regulations?
- How does your program demonstrate credible follow-up for each violation that is noted during an inspection? How do you emphasize risk factors that most often contribute to foodborne illness?
- How do you demonstrate that a resolution was successfully achieved for all out-of-control factors or interventions that were recorded on the selected routine inspection?
- How do you ensure risk factors are not continually cited during subsequent routine inspections?
- How has your agency overcome these barriers/challenges in implementing a compliance and enforcement program?

Topic V: Barriers and Strategies in Overcoming Barriers

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- When implementing a risk-based inspection program, what were the greatest challenges you faced?
- What resources would be useful for your agency/department to assist with implementing a risk-based inspections program?
 - ◊ Technical Assistance
 - ◊ Internet-based training (e.g., webinars, e-learning courses, podcasts)
 - ◊ In-person training
 - ◊ Fact sheets or issue briefs
 - ◊ Case studies/examples of successful inclusion
 - ◊ Grant opportunities
 - ◊ Outreach/communications to people with disabilities
 - ◊ Mentorship/coaching opportunities
 - ◊ Assistance with county/city management buy-in
 - ◊ Other (please specify)
- What are three strategies/tips that you would give to jurisdictions to help them successfully implement a risk-based inspection program?
- What, if any, perceived outcomes have your agency seen as a result of implementing a risk-based inspection approach? (e.g., decreased repeat violations, impact frequencies of inspections, focus on critical, direct correlation of FBI Outbreaks to risk factor violations that align with enforcement procedures).

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- How did you overcome these challenges/barriers in implementing risk-based inspections?
- How would resources/funding/technical assistance help jurisdictions implement risk-based inspection methods?
- How have you implemented these strategies to overcome barriers and challenges in implementing a risk-based inspection program?
- What has resulted from implementing these strategies?
- How has implementing a risk-based inspection approach resulted in (enter the perceived outcome they included in survey)?
- What changes/modifications have you made to inspections due to COVID-19?
 - ◊ How has COVID-19 impacted implementation of your risk-based inspection program?
 - ◊ How have you been able to overcome these challenges due to COVID-19?

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1201 Eye Street, NW, Fourth Floor • Washington, DC 20005

Phone: 202-783-5550 • Fax: 202-783-1583

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