VOLUNTARY NATIONAL RETAIL FOOD REGULATORY PROGRAM STANDARDS
IN THE BEGINNING...

Steven Nattrass
Consumer Safety Officer, FDA
HISTORY

• March 1996 Stakeholder Meeting

• Key Outcomes:
  • Formation of the Retail Food Steering Committee
  • Development of Five-Year Operational Plan
HISTORY

• Five-Year Operational Plan
  
  • Promote active managerial control of the risk factors most commonly associated with foodborne illness in food establishments
  
  • Establish a recommended framework for retail food regulatory programs within which the active managerial control of the risk factors can best be realized
HISTORY

• Framework developed that:

  • Establishes a foundation and system upon which all regulatory programs can build through a continuous improvement process.

  • Focuses attention on the factors that cause and contribute to foodborne illness, with the ultimate goal of reducing the occurrence of those factors.
HISTORY

• 1998 - Retail Program Standards were drafted with stakeholder input

• 1999 – Piloted in each of the five FDA regions

• 2001 – Improvements incorporated into the January 2001 version

• 2002 – March 2002 version endorsed by the Conference for Food Protection (CFP)
• 1998 - Retail Program Standards were drafted with stakeholder input
WHERE ARE WE NOW?

1) FDA provides funding to enrolled retail food regulatory programs through the following three mechanisms:

• Multi-year, direct Cooperative Agreements
• Single-year grants, awarded through a Retail Association Cooperative Agreement
• Single-year contracts, awarded through the Mentorship Program
WHERE ARE WE NOW?

2) Retail Program Standards Mentorship Program

• Learn from experienced enrollees
• Share tools, resource documents and ideas for implementation of the Standards
• Participate in webinars highlighting enrollees’ successful implementation of the Standards
WHERE ARE WE NOW?

3) Retail Program Standards Resource Center on FoodSHIELD

- Foster collaboration among retail food regulatory programs
- Share templates, tools, and resource documents
- Contact FDA Retail Food Specialist for access
WHERE ARE WE NOW?

• Animal Food Regulatory Program Standards

• Manufactured Food Regulatory Program Standards

• Retail Food Regulatory Program Standards
REVIEW OF THE RETAIL FOOD PROGRAM STANDARDS

Lisa Staley
Maryland Dept. of Health & Mental Hygiene

http://www.fda.gov/food/guidanceregulation/retailfoodprotection/programstandards/default.htm
STANDARD 1 – REGULATORY FOUNDATION

• This Standard applies to the regulatory foundation used by a food program.

• Regulatory foundation includes any statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that governs the operation of a retail food establishment.
STANDARD 1 – REGULATORY FOUNDATION

• Provisions made for:
  • Public health interventions contained in most current published edition of *Food Code* or 1 of the 2 most recent previous editions of the *Food Code*
  • Control measures for risk factors known to contribute to foodborne illness
  • Good Retail Practices at least as stringent as the *Food Code* edition as specified above
  • Compliance and enforcement at least as stringent as the selected provisions in the *Food Code* and the Annex 1 of the *Food Code* edition as specified above
• This Standard applies to the essential elements of a training program for regulatory staff.
STANDARD 2 – TRAINED REGULATORY STAFF

• Complete the 5-step training & standardization process
  • Complete “Pre” curriculum courses from Appendix B-1
  • Complete minimum of 25 joint field training inspections & the jurisdiction’s Field Training Plan
  • Complete minimum of 25 independent inspections & remaining curriculum courses from Appendix B-1
  • Complete standardization process
• Complete 20 contact hours of food safety every 36 months after initial training complete
STANDARD 3 – INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

• This Standard applies to the utilization of HACCP principles to control risk factors in a retail food inspection program.
STANDARD 3 – INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

• Implements an inspection form that:
  • Identifies risk factors & interventions
  • Documents compliance status for each risk factor & intervention
  • Documents compliance & enforcement activities
  • Requires selection of IN, OUT, NO, NA
• Develops & uses process that groups establishments into at least 3 categories based on potential & inherent food safety risks
STANDARD 3 – INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

• Develops & implements program policy that requires:
  • On-site correction as appropriate to violation type
  • Discussion of long-term control of risk factor options
  • Follow-up activities

• Establishes & implements written policies addressing code variance requests related to risk factors & interventions

• Establishes written polices regarding the verification & validation of HACCP plans when a plan is required by the code
STANDARD 4 – UNIFORM INSPECTION PROGRAM

• This standard applies to the jurisdiction’s internal policies and procedures established to ensure uniformity among regulatory staff in the interpretation of regulatory requirements, program policies and compliance/enforcement procedures.
STANDARD 4 – UNIFORM INSPECTION PROGRAM

• Implementation of an on-going quality assurance program
  • Evaluates for inspection uniformity to insure quality inspections, inspection frequency and uniformity among the regulatory staff
• Must be an on-going program
• Describe the actions that will be implemented with the program analysis identifying deficiencies in quality or consistency in a program aspect.
STANDARD 4 – UNIFORM INSPECTION PROGRAM

• Assure each inspector:
  • Determines & documents compliance status of each risk factor & intervention through observation & investigation
  • Completes an inspection report that is clear, legible, concise & accurately records findings, observations & discussions with establishment management
  • Interprets & applies laws, regulations, policies & procedures correctly
  • Cites the proper local code provisions for CDC-identified risk factors & Food Code interventions
  • Reviews past inspection findings & acts on repeated or unresolved violations
STANDARD 4 – UNIFORM INSPECTION PROGRAM

• Assure each inspector:
  • Follows through with compliance & enforcement
  • Obtains & documents on-site corrective action for out-of-control risk factors at the time of inspection as appropriate to the type of violation
  • Documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factors occur on consecutive inspections
  • Verifies that the establishment is in the proper risk category & that the required inspection frequency is being met
  • Files reports & other documentation in a timely manner
STANDARD 5 – FOODBORNE ILLNESS & FOOD DEFENSE PREPAREDNESS AND RESPONSE

• This Standards applies to the surveillance, investigation, response and subsequent review of alleged food-related incidents and emergencies, either unintentional or deliberate, which results in illness, injury and outbreaks.
STANDARD 5 – FOODBORNE ILLNESS & FOOD DEFENSE PREPAREDNESS AND RESPONSE

• Investigative Procedures
• Reporting Procedures
• Laboratory Support Documentation
• Trace-back Procedures
• Recalls
• Media Management
• Data Review & Analysis
STANDARD 6 – COMPLIANCE & ENFORCEMENT

• This Standard applies to all compliance and enforcement activities used by a jurisdiction to achieve compliance with regulations.
STANDARD 6 – COMPLIANCE & ENFORCEMENT

• Written step-by-step procedures that describe how compliance & enforcement tools are to be used to achieve compliance.

• Inspection report form(s) that records & quantifies the compliance status of risk factors and interventions (i.e. IN/OUT/NO/NA)

• Documentation of establishment inspection report form or in establishment file using the statistical method for file selection
  • Inspection & enforcement staff takes compliance & enforcement actions according to procedure
  • Resolution was successfully achieved for all out-of-control risk factors or interventions that were recorded on the selected routine inspection
STANDARD 7 – INDUSTRY & COMMUNITY RELATIONS

• This Standard applies to industry & community outreach activities utilized by a regulatory program to solicit a broad spectrum input into a comprehensive regulatory food program, communicate sound public health food safety principles and foster and recognize community initiatives focused on the reduction of foodborne disease risk factors.
STANDARD 7 – INDUSTRY & COMMUNITY RELATIONS

• Industry & Community Interaction
• Educational Outreach
STANDARD 8 – PROGRAM SUPPORT & RESOURCES

• This Standard applies to program resources (budget, staff, equipment, etc.) necessary to support an inspection and surveillance system that is designed to reduce risk factors and other factors known to contribute to foodborne illness.
STANDARD 8 – PROGRAM SUPPORT & RESOURCES

- Staffing Levels
- Inspection Equipment
- Administrative Program Support
- Regulatory Foundation
- Trained Regulatory Staff
- Inspection Program Based on HACCP Principles

- Uniform Inspection Program
- Foodborne Illness & Food Defense Preparedness & Response
- Compliance & Enforcement
- Industry & Community Relations
- Program Assessment
- Accredited Laboratory
STANDARD 9 – PROGRAM ASSESSMENT

• This Standard applies to the process used to measure the success of a jurisdiction’s program in deducing the occurrence of foodborne illness risk factors to enhance food safety and public health in the community.
STANDARD 9 – PROGRAM ASSESSMENT

• Conduct a Risk Factor Study on the occurrence of the 5 foodborne illness risk factors
  • Repeat at least once every 5 years to measure trends
• Analyze collected data & write a report on the outcomes and conclusions of the Risk Factor Study
• Develop a targeted intervention strategy designed to address the occurrence of the risk factor(s) identified in the Risk Factor Study
  • Implement strategy & monitor effectiveness of strategy through subsequent Risk Factor Studies
CFP’S ROLE IN THE RETAIL PROGRAM STANDARDS

Angie Cyr
Minnesota Department of Health
• CFP has had a long-standing partnership with the FDA on matters related to retail food

• CFP constituency includes representatives from the food industry, government, academia and consumer & professional organizations
MEMORANDA OF UNDERSTANDING WITH FDA

• Has been in effect since 1992
• Recognizes CFP as a voluntary national organization that is well qualified to provide technical guidance and information to industry, state and local governments, academic institutions and consumer groups on matters relating to development and implementation of codes and standards dealing with retail food service, retail food stores and retail food vending operations

http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/OtherMOUs/ucm118390.htm
CFP ISSUES RELATED TO THE RETAIL PROGRAM STANDARDS

• 63 issues during the last 8 conferences have been submitted to CFP associated with the Retail Program Standards (RPS)

• Related to the review, endorsement, revision and additions to the RPS
CFP ENDORSED RETAIL PROGRAM
STANDARDS IN 1998

• Created initial CFP-FDA partnership in the Retail Program Standards
• CFP Accreditation Study Committee was charged with the assessment and review of the RPS
• CFP participated in a 2-year pilot project with FDA with the goal to finalize the RPS at the 2000 CFP
2000 CFP

- It was determined that the Accreditation Study Committee would continue to work with FDA to revise the National Voluntary Retail Food Regulatory Program Standards as necessary
- CFP promised to lend assistance to FDA in promoting the Program Standards nationally
2002 CFP (3 ISSUES)

• CFP endorsed the June 2001 Draft Recommended National Regulatory Retail Food Program Standards (RPS)
• CFP became one of the primary mechanisms for reviewing and commenting on future changes within the RPS
• CFP agreed to seek on-going input on the RPS from the CFP members
2004 CFP (4 ISSUES)

CFP recommended:

• Changes to Standard 1 and Appendix A-1 to extend phase in time for compliance with all of the 11 risk factors and interventions by the third audit
• Changes to Standard 1 and Appendix A-5
• Changes to the Standard 9 baseline survey to make it a 5 year cycle
• Endorsement of FDA field testing the draft audit manual for self-assessments
2006 CFP (10 ISSUES)

- Created the Program Standards Committee
- CFP endorsed and recommended revisions to the following:
  - Standard 2 (3 issues)
  - Standard 3
  - Standard 4 and Appendix D
  - Standard 6 and Appendix F (3 issues)
  - Standard 9
2008 CFP (9 ISSUES)

• Program Standards Committee re-created to serve as the stakeholder group to provide input to FDA on the RPS

• Recommended that the FDA evaluate State Retail Food Programs based on the Standards
• CFP endorsed and recommended revisions to:
  • Changes to the definitions in the Standards
  • Standard 1
  • Clarify language for Standard 2, Step 2
  • Standard 2, Appendix B-1
  • CFP Guide to Conducting an Assessment of Training Needs in Standard 2, Appendix B-2 replaced with CFP Field Training Manual for Regulatory Retail Food Inspection Officers
  • Standard 5
  • Revise language in the Education Provision for Program Standards language in the introduction to the Standards
• CFP endorsed and recommended revisions to:
  • Definition for the Standards
  • Clarify Standard 2, Step 2
  • Clarify the definitions for Standard 2, Step 4
  • Include FDA allergen management course in Standard 2, Appendix B-1
  • Include Emergency Management Course additions to Standard 2, Appendix B-1
  • “Outcome” section of Standard 5
  • Standard 6, Appendix F
  • Standard 9
2010 CFP (12 ISSUES), CONTINUED

- Recommended financial support from FDA to enrollees in the Standards
- Recommended coordination of the two current FDA food program standards (Retail and Manufacturing)
- Program Standards Committee report
- Re-created Certified Food Safety Regulatory Professionals Committee
2012 CFP (7 ISSUES)

• CFP endorsed and recommended revisions to:
  • Administrative Procedures for the Standards
  • Standard 4
  • Standard 5, include Council to Improve Foodborne Outbreak Response (CIFOR) documents
  • Standard 8, assessment workbook and instruction guide
  • Standard 9

• Program Standards Committee report
• Re-create Program Standards Committee
2014 CFP (5 ISSUES)

• Re-create Program Standards Committee (became a Standing Committee)
• Program Standards Committee proposed changes to CFP governing documents
• Certification of Food Safety Regulation work group to assess the changes needed to Standard 2
• Align the competency of inspectors (8-402.10) with Standard 2
• Program Standards Committee report
2016 CFP (13 ISSUES)

- Program Standards Committee (PSC) report
- Recommendations from Issue 2014-II-003
- Recommendations from Issue 2014-II-005
- Amend Standard 4 (2 issues)
- Amend Standard 7
- Amend Standard 9
- Posting of infographic on CFP website
2016 CFP (13 ISSUES), CONTINUED

• Provide recommended Food Code adoption process in Standard 1
• Clarification for re-standardization in Standard 2
• Reevaluation of RPS Standard 8
• Reassign charges from the Certification of Food Safety Regulation Professionals work group to PSC
• Reassign charges from the Interdisciplinary Foodborne Illness Training Committee to PSC
FUNCTIONS OF THE PROGRAM
STANDARDS COMMITTEE

• Reports to the CFP Board and provides ongoing input to the FDA on issues that arise with the Retail Food Program Standards. The Committee indirectly assists enrollees in making progress toward meeting the Standards.

• Liaison with the FDA

• Reviews proposed changes

• Suggests changes

• Involves industry
ADDITIONAL CFP DELIVERABLES & SUPPORT OF RPS


• Clearinghouse Work Group Q & A document on website

• Partner documents, such as the FDA audit manual for self assessment evaluations, on website
QUESTIONS?
RETURN ON THE INVESTMENT

James O’Donnell
Hussmann Corporation
Issue 2014-II-003

• To solicit the support of industry to:
  • Identify the benefits to industry for Regulatory Authorities to achieve Standard 2, 4 and 7

• 116 Survey’s completed with:
INFOGRAPHIC HIGHLIGHTS

- Teamwork
- Consistent Approach to Inspections
- Focus on the Risk Factors to reduce Foodborne Illness
- Continuous Improvement
QUESTIONS?
THE CLEARINGHOUSE WORK GROUP

Steven Nattrass
Consumer Safety Officer, FDA

http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/UCM372615.pdf
CLEARINGHOUSE WORK GROUP

- Ad hoc group of representatives from state, local, and tribal jurisdictions representing the 5 FDA regions and the CFP’s Program Standards Committee

- Purpose:
  - Work with FDA staff to answer questions about the Retail Program Standards
CLEARINGHOUSE WORK GROUP

• Recent update

• Document can be found by going to: www.fda.gov/RetailProgramStandards

• Announcements sent out via Retail Food Protection ListServ.
QUESTIONS?
PANEL DISCUSSION ABOUT THE PROGRAM STANDARDS

Melody Bowyer, South Central Public Health District, Idaho
Shana Davis, The Kroger Company, - Nashville Division
Rebecca Krzyzanowski, Michigan Department of Agriculture & Rural Development
Geoff Luebkermann – Florida Restaurant & Lodging Association
Andre’ Pierce, Wake County, North Carolina
Angela Sanchez, CKE Restaurants Holdings, Inc.

Moderated by Angie Cyr and Debbie Watts
ANY FINAL QUESTIONS?
Special Thanks to.....

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• Angie Cyr
• Caroline Friel
• Todd Mers

• Amanda Douglas
• Lisa Staley
• Stephen Hughes
• David McSwane

For all their help in preparing the presentation & arranging the speakers for today’s session...