Specializing in FDA Regulatory Matters

How to Take ACTIVE Control of Your Food Safety Management System

Charles S. Otto, III
EAS Independent Consultant
former USPHS Environmental Health Officer and
former Deputy Chief at the Centers for Disease Control and Prevention
Food Safety Puzzle
Food Safety Puzzle

Food Code
Food Safety Puzzle

Food Code

HACCP
Food Safety Puzzle

Food Code

Active Managerial Control

HACCP
Food Safety Puzzle

Food Code

Active Managerial Control

HACCP

Food Safety Management System
Food Safety Risk
Food Safety Risk

CDC estimates that each year roughly 1 in 6 Americans (or 48 million people) gets sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases.
Food Safety Risk

Estimated Cost to a Restaurant of a Foodborne Illness Outbreak

Sarah M. Bartsch, MPH¹, Lindsey Asti, MPH¹, Sindiso Nyathi, BA¹, Marie L. Spiker, MSPH, RD¹, and Bruce Y. Lee, MD, MBA¹

Abstract

Objectives: Although outbreaks of restaurant-associated foodborne illness occur periodically and make the news, a restaurant may not be aware of the cost of an outbreak. We estimated this cost under varying circumstances.

Methods: We developed a computational simulation model; scenarios varied outbreak size (5 to 250 people affected), pathogen (n = 15), type of dining establishment (fast food, fast casual, casual dining, and fine dining), lost revenue (i.e., meals lost per illness), cost of lawsuits and legal fees, fines, and insurance premium increases.

Results: We estimated that the cost of a single foodborne illness outbreak ranged from $3968 to $1.9 million for a fast-food restaurant, $6330 to $2.1 million for a fast-casual restaurant, $8030 to $2.2 million for a casual-dining restaurant, and $8273 to $2.6 million for a fine-dining restaurant, varying from a 5-person outbreak, with no lost revenue, lawsuits, legal fees, or fines, to a 250-person outbreak, with high lost revenue (100 meals lost per illness), and a high amount of lawsuits and legal fees ($1.656,569) and fines ($100,000). This cost amounts to 10% to 790% of a restaurant's annual marketing costs and 0.3% to 101% of annual profits and revenue. The biggest cost drivers were lawsuits and legal fees, outbreak size, and lost revenue. Pathogen type affected the cost by a maximum of $337,000, the difference between a Bacillus cereus outbreak (least costly) and a listeria outbreak (most costly).

Conclusions: The cost of a single foodborne illness outbreak to a restaurant can be substantial and outweigh the typical costs of prevention and control measures. Our study can help decision makers determine investment and motivate research for infection-control measures in restaurant settings.
Risk Factors

1. Unsafe food source
2. Poor employee health and hygiene
3. Improper cooking temperatures
4. Time and temperature abuse of foods
5. Contaminated equipment
EHS-Net Contributing Factors

WHAT ARE THE MOST COMMON CONTRIBUTING FACTORS?

THE TOP FOUR CONTRIBUTING FACTORS FOR OUTBREAKS IN RESTAURANTS ARE

1. Sick food worker contaminates ready-to-eat food through bare-hand contact.

2. Sick food worker contaminates food through a method other than hand contact, such as with a utensil they contaminated.

3. Sick food worker contaminates ready-to-eat food through glove-hand contact.

4. Food handling practices lead to growth of pathogens, such as food not kept cold enough.

2009 - 2013 / 297 outbreaks @ https://www.cdc.gov/nceh/ehs/docs/factsheets/cf-infographic.pdf
single establishments in study
ACTIVE Food Safety Team

Restaurants with well-developed FSMS had less than half as many risk factors and food safety practices that were out of compliance than restaurants with non-existent FSMS.

FDA Retail Food Risk Factor Study, 2013-2014
ACTIVE Managerial Control

Policies

Verification

A Continuous Improvement
Food Safety Management System

Training
Follow the Food
Analyze the Risks

Sourcing → Receiving → Storing → Contaminated → TCS issues → TCS issues / Cross contamination

Prepping → Cooking → Holding → Other Risks?

Cooling → Holding → Reheating → Other Risks?

Assembling → Serving → Other Risks?
ACTIVE Program Assessment

Policies and Procedures GAP Analysis

<table>
<thead>
<tr>
<th>Have a Written Policy</th>
<th>Purpose Statement</th>
<th>Scope Statement</th>
<th>Defined Procedure</th>
<th>Process for Monitoring</th>
<th>Corrective Actions Employees Can Take</th>
<th>Process for Record Keeping</th>
<th>Record of Employee Training</th>
<th>Being Reviewed on Periodic Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Safe Food Handler</td>
<td>Personal Hygiene Practices</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Washing Hands</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Single Use Gloves</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Reporting Health Issues</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**Strategic Analysis - Highest Risk First**

**Suggest Simple Start - One People Policy / One Process Policy**

**Customized - Facilities, Equipment, People, Food, Processes, Changing Menus, Specials, Deliveries**
ACTIVE Policy Development

ENGLISH AMC TOOLBOX

https://www.maricopa.gov/4533
ACTIVE Policy Development

HOW TO GET STARTED
DEVELOPING YOUR PLAN

2. Review These Documents
   - AMC Features (PDF)
   - AMC Overview Guidance (PDF)
   - Employee Health Challenges Guidance (PDF)

3. Need Help Developing Your Policy?
   - Employee Health Policy Poster (PDF)
   - Policies Are Actions (PDF)
   - Employee Health Policy Guidance (PDF)
   - Employee Health Policy Sample Language (PDF)
   - Employee Health Policy Template (PDF)

4. Need Help Implementing a Training Program?
   - Employee Health Training Poster (PDF)
   - Teach Demonstrate Practice (PDF)
   - Employee Health Training Guidance (PDF)
   - Employee Illness Form 1A (PDF)
   - Employee Illness Form 1B (PDF)

5. Need Help Establishing Verification Methods?
   - Employee Health Verification Poster (PDF)
   - Verification Ensures Success (PDF)
   - Employee Health Verification Guidance (PDF)

6. Need Additional Resources?
   - Communication Is Key (PDF)
ACTIVE Policy Development

Active Managerial Control Policy: Employee Health

Business Name: 
Effective Date: 
Next Review Date: 

Why this is important: Proper management of a food establishment operation begins with employing healthy people and instituting a system of identifying employees who present a risk of transmitting foodborne pathogens to food or to other employees.

Who does this apply to:
(Critical Elements: Describe who is responsible for ensuring employees are in a healthy state while working in your food service establishment. Include those personnel in this development process.)

PROCEDURES

When will this be performed:
(Critical Elements: Describe when ensuring employees are in a healthy state while working is performed at your food service establishment.)
# ACTIVE Policy Development

<table>
<thead>
<tr>
<th>Where does this take place:</th>
<th>Where?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Critical Elements: Describe where ensuring employees are in a healthy state while working is performed at your food service establishment]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How is this completed:</th>
<th>How?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Critical Elements: Describe how ensuring employees are in a healthy state while working is conducted at your food service establishment. Regulations 2-201.11 thru 2-201.13 require all employees to be free from some symptoms and report some illnesses while working]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Corrective Action:</th>
<th>Corrective Action?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Critical Elements: Describe what corrective actions are taken if employees are found to be working while in an unhealthy state]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitoring Steps:</th>
<th>Monitoring?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Critical Elements: Describe how ensuring employees are in a healthy state while working is monitored at your food service establishment. If you use monitoring logs, describe their use here]</td>
<td></td>
</tr>
</tbody>
</table>
ACTIVE Policy Development

Training?

Verification?
ACTIVE Training

Journal of Food Protection, Vol. 69, No. 11, 2006, Pages 2697–2702

Systematic Environmental Evaluations To Identify Food Safety Differences between Outbreak and Nonoutbreak Restaurants

CRAIG W. HEDBERG,1* S. JAY SMITH,2 ELIZABETH KIRKLAND,2 VINCENT RADKE,2 TIM F. JONES,3 CAROL A. SELMAN,2 AND THE EHS-NET WORKING GROUP

“…presence of a certified food safety kitchen manager was the major distinguishing factor between restaurants in which foodborne illness outbreaks occurred and restaurants in which foodborne illness outbreaks did not occur.
ACTIVE Training

- Cornerstone to Success
- Policy Focus
- Duties Focus
- Cross-Train
- Valuable Feedback
ACTIVE Training

- Interesting
- Memorable
- Interactive
- Short • Frequent
ACTIVE Verification

ACTIVE Managerial Control – Assessment

<table>
<thead>
<tr>
<th>Role</th>
<th>In</th>
<th>Out</th>
<th>NO</th>
<th>NA</th>
<th>ASSESSMENT AREAS</th>
<th>CORRECTIVE ACTIONS For Out of Control Items: (Who, What, How, &amp; When)</th>
<th>Date Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>PERSONNEL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Employee Training</td>
<td>01</td>
<td>Certified Food Protection Manager as Person-In-Charge / # certified</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>02</td>
<td>All employees trained in food safety, as it relates to their duties / # records reviewed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employee Health</td>
<td>03</td>
<td>Employees observed to assure not working ill, with follow-up questions / # employees observed and health status discussed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>04</td>
<td>Knowledge of foodborne illness symptoms / conditions by questions / # of managers and employees interviewed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>05</td>
<td>Applicant and Food Employee Reporting Interview Forms complete and current</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>06</td>
<td>Food Employee Reporting Agreements on File</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>07</td>
<td>Record of Staff Absences due to illnesses current month / # out with illnesses this month with dates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hand Hygiene</td>
<td>08</td>
<td>Deficiencies in handwashing procedures / # employees observed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>09</td>
<td>HWI sink accessible, soap, towels, water temperature, and pressure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>No Bare Hand Contact – RTE Food</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lintels/rolls/single use gloves used with RTE foods / List foods observed for photos</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Frequency?  
Time?  
Quantitative?  
Who?  
Analysis?
ACTIVE Verification

How Is Data Collected and Reviewed?

What Happens?
ACTIVE Verification

Fix:
Problem
or
Root Cause
Maricopa County (AZ) AMC

Samuel J. Crumbine Excellence in Food Protection Award
Maricopa County (AZ) AMC

Active Managerial Control
Food safety systems are successful when:
- They establish a food safety culture
- They speak your language
- They get the right people at the table
- They promote continued business improvement

Policies Are More Than Words
They’re a set of Actions!
- People
- Process
  - 02 Storage
  - 03 Preparation
  - 04 Cooking

Time for Action
Correct
Revise
Make a Change
Maricopa County (AZ) AMC

Before Class

2.04

Priority Violations / Inspection

1st Post Inspection

.71

4th Post Inspection

.86

Robert Stratman
Maricopa County (AZ) AMC

Pre-Legal Status

81%
193 Permits

Legal Status

86%
50 Permits

Breaking the Pattern
National Restaurant Association

Weeks:
1. Understand the Process
2. Provide Input
3. Refine the Process
4. Maintain Your Commitment

https://www.foodsafetyfocus.com/
National Restaurant Association

Controlling Risk: The Elements of a Food Safety Management System

Week 1

UP

UNDERSTAND THE PROCESS
Start by understanding the impact of your role in a Food Safety Management System (FSMS) and how food safety hinges on your personal performances. You're the key to making it all work!

What an FSMS does for you!

- Makes your job easier
  Creates consistency in how and when employees perform food safety tasks more efficiently in varying situations.

- Defines your role in the system
  By educating all food preparation and handling workers, it illustrates the vital importance of each person's job in controlling food hazards.

- Builds Teamwork
  Knowing how each person relies on every other for overall food safety unites the team to a common purpose: protecting the public and keeping the restaurant open.

- Puts Theory into Practice
  A restaurant's operation needs the input of those employees who perform the day to day tasks. Let your boss know what is or isn’t working.

Food safety comes down to you!

https://www.foodsafetyfocus.com/
National Restaurant Association

National Food Safety Education Month

Taking Food Safety to the Next Level: Creating and Implementing Effective Policies and Procedures

Sponsored by Tork, an Essity brand

September 18, 2019
Fairfax County (VA)

Active Managerial Control (AMC) Tool Kit Table of Contents

1. What is Active Managerial Control (AMC)?
   This document has information on AMC and what important parts make up AMC.

2. Self-Assessment
   This 2-page form allows food managers to evaluate overall current food safety practices and to obtain a status on how well the facility demonstrates AMC.

3. Introduction to Standard Operating Procedures (SOPs)
   This document has information on SOPs and why they are important for AMC.

4. SOP Checklist
   This list allows food managers to review existing SOPs in the facility and to track which policies are in need of development.

5. SOP Sample
   This document provides a helpful model for facilities who need to develop new SOPs.

6. SOP Template
   This document provides a template for facilities to easily print and fill out with their own SOP information.

7. Daily Self-Inspection
   This 2-page logbook allows facilities to track many food safety practices and to document corrective actions during each shift.

8. AMC Progress Report
   This form allows Health Department officials to briefly evaluate current food safety practices and to provide the facility with quick feedback or suggested improvements.

9. AMC Resources List
   This list gives facilities a quick reference to a Health Department library of materials available for AMC.
Fairfax County (VA)

Fairfax County Health Department

**Active Managerial Control (AMC) Self-Assessment**

Active managerial control (AMC) enables managers in food service to become proactive and lead food employees in managing safer food handling practices. By using AMC, a facility can reduce the risk of the occurrence of foodborne illness risk factors and provide a safer environment for serving food to customers.

This self-assessment provides your facility with a helpful tool in reviewing how actively you and your staff are managing food safety practices.

**Instructions:** Please circle Yes (Y) or No (N) to the following questions. Each (Y) will give you 5 or 10 points depending on the question. Once your facility has completed the self-assessment, you may total up the points and see the point system chart to see where you rank in terms of practicing AMC.

<table>
<thead>
<tr>
<th>Question</th>
<th>Points Possible</th>
<th>Points Scored</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does your facility have a Certified Food Manager (CFM) during all hours of operation?</td>
<td>Y N</td>
<td>10</td>
</tr>
<tr>
<td>2. Have all employees with food handling responsibilities received food safety training?</td>
<td>Y N</td>
<td>10</td>
</tr>
<tr>
<td>a. Is employee training tracked &amp; documented?</td>
<td>Y N</td>
<td>5</td>
</tr>
<tr>
<td>3. Are 3rd party, private, corporate, or self-inspections conducted?</td>
<td>Y N</td>
<td>10</td>
</tr>
<tr>
<td>4. Are thermometers available for use &amp; properly calibrated?</td>
<td>Y N</td>
<td>10</td>
</tr>
<tr>
<td>5. Does the facility have preventative maintenance procedures or contracts for:</td>
<td>Y N</td>
<td>10</td>
</tr>
<tr>
<td>a. Equipment (i.e. refrigerators, freezers, dishmachines, grease traps, hoods)</td>
<td>Y N</td>
<td>5</td>
</tr>
<tr>
<td>b. Pests</td>
<td>Y N</td>
<td></td>
</tr>
</tbody>
</table>
Fall 2019 Recognized Establishments

AMC Recognized Restaurants

https://www.fairfaxcounty.gov/health/food/awards-programs/active-managerial-control
ACTIVE Working Smarter

Digital Food Safety Management Systems

- Block Chain Technology
- Automatic Monitoring / Push Alerts
- Mobile Platform
- Interactive Training
- Artificial Intelligence
- Systems Integration
- Remote Video Options
- Cloud Connectivity
- Dashboards
- Trend Analysis / Flexible Reports
ACTIVE Summary

Webinar Focus:

- AMC / FSMS = ACTIVE Food Code Compliance
- ACTIVE Current Program Assessment
- Develop and Implement ACTIVE Programs
## Acknowledgements

<table>
<thead>
<tr>
<th>EAS Consulting Group, LLC</th>
<th>Olmsted County (MN) Public Health Services</th>
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<tbody>
<tr>
<td>National Restaurant Association</td>
<td>CDC / Environmental Health Specialist Network (EHS-Net)</td>
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<tr>
<td>- ServSafe&lt;sup&gt;®&lt;/sup&gt;</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>- Food Safety Focus</td>
<td>Dr. Hal King / Public Health Innovations</td>
</tr>
<tr>
<td>Maricopa County (AZ) Environmental Services</td>
<td>CDC / VSP &amp; Cruise Industry Public Health Managers and Ship Staff and Crew</td>
</tr>
<tr>
<td>Fairfax County (VA) Health Department</td>
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Links on downloadable presentation
Specializing in FDA Regulatory Matters

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www.restaurant.org / 202-331-5900
How to Take ACTIVE Control of Your Food Safety Management System

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former Deputy Chief at the Centers for Disease Control and Prevention