An Indirect and Direct Connection to Controlling Risks

September, 2006

FDA

FDA's Regulatory Responsibility

FDA has authority over the following products in interstate commerce:

- Food & Cosmetics
- Drugs
- Veterinary Medicine
- Medical Devices & Rad Health
- Biologics (Tissues, Blood, etc.)

FDA's National Retail Food Team

- **Regional Food Specialists**

   (Field Support, Program Standards)

- **Division of Human Resource Development (State Training Team)**

- **Office of Regulatory Affairs**

   (HQ, Field Policy)

- **Center for Food Safety & Applied Nutrition   (HQ, Food Code Policy)**

INDIRECT CONNECTION

- FDA authority under the PHS Act to assist States

- Indirect authority for controlling risks/contributing factors to foodborne illness

INDIRECT CONNECTION

- **Primary responsibility/direct authority is with State and local regulatory authorities and tribal entities**

- **Emphasis of "Active Managerial Control (AMC) of Risk Factors at Retail**

INDIRECT CONNECTION

- **Emphasis on Food Defense at Retail - ALERT**

INDIRECT IMPACTS

- **Model codes**
- **Baseline projects**
- **HACCP Guide for Regulators**
- **HACCP Guide for Operators**
- **Conference stakeholders**
  - **CFP, NCIMS, ISSC**

Risk Factor Database

- **1998- Begins the process for establishing multiple data collection periods. Established a Baseline on the occurrence of risk factors in food service and retail food establishments.**

- **2003- Second data collection**

RISK FACTOR DATABASE

- **2008-will begin the process of analyzing the three data sets (1998, 2003, and 2008) to assess improvement or regression changes from the 1998 Baseline**

INTRODUCTION AND PURPOSE

- **Agency effort to change behaviors / practices related to foodborne illness**

- **Measure trends in regulatory & industry efforts to reduce the occurrence of FBI risk factors**

INTRODUCTION AND PURPOSE

- **Healthy People 2010**
  - **Food Safety Objective 10.6**

- **Baseline is National in Scope**

Foodborne Illness Risk Factor in Need of Priority Attention (2000 Report)

- Improper Holding/Time and Temperature

- Poor Personal Hygiene

- Contaminated Equipment / Protection from Contamination

Foodborne Illness Risk Factor in Need of Priority Attention (2004 Report)

- Improper Holding/Time and Temperature

- Poor Personal Hygiene

- Contaminated Equipment / Protection from Contamination

BASELINE DATA COLLECTION FORM

- **Foodborne Illness Risk Factors**
  - Food from Unsafe Sources
  - Inadequate Cooking
  - Improper Holding/Time-Temp
  - Contaminated Equipment/ Protection from Contamination
  - Poor Personal Hygiene

Determining the
Out of Compliance percentage
for each
FOODBORNE ILLNESS RISK FACTOR

Percent Out of Compliance =

$$\frac{\text{Total Out of Compliance Observations for a Risk Factor}}{\text{Total number of Observations (IN and OUT) for the Risk Factor}} \times 100\%$$

HACCP at RETAIL

- **Process HACCP- application of HACCP principles at retail**
- **Risk Control Plans- voluntary compliance strategy to assist operators in attaining Active Managerial Control of the Risk Factors**

DIRECT CONNECTION

- **Primary responsibility/direct authority is with State and local regulatory authorities and tribal entities**
  - **Introduction and education to industry on the use of RCPs**
  - **Risked-based inspections**
  - **Education on handwashing and personal hygiene**

DIRECT CONNECTION

- **Industry role**
  - **AMC**
  - **Process HACCP**
  - **Food employee training**

RECOMMENDATIONS for REGULATORY

- **Self-Assess Program effectiveness**
  FDA's Recommended National Retail Food Program Standards

- **Adopt uniform regulatory standard - FDA Food Code**

RECOMMENDATIONS for REGULATORY

- **Use risk-based inspection methodology**

- **Provide flexible work schedules**

RECOMMENDATIONS for REGULATORY

- **Properly train and equip field personnel**

- **Document compliance determination (IN; OUT; N.O.; N.A.)**

RECOMMENDATIONS for REGULATORY

- **Take appropriate corrective action (Risk Control Plans)**

- **Establish own jurisdictional baseline**

RECOMMENDATIONS for INDUSTRY

- **Develop and implement Standard Operating Procedures (SOPs) to address FBI risk factors**

RECOMMENDATIONS for INDUSTRY

- **Provide employees with specific training and equipment to implement the SOPs**

RECOMMENDATIONS for INDUSTRY

- **Incorporate critical limits and measurable standards for control of FBI risk factors in SOPs**

RECOMMENDATIONS for INDUSTRY

- **Establish monitoring procedures that focus on critical processes and practices**

RECOMMENDATIONS for INDUSTRY

- **Identify methods to routinely assess the effectiveness of the SOPs**

RECOMMENDATIONS for INDUSTRY

ACTIVE MANAGERIAL

CONTROL OF FOODBORNE

ILLNESS RISK FACTORS

FDA INTERVENTION STRATEGIES

- **Support implementation of *FDA's Recommended National Retail Food Regulatory Program Standards (Standards)***

FDA INTERVENTION STRATEGIES

- **State Food Safety Task Forces Forces**

  -- **Implement & participate in**

  -- **Includes regulators, industry, consumers, academia, and others**

FDA INTERVENTION STRATEGIES

- **Expand standardization of local health jurisdiction personnel through work with States**

FDA INTERVENTION STRATEGIES

- **Support regulatory agencies in adopting the FDA Food Code**

FDA INTERVENTION STRATEGIES

- **Complete risk-based standardization of regulatory officials in application of the FDA Food Code**

FDA INTERVENTION STRATEGIES

- **Review Report with industry and consumer groups**

- **Develop strategies for addressing areas of noncompliance and consumer protection**

FDA INTERVENTION STRATEGIES

- **Continue to educate consumers through the Agency's hotline and the Fight BAC! ™ campaign.**

FDA INTERVENTION STRATEGIES

- **Assess need for Food Code standardization for personnel in agencies serving highly susceptible populations.**

FDA INTERVENTION STRATEGIES

- **Develop work plan initiatives to meet this need (Federal Food Safety Coalition).**

FDA INTERVENTION STRATEGIES

- **Provide technical support for regulatory initiatives designed to enhance the application of the principles of HACCP at the retail level (Standard #3 - Risk Control Plans and HACCP Principles at Retail Manual)**

FDA INTERVENTION STRATEGIES

- **Assess retail food processes and procedures related to targeted high priority items (e.g., egg safety; Listeria risk assessment; raw seed sprouts; unpasteurized juice)**

FDA INTERVENTION STRATEGIES

- **Expand to other Industry segments or sub-categories (e.g., day care; secondary schools; temporary food establishments)**

Voluntary National Retail Food Regulatory Program Standards

1. Regulatory Foundation

2. Staff Training

3. HACCP Principles-based Inspection
      Program

4. Inspection Uniformity

5. Foodborne Illness and Food Security
      Preparedness and Response

Voluntary National Retail Food Regulatory Program Standards

6. Compliance and Enforcement

7. Industry and Community Relations

8. Program Support and Resources

9. Self Assessment

# Voluntary National Retail Food Regulatory Program Standards

- **Identify program areas where an agency can have the greatest impact on retail food safety.**

- **Promote wider application of effective FBI risk factor intervention strategies**

Voluntary National Retail Food Regulatory Program Standards

- **Assist in identifying program areas most in need of additional resources**

Standards as a Tool for Continuous Improvement

Measure

Improve

Plan

***Self Assess**
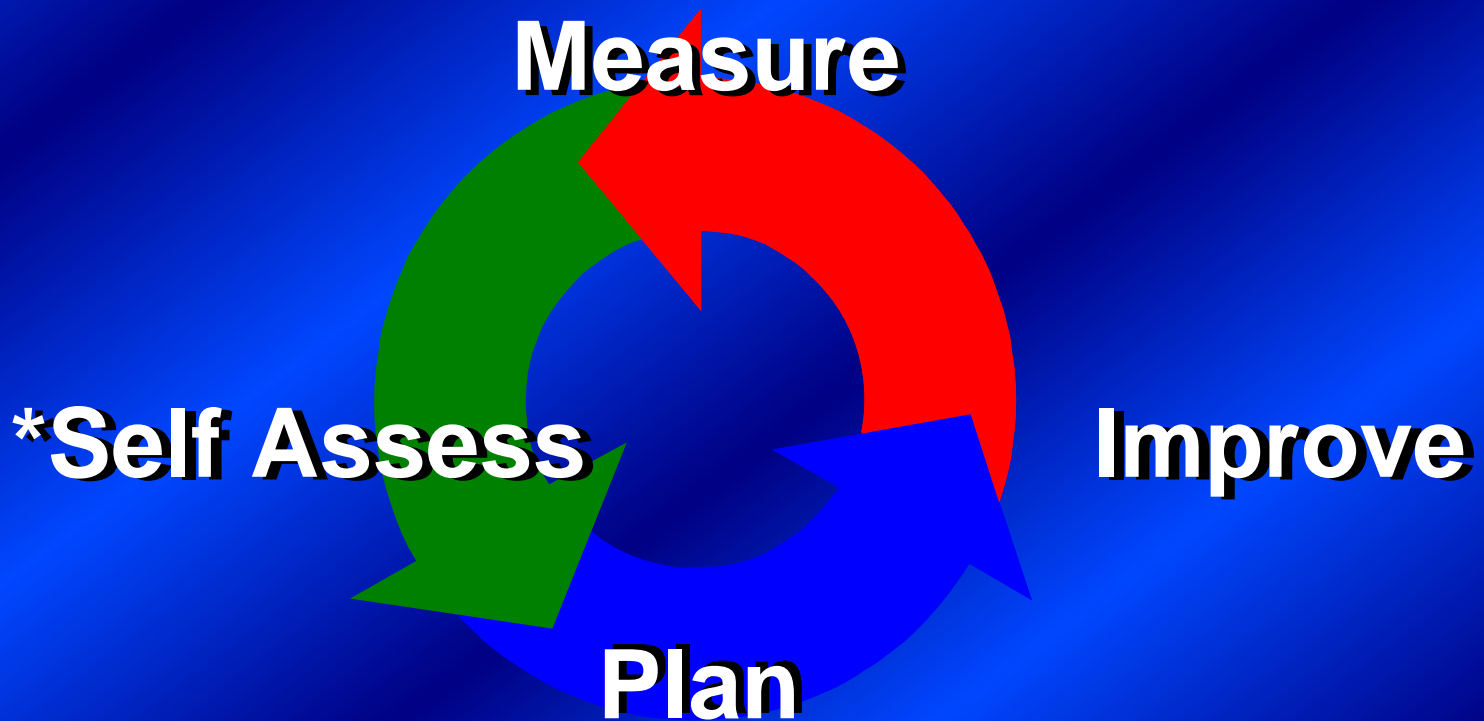
PROGRAM GOAL

ACTIVE MANAGERIAL CONTROL

OF

FOODBORNE ILLNESS RISK FACTORS

U.S. FOOD AND DRUG ADMINISTRATION

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION AND

OFFICE OF REGULATORY AFFAIRS

Presents via Satellite Broadcast

"REDUCING RISK FACTORS AT RETAIL AND FOOD SERVICE"

(FD216)

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1:00 P.M. – 3:30 P.M. Eastern Standard Time

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