



# **Food Pathogens and Recalls Challenges Old and New**

AFDO/2008

112<sup>th</sup> Annual Educational Conference  
Saturday, June 7, 2008

# Prevention and Intervention Strategies

- ▶ Food Protection Plan
  - Prevent Foodborne Contamination
    - Promote Corporate Responsibility to Prevent Foodborne Illness
    - Identify Food Vulnerabilities and Assess Risks
    - Expand the Understanding and Use of Effective Mitigation Measures

# Prevention and Intervention Strategies

- ▶ Food Protection Plan
  - Intervention at Critical Point in the Food Chain
    - Focus Inspections and Sampling Based on Risk
    - Enhance Risk Based Surveillance
    - Improve the Detection of Food System 'Signals' that Indicate Contamination

# Prevention and Intervention Strategies

- ▶ Modernization of the GMPs
  - Education and Training
  - Written Allergen Control Program
  - Environmental Pathogen Control
  - Written Sanitation Procedures
  - Application of the GMPs to Agriculture Operations
  - Temperature Control
  - Records Maintenance and Access

# Challenges – Old and New

## ▶ Old

- Relied more on Inspection and compliance to GMPs and Prerequisites
- 402(a)4 considers that food may be adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health.
- Inspections
  - An assessment at a “moment in time” which identifies positive and negative conditions
  - An extensive physical examination of a facility and its equipment and observations of practices in order to collect information to determine compliance with plant programs
  - Structured to initiate immediate corrective action, when it is required
  - Structured to often lead to an evaluation of programs and systems

# Challenges – Old and New

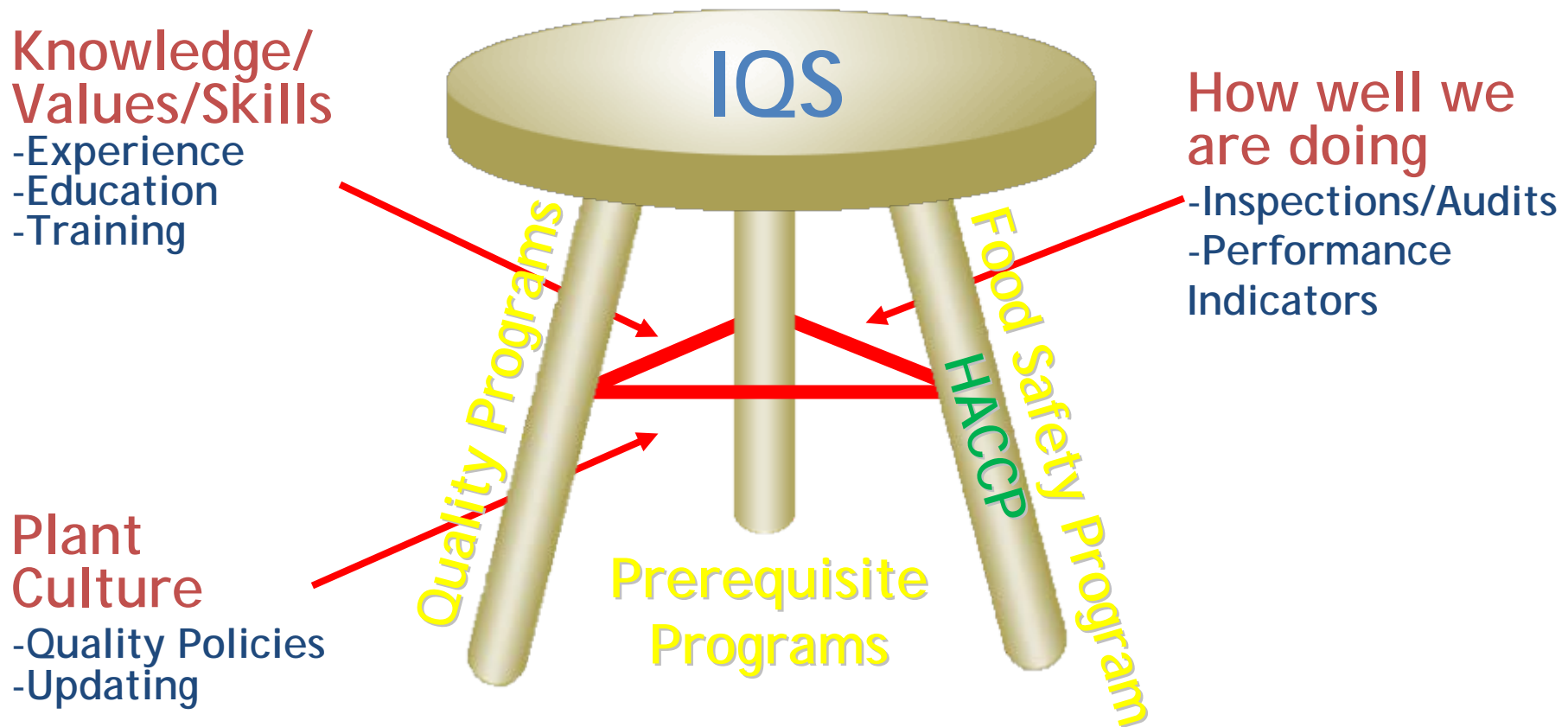
## ▶ New

- Audits and Audit Schemes
- GFSI (BRC, IFS, SQF and Dutch HACCP), GMA-Safe, Branded Audits, ISO schemes
- Audit
  - A systematic evaluation to determine if programs and related activities achieve planned expectations
  - The review or challenging of written programs; documentation of activities; corrective actions; trends
  - An aid to determining the correlation between documentation procedures and activities and actual execution
  - A potential assistance in identifying root cause, which can lead to long term corrective action

YET,  
MARKET FAILURES  
CONTINUE

Then,  
What are we missing?

# An Integrated Quality System





# What Are We Missing?

- ▶ Are we losing perspective of the importance of the GMPs & Prerequisites
  - A general shift to audit schemes
    - Everything looks good on paper
    - Disconnect between floor and paperwork
      - The auditor passes the plant
      - The inspector fails the plant
  - A Due Diligence mentality
    - A cost of doing business
    - Prepare for an announced audit
    - Get the piece of paper and go back to what you were doing
    - Shop for the cheapest certifying body

# What Are We Missing?

- ▶ Language Barriers
  - Managerial and Operations
  - Food Safety and Management and Operational Personnel
- ▶ Educational and Training Barriers
  - Tell me what you do = Education
  - Tell me why you do it = Education
  - Tell me how you do = Training
  - Tell me when you do it = Education

# What Are We Missing?

- ▶ Managerial Component
  - Education and Training
  - Monitoring
    - Results are satisfactory
  - Verification
    - Program is being implemented
  - Validation
    - Program is effective
  - Documented

# What Are We Missing?

- ▶ Structure
- ▶ Formalization of our Systems
  - Objectives(s) = desired measurable condition(s)
  - Formal ways and means = structure
  - Application of formal ways and means = results
  - Results = formal measurable criteria
  - Measurements are compared with objective(s)
  - Discrepancies are addressed and resolved until  $MC=MB$ 
    - $MC$  = Marginal cost = investment to address issue
    - $MB$  = Marginal benefits = benefit of removing issue

# Reliability Centered Maintenance (RCM)

- ▶ Cost function of maintenance

- $F_c = \Sigma (x_1 + x_2 + x_3 + \dots + x_n)$

- ▶ Cost function of repair

- $F_c = \Sigma (x_1 + x_2 + x_3 + \dots + x_n + y_1 + y_2 + y_3 + \dots + y_n)$

- ▶ Where:

- $x_1$  = Labor

- $y_1$  = Lost production / sales

- $x_2$  = Spare parts

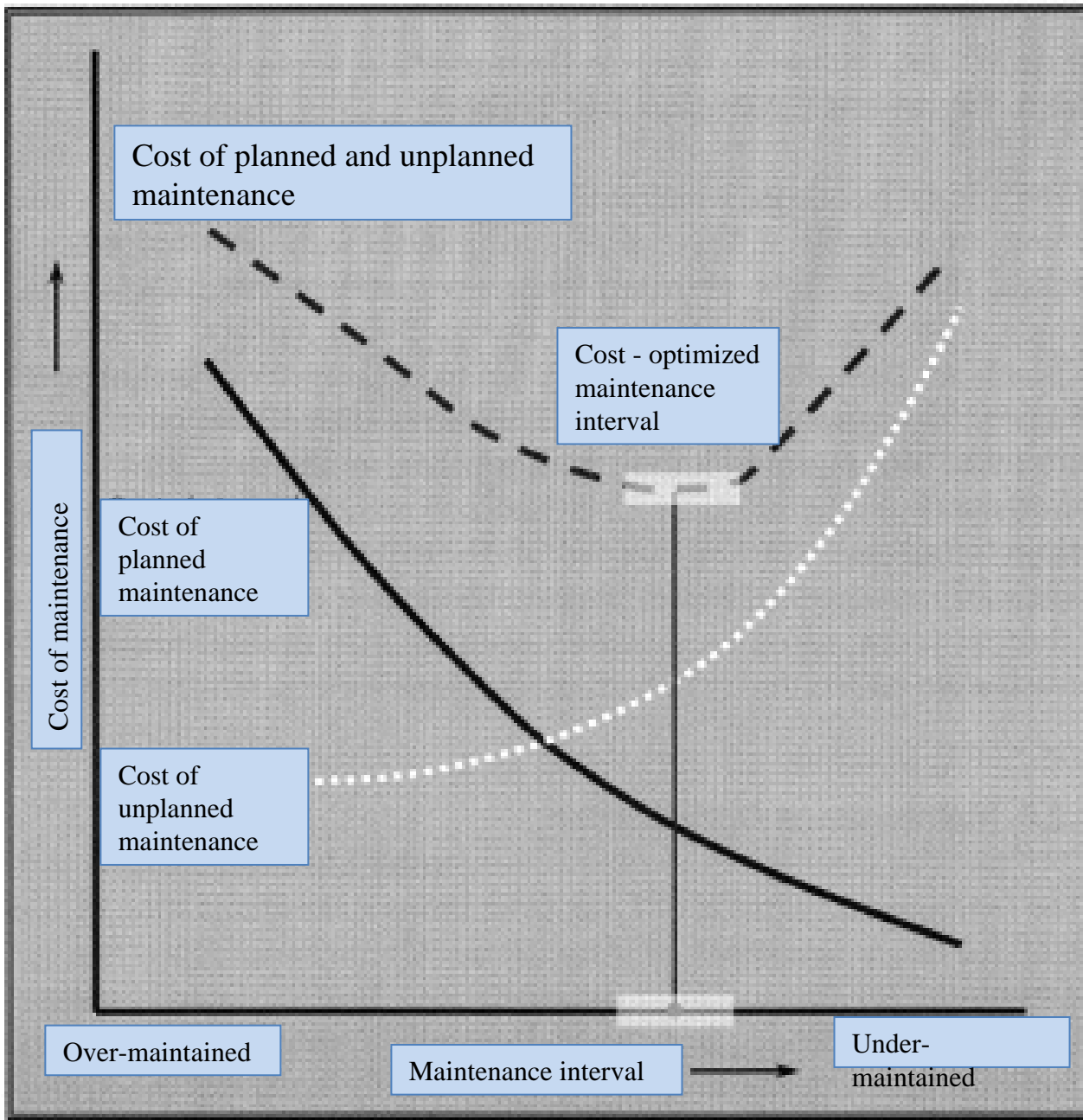
- $y_2$  = Over time

- $x_3$  = Mgmt / control

- $y_3$  = emergency purchase

- $x_n$  = Other cost

- $y_n$  = Other cost



- Are we maintaining or repairing the manufacturing environment?
- Are we spending or investing?

Figure 2: Optimized maintenance interval and maintenance cost

# Corporate Responsibility

- ▶ Inspections and Audits
- ▶ Program Revisions
  - Annually or on established risk based schedule
  - When 'Signals' are detected
- ▶ Analysis of Information
  - Effectiveness
  - Efficiency
  - Tendencies
- ▶ Identify & Implement Corrective Actions
  - Regain control over unsatisfactory situations
  - Root Cause analysis
  - Elimination of root cause
- ▶ Documentation
  - Written evidence of activities and results

# The I.C.E. Concept

**I = Identify, Introduce, Intensify**

- Recognize 1) GMP and Prerequisite , 2) Safety, or 3) Quality issue
- Achieve consensus

**C = Control / Correction**

- Establishing timely and appropriate control measures within the process or distribution environment to protect product integrity and/or contact surfaces

**E = Eliminate / Corrective Action**

- Develop and implement reasonable and practical solutions which effectively address underlying causes / reasons



# Cost Functions For Non-Compliance of Any IQS Criteria

- ▶ Elements of cost functions
  - Fixed and variable expenditures associated with the “I” of I.C.E.
    - Cost of I =  $\Sigma (x_1 + x_2 + x_3 + \dots + x_n)$
  - Fixed and variable expenditures associated with the “C” of I.C.E.
    - Cost of C =  $\Sigma (y_1 + y_2 + y_3 + \dots + y_n)$
  - Total cost of non-compliance
    - $TC = \Sigma (CI + CC)$

# What is Missing?

- ▶ Educated and trained personnel to speak to management in their language of \$
- ▶ Missing the assumptions and data to calculate and determine our internal risk
- ▶ Losing the skills of inspection in both industry and regulatory fields
- ▶ We need to learn to understand the results of both audits and inspections