

# Prerequisite Programs, Approved Supplier Programs, and Certificates of Analysis

USDA Public Meeting;  
Control of  
*E. coli* O157:H7

Timothy P. Biela; Chief Food  
Safety & Quality Officer

# Standard Sanitation Operating Procedures

**“Good sanitation** is a fundamental requirement of federal meat and poultry inspection laws and is necessary for safe food production. Yet, **poor sanitation practices** are the most frequent deficiencies found in some meat and poultry plants. **There is a direct link between insanitary practices in these plants and the likelihood of product contamination with pathogenic bacteria.”**

USDA FSIS January 1995

Timothy P. Biela; Chief Food  
Safety & Quality Officer

# Pathogen Reduction and HACCP

A HACCP System is generally considered the best approach available to ensure safe foods because it focuses on **preventing** contamination rather than **detecting** contamination once it has occurred.

FSIS believes that to achieve its food safety goal it must clearly define the minimum requirements all establishments must meet to produce safe meat and poultry and make establishments **accountable** for meeting them.

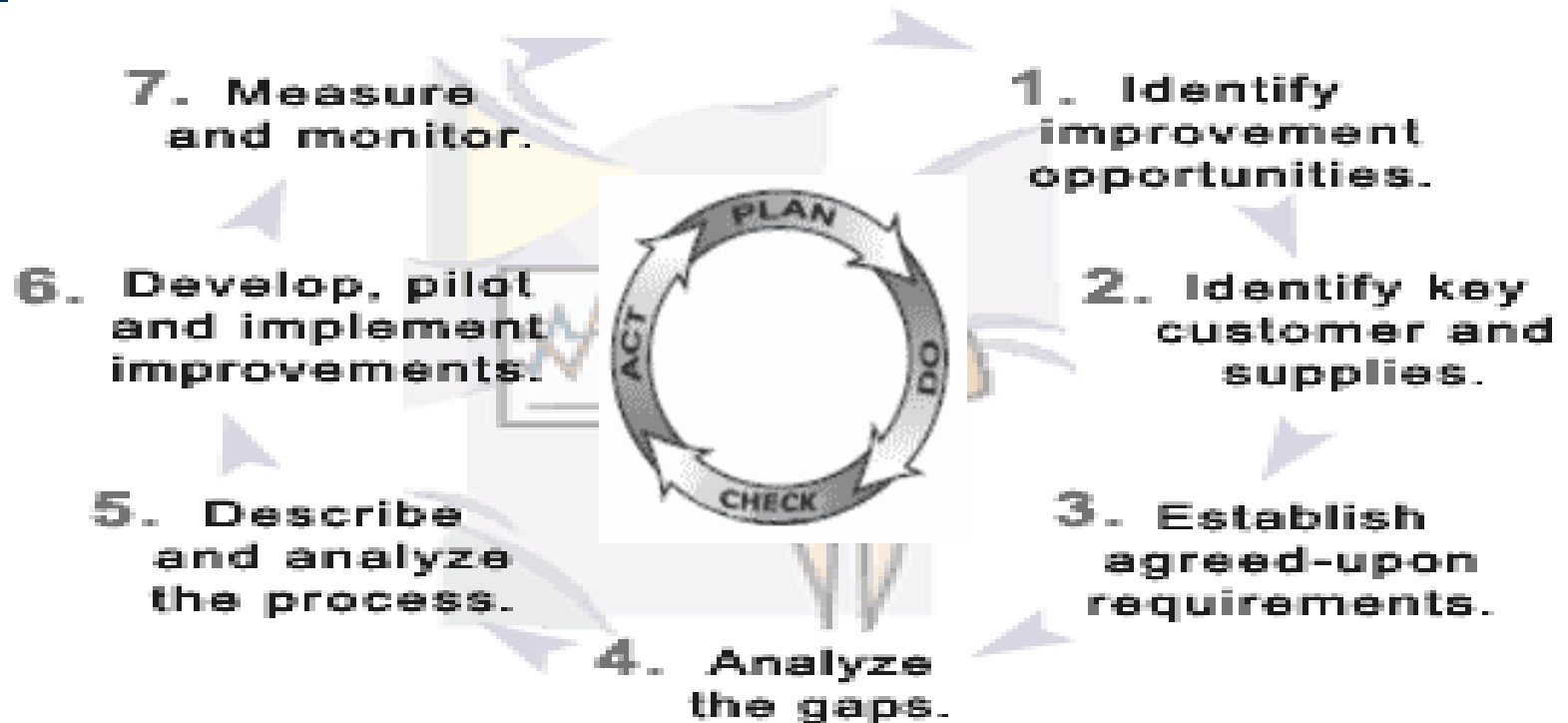
Federal Register Proposed Rules; February 1995

Timothy P. Biela Chief Food  
Safety & Quality Officer

# Regulatory Oversight

- **Evaluation** – determine that every plants sanitation SOP's and HACCP Plans conform to regulatory requirements and are capable of controlling the hazards
- **Verification** – determine that every plant is carrying out its' defined plans
- **Documentation** – prepare written materials to document failure to meet standards
- **Enforcement** – take appropriate actions when plants are not in compliance with standards

# Continuous Process Improvement



# Continuous Process Improvement

When we engage in process improvement, we seek to learn what causes things to happen and then use this knowledge to:

1. Reduce variation.
2. Remove activities that have no value.
3. Improve customer satisfaction / product safety.

# Raw Material Source

- Process Interventions and Controls for Food Safety
  - HACCP Programs
  - Control Programs for *E. coli* O157:H7
- Microbiological Testing / Pre-Screening Requirements (n=60)

# The Processor's Perspective

Processors of raw beef products have no other methods available to control bacterial hazards than to control their raw material supplies and suppliers.

Therefore it is essential to develop a system that ensures that raw material suppliers have systems and controls in place to prevent contamination.



# Approved Supplier Programs

Beef companies should encourage and support actions in all sectors of the industry to reduce microbial contamination and food borne illness.

Companies are responsible for outlining the requirements for raw material suppliers and for establishing procedures (**process controls**) for **verifying** those are implemented and working as designed (**validation**).

# Supplier Evaluations

- New Supplier Approval
  - Specifications, acknowledgement, audits, AQL's
- Ongoing Supplier Evaluations
  - Data collection; Micro, Audits, AQL's, Defects, Age, Temperature, On time delivery
- Pre-receipt of Raw Materials Verification
  - Negative pre-screening for *E. coli* O157:H7 for raw materials to be used in raw ground products
  - Trailer seal integrity

# Pre-screening Certificates of Analysis

- Pre-Screening for *E. coli* O157:H7 **MUST** be conducted on all raw materials used in raw ground products
- Certificate of Analysis must include:
  - Analytical Method (MUST be equivalent to USDA)
  - Analytical unit used for testing in lab
  - Specific tracking information tied to boxes or bins
  - MUST be signed by the laboratory personnel

# Microbiological Verification Actions

- For Raw Materials
  - Use APC, coliform and generic *E. coli*
  - **Track and trend** all raw materials by supplier
  - Define specification targets and action limits
  - Document out of specification or important trend indications and communicate back to suppliers
  - Require an action plan from suppliers and then track / trend data to show acceptable performance

# Microbiological Verification Actions

- For Finished Products
  - Use APC, coliform and generic *E. coli*
  - **Track and trend** all finished products
  - Define specification targets and action limits
  - Document out of specification or important trend indications and action plans for correction
  - Track / trend data to show acceptable performance

# Finished Product Sampling and Testing

- Can be used for “profiling” finished products
  - Aerobic Plate Counts
  - Coliform and generic *E. coli*
- Can be used for sub-lotting finished products
  - Microbiological profiles
  - *E. coli* O157:H7

# Microbiological Testing Programs for Raw Ground Products

Programs should be designed so that they are:

- Robust sampling
- Scientifically sound
- Defensible
- Validated for the location where they are being used
- Verified and verifiable
- Constantly challenged

# Summary

HACCP is based on **prevention** and **reduces the reliance on end-product inspection and testing.**

If in fact the concept is applied correctly and actual **verification** and **validation** are used in a continuous process improvement program then it can in fact reduce the risk associated with *E. coli* O157:H7 in beef products.