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USDA Regulations for Hazard Analysis and Critical Control Point (HACCP) Systems

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Reasoning for HACCP

- HACCP is a process control system.
- HACCP offers the best system for food safety.
- HACCP is scientifically based

9 CFR Part 417 - (HACCP)

- Section 417.2 Hazard Analysis and HACCP Plan, Hazard analysis
  - Every official establishment shall conduct, or have conducted for it, a hazard analysis.
  - A flow chart of the process
  - Food safety hazards might include natural toxins, microbial, chemical, pesticides, drug residues, diseases, decomposition, parasites, unapproved additives, and physical hazards.

9 CFR Part 417 - (HACCP)

- Section 417.2 Hazard Analysis and HACCP Plan, HACCP Plan
  - Every official establishment shall develop and implement a written HACCP plan.
  - A single HACCP plan may encompass multiple products within a single process category.

9 CFR Part 417 - (HACCP)

- Process Categories
  - Slaughter
  - Raw product, ground
  - Raw product, not ground
  - Thermally processed, commercially sterile
  - Not heat treated, shelf stable
  - Heat treated, shelf stable
  - Fully cooked, not shelf stable
  - Heat treated, not fully cooked, not shelf stable
  - Product with secondary inhibitors, not shelf stable

The HACCP Plan Shall Address:

- List of food safety hazards identified which must be controlled
- List the critical control points
- List the critical limits
- Monitoring procedures
- Corrective actions
- Record-keeping
- Verification procedures
- Signed and dated

417.3 Corrective Actions

- Cause is identified and eliminated
- CCP is under control after corrective action
- Measures to prevent recurrence are established
- No product that is injurious to health or adulterated enters commerce
- All actions shall be recorded

417.4 Validation, Verification, Reassessment

- Every establishment shall validate the HACCP plan
- Reassess the HACCP plan at least annually and whenever changes occur
- Reassess the hazard analysis if no food safety hazards were identified whenever a change occurs.

417.5 Records

- Establishment shall maintain the following records
  - Hazard analysis
  - HACCP plan
  - Monitoring of CCP's, CL's, Corrective Actions and Verification
  - Recorded at the date and time occurs
  - Review records prior to shipping
  - One year and two years (shelf stable)
  - Records reviewed by FSIS

417.7 Training

- Individual in charge of developing HACCP plan shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

417.7 Agency verification

- Reviewing the HACCP plan
- Reviewing the CCP records
- Reviewing and determining the adequacy of corrective actions
- Reviewing the CL
- Direct observation or measurement of CCP
- Sample collection for product safety standards

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USDA Regulations for Sanitation SOP

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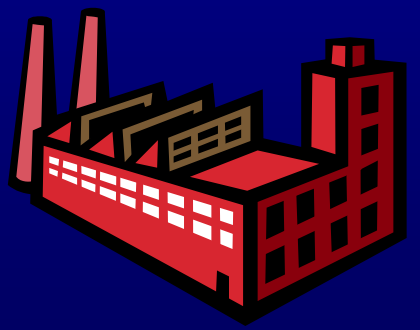
9 CFR Part 308 & 381-Sanitation

- Section 308.3 is amended by adding a sentence to the end of paragraph (a) to read as follows:
  - ..... The provisions of part 416 of this chapter also apply to all establishments, except establishments that are exempt in accordance with 303.1 of this chapter.
- Section 381.45 reads as:
  - The provisions of 381.46 and 381.61 inclusive, and part 416 of this chapter shall apply shall apply with respect to all official establishments.

Part 416.11 General Rules

- Each official establishment shall develop, implement and maintain written SSOP's.



Part 416.12 Development of SSOP's

- Describe all procedures conducted daily, before and during operations, sufficient to prevent direct contamination or adulteration of product.
- SSOP signed by on-site or higher level official of establishment. Dated at implementation and modification.

Part 416.12 Development of SSOP's

- Procedures identified at minimum the cleaning of contact surfaces of equipment, facilities and utensils.
- SSOP identify the frequency of the procedure and the individual responsible for implementation and maintenance of such procedure.

Part 416.13 Implementation of SOP's

- Each official establishment shall...
  - conduct the pre-operational procedures before the start of operation.
  - conduct all other procedures in the Sanitation SOP's at the frequencies specified.
  - monitor daily the implementation of the procedures in the Sanitation SOP's.

416.14 Maintenance of Sanitation SOP's

- Routinely evaluate the effectiveness of SSOP.
- Revise SSOP as necessary.
- Keep current with respect to changes in facilities, equipment, utensils, operations, or personnel.

416.15 Corrective Actions

- Take corrective action when either the establishment or FSIS determines the SOP or procedure has failed to prevent direct contamination or adulteration of product.

416.15 Corrective Actions

- Includes procedures to ensure appropriate disposition of product that may be contaminated, restore sanitary conditions and prevent the recurrence of direct contamination or adulteration of products, including appropriate reevaluation and modification of the SSOP and the procedures specified there in or appropriate improvements in the execution of the SSOP or the procedures specified therein.

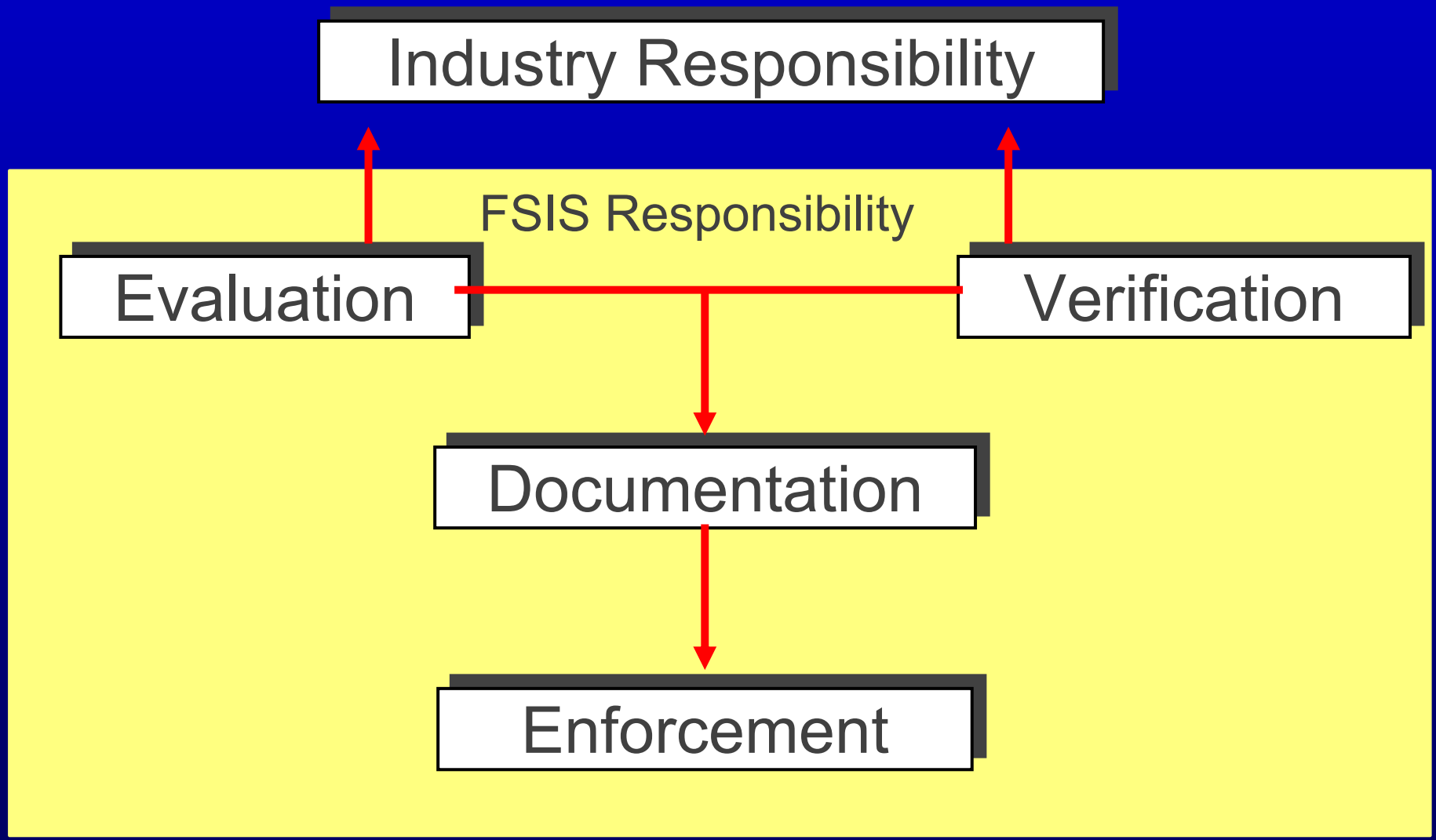
416.16 Record-keeping Requirements

- Maintain daily records on implementation, monitoring and corrective actions taken. Records are initialed by employee specified in SOP.
- Records may be maintained on computer with assurance of integrity.
- Maintained for 6 months, 48 hr at establishment, available with 24 hr to FSIS.

416.17 Agency verification

- Verification may include:
  - Reviewing the SSOP.
  - Reviewing the daily records.
  - Direct observation of the implementation of the SSOP and the procedures.
  - Direct observation or testing to assess the sanitary conditions in the establishment.

Role of Inspection and Industry



FSIS Role in Sanitation SOP

- Evaluation
- Verification
- Enforcement

Evaluation of Written SSOP

- Identifies procedures the establishment will conduct prior to the start of operations
- Describes daily procedures the establishment will conduct during operations
- Is signed and dated by an official with overall authority on-site or a higher level official of the establishment

Evaluation of Written SSOP

- Identifies establishment employees who have responsibility for implementing and maintaining daily sanitation activities.
- Identifies the records to be maintained that on a daily basis document the implementation and monitoring of SSOP's and any corrective actions taken

Records Verification

- Records should document:
  - Effectiveness of Sanitation SOP's
  - Procedures specified in SOP's
  - Any corrective actions taken or required
- Corrective actions should include procedures for:
  - Disposition of contaminated product
  - Prevention of recurrence
  - Re-evaluation and modification of SSOP's

Hands-on Verification

- Purpose: to verify that plant is
  - Implementing and monitoring activities of SSOP; and
  - Initiating corrective actions when necessary

Deficiency Classification Guide

- Will the deficiency result in adulterated or misbranded product?
- Will adulterated or misbranded product reach consumers?
- Will the product have a detrimental effect on consumers?
  - _____Certain
  - _____Likely
  - _____Potential

Classify Deficiencies

- Assumptions based on:
  - Critical: Certain in A, B, & C
  - Major: No less than likely in A, B, & C
  - Minor: Potential in either A, B, or C

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USDA Regulations for Post Mortem Inspection; *E. Coli* and *Salmonella* Testing

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HACCP and Food Safety Help for Small Meat and Food Processing Operations

Reasoning for *E. Coli* testing

- Establish a criteria for verifying process control.
- *E. Coli* testing was selected as an indicator of whether process controls in slaughter establishments are effectively preventing fecal contamination.
- Proposal was for *Salmonella* as a process control indicator.

9 CFR Part 310 – Post Mortem Inspection

- **Section 310.25 Contamination with microorganisms; pathogen reduction performance standards for *Salmonella*.**
- ***E. Coli* testing**
  - **Each official establishment that slaughters cattle and or swine shall test for *E. Coli* Biotype 1. Establishments that slaughter more than one type of livestock or both livestock and poultry, shall test the type of livestock or poultry slaughtered in the greatest number.**

Part 310.25

- *E. Coli* testing
  - Each official establishment shall collect samples.
  - Obtain analytic results.
  - Maintain records of results.

Part 310.25

- *E. Coli* test, sampling requirements
  - Written procedures.
  - Samples for chilled swine or cattle, by sponging or excising tissue from 3 sites.
    - Flank, brisket and rump
    - Ham, belly, jowl
  - Frequency of sampling
    - 1 per 300 or 1 per week, cattle
    - 1 per 1000 or 1 per week, swine

Part 310.25

- *E. Coli* test, sampling requirements

4. Sampling very low volume establishments
   - less than 6,000 cattle or 20,000 swine
   - After June 1 collect 1 sample per week until 13 samples have been collected or until a series of 13 samples meet the criteria for lower and upper marginal range.
5. Approved methods
6. Records retained for 12 months

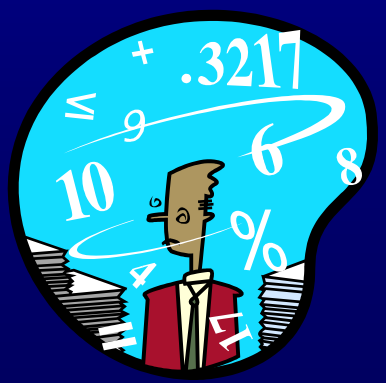
Part 310.25

- *E. Coli* test
  - 5. Criteria for evaluation of tests

	Lower Limit	Upper Limit	Number of Samples	Maximum Number in Marginal Range
Cattle	Negative (5 CFU/cm^2)	100 CFU/cm^2	13	3
Swine	10 CFU/cm^2	10,000 CFU/cm^2	13	3
Chicken	100 CFU/cm^2	1000 CFU/cm^2	13	3

Part 310.25

- *E. Coli* test
  5. Criteria for evaluation of tests
     - Establishments sponging carcasses shall evaluate *E. coli* test results using statistical process control techniques.



Part 310.25

- *Salmonella* test
  - FSIS will test for *Salmonella* and will follow the following positive rate:

	Performance Standard	Number of Samples	Max. Number of Positives
Steers/Heifers	1.0%	82	1
Cows/Bulls	2.7%	58	2
Ground Beef	7.5%	53	5
Hogs	8.7%	55	6

Part 310.25

- *Salmonella* test
  - FSIS will test for *Salmonella* and will follow the following positive rate:

	Performance Standard	Number of Samples	Max. Number of Positives
Broilers	20.0%	51	12
Ground Chicken	44.6%	53	26
Ground Turkey	49.9%	53	29