# HACCP-based Inspection Models Project
# In-plant Slaughter

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Food Safety and Inspection Service
Office of Policy, Program Development, and Evaluation
Inspection Systems Development Division

July 7, 1998

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## IN-PLANT SLAUGHTER

# HACCP Inspection Models Project

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## Background

The Food Safety and Inspection Service (FSIS) issued the "Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems final rule" (PR/HACCP) on July 25, 1996. This final rule was designed to reduce, to the maximum extent possible, the risk of foodborne illness associated with the consumption of meat and poultry products. FSIS is requiring establishments to institute HACCP, a science-based process control system for food safety.

The initial effort to define Agency and industry roles in assuring the safety and integrity of meat and poultry products concentrates on production from just before slaughter through retail sale or food service to consumers. Inspection models for providing oversight and verification that regulatory standards are being met must be developed incorporating inspection procedures that are consistent with the PR/HACCP final rule. For the first component of the HACCP-based Inspection Models Project, FSIS is developing inspection models for slaughter establishments. The objective of the models project is to help define what FSIS and the regulated industry will do in slaughter establishments operating under HACCP. A concurrent effort is underway to address FSIS activities in distribution channels.

## Study Objectives

Objectives: (1) Determine the achievements of the present inspection system in slaughter establishments by collecting and analyzing data on the gross pathology,

microbiology, and wholesomeness of carcasses processed under the current system;

and (2) test new inspection models at establishments, where the establishment performs slaughter process control and FSIS inspects using oversight and verification, and determine the effectiveness of the inspection models by the collection and analysis of data.

**Microbial Sampling**

Data on pathogenic and nonpathogenic microorganisms will be collected at two sites along the slaughter line on carcasses processed under the current FSIS organoleptic inspection system, to determine the prevalence and levels of certain bacteria on fed cattle, market hogs, young turkeys, and young chickens (See Table A). Data for the same bacteria will also be collected at comparable sites after implementation of a new inspection model at the establishment. The results will be evaluated to determine whether changes from current FSIS organoleptic slaughter inspection will have any effect on the microbial profile of carcasses. FSIS intends to continue to collect comparable data periodically from a representative sample of establishments after new inspection models are implemented to determine whether changes to industry processing technology over time result in a downward trend in microbial levels on product.

**Table A: Organisms Selected for Testing by Type of Animal Slaughtered**

| | | | |
|---|---|---|---|
| **Fed cattle** | *Salmonella* | generic *E. coli* | APC |
| **Market hogs** | *Salmonella* | generic *E. coli* | |
| **Young turkeys** | *Salmonella* | generic *E. coli* | |
| **Young chickens** | *Salmonella* | generic *E. coli* | |

**Study Design**

A notice was published in the June 10, 1997 Federal Register inviting establishments interested in participating in the inspection models project to notify FSIS, provided those establishments met certain criteria. As of April 20, 1998, four establishments have been selected to participate in the project: two market hog establishments, one young turkey establishment, and one broiler establishment.

The models effort will focus on fed cattle, market hogs, and young poultry because these types of livestock and birds come to slaughter when they are young, healthy and uniform. There will be two baseline data collection and analysis studies, one to develop an organoleptic performance level and one to develop microbial profiles. The organoleptic performance level is a measurement to compare

inspection disposition decisions with decisions of technical experts. The microbial profiles will include measurement of the prevalence and levels of specified bacteria on meat or poultry carcasses produced under inspection at an individual establishment. Initially, baseline data will be collected to measure what the current system of inspection accomplishes in establishments operating under PR/HACCP. Data will then be collected to make a comparison of inspection approaches. FSIS intends to ensure the present level of inspection achievements is maintained. In this package there are separate documents for fed cattle, market hogs, and young poultry that cover in-plant ante-mortem and post-mortem inspection and activities for organoleptic performance level data collection.

**Selection of Organisms**

FSIS received several recommendations from the National Academy of Sciences (NAS) to evaluate new inspection technology using scientifically valid methods. In 1985, the NAS report, *Meat and Poultry Inspection*: *The Scientific Basis of the Nation's Program* recommended that FSIS focus on pathogenic organisms and require that all official establishments operate under a Hazard Analysis and Critical Control Point (HACCP) system for control of pathogens and other safety hazards. Two years later, the 1987 NAS report *Poultry Inspection: The Basis for a Risk*

*Assessment Approach* reinforced this recommendation concluding that the present system of inspection does very little to protect the public against microbial hazards in young chickens. The 1990 NAS report *Cattle Inspection: Committee on Evaluation of USDA Streamlined Inspection System for Cattle (SIS*-C) added that traditional meat inspection, relying on organoleptic examinations, is not fully effective in protecting the public against foodborne health hazards not detectable with these techniques.

FSIS responded to these recommendations with the FSIS Nationwide Microbiological Baseline Data Collection Program series, which laid the foundation for selection of organisms, sampling and laboratory analytical methodology used by FSIS for measuring microbial prevalence and levels on carcasses. The National Advisory Committee on Meat and Poultry Inspection (NACMPI) and the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) were asked to recommend what organisms should be chosen for analysis to evaluate new inspection models if FSIS continued its microbial testing approach for the HACCP-based Inspection Models Project.

In January 1998, the NACMPI included microbiological data parameters for establishment-specific profiles recommending that FSIS test all species for generic *E. coli, Salmonella,* and Aerobic Plate Count (APC). It also recommended FSIS consider

testing young poultry for *Campylobacter*, market hogs for *Yersinia* and fed cattle for *E. coli 0157:H7* and forward the NACMPI recommendations to the NACMCF for consideration.

The NACMCF agreed microbial testing was appropriate, approved the data collection sites, and suggested collecting data during the same season of the year. It considered the NACMPI selection of organisms and recommended FSIS not collect *Campylobacter*, *Yersinia*, or *E. coli 0157:H7* data, the latter two due to the low prevalence. It recommended collecting APC as an indicator of the effectiveness of the slaughter process for fed cattle because generic *E. coli* counts were expected to be low for this species.

In May 1998, the NACMCF recommendations were presented to the NACMPI and discussed at length. The discussion focused on *Campylobacter* data collection. FSIS had not completed its work with the Agricultural Research Service to develop a cost-effective quantitative method for *Campylobacter*. Qualitative (presence or absence) results for *Campylobacter* in poultry are expected to be high. Quantitative methods that measure actual numbers of organisms present are needed to explore the parameters affecting this organism during poultry processing. FSIS proposed a separate nationwide data collection effort for *Campylobacter* and will reconsider adding it to the HACCP-based Inspection Models Project when more plants are involved.

The recommendations from both committees were fully considered. FSIS has decided to collect the following microbial data in addition to the microbial samples collected to meet the PR/HACCP rule.

- All species: generic *E. coli*, *Salmonella*
- Fed cattle: APC

FSIS believes that by analyzing meat and poultry carcasses for generic *E. coli* and *Salmonella* and fed cattle for APC, it will best be able to compare the achievements of the current inspection system with the new inspection models to be tested.

**Sample Size**

For microbiological sampling, FSIS has selected a sample size of 300 sample-sets at each of two sampling locations, pre-evisceration and post-chill, for fed cattle, 300 for market hogs, 300 for young turkeys, and 300 for young chickens to ensure reasonable levels of precision for establishing baseline profiles.

With a sample size of 300, if 2 percent of the samples were positive for a given microorganism then the estimate of the percentage positive would have a margin of error with 95 percent confidence of approximately $\pm$ 1.75 percent. Similarly, an

estimated rate of 20 percent positive samples would have a margin of error with 95 percent confidence of $\pm$ 4.69 percent. Table 2 shows these values, as well as the margins of error for other percentages and other samples sizes (See Table B).

**Table B: Estimating the Margin of Error with 95 percent confidence for a given percentage prevalence of positive microbial specimens by sample size**

| *Percent Incidence* | *Sample Size* | | | |
|---|---|---|---|---|
| | 100 | 200 | 300 | 400 |
| 1 | 2.45 | 1.63 | 1.29 | 1.10 |
| 2 | 3.24 | 2.19 | 1.75 | 1.50 |
| 5 | 4.77 | 3.27 | 2.63 | 2.26 |
| 10 | 6.38 | 4.41 | 3.56 | 3.06 |
| 15 | 7.50 | 5.20 | 4.21 | 3.62 |
| 20 | 8.34 | 5.79 | 4.69 | 4.04 |
| 25 | 8.99 | 6.25 | 5.07 | 4.37 |

A sample size of 300 should provide reasonable levels of precision at the establishment level for most of the microorganisms. To achieve this number, 25 samples per establishment/microorganism/site will be randomly selected each week for 12 weeks during the baseline phase and 12 weeks during the model phase after the final inspection model is in place.

**Sampling Procedure for Organisms in Table A**

A sample is defined as a composite of three sponged sites on a single carcass side for fed cattle and market hogs, a composite of two sponged sites on a single carcass for young turkeys, or a whole-bird rinse of a single carcass for young chickens. A separate sample will be collected for each microbial analysis. The carcass sites sponged are the same as those listed in the PR/ HACCP rule for generic *E. coli* testing.

Three samples will be collected for each fed cattle sample-set from three separate carcass sides. A fed cattle sample-set will be one sample for *Salmonella,* one sample for generic *E. coli*, and one sample for APC.

Two samples will be collected for each market hog sample-set from two separate carcass sides. A market hog sample set will be one sample for *Salmonella* and one sample for generic *E. coli.*

Two samples will be collected for each young turkey sample-set from two separate carcasses. A young turkey sample set will be one sample for *Salmonella* and one sample for generic *E. coli.*

Two samples will be collected for each young chicken sample-set from two separate carcasses. A young chicken sample set will be one sample for *Salmonella* and one sample for generic *E. coli.*

The sampling sites will be the same as those listed in the PR/HACCP final rule for generic *E. coli.* In fed cattle, the sponged sampling sites are the rump, flank, and brisket. In market hogs, the sponged sampling sites are the belly, jowl, and ham. For young turkeys, the sponged sampling sites are the back and thigh. Sample collection for young chickens will be accomplished by using a whole-bird rinse.

A team consisting of independent contract employees, Agency personnel, and establishment personnel will collect microbial data.

Points in the process were selected where the achievements of the slaughtering process can be measured. The points vary among the species. For fed cattle and market hogs, the points where samples will be taken are (1) pre-evisceration and (2) after carcasses have been chilled for 12 or more hours. For poultry, the points where samples will be taken are (1) after the carcass washer that follows feather removal and (2) after carcass

chilling.

# HACCP Inspection Models Project

Fed Cattle Slaughter Inspection Models

# FED CATTLE SLAUGHTER INSPECTION MODELS

## Summary

The need to reconsider the current FSIS procedures for slaughter inspection was discussed in a June 10, 1997 Federal Register Notice and at a public meeting held June 24-25, 1997. All current procedures may be considered for change as long as the Agency can fulfill its responsibilities to ensure that the industry produces safe, wholesome, and properly labeled meat and poultry products.

Under the inspection model tested, the establishment would separate acceptable from unacceptable animals, carcasses, and parts to meet current regulatory standards for ante-mortem and post-mortem conditions of animals, carcasses, and parts. Establishments would also develop slaughter process control plans. The establishment process control plan must be a written document; the portions applicable to 9 CFR Part 417 should be incorporated into the establishment's HACCP plan. The process control plan must be shared with FSIS before initiating the model-testing phase.

FSIS expects that the inspection model tested will have three main components: establishment implementation of slaughter organoleptic and PR/HACCP microbial

performance standards, FSIS oversight of the standards being implemented, and verification by FSIS of the standards by product sampling.

## Ante-mortem Fed Cattle Inspection Model

### *Industry Responsibilities*

- To present and slaughter only healthy cattle suitable for the food supply.
- Perform ante-mortem process control.

### *FSIS Inspection Responsibilities*

- Ensure establishment's ante-mortem process control meets regulatory standards through oversight and verification.

### *Ante-mortem Inspection Model step 1*

- Establishment personnel examine and appropriately segregate animals showing signs of abnormalities.
- FSIS inspectors determine the effectiveness of the establishment's ante-mortem process control by observing 100 percent of all cattle at rest, 100 percent of abnormal animals in motion, and at least 10 percent of normal animals in motion.

- There will be a team of data collectors to observe and record specific information on the effectiveness of FSIS oversight and verification of the establishment's ante-mortem process control. The data collectors will:
  a) randomly select ten head of cattle an hour that the establishment has found to be normal appearing to determine whether they have been correctly categorized by the establishment.
  b) randomly select up to ten head of cattle a day that the establishment has found to be abnormal-appearing to determine whether they have been correctly categorized and appropriately segregated.
  c) review establishment records to ensure cattle not suitable for slaughter are condemned and disposed of according to regulatory performance standards.

***Ante-mortem Inspection Model Step 2***

- The establishment provides ante-mortem process control as described in Step 1.
- The establishment takes full responsibility for humane slaughter while Federal meat inspectors continue to make such inspections as would be necessary to prevent inhumane slaughtering.
- A veterinarian (FSIS veterinarian or establishment veterinarian who is accredited by APHIS) must examine cattle segregated as abnormal and further subdivide them into a group of abnormal cattle considered suitable for use as

food and a group of abnormal cattle not suitable for food use. Any animal with a reportable disease must be processed according to current regulatory standards.

- Abnormal cattle that are nevertheless considered suitable for food will be held and slaughtered as a separate group.
- Abnormal cattle that are not considered suitable for food will be disposed of in a manner consistent with existing regulatory standards. For example, animals showing signs consistent with reportable diseases, showing central nervous system (CNS) signs, or branded for conditions such as tuberculosis or brucellosis will be identified to FSIS in order to meet requirements of the Animal and Plant Health Inspection Service.

***FSIS Responsibilities***

- FSIS inspectors will be retrained to perform oversight and verification using procedures developed during step 1.
- The data collection team will continue to collect the following data as specified in step 1:

a) randomly select ten head of cattle an hour that the establishment has found to be normal appearing to determine whether they have been correctly categorized by the establishment as healthy and suitable for food.

b) randomly select up to ten head of cattle a day that the establishment has found to be abnormal-appearing to determine whether they have been correctly categorized and appropriately segregated.

c) review establishment records to ensure cattle not suitable for food are condemned and disposed of according to regulatory standards.

**Post-mortem Fed Cattle Inspection Model**

***Industry Responsibilities***

Individual establishments will perform slaughter process control and meet organoleptic standards established in the baseline phase and microbial PR/HACCP criteria and standard for generic *E. coli* and *Salmonella*. Establishments may alter, modify, or change slaughter process control procedures as long as they meet organoleptic and microbial FSIS regulatory standards and the organoleptic performance level measured in the baseline phase.

Organoleptic defects can result in both food safety hazards and other consumer protection conditions, such as aesthetic defects like pieces of hide or economic adulteration. Organoleptic decisions that need to be made on the slaughter floor include (a) decide whether to pass product suitable for food without further action, (b) determine if product should be trimmed or otherwise reworked, (c) determine if product should be condemned, and (d) determine how product that cannot be reworked

should be handled. The establishment's slaughter process control system (using establishment-validated methods) must meet the following organoleptic and microbial standards:

(1) Carcasses contaminated with visible fecal material, ingesta, and milk are processed to meet the zero tolerance standards.

(2) Product containing localized food safety or localized OCP defects is processed to remove the defects.

(3) Product containing generalized food safety or generalized OCP defects is condemned (metastatic neoplasia, pyemia, septicemia, and toxemia).

(4) Product that cannot be reworked in the slaughter environment (carcasses showing signs of tuberculosis and beef measles) is handled according to regulatory standards.

(5) Product must meet the microbial performance criteria and standard in the PR/HACCP final rule for generic E. *coli* and *Salmonella.*

### *FSIS Inspection Responsibilities*

FSIS will oversee and verify that establishment slaughter process control systems meet organoleptic and microbial FSIS regulatory standards. Determinations of

whether an establishment's slaughter process is in or out of control will be based on the organoleptic performance level and microbial profile collected during the baseline phase.

### *Organoleptic Data Collection for Baseline Phase*

Organoleptic data for processing defects and pathology defects will be recorded from 10 carcasses and 10 boxes of product (variety meats) examined per hour. A team will consist of independent contract employees, Agency personnel, and establishment personnel used as recorders as needed. The team will (1) observe carcasses and record data at a point immediately after the final wash and (2) observe and record data from variety meats at appropriate points. Recorded observations will address at least the following:

(a) trimmable food safety defects (milk/feces/ingesta)

(b) trimmable defects other than those in (a) above, and

(c) whole carcass condemnable defects or other carcass defects that cannot be handled on the slaughter floor (generalized conditions, metastatic neoplasia/beef measles, and tuberculosis)

### *Sample Size*

A proposed sample size of 2,000 randomly selected carcasses at each establishment/site and 2000 randomly selected byproducts will provide appropriate levels of precision of the expected percentage of error for organoleptic defects during inspection. To achieve this number at each establishment and site within plant, ten samples per hour would be selected during an eight-hour shift over a five-week period (10 per hour x 8 hours x 5 days x 5 weeks = 2,000 samples).

**Table 1: Estimating the Margin of Error with 95 percent confidence for a given percentage error in organoleptic defects by sample size**

| *Percent error* | *Sample Size* | | |
|---|---|---|---|
| | 1000 | 2000 | 3000 |
| 0.5 | 0.49 | 0.33 | 0.27 |
| 1.0 | 0.67 | 0.46 | 0.37 |
| 2.0 | 0.92 | 0.64 | 0.52 |
| 3.0 | 1.11 | 0.77 | 0.63 |
| 4.0 | 1.26 | 0.88 | 0.72 |
| 5.0 | 1.40 | 0.98 | 0.80 |

For a sample size of 2,000, if 2 percent of the sampled carcasses have an organoleptic defect, then the estimate of percentage of defects would have a margin of error with 95 percent confidence of approximately $\pm$ 0.64 percent.

### *Inspection Model Step 1*

#### *Five weeks*

- Establishment performs slaughter process control to identify and remove trim defects.

- FSIS organoleptic inspection procedures remain unchanged except that trim defects are not identified for the establishment.

- A data collection team records information to check organoleptic performance level.

- If the establishment meets the organoleptic performance level for trim defects established during the baseline phase and the PR/HACCP microbial regulatory criteria and standard for generic E. *coli* and *Salmonella,* it moves to Model Step 2.

- If the establishment does not meet the organoleptic performance level and the PR/HACCP microbial regulatory criteria and standard for generic E. *coli* and *Salmonella*, it must remain in Inspection Model Step 1 until data analysis for three consecutive weeks demonstrates slaughter process control. Establishment cannot move to Inspection Model Step 2 until criteria for Inspection Model Step 1 are met.

### *Inspection Model Step 2*

#### *Five weeks*

- Establishments perform slaughter process control meeting regulatory standards for condemnable conditions and whole carcass conditions that cannot be reworked in the slaughter environment in addition to their successful controls for trimmable defects.

- FSIS organoleptic inspection procedures remain unchanged except FSIS inspectors no longer identify or have responsibility to detect, for the establishment, trimmable defects, condemnable conditions, or whole carcass conditions that cannot be reworked in the slaughter environment.
- Data collectors oversee plant process control and record information to verify that organoleptic performance meets established standard.
- If establishment meets established organoleptic performance level and PR/HACCP microbial regulatory criteria and standard for generic E. *coli* and *Salmonella*, it may move to step 3.
- If an establishment does not meet the standard for organoleptic performance level and PR/HACCP microbial regulatory criteria and standard for generic E. *coli* and *Salmonella*, it must remain in Inspection Model Step 2 until data analysis indicates establishment meets standards for three consecutive weeks. Establishment cannot move to Inspection Model Step 3 until criteria for Inspection Model Step 2 are met.

### *Inspection Model Step 3*

#### *Five weeks (organoleptic) and twelve weeks (microbial)*

- Establishment performs all tasks related to slaughter process control.

- Data collectors gather information to verify that organoleptic performance standard is met.
- Microbial sampling identical to microbial sampling in the baseline phase begins and continues for 12 weeks.
- The data collected must show that the establishment meets the organoleptic performance standard and PR/HACCP microbial criteria and standard for generic E. *coli* and *Salmonella* to demonstrate success in step 3.

# HACCP Inspection Models Project

Market Hogs Slaughter Inspection Models

# MARKET HOGS SLAUGHTER INSPECTION MODELS

## Summary

The need to reconsider the current FSIS procedures for slaughter inspection was discussed in a June 10, 1997 Federal Register Notice and at a public meeting held June 24-25, 1997. All current procedures may be considered for change as long as the Agency can fulfill its responsibilities to ensure that the industry produces safe, wholesome, and properly labeled meat and poultry products.

Under the inspection model tested, the establishment would separate acceptable from unacceptable animals, carcasses, and parts using current regulatory standards for ante-mortem and post-mortem conditions of animals, carcasses, and parts. Establishments would also develop slaughter process control plans. The establishment process control plan must be a written document; the portions applicable to 9 CFR Part 417 should be incorporated into the establishment's HACCP plan. The process control plan must be shared with FSIS before initiating the model-testing phase.

FSIS expects that the inspection model tested will have three main components: establishment implementation of slaughter organoleptic and PR/HACCP microbial

performance standards, FSIS oversight of the standards being implemented, and verification by FSIS of the standards by product sampling.

## Ante-mortem Market Hogs Inspection Model

### *Industry Responsibilities*

- To present and slaughter only healthy hogs suitable for the food supply.
- Perform ante-mortem process control.

### *FSIS Inspection Responsibilities*

- Ensure establishment's ante-mortem process control meets regulatory standards through oversight and verification.

### *Ante-mortem Inspection Model step 1*

- Establishment personnel examine and appropriately segregate animals showing signs of abnormalities.
- FSIS inspectors determine the effectiveness of the establishment's ante-mortem process control by observing 100 percent of all hogs at rest, 100 percent of abnormal animals in motion, and at least 10 percent of normal animals in motion.

- There will be a team of data collectors to observe and record specific information on the effectiveness of FSIS oversight and verification of the establishment's ante-mortem process control. The data collectors will:

a) randomly select ten head of hogs an hour that the establishment has found to be normal appearing to determine whether they have been correctly categorized by the establishment.

b) randomly select up to ten head of hogs a day that the establishment has found to be abnormal-appearing to determine whether they have been correctly categorized and appropriately segregated.

c) review establishment records to ensure hogs not suitable for slaughter are condemned and disposed of according to regulatory performance standards.

***Ante-mortem Inspection Model Step 2***

- The establishment provides ante-mortem process control as described in Step 1.
- The establishment takes full responsibility for humane slaughter while Federal meat inspectors continue to make such inspections as would be necessary to prevent inhumane slaughtering.
- A veterinarian (FSIS veterinarian or establishment veterinarian who is accredited by APHIS) must examine hogs segregated as abnormal and further subdivide them into a group of abnormal hogs considered suitable for use as

food and a group of abnormal hogs not suitable for food use. Any animal with a reportable disease must be processed according to current regulatory standards.

- Abnormal hogs that are considered nonetheless suitable for food will be held and slaughtered as a separate group.
- Abnormal hogs that are not considered suitable for food will be disposed of in a manner consistent with existing regulatory standards. For example, animals showing signs consistent with reportable diseases or showing central nervous system (CNS) signs will be identified to FSIS in order to meet requirements of the Animal and Plant Health Inspection Service.

### *FSIS Responsibilities*

- FSIS inspectors will be retrained to perform oversight and verification using procedures developed during step 1.
- The data collection team will continue to collect the following data as specified in step 1:

a) randomly select ten head of hogs an hour that the establishment has found to be normal appearing to determine whether they have been correctly categorized by the establishment as healthy and suitable for food.

b) randomly select up to ten head of hogs a day that the establishment has found to

be abnormal-appearing to determine whether they have been correctly categorized and appropriately segregated.

c) review establishment records to ensure hogs not suitable for food are condemned and disposed of according to regulatory standards.

## Post-mortem Market Hogs Inspection Model

### *Industry Responsibilities*

Individual establishments will perform slaughter process control and meet organoleptic standards established in the baseline phase and microbial PR/HACCP criteria and standard for generic *E. coli* and *Salmonella*. Establishments may alter, modify, or change slaughter process control procedures as long as they meet organoleptic and microbial FSIS regulatory standards and organoleptic performance level measured in the baseline phase.

Organoleptic defects can result in both food safety hazards and other consumer protection conditions, such as aesthetic defects like hair or economic adulteration. Organoleptic decisions that need to be made on the slaughter floor include (a) decide whether to pass product as suitable for food without further action, (b) determine if product should be trimmed or otherwise reworked, (c) determine if product should be condemned, and (d) determine how product that cannot be reworked should be

handled. The establishment's slaughter process control system (using establishment-validated methods) must meet the following organoleptic and microbial standards:

(1) Carcasses contaminated with visible fecal material and ingesta are processed to meet the zero tolerance standards.

(2) Product containing localized food safety or localized OCP defects is processed to remove the defects.

(3) Product containing generalized food safety or generalized OCP defects is condemned (metastatic neoplasia, pyemia, septicemia, and toxemia).

(4) Product that cannot be reworked in the slaughter environment (carcasses showing signs of tuberculosis and swine measles) is handled according to regulatory standards

(5) Product must meet the microbial performance criteria and standard in the PR/HACCP final rule for generic E. *coli* and *Salmonella.*

### *FSIS Inspection Responsibilities*

FSIS will oversee and verify that establishment slaughter process control systems meet organoleptic and microbial FSIS regulatory standards. Determinations of whether an establishment's slaughter process is in or out of control will be based

on the organoleptic performance level and microbial profile collected during the baseline phase.

### *Organoleptic Data Collection for Baseline Phase*

- Organoleptic data for processing defects and pathology defects will be recorded from 10 carcasses and 10 boxes of product (variety meats) examined per hour. A team will consist of independent contract employees, Agency personnel, and establishment personnel used as recorders as needed. The team will (1) observe carcasses and record data at a point immediately after the final wash and (2) observe and record data from variety meats at appropriate points. Recorded observations will address at least the following:

  (a) trimmable food safety defects (feces/ingesta)

(b) trimmable defects other than those in (a) above, and

(c) whole carcass condemnable defects or other carcass defects that cannot be handled on the slaughter floor (generalized conditions, metastatic neoplasia, swine measles, and tuberculosis)

### *Sample Size*

- A proposed sample size of 2,000 randomly selected carcasses at each

establishment/site and 2000 randomly selected byproducts will provide appropriate levels of precision of the expected percentage of error for organoleptic defects during inspection. To achieve this number at each establishment and site within plant, ten samples per hour would be selected during an eight-hour shift over a five-week period (10 per hour x 8 hours x 5 days x 5 weeks = 2,000 samples).

**Table 1: Estimating the Margin of Error with 95 percent confidence for a given percentage error in organoleptic defects by sample size**

| *Percent error* | *Sample Size* | | |
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| 3.0 | 1.11 | 0.77 | 0.63 |
| 4.0 | 1.26 | 0.88 | 0.72 |
| 5.0 | 1.40 | 0.98 | 0.80 |

For a sample size of 2000, if 2 percent of the sampled carcasses have an organoleptic defect, then the estimate of percentage of defects would have a margin of error with 95 percent confidence of approximately $\pm$ 0.64 percent

### *Inspection Model Step 1*

### *Five weeks*

- The establishment performs slaughter process control to identify and remove trim defects.
- FSIS organoleptic inspection procedures remain unchanged except that trim defects are not identified for the establishment.

- A data collection team records information to check organoleptic performance level.
- If the establishment meets the organoleptic performance level for trim defects established during the baseline phase and the PR/HACCP microbial regulatory criteria and standard for generic *E. coli* and *Salmonella*, it moves to Inspection Model Step 2.
- If the establishment does not meet the organoleptic performance level established during the baseline phase and the PR/HACCP microbial regulatory criteria and standard for generic *E. coli* and *Salmonella*, it must remain in Inspection Model Step 1 until data analysis for three consecutive weeks demonstrates slaughter process control. Establishment cannot move to Inspection Model Step 2 until criteria for Inspection Model Step 1 are met.

### *Inspection Model Step 2*

### *Five weeks*

- The establishment performs slaughter process control meeting regulatory standards for condemnable conditions and whole carcass conditions that cannot be reworked in the slaughter environment in addition to their successful controls for trimmable defects.

- FSIS organoleptic inspection procedures remain unchanged except FSIS inspectors no longer identify or have responsibility to detect, for the establishment, trimmable defects, condemnable conditions, or whole carcass conditions that cannot be reworked in the slaughter environment**.**
- Data collectors oversee plant process control and record information to verify that organoleptic performance meets established standard.
- If the establishment meets established organoleptic performance level and the PR/HACCP microbial regulatory criteria and standard for generic *E. coli* and *Salmonella*, it may move to Inspection Model Step 3.
- If an establishment does not meet the standard for organoleptic performance level and PR/HACCP microbial regulatory criteria and standard for generic *E. coli* and *Salmonella*, it must remain in Inspection Model Step 2 until data analysis indicates establishment meets standards for three consecutive weeks. Establishment cannot move to Inspection Model Step 3 until criteria for Inspection Model Step 2 are met.

### *Inspection Model Step 3*

#### *Five weeks (organoleptic) and twelve weeks (microbial)*

- Establishment performs all tasks related to slaughter process control.

- Data collectors gather information to verify that organoleptic performance standard is met.
- Microbial sampling identical to microbial sampling in the baseline phase begins and continues for 12 weeks.
- The data collected must show that the establishment meets the organoleptic performance standard and PR/HACCP microbial criteria and standard for generic *E. coli* and *Salmonella* to demonstrate success in step 3.

# HACCP Inspection Models Project

Young Poultry Slaughter Inspection Models

# YOUNG POULTRY SLAUGHTER INSPECTION MODELS

## Summary

The need to reconsider the current FSIS procedures for slaughter inspection was discussed in a June 10, 1997 Federal Register Notice and at a public meeting held June 24-25, 1997. All current procedures may be considered for change as long as the Agency can fulfill its responsibilities to ensure that the industry produces safe, wholesome, and properly labeled meat and poultry products.

Under the inspection model tested, the establishment would separate acceptable from unacceptable animals, carcasses, and parts using current regulatory standards for ante-mortem and post-mortem conditions of animals, carcasses, and parts. Establishments would also develop slaughter process control plans. The establishment process control plan must be a written document; the portions applicable to 9 CFR Part 417 should be incorporated into the establishment's HACCP plan. The process control plan must be shared with FSIS before initiating the model-testing phase.

FSIS expects that the inspection model tested will have three main components: establishment implementation of slaughter organoleptic and PR/HACCP microbial

performance standards, FSIS oversight of the standards being implemented, and verification by FSIS of the standards by product sampling.

## Ante-mortem Young Poultry Inspection Model

### *Industry Responsibilities*

- To present and slaughter only healthy poultry suitable for the food supply.
- Perform ante-mortem process control

### *FSIS Inspection Responsibilities*

- Ensure establishment's ante-mortem process control meets regulatory standards through oversight and verification.

## Ante-mortem Step

- Establishment observes poultry on the truck. Establishment personnel examine and appropriately segregate poultry showing signs of abnormalities, for example, poultry showing signs consistent with reportable diseases or lots showing disease conditions of the flock as a whole will be identified to FSIS in order to meet requirements of the Animal and Plant Health Inspection Service.
- FSIS inspectors will determine the effectiveness of the establishment's ante-mortem process control by observing poultry ante-mortem as determined

necessary by the inspector in charge. FSIS inspectors will observe poultry ante-mortem that is identified by the establishment as not suitable for food. Any animal with a reportable disease must be processed according to current regulatory standards.

- If FSIS inspectors identify conditions post-mortem that may be associated with ante-mortem signs of disease, they should conduct ante-mortem inspection of the flock.

## Post-mortem Young Poultry Inspection Models

### *Industry Responsibilities*

Individual establishments will perform slaughter process control and meet organoleptic performance levels established in the baseline phase and microbial PR/HACCP criteria and standard for generic *E. coli* and *Salmonella*. Establishments may alter, modify, or change slaughter process control procedures as long as they meet organoleptic and microbial FSIS regulatory standards and organoleptic performance level measured in the baseline phase.

Organoleptic defects can result in both food safety hazards and other consumer protection conditions, such as aesthetic defects like feathers or economic adulteration. Organoleptic decisions that need to be made on the slaughter floor include (a) decide

whether to pass product as suitable for food without further action (b) determine if product should be trimmed or otherwise reworked, and (c) determine if product should be condemned. The establishment's slaughter process control system (using establishment-validated methods) must meet the following organoleptic and microbial standards:

(1) Carcasses contaminated with visible fecal material are processed to meet the zero tolerance standards.

(2) Product containing localized food safety or localized OCP defects is processed to remove the defects.

(3) Product containing generalized food safety or generalized OCP defects is condemned (metastatic neoplasia, cadavers, septicemia, and toxemia).

(4) Product must meet the microbial performance criteria and standard in the PR/HACCP final rule for generic *E. coli* and *Salmonella*.

### *FSIS Inspection Responsibilities*

FSIS will oversee and verify that establishment slaughter process control systems meet organoleptic and microbial FSIS regulatory standards. Determinations of whether an establishment's slaughter process is in or out of control will be based

on the organoleptic performance level and microbial profile collected during the baseline phase.

### *Organoleptic Data Collection for Baseline Phase*

Organoleptic data for processing defects and pathology defects will be recorded from 10 carcasses and 10 boxes of cut up parts or giblets examined per hour. A team will consist of independent contract employees, Agency personnel, and establishment personnel used as recorders as needed. The team will (1) observe carcasses and record data at a point immediately after the final wash but before the chiller and (2) observe and record data from cut up parts or giblets and collect data at appropriate points. Recorded observations will address at least the following:

(a) trimmable food safety defects (feces)

(b) trimmable defects other than those in (a) above, and

(b) whole carcass condemnable defects such as metastatic neoplasia and cadavers.

### *Sample Size*

A proposed sample size of 2,000 randomly selected carcasses at each establishment/site and 2000 randomly selected cut-up parts or giblets will provide appropriate levels of precision of the expected percentage of error for organoleptic defects during inspection. To achieve this number at each establishment and site

within plant, ten samples per hour would be selected during an eight-hour shift over a five-week period (10 per hour x 8 hours x 5 days x 5 weeks = 2,000 samples).

**Table 1: Estimating the Margin of Error with 95 percent confidence for a given percentage error in organoleptic defects by sample size**

| *Percent error* | *Sample Size* | | |
|---|---|---|---|
| | **1000** | **2000** | **3000** |
| **0.5** | **0.49** | **0.33** | **0.27** |
| **1.0** | **0.67** | **0.46** | **0.37** |
| **2.0** | **0.92** | **0.64** | **0.52** |
| **3.0** | **1.11** | **0.77** | **0.63** |
| **4.0** | **1.26** | **0.88** | **0.72** |
| **5.0** | **1.40** | **0.98** | **0.80** |

For a sample size of 2,000, if 2 percent of the sampled carcasses have an organoleptic defect, then the estimate of percentage of defects would have a margin of error with 95 percent confidence of approximately $\pm$ 0.64 percent.

### *Inspection Model Phase*

#### *Five weeks (organoleptic) and twelve weeks (microbial)*

- The establishment continues its successful slaughter process controls for

trimmable defects. Since the 1980's, the poultry industry has been responsible to identify and trim localized OCP and localized food safety conditions, lesions such as breast blisters, bruises, and localized pathology.

- The establishment performs slaughter process control for condemnable conditions and whole carcass conditions that must be reworked.

  The establishment may initiate its model in two steps, the first is process control for carcass conditions that must be reworked, such as reprocessing of contaminated carcasses, salvage for airsacculitis or turkey osteomyelitis.

  The second step adds process control for condemnable carcass conditions. If two steps are used there will be five weeks for each step.

- FSIS inspectors no longer identify or have responsibility to detect, for the establishment, trimmable defects, condemnable conditions, or carcass conditions that must be reworked.
- A data collection team records information to check organoleptic performance level.
- Microbial sampling identical to microbial sampling in the baseline phase begins and continues for 12 weeks once the final inspection model is in place.
- The data collected must show that the establishment meets the organoleptic performance standard and PR/HACCP microbial regulatory criteria and

standard for generic *E. coli* and *Salmonella* to demonstrate success.