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04-026N-11
04-026N
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National Chicken Council

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street, SW
Room 102 Cotton Annex
Washington, DC 20250

RE: Docket Number 04-026N, "Salmonella Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection". Federal Register: February 27, 2006 (Volume 71, Number 38), pages 9772-9777.

Dear Sir or Madam:

The Food Safety and Inspection Service (FSIS) has requested interested persons to submit comments on the Salmonella Initiative published February 27, 2006. The comments herein are submitted on behalf of the National Chicken Council (NCC) by the NCC Technical and Regulatory Committee.

FSIS has stated that the Agency would consider modifying its approach to inspection if widespread industry performance provides a basis for reducing Agency concern about control for pathogens in classes of raw product. Additionally, FSIS stated that they would be prepared to consider allowing increased linespeeds if industry results were maintained at half or below half the current standard/baseline guidance.

The attached proposal incorporates certain changes in inspection procedures and increases in linespeeds provided consistent control of Salmonella at less than half the current standard is achieved and maintained. Additionally, we are proposing a waiver of certain provisions related to carcass chilling and temperature of product during processing. It is our understanding that these waivers would be allowed under 9 CFR 381.3b. The NCC Technical and Regulatory Committee strongly feel that a waiver of the current provisions referenced in the proposal is warranted and will pose no public health hazard.

A representative group from the NCC Technical and Regulatory Committee is prepared to discuss this proposal with FSIS at any time. Please address any question and concerns that the Agency may have to Steve Pretanik at the National Chicken Council offices in Washington, DC.

Sincerely yours,

Stephen Pretanik

John T. Rice

Stephen Pretanik
Director of Science & Technology

John T. Rice, PhD,
Chairman
Technical and Regulatory Committee

Incentive-based Salmonella Control Pilot Inspection System

1) Eligibility for Participation

In order for a broiler slaughter establishment to be eligible to participate in the Incentive-based Salmonella Control (ISC) Pilot Inspection System, it must demonstrate process control regarding its *Salmonella* performance standard by achieving an 8% or less positive incidence rate of Salmonella isolations from samples collected and tested as specified in Section 2 below for at least two consecutive quarters.[1]

2) Determining Salmonella Incidence Rates.

Any establishment wishing to operate under this section and each establishment operating under this section shall test for *Salmonella* as specified below and meet or exceed the requirements for *Salmonella* testing as currently employed by the USDA, FSIS Laboratories.

a) **Written procedures.** Each establishment shall prepare written collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity.

b) **Sample collection**. A whole carcass must be taken from the end of the chilling process following all (if any) post-chill applications the establishment has enacted to reduce microbial contamination of carcasses. Samples must be collected by rinsing a whole carcass in a manner that meets or exceeds those procedures described in the Pathogen Reduction, Hazard Analysis and Critical Control Point Systems.[2]

c) **Sampling frequency**. Establishments shall sample (on average) at least one carcass per 88,000 carcasses processed.

d) **Methodology.** The samples must be analyzed for *Salmonella* as described in MLG 4.03, Isolation and Identification of Salmonella from Meats, Poultry and Egg Products[3] and/or MLG 4C.01, FSIS Procedure for the Use of the BAX System PCR Assay for Screening Salmonella in Raw Meat, Carcass Sponge Samples, Whole Bird Rinses, Ready-to-Eat Meat and Poultry Products and Pasteurized Egg Products.[4]

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[1] One quarter shall equal a time period of 3 months or 60 production days.

[2] Federal Register/ Vol. 61. No. 144/ Thursday, July 25,, 1996/Rules and Regulation/ Poultry Carcass Selection, Chicken Carcass Rinse Sampling Procedure, pp. 38940-38941.

[3] Laboratory Guidebook, Isolation and Identification of Salmonella from Meat, Poultry, and Egg Products, effective 10/1/04. USDA, FSIS, Office of Public Health Science, Laboratory QA/QC Division, 950 College Station Rd., Athens, GA 30605.

[4] Laboratory Guidebook, Procedure for the use of the BAX System PCR Assay for Screening Salmonella in Raw Meat, Carcass Sponge Samples, Whole Bird Rinses, Ready-to-Eat Meat and Poultry Products and Pasteurized Egg Products, effective 10/6/03. USDA, FSIS, Office of Public Health and Science, Laboratory QA/QC Division, 950 College Station Rd., Athens, GA 30605.

e) **Recording of results**. The establishment shall record the results and maintain those results on a quarterly basis. A quarter shall consist of 60 days of production or 3 calendar months.

3) ***Evaluation of Test Results:***

a) The establishment incidence rate is calculated by dividing the number of positive samples by the total number of samples over the period of one quarter. Establishments must achieve the *Salmonella* performance standard of 8% or less for the preceding two quarters to participate in the program.

b) For establishments already operating under this section, the quarterly results must continue to be in compliance with the *Salmonella* performance objective. In the analysis of quarterly results, consideration will be given to statistical variation within the sample in that questionable results will be further evaluated and those found to be erroneous will not be included in the statistical evaluation.

4) E. coli and Campylobacter Monitoring:

Data on generic E. coli[5] and Campylobacter[6] numbers pre-evisceration and post-chill from the same flock (10 whole carcass rinses at each point) will be assessed once each calendar month to show that the evisceration and chilling processes are producing a reduction in microbial numbers.

5) ***Access and Maintenance of Records***.

a) FSIS personnel shall have access to any records, including laboratory results, generated by the establishment under this section.

b) Records generated under this section shall be maintained in the same manner and for the same duration as HACCP records, as specified in § 417.5.

6) ***Participating establishments.***

Establishments achieving the *Salmonella* performance objective have demonstrated an acceptable total food safety system in design and implementation. If an

[5] Use AOAC approved methodology as specified in the HACCP/Pathogen Reduction Regulation, Federal Register, Vol. 61, No.144, July 25, 1996, page 38843.
[6] ARS/FSIS Broiler Rinse Study, Campylobacter spp. Enumeration Method. In Analytical Utility of Campylobacter Methodologies. National Advisory Committee on Microbiological Criteria for Foods. Adopted September 28, 2005, Coral Gables, FL. Appendix I.

establishment is meeting this *Salmonella* performance objective, the establishment can process at line speeds up to 180 birds per minute. Establishments may exceed 180 birds per minute based on that establishment's process capabilities. Increased line speeds are subject to the following:

a) **Manner of Inspection:**

i) One FSIS inspector will be stationed at the end of each evisceration line to conduct bird-by-bird inspection prior to the carcasses entering the chiller.

ii) One FSIS inspector will be staffed off-line to ensure compliance with the performance standards below and other regulatory requirements.

b) **Performance Standards:**

i) Establishments operating under this section shall establish and maintain compliance with the *Salmonella* as well as the carcass quality performance standards outlined below. The Carcass Quality performance standards involve the identification and removal of the following **Major (Bold)** and *Minor (italics)* non-conformances. Major non-conformances must be included, Minor non-conformances may include, but are not limited to those listed below:

Processing Defects	Carcass Defects (Condemn or trim)
Fecal (Zero Tolerance)	**Septicemia/Toxemia** (condemn)
Cadaver (condemn)	**Mareks (condemn or trim)**
Overscald/Mutilation (condemn or trim)	**Airsaculitis and ascites**
Trachea	**Pericarditis, salpingitis**
Crop	**Inflammatory process (IP)**
Esophagus	**Tenosynovitis**
Ingesta	*Keratoacanthomas*
Cloaca	*Blister (Breast blisters)*
Oil gland	*Bruises*
Bursa	*Scabs and sores*
Lung	
Bile	
Feathers	

ii) Establishments are responsible for establishing the Carcass Quality performance standards for their processes as well as providing supporting documentation for establishing those standards.

iii) Establishment personnel are responsible for the identification of carcass quality defects and the removal or reconditioning of carcasses and/or parts thereof.

iv) Establishments are responsible for developing and implementing a slaughter process control procedure(s) describing how the establishment will ensure compliance with their performance standards.

(1) The procedure shall describe how the establishment will monitor, verify and document compliance and procedures for identifying and removing carcasses that do not meet these standards.

(2) The procedure will describe how process control will be determined in regards to the performance standards, for example:

(a) If no defects exceed the performance standard, the process will be considered in control.

(b) If a defect in excess of the performance standard is observed during the conduct of the verification procedure, the establishment will immediately expand the sample to determine if the process is out of control. (Note: The number of the expanded sample will be determined statistically from the performance standard).

(c) If the expanded sample demonstrates that the evisceration process is in compliance with the applicable performance standard and appropriate disposition has been made to the initial carcasses, the process will be considered to be in-control and no additional action is required.

(d) If the expanded sample demonstrates that the evisceration process is not in compliance with regards to that performance standard, the establishment must take immediate action to restore control. In addition, the establishment must implement corrective actions on affected products. The establishment must also implement a statistically valid sampling plan, such as MIL-STD-85E, on the product to assure that those corrective actions were effective.

c) At a frequency determined by the ISPG system, FSIS in-plant inspectors may conduct carcass checks to verify that the establishment is achieving process control.

i) FSIS inspectors are to observe establishment employees randomly select 10 carcasses from each evisceration line prior to entering the chiller. These carcasses should be evaluated for meeting the performance standards as described in the establishments plan.

ii) If a defect(s) is found in excess of the establishments performance standard is observed during the conduct of the verification procedure, the inspector will observe and verify the establishment's implementation of corrective actions

and appropriate verification procedures (See above) to assure that process control is established and maintained.

d) Participating establishments will be allowed to operate under a suspension of regulation 381.66(b)(1), 381.66 (b)(2), 381.66(c)(3), and 381.66(e), which provide for carcass temperatures of 40°F or less within a specified time after slaughter and 55°F or less during processing. Establishments will be allowed to suspend these regulations provided documentation shows that temperature controls are in place to prevent significant growth of pathogens or indicator organisms under alternate time/temperature controls.

7) ***Line Speed Restrictions.*** To participate in this program, the establishment must periodically calculate the percent incidence of the plant's most recent 200 *Salmonella* test results. The sample window of 200 tests must be calculated for percent incidence at least quarterly, and may also be calculated monthly, weekly, or daily at the discretion of the establishment. After the establishment calculates the *Salmonella* incidence of its most recent 200 samples, the plant's evisceration line speeds must be adjusted according to the table below. The adjusted line speeds must be maintained until process control is re-established through additional *Salmonella* testing and subsequent recalculation of the *Salmonella* incidence rate. The most extreme line speed reductions required per this program will be that the establishment must revert back to its line speeds prior to ISCP implementation, regardless of the *Salmonella* incidence. If the participating establishment's data for two successive calendar quarters indicates a *Salmonella* isolation rate of greater than 20% for each quarter, the establishment will be required to revert to the line speed prior to ISCP implementation for the subsequent calendar quarter.

Salmonella Percent	Line Speed Reduction in %
< or = 8%	0
> 8% up to 12%	5%
> 12% up to 16%	10%
> 16% up to 20%	15%
> 20%	revert to line speed prior to ISCP implementation