

# FSIS PERSPECTIVE ON PATHOGEN PERFORMANCE STANDARDS

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# FSIS PERSPECTIVE ON PATHOGEN PERFORMANCE STANDARDS

## ■ Overview

- Previous speakers addressed some of the technical issues surrounding the development and implementation of risk-based performance standards for pathogens, as well as the practicalities of devising consistent, effective, enforceable performance standards.
- I will describe FSIS's experience in developing pathogen performance standards for both raw and processed meat, poultry, and egg products.
  - How the performance standards were derived
  - How well they appear to be working
  - Lessons learned
  - Future directions

# FSIS PERSPECTIVE ON PATHOGEN PERFORMANCE STANDARDS

- Pathogen Reduction / HACCP Final Rule
  - Issued July 25, 1996
  - Established performance standards for *Salmonella* spp. on raw product - carcasses and ground meat and poultry products
  - Part of fundamental shift in regulatory philosophy away from command and control type regulations
  - Performance standards are a good fit with HACCP
    - Clear objectives for industry to meet
    - Flexibility for industry in how they are achieved
    - Encourage development of new technologies
    - Measurable standards that can be verified by FSIS

# FSIS PERSPECTIVE ON PATHOGEN PERFORMANCE STANDARDS

- Performance Standards for *Salmonella* on Carcasses and Raw Ground Product
  - Why FSIS chose *Salmonella* as the target organism for pathogen reduction
  - How the performance standards were derived
  - How FSIS ensured compliance with the performance standards

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- Why *Salmonella* as the target organism?
  - Among the most common causes of foodborne illness associated with meat and poultry
  - Methodology exists to detect *Salmonella* in a variety of meat and poultry products
  - Serves as a useful indicator of effectiveness of interventions aimed at other enteric pathogens
  - Occurs at frequencies high enough so that changes can be detected and monitored

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- How Were the Performance Standards Derived?
  - Separate standards for carcasses of steers / heifers, cows / bulls, market hogs, and young chickens
  - Based on baseline studies which provide a national estimate for the percentage of product that contains *Salmonella*
  - FSIS measures compliance with the standard using a series of sample sets. For each product type, FSIS determined the number of samples constituting a set and the maximum number of sample positives that can occur with the establishment still being in compliance

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- How Were the Performance Standards Derived ? (cont.)
  - Number of samples per set is greater than 50 for each product type in order to monitor process control over time
  - Number of positives permitted was set so that an establishment that was operating at the performance standard would have an 80% probability of passing the set
  - Performance standard was not derived from a risk assessment or an infectious dose
  - Rather they were based on a judgment that reducing the percentage of product with *Salmonella* would reduce the risk of foodborne illness from enteric pathogens
  - Set so that majority of plants would meet the national average. Some plants would have to improve to come up to the standard

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- How Did FSIS Intend to Ensure Compliance With the Performance Standards?
  - Sampling frequency is generally one sample per day. Number of positives in a set is compared to the maximum permitted number for that product category
  - If the establishment exceeds the maximum permitted number of positives, it fails that set

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- How Did FSIS Intend to Ensure Compliance With the Performance Standards? (cont.)
  - After a sample set failure, the establishment is required to take appropriate corrective actions
  - If the establishment fails a second sample set, it is required to reassess its HACCP plan
  - If the establishment fails a third sample set, FSIS would notify the establishment of its intention to suspend inspection. Third failure constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan
  - HACCP regulations require the establishment to address in their hazard analysis, hazards that can occur before, during and after entry into the establishment

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- Enforcement Strategy Challenged
  - Grinding establishment, after third set failure, sued FSIS to prevent suspension of inspection
  - Establishment contended that the presence of *Salmonella* in its ground product was not indicative of the sanitary conditions in the plant, but rather was characteristic of the raw material purchased by the establishment
  - Raw material had been inspected and passed by FSIS
  - December, 2001 – decision by the U.S. Court of Appeals found in favor of the establishment

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## ■ Modified Enforcement Strategy

- *Salmonella* set failure triggers in-depth verification of plant's HACCP system by FSIS.
- Use failure to meet the performance standard as one indicator of overall control
- Failure by the plant to take appropriate corrective action will trigger enforcement action

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- Performance Standards in Ready-to-Eat (RTE) Product
  - Proposed Rule on Performance Standards for the Production of Processed Meat and Poultry Products (66 FR 12590, February 27, 2001)
    - Lethality performance standards
    - Stabilization performance standards

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## ■ Proposed Lethality Performance Standards

- For dried, salt-cured, fermented, cooked or otherwise processed whole or comminuted products
  - Standards expressed as probabilities of remaining numbers of *Salmonella* in 100g of “worst case” product after lethality treatment
  - Also expressed as number of decimal reductions of *Salmonella* necessary to achieve those probabilities in “worst case” product
  - *Salmonella* chosen because it has been source of illness outbreaks and has a relatively high heat resistance
  - “Worst case” product based on high confidence level of the maximum observed level in a national baseline

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- Proposed Lethality Performance Standards (cont.)
  - For fermented product containing beef, also proposing standards for *E. coli* O157:H7
    - Also expressed in terms of probabilities of remaining organisms or log reductions necessary to achieve these probabilities
    - Outbreaks in 1994 and 1995 traced to *E.coli* O157:H7 in fermented beef sausages

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- Proposed Lethality Performance Standards (cont.)
  - For low-acid, thermally processed, commercially sterile product, FSIS proposed to replace the detailed, prescriptive processing requirements with performance standards
    - Process must result in a probability of  $10^{-9}$  or less that there are spores of *C. botulinum* capable of growing, assuming an initial load of  $\leq 10^3$  spores / container
    - Alternatively, process must achieve a  $12 - \log_{10}$  reduction of *C. botulinum*

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- Proposed Stabilization Performance Standards
  - Prevent multiplication of spore – forming organisms and subsequent toxin formation during cooling of cooked product
  - No multiplication of toxigenic organisms such as *C. botulinum* and no more than  $1 - \log_{10}$  multiplication of *C. perfringens*

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- Role of Performance Standards in HACCP – Based Food Safety Systems
  - U.S. Congress (2001) commissioned the NAS to provide recommendations to FSIS and FDA on the role and appropriate use of performance standards for improving food safety
    - Evaluate the scientific basis for the existing performance standards
    - Define the process for establishing food safety criteria
    - Examine whether current criteria accomplish their goals
    - Review the need for performance standards as measures of process control and how they should be used under HACCP

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- NAS Report Conclusions and Recommendations
  - *Salmonella* pathogen reduction performance standards have achieved their goal of reducing the incidence of salmonellae on meat and poultry
    - FSIS observed declines in prevalence of *Salmonella* in meat and poultry products after introduction of Pathogen Reduction / HACCP
    - HHS reported a 15% decline in the overall rate of *Salmonella* infections in the U.S. population between 1996 and 2002, based on FoodNet data
  - Recommended completion of a new *Salmonella* baseline study in order to determine whether the current performance standards should be revised

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- NAS Conclusions and Recommendations (cont.)
  - Characterized the lethality performance standards as excessively conservative
  - Characterized the margin of safety embodied in the stabilization performance standards as too conservative

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- FSIS (2001) charged the NACMCF with providing
  - Advice on the scientific principles for the establishment of performance standards
  - An assessment of the current *Salmonella* performance standards for ground products
- NACMCF Conclusions and Recommendations
  - Risk must be considered in establishing performance standards in order to link the standard with public health goals
  - A risk assessment is needed in order to estimate the impact of the *Salmonella* performance standards on public health

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- NACMCF Conclusions and Recommendations (cont.)
  - A new nationwide baseline study be conducted by FSIS in order to determine whether the current *Salmonella* performance standards for raw ground product need to be revised
  - The reductions in frequency of *Salmonella* positives in FSIS verification samples and the 15% decrease in salmonellosis cases between 1996 and 2001 are indicative of the effectiveness of the pathogen reduction performance standards

# FSIS PERSPECTIVE ON PATHOGEN PERFORMANCE STANDARDS

- Where Do We Go From Here ?
  - FSIS will continue to replace prescriptive “command and control” type regulations with performance standards
  - FSIS will conduct new baseline studies on pathogens, including *Salmonella* and *E. coli* O157:H7 to use in developing pathogen reduction performance standards
  - FSIS will develop risk – based performance standards for processed products. Rather than using single point, worst case levels, FSIS will use risk assessment to evaluate the public health impact of different performance standards

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- Where Do We Go From Here? (cont.)
  - FSIS intends to develop lethality and stabilization performance standards for RTE meat and poultry products using risk assessments on *Salmonella* in RTE Product and *C. perfringens* and *C. botulinum* in cooked product after cooling
  - FSIS also intends to develop risk-based performance standards for pasteurized liquid egg products
  - FSIS will address the issue of cross contamination from raw meat, poultry and egg products

# FSIS PERSPECTIVE ON PATHOGEN PERFORMANCE STANDARDS

## ■ Summary

- Examples of pathogen performance standards developed by FSIS for both raw and processed meat and poultry products
- Discussed some indicators used to judge how well the standards are working
- Talked about some lessons learned and outlined some future directions