



SALMONELLA SUBTYPING RESULTS IN RAW PRODUCTS

FSIS Notice 27-10



PURPOSE

- IPP increasingly see *Salmonella* test results from samples of raw product
 - Agency sample collection and analysis
 - Establishment testing
- Provide IPP with a brief overview of key terms and explain what they mean



BACKGROUND

- What is *Salmonella*?
- What is a “Subtype”?
- FSIS verification testing program of establishments’ process control
- Reporting of Results through *Salmonella* End-of-Set Letters



***SALMONELLA* PERFORMANCE STANDARD PROCESS CONTROL CATEGORIES**

Consistent Process Control

- The total number of positive samples in the set is 50% or less of the performance standard or baseline guidance
- In other words: The number of positives is at or below half of the performance standard or baseline guidance
- This performance demonstrates the best process control for this pathogen



***SALMONELLA* PERFORMANCE STANDARD PROCESS CONTROL CATEGORIES**

Variable Process Control

- The total number of positive samples in the set is greater than 50% of the performance standard or regulatory guideline but equal to or less than the performance standard or baseline guidance
- In other words: number of positives is above half of the performance standard or baseline guidance but does not exceed it
- This performance demonstrates intermediate process control for this pathogen



***SALMONELLA* PERFORMANCE STANDARD PROCESS CONTROL CATEGORIES**

Highly Variable Process Control

- The total number of positive samples in the set is greater than the performance standard or baseline guidance
- In other words: The number of positives is above the performance standard or baseline guidance
- This performance demonstrates the least process control for this pathogen and means the establishment has **failed** the *Salmonella* verification set



***SALMONELLA* PERFORMANCE STANDARD PROCESS CONTROL CATEGORIES**

Category 1

- The establishment maintained consistent process control over the past two *Salmonella* verification testing sets
- In other words: The two most recent sets are at or below 50% of the performance standard



***SALMONELLA* PERFORMANCE STANDARD PROCESS CONTROL CATEGORIES**

Category 2T

- The establishment was not able to maintain consistent process control over the previous *Salmonella* verification testing set but maintained consistent process control over the most recent set
- In other words: The most recent set is at or below 50% of the performance standard and any result in the prior set



***SALMONELLA* PERFORMANCE STANDARD PROCESS CONTROL CATEGORIES**

Category 2

- The establishment was not able to maintain consistent process control over the past two *Salmonella* verification testing set but maintained variable process control over the most recent set
- In other words: The most recent set meets the standard but is above 50% of the performance standard and any result in prior set



***SALMONELLA* PERFORMANCE STANDARD PROCESS CONTROL CATEGORIES**

Category 3

- The establishment was not able to maintain consistent process control over the past two *Salmonella* verification testing sets and showed highly variable process control over the most recent set
- In other words: The most recent set does not meet the performance standard and any result in prior set



HISTORICAL ASSOCIATION OF SUBTYPES WITH HUMAN ILLNESS

PulseNet (CDC) and VetNet (ARS) Searches

- Comparisons between systems
- Identify historical trends
- Determine historical association of isolate pattern with human illness
- Clusters



HISTORICAL ASSOCIATION OF SUBTYPES WITH HUMAN ILLNESS

FSIS Regulatory Performance Standards

- Only for total number of positives in set
- NOT for subtypes (serotype or PFGE pattern)

FSIS **cannot** use subtype information to determine whether the establishment is considered to have passed or failed a Salmonella verification set



HISTORICAL ASSOCIATION OF SUBTYPES WITH HUMAN ILLNESS

Isolates with Matching Pattern in PulseNet

- Does **not** automatically implicate the sampled product as the cause for any human illness
- Does **not** necessarily mean that the food safety system is ineffective (also applies to serotypes commonly associated with human illness)



HISTORICAL ASSOCIATION OF SUBTYPES WITH HUMAN ILLNESS

Revised End-of-Set Letters

- FSIS will provide the additional public health-focused *Salmonella* subtyping information to establishments through revised *Salmonella* EOS letters starting this year
- Will be announced through a separate FSIS Notice



HISTORICAL ASSOCIATION OF SUBTYPES WITH HUMAN ILLNESS

PFGE pattern of *Salmonella* isolates identified as part of a recent cluster of human illnesses

- PFGE pattern included in a recently recognized cluster of human illnesses reported by PulseNet
- Has a prior or current association with human illness



HISTORICAL ASSOCIATION OF SUBTYPES WITH HUMAN ILLNESS

PFGE pattern of *Salmonella* isolates identified as part of a recent cluster of human illnesses

- Such patterns have a history of causing significant negative public health impact and human illness and are, or were recently, under CDC investigation as part of a cluster of human illness

Because of this history, FSIS considers isolates with associated patterns to generally have the highest potential to cause future human illness



HISTORICAL ASSOCIATION OF SUBTYPES WITH HUMAN ILLNESS

PFGE pattern of isolate indistinguishable from one associated with human illness

- PFGE pattern is indistinguishable from the PFGE pattern of an isolate from an ill person identified in the national PulseNet database
- Has a prior or current association with human illness



HISTORICAL ASSOCIATION OF SUBTYPES WITH HUMAN ILLNESS

PFGE pattern of isolate indistinguishable from one associated with human illness

- Have a history of causing a negative public health impact and human illness even though they may not have recently been under CDC investigation as part of a cluster of human illness

Because of this history, FSIS considers isolates with associated patterns to generally have a very high potential to cause future human illness



HISTORICAL ASSOCIATION OF SUBTYPES WITH HUMAN ILLNESS

Serotype commonly associated with human illness

- Have a *serotype* that is commonly associated with human illness
- PFGE pattern, to date, does not have an association with human illness



HISTORICAL ASSOCIATION OF SUBTYPES WITH HUMAN ILLNESS

Serotype commonly associated with human illness

- A list of the serotypes that are more commonly associated with human illness can be found on the CDC web site (2006 data most recent)

FSIS considers isolates with these listed serotypes to generally be of significant public health concern and have a high to very high potential to cause human illness



HISTORICAL ASSOCIATION OF SUBTYPES WITH HUMAN ILLNESS

Serotype not included on the CDC list

- Serotype is less frequently associated with human illness
- However, all *Salmonella* serotypes are considered to be capable of causing illness in humans



IPP ACTIONS

- Advise establishment management that the Agency expects the establishment to consider the FSIS results provided in EOS letters and establishment *Salmonella* testing process control and subtype results when evaluating the effectiveness of its overall food safety system



IPP ACTIONS

- Communicate this information at a weekly meeting in accordance with the instructions in FSIS Directive 5000.1, V.C.
- Document this discussion in the memorandum of interview (MOI) of the weekly meeting



IPP ACTIONS

- If IPP have concerns that an establishment has not considered the *Salmonella* data when evaluating its food safety system, they are to contact their immediate supervisor for guidance



IPP ACTIONS

- Other than verifying associated corrective actions the establishment takes, there is no follow-up verification for IPP to perform, or enforcement action to take, based on the information and results reviewed in FSIS or establishment records unless instructed otherwise by the District Office (DO)