

Measuring Establishment Risk Control for Risk-Based Inspection

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Risk-Based Inspection (RBI)

FSIS is developing a new system of inspection to better allocate Agency resources to control the risks posed to the public health by meat and poultry products.



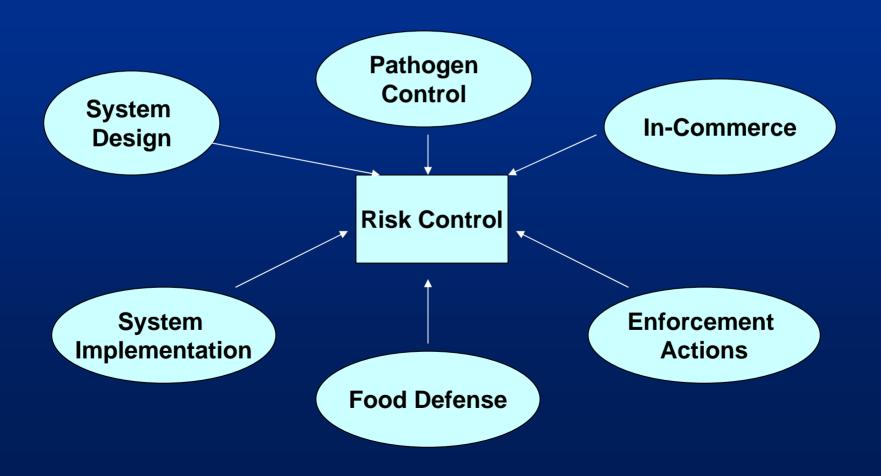
RBI and Measures of Risk

Allocation of Agency resources under RBI at each inspected processing establishment will rely upon two measures of risk:

- Inherent Risk: a measure of the inherent risk posed to the public health by each type of processed meat and poultry product, assuming typical process control by the producing establishment, and;
- Risk Control: a measure of the amount of actual risk control achieved by each establishment.



Establishment Risk Control





Food Safety System Design

Objective: Gauge efficacy of the design of the establishment's Food Safety system

- Food Safety Assessment (FSA) findings
- 9 CFR 430 RTE *Lm* control alternative 1,2, or 3
- Other?



Food Safety System Implementation

Objective: Measure consistency of Food Safety system implementation

- FSIS continues under RBI to document all regulatory non-compliances
- Only significant NRs related to public health are considered in the risk control measure



Implementation (continued)

- We received input from NACMPI regarding NRs with public health significance
- FSIS is considering NRs that cite 416.15
 (Sanitation Corrective Actions) / 417.3 (HACCP Corrective Actions); those for which regulatory control action was taken; those issued for inadequate validation or verification; and possibly others
- FSIS is currently reviewing NRs to validate these categories



Pathogen Control

Objective: Measure pathogen control effectiveness

- RTE testing program results
- E. coli O157:H7 testing program results
- Salmonella verification category
- Suppliers to establishments with *E. coli* O157:H7 positive test results
- Agricultural Marketing Service school lunch program testing results



In-Commerce Findings

Objective: Measure how well establishments prevent shipping products with hazards

- Significant public health, verified (tracedback), and validated consumer complaints
- Class I or II recalls
- Product control actions (detentions, seizures)



Enforcement Actions

Objective: Capture enforcement-related indicators of loss of process control

- Enforcement actions not captured elsewhere
 - (e.g. NOIEs not resulting from FSAs or repeated NRs; injunctive actions, consent decrees, and reinstitution of suspension after failure to meet corrective actions under deferral)



Food Defense

Objective: Measure Food Defense Risk

- Product/Process Vulnerability
- Production Volume/Exposure
- Food Defense Plan Efficacy
- Food Defense Verification Results



Are these 6 components appropriate and adequate?



Are some components more important than others, and thus should some be weighted more than others?



Is there other useful information about establishment risk control that FSIS is not considering?



Are there other ways besides Food Safety Assessments to evaluate establishment food safety system design?



Are the NRs FSIS is considering public health-related inclusive or are there others FSIS should be considering?



What is an appropriate look-back window?