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Continuous Food Safety Innovation as a Management Strategy:

Public Perspective

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FSIS Responsibility

FSIS is the public health regulatory agency within USDA

- FSIS ensures that the commercial supply of ***meat***, ***poultry***, and processed ***egg*** food products in the U.S. is not adulterated or misbranded
  - FSIS authorizing authorities (FMIA, PPIA, EPIA) do ***not*** bind the Agency to in-plant activity

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FSIS Activity

In FY06

- ~ 7,600 full-time inspectors
- ~ 5,921 processing establishments inspected daily
- ~ 1,100 slaughter establishments in which ***every*** animal inspected
- ~ 140 million head of livestock; 9.3 billion poultry carcasses; 4.4 billion pounds of liquid egg product
- ~ 8 million inspection procedures annually
- ~ 3.9 billion pounds of meat and poultry and ~ 5.9 million pounds of liquid egg products presented for import inspection

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FSIS Inspection Systems

Traditional system (beginning - 1906)

- Regulatory enforcement
  - Animal disease
  - In-plant focus of sanitary operations

HACCP system (beginning - 1996)

- Food safety hazard control
  - Prevent, eliminate, reduce biological, chemical, and physical hazards reasonably likely to occur

Risk-based system (evolving beyond HACCP - 2006)

- Focus on risk of product and the degree of control of risk
- Conducting inspection in a manner designed to measurably impact public health and effectively use inspection resources

New FSIS Approach

"Educate before we regulate"

- What does this mean?

  - Better defining regulatory expectations to FSIS employees and the regulated industry

  - Stepping up outreach efforts to give regulated establishments meaningful information to meet FSIS expectations for regulatory requirements
    - Giving establishments "how to" examples
    - Giving establishments validated procedures for controlling hazards
    - Identifying where and how control can best be impacted

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What Drives FSIS Actions?

The association between FSIS regulated products and public health trends

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Healthy People 2010 Objectives

Campylobacter infections*:

1997 Baseline	2010 Target
24.6	12.3

Escherichia coli O157:H7 infections*:

1997 Baseline	2010 Target
2.1	1.0

Listeria monocytogenes infections*:

1997 Baseline	2010 Target**
0.5	0.25

Salmonella infections*:

1997 Baseline	2010 Target
13.7	6.8

*Laboratory confirmed cases/100,000 humans (FoodNet)
** Changed to year 2005 by E.O. (President Clinton)

Other Healthy People 2010 Objectives

No Increase in Antimicrobial Resistant *Salmonella*

Human isolates:

	1997 Baseline	2010 Target*
Fluoroquinolones	0	0
3rd-generation cephalosporins	0	0
Gentamicin	3	3
Ampicillin	18	18

Cattle, broiler, market hog slaughter isolates:

	2010 Targets*
Fluoroquinolones	(Developmental)
Third-generation cephalosporins	
Gentamicin	
Ampicillin	

Other Food Safety and Food Defense Focus

- BSE
- HPAI
- Pathogens not yet identified as adulterants or food safety hazards reasonably likely to occur (e.g., MDR *Campylobacter* and *Salmonella*, non-O157:H7 STEC)
- Residues in a HACCP environment
- Threat agents

HOW DOES FSIS EFFECT CHANGE?

- Risk management options
  - Incentives
    - *Positive* - create categories/alternatives tied to level of inspection/testing (risk-based verification testing); consider changes in inspection methods
    - *Negative* – increase level of inspection activity, especially testing if poor control (creates increased chance of associating product produced at an establishment with human illness); publish name and performance level on FSIS webpage

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SALMONELLA INITIATIVE

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Salmonella Categories

Set History

Previous	Current	Category
≤ 50% of standard	≤ 50% of standard	**1**
• No prior set • >50% • Above standard	≤ 50% of standard	**2**
Any result	> 50% of standard without failing	
Any result	Exceeded standard	**3**

71 FR 9772; February 27, 2006

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BROILERS

Every Category Tells a Story

- Category I: Consistent *Salmonella* control possible
- Category II: Can improve *Salmonella* control with assessment, guidance, verification
- Category III: Failed to meet the standard

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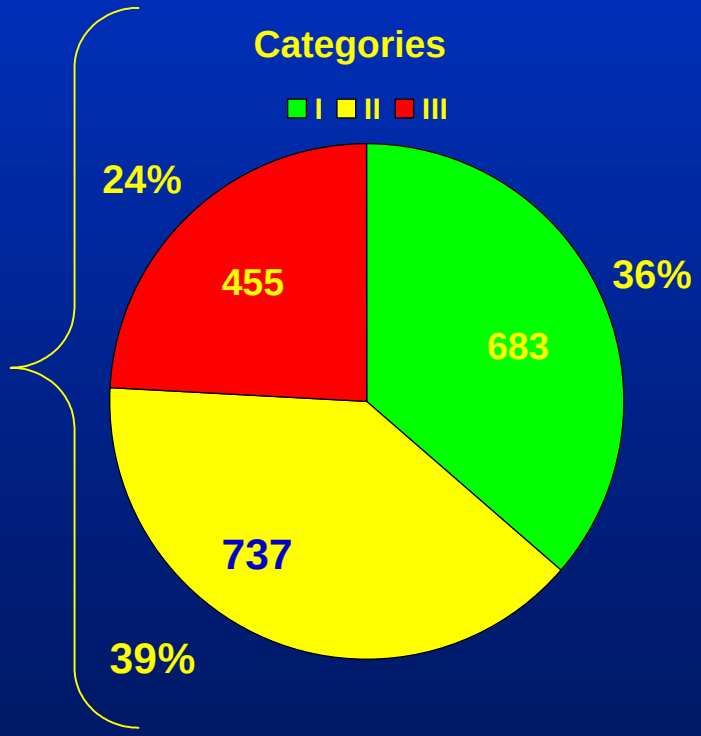
BROILERS

Does any category account for the Lion's share of these serotypes?*

Categories II & III accounted for only 32% of sets but 63% of common serotypes of human illness



Serotypes Heidelberg, Typhimurium, Enteritidis; 4,5,12:i:-; Montevideo, Thompson, Newport, Infantis, Braenderup, Agona, Hadar, Saint-Paul

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Salmonella serotypes of human illness:† Poultry versus red meat

	Number of isolates per set by product class		
Product classes	**25th percentile**	**50th percentile**	**75th percentile**
Ground chicken and turkey	**0-2**	**3-9**	**10**
Broilers and turkeys	**0**	**1-4**	**5**
Red meat carcasses/ Ground beef	**0**	**1**	**2**

† Top 20 serotypes of human illness, updated annually; descending frequency, 2004: Typhimurium, Enteritidis, Newport, Javiana, Heidelberg, Montevideo, 4,[5],12,i:-, Muenchen, Saintpaul, Braenderup, Infantis, Mississippi, Oranienburg, Thompson, Berta, Agona, Paratyphi B, Typhi, Hadar, Anatum (Source: CDC)

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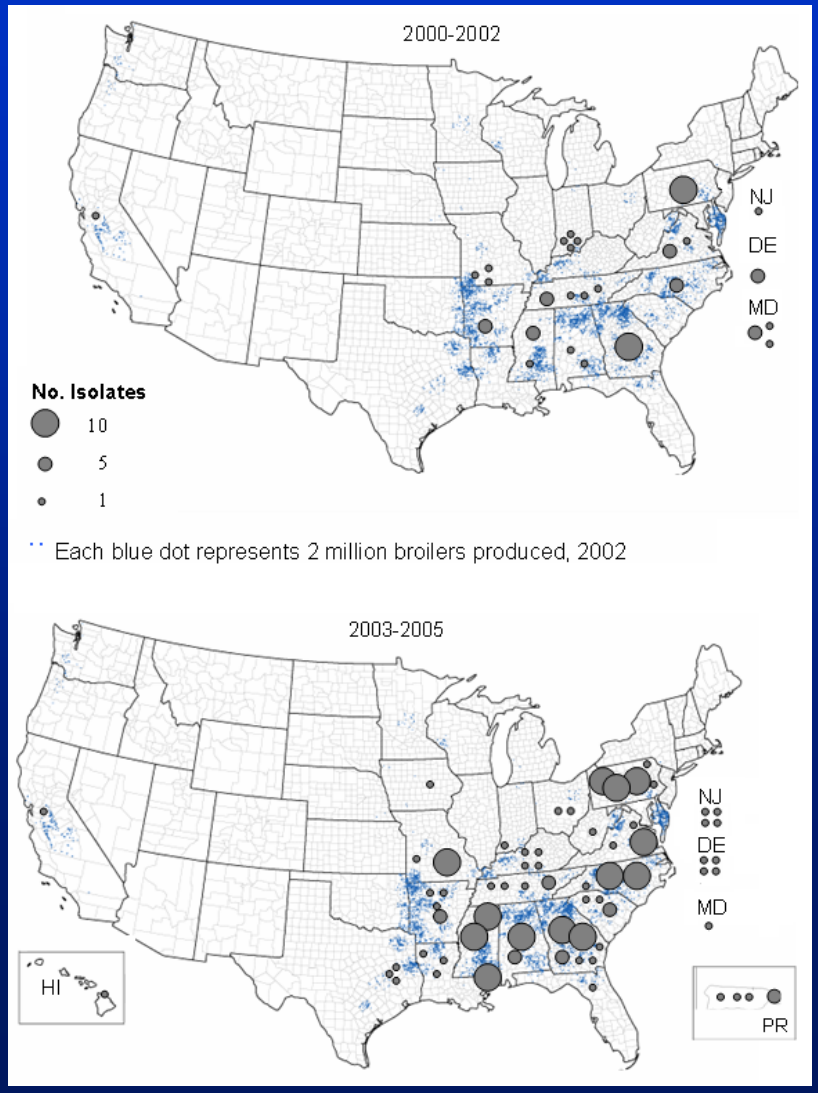
Salmonella Enteritidis in Broilers, 2000–2005



FSIS saw a three-fold increase in SE in broilers since 2000

Recent FoodNet studies showed an association between eating chicken and sporadic SE infection

Chicken is also implicated in some outbreaks of SE

More SE positive broiler rinses in 2006

Salmonella Enteritidis in Broiler Chickens, United States 2000-2005. (Altekruse and colleagues) Emerg Infect Dis 2006; 12: 1848-52.

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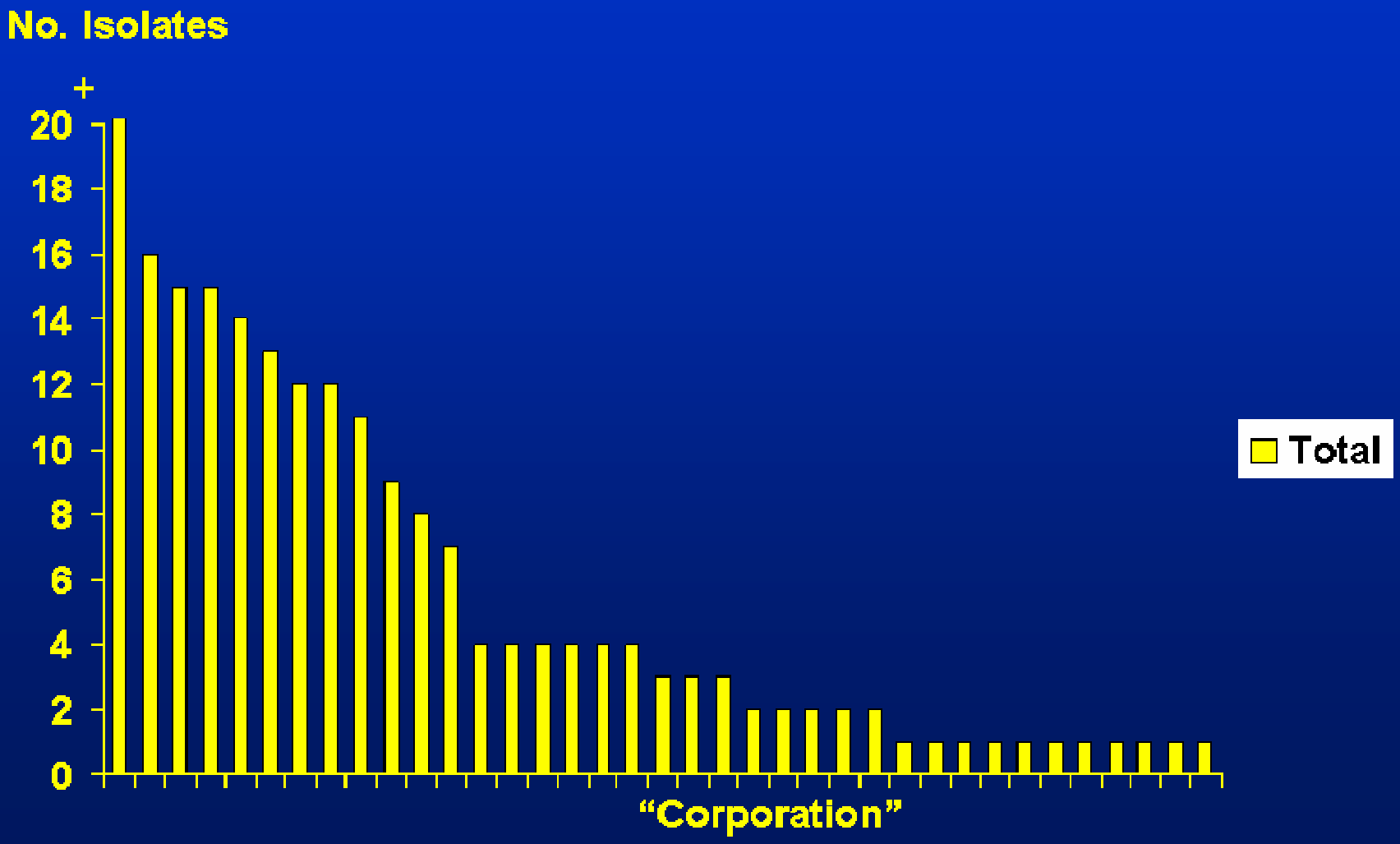
SE Isolates by "Corporation", 1998-2005



Current Thinking on Pathogen Subtyping

- Pathogen subtyping, including PFGE, and interlaboratory comparisons ***must*** be an integral part of risk management policy at FSIS

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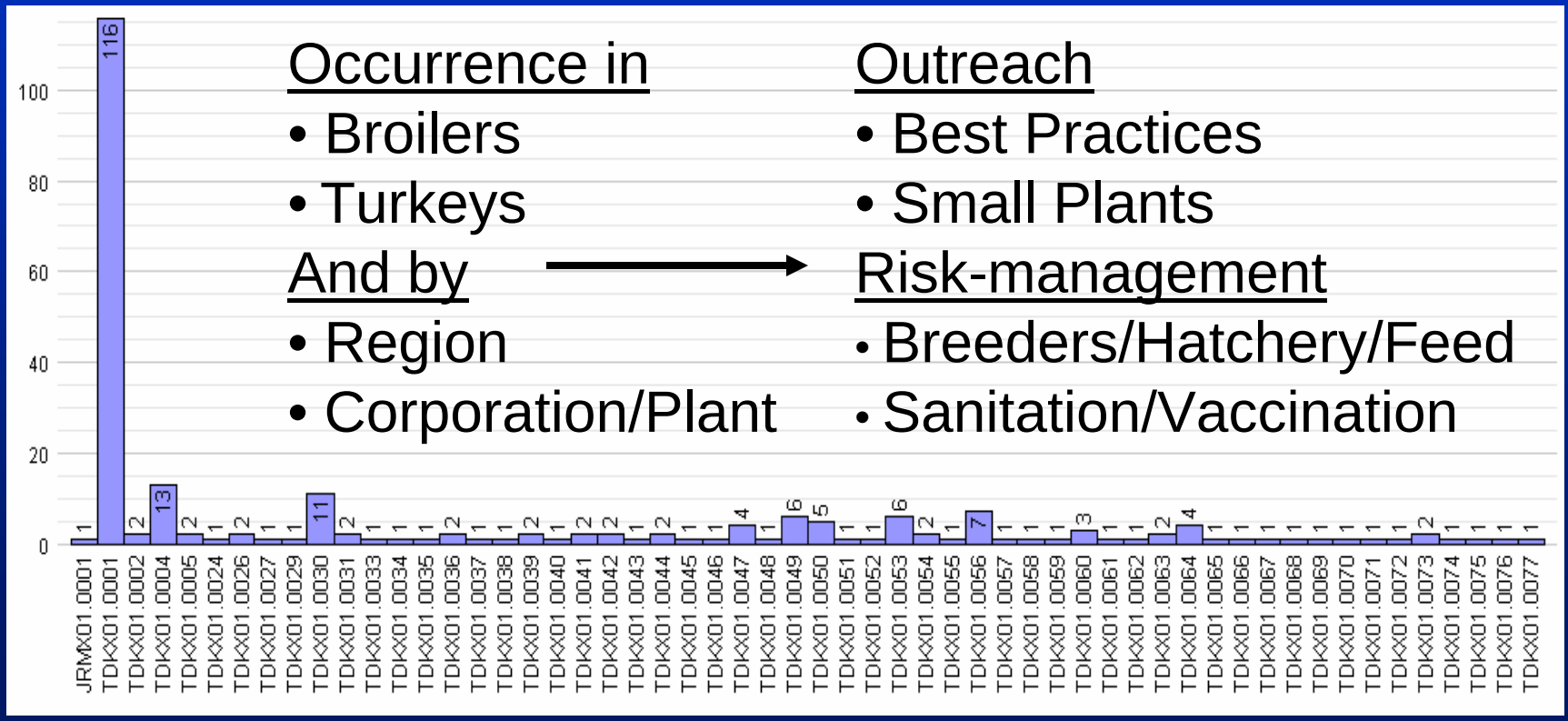
S Hadar PFGE types in humans, 2006

* Predominant human pattern



Source: PulseNet

PFGE XbaI pattern

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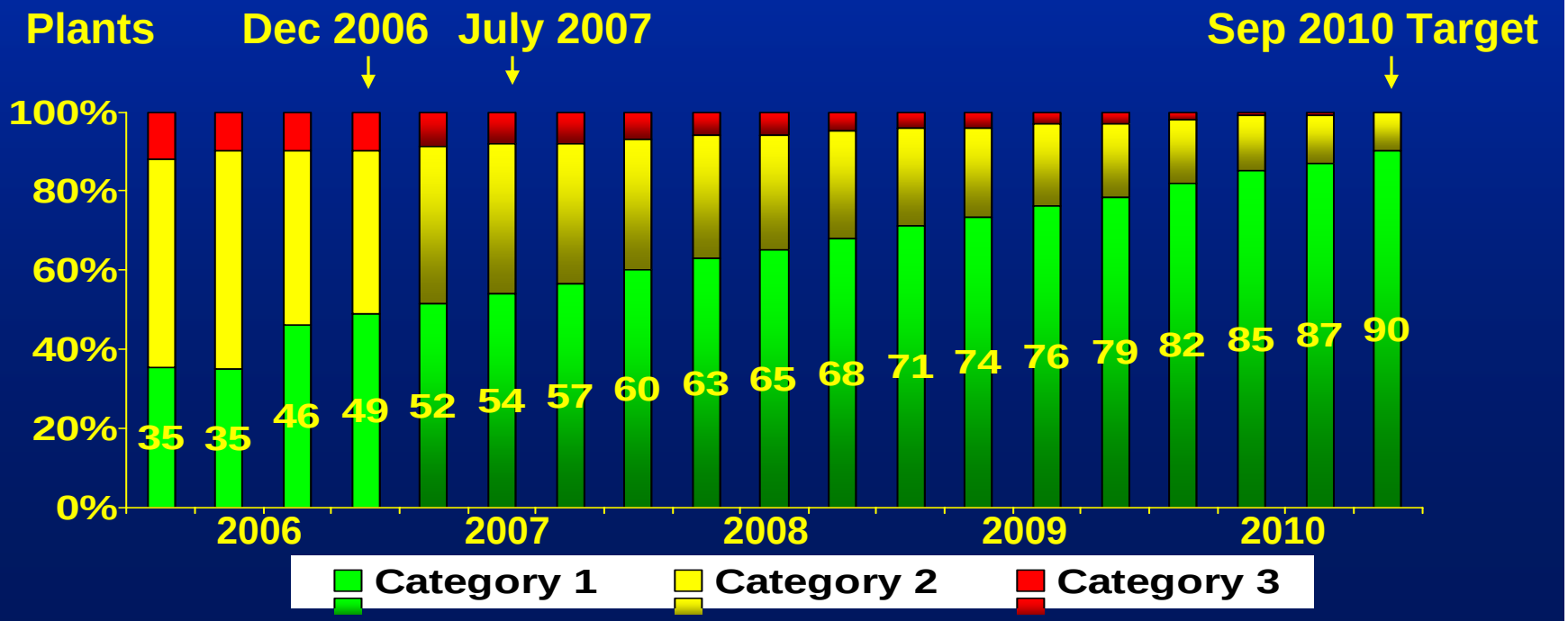
Program effectiveness: *Salmonella* in broilers

FSIS performance measure: 90% of plants in Category 1 by October 2010
(Need 5 or 6 more plants in Category 1 every three months)



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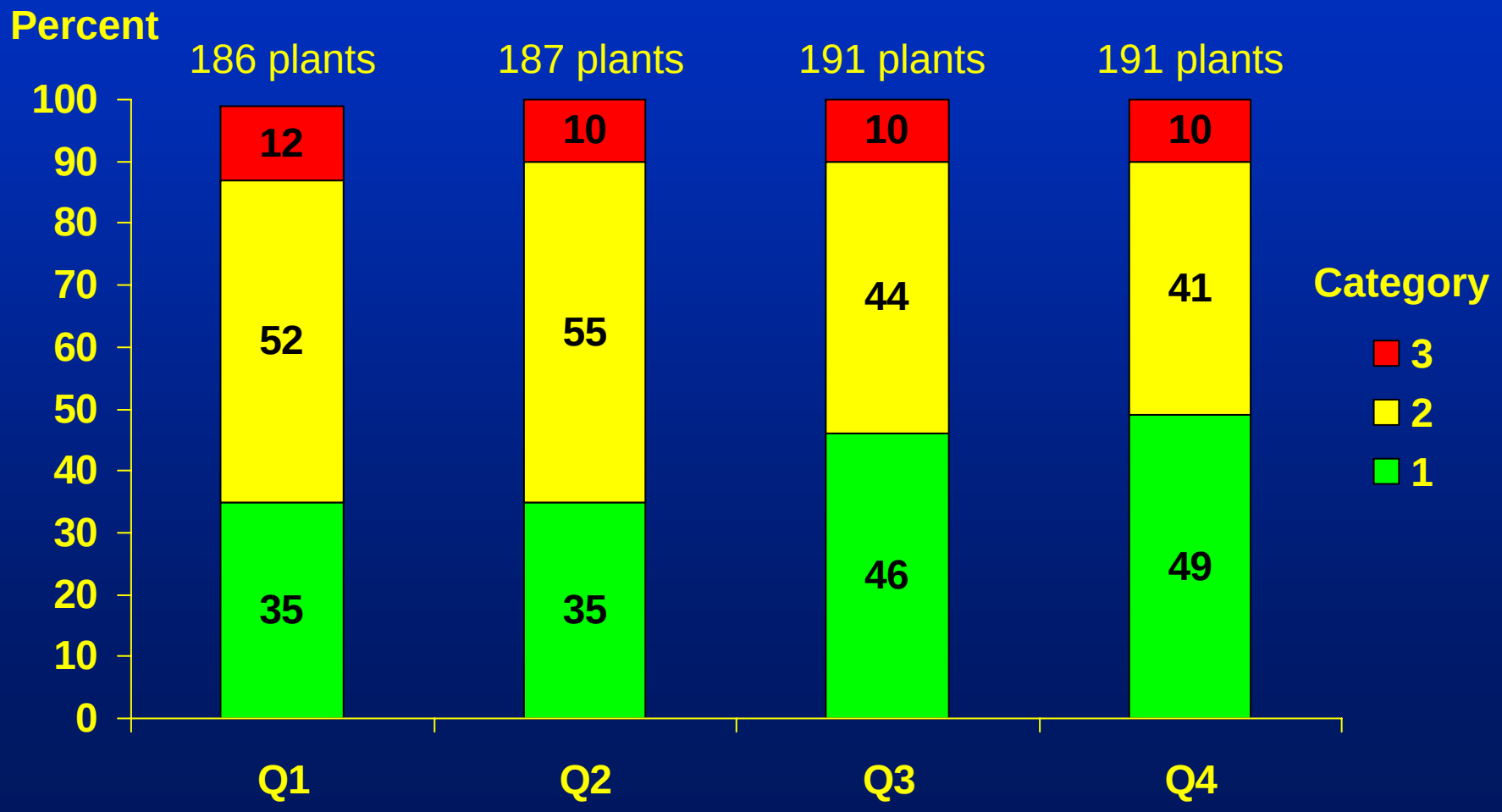
Salmonella performance of broiler establishments by quarter, CY2006



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Recent Improvements in Broiler *Salmonella* Performance

Of 29 plants tested twice in past 6 months:

19 improved on the most recent set (66%)

3 did the same on both sets (10%)

Only 7 did worse (24%)

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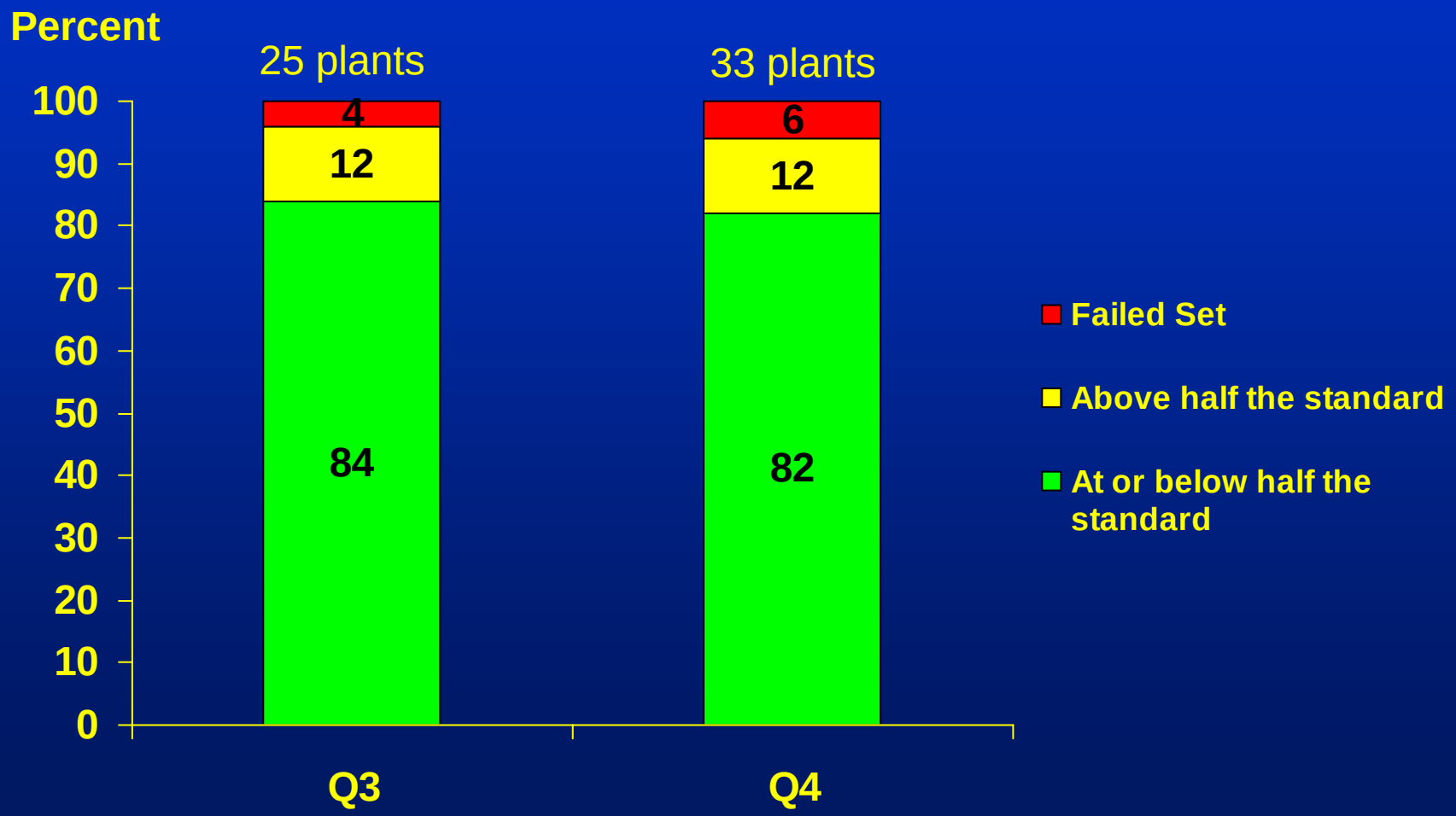
Salmonella Performance, Young Turkeys, 2006



July 2007 Status: FSIS Considerations

If great majority of plants are not below half the acceptable number of positives on their most recent verification set, FSIS will consider whether further actions should be taken to improve *Salmonella* control.

- *One approach FSIS favors is posting results from completed sample sets for establishments on the web by product class.*

71 FR 9772; February 27, 2006

Salmonella Initiative Status

- FSIS has received comment to docket #04-026N, including a written proposal from the National Chicken Council
  - Requesting a regulatory waiver via 9 CFR 381.3b to:
    - Line Speed
    - Chilling carcasses
  - Proposal
    - Eligibility for participation (</= 8% positive rate; 2 consecutive quarters)
    - Post-chill *Salmonella* incidence rate established 1 per 88,000 carcasses
    - Pre-evisceration and post-chill *Escherichia coli* and *Campylobacter* monitoring of 10 carcasses (same flock) monthly
- FSIS continues to pursue a mechanism to study the NCC proposal
  - HIMP and current operations under consideration –- RBI slaughter

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LISTERIA MONOCYTOGENES (Lm) INITIATIVE

FSIS Risk-Based *Lm* Testing

- Historically, sampling was randomly scheduled

- Now, drive for more effective use of resources; impact on public health
  - Targeted to those products most likely to result in illness; amplifies impact; focuses follow-up verification activity
  - Data-driven mechanistic model (risk factors are weighted)

Risk Management

For *Lm* in RTE:

- Interim final rule for post-lethality exposed RTE (October 2003)
  - Effective control measures through HACCP plan, Sanitation SOP, or other prerequisite program:
    - Alternative 1 – post-lethality treatment **and** antimicrobial growth inhibitor
    - Alternative 2 – post-lethality treatment **or** antimicrobial growth inhibitor
    - Alternative 3 – Sanitation

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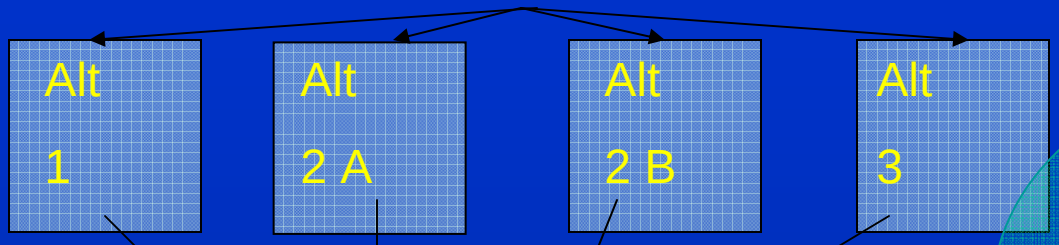

Establishments within each Alternative have characteristics:

Growth potential of product, compliance history; volume of production; product, food-contact surface, and environmental testing; results of FSA report; etc.

Risk-Based categories defined by RA model, Interim Final Rule

Secondary Stratification

Nearly 16,000 tests in CY 2006 vs. 6,600 tests in CY2003

Lm Verification Sampling "RTE001"

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CY2006 *Lm* Testing Results

% Positive in 25g:

- ALLRTE 0.64 (18/2806)*
- RTE Risk1 0.64 (39/6072)
- RTE001 0.72 (51/7089)

Overall 0.68 (108/15,967)

*FSIS uses the target of 0.70% (ALLRTE) for action

Chemicals

- Applications to live animal* and decontamination treatments to food product
  - Consumer expectations
  - International trade
  - Cumulative impact
  - Occupational safety
  - Measurement/detection

*Residue violator list published on FSIS and FDA website at:
http://www.fsis.usda.gov/PDF/Residue_Violators_List.pdf

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Risk-Based Inspection (RBI)

Deployment of Resources

Traditional

- Based on what needs to be done
  - Inspecting carcasses
  - Making inspection once per plant per shift

Risk-Based

- Align resources also with level of risk:
  - Hazards based on species and process
  - Likelihood of hazard
  - Exposure potential
  - Risk control effectiveness

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.**

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Inherent Risk Formula

Hazard *x* Exposure = Risk

Species/Process Value *x* Volume = Inherent Risk

Species/Process Values

- **FSIS has determined the initial values for 24 species/process categories through expert elicitation.**
- **Expert elicitation is commonly used to supplement, integrate and interpret existing qualitative and quantitative data into a framework for making decisions.**

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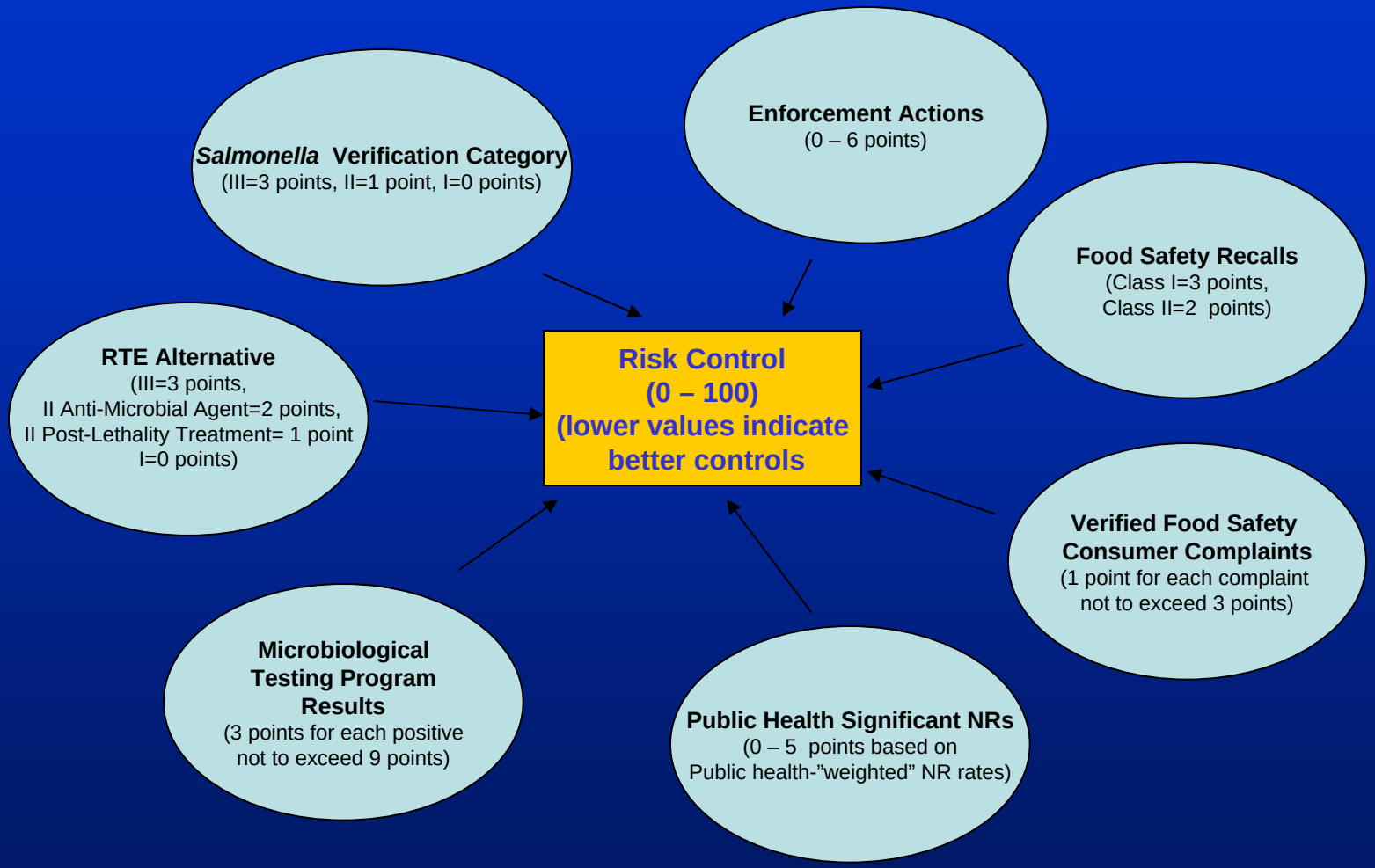
Risk Control Measure for RBIS Phase I



Food Safety System Implementation

- System implementation consistency
- FSIS documents all regulatory noncompliances– and will continue to do so under RBI
- However, not all NRs are equally indicative of risk control deficiencies
- Our goal is to identify, enumerate, and properly weight public health-related NRs

Pathogen Control

- **Pathogen Control in Ready-to Eat Products, Ground Beef, and Other Raw Products**
  - *Lm*, *Salmonella*, and *E. coli* O157:H7 RTE testing program results
  - *E. coli* O157:H7 (raw ground beef) testing program results
  - *Salmonella* verification testing program results

In-Commerce Findings

- Adverse Findings In-Commerce
  - Significant Consumer Complaints?
  - Class I or II Recalls?

Enforcement Actions

- FSA Documents Regulatory Non-Compliance
- NOIE Under Deferral
- Suspension
- Suspension Held in Abeyance
- Reinstatement of Suspension
- Reinstatement Held in Abeyance
- Complaint to Withdraw Inspection
- Inspection under Consent Order

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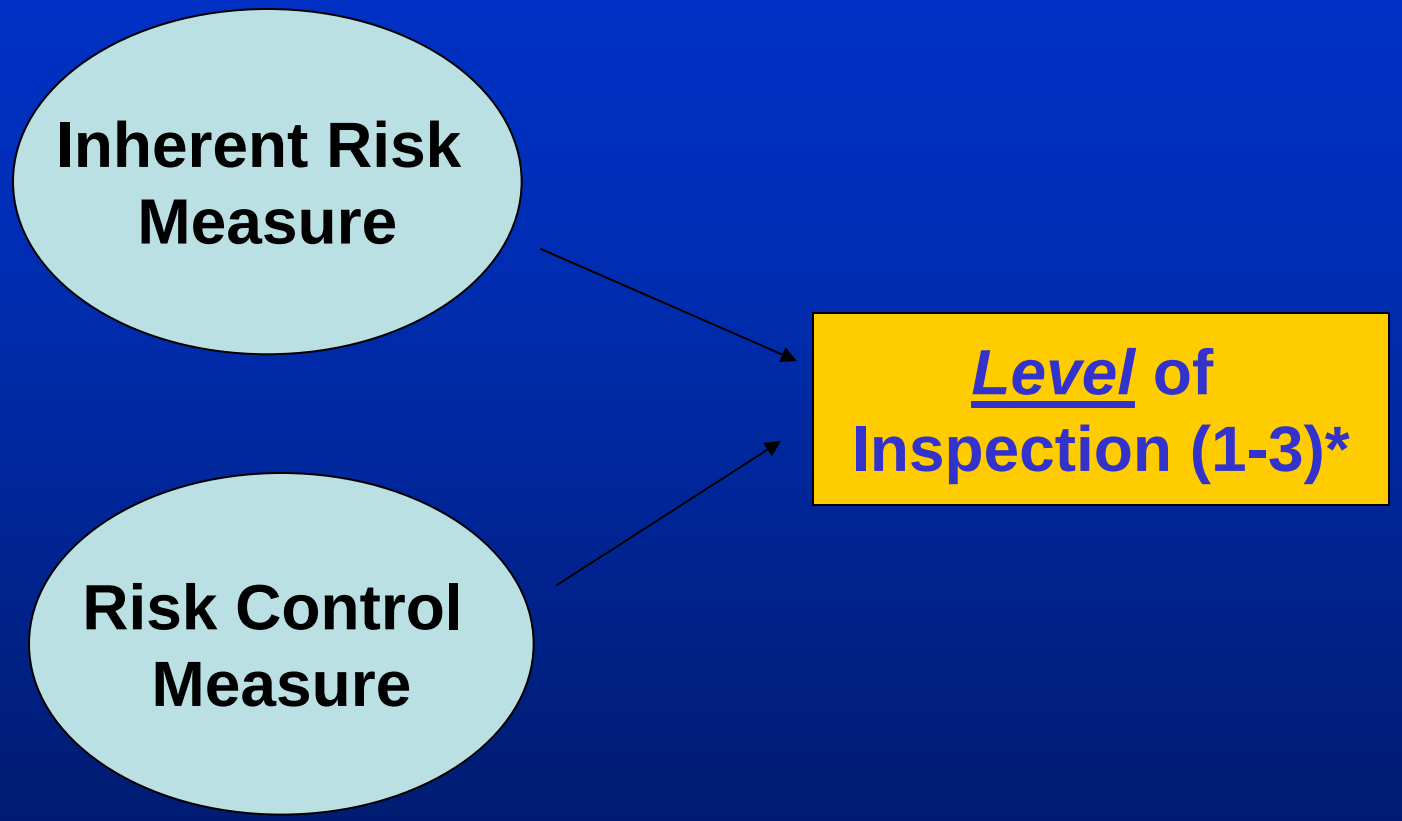
Levels of Inspection in RBI Phase I



* Generally either a higher, same, or lower number of inspection procedures than current PBIS system

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QUESTIONS?