

United States Department of Agriculture
Food Safety and Inspection Service



A More Robust Risk-Based Inspection System



The Roots of Our Risk-Based Vision

- ◆ HACCP
 - ◆ Risk-Based Pathogen Control
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- ◆ Processing Inspection Optimization System (PIOS)
 - ◆ Hazard Control Coefficient (HCC)
 - ◆ Hazard Coefficient (HC)



Progress Made in Pathogen Control

- ◆ *Listeria monocytogenes* (*Lm*) verification sampling
- ◆ FSIS tailors verification activities based on interventions that plants adopt and for the potential of *Lm* growth in products.



Further Progress

- ◆ In February, FSIS unveiled its 11 step risk-based *Salmonella* reduction strategy.

Notices		Federal Register
		Vol. 71, No. 28
		Monday, February 27, 2006
<p>This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and function are examples of documents appearing in this section.</p>		
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DEPARTMENT OF AGRICULTURE		
Food Safety and Inspection Service		
[Docket No. 04-028N]		
Salmonella Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection		
AGENCY: Food Safety and Inspection Service, USDA.		
ACTION: Notice and response to comments.		
compares to the existing regulatory standard or nationwide baseline results and to the presence of serotypes of <i>Salmonella</i> that are common causes of human illness.		
To further encourage industry process control efforts, the Agency is providing a new compliance guideline containing information that FSIS has found to be relevant to control of <i>Salmonella</i> , particularly for poultry.		
FSIS intends to monitor closely the percent positive in verification samples month-by-month over the course of a full calendar year, beginning in 2006. After one year FSIS will evaluate these data, reassess how it reports <i>Salmonella</i> results for each class of products, and consider making additional changes in how it reports and publishes results.		
ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by any of the following methods:		
comments also will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.		
DATES: Effective Date: May 30, 2006.		
FOR FURTHER INFORMATION: For further information contact Daniel Engeljohn, Ph.D., Deputy Assistant Administrator for Office of Policy, Program and Employee Development, FSIS, U.S. Department of Agriculture, Room 3147 South Building, 14th and Independence SW., Washington DC 20250-3700; telephone (202) 205-0496, fax (202) 401-1786, e-mail: daniel.engeljohn@fsis.usda.gov .		
SUPPLEMENTARY INFORMATION:		
Background		
On July 26, 1996, FSIS published "Pathogen Reduction: Hazard Analysis and Critical Control Point (PR/HACCP Systems)" (61 FR 39890). This final rule		

- ◆ It is outlined in more detail in the *Federal Register* notice that can be viewed at www.fsis.usda.gov.



Further Progress

- ◆ Our goal is to further enhance and strengthen our risk-based approach for pathogen control.
- ◆ We are developing a risk-based verification strategy for *E. coli* O157:H7.



Use of Data

- ◆ Using data to determine the level of inspection at processing plants and off-line slaughter assignments
- ◆ Soliciting input on public health data used to make risk-based decisions



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 or poultry product
- Risk Control: a measure of the amount of actual risk control achieved by each establishment



Using Data more Broadly to Protect Public Health

Protecting public health means getting the *right* information to the *right* people at the *right* time to make the *right* decisions.





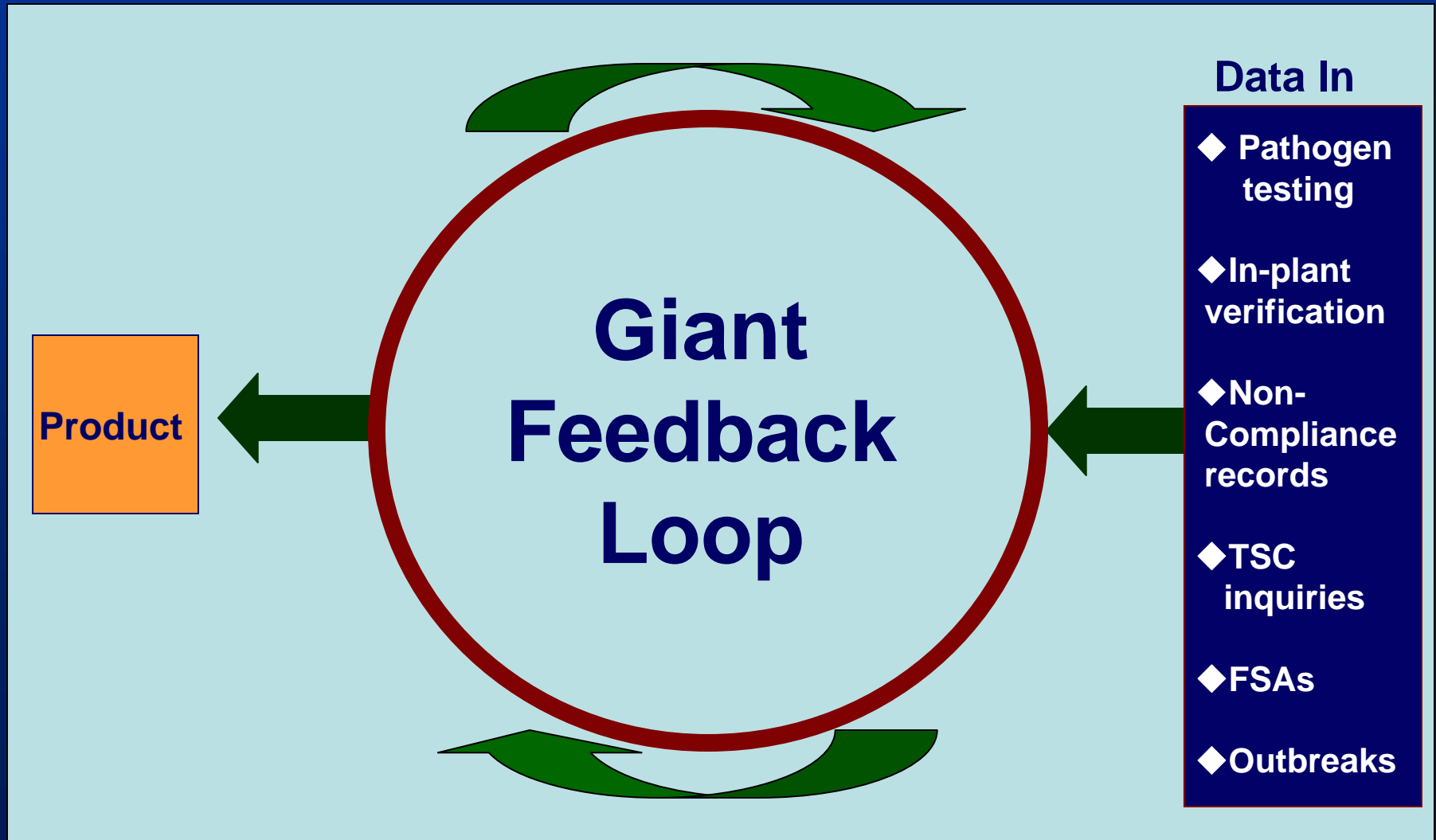
Public Health Data Infrastructure

Our risk-based approach must and will be driven by data to ensure it:

- ◆ Enables us to Collect, Analyze and Respond;
- ◆ Flows in real-time;
- ◆ Reliable, and securely accessible; and
- ◆ Permits strategic decisions to be traceable and easily audited



Public Health Data Infrastructure





Inspection Level

- Inherent Risk
- Risk Control
 - Algorithm or mathematical formula



Risk-Based Inspection System

- The Agency will also be using data more broadly.
- FSIS will be using data to be proactive to protect public health.
- All Agency decisions will be driven by data.



Traditional Approach

- FSIS learns about a *Salmonellosis* outbreak from CDC or a State public health agency.
- FSIS would conduct a food safety assessment to determine compliance with all applicable regulatory requirements.
- FSIS would take action against the product and/or establishment as appropriate.



Risk-Based Approach

- FSIS will be looking at clusters of high risk isolates from FSIS verification samples to see if they come from a particular establishment or geographic part of the country.
- FSIS then initiates an FSA at a particular establishment before a potential outbreak occurs rather than as part of an investigation of why an outbreak occurred.

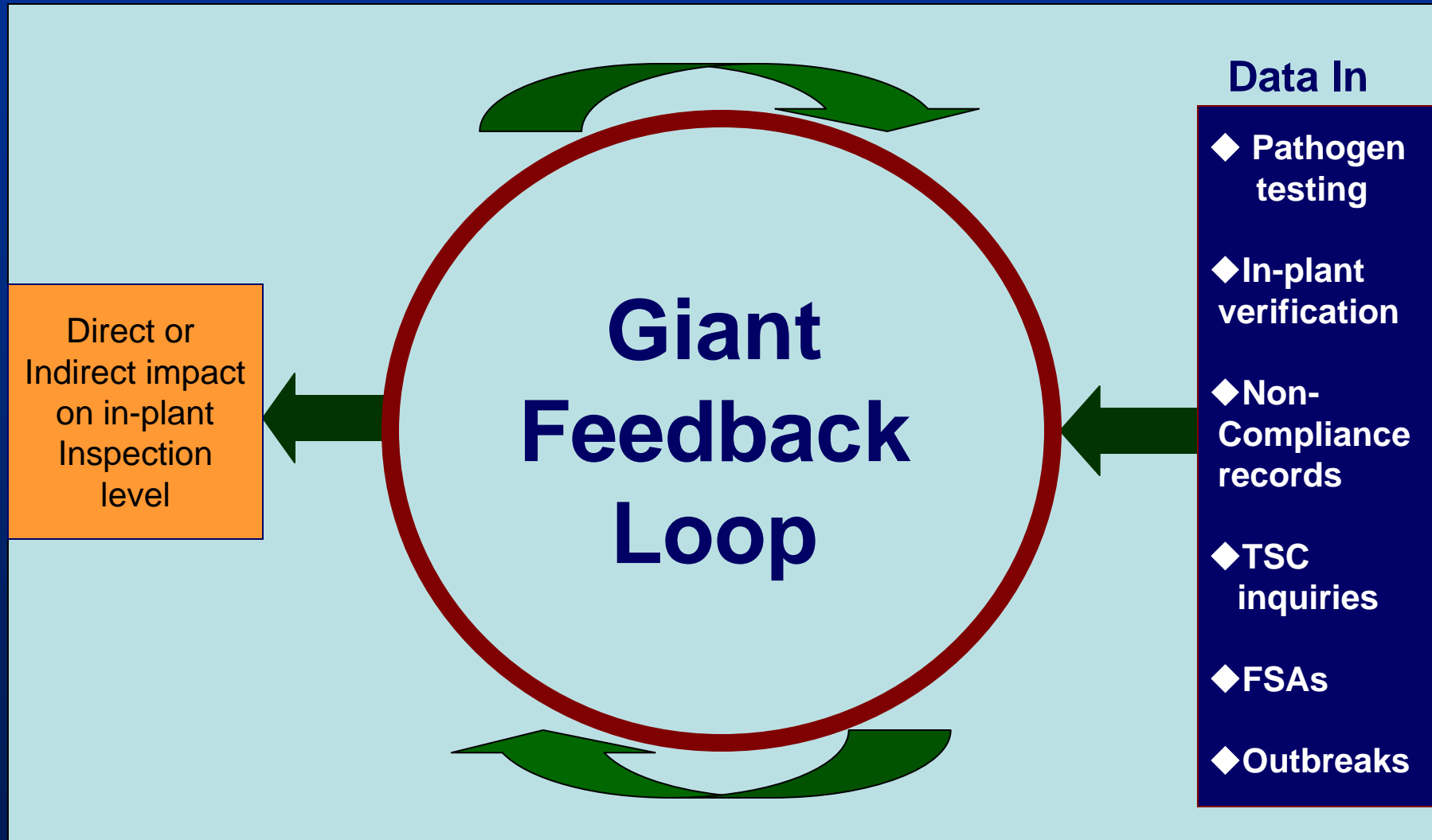


Risk-Based Approach

- If the cluster was from a particular geographic area, but no particular establishment had multiple occurrences, FSIS could immediately schedule more sampling in the area to determine whether an unusual prevalence of the high risk serotype is occurring.
- FSIS can do “epi trace forwards” with the information by working with CDC to try and prevent outbreaks from occurring.



Public Health Data Infrastructure





Risk-based Approach

- We recognize that our challenge is to anticipate and quickly respond to food safety and food defense challenges before they affect public health!
- We know that the only way to accomplish this is through the use of data!



Risk-based Time

- We are replacing dial-up connections with high-speed access at all HQ plants to make sure FSIS is equipped with a fully-integrated, real-time communications infrastructure.
- We anticipate that this will be done early in 2007.



Risk-based Approach

- We must be proactive and make decisions based on real-time data!



Transparent Process

- ◆ FSIS will continue to use a transparent and inclusive process to seek your input. We have demonstrated our responsiveness by:
 - 1) Sought a third-party facilitator, to assist us in gaining stakeholder input
 - 2) Seeking feedback on NRs that don't pose significant food safety risks
 - 3) Posting two technical papers on our Web site at http://www.fsis.usda.gov/regulations_&_policies/Risk_Based_Inspection/index.asp.



Conclusion

This RBIS Workshop and the NACMPI Public Meeting on October 12-13, 2006 are opportunities for discussion.