

## Measuring Establishment Risk Control for Risk-Based Inspection

### Background

The Food Safety and Inspection Service (FSIS) is the public health regulatory agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. FSIS is accountable for protecting the lives and well-being of 295 million U.S. citizens and millions more around the world.

To meet the realities of food safety and public health challenges, FSIS is moving to a more robust risk-based inspection system that continues to rely on science-based policies. Although the Agency acknowledges that some types of meat and poultry products pose greater health risks than others, and some establishments control risks better than other establishments, under the current system of processing inspection, a Consumer Safety Inspector visits every plant at least once every shift to perform a variety of verification procedures scheduled by PBIS- the Performance Based Inspection System. PBIS schedules inspection procedures the same way in all processing plants, regardless of the particular food safety hazard associated with one plant versus another, or the potential risk to the public one plant or process may pose versus another.

In July 2004, the Agency outlined the basic features of a predictive model that would permit FSIS to improve resource allocation by considering the inherent risks and risk control effectiveness of the many meat and poultry establishments under federal inspection.<sup>1</sup> Since that time, FSIS has continued developing and refining these ideas. In November 2005 FSIS addressed the National Advisory Committee on Meat and Poultry Inspection (NACMPI) on our progress toward a Risk-Based Inspection System (RBIS). In May 2006, the Agency again addressed NACMPI—this time on ideas the Agency has on measuring establishment risk control effectiveness for RBI.<sup>2</sup>

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<sup>1</sup> Fulfilling the Vision: Updates and Initiatives in Protecting Public Health, July 2004, Food Safety and Inspection Service. [www.fsis.usda.gov/PDF/Fulfilling\\_the\\_Vision.pdf](http://www.fsis.usda.gov/PDF/Fulfilling_the_Vision.pdf)

<sup>2</sup> The reports and presentations from the advisory committee are available at: [http://www.fsis.usda.gov/Regulations\\_&Policies/National\\_Advisory\\_Committee\\_on\\_Meat\\_&Poultry/index.asp](http://www.fsis.usda.gov/Regulations_&Policies/National_Advisory_Committee_on_Meat_&Poultry/index.asp)

Measuring establishment risk control effectiveness, and adjusting the amounts and types of inspection activities we perform in establishments accordingly, is a key component of RBI.<sup>3</sup> As shown in Figure 1, FSIS believes we can improve public health by performing more inspection in establishments with less-effective risk controls.

### **Policy Options**

FSIS is considering a system to measure establishment risk control effectiveness using Agency data for five risk-control realms: food safety system design; food safety system implementation; pathogen control; in-commerce performance; and other performance indicators. Each of our five risk control realms has a different measurement objective (see Figure 1). Food safety system *design* and *implementation* are considered separately since performance depends on both, and good implementation does not always accompany a good system and vice versa. Pathogen control effectiveness is measured separately because microbiological hazards are the leading cause of human illnesses attributed to meat and poultry products. Both product recalls and valid and health-significant consumer complaints are indicators that, while not common, are clear indications of process control concerns in those establishments. Finally, there can be other events or circumstances that evidence how well individual establishments are controlling risk (e.g. enforcement actions).

### **System Design**

An establishment's risk control effectiveness is limited by the intrinsic effectiveness of its risk control system's design features. Effective food safety risk management thus begins with the design of a sound food safety system. All else equal, establishments with more adequate systems will control food safety risks better than establishments with less adequate systems.

The information collected by FSIS during a food safety assessment (FSA) yields the Agency's best evidence about the design of an establishment's food safety system. Enforcement, Investigation and Analysis Officers (EIAOs) periodically perform FSAs in meat and poultry establishments to "consider all

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<sup>3</sup> FSIS intends to continue performing inspection for every establishment during every operating shift under RBI.

food safety aspects that relate to the establishment and its products, the nature and source of all materials received, the establishment’s processes, and the environment of the establishment.”<sup>4</sup>

**Figure 1. Risk Control Measurement Objectives**

<b>Risk Control Realm</b>	<b>Measurement Objective</b>
Food Safety System Design	Assess the intrinsic ability of an establishment’s food safety system to control risks
Food Safety System Implementation	Assess how well and how consistently establishments implement their food safety system
Pathogen Control	Assess how well establishments control microbiological hazards
In Commerce Findings	Assess how well establishments prevent shipping contaminated, adulterated, or hazardous products
Other Performance Indicators	Assess other indicators of how well establishments control food safety risks

During an FSA, EIAOs focus on the design and recent implementation of the establishment’s prerequisite programs, Sanitation Standard Operating Procedures, and HACCP system—as well as their recent compliance with Sanitation Performance Standards.<sup>5</sup>

<sup>4</sup> FSIS Directive 5100.1, *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology*. Issued 9/30/2005. [http://www.fsis.usda.gov/regulations\\_&\\_policies/5000\\_Series-Program\\_Services/index.asp](http://www.fsis.usda.gov/regulations_&_policies/5000_Series-Program_Services/index.asp)

<sup>5</sup> SPS regulations do not require establishments to maintain records associated with SPS requirements, and there is no design requirement for SPS regulations.

## System Implementation

A well-designed and rigorous food safety system does *not* guarantee highly-effective risk control in practice. Establishments must also *implement* their systems consistently. Since the 1996 Pathogen Reduction and Hazard Analysis and Critical Control Points (PR/HACCP) regulation, the Agency has based its inspection system on the verification that establishments implement their documented food safety systems as designed. Toward that end, FSIS inspection program personnel regularly conduct inspection activities in meat and poultry processing establishments. They perform observational, record review, product and environmental sampling, and other activities designed to verify that the establishment:<sup>6</sup>

- implements its HACCP plans
- implements SSOP plans
- conducts generic *E. coli* testing
- meets (applicable) *Salmonella* pathogen reduction performance standards
- meets (applicable) *E. coli* O157:H7 zero-tolerance standards
- meets (applicable) ready-to-eat product zero tolerance standards, and
- complies with sanitation performance standards.

As inspection program personnel perform these ongoing activities, they document instances in which establishments fail to implement documented features of their own systems or fail to meet explicit regulatory requirements. “Noncompliance Records” (NRs) document in the Agency’s Performance Based Inspection System (PBIS) the time, date, and nature of any observed regulatory noncompliance. PBIS is consequently one of the most important sources of information with which the Agency can assess how well establishments control food safety risks. NRs—at least some NRs—indicate how consistently establishments comply with food safety regulatory requirements.<sup>7</sup> High *rates* of noncompliance, certain *patterns* of noncompliance, or even certain individual instances or *types* of noncompliance are suggestive of an establishment’s losing—or actual loss of—adequate food safety system process control.

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<sup>6</sup> See FSIS’s 1998 “Key Facts: Role of the Inspector Under HACCP” for more information.  
<http://www.fsis.usda.gov/oa/background/keyrole.htm>

<sup>7</sup> Some NRs document noncompliance with non-food safety requirements (e.g. standard of identity, moisture content, etc). Still other NRs document noncompliance with recordkeeping or other requirements believed to have little bearing on food safety.

While noncompliance with a regulatory requirement will *always* be documented under RBI (as today), the Agency believes that some NRs are more indicative than others of a loss of process control and thus of food safety risk. FSIS is currently performing data analyses to identify what types of noncompliances are more predictive of adverse outcomes and is considering how to weight such NRs in our measure of risk control effectiveness. The Agency is considering how to define, and include in the calculation, food safety non-compliances considered significant. These may include NRs citing non-compliance with the requirements of 416.15 or 417.3, those issued because of adulterated or contaminated product, those for which a regulatory control action was taken, those issued for inadequate validation or inadequate verification, those issued for non-compliance with the Sanitation Performance Standards regulations, and possibly others. This was a topic for discussion with the NACMPI on May 24, 2006.

### Pathogen Control

Control of microbiological hazards should be an important goal of every establishment's food safety system because pathogenic microorganisms account for the majority of all foodborne illnesses attributable to meat and poultry products. Further, pathogenic microorganisms are an indicator of the effectiveness of SSOP and HACCP programs that is not prone to human bias. As part of the 1996 PR/HACCP regulation, the Agency embarked on a major initiative to more fully integrate microbiological testing into its food safety inspection program. Slaughter plants are required to conduct microbial testing for generic *E. coli* to verify that their process control systems are working as intended to prevent fecal contamination, a primary avenue of contamination of raw product with harmful bacteria. Many of these same slaughter establishments, and many "processing-only" establishments that produce certain types of raw products but do not slaughter, are also subject to *Salmonella* testing to verify that HACCP systems are effective in controlling contamination with *Salmonella*.

Pathogens in ready-to-eat products are considered adulterants. FSIS began testing ready-to-eat products for *Salmonella* in 1983 and *Listeria monocytogenes (Lm)* in 1987.<sup>8</sup> These are zero-tolerance programs, and any positive sample results are indicative of establishment risk control problems.

In 1994 FSIS declared *E. coli* O157:H7 an adulterant in raw ground beef and instituted a testing program for the pathogen. FSIS established the end-product sampling program for raw ground beef to keep contaminated product from reaching consumers and to spur industry to institute pathogen reduction and HACCP-associated verification programs to reduce the risk of this pathogen in beef products. As with

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<sup>8</sup> FSIS also tests certain ready-to-eat products containing beef for *E. coli* O157:H7.

the RTE testing programs, the *E. coli* O157:H7 testing program is a zero-tolerance program, and any positive sample results are indicative of establishment risk control problems.

### In Commerce Findings

The Agency believes verifiable consumer complaints of public health significance, Class I and Class II recalls, and certain other findings in commerce evidence process control problems at the establishments that shipped the implicated products. The FSIS Consumer Complaint Monitoring System (CCMS) is a passive national surveillance system that records and tracks complaints from consumers, facilitating the identification of possible food hazards and the ensuing investigations. As such, it is a database used by the agency to record, triage, analyze, and track all consumer complaints about meat or poultry products. Most consumer complaints involve illnesses that occurred after eating meat or poultry products, injuries (from foreign objects) that occurred while eating meat or poultry products, foreign objects found in meat or poultry products, allergic reactions that occurred after eating meat or poultry products, suspected under-processing of RTE products, allegations of improper labeling, and dissatisfaction with the quality of meat or poultry products. With few exceptions,<sup>9</sup> all consumer complaints reported to FSIS are entered into the CCMS.

Consumer complaints are triaged to determine the need for further investigation by FSIS. When the CCMS staff determines that a complaint should be investigated, it contacts the relevant OFO District Office and requests an investigation. Eventually, many (but not all) consumer complaints are found to meet two criteria that FSIS believes are indicative of a food safety process control problem in an establishment: they are valid and have public health significance. A valid consumer complaint is one that the Agency determines, through its investigative process, to have actually caused harm to the consumer, and to be reliably traceable to a particular establishment. Not all consumer complaints have public health significance however. Only consumer complaints that actually did, or had the potential to, cause illness or injury are public health complaints. Valid public health consumer complaints are evidence of an establishment with food safety process control concerns.

### Other Performance Indicators

There are occasionally other events or circumstances that can be informative about how well an establishment is controlling food safety risks. Factors in this category include:

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<sup>9</sup> See FSIS Directive 5610.1 (August 2005) for these exceptions, and extensive information about the CCMS.

- *System Tracking E. coli O157:H7 Positives (STEPS) Results.* An establishment that produces intact beef products (e.g. beef trim) and appears on the supplier list of one or more producers of raw ground beef products that have tested positive for *E. coli* O157:H7. The Agency should take a closer look at establishments identified in this way.
- *Agricultural Marketing Service Laboratory Results.* An establishment that has one or more products test “positive” for *E. coli* O157:H7 in the AMS school lunch testing program may warrant enhanced inspection.
- *Enforcement Actions.* An establishment that was the subject of a recent enforcement action that is not captured elsewhere in the measure of establishment risk control may require additional oversight to protect public health.

### *Methodology for Measuring Establishment Risk Control Effectiveness*

There are approximately 5,200 federally-inspected meat and poultry processing establishments for which risk control effectiveness must somehow be measured and monitored for RBI.<sup>10</sup> The large amount of data for our five factors, combined with the many establishments that will be under RBI, challenges our ability both to measure risk control effectiveness and to act when there is evidence of a loss of control. An added complication is that we believe food safety system process control effectiveness can significantly change in an establishment over the course of weeks. This means we need to *re-measure* risk control effectiveness frequently.

FSIS plans to regularly—perhaps monthly—retrieve data for the five factors for every meat and poultry processing establishment for a recent period of time- or “window.” FSIS is considering ways to use all of this valuable information to form an overall measure of risk control effectiveness for every active, federally-inspected meat or poultry establishment.

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<sup>10</sup> Active, federally-inspected (including Talmadge-Aiken) meat and poultry processing establishments under mandatory meat and/or poultry processing inspection and subject to HACCP requirements. These include processing-only establishments and combination slaughter-processing establishments (but excludes slaughter-only establishments).