

THE EVOLUTION OF RISK-BASED INSPECTION

During the past two decades, the Food Safety and Inspection Service (FSIS) has evolved from organoleptic inspection based on sight, smell, and touch, to risk-based inspection based on science, with major milestones accomplished along the way. The process of evolving to risk-based inspection is dynamic and ongoing. It has also been thoughtful, planned, collaborative, and open. During the same period, FSIS completed its transition from an inspection agency to a public health regulatory agency.

Widespread Impetus for Change

A major impetus for risk-based inspection began in the mid-1980s. In the mid-1980s through the 1990s, studies conducted by the National Academy of Sciences (NAS), the then-General Accounting Office, and FSIS established the need for fundamental change in the meat and poultry inspection program. Two recurring elements were that FSIS should modernize inspection to: (1) Improve food safety through a reduction in foodborne illness caused by pathogenic bacteria on meat and poultry products and (2) Make better use of its resources. Bacteria, including *Salmonella*, *E. coli* 0157:H7, *Campylobacter*, and *Listeria monocytogenes*, were cited as significant food safety hazards associated with meat and poultry products, hazards that traditional inspection did not adequately address.

The NAS published several reports, with recommendations establishing the theme that FSIS should reduce its reliance on organoleptic inspection and shift to prevention-oriented inspection systems based on risk assessment. In 1985 NAS published “Meat and Poultry Inspection: The Scientific Basis of the Nation’s Program.” The NAS recommended that FSIS focus on pathogenic organisms and require that all official establishments operate under a Hazard Analysis and Critical Control Point (HACCP) system to control pathogens and other safety hazards. This report strongly encouraged “FSIS to move as vigorously as possible in the application of the HACCP concept to each and every step in establishment operations, in all types of enterprises involved in the production, processing, and storage of meat and poultry products.”

In 1987, NAS published its follow-up report, “Poultry Inspection: The Basis for a Risk Assessment Approach.” The report concluded that “the present system of inspection does very little to protect the public against microbial hazards in young chickens.” It also stated that “[Agency] resources are not always allocated to the right points and the resources that are properly directed are not achieving measurable results.” Subsequent reports elaborated on the same theme.

The GAO advocated similar improvements to meat and poultry inspection in a number of reports: “Food Safety: A Unified, Risk-Based Food Safety System Needed” (1994); “Meat Safety: Inspection System's Ability to Detect Harmful Bacteria Remains Limited” (1994); “Food Safety: Building a Scientific, Risk-Based Meat and Poultry Inspection System” (1993); and “Food Safety and Quality – Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply” (1992). The GAO endorsed HACCP as a scientific, risk-based system that would permit redeployment of FSIS resources in a manner that would better protect the public from

foodborne illness. GAO's 1994 Meat Safety report stated the resource problem clearly: "Labor-intensive inspection procedures and inflexible inspection frequencies drain resources that could be put to better use in a risk-based system. To better protect the public from foodborne illnesses, FSIS must move to a modern, scientific, risk-based inspection system. Such a system would allow FSIS to target its resources toward the higher-risk meat and poultry products by increasing inspection of such products."

A major outbreak of foodborne illness in several western states in 1993, attributed to the presence of the pathogen *E. coli* O157:H7 in ground beef, focused public concern on pathogens and strengthened the need for a risk-based inspection system.

HACCP—A Landmark Rule

These and other scientific studies and reports paved the way for FSIS to publish its landmark rule, the Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) Systems rule, on July 25, 1996. The rule focuses on the prevention and reduction of all hazards, including microbial pathogens on raw products that can cause illness, and represented a fundamental shift in the Agency's approach to inspection. Under the HACCP rule, industry is responsible for assessing potential food safety hazards and systematically preventing and controlling those hazards. FSIS is responsible for verifying that establishments' HACCP systems are working and that they prevent adulterated meat and poultry products from entering commerce. The introduction of HACCP initiated the ongoing evolution of a risk based inspection system. Implementation of the HACCP rule was completed January 25, 2000, but improvements have been continuous.

To evaluate a model system of inspection, operating under HACCP principles, FSIS initiated the HACCP-Based Inspection Models Project (HIMP) in 1998. A *Federal Notice* announcing the project and inviting comment was published in June 1997.

Evolution of Inspection Based on Risk

Since before 2000, FSIS has been exploring the risk-based inspection approach. The thinking has evolved with lessons learned at each stage. The risk-based inspection system currently being developed reflects that evolution.

A major milestone in the evolution was the publication, on June 6, 2003, of the interim final rule for control of *Listeria monocytogenes* in Ready-to-Eat meat and poultry products. The regulation is based on a scientific risk assessment and provides establishments with different options to control contamination in order to produce safe, unadulterated product. FSIS tailors its verification activities to the interventions that an establishment chooses to adopt and to the potential for *Listeria* growth in its products.

Based on the success of the *Listeria* initiative, in February 2006, FSIS announced an 11-point program that's a risk-based strategy for *Salmonella*. The initiative includes concentrating resources at establishments with higher levels of *Salmonella*.

An Open, Transparent Process

In June 1997, FSIS invited the public and all stakeholders to a public meeting to participate in the development of new inspection models for slaughter and processing in a HACCP environment. The Agency has continued to plan and implement the evolution of inspection in a transparent manner, with full public input.

For example, in July 2004, FSIS outlined the basic features of a predictive model that would permit FSIS to consider the inherent risks and risk control effectiveness of meat and poultry establishments under Federal Inspection. The Agency continued developing and refining those ideas.

In May 2006, FSIS contracted with an objective third party, RESOLVE, Inc. to assist in obtaining broad stakeholder input relating to the development of risk-based inspection in processing.

In another instance, FSIS held a two-day public meeting October 10-11, 2006, to review and discuss issues relating to a risk-based inspection system.

The Molding of Risk-Based Inspection

Two advisory committees, composed of experts in various disciplines and representatives from a variety of stakeholders, have played a major role in molding the evolution of risk-based inspection.

In November 2005, FSIS addressed the National Advisory Committee on Meat and Poultry Inspection (NACMPI) on the Agency's progress toward a risk-based inspection system. In May 2006, the Agency addressed the Committee again, on ideas the Agency had for measuring processing establishment risk control effectiveness for risk-based inspection. NACMPI endorsed the concept and provided significant advice on the practical aspects of such a system, in both May and October of 2006.

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) has been a proponent of both HACCP and risk-based inspection. The Committee has supported the use of risk analysis for allocation of resources to control food safety and has prepared reports on the development and implementation of HACCP.

Testing for Pathogens Increased Greatly

During the past two decades, FSIS has moved light years ahead in terms of scientific testing. Testing of both raw and processed product is a major component of HACCP. Based on the inspection changes and the results of testing, FSIS has successfully implemented major initiatives to control *Salmonella*, *E. coli* O157:H7, and *Listeria*.

The Agency had already begun testing ready-to-eat products for *Salmonella* in 1983 and for *Listeria monocytogenes* (Lm) in 1987. In 1994, FSIS declared *E. coli* O157:H7 an adulterant in raw ground beef and instituted a testing program for the pathogen. All three of these programs are zero-tolerance programs, and any positive sample results are indicative of establishment risk control problems. Measuring establishment risk control effectiveness, and increasing or

decreasing the number of inspection procedures performed compared to the number currently scheduled in those establishments, is a key component of risk-based inspection.

Public Health Results

FSIS believes that two decades of evolution toward risk-based inspection have led to impressive real-world results. In April 2006, the Centers for Disease Control and Prevention (CDC) reported a sustained decline in foodborne illnesses, as reported in the Foodborne Diseases Active Surveillance Network (Foodnet). Compared to the 1996-1998 baseline, data showed that in 2005 there were major declines for illnesses from *Listeria* (32%), *E. coli* O157:H7 (29%), *Shigella* (43%), *Yersinia* (49%), *Campylobacter* (30%), and *Salmonella* (9%). The CDC has cited HACCP implementation as an important factor in these overall declines in bacterial food-borne illnesses.

FSIS believes that continued evolution of a risk-based inspection system will further reduce foodborne illnesses and improve the public health.