

Risk Assessments for *Salmonella* Enteritidis in Shell Eggs and *Salmonella* spp. in Egg Products

Executive Summary

The United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) is responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. FSIS regulates egg products under the authority of the Egg Products Inspection Act of 1970 and officially inspected egg products bear the USDA mark of inspection. FSIS undertook two quantitative microbial risk assessments to assist FSIS risk managers in evaluating egg handling and pasteurization performance standards for reducing the likelihood of *Salmonella enterica* serovar Enteritidis (SE) contamination in shell eggs and *Salmonella* spp. contamination in egg products, and subsequently, for reducing the risk of human illness, hospitalization, and death associated with eggs and egg products.

REGULATORY CONTEXT

Foodborne *Salmonella* are the estimated cause of 1.3 million illnesses, 15,000 hospitalizations, and 500 deaths each year in the United States. *Salmonella* related illnesses are characterized by fever, stomach cramps, and diarrhea. Symptoms develop 8 hours to 3 days after eating contaminated food and last 4 to 7 days. The disease is typically self-limiting; yet may be fatal in persons with weakened immune systems.

Shell eggs and egg products may transmit *Salmonella* to humans. The period 1976 to 1995 saw an 8-fold increase in infections with SE and more than 75% of these infections were associated with egg-containing foods. Based largely on these observations, Federal and State agencies worked with industry and consumers to implement farm-to-table interventions to reduce the risk of illness from SE in eggs.

In 1996, FSIS and the United States Department of Health and Human Services (HHS) Food and Drug Administration (FDA) initiated a risk assessment for SE in eggs and egg products (SERA). The results indicated multiple interventions along the farm-to-table chain were necessary to reduce significantly the risk of illnesses from SE. The results also served as basis for a comprehensive and coordinated Federal and State action plan – the Egg Safety Action Plan – to address shell egg and egg product safety. While 1999 data from the Centers for Disease Control and Prevention (CDC) indicated a drop in the incidence of SE infection, from 3.9 cases per 100,000 people in 1995, to 1.98 cases per 100,000 in 1999, FSIS continued to consider options to reduce SE related illnesses.

Since the development of the SERA, additional data became available, including contamination data from the FSIS national baseline survey of *Salmonella* in pasteurized liquid egg products; published studies on SE contamination in egg yolk and lethality kinetics of *Salmonella* spp. in egg products; and an improved dose-response model. FSIS utilized this information to revise components of the SERA and create two new risk assessments; one estimating the risk of illness associated with SE in shell egg and the other estimating the risk of illness associated with *Salmonella* spp. in pasteurized egg products. FSIS developed these risk assessments to address specific risk management questions designed to guide the development of performance standards for eggs and egg products.

RISK MANAGEMENT QUESTIONS

FSIS risk managers requested that the risk assessments respond to the following questions:

- What is the number of illnesses per serving and annual number of illnesses from SE in pasteurized and non-pasteurized shell eggs?
- What is the number of illnesses per serving and annual number of illnesses from *Salmonella* spp. in pasteurized egg products (e.g., liquid whole eggs, yolks, and egg whites)?
- What is the effect of the temperature and length of time (in days) before eggs are collected after they are laid by the hen and then refrigerated and further processed on the estimated risk of illness?

DEVELOPMENT AND STRUCTURE OF THE RISK ASSESSMENTS

FSIS developed the current SE in shell eggs and *Salmonella* spp. in egg products risk assessments by using the 1998 SERA and incorporating current scientific information and updated modeling techniques. The risk assessments are farm-to-table in scope.

The hazard identification (chapter 2) describes the public health information for *S. Enteritidis* and other *Salmonella* spp. The exposure assessment (chapter 3) describes how consumers are exposed to SE from shell eggs and *Salmonella* spp. from egg products. Estimates are presented for the prevalence and level of SE in shell eggs produced on the farm and for the level of SE in shell eggs at consumption. Estimates are also presented for the prevalence and level of *Salmonella* spp. in egg products before pasteurization and the level of *Salmonella* spp. in egg products at consumption. The hazard characterization (chapter 4) describes how the estimated levels of SE or *Salmonella* spp. in a serving of food were used to estimate the likelihood of illness. The risk characterization (chapter 5) provides estimates for the likelihood of illness and the number of annual illnesses from SE in shell eggs and *Salmonella* spp. in egg products. This chapter also provides answers to each of the risk management questions together with information about the efficacy of alternative performance standards in mitigating the risk of illness. A sensitivity analysis is included to describe the areas to consider in reviewing and refining mitigation strategies and to identify data gaps and key uncertainties in the assessments. The research needs section (chapter 6) describes areas of research that should be undertaken to strengthen future risk assessments for *Salmonella* in eggs. Finally, the accompanying annexes provide in-depth information about data used in the assessments.

The risk assessments were independently peer reviewed by a multi-disciplinary group of experts in accordance with the Office of Management and Budget (OMB) guidelines for peer review. Drafts of the risk assessments were also presented at a public meeting on October 22, 2004. FSIS revised the risk assessments based on peer review input and public comments, and in consultation with the FDA, CDC, and the USDA Agricultural Research Service.

RISK ASSESSMENT OUTPUTS

- *Pasteurization was predicted to be effective for reducing illnesses from SE in shell eggs.* If all eggs produced in the U.S. were pasteurized for a 3- \log_{10} reduction of SE, the annual number of illnesses would be reduced from 130,000 to 41,000. A 5- \log_{10} reduction would reduce the annual number of illnesses to 19,000.
- *Storage time and temperature were predicted to be effective for reducing illnesses from SE in shell eggs.* If eggs are stored and held at 7.2°C (45°F) within 12 hours of lay, the estimated number of human illnesses would be reduced from 130,000 to 28,000.
- *Pasteurization was predicted to be effective for reducing illnesses from *Salmonella* spp. in egg products.* If all liquid egg products produced in the U.S. were pasteurized for a 6- \log_{10} reduction of *Salmonella*, the annual number of illnesses would be reduced from 5,500 to 3,200.

- Initial levels of *Salmonella* in unpasteurized egg products and the way in which products are prepared for consumption had the greatest impact on human health in the *Salmonella* spp. in egg products risk assessment.

OPPORTUNITIES FOR FURTHER RESEARCH

The risk assessments identified the following opportunities for additional research:

- A nationally representative survey for the prevalence of SE in domestically produced flocks, hens, and shell eggs. The survey should be conducted over all seasons.
- Characterization of growth parameters of SE in shell eggs.
- Quantitative study of cross-contamination during shell egg and liquid egg product processing.
- Studies on how SE differs from other salmonellae in ability to persist in chicken reproductive tissue and egg contents.
- Characterization of egg storage times and temperatures on farms and in homes, for eggs produced off-line, and for eggs at retail.

CONCLUSION

The risk assessments for SE in shell eggs and *Salmonella* spp. in liquid egg products are based on the best available science. The risk assessments received stakeholder input and thorough review according to OMB guidelines. Pasteurization and rapid cooling of eggs are predicted to be effective for reducing illnesses from SE in eggs and *Salmonella* spp. in egg products. Data from the assessments will assist FSIS risk managers in developing regulatory performance standards.