

**DRAFT RISK ASSESSMENTS OF *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) 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 the subsequent risk of human illness, hospitalization, and death.

BACKGROUND

Foodborne *Salmonella* are estimated to cause roughly 1.3 million illnesses, 15,000 hospitalizations, and 500 deaths each year in the United States.¹ Illness from *Salmonella* is characterized by fever, stomach cramps, and diarrhea. Symptoms develop 8 hours to 3 days after consumption of contaminated food and last 4 to 7 days. The disease is typically self-limiting, though it may be fatal in persons with weakened immune systems. The poorer the individual's health and the more *Salmonella* ingested, the greater the likelihood for serious illness and death.

Shell eggs and egg products transmit *Salmonella* to humans.^{2,3} The period 1976 to 1995 saw an 8-fold increase in reported infections with SE, greater than 75% of which were associated with foods containing undercooked eggs.⁴ 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.⁵

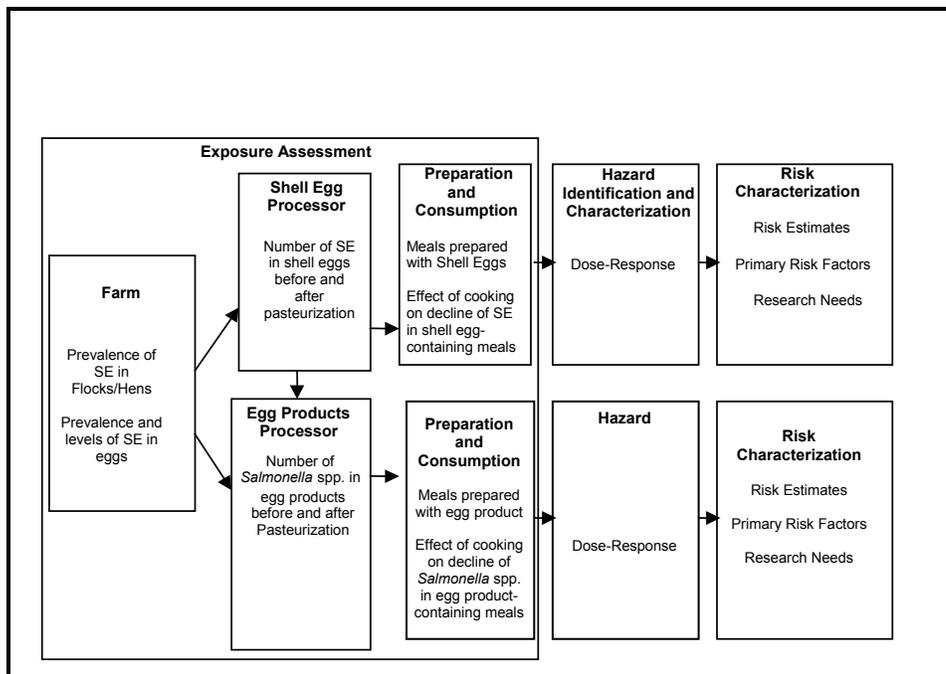
In 1996, FSIS, in collaboration with the U.S. Food and Drug Administration (FDA), initiated a risk assessment for SE in eggs and egg products.⁶ Results of the assessment indicated multiple interventions along the farm-to-table chain were necessary to reduce significantly the risk of illnesses from SE and served as basis for a comprehensive and coordinated Federal and State action plan – the Egg Safety Action Plan⁷ – to address shell egg and egg product safety.

However, results of the risk assessment were not deemed sufficient for evaluating FSIS risk management options for developing egg and egg product performance standards.

Since then, however, data have become available to develop robust risk assessments for SE in eggs and *Salmonella* spp. in egg products. FSIS has conducted a national baseline survey to measure *Salmonella* levels in liquid egg products produced in the U.S; recent experimental studies have clarified scientific issues associated with SE contamination in egg yolk;⁸⁻¹⁰ the United Egg Board sponsored studies on lethality kinetics of *Salmonella* spp. in liquid egg products;¹¹ and an improved dose-response model for *Salmonella* spp. has been developed.¹² Because of these newly available data, two new risk assessments were undertaken. One estimates the risk of illness associated with SE in shell eggs. The other estimates the risk of illness associated with *Salmonella* spp. in pasteurized egg products. The risk assessments were done to assist FSIS risk managers in developing performance standards to mitigate the likelihood of SE contamination in shell eggs and *Salmonella* spp. in egg products.

STRUCTURE AND SCOPE OF THE ASSESSMENTS

The risk assessments were farm-to-table in scope, as illustrated below.



The exposure assessment (chapter 3) describes how consumers become 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.

RESULTS

- **Pasteurization was predicted to be effective for reducing the risk of illness due to SE in shell eggs.** The annual number of illnesses attributable to SE in shell eggs was predicted to be ca. 350,000. 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 to ca. 110,000. A 5- \log_{10} reduction would reduce the annual number of illnesses to ca. 52,000.
- **Storage time and temperature were predicted to be effective for reducing the risk of illness due to SE in shell eggs.** If eggs are stored and held at 45° F within 12 hours of lay, the estimated number of human illnesses decreases from ca. 350,000 to ca. 77,000. Cooling eggs rapidly to 45° F makes pasteurization more effective.
- **Pasteurization was predicted to be effective for reducing the risk of illness due to *Salmonella* spp. in liquid egg products.** The annual number of illnesses attributable to *Salmonella* spp. in liquid egg products was estimated to be ca. 50,000. Pasteurization of liquid egg products for 6- \log_{10} reduction would reduce the annual number of illnesses to ca. 30,000.

UNCERTAINTY AND SENSITIVITY ANALYSIS

The risk assessments were developed using first-order models, which account for variability in a system by iterating through specific values and distributions. The effect of uncertainty in these assessments was evaluated by running a series of scenarios, each of which consisted of setting all inputs except one to baseline values. The remaining input was set to an upper or lower bound. This type of analysis is useful for evaluating the effect of each input on model output. Inputs with the greatest effect on model output for the SE in shell eggs risk assessment were related to the prevalence of SE-contaminated eggs, growth parameters of SE in eggs, and egg storage temperatures. Inputs with the greatest effect on model output in the *Salmonella* spp. in egg products risk assessment were related to the initial levels of *Salmonella* in unpasteurized egg products and to how egg products were prepared and consumed.

RESEARCH NEEDS

Based on uncertainty and sensitivity analysis, the following research needs were deemed important for future risk assessments of *Salmonella* in eggs:

- **A nationally representative survey over all seasons on the prevalence of SE in domestically produced flocks, hens, and shell eggs.** In lieu of this data, the risk assessment for SE in shell eggs used data from a USDA spent hen survey¹³ and from studies of experimentally inoculated chickens.⁸⁻¹⁰
- **Characterization of growth parameters of SE in shell eggs.** This is needed to improve estimates of the effects of pre-processing mitigations for reducing SE-contaminated eggs. Studies should include characterization of growth parameters for SE in egg yolk and during yolk membrane breakdown.
- **Investigation into the behavior and survival of SE in eggs.**
- **Quantitative study of cross-contamination during processing of shell eggs and liquid egg products.** Data from such studies would likely facilitate methodologies for modeling cross-contamination.
- **Studies on how SE differs from other salmonellae in their ability to persist in chicken reproductive tissue and egg contents.**
- **Characterization of egg storage times and temperatures on farm and in homes; for eggs produced off-line; and at retail.**
- **Studies to determine the initial levels of *Salmonella* spp. in liquid egg products prior to pasteurization.**
- **The effect of pasteurization on reducing SE in shells eggs and *Salmonella* spp. in liquid egg products.** Studies should include analysis of various pasteurization times and temperatures on overall pathogen reduction.
- **Studies to determine the fraction of U.S. salmonellosis cases attributable to shell egg and liquid egg product consumption.** Such data would facilitate anchoring the model predictions of illness and validation of the *Salmonella* dose-response relationship.

SUMMARY

Pasteurization and rapid cooling are predicted to be effective targeted interventions for reducing the risk of illness from SE in shell eggs and *Salmonella* spp. in egg products. Data from these risk assessments provide the scientific basis for future decision-making.

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