Salmonella Enteritidis Risk Assessment

Shell Eggs and Egg Products

Final Report

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Prepared for The Food Safety and Inspection Service
by the *Salmonella* Enteritidis Risk Assessment Team

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The *Salmonella* Enteritidis Risk Assessment Team wishes to explicitly state that the results of our efforts in producing this document were only possible because of the help we received from many individuals who are recognized as experts in their respective fields. It is because we were able to stand on the shoulders of these experts, who are giants in their fields, that we were able to see further. In the words of Samuel Taylor Coleridge, "A dwarf sees farther than the giant when he has the giant's shoulders to mount on." (The Friend, sect. I. essay viii).

The *Salmonella* Enteritidis Risk Assessment Team acknowledges the contributions of Kaye Wachsmuth to developing the capacity of the Food Safety and Inspection Service for conducting risk assessment and to developing the skills of the *Salmonella* Enteritidis Risk Assessment Core Group.

We also acknowledge the members of the Resource Group for their critical review of early drafts and for providing data with which to support the *Salmonella* Enteritidis Risk Assessment for Shell Eggs and Egg Products. They were invaluable to our effort. We thank them, and we salute them.

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Executive Summary

This document summarizes the risk assessment process from the development of a conceptual framework to the careful organization of information obtained from published scientific literature and unpublished academic, government and industry sources, to the incorporation of available data into a comprehensive quantitative model which characterizes the public health effects associated with the consumption of *Salmonella* Enteritidis-infected shell eggs and egg products.

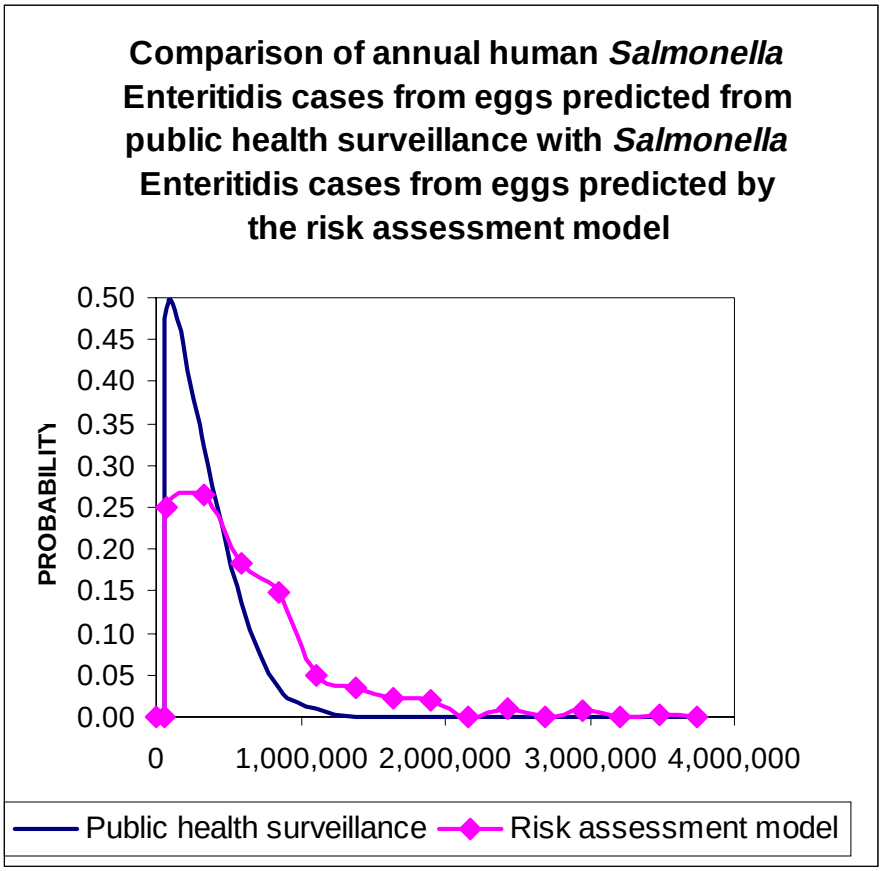
The Food Safety and Inspection Service (FSIS) began a comprehensive risk assessment of *Salmonella enterica* serotype Enteritidis (*Salmonella* Enteritidis) in December 1996 in response to an increasing number of human illnesses associated with the consumption of shell eggs. The objectives of this risk assessment are to: establish the unmitigated risk of foodborne illness from *Salmonella* Enteritidis, identify and evaluate potential risk reduction strategies, identify data needs, and prioritize future data collection efforts. The risk assessment model consists of five modules. The first module, the Egg Production Module, estimates the number of eggs produced that are infected (or internally contaminated) with *Salmonella* Enteritidis. The Shell Egg Module, the Egg Products Module, and the Preparation and Consumption Module estimate the increase or decrease in the numbers of *Salmonella* Enteritidis organisms in eggs or egg products as they pass through storage, transportation, processing, and preparation. The Public Health Module then calculates the incidences of illnesses and four clinical outcomes (recovery without treatment, recovery after treatment by a physician, hospitalization, and mortality) as well as the cases of reactive arthritis associated with consuming *Salmonella* Enteritidis positive eggs.

The baseline model for shell eggs presented in this report simulates an average production of 46.8 billion shell eggs per year in the U.S., 2.3 million of which contain *Salmonella* Enteritidis. The consumption of these eggs results in a mean of 661,633 human illnesses per year ranging from 126,374 to 1.7 million cases per year (5^{th} and 95^{th} percentiles) as shown in Table 3. It is estimated that about 94% of these cases recover without medical care, 5% visit a physician, an additional 0.5% are hospitalized, and 0.05% of the cases result in death. Twenty percent of the population is considered to be at a higher risk for salmonellosis from *Salmonella* Enteritidis (i.e. infants, elderly, transplant patients, pregnant women, individuals with certain diseases) because they may be more susceptible to infection and because they may disproportionately experience the manifestations of *Salmonella* Enteritidis infection.

A comparison of the total number of illnesses due to *Salmonella* Enteritidis positive eggs simulated with this model, with a distribution of illnesses from *Salmonella* Enteritidis positive eggs predicted from national public health surveillance shows substantial overlap between these two independently derived distributions (see **Figure 1**). The surveillance data has been used to derive an estimate of *Salmonella* Enteritidis related human illnesses averaging 637,000 cases per year with a range from 254,000 to 1,167,000 cases of human illness from *Salmonella* Enteritidis positive eggs. The median estimates for this simulation model and the surveillance data are 504,082 cases and 332,400 cases of human illness from *Salmonella* Enteritidis positive eggs per year, respectively. Such agreement suggests the model is reasonably accurate in its depiction of the number of cases of human illnesses due to *Salmonella* Enteritidis positive eggs in the U.S.

Figure 1

The baseline egg products model predicts that the probability is low that any cases of *Salmonella* Enteritidis will result from the consumption of pasteurized egg products. However, the current FSIS time and temperature regulations do not provide sufficient guidance to the egg products industry for the large range of products the industry produces. Time and temperature standards based on the amount of bacteria in the raw product, how the raw product will be processed, and the intended use of the final product will provide greater protection to the consumers of egg products.



Mitigation elasticity is an indication of how changes in module variables affect model output. For example, a 25 percent reduction in a few input variables were simulated as examples of how this elasticity could be used. No single input variable modeled as a potential mitigation achieved an equivalent reduction (i.e. 25%) in total human illnesses. However, combinations of mitigations may potentially be more effective in reducing total human illnesses (i.e., a Mitigation elasticity $\geq$ 1). In one such combination of mitigations in the Production Module and in the Preparation & Consumption Module an equivalent reduction (i.e. 25%) in human illnesses resulted. This finding implies that a broadly based policy may be more effective than a policy directed solely at one area of the egg production-to-consumption chain.

The percent reduction for total human illnesses was calculated for two scenarios within the Shell Egg Processing and Distribution module. In the first scenario we found a 12% reduction in human illnesses if all eggs are **immediately cooled after lay to an internal temperature of 45° F**, then maintained at that temperature throughout shell egg processing and distribution as opposed to the current diversity of temperatures experienced throughout this stage of production. In the second scenario we found a 8% reduction in illnesses when **eggs are maintained at an ambient (i.e air) temperature of 45° F throughout shell egg processing and distribution** compared to current practices. These two scenarios represent the best results that could be expected from implementing temperature strategies during shell egg processing and distribution.

Executive Summary

Mitigation elasticity measures the effect of specific interventions. We compared the effect of diverting eggs from *Salmonella* Enteritidis positive flocks out of the shell egg market and into the egg products market for pasteurization and found a substantial reduction in the number of illnesses.

Some cautions on the appropriate use of this risk assessment are in order. This risk assessment effort is a significant advancement in our ability to comprehensively model risk throughout the egg and egg products continuum. The model can continually be refined and updated for use in future risk assessments for shell eggs and egg products. Furthermore, the farm-to-table approach provides a framework for developing similar risk assessment efforts for other pathogen-product pairs, or for other livestock production systems. However, the risk assessment results provide only part of the information needed by decision makers and regulators. Cost-benefit analyses will need to be applied to the risk assessment results to provide additional information for formulating efficient policy. The risk assessment results detailed in this Final Report will be used by the agency, working in conjunction with economists from within and from outside the agency, to conduct cost-effectiveness studies and cost-benefit analysis in order to set forth recommendations for policy.