1 Introduction

Federal and state agencies have worked with industry and consumers to implement interventions along the farm-to-table chain to mitigate the risk of illness from *Salmonella enterica* serovar Enteritidis (SE) in eggs. These interventions included good agricultural practices, such as voluntary quality assurance programs for egg production, refrigeration during transport to limit SE growth in eggs, and consumer education efforts aimed at cooking eggs fully, all of which likely contributed to the decline in SE infections reported to the Centers for Disease Control and Prevention (CDC) from 1996 to 1998.[1-3]

To target resources for further reducing egg-related salmonellosis, the Food Safety and Inspection Service (FSIS), in collaboration with the Food and Drug Administration (FDA), initiated a farm-to-table risk assessment for SE in eggs and egg products in 1996.[6] Results of the assessment indicated multiple interventions were necessary to reduce significantly risk of illnesses from SE and were the basis for a comprehensive and coordinated federal and state action plan — the Egg Safety Action Plan[4] — to address the safety of shell eggs and egg products along the farm-to-table chain. The results, however, were not deemed sufficient for evaluating FSIS risk management options for developing performance standards. Consequently, new risk assessments were begun using newly available data, updated modeling techniques, and more germane risk assessment objectives to evaluate the effectiveness of egg safety performance standards in mitigating the risk of illness from SE in eggs and *Salmonella* spp. in egg products.

A Call for Performance Standards

During development of the Egg Safety Action Plan, consumer groups and the egg industry cited the need for national egg safety standards to ensure all eggs meet uniform safety standards thus providing producers and processors "a level playing field".[4] Such standards, known as "performance standards," would complement FSIS's recently implemented 1996 landmark rule, Pathogen Reduction/Hazard Analysis and Critical Control Point Systems, by setting guidelines for industry to ensure the safety of their products.[5]

SALMONELLA AND EGG SAFETY

Estimates suggest foodborne *Salmonella* cause ca. 1.3 million illnesses, 15,000 hospitalizations, and 500 deaths each year in the U.S.[7] In the mid-1980s, intact eggs were identified as a source of *Salmonella* infections. The predominant *Salmonella* found in shell eggs is SE. Eggs and egg-containing foods have been identified as the vehicle in roughly 80% of known-source SE infections in the U.S.[8-10]

Salmonellosis, the illness from *Salmonella* infection, is characterized by fever, stomach cramps, and diarrhea. Symptoms develop 8 hours to 3 days post-ingestion and last 4 to 7 days. Most cases are self-limiting. The degree to which a person becomes sick depends on his or her health status and the number and virulence of *Salmonella* spp. ingested. In general, the poorer the individual's health and the more *Salmonella* ingested, the greater the likelihood for serious illness and death.

Salmonellosis is a notifiable disease, physicians and medical laboratories being required to report identified infections to their local health department. The reports are forwarded to state health departments, which summarize the information and send it to the CDC as part of a nationwide, passive reporting system for *Salmonella*. While the numbers of other common *Salmonella* serotypes remained relatively steady from 1976 to 1995, SE infections increased more than eight-fold. Though the number of reported SE infections from 1996 to 1998 decreased by 44%,[11] the estimated number of SE infections remains high. [12]

In addition to passive surveillance for sporadic infections (single cases) of salmonellosis, the CDC maintains surveillance for outbreaks of infection (two or more related cases) from SE.[13] In 1985 states reported 26 outbreaks of SE infection. The number of SE outbreaks increased in the late 1980s and early 1990s but decreased dramatically in the late 1990s. From 1985 through 1998, 794 SE outbreaks were reported to CDC involving 28,644 illnesses, 2,839 hospitalizations, and 79 deaths. Many of these outbreaks were attributed to foods served in commercial establishments and prisons; most (>75 percent) were associated with undercooked eggs. Despite federal and state efforts, outbreaks of infection from SE-contaminated eggs continue.[14]

Regulatory Context

To achieve further reductions in the incidence of egg-related SE infections, FSIS is implementing a broad and long-term science-based strategy to improve shell egg and egg product safety.[4] As part of this strategy, FSIS completed implementation of the rule on Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) systems.[5] Under this system, establishments are responsible for producing safe product. As a complement to HACCP, FSIS plans to establish performance standards as guidelines for industry to ensure their products are safe. FSIS plans to establish three types of performance standards: 1) amend the egg and egg products inspection regulations by converting into performance standards regulations governing egg product processing (9 CFR 590.570); 2) add new performance standards for production of ready-to-eat shell eggs, also known as "in-shell" pasteurized eggs (9 CFR 590.575); and 3) establish performance standards for handling and storage of shell eggs from lay until processing. The scientific basis for establishing these performance standards is provided in the risk assessments described here. The results of the risk assessments will be used with a cost-benefit

analysis to evaluate the effectiveness of various performance standards in mitigating the likelihood of SE in eggs and *Salmonella* spp. egg products, and the subsequent risk of illness.

Performance Standards and HACCP

Performance standards are an integral part of HACCP. The 1996 rule for Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) systems provided the framework industry development of science-based controls to mitigate microbiological hazards in foods. Performance standards set by FSIS to serve as guidelines for establishments to achieve through their HACCP plan. Performance standards provide the objective level of food safety performance that establishments must meet, but they allow individual establishments to develop and implement customized processing controls.

Lethality performance standards are expressed as the decimal reduction (X $\log_{10}$) of target pathogen(s). This can also be expressed probabilistically. A performance standard for a 3-$\log_{10}$ reduction, for example, means that 99.9% of the bacteria would be killed. If there were one bacterium, the probability of it being killed would be 99%. Egg-handling performance standards establish the maximum relative growth of *Salmonella* allowable in eggs during handling and storage.

The 1998 *Salmonella* Enteritidis Risk Assessment

FSIS, in collaboration with FDA, began a comprehensive risk assessment for SE in eggs and egg products in December 1996. The risk assessment was initiated in response to the increase in egg-related SE infections from 1976 to 1995. The *Salmonella* Enteritidis Risk Assessment (SERA), a quantitative farm-to-table risk assessment of SE in shell eggs and egg products, was published in 1998.[6] It was developed to characterize the human health risk of SE in eggs and egg products and to identify and evaluate risk reduction strategies. The SERA provided insight into the factors that contribute to the public health risks associated with SE in shell eggs and suggested multiple interventions in the farm-to-table continuum were necessary to reduce significantly the risk of illness from eggborne SE. The results of the SERA formed the cornerstone for the Egg Safety Action Plan, which outlined a broad egg safety strategy to reduce the incidence of egg-associated SE infections by 50% from 1998 to 2005 and to eliminate it entirely by 2010.[4] The results were not deemed sufficient, however, for development of performance standards for egg packers and processors, as requested by consumer groups and the egg industry during the development of the Egg Safety Action Plan. Since 1998, however, data have become available to produce risk assessments more useful for developing performance standards for SE in eggs and *Salmonella* spp. in egg products. FSIS has conducted a national baseline survey to measure *Salmonella* spp. levels in liquid egg products;[15] recent studies have clarified scientific issues associated with SE contamination in egg yolk;[16-18] the United Egg Board sponsored studies on lethality kinetics of *Salmonella* spp. in liquid egg products;[19] and the Food and Agricultural Organization/World Health Organization (FAO/WHO) developed a dose-response model for *Salmonella* spp.[20]

President's Council on Food Safety Egg Safety Action Plan

The President's Council on Food Safety has identified egg safety as warranting immediate federal, interagency action. The Egg Safety Action Plan identifies the systems and practices that must be implemented to reduce and ultimately eliminate eggs as a source of infection from SE. The overarching public health goal of the Council is to eliminate SE illnesses associated with the consumption of eggs by 2010. The interim goal of the Egg Safety Action Plan is a 50% reduction in egg-associated SE illnesses by 2005.

Americans consume an average of 234 eggs per person per year. Eggs contaminated with SE can cause illness if eaten raw or undercooked. Because eggs can become contaminated internally from the hen, common egg-handling practices are not considered safe. These practices include temperature abuse, inadequate cooking, and pooling eggs to prepare a large volume of an egg-containing food that is subsequently temperature abused or inadequately cooked.

The SE risk assessment model for shell eggs and egg products, developed jointly by FSIS and FDA in 1998, predicted that using multiple interventions could achieve a more substantial reduction in SE illnesses than using any one intervention alone. This finding suggested that a broad based policy is likely to be more effective in eliminating egg-associated SE illnesses than a policy directed solely at one stage of the farm-to-table continuum.

The President's Council on Food Safety Egg Safety Action Plan offered industry the flexibility to choose from two equivalent SE reduction strategies involving both the diversion of potentially SE-positive eggs and lethal treatment, or "kill step," at the packer/processor. To consolidate egg safety oversight responsibilities, the President's Council on Food Safety identified one agency as responsible for each stage of the farm-to-table continuum, based on the strength of each agency as follows: FDA develops standards for the producer, and states provide inspection and enforcement on the farms; FSIS develops standards for shell egg packers and egg products processors, and provides inspection and enforcement for both; FDA and CDC conduct surveillance and monitoring activities.

For more information, visit the Egg Safety Action Plan website: http://www.foodsafety.gov/~fsg/ceggs.html.

PURPOSE AND SCOPE OF THE RISK ASSESSMENTS

The risk assessments were done to assist FSIS risk managers in evaluating egg-handling and pasteurization performance standards to mitigate the likelihood of SE contamination in shell eggs and *Salmonella* spp. in egg products. The risk assessments were not designed to estimate retrospectively the number of illnesses from *Salmonella*. These assessments are intended to answer the following risk management questions:

- What is the number of SE in shell eggs before and after a specified pasteurization scenario?
- 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 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?
- What is the number of *Salmonella* spp. in a liter of egg product (whole, yolk, albumen) before and after a specified pasteurization scenario?

- 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)?

To answer these risk management questions, the risk assessments were designed to evaluate the following scenarios as part of the risk characterization:

- **Shell egg pasteurization scenarios.** Less than 0.05% of shell eggs processed in the U.S. are pasteurized. The purpose of pasteurization is to achieve a high likelihood of no *Salmonella* spp. in shell eggs, with a high level of confidence. Risk managers requested that the risk assessment consider the per annum risk of illness if 0.05%, 1%, 5%, 10%, 25%, 50%, 75%, or 100% of the industry were to pasteurize shell eggs. The risk assessments have the flexibility to examine different shell egg pasteurization scenarios and can incorporate new information as it becomes available. Limited information on industry practices constrained the extent of the pasteurization practices investigated.

- **Egg product pasteurization scenarios.** Command-and-control regulations for the pasteurization of egg product are based on specific time and temperature requirements (9 CFR 590.570). These regulations do not cover all liquid egg products, nor do they differentiate the various types of liquid egg product, e.g. whole egg, yolk, or albumen, which may vary in the prevalence and/or level of *Salmonella* prior to pasteurization. Moreover, these prescriptive regulations do not allow industry the flexibility to implement hazard controls for specific processes and products. Risk managers requested that these assessments consider egg product pasteurization scenarios in which the level of *Salmonella* in egg products is reduced by 7 to 12 $\log_{10}$.

- **Shell egg handling scenarios.** Because SE within a contaminated egg may increase over time, the point at which shell eggs are pasteurized is important. FSIS risk managers requested that these assessments consider shell egg age and the corresponding storage times and temperatures prior to eggs reaching the processor. These assessments also consider multiple egg-handling and storage scenarios for eggs followed by refrigeration at 45ºF until eggs are pasteurized. By considering these egg-handling scenarios, the assessments provide insight to the effectiveness of various egg-handling performance standards to limit the growth of SE in shell eggs.

- **Egg production risk factors for SE.** Risk managers requested that these risk assessments evaluate effects of season and flock molting on production of SE-contaminated eggs. Data were not available to estimate fully the effect of season on production of SE-contaminated eggs. The assessments do include the effects of molting of flocks on the prevalence of SE-contaminated eggs.

RISK ASSESSMENT COMPONENTS

These risk assessments reflect, to the extent practicable, a full range of current practices, behaviors, and conditions in the farm-to-table continuum. FIGURE 1-1 (below) shows the major components of the assessments.

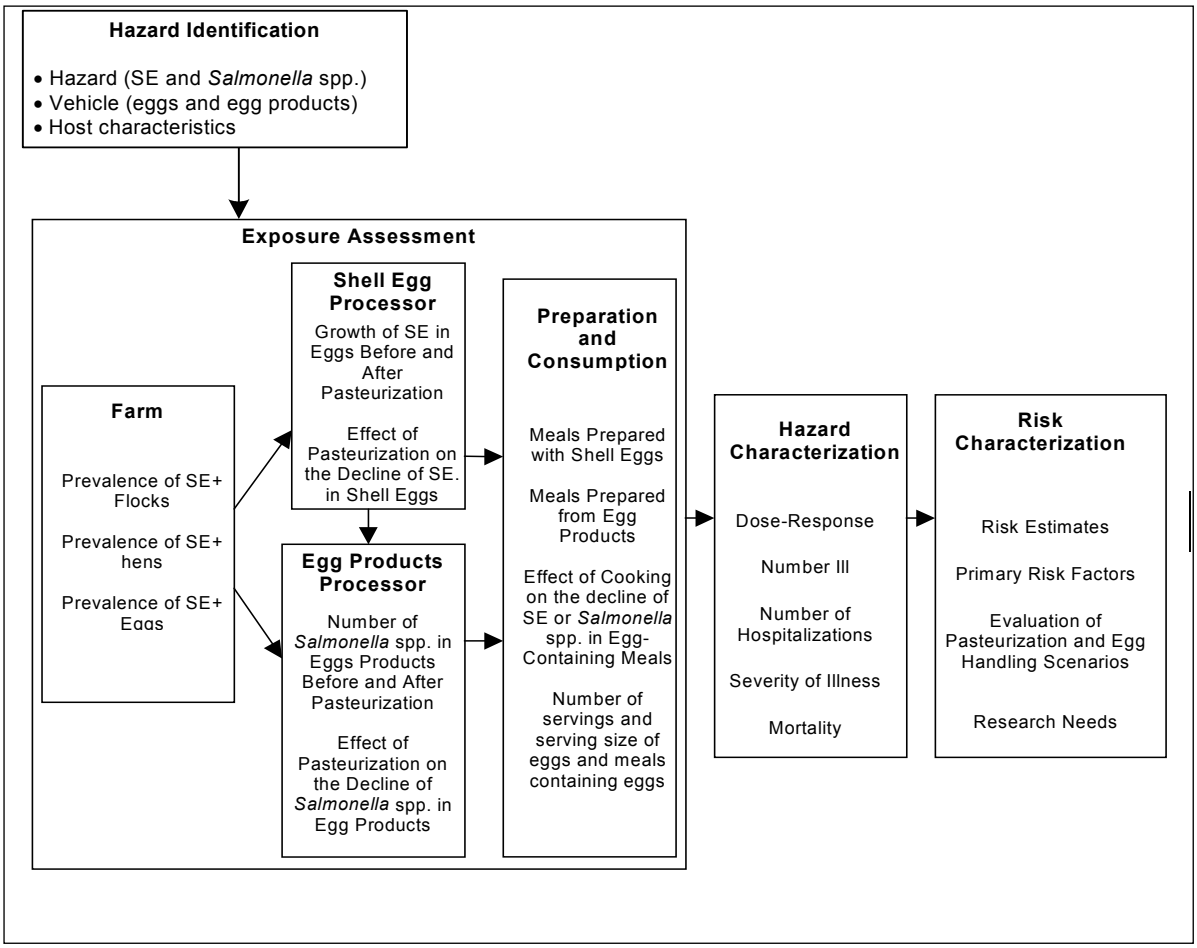


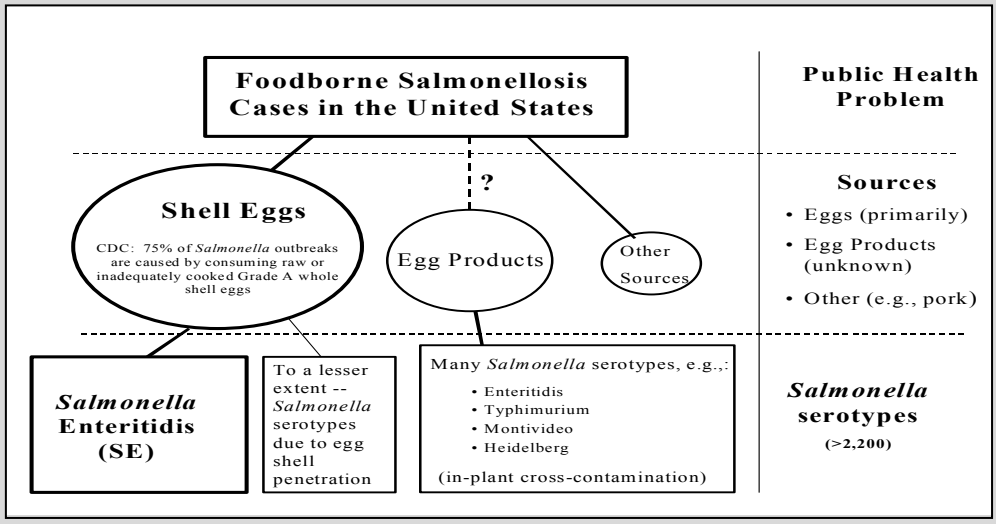
FIGURE 1-1 RISK ASSESSMENT STRUCTURE FOR SE IN SHELL EGGS AND *SALMONELLA* SPP. IN EGG PRODUCTS.

Hazard Identification discusses the characteristics of the hazard of concern, the vehicle of human exposure, and host characteristics such as human susceptibility to illness. *Exposure Assessment* describes consumer exposure to SE from shell eggs and to *Salmonella* spp. from egg products. It estimates the prevalence and level of SE in shell eggs produced on the farm and translates that to the level of SE in shell eggs consumed directly or as an ingredient in a meal. This translation involves considering the change in the level of SE in shell eggs during distribution, storage, and preparation of the eggs as part of a meal. The effects of shell egg handling and pasteurization are also evaluated. Similarly, the prevalence and level of *Salmonella* spp. in egg products before pasteurization are estimated and translated the level of *Salmonella* spp. in egg products consumed directly or as an ingredient in a meal. The output of the *Exposure Assessment* is the prevalence and level of SE in shell eggs or *Salmonella* spp. in egg products that consumers are exposed to as a function of pasteurization and refrigeration of shell eggs during distribution from farm to processor. *Hazard Characterization* estimates the likelihood of illness based on the levels of SE or *Salmonella* spp. in a serving of food eaten. These estimates are based on the aforementioned *Salmonella* dose-response relationship developed by FAO/WHO.[20] *Risk Characterization* estimates illnesses, hospitalizations, and deaths on a per-serving and per annum basis. Answers are provided to the four specific risk management questions discussed above. A

sensitivity analysis is included to identify areas to consider in reviewing and refining mitigation strategies and to identify important data gaps and key uncertainties in the assessments.

Rationale for Focusing on SE in Shell Eggs vs. *Salmonella* spp. in Egg Products

FSIS risk managers are developing performance standards for *Salmonella* in eggs and egg products. Although these risk assessments focus on *Salmonella* in egg products, it specifically considers SE in shell eggs. The reason for this difference is illustrated in the schematic below. Most cases of foodborne salmonellosis in the U.S. are associated with the consumption of shell eggs. The predominant *Salmonella* serotype in shell eggs is SE, which is transferred from infected hens before the egg is laid. Because egg products comprise whole or parts of eggs, they may also contain SE. In addition, however, contaminated egg products include a variety of other *Salmonella* serotypes,[15] partly because *Salmonella* on the egg shell, equipment, and other environmental sources may contribute to contamination. The following schematic illustrates the connection between foodborne salmonellosis and shell eggs and a potential connection to egg products, including the difference in hazards for each.



AUDIENCE AND STRUCTURE OF THE REPORT

Risk managers are the primary audience of this report. Its primary purpose is to answer specific risk management questions. Its secondary audience is the general scientific community. The report's chapters follow the generally accepted structure for microbiological risk assessments. The report includes annexes to provide in-depth information on all aspects of data analysis used in the risk assessments.

SUMMARY

Foodborne salmonellosis remains a public health problem in the U.S. Industry and consumer groups have requested development of science-based performance standards for storage and handling of eggs from farm to processor and for pasteurization in processing shell eggs and egg products. The risk assessments described here provide the scientific basis for developing egg handling and pasteurization performance standards for shell eggs and egg products.

REFERENCES

1. Centers for Disease Control and Prevention. *Salmonella* surveillance: Annual summary, 1996. U.S. Department of Health and Human Services. Atlanta. 1997.

2. Centers for Disease Control and Prevention. *Salmonella* surveillance: Annual summary, 1997. U.S. Department of Health and Human Services. Atlanta. 1998.

3. Centers for Disease Control and Prevention. *Salmonella* surveillance: Annual summary, 1998. U.S. Department of Health and Human Services. Atlanta. 1999.

4. Food Safety and Inspection Service/Food and Drug Administration. Egg safety action plan. Available at http://www.foodsafety.gov/~fsg/cegs.html. 1999.

5. Food Safety and Inspection Service. Pathogen reduction; hazard analysis and critical control point (HACCP) system. Final Rule. Fed Regist 1996;61:38806-989.

6. Food Safety and Inspection Service/Food and Drug Administration. *Salmonella* Enteritidis risk assessment. Shell eggs and egg products. Final Report. Available at http://www.fsis.usda.gov/ophs/index.htm. 1998.

7. Mead PS, Slutsker L, Dietz V, McCaig LF, Bresee JS, Shapiro C, et al. Food-related illness and death in the United States. Emerg Infect Dis 1999 Sep-1999 Oct;5(5):607-25.

8. St Louis ME, Morse DL, Potter ME, DeMelfi TM, Guzewich JJ, Tauxe RV, et al. The emergence of grade A eggs as a major source of *Salmonella enteritidis* infections. New implications for the control of salmonellosis. JAMA 1988 Apr;259(14):2103-7.

9. Hedberg CW, David MJ, White KE, MacDonald KL, Osterholm MT. Role of egg consumption in sporadic *Salmonella enteritidis* and *Salmonella typhimurium* infections in Minnesota. J Infect Dis 1993 Jan;167(1):107-11.

10. Centers for Disease Control and Prevention. From the Centers for Disease Control and Prevention. Outbreaks of *Salmonella* serotype Enteritidis infection associated with consumption of raw shell eggs--United States, 1994-1995. JAMA 1996 Oct;276(13):1017-9.

11. Centers for Disease Control and Prevention. Incidence of foodborne illnesses: preliminary data from the Foodborne Diseases Active Surveillance Network (FoodNet)--United States, 1998. MMWR Morb Mortal Wkly Rep 1999 Mar;48(9):189-94.

12. Centers for Disease Control and Prevention. Summary of notifiable diseases, United States, 1999. MMWR Morb Mortal Wkly Rep 2001;48:1-104.

13. Centers for Disease Control and Prevention. Appendix B: Guidelines for confirmation of foodborne-disease outbreaks. MMWR Morb Mortal Wkly Rep 2000;49:54-62.

14. McNeil MM, Sweat LB, Carter SL Jr, Watson CB, Holloway JT, Manning R, et al. A

Mexican restaurant-associated outbreak of *Salmonella* Enteritidis type 34 infections traced to a contaminated egg farm. Epidemiol Infect 1999 Apr;122(2):209-15.

15. Cook L, Levine P, Oatman N. *Salmonella* spp. and *Listeria monocytogenes* in raw liquid egg products in federally inspected processing establishments. 2004. International Association for Food Protection General Meeting. Phoenix.

16. Gast RK, Holt PS. Deposition of phage type 4 and 13a *Salmonella enteritidis* strains in the yolk and albumen of eggs laid by experimentally infected hens. Avian Dis 2000 Jul-2000 Sep;44(3):706-10.

17. Gast RK, Holt PS. Influence of the level and location of contamination on the multiplication of *Salmonella enteritidis* at different storage temperatures in experimentally inoculated eggs. Poult Sci 2000 Apr;79(4):559-63.

18. Gast RK, Holt PS. Assessing the frequency and consequences of *Salmonella enteritidis* deposition on the egg yolk membrane. Poult Sci 2001 Jul;80(7):997-1002.

19. United Egg Producers. Lethality data for liquid egg products. Provided to the Risk Assessment Center by Food Safety and Inspection Service. March 26, 2001.

20. Food and Agricultural Organization of the United Nations/World Health Organization. Risk assessments of *Salmonella* in eggs and broiler chickens. Rome: FAO/WHO, 2002.