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

FSIS

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# 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 to 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.

# 1 Introduction

Foodborne *Salmonella* are estimated to cause approximately 1.3 million illnesses, 15,000 hospitalizations, and 500 deaths each year in the U.S.[1] About 300,000 of these illnesses may be attributable to *Salmonella* Enteritidis (SE).[1] Most, perhaps as many as 80%, of SE infections are associated with eggs.[2;3] Federal and state agencies work with industry and consumers to implement interventions along the farm-to-table chain to mitigate the risk of illness from SE in eggs. These include good agricultural practices to curtail the production of SE-contaminated eggs, refrigeration during transport to limit SE growth in eggs, and consumer education efforts aimed at cooking eggs fully. These efforts likely contributed to the decline in SE infections reported to the Centers for Disease Control and Prevention (CDC) from 1996 to 1998.[4-6]

To target resources to achieve greater reductions in egg-related salmonellosis cases, 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.[7] Results of the assessment indicated multiple interventions were necessary to reduce substantially risk of illnesses from SE. These results were the basis for a comprehensive and coordinated federal and state action plan — the Egg Safety Action Plan[8] — to address the safety of shell eggs and egg products along the farm-to-table chain.

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."[8] Such standards, known as "performance standards," would complement the recently implemented 1996 landmark rule, Pathogen Reduction/Hazard Analysis and Critical Control Point Systems (HACCP), by setting guidelines for industry to ensure the safety of their products.[9]

**Shell Eggs vs. Egg Products**

Shell eggs are those typically sold by the dozen and are the ones with which consumers are most familiar. Eggs that are cracked or do not meet other quality criteria are shipped from the processor to a "breaker" plant where they are broken into large vats of liquid whole eggs, yolks, or whites. These "egg products" are pasteurized and shipped primarily for use by commercial establishments. Alternatively, they are further processed into products such as cakes, ice cream, and the like. A small fraction of these egg products is sold in grocery stores; an example is cholesterol-free liquid egg product.

Performance standards are a move away from command-and-control regulations and towards risk-based public health guidelines. They will allow industry greater flexibility in controlling *Salmonella* contamination during egg and egg product manufacture. Selection of performance standards is based on the impact they have in reducing the risk of illness from *Salmonella* in eggs and egg products, as determined by risk assessment. Although the 1998 SE risk assessment was useful to risk managers in developing the Egg Safety Action Plan, it was not 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. This was done 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.

## *SALMONELLA* AND EGG SAFETY

About 95% of *Salmonella* infections in humans are foodborne.[1] In the mid-1980s, intact eggs were identified as a source of *Salmonella* infections. The predominant *Salmonella* serotype 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.[2;10-13]

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 for 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 consumer's health and the more *Salmonella* ingested, the greater the likelihood for serious illness and death. About two percent of those who recover from salmonellosis develop recurring joint pain and arthritis.

**SE-Contaminated Shell Eggs**

Not all flocks of laying hens in the U.S. are contaminated with SE. It has been estimated that of the 47 billion eggs consumed annually as shell eggs, 2.3 million are contaminated with SE.[14] Based on the FDA Food Safety Survey conducted in 1993, 53% of a nationally representative sample of 1,620 respondents reported ever eating foods containing raw eggs. Many persons may eat raw or undercooked eggs because they are unaware that eggs are a potential source of *Salmonella* and that certain foods (e.g., homemade ice cream, cookie batter, Caesar salad, and hollandaise sauce) contain raw eggs.

The disease itself is notifiable, 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. This is the 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%,[15] – a decline attributed to improved egg production controls and consumer behavior practices – the estimated number of SE infections remains high and recent data indicate the decline in reported SE infections may be reversing.[16;17]

In addition to passive surveillance for sporadic infections (single cases) of salmonellosis, the CDC maintains surveillance of outbreaks of infection from SE. A foodborne-disease outbreak is an incident in which *two or more* persons experience a similar illness resulting from ingesting a common food.[2;16] 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.[18]

## 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.[8] As part of this strategy, FSIS completed implementation of the rule on Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) systems.[9] 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: (i) amend the egg and egg products inspection regulations by converting into performance standards regulations governing egg product processing (9 CFR 590.570); (ii) add new performance standards for production of ready-to-eat shell eggs, also known as "in-shell" pasteurized eggs (9 CFR 590.575); and (iii) 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 for industry development of science-based controls to mitigate microbiological hazards in foods. Performance standards set by FSIS 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 was one bacterium, the probability of it being killed would be 99%.

### 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) was published in 1998.[7] The SERA is a quantitative farm-to-table risk assessment of SE in shell eggs and egg products. 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 farm-to-table continuum were necessary to reduce substantially the risk of illness from eggborne SE.

Since 1998, data have become available to produce risk assessments more useful for developing performance standards for SE in eggs and *Salmonella* spp. in egg products. First, FSIS conducted a national baseline survey to measure *Salmonella* spp. levels in liquid egg products.[19] Second, recent studies clarified scientific issues associated with SE contamination in egg yolk.[20-22] Third, the United Egg Board sponsored studies on lethality kinetics of *Salmonella* spp. in various liquid egg products.[23] Fourth, the Food and Agricultural Organization/World Health Organization (FAO/WHO) developed a dose-response model for *Salmonella* spp.[24]

## 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 predict the number of illnesses due to *Salmonella*. That information can be estimated by data from the CDC. Instead, these risk assessments were designed to evaluate the effectiveness of various performance standards for reducing illnesses from salmonellae in eggs.

These assessments are intended to answer the following risk management questions:

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

- 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 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?

To answer these risk management questions, the risk assessors were directed to use the risk assessment 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. is 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 that are most effective 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 which shell eggs are pasteurized is important. These assessments consider multiple egg-handling and storage scenarios for eggs – the cooling of eggs commences at 24 and 36 hours for eggs that are 1 to 60 days old and stored at temperatures anywhere from 45 to 60$^{o}$F (7.2 to 15.6°C) – followed by refrigeration at 45$^{o}$F (7.2°C) 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 and mitigate the risk of illness.

- **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 the production of SE-contaminated eggs and the subsequent risk of illness. 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 shows the major components of the assessments.

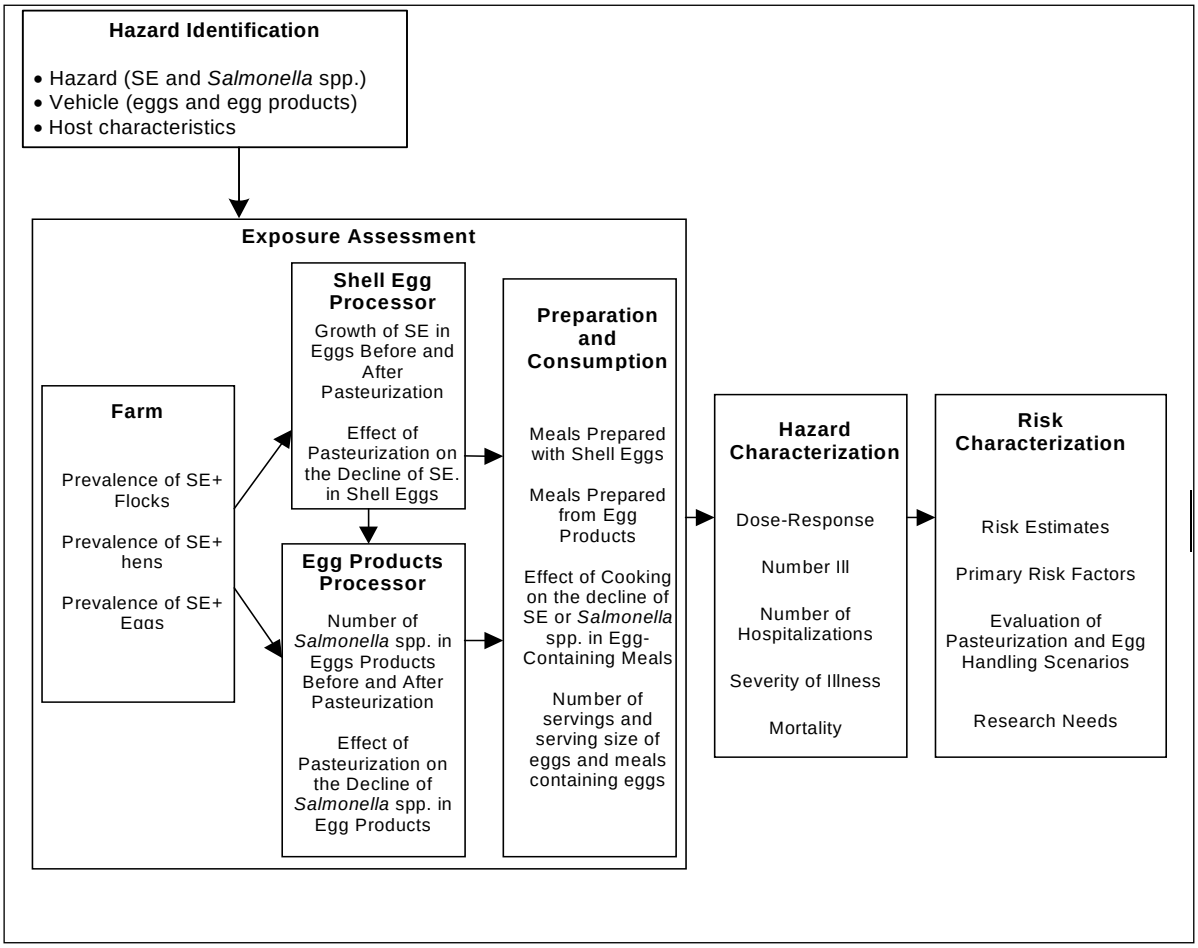



FIGURE 1-1 RISK ASSESSMENT STRUCTURE FOR SE IN SHELL EGGS AND *SALMONELLA* SPP. IN EGG PRODUCTS.

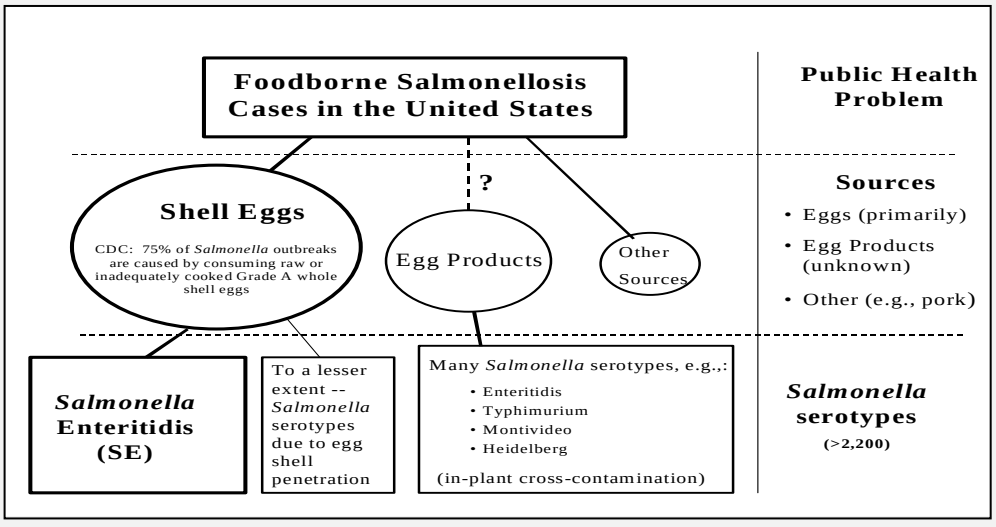
*Hazard Identification* discusses the characteristics of the hazard of concern, the vehicle of human exposure, and host characteristics such as human susceptibility to illness. *Exposure Assessment* describes consumer exposure to SE from shell eggs and to *Salmonella* spp. from egg products. It estimates 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 used to estimate the number 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.[24] *Risk Characterization* estimates illnesses, hospitalizations, and deaths on a per serving and per annum basis. Answers are provided to the five specific risk management questions discussed above. A sensitivity analysis is included to identify areas to consider in reviewing and refining mitigation strategies; it identifies important data gaps and key uncertainties in the assessments.

Scientific data are the foundation of risk assessment. The assessments presented here include data available through August 2002. They provide a structured framework to integrate data into predictive models to inform decision makers. Describing risk rarely involves the certainty of direct, measurable observations relevant to human health; it involves statistical estimation and prediction, as well as transparent expressions of uncertainty.

**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. 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,[19] 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 for 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 these risk assessments.

## SUMMARY


- Industry and consumer groups 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 provide the scientific basis for selecting egg handling and pasteurization performance standards for shell eggs and egg products.

- The risk assessments were designed to evaluate the effectiveness of various performance standards for reducing illnesses from SE in shell eggs and *Salmonella* spp. in liquid egg products.

# 2 Hazard Identification

These risk assessments focus on *Salmonella* Enteritidis (SE) in shell eggs and *Salmonella* spp. in egg products. Eggs are vehicles of *Salmonella*. Most human illnesses associated with shell egg consumption are from SE. Therefore, our discussions pertaining to shell eggs focus on SE. Because several *Salmonella* serotypes have been isolated from egg products,[19] both before and after pasteurization, our discussions related to liquid egg products focus more broadly on *Salmonella* spp.

## THE PATHOGEN

*Salmonella* cause illness in humans and animals. Most *Salmonella* serotypes are naturally occurring in food animals. They may be transmitted to humans upon consumption of contaminated foods at slaughter. Food may also become contaminated with *Salmonella* by unwashed hands of infected food handlers.[25]

Virulence factors may have special significance in the ability of *Salmonella* to contaminate and survive in chicken eggs. Siderophores, which chelate iron, are necessary for the accumulation of sufficient environmental iron to allow growth of *Salmonella* in some environments. The ability to accumulate iron is especially important in the albumen of eggs. A number of virulence factors identified in non-typhoid *Salmonella* may be important determinants of the likelihood of disease in humans. To cause illness, *Salmonella* must survive the pH of the stomach and, after passage into the intestine, must attach to and invade intestinal epithelia and/or Peyer's patches.[26] Specific fimbriae, chromosome-encoded bacterial surface adhesions, hemagglutinins, and epithelial cell induction of bacterial polypeptides can promote colonization and adhesion.[27;28] Other factors, such as cytotoxins and diarrheagenic enterotoxins,[29] affect the ability of *Salmonella* to cause disease.

## Epidemiology of *Salmonella*

*Salmonella* is estimated to cause 1.4 million illnesses, 31,000 hospitalizations, and 1,100 deaths each year in the U.S.[1] Costs of foodborne salmonellosis may be upwards of $2 billion annually.[30] The number of reported *Salmonella* clinical isolates in the U.S. increased considerably from 1976 to 1988, declined from 1988 to 1992, and fluctuated between 30,000 and 40,000 from 1993 to 2000 (Figure 2-1).

SE and *S.* Typhimurium have been the most common *Salmonella* serotypes associated with human illness in the U.S.[4-6;28;31-52] (Figure 2-1), accounting for half of all human salmonellosis cases in the U.S.[52] During the late 1970s and early 80s, SE emerged as the leading causes of salmonellosis in the U.S. Between 1985 and 1998, 796 outbreaks caused by SE were reported to the CDC. A total of 28,689 cases of illness were associated with these outbreaks, resulting in 2,839 hospitalizations and 79 deaths.[13] SE was the most common serotype reported to CDC in four of the fifteen years between 1987 and 2001. In every other year, SE has been the second-most commonly reported serotype.

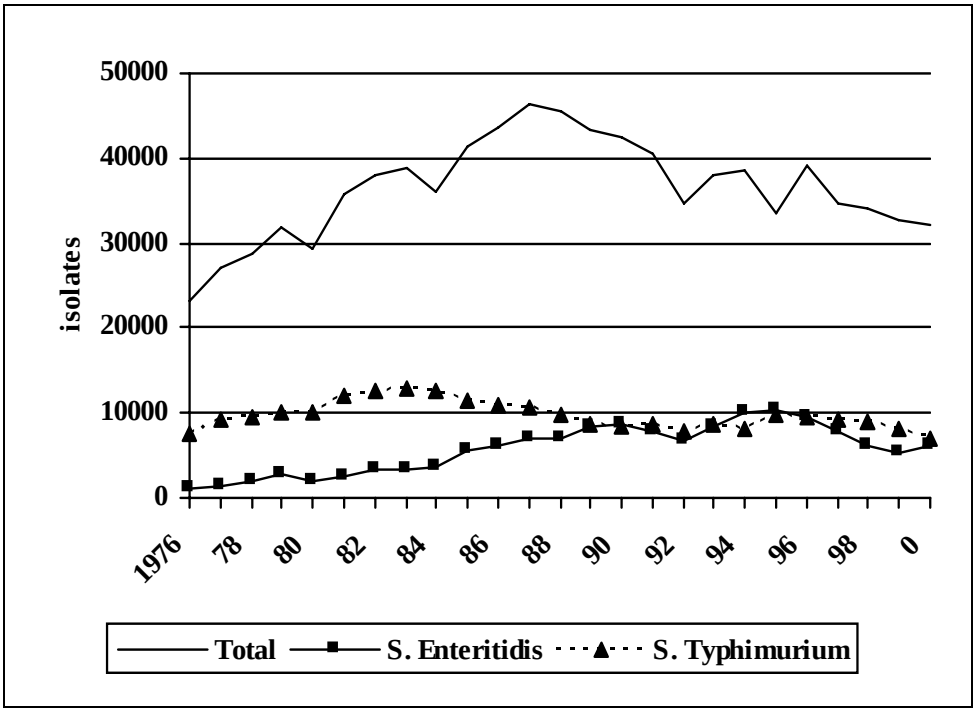



FIGURE 2-1 *SALMONELLA* ISOLATES FROM HUMAN SOURCES BY SEROTYPE AND YEAR, 1976-2000.[4-6;31-52]

The rate of clinical SE isolates reported to CDC increased from 0.6 per 100,000 in 1976 to 3.6 per 100,000 in 1996.[13] From 1996 to 1998 the rate of culture-confirmed SE cases declined to 2.2 per 100,000; this decline was partially reversed by an increased incidence in 2000 and 2001.[25]

From the mid-1970s to the late 1980s, most SE outbreaks in the U.S. occurred in the Northeast, where they increased more than six-fold.[53;54] *Salmonella* isolates from the Mid Atlantic region declined from 1989 through 1999 (Figure 2-2), while in the Pacific region, SE isolates increased more than three-fold between 1990 and 1994.[13]

A U.S. Department of Agriculture (USDA) survey of spent hens at slaughter and unpasteurized liquid eggs at breaker plants revealed an overall increase in the prevalence of SE isolates in most regions of the U.S. between 1991 and 1995.[55] These data were consistent with human isolate data in that neither poultry nor human data showed a decline in SE between 1991 and 1995. However, there was no apparent correlation between SE in humans, layer flocks, and unpasteurized liquid eggs across regional areas of the U.S.[55]

The increase in the Pacific region was concurrent with the emergence of SE phage type 4 (PT4) in poultry flocks and humans in the western U.S.[56] SE PT4, the predominant SE phage type in other parts of the world, emerged in the egg industry in the western part of the U.S. in 1993, concurrent with a sharp increase in the number of sporadic human SE PT4 isolates in California and Utah.[56] SE PT4 continues to be an important cause of sporadic illness, especially in the Western U.S. Of the 30 outbreaks for which an isolate was submitted to CDC for phage typing in 1998, 15 (50%) were SE PT4. Of these, 11 occurred in California, two in Utah, and one each in Hawaii and Wyoming.

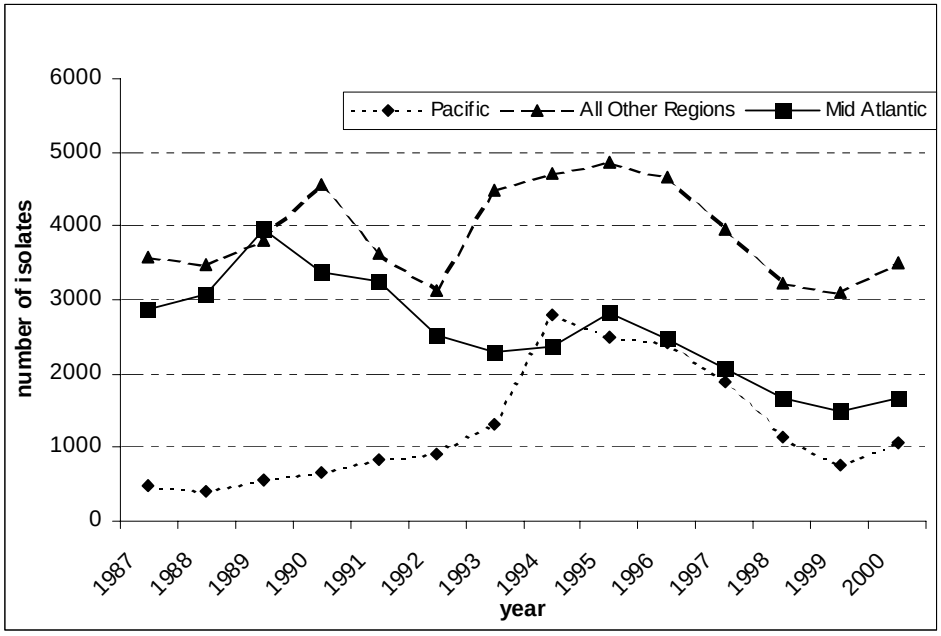



FIGURE 2-2 *SALMONELLA* ENTERITIDIS ISOLATES REPORTED TO THE CDC BY REGION FROM 1987-2000.[31-34 4-6;35-52]

Temperature is a major factor influencing the growth of *Salmonella* (Table 2-1). Growth for most *Salmonella* and is inhibited or slowed considerably at temperatures below 15ºC and does not occur below 7ºC,[57;58] although some strains have been reported to grow below 5ºC.[59] *Salmonella* are susceptible to heat and killed at temperatures ≥55°C.[59] Ordinary cooking is sufficient to destroy *Salmonella*, provided sufficient time.[60]

TABLE 2-1 EFFECT OF PH AND TEMPERATURE ON GROWTH OF *SALMONELLA*.

| Condition | Minimum | Optimum | Maximum |
|---|---|---|---|
| Temperature (ºC) | 5.2 | 35–43 | 46.2 |
| pH | 3.8 | 7–7.5 | 9.5 |

## Transmission of *Salmonella* to humans

Most human infections with *Salmonella* occur from ingesting contaminated food. SE is transmitted to eggs through two routes: trans-ovarian (vertical) transmission and trans-shell (horizontal) transmission. In the former, SE is introduced to the egg from infected ovaries or oviduct tissue before the hen lays the egg. This type of transmission is the primary route by which eggs are contaminated with SE.[61] Experimental studies suggest *Salmonella* interact with a cellular component of the preovulatory follicle in chickens.[62] The possibility of SE reaching the yolk contents through the oviduct and ultimately contaminating the albumin cannot, however, be ruled out. *Salmonella* may also penetrate the eggshell.[63-65] This secondary route of contamination can result from fecal contamination of the eggshell.

An individual consumes on average 230 eggs per year, not including eggs consumed as part of cake mixes, noodles, etc. The value of shell eggs is approximately $4 billion per year. [66] Although domestic egg consumption is largely stable, international trade in egg products is small, but growing rapidly. The U.S. has approximately 300 million laying hens, with an estimated value of nearly $1 billion.[66] Egg production increasingly occurs on farms with over 100,000 hens. According to the United Egg Producers' (UEP),[67] egg production farms have grown in size, and approximately 94% of U.S. eggs are produced on just over 300 farms. These large farms are known as "in-line facilities" because egg laying, cleaning, sorting, packing, and distribution occur in a streamlined process within one facility. However, many eggs are produced in traditional or "off-line facilities." In these operations, laying farms store and then ship their daily egg production to an off-site facility for processing, packing, and distribution. Although the exact processing steps vary from facility to facility, a general outline includes the following sequential steps: egg washing, rinsing, and sanitizing; drying; candling; sorting and grading; packing and palletizing; and storing in a cooler before shipping.[68] Chapter 3 further discusses these husbandry and production practices, as well as the incidence of flock colonization with *Salmonella* and subsequent egg contamination.

Because of *Salmonella* thermal susceptibility, foodborne SE infection is frequently associated with consuming raw eggs and foods containing raw eggs, such as homemade eggnog, cookie batter, tiramisu, pasta, homemade ice cream, mayonnaise, Caesar salad dressing, and Hollandaise sauce. Approximately 80% of vehicle-confirmed SE outbreaks have been associated with grade A shell eggs[69] or egg-containing foods[2] (Table 2-2). Between 1993 and 1997, an average of 80% of vehicle-confirmed outbreaks was egg-associated, with a range of 68% to 95%. In 1998, of the 18 outbreaks for which a vehicle could be confirmed, 15 (83%) were associated with eggs.[6]

TABLE 2-2 FOOD VEHICLES IN 35 SE OUTBREAKS OF KNOWN CAUSE IN THE NORTHEASTERN U.S., JANUARY 1985 TO MAY 1987.

| Food Vehicle | Number of Outbreaks |
|---|---|
| Egg Containing | |
| Scrambled or fried eggs and omelets | 7 |
| Hollandaise sauce and eggs benedict | 4 |
| Commercial frozen pasta products with raw egg-cheese dishes | 3 |
| Homemade pasta dishes | 3 |
| Blenderized meals | 2 |
| Stuffing for seafood dishes | 2 |
| Rice balls and meatballs made with egg | 2 |
| Eggnog | 1 |
| Potato-egg salad | 1 |
| Cake fillings | 1 |
| Caesar salad dressing (with raw egg) | 1 |
| Total—egg-containing foods | 27 |
| Not Egg Containing (or unknown) | |
| Roast beef and hamburger | 3 |
| Stuffed potatoes | 2 |
| Ricotta cannoli | 1 |
| Lettuce and tomato | 1 |
| Gravy and succotash | 1 |
| Total—Not egg containing or unknown foods | 8 |

Source: St. Louis et al.[2]

Outbreaks caused by *Salmonella* occur most frequently in summer[25] (Figure 2-3). Similar seasonal patterns have been documented for SE outbreaks[54] and for *Salmonella*-positive spent hens at slaughter.[55] Warm temperatures provide an environment in which *Salmonella* can grow during the processes of production, transport, and storage.[60]

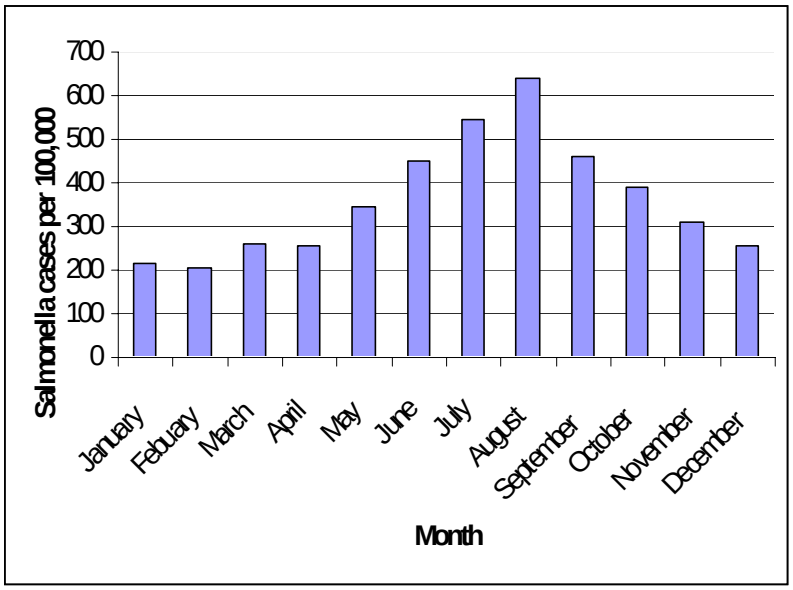



FIGURE 2-3 *SALMONELLA* CASES PER 100,000 BY MONTH. SOURCE: FOODNET 2000. ADVERSE HEALTH OUTCOMES ASSOCIATED WITH *SALMONELLA* SPP.

## Disease Characteristics

Salmonellosis is characterized by diarrhea, fever, abdominal pain or cramps, vomiting, headache, and nausea. The incubation period ranges from 8 to 72 hours with symptoms lasting up to a week. The severity of *Salmonella* infections varies. While most are self-limiting, some are fatal. The national average case-fatality rate among reported salmonellosis cases between 1996 and 1997 was 0.0078.[1] Fatalities occur most often in infants, the elderly, and the immunocompromised. Between 1985 and 1991, 54 SE outbreaks occurred in hospitals or nursing homes. These outbreaks accounted for 90% of all *Salmonella*-associated deaths, but only 12% of all cases, during that time. In 1995, five deaths occurred as a result of SE infection, four (80%) of which occurred in nursing homes.[50] In 1998, three (6%) of the 45 SE outbreaks occurred in nursing homes.[6]

The age of patients with *Salmonella* infections follows a bimodal distribution, with most infections occurring in those at the extremes of age. The highest number of cases is seen among children[70] (Figure 2-4). The association between salmonellosis and age, however, may be due to reporting bias because children and the elderly with diarrhea may be more frequently cultured than other age groups.[71] In addition, there may be confounding factors associated with behavioral characteristics of children.[72]

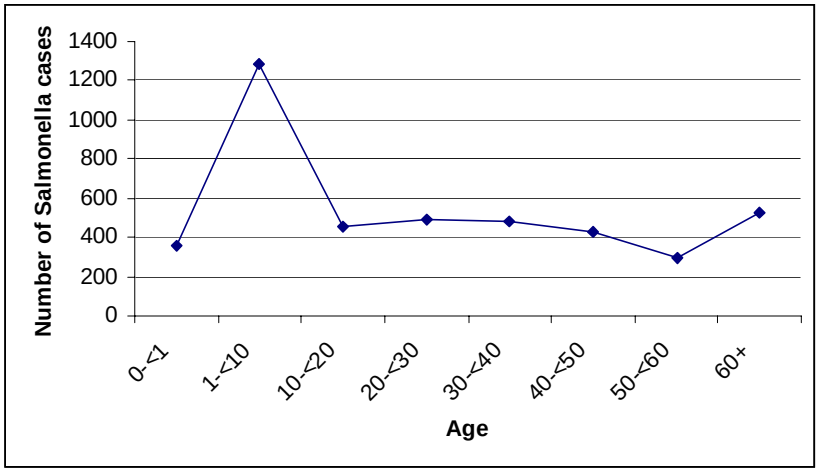



FIGURE 2-4 INCIDENCE OF *SALMONELLA* INFECTIONS BY AGE GROUP. SOURCE: FOODNET SITES 2000.

Antimicrobial resistance may affect severity of illness from *Salmonella*. Patients infected with antimicrobial-resistant *Salmonella* appear likely to be hospitalized than those infected with antimicrobial-susceptible Salmonella.[73] Duration of illness and hospitalization also appears positively correlated with antimicrobial-resistant *Salmonella* infections. The National Antimicrobial Resistance Monitoring System provides susceptibility information on *Salmonella* from human and animal populations. A summary of susceptibility testing of *Salmonella* recovered from food animals[74] is shown in Table 2-3. Increasing evidence indicates *Salmonella* are developing resistance to multiple antimicrobials, including frontline drugs such as ciprofloxacin and ceftriaxone.[75-77]

TABLE 2-3 ANTIMICROBIAL SUSCEPTIBILITY OF *SALMONELLA* RECOVERED FROM FOOD ANIMALS, NATIONAL ANTIMICROBIAL RESISTANCE MONITORING SYSTEM (NARMS), 1999.

| Antimicrobial | % Susceptible |
|---|---|
| Amikacin | >99.9 |
| Amoxicillin/clavulanic acid | 88.4 |
| Ampicillin | 81.9 |
| Apramycin | 98.9 |
| Ceftiofur | 96.0 |
| Ceftriaxone | 97.7 |
| Cephalothin | 92.3 |
| Chloramphenicol | 90.1 |
| Ciprofloxacin | 100.0 |
| Gentamicin | 90.8 |
| Kanamycin | 87.7 |
| Nalidixic Acid | 98.8 |
| Streptomycin | 69.0 |
| Sulfamethoxazole | 71.1 |
| Tetracycline | 64.8 |
| Trimethoprim/sulfa | 96.6 |

Source: Dargatz et al.[74]

## SUMMARY

*Salmonella* in eggs constitute a public health threat. The hazards of interest in this risk assessment are SE in shell eggs and *Salmonella* spp. in egg products. SE may colonize the ovaries of hens and contaminate the internal contents of eggs. The shell eggs risk assessment focuses on this serotype. A number of *Salmonella* spp. have been found in egg products, but no cases of human illness from *Salmonella* in egg products have been reported to CDC since the Egg Production Inspection Act was passed in early 1970.

# 3 Exposure Assessment

## EXPOSURE ASSESSMENT OF *SALMONELLA* ENTERITIDIS IN SHELL EGGS

### Introduction

*Salmonella* Enteritidis (SE) is one of few *Salmonella* serotypes known to colonize the reproductive tissues of hens and, consequently, the eggs they lay. Once inside an egg, SE survives cleaning and disinfecting of the shell surface. Furthermore, SE can multiply within the egg depending on how the egg is handled between the times it is laid and consumed. The first part of this exposure assessment estimates the frequency with which people are exposed to different doses of SE in servings prepared from eggs in the shell. The second part estimates exposures to all *Salmonella* spp. in servings of pasteurized eggs products.

The amount of SE present when an egg is consumed depends on whether SE were present when the egg was laid and, if so, how they grew (or died off) during handling. This exposure assessment follows eggs from the farm to the pasteurizer and from the pasteurizer to consumption. Figure 3-1 shows the most important components of this process. Pasteurization has special prominence in this assessment because it is *the principal risk management measure* being evaluated by this risk assessment.

The occurrence of SE within an egg depends on whether the hen that laid it was infected with SE. Although SE-contaminated eggs only come from infected hens, not all eggs produced by infected hens are SE contaminated. Furthermore, infected hens are only found on farms in which SE is present, and on such farms, not all hens are infected. Thus, for an egg to be contaminated with SE three conditions must exist: SE must be present on the farm, SE must infect one or more hens, and SE-infected hens must be susceptible to producing SE-contaminated eggs.

If an egg is laid with SE inside, these bacteria may die, remain dormant, or multiply. Multiplication depends primarily on time and temperature of storage. Higher temperatures (up to 37°C) favor SE growth, and longer storage times at temperatures permitting growth favor greater amounts of SE growth. Thus, the interaction of time and temperature determines how much SE growth occurs inside an egg.

On farms, eggs are typically stored for a short time in the laying house. The laying house holds all the hens of the flock; eggs are stored there from the time they are laid until they can be gathered, either mechanically or by hand. After the egg is gathered, it is stored in a warehouse on the farm for a variable period whereupon it may be either processed at the farm or trucked to a processing facility and stored in another warehouse.

Processing involves candling of eggs to detect defects and washing the shell; it may or may not include pasteurization and packaging of eggs into cartons. If the eggs are pasteurized, they are done so just before packaging. Pasteurization of shell eggs involves submersing the eggs in hot water for sufficient time to destroy SE, but not so long to cause changes to the liquid inside the egg. Consequently, a properly pasteurized shell egg appears grossly similar to an unpasteurized egg.

After processing, further growth of SE within an egg is possible, even in pasteurized eggs. Either some SE may survive pasteurization and grow or the egg may not be pasteurized and the SE inside continue to grow.

An egg is shipped to retailers or wholesalers to be purchased for food. The egg may be stored for varying times and temperatures before shipment, during shipment, and after shipment. For example, an egg may stay on a grocery shelf for several days before it is purchased. Furthermore, the egg will likely be stored for some time in a consumer's refrigerator at home before it is consumed. All of these steps could present additional opportunities for SE growth.

Eggs are served in a wide array of foods, and a single egg may contribute to a meal that serves many people. During preparation of a meal, SE within an egg dish seems likely to be distributed homogeneously within the meal; therefore, when multiple servings from a single egg are simulated, there are multiple exposures per egg, albeit with fewer SE per serving than what were in the original egg.

Most meals prepared with eggs are typically cooked prior to consumption. Cooking can kill some, most, or all of the SE in a serving. Nevertheless, cooking of meals containing eggs is highly variable, and some meals, such as eggnog, are not heated before consumption.

This exposure assessment, and the risk characterization that follows in Chapter 5, will help decision makers determine the extent to which different factors influence human exposures to SE and subsequent illnesses, based on data and assumptions that are inputs to the risk assessment model. Specifically, the risk characterization evaluates the effectiveness of pasteurization in reducing exposures of consumers to SE from shell eggs. Pasteurization of shell eggs is not currently a common practice in the egg industry. FSIS wants to establish standards for pasteurizing shell eggs to ensure a consistent and safe product for consumers purchasing pasteurized eggs. Greater consumer demand for pasteurized shell eggs may consequently reduce the occurrence of human illness associated with SE in eggs.

The exposure assessment will help identify combinations of time and temperature of storage before pasteurization that result in no or very limited growth of SE within contaminated eggs. Such conditions would improve the effectiveness of pasteurization by minimizing the initial bacterial levels during pre-pasteurization storage. A decision could be made to require eggs to be stored according to specific guidelines before egg pasteurization. Alternatively, if storage conditions allow for substantial growth of SE within eggs, the effectiveness of the pasteurization procedure itself should be adjusted to kill more bacteria.

A quantitative model has been developed to represent the most important elements of the process described above. The model estimates the number of SE at various points in time as they grow in an individual egg, from the times it is laid until it is consumed. The basic mathematical

structure of that model is presented initially in the next section. Additional details will be found in the remainder of this chapter, and a complete development of the concepts presented here can be found in the various supporting annexes. Figure 3-1 shows the farm-to-table progression of eggs as modeled in this risk assessment.

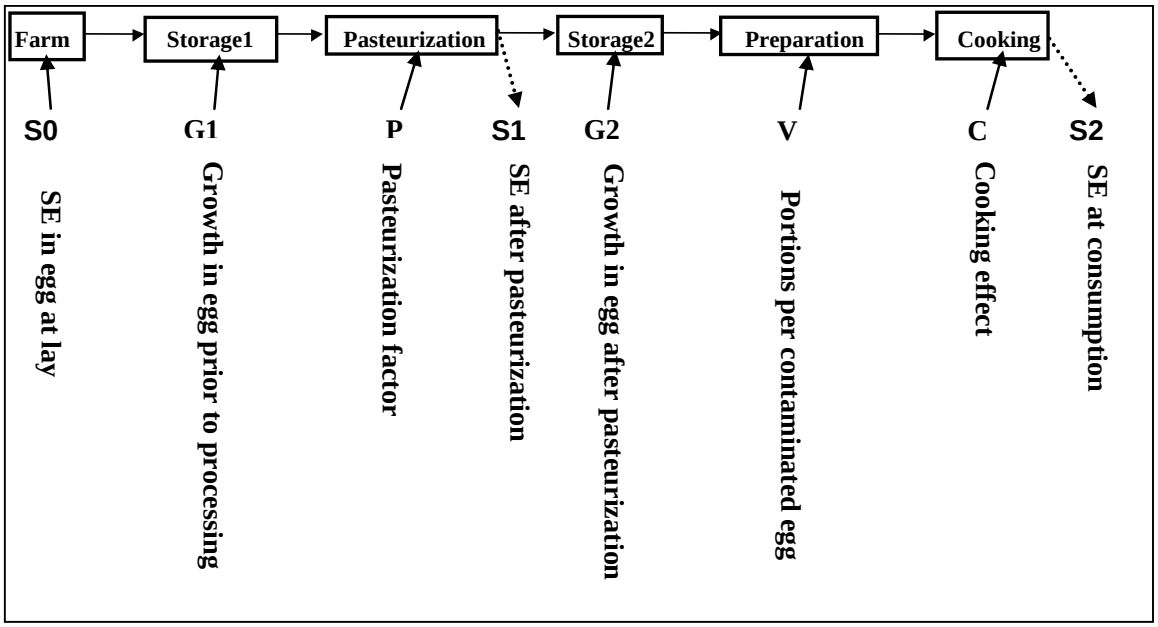



FIGURE 3-1 FARM-TO-TABLE PROGRESSION OF EGGS IN THE EXPOSURE ASSESSMENT.

## Mathematical Overview of the Shell Egg Exposure Assessment Model

Four equations summarize the SE in shell eggs model. Although this section does not follow the same chronological progression shown in Figure 3-1, it serves to introduce all the key variables and inputs addressed in this risk assessment. Subsequent sections in this part of the risk assessment will describe these inputs and provide the chronological development of the process. This model overview is presented at the outset to provide a better understanding of how the farm and first storage steps, etc. fit into the overall exposure assessment. The model presented in this chapter begins by estimating the number of SE that remains after pasteurization (Equation 3.1). Equation 3.2 estimates the dose of SE consumed by an individual. Illness is not necessarily the outcome from consuming SE. Therefore, the frequency that illness occurs for a given dose in a serving is estimated using the dose-response relationship developed in Chapter 4 (Equation 3.3). Finally, this frequency of illness per serving is converted to a frequency of illness per egg to account for some eggs that contribute to multiple servings (Equation 3.4). Each of these relationships is developed below.

### *Bacteria after Pasteurization*

The number of SE in an egg after it is pasteurized depends on the number of SE in the egg at lay, growth of these bacteria before processing, and the effectiveness of pasteurization in reducing SE numbers within contaminated eggs (Equation 3.1).

$$S_1 = S_0 \text{ x } G_1 \text{ x } P \qquad (3.1)$$

where

$S_1$ = the number of SE cells per egg after pasteurization

$S_0$ = the number of SE cells per egg at the time of lay

$G_1$ = the relative growth of SE from the time of lay to the time of pasteurization. This value generally ranges over the [1, $10^{10}$] interval where 1 means that no growth occurred and $10^{10}$ means that one organism in an egg at the time of lay grew to 10 billion organisms at the time of pasteurization.

**Example**

$S_0$ = 134 SE

$G_1$ = 2.6 $\log_{10}$ of growth (a multiplier of $10^{2.6}$ = 398)

$P$ = 5 $\log_{10}$ reduction due to pasteurization (a multiplier of $10^{-5}$ = 0.00001)

$S_1$ = 134 x 398 x 0.00001 = 0.53, which is the estimated number of SE.

Note that there are no units for any of the values except $S_0$ and $S_1$. $G_1$ and $P$ are simply multipliers.

$P$ = the fraction of SE cells that survive pasteurization. This fraction can range over the [0,1] interval where 0 is complete elimination of the bacteria and 1 is complete survival.

Equation 3.1 shows that the number of SE present at the time of lay are allowed to increase until the time of pasteurization. At pasteurization, the total number of bacteria is reduced to the $S_1$ level of contamination by the pasteurization process. Clearly, the determination of these variable values is a critical task of this risk assessment. The values for $S_0$ are estimated using probability distributions to represent the variability in bacteria per egg. The value for $G_1$ is based on the predicted behavior of SE within eggs, which depends on time and temperature probability distributions. The value for $P$ is constant for all eggs and is a selected input for the model. Given that thousands of contaminated eggs were modeled, the output of Equation 3.1 is a distribution of values that capture the variability attending the estimate of this post-pasteurization value.

***Bacteria after Cooking***

The number of SE consumed in a given serving depends on the number of SE in the product after pasteurization ($S_1$ above), the growth of these bacteria after pasteurization, the attenuating effect of cooking, and the number of servings per egg.

$$S_2 = (S_1 \text{ x } G_2 \text{ x } C) / V \qquad (3.2)$$

where $S_1$ is as defined above and

$S_2$ = the number of *Salmonella* cells per serving of an egg meal at the time of consumption. An egg meal can be any meal prepared from shell eggs.

$G_2$ = the relative growth of SE from the time of pasteurization to the time of preparation and cooking. Its values can range as described for $G_1$.

**Example**

$S_1$ = 0.53 SE / egg

$G_2$ = 4 $\log_{10}$ of growth (a multiplier of $10^4$ = 10,000)

$C$ = 0.9 $\log_{10}$ reduction due to cooking (a multiplier of $10^{-0.9}$ = 0.126)

$V$ = 3 servings / egg

$S_2$ = 0.53 x 10,000 x 0.126 / 3 = 222, which is the estimated number of SE per serving.

Note that there are units only for $S_1$ and $V$. $G_2$ and $C$ are multipliers.

$C$ = the fraction of cells that survive cooking. As described for pasteurization, this fraction can range over the [0,1] interval where 0 is complete elimination of the bacteria and 1 is complete survival.

$V$ = the number of portions or servings created from a meal containing an egg.

Equation 3.2 starts with the SE that survive pasteurization and allows them to grow until the egg meal is cooked. This number is then reduced by the effect of cooking, and the resultant surviving number of cells is divided by the number of servings to produce the number of bacteria per serving.

***Frequency of Illness per Serving***

The likelihood of illness per serving is calculated using a dose-response function with the number of SE per serving as its argument.

$$I_S = DR(S_2) \tag{3.3}$$

where

$I_S$ = the frequency of illness resulting from consuming a serving of an egg meal. This frequency can range over the [0,1] interval.

$S_2$ = as defined above.

**Example**
$S_2$ = 222 SE / serving
*DR(222)* = 0.25 likelihood of illness given a dose of 222 SE per serving

Thus, out of 100 individuals experiencing this dose, 25 individuals would become ill.

The function relating the dose to the frequency of illness is discussed at length in the Hazard Characterization chapter. Given a particular dose resulting from a contaminated egg, Equation 3.3 calculates the frequency that the dose would cause illness.

***Illnesses per Egg***

The number of illnesses per egg is simply the frequency of illness per serving times the number of servings per egg.

$$I_E = I_S \text{ x } V \tag{3.4}$$

**Example**
$I_S$ = 0.25 likelihood of illness per serving
$V$ = 3 servings / egg
*IE* = 0.25 x 3 = 0.75 per egg

Thus, this egg has a 75% chance of causing an illness.

Although the frequency of illness per serving is between 0 and 1, if multiple servings were generated from a contaminated egg, it is possible to have many illnesses that result from the consumption of that egg. For example, if an egg was used to prepare a meal that served four people, and the egg contained sufficient SE to result in the frequency of illness per serving being 1.0, then we would expect four illnesses from that single egg. Nevertheless, if only one person consumed an egg, and the serving contained just a few SE, then less than one illness could result from consuming that egg.

## Modeling Plan

The four relationships described above are combined in a probabilistic mathematical model. In general, the model follows a single contaminated egg from the farm through consumption and determines the number of illnesses that egg would cause. It then repeats this determination multiple times for multiple eggs. The model begins with an estimate of the variation in the number of SE per egg, which is obtained from analyzing the prevalence of SE in flocks, hens, and eggs found in Annex B and summarized below. The resulting probability distribution of SE per egg is sampled repeatedly to estimate the number of SE in each particular egg. Specific parameters, also the result of sampling probability distributions, for time, temperature, cooking, and other inputs are applied to the egg. These parameters are themselves the results of equations whose inputs are uncertain and/or variable. The values of these equation inputs are likewise sampled from other probability distributions. Thus, the variables in the four-equation model above are themselves the outputs of complex analytical processes. For example, although the relative growth might enter an equation as a rather simple numerical value the process of deriving that simple value is quite complex. The details of the derivation of these variables' values can be found in the annexes to this main report. A summary of those derivations follows.

The model is programmed in *Visual Basic for Applications*. Inputs and outputs are stored in Excel spreadsheets. The model is available at the FSIS website (http://www.fsis.usda.gov).

The shell egg exposure assessment is complex. A large number of variables and parameters are needed to estimate the inputs described in the four-equation model above. To model growth, for example, equations that predict growth behavior of SE in eggs are needed. These equations depend on the storage times and temperatures an egg experiences during the various stages it traverses between the time it is laid and the time it is consumed. These equations depend on mathematical parameters that have been estimated from available data. Furthermore, probability distributions that describe how time and temperature during storage vary for eggs in these stages are needed. These distributions are estimated from data as well.

Estimation of parameters and distributions results in uncertainty about the true values or distributions of these parameters and variables. Estimates produced by the model are conditional on the values of the model's inputs. One set of model inputs will result in an estimate of a single value in the resulting distribution of illnesses per egg. Because input values are variable, the model must be run repeatedly using different input values to estimate the full range of possible outcomes. This enables decision makers to examine and consider the effect of this variation in possible outcomes on the answers to their risk management questions. An example of variability in model inputs is that some eggs are stored for two days on the farm while other eggs are stored for four days.

### *Handling uncertainty*

That this variability exists is only part of the estimation challenge. There is also uncertainty about the variability. In the example above, the number of days of storage varies. That variability can be modeled as a continuous or a discrete variable. There is uncertainty about the frequency with which the varying numbers of days occur. For purposes of presentation in this chapter, the input values or distributions presented are the best estimates from the annexes to this report.

The discussion in this chapter does not include explicit references to the estimates' uncertainty. The primary reason for this is that there is good epidemiologic evidence that is able to narrow the uncertainty about the output of the model. Thus, the aggregate effect of even a few uncertain variables in the model is to overwhelm the uncertainty derived from the epidemiologic

evidence. The model, therefore, focuses on the contribution of the various inputs to model output. In general, sensitivity analysis is used as a proxy for uncertainty analysis. Chapter 5 on risk characterization will examine the effect making changes in different model assumptions has on the expected number of human illnesses. This sensitivity analysis will assess which inputs most influence the output of this exposure assessment.

A description of the scientific evidence and procedures used to estimate model inputs can be found in the annexes. This chapter makes extensive use of the science presented in those annexes. It is assumed that the interested reader will pursue the details of any elements of further interest in the appropriate annex. In those few instances where inputs are not developed in the annexes, the relevant data and estimation procedures are presented in this chapter.

### *SE per Egg at Lay,* $S_0$

The number of SE per egg varies from egg to egg. The distribution of all these values is described by a probability distribution. The purpose of this section is to describe how the variability in SE per egg is distributed. Figure 3-2 is a schematic illustration of this estimation. The output is shown at the top of the model. The four branches stemming from this output are the primary inputs. Each of these in turn has one or more inputs and so on. For example, the fraction of contaminated eggs laid by infected hens depends on whether the flock is molted. If the flock is molted, this fraction further depends on the time in weeks since molting was completed. The number of SE deposited within a contaminated egg depends on the site of contamination. Sites of contamination include the internal surface of the shell, the albumen, the vitelline membrane that separates the albumen from the yolk, and the yolk.

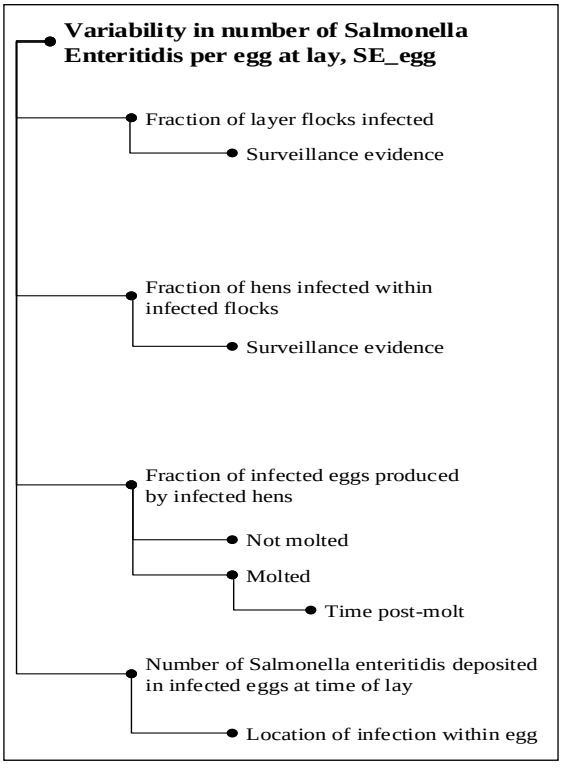



FIGURE 3-2 KEY INPUTS TO DISTRIBUTION OF SE PER EGG.

Fractions of Eggs that are Contaminated with SE

The model is based on the assumption that only an infected hen can lay an internally contaminated egg. Some flocks of hens are free of SE. Therefore, if the flock is not infected or the flock is infected but the hen is not infected, then the egg is not infected and the number of SE per egg is zero. To estimate the fraction of all eggs produced with no SE, the algorithm summarized in Table 3-1 is used. The algorithm shows the nature of the calculation directly, and it suggests the extent of the scientific evidence that was required to arrive at those calculations. The fraction of all U.S. flocks that are infected is estimated to be 20%. No further distinction is made about the extent of infection within a flock; it is simply a yes/no estimation. Given that a flock is infected, the fraction of hens within that flock that is infected varies from flock to flock. The variation in the number of infected laying hens is represented by a Weibull distribution. The best parameter estimates for this distribution, estimated in Annex B, are $\alpha = 0.43$ and $\beta = 0.0054$.

Effect of Molting

Molting is the shedding and regrowth of feathers by hens. Flocks are molted because the process rejuvenates hens' production of eggs. If a flock is not molted, it begins egg production at about 20 weeks of age and continues producing eggs for 1 year. Rates of egg production decline as the flock approaches its anniversary and the flock ceases to be economical. Therefore, the flock is destroyed and replaced by a new flock of hens. Molting is an alternative management strategy that maintains the same flock in production for an extended period. A flock is typically molted several weeks before its anniversary. Molting is forced by restricting feed and light. The molting period can last 10 weeks and no eggs are produced during this time. Once molting is complete, the hens regain their earlier productivity and will lay eggs for nearly another year.

TABLE 3-1 INPUTS USED TO CALCULATE THE FRACTION OF EGGS CONTAMINATED WITH SE.

| Variable Name | Description | Estimation |
|---|---|---|
| $f$ | Fraction of flocks detected as infected via surveillance | 9.6% from data |
| $g$ | Surveillance adjustment multiplier | 2.065 from data |
| $h$ | Fraction of flocks infected | $f$ x $g$ = 20% |
| $K$ | Fraction of infected hens within a flock given that the flock is infected | Weibull(0.43, 0.0054) distribution estimated from data |
| $j$ | Fraction of flocks in immediate post-molt period | 22% from data |
| $e_{nm}$ | Fraction of contaminated eggs produced given that hen is infected and flock is not molted | 9.4% from data |
| $W$ | Time (weeks) post-molt | Uniform(0,20) |
| $M(w)$ | Multiplier, as function of time post-molt, to adjust infected egg fraction for molted flocks | $(e^{(-6.1-0.23W)}) / ((0.00023)(1+(e^{(-6.1-0.23W)}))$ where the coefficients are estimated from data |
| $e_m$ | Fraction of contaminated eggs produced given that hen is infected and flock is molted | $M$(w) x $e_{nm}$ |
| $E$ | Fraction of contaminated eggs among all eggs produced | $EV$ [$K$ x $h$ x ($e_{nm}$ x {1 – $j$} + $e_m$ x $j$)] |

The stress of molting is thought to result in an increased susceptibility of hens to SE infection. Evidence from field studies suggests that molted flocks, in the first 20 weeks of post-molt production, will produce SE-contaminated eggs more frequently than non-molted flocks.

At any given time of year, the fraction of all flocks that are molted is estimated to be about 22%; only those flocks that are molted and in their first 20 weeks of production post-molt are of interest for this part of the exposure assessment. A non-molted flock will produce eggs for 52 weeks. Therefore, over 2 years there are 104 weeks of production. If the flock molts, the period in molt is about 10 weeks, and there are 94 weeks of production available. As such, the pre-molt and post-molt production periods constitute about 47 weeks each. The first 20 weeks of one of these production periods is about 42% of the production year. Consequently, 9.4% (22% x 42%) of flocks are molted and in their first 20 weeks of post-molt production. This fraction of infected flocks represents the flocks producing contaminated eggs at higher frequencies than the remainder of infected flocks.

Estimating the Fraction of Contaminated Eggs per Hen

The fraction of eggs produced by an infected hen is provided in Annex B. The best estimate of the fraction of eggs that is contaminated given that the hen is infected and the flock is not molted is 8.6%. For molted flocks, the fraction of eggs that is contaminated depends on the number of weeks post-molt. Early in the post-molt period, the fraction of eggs contaminated is much greater than that estimated for a non-molted flock. As the flock approaches 20 weeks post-molt, the fraction of eggs contaminated reduces to a level equivalent to that of a non-molted flock. This value varies as a function of the time post-molt and does not lend itself to a simple numerical expression.

Initial Contamination by Location in Egg

Given that an egg is contaminated with SE, the number of organisms initially deposited inside the egg depends on the location of the bacteria. Table 3-2 lists nine types of contaminated eggs considered in this analysis and the proportions of each of these egg types. SE may initially be deposited in the albumen, in the yolk, in the vitelline membrane (VM), or on the inner shell membranes (shell).

TABLE 3-2 BASELINE ESTIMATES OF FRACTIONS OF VARIOUS TYPES OF SE-CONTAMINATED EGGS.

| Type | Fraction | Type | Fraction | Type | Fraction | Type | Fraction | Type | Fraction |
|---|---|---|---|---|---|---|---|---|---|
| Shell | 0.19 | | | | | | | Shell | 0.19 |
| Internal | 0.81 | Albumen | 0.75 | Close | 0.15 | Growth | 0.79 | Alb C G | 0.07 |
| | | | | | | No growth | 0.21 | Alb C N | 0.02 |
| | | | | Far | 0.85 | Growth | 0.39 | Alb F G | 0.20 |
| | | | | | | No growth | 0.61 | Alb F N | 0.31 |
| | | VM or Yolk | 0.25 | VM | 0.90 | Low value | 0.93 | VM low | 0.17 |
| | | | | | | High value | 0.07 | VM high | 0.01 |
| | | | | Yolk | 0.10 | Low value | 0.93 | Yolk low | 0.02 |
| | | | | | | High value | 0.07 | Yolk high | 0.00 |

For albumen-contaminated eggs (Alb), the site of contamination is further distinguished as being close to or far from the yolk. This distinction only pertains to growth behavior. It is introduced here to make it clear that these types of eggs must be modeled separately. It is likely that growth in the albumen of some of these eggs will not occur regardless of how the eggs are stored. A higher fraction of albumen-contaminated eggs will support albumen growth if the SE is deposited close to the yolk as opposed to far from the yolk. Shell membrane-contaminated eggs will never support growth of SE in albumen. Yolk- and VM-contaminated eggs are further separated into those that have a low number of SE initially deposited inside them (low value) and those with high numbers initially inside them (high value).

We believe the most common form of contamination is likely the albumen-contaminated egg in which contamination is far from the yolk and no growth occurs in the albumen. Albumen-contaminated eggs in which contamination is far from the yolk but supports growth (Alb F G) are the next most common egg type. A shell-contaminated egg that does not allow growth of the SE until yolk nutrients are available is almost as frequent. Eggs whose VM is contaminated, but with low levels of bacteria, also occur frequently. Figure 3-3 shows the relative frequency of different contamination locations.

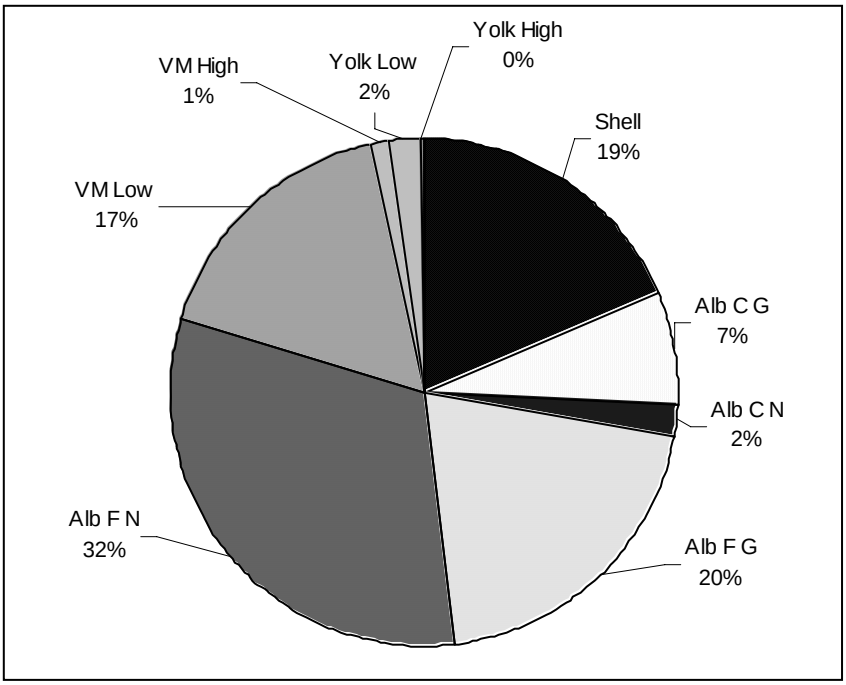



FIGURE 3-3 LOCATION OF INITIAL CONTAMINATION IN THE EGG

The location of the initial contamination in part determines the number of bacteria present at the time of lay. The number of bacteria per egg varies and is represented by a probability distribution. This distribution is a composite of the variable types of eggs and the variability in initial bacteria deposited for each type. Roughly 80% of all contaminated eggs are contaminated in the albumen or shell. For these eggs, the number of SE deposited is lognormally distributed (Table 3-3). Equivalently, ln(bacteria per egg) is normally distributed. The best-fitting parameters for this normal distribution are a mean of 2.6 and a standard deviation of 1.3. Therefore, we expect that $S_0$ is a random value from this distribution for about 80% of contaminated eggs.

TABLE 3-3 INITIAL NUMBERS OF SE DEPOSITED IN CONTAMINATED EGGS BY EGG TYPE.

| Egg Type | Initial Bacteria Estimate |
|---|---|
| Shell | $e^{Normal\ (2.6,\ 1.3)}$ |
| Alb C G | |
| Alb C N | |
| Alb F G | |
| Alb FN | |
| VM low | *Poisson*(1.39) without zeros |
| Yolk low | |
| VM high | Assume one organism begins exponential |
| Yolk high | growth immediately at lay |

Roughly 19% of all contaminated eggs (Table 3-2) are low-value VM or yolk-contaminated eggs. For these types of contaminated eggs, the initial number of bacteria is estimated using a Poisson distribution with zero values censored. The best-fitting parameter for this Poisson distribution is 1.39. Therefore, we expect $S_0$ is a random value from this distribution for about 19% of contaminated eggs.

About 1% of all contaminated eggs are high-value VM or yolk-contaminated eggs. For these types of contaminated eggs, the initial number of bacteria is assumed a single organism that can grow immediately. This organism does not experience any lag period and multiplies exponentially soon after lay. Such growth can be substantial but is variable from egg to egg, depending on how the egg is stored. Predicting this growth requires modeling the exponential growth occurring within contaminated eggs. Although these eggs seemingly start with the minimum amount of contamination possible, the warm temperature of the egg at the time it is laid guarantees substantial multiplication of bacteria within just a few hours. Therefore, we expect $S_0$ to be one organism for 1% of contaminated eggs, but this one organism becomes several very quickly.

**Simulating Poisson Deviates Without Zeros**

A random draw, $p1$ is generated from a Uniform(0, 1, rand()); the Poisson probability of zero is calculated ($P(0)$); the $p2$ for generating the deviate is taken from a new Uniform(P(0), 1, $p1$) distribution; this is used to generate the deviate from a Poisson(mean, $p$).

The distribution for $S_0$ also includes those eggs that are not contaminated. The fraction of all eggs that are not contaminated, and for which $S_0$ is equal to zero, is 1 minus the fraction of contaminated eggs among all eggs produced ($E$ from Table 3-1). For the remaining fraction of eggs that are contaminated, the probability (or fraction) of eggs with differing amounts of $S_0$ must be estimated using Monte Carlo simulation. This simulation will sample distributions for $S_0$ according to the fractions shown in Table 3-4. In this manner, the variability in $S_0$ across all eggs produced in the U.S. can be estimated.

TABLE 3-4 THE FRACTION OF ALL EGGS CONTAINING VARIOUS LEVELS OF INITIAL BACTERIA AS PREDICTED BY VARIOUS DISTRIBUTIONS. THESE DISTRIBUTIONS ARE MIXED TO ESTIMATE THE NUMBER OF SE INITIALLY DEPOSITED INSIDE EGGS, $S_0$.

| Fraction | $S_0$ |
|---|---|
| $1 - E$ | 0 (no contamination) |
| $E$ x 80% | *Normal(μ,σ)* |
| $E$ x 19% | *Poisson(λ)* without zeros |
| $E$ x 1% | Assume one organism begins exponential growth immediately at lay |

***Growth effect before processing,* $G_1$**

The risk associated with eggs laid with *Salmonella* depends on the number of *Salmonella* present at the time of consumption. Because *Salmonella* have the ability to reproduce and grow inside the egg, the nature of this growth is of special importance to this exposure assessment. *Salmonella* have specific requirements for growth. The most important of these is temperature, but factors such as pH and the availability of iron also affect growth of *Salmonella*. This section presents background material, mathematical concepts, derivation of inputs, functional relationships, and computer programming topics that concern growth of SE in contaminated eggs before processing ($G_1$).

A contaminated egg may bear a nominal amount of SE. In the conceptual model presented in Equations 3.1 through 3.4 above, the amount of SE growth per egg before processing, $G_1$, is presented as a growth factor that functions as a multiplier. In the computer model $G_1$ is the result obtained by dividing the number of SE in an egg just before processing by the number of SE in that egg at the time of lay. Thus, $G_1$ can be thought of as a summary representation of a complex set of interactions.

$G_1$ is treated separately from $G_2$ (below) to better model the effectiveness of pasteurization during the processing of eggs. The amount of bacteria surviving pasteurization depends on the initial number of bacteria and the treatment efficacy. The growth behavior of SE in eggs after pasteurization ($G_2$) is also influenced directly by growth before processing and the effectiveness of pasteurization. The model simulates individual eggs from the point of lay through consumption. To aid transparency, the individual stages of the model are presented as if these stages were independent. As shown later, the storage conditions that influence growth vary for individual eggs. Thus, $G_1$ is estimated for each individual egg. Ultimately, $G_1$ is represented by a distribution representing the variation in growth possible in all eggs. Thus, the value of $G_1$ varies from egg to egg. The values of $G_1$ developed here are expressed by a probability distribution. This distribution reflects the different amounts of growth that could occur in the population of SE-contaminated eggs from the laying house to the processor.

Growth of SE within eggs is a complex phenomenon about which the scientific evidence is somewhat vague. Conventionally, it has been argued that most eggs are initially contaminated in the albumen of the egg. The albumen is an environment that is suboptimal for SE growth. The scientific explanation for slow or poor growth of SE in albumen is based on mineral-nutrient limitation in albumen. For instance, presence of iron-binding molecules (siderophores) within albumen limit the availability of this critical element to SE.

Growth of any prokaryotic organism involves the process of binary fission, or cell division. The bacteria require nutrients in the environment to divide. Albumen does not provide the same nutritive environment as the yolk. The yolk in an egg is separated from the albumen by a thin membrane, the VM (or yolk membrane). It is hypothesized that, as the egg ages, the yolk membrane deteriorates so it ceases to completely separate nutrients in the yolk from the albumen. This deterioration depends on the internal temperature of the egg: high temperatures hasten the rate of deterioration, while low temperatures lessen it.

The hypothesis of yolk membrane deterioration, or breakdown, appears equivocal based on conflicting data sets. At this time, experimental and observational studies suggest there is some time in the life of a contaminated egg when the rate of growth of SE increases dramatically. This time is considered to be when yolk membrane breakdown (YMB) occurs. Hypothetically, the rapid growth of bacteria after this time is thought to be a result of either the bacteria penetrating

the deteriorating yolk membrane or some yolk nutrients passing through the yolk membrane into the albumen where the bacteria reside (see Figure 3-4 and 3-5).

Both mechanisms may play a role in the sudden change in SE growth behavior in eggs. There is still much to learn about this phenomenon. Nevertheless, at the least, assessing the risk from SE inside eggs hinges on predicting when this rapid growth can occur.

Once YMB occurs, growth behavior of SE is assumed consistent with experimental studies where SE is inoculated directly into yolk material. The rate of growth inside albumen is a function of the internal egg temperature but is generally much slower than growth inside the yolk.

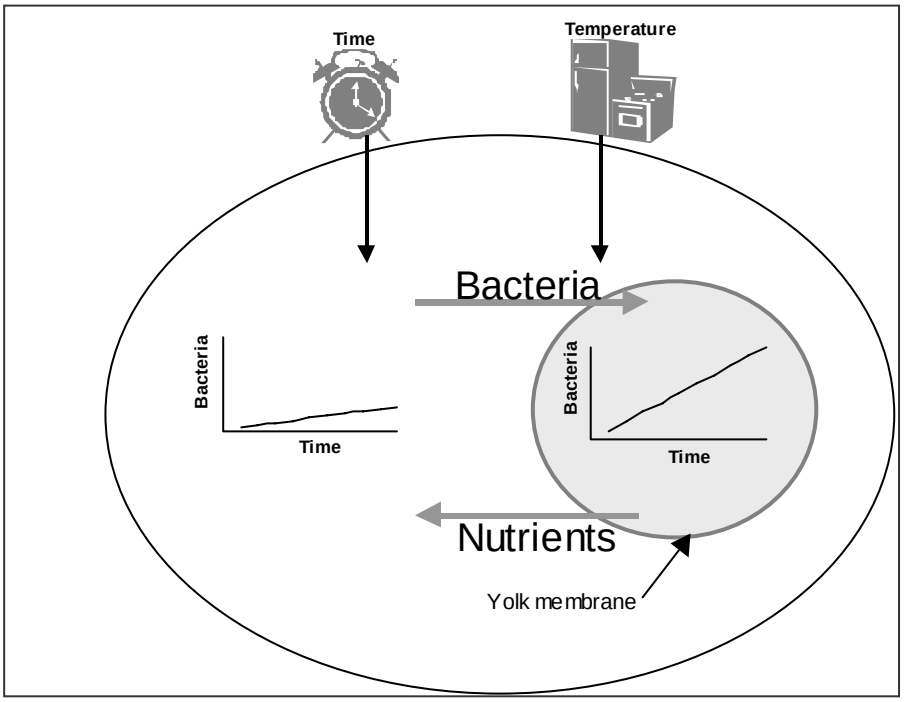



FIGURE 3-4 SCHEMATIC REPRESENTATION OF FACTORS AFFECTING THE GROWTH OF BACTERIA IN SHELL EGGS.

Mathematical Concepts

The probability distribution of $G_1$ must be estimated for the population of all contaminated eggs. The number of bacteria in an individual egg can be modeled by estimating the growth between the time it is laid and the time just before it is processed. Dividing the ending number of bacteria in the egg by the starting number of bacteria in the egg produces the growth factor, $G_1$, for that egg, as shown below.

$$G_1 = \text{(bacteria in egg just before processing)} / \text{(bacteria in egg when laid)} \quad (3.5)$$

Let $S_t$ be the number of bacteria in the egg at time $t$, where $t = 0$ when the egg is laid. The number of bacteria in an egg depends on several things, including: how many bacteria were in the egg at the time of lay ($S_0$); the age of the egg ($A$); the type of contaminated egg (e.g.,

contamination initially in the albumen, on the vitelline membrane, or in the yolk) ($E_i$); the growth rate in the applicable compartment ($G$); and the time at which YMB occurs ($M$).

$S_t$ can then be defined as:

$$S_t = S(S_0, A, E_i, G, M) \tag{3.6}$$

In the center of Figure 3-4, we see that the growth of bacteria in an egg depends on the factors just introduced. Along the right side of this figure is the portion of the farm-to-table path that eggs travel before pasteurization. The model determines the number of bacteria inside a particular egg at the end of storage in the layer house, after it is stored on the farm, after it is transported, and after it is stored at the processor. The left side of this figure illustrates that YMB ($M$) depends on storage time and temperature, the rate of cooling, and the initial bacteria in the egg ($S_0$). The exponential growth rate depends on time and temperature too. It also depends on the type of egg and the serologic status of the egg. Because storage temperatures change as the egg moves from the layer house to on-farm storage to transport to the processor, the calculations of YMB and exponential growth rate change with time in the model. This graphic depiction of the dependencies of critical model calculations introduces the mathematical relationships developed further in this section covering $G_1$. Furthermore, the principles of estimating growth inside eggs discussed for $G_1$ also apply to estimating growth after pasteurization until the egg is consumed. This portion of the farm-to-table path is defined as $G_2$ above.

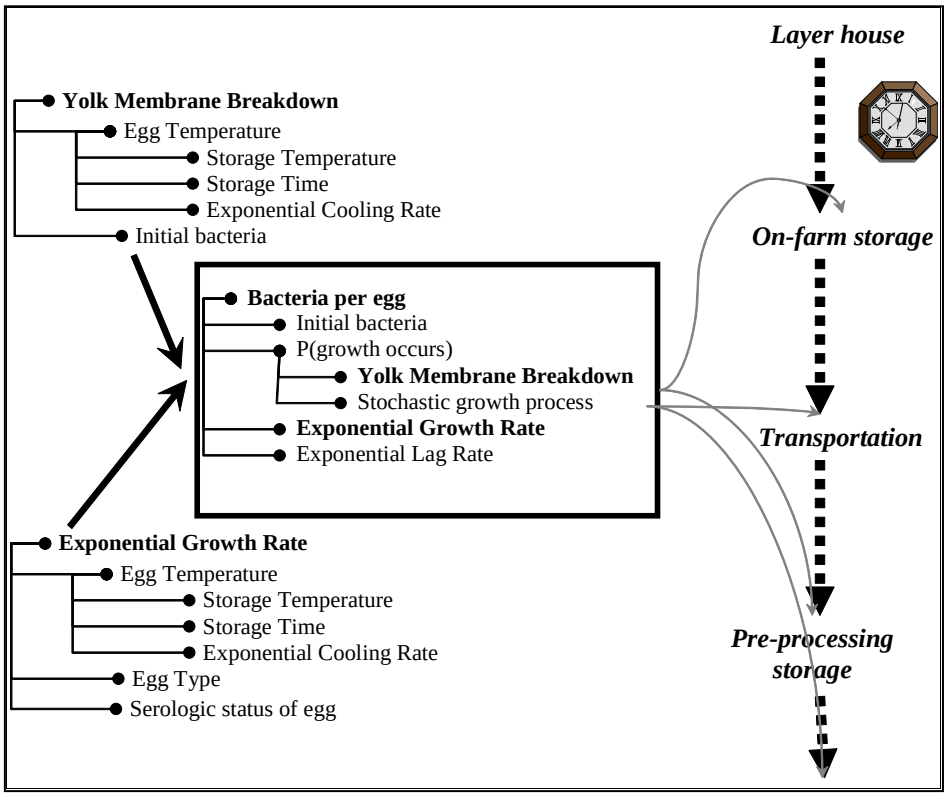



FIGURE 3-5 SCHEMATIC OF CRITICAL DEPENDENCIES AND STEPS WITHIN THE *G1* MODEL.

We know that growth rate and YMB depend on the internal egg temperature ($T_t$):

$$G_t = G(T_t) \tag{3.7}$$

where $G_t$ is the exponential growth rate per day at time $t$ and $T_t$ is the egg temperature at time $t$.

$$M_t = M(T_t) \tag{3.8}$$

where $M_t$ is the time to YMB at time $t$.

Later in this chapter, an additional argument is added to Equation 3.7 to introduce the presence of detectable anti-SE antibodies in a particular egg. The initial bacteria in the egg also influences the time of YMB.

The internal egg temperature ($T_t$) depends on the initial egg temperature ($T_0$), the ambient temperature ($T_a$) of storage, the time of storage ($t$), and the rate at which the internal egg temperature changes. For now, this cooling rate is assumed constant and equal to $k$. The functional dependencies of $T_t$ are the following:

$$T_t = T(T_0, T_a, t, k). \tag{3.9}$$

By substitution, Equation 3.5 can be rewritten:

$$G_1 = (S(S_0, E_i, T_0, \{t\}, \{T_a\}, \{k\})) / S_0 \tag{3.10}$$

For an individual egg, the initial number of bacteria at lay and the initial temperature at lay are fixed at the values returned by sampling from their parent distributions. An individual contaminated egg is also of a specific type. For an individual egg, however, the ambient temperature of storage is likely to vary between the times of lay and processing. The ambient temperatures also apply to particular times of storage. Similarly, the cooling rate, which depends on how the egg is packaged, is likely to change. These changes are addressed by using vectors of ambient temperatures, times, and $k$ values (vectors are signified by the {} brackets). The time and ambient temperature profile for this egg can also be referenced.

**Egg Age and Time**

The age of an egg describes the amount of time that has elapsed since it was laid. In this model, egg age and time are the same. For example, consider an egg that is laid and remains in the layer house for 6 hours, then is stored an additional 24 hours somewhere on the farm before being transported to a processor. Transport takes 3 hours after which the egg is stored another 24 hours before being processed. When laid, the egg's age is zero and time elapsed is zero. When the egg begins to be processed, its age is the time that elapsed since it was laid. Therefore, Age = $t$ = 6 + 24 + 3 + 24 = 57 hours for this particular egg.

The calculation of Equation 3.10 is not simple, in part because growth rate and YMB (Equation 3.7 and Equation 3.8) are functions of the internal egg temperature (Equation 3.9), which changes across time for a given ambient temperature and $k$ value. The ambient temperature and $k$ values also change across time. In the sections to follow, a solution method that calculates the bacterial growth in an individual egg across time by recalculating growth in small time increments is described.

Although the inputs $S_0$ and $E_i$ are described in Annex B, the other inputs to Equation 10 are introduced below. Furthermore, the specific functional relationships, which are only alluded to above, must be explained. Inputs are described below under "Derivation of Storage Times, Temperatures, and Exponential Cooling Rates." Functions are described below under

"Functional Relationships." Next, however, a brief description of the modeling protocol for $G_1$ is given. This protocol provides perspective on how the inputs and functions are used in the model. Descriptions of inputs and functions follow this section.

Modeling Protocol for $G_1$

This section explains the computer model calculations for the $G_1$ phase of this risk assessment. Beginning when an egg is laid the model steps through time increments to determine the amount of growth inside a contaminated egg. The $G_1$ phase of growth ends just as the egg begins to be processed. The following explanation describes how the model determines the number of bacteria in a contaminated egg just before it is processed.

- Step 0: The model iteratively simulates the fate of a single egg.
- Step 1: Select the type of egg production facility where the egg was laid: The first step in modeling is selection of an in-line or off-line egg production facility from a probability distribution. The type of egg production facility determines the number of steps modeled within $G_1$. Distinctions between in-line and off-line facilities are explained below in "Derivation of Storage Times, Storage Temperatures, and Exponential Cooling Constants."
- Step 2: Select ambient temperature, time, and $k$ values for steps: The time and temperature profile for the egg is determined next. Storage temperatures, times, and exponential cooling rates for the egg are selected probabilistically from frequency distributions described below. For an egg produced by an off-line facility, this profile amounts to determining several factors. These factors include: the time spent in the layer house and the ambient temperature in the layer house; the time spent in storage on the farm and the ambient temperature in the storage facility; the time spent being transported to the processing facility and the ambient temperature of the transport vehicle; and the time spent in storage at the processing facility before processing and the ambient temperature at this facility. Therefore, before the model calculates growth within the egg, it determines the total time and ambient temperature history for that egg. Similarly, exponential cooling rates applicable to each storage period are determined for the egg.

  Time and temperature of egg storage are not correlated in the model. In other words, eggs stored for 18 days are just as likely to be held at 19.7°C as those stored for 2 days. It may seem reasonable to assume that someone storing eggs for a longer period would be more likely to refrigerate the eggs. On the other hand, an argument can be made against this possibility because someone storing eggs for a long period may be less able to manage storage times and temperatures and these eggs could be stored at higher temperatures. Lacking direct evidence of a correlation of time and temperature, it is not reflected in the model.
- Step 3: Select egg contamination location: The type of egg is selected probabilistically based on the frequencies described in Table 3-2. The type of contaminated egg determines the initial level of SE within the egg and the growth characteristics for that egg.

  Nine types of shell eggs are modeled.

  1. Shell: Inner shell membrane contaminated, no growth until after YMB
  2. Alb C G: Albumen contaminated close to yolk, growth can occur anytime
  3. Alb C N: Albumen contaminated close to yolk, no growth until after YMB

4. Alb F G: Albumen contaminated far from yolk, growth can occur anytime
5. Alb F N: Albumen contaminated far from yolk, no growth until after YMB
6. VM Low: Vitelline membrane contaminated, low initial contamination egg
7. VM High: Vitelline membrane contaminated, high initial contamination egg.
8. Yolk Low: Yolk contaminated, low initial contamination egg
9. Yolk High: Yolk contaminated, high initial contamination egg

The initial level of contamination for types 1, 2, 3, 4, and 5 eggs are randomly selected according to the lognormal distributions described in Table 3-3. Initial levels of contamination for type 6 and 8 eggs are randomly selected according to a Poisson distribution. Contamination types 7 and 9 start with one organism but begin immediate exponential growth.

- Step 4. Aging of the egg: Time is incremented for each egg in fraction of day units that can be specified and varied by the user. The model allows the user to set the increment at any amount desired. The stability of the outcome distribution for $G_1$ depends somewhat on size of the time increment. A smaller increment allows more precision in bacterial growth calculations but takes additional run time.
- Step 5. Calculate internal temperature at each time increment. The internal temperature of the egg for each time increment is calculated. This internal temperature, in turn, determines how much growth will occur in that egg during that time.
- Step 6. Calculate time of YMB: For each time increment, YMB occurrence is modeled for all egg types but 8 and 9 above. Once YMB occurs in an egg, this step is skipped for future time increments.
- Step 7. Exponential growth rates: Depending on where the contamination resides within the egg, an exponential growth rate multiplier is calculated for each time increment. Because egg types 3 and 5 do not experience growth within the albumen, this step is skipped for these eggs until YMB occurs.
- Step 8. Calculating growth in eggs: An algorithm is used to select the number of bacteria in the egg at each time increment in a deterministic fashion. Alternatively, if stochastic growth is assumed, as explained under the "Functional Relationships" section, then the number of bacteria is only determined at the end of each step in the model. In this case, the number of bacteria is calculated after layer house storage, after on-farm storage, after transportation, and after pre-processing storage.

Derivation of Storage Times, Storage Temperatures, and Exponential Cooling Constants

An egg experiences different environments as it moves from the layer house to on-farm storage to a truck for transport and to a processor. In the model, these environments are characterized by their ambient temperatures and the packaging material used to store the eggs. For a particular egg, the ambient temperature in the layer house is probably not the same as the ambient temperature when it is stored at the processor. Furthermore, eggs may be stored in a variety of manners. In the layer house, they simply sit on conveyor belts awaiting collection. Elsewhere, they may be stored in trays on racks, in boxes, or in cardboard or Styrofoam cartons. The manner of storage affects the rate at which the internal egg temperature equilibrates to the ambient temperature. The cooling rate, therefore, depends on the packing method and material.

As mentioned before, an individual egg's temperature can be characterized by vectors of ambient temperature, storage time, and exponential cooling rate. For example, it is assumed that the layer house an egg was laid in has a particular ambient temperature during the time the egg

remains in the house. The first element of the ambient temperature vector for this egg is the layer house temperature. The first element of the storage time vector is the time that the egg spends in the layer house. The first element of the exponential cooling rate vector is the applicable cooling rate for an egg sitting on a conveyor belt. Subsequent elements for these vectors will refer to on-farm storage, transportation, and preprocessing storage. Therefore, these vectors each contain four different values reflecting the environmental characteristics of the different places an egg travels between lay and processing. For example, the ambient temperature will include a single air temperature for each of the on-farm, storage, transportation, and pre-processing storage steps. These will each have been sampled from a distribution of possible air temperatures. The same is true for storage time and exponential cooling rate.

In the model, each egg is modeled independently of every other egg. If two eggs are handled in exactly the same manner, then these eggs are probably produced in the same layer house and are packaged, transported, and processed together. Such associations are likely to occur through processing. However, because the model determines the likelihood from a single egg during each iteration, it seems reasonable to treat each egg independently.The probability distributions for storage time and temperature and the exponential cooling rates are estimated from available data to represent the natural variability in these values.

Eggs are produced in either an in-line or an off-line facility. In-line facilities have egg-processing equipment on the same premises as the layer houses. Eggs produced in such facilities generally take less time to process than off-line facilities. Off-line facilities must transport their eggs to an off-site processor. Eggs produced in these facilities are usually stored somewhere on the farm to await transport to a processing facility some distance from the farm. A national survey of the layer industry in 1999[78] found 13.5% of egg-producing farms were in-line facilities. Off-line processing was used by the remaining 86.5% of farms. Egg handling between the time of lay and the time they are processed for retail sale varies based on whether the eggs are produced in an in-line or off-line facility. The model reflects these differences.

To account for changing ambient temperatures and cooling rates, *k* values and time and temperature effects are explicitly considered in the model for the following steps in the handling process: laying house; on-farm storage (off line only); transportation to the processor (off line only); and pre-processing storage. Although the times, ambient temperatures, and *k* values for each of these steps vary among the population of all eggs produced in the U.S., these values are constant for individual eggs in the model. To illustrate this assumption, consider the ambient temperature inside laying houses. It varies from laying house to laying house because it depends on management practices such as the thermostat setting a particular manager chooses, the number of fans in the house, climate, and weather. Nevertheless, the ambient temperature an individual egg produced in a specific laying house experiences may be reasonably constant during the time that egg awaits collection. This model treats it as constant.

*Storage Times*

Table 3-5 (following page) shows the available data for time inputs. Information was available only for the time of on-farm storage and the time eggs were stored at the processor for both in-line and off-line processors. Furthermore, the information was reported in ranges. For on-farm storage, the reported value is the “average number of days between egg pickups.” Thus, it is reasonable to assume that the average egg being picked up would have been stored for about half of the time reported for the range.

TABLE 3-5 AVAILABLE INFORMATION ON TIME INPUTS FOR $G_1$.

| On Farm[a] | | Pre-processing[b] | | |
|---|---|---|---|---|
| Average Number of Days between Egg Pickups | Percent Farm Sites | Average Number of Days | % Producers (in line) | % Packers (off line) |
| 1 to 2 | 48.5 | <1 | 23% | 51% |
| 3 to 5 | 45.1 | 1 to 3 | 46% | 29% |
| 6 to 9 | 6.2 | 4 to 6 | 22% | 11% |
| 10 or more | 0.2 | 7 to 10 | 7% | 6% |
| Total | 100 | 11 to 15 | 1% | 1% |
| | | 16 to 20 | 1% | 1% |
| | | > = 20 | 0% | 0% |
| | | Total | 100% | 99% |

[a]Source: National Animal Health Monitoring System.[78]

[b]Source: Research Triangle Institute (RTI). RTI Egg Industry Teleconference Panel.[79]

Lognormal distributions were fit to the average number of days between egg pickups. These distributions were assumed to describe the variability in average storage times among farms and among processors. Distributions were fit by minimizing the squared differences between the cumulative empirical distribution and the theoretical cumulative lognormal distribution. A lognormal distribution was chosen because it "is useful for modeling naturally occurring variables that are the *product* of other naturally occurring variables."[80] The times of storage are considered the products of many other factors (e.g., management, weather, market). Reasonable visual fits to relatively limited information, as seen in Figure 3-6, are consistent with the choice of a lognormal distribution. Figure 3-7 compares a lognormal distribution with the storage time at the processor for off-line eggs, and Figure 3-8 shows a similar comparison for in-line eggs. Note that because these inputs are modeled with lognormal distributions, values for storage time more extreme than those observed can be returned. These extreme values are limited in the model by truncating the lognormal distribution at the 99.9$^{th}$ percentile.

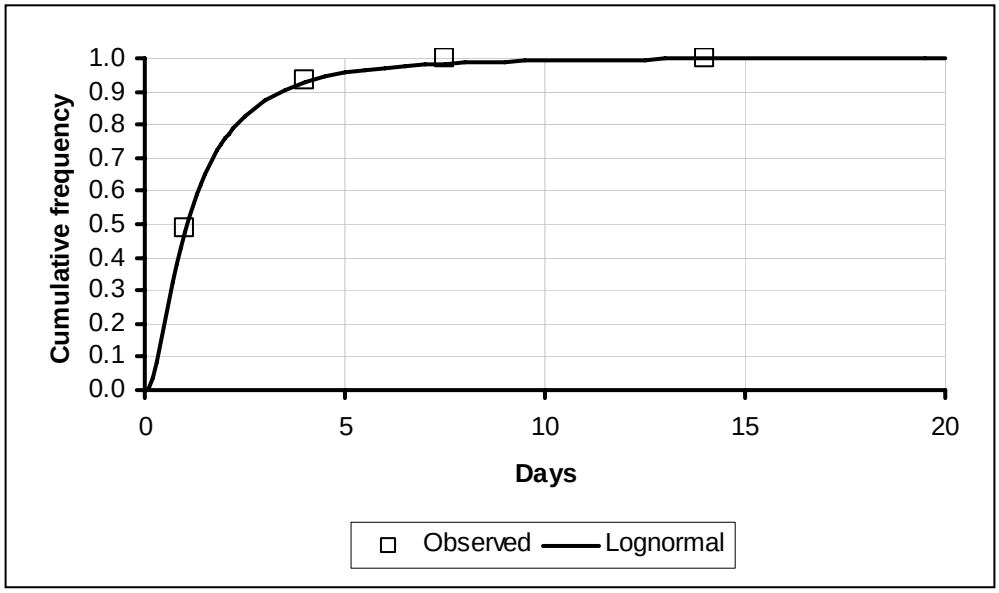



FIGURE 3-6 COMPARISON OF OBSERVED AND PREDICTED RESULTS FROM A LOGNORMAL DISTRIBUTION FOR ON-FARM STORAGE TIME.

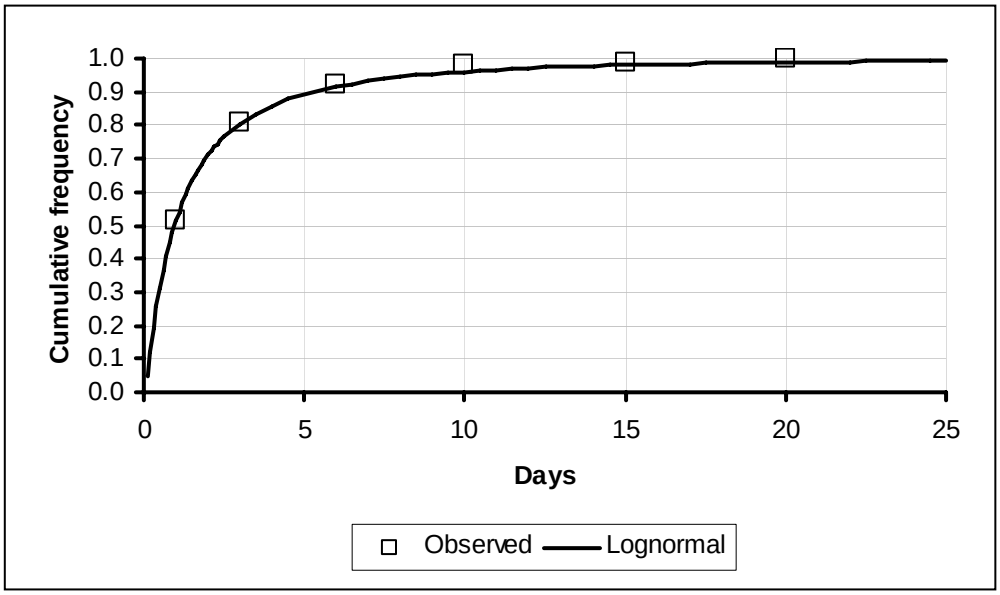



FIGURE 3-7 COMPARISON OF OBSERVED AND PREDICTED RESULTS FROM A LOGNORMAL DISTRIBUTION FOR STORAGE TIME OF OFF-LINE EGGS BEFORE PROCESSING.

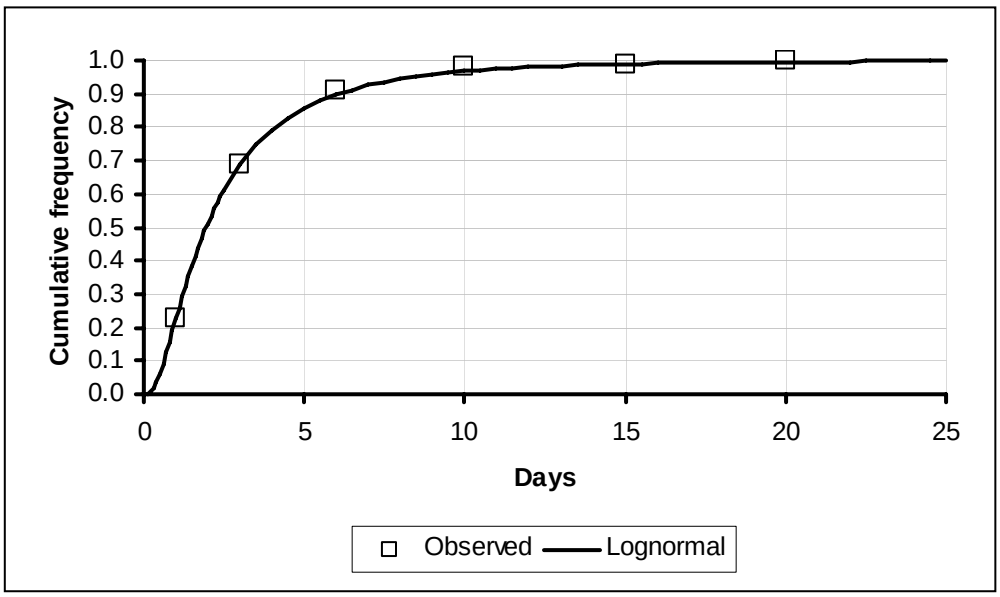



FIGURE 3-8 COMPARISON OF OBSERVED AND PREDICTED RESULTS FROM A LOGNORMAL DISTRIBUTION FOR STORAGE TIME OF IN-LINE EGGS BEFORE PROCESSING.

Data to estimate the time that eggs remain in the layer house were unavailable. This time is distinct from the time eggs are stored on the farm. A lognormal distribution was used to represent the variability in this time. Eggs are normally collected from the layer house twice a day. If eggs are collected twice a day, then the average egg remains in the layer house 6 hours or 0.25 days until it is collected. A value of ln(0.25 days) = –1.39 was used for the mean of the lognormal distribution. The standard deviation was set equal to the 0.59 standard deviation for on-farm storage time.

There are also no data for the time it takes to transport eggs to the processor. An arbitrary value of 6 hours was selected to represent the time it takes to transport eggs from the farm to the processor. Assuming a lognormal distribution, the standard deviation was set by default to the same value used for the layer house and on-farm storage. Table 3-6 shows the modeled parameters for the lognormal distributions of storage time for the four steps before processing.

TABLE 3-6 PARAMETERS FOR LOGNORMAL DISTRIBUTIONS FOR TIME OF EGG STORAGE AT DIFFERENT MODEL POINTS.

| Input | Time | | |
|---|---|---|---|
| | **Supported by Data?** | **Mean** | **Std Dev** |
| Layer house | No | -1.39 | 0.59 |
| On-farm | Yes | 0.72 | 0.59 |
| Transportation from farm | No | -1.39 | 0.59 |
| Pre-processing off line | Yes | -0.04 | 1.33 |
| Pre-processing in line | Yes | 0.67 | 0.89 |

Storage Temperatures

The temperature of the egg is critically important to the growth of any SE present in the egg. To estimate this growth, ambient air temperatures are needed to estimate changes in the temperature of the egg. This section presents information on ambient air temperatures in the layer house, on the farm, during transport, and in storage before processing

Table 3-7 shows available information regarding ambient temperature during on-farm storage, during transport to processing, and during pre-processing storage. This information does not directly pertain, however, to the layer house environment.

TABLE 3-7 AVAILABLE TEMPERATURE INPUTS FOR $G_1$.

| On-Farm[a] | | Transportation to Processor[b] | | Storage before Processing[b] | | |
|---|---|---|---|---|---|---|
| **Temperature for Egg Storage** | **% Farm Sites** | **Temperature of Refrigerated Trailer** | **% Trailers** | **Temperature of Refrigerated Storage Space** | **% Producers (in line)** | **% Packers (off line)** |
| <10°C | 21% | Unrefrigerated | 6% | Unrefrigerated | 0% | 0% |
| 10-15°C | 51% | <7.2°C | 18% | <7.2°C | 12% | 37% |
| ≥15.6°C | 28% | 7.2-15°C | 66% | 7.2-15°C | 66% | 56% |
| Total | 100% | 15.6-23.9°C | 10% | 15.6-23.9°C | 21% | 7% |
| | | ≥23.9°C | 0% | ≥23.9°C | 1% | 0% |
| | | Total | 100% | Total | 100% | 100% |

[a]Source: National Animal Health Monitoring System.[78]

[b]Source: Research Triangle Institute. RTI Egg Industry Teleconference Panel.[79]

The information in Table 3-7 is available only in ranges. Lognormal distributions were fitted using the mid point of the temperature class as the most likely empirical value. The following figures compare the cumulative empirical frequency distributions with the lognormal

distributions for temperature of on-farm storage (Figure 3-9), transportation to the processor (Figure 3-10), pre-processing storage of off-line eggs (Figure 3-11), and pre-processing storage for in-line eggs (Figure 3-12).

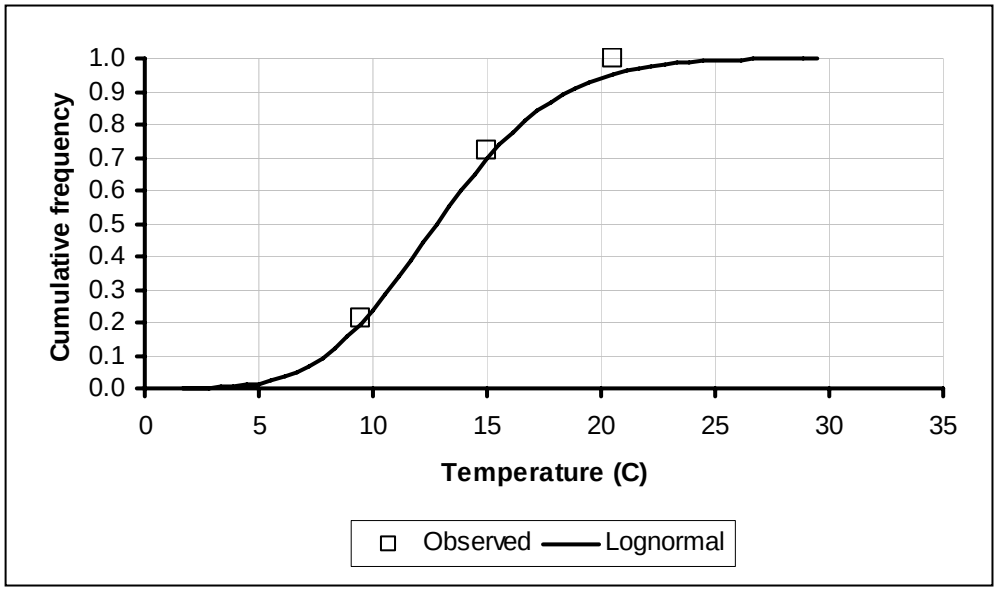



FIGURE 3-9 COMPARISON OF OBSERVED AND PREDICTED RESULTS FROM A LOGNORMAL DISTRIBUTION FOR STORAGE TEMPERATURE OF EGGS STORED ON THE FARM BEFORE TRANSPORTATION TO THE PROCESSOR.

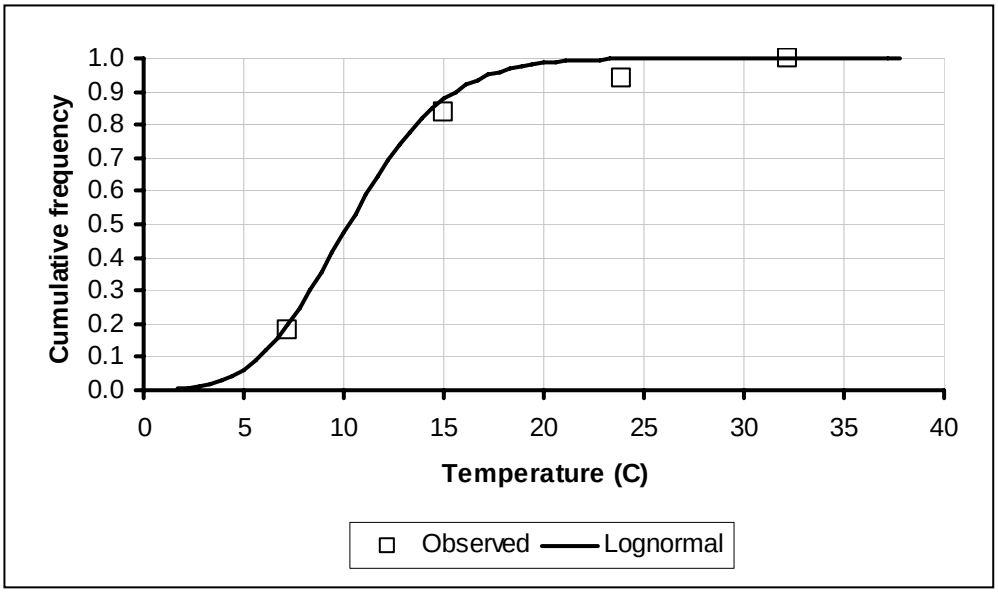



FIGURE 3-10 COMPARISON OF OBSERVED AND PREDICTED RESULTS FROM A LOGNORMAL DISTRIBUTION FOR AMBIENT TEMPERATURE DURING TRANSPORTATION OF EGGS TO THE PROCESSOR.

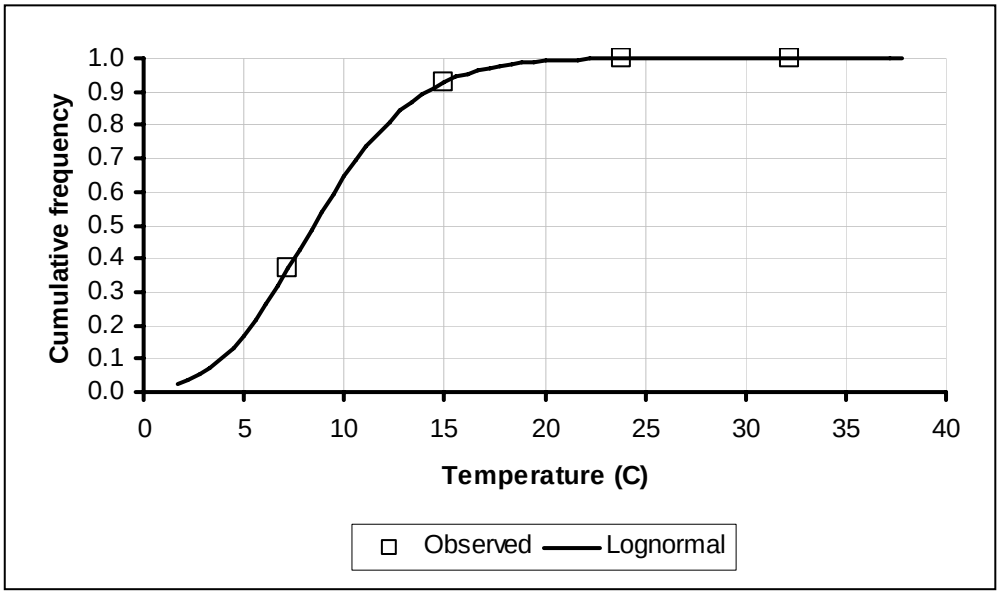



FIGURE 3-11 COMPARISON OF OBSERVED AND PREDICTED RESULTS FROM A LOGNORMAL DISTRIBUTION FOR STORAGE TEMPERATURE OF OFF-LINE EGGS BEFORE PROCESSING.

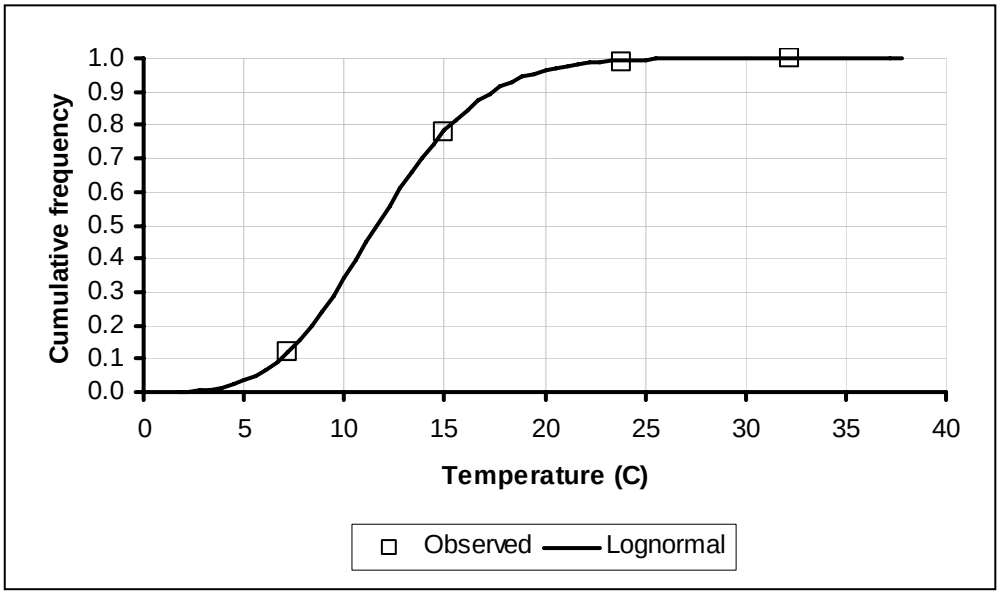



FIGURE 3-12 COMPARISON OF OBSERVED AND PREDICTED RESULTS FROM A LOGNORMAL DISTRIBUTION FOR STORAGE TEMPERATURE OF IN-LINE EGGS BEFORE PROCESSING.

The distribution for ambient temperature in the layer houses is derived as follows. Although commercial egg-laying facilities generally monitor and control the house environment closely, there was no survey evidence available describing the variability of temperatures across layer

houses. There is, however, evidence that suggests likely temperature ranges. First, the American Egg Board[81] states the following regarding ambient temperature, "Laying houses maintained between 57 and 79°F (14 and 26°C) are desirable." Table 3-8 provides evidence of recommended temperature variability in layer houses. It gives recommended ambient temperatures for layer houses by week of flock production. Recall that flocks begin production when the hens are about 20 weeks of age. Together, this evidence suggests that ambient temperatures might vary from layer house to layer house by age of hen and might vary within houses by time of day. Furthermore, we can assume that ambient temperature is influenced by time of year—the temperature would be hotter in summer and cooler in winter.

TABLE 3-8 RECOMMENDED AMBIENT TEMPERATURES BY WEEK OF FLOCK PRODUCTION.

| Week of Production for Flock | Ambient Temperature |
|---|---|
| 1 | 90°F (32.2°C) |
| 2 | 85°F (29.4°C) |
| 3 | 80°F (26.7°C) |
| 4 | 75°F (23.9°C) |
| 5 | 70°F (21.1°C) |
| 6 until end of production | 70°F (21.1°C) |

Source: Meunier and Latour.[82]

Given the complexity of factors influencing ambient temperature in layer houses and the absence of survey data from which to infer a probability distribution that captures the natural variability in temperatures, it is assumed that the variability in temperatures among layer houses follows a lognormal distribution. Furthermore, the mean temperature within layer houses is assumed to be 24°C (i.e., room temperature). Because the standard deviation varies little among the steps for which there are data, the standard deviation is assumed approximately the same within the layer house as for all the other steps, in this case 0.15. Table 3-9 shows the modeled parameters for the lognormal distributions of storage temperature for the four steps before processing.

TABLE 3-9 PARAMETERS FOR LOGNORMAL DISTRIBUTIONS FOR TEMPERATURE OF EGG STORAGE AT DIFFERENT MODEL POINTS

| Input | Temperature (parameters in model entered as ln(°F)) | | |
|---|---|---|---|
| | Supported by Data? | Mean | Std Dev |
| Layer house | No | 4.32 | 0.15 |
| On-farm | Yes | 4.01 | 0.14 |
| Transportation from farm | Yes | 3.92 | 0.14 |
| Preprocessing off-line | Yes | 3.86 | 0.15 |
| Preprocessing in-line | Yes | 3.97 | 0.14 |

Determination of Exponential Cooling Rates

As eggs are stored, temperatures may change; when stored in refrigerated environments, eggs cool. Cooling slows or stops the growth of *Salmonella* and, as such, warrants separate consideration.

The cooling rate, *k*, describes the reduction in degrees of temperature per hour of storage at an ambient temperature and its units are in 1/hrs. The smaller the value of *k*, the less change in egg temperature occurs in an hour. The more insulated an egg is from its environment, the lower the *k* value is likely to be. For example, an egg stored in a large cardboard box with hundreds of

**An Example of Using *k* Values to Determine Internal Egg Temperature**

Using a $k$ value of 0.10, an ambient temperature ($T_a$) of 12°C and a starting internal egg temperature ($T_{i0}$) of 20°C, the equation for determining the internal temperature of an egg after 3 hours is

$T_{i3} = e^{(-k(t\ hours)\ /\ hours)} \times (T_{i0} - T_a) + T_a$

$= e^{(-0.10 \times 3)} \times (20 - 12) + 12 = 17.9$

other eggs surrounding it is insulated from the ambient air temperature. In contrast, an egg sitting on a conveyor belt is not insulated and quickly adapts to the ambient air temperature. Very rapid changes in egg temperature are associated with large $k$ values. The function that predicts how egg temperature changes with time, using this cooling rate, is described later in this chapter. A detailed discussion of the derivation of cooling rates (i.e., $k$ values) is provided in Annex D.

Some key findings of that analysis are presented in Table 3-10. This analysis suggests that $k$ values range from 0.0063 to 0.615 depending on how the eggs are packaged. Note that the $k$ values in Table 3-10 are averages estimated from the experimental evidence. Furthermore, these $k$ values were estimated from measurements of eggs in the center of flats, cases, or pallets.

TABLE 3-10 THE ESTIMATED COOLING RATES OF EGGS WITH VARIOUS PACKING METHODS.

| Packing Method | Exponential Cooling Rate per Hour, *k* |
|---|---|
| Pallet of cardboard (off line) (constant ambient temperature) | $k = 0.0063$ |
| Pallet, cardboard (off line) (fluctuated ambient temperature) | $k = 0.0064$ |
| Pallet of cardboard cases | $k = 0.0075$ |
| Pallet of cardboard (in line) | $k = 0.0094$ |
| Individual case/basket temperature | $k = 0.0131$ |
| Pallet, cardboard cases (traditional cooling) | $k = 0.0215$ |
| Pallet of cardboard cases (flats) | $k = 0.0472$ |
| Pallet of plastic basket cases | $k = 0.0524$ |
| – Plastic and fiber filler flats, fiber case, closed | $k = 0.0628$ |
| – Formed and folded cartons, fiber case, closed | |
| – Formed and folded cartons, open stack | $k = 0.1000$ |
| – Formed and folded cartons, wood case | |
| – Plastic and fiber filler flats, wood case | |
| – Plastic and fiber filler flats, fiber case, open | |
| (1) Filler flats | $k = 0.2280$ |
| (2) Fiberboard case (30 dozen)—foam cartons (closed top) | |
| (3) Fiberboard case (30 dozen)—foam cartons (slotted top) | |
| Plastic and fiber filler flats, open stack | $k = 0.2750$ |
| Fiber filler flats or fiber cases with forced air cooling through opening in cases | $k = 0.6150$ |

The table shows that the cooling rate differs by packing methods. It also varies somewhat for the same basic packing method. To simplify the analysis, three basic packing methods are selected and the cooling rate for the center egg in each is assigned as shown in Table 3-11

TABLE 3-11 EXPONENTIAL COOLING RATES FOR USE IN BASELINE MODEL (CENTRAL EGG).

| Packing Method | Exponential Cooling Rate per Hour, *k* |
|---|---|
| Cases within a pallet | 0.01 |
| Stacks of cartons or flats within or without a case | 0.1 |
| Egg exposed to ambient air or carton in home refrigerator | 1.0 |

These selected cooling rates for each packing method are supported with three separate arguments: simplicity, consistency with the data, and model predictions.

*Simplicity*

Packing and packaging materials for eggs vary. Cooling methods and airflow in layer houses, farms, processing plants, vehicles, retail facilities, and homes vary. Attempts to disaggregate cooling constants by packing material or cooling methods are likely to be frustrated by the lack of data on material or methods. Furthermore, the effect of differences in cooling rates on internal egg temperature diminishes as the cooling constant increases.

Figure 3-13 shows the effect of cooling rate on the change in temperature in an egg by showing how many days it would take to cool an egg below 11°C given that the egg started at an internal temperature of 41.1°C and was stored in an ambient temperature of 10°C. If we calculate the change in temperature on an hourly basis, we can show that at an ambient temperature of 10°C and an internal egg temperature of 41.1°C, it would take approximately 15 days to cool the internal temperature below 11°C given a cooling rate of 0.01, and approximately 1 day if the cooling rate is 0.1. Nevertheless, it would take 5 hours given a cooling rate of 0.75 and approximately 4 hours if the cooling rate were 1.0. Therefore, little difference is apparent between cooling rates of 0.75 and 1.0.

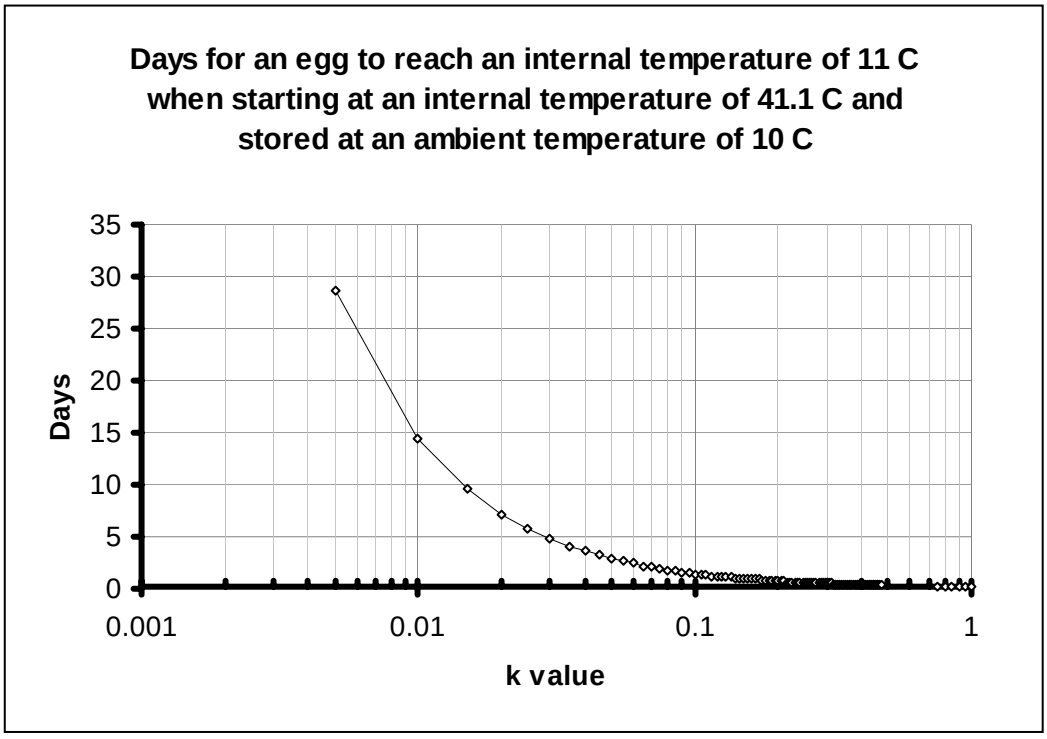



FIGURE 3-13 EFFECT OF *K* VALUE ON DAYS FOR AN EGG TO REACH A GIVEN INTERNAL TEMPERATURE.

Exponential cooling rates for all eggs are represented by three values: 0.01 for pallets, 0.1 for cases, and 1.0 for ambient air and individual cases. Nevertheless, the exponential cooling rate for an individual egg can vary from 0.01 to 1.0 depending on where that egg is stored within a case or pallet. These cooling rates are used to predict the internal temperature of eggs at different

times along the farm-to-table continuum. For example, an applicable cooling rate for an egg held in the layer house is used to predict the internal temperature of that egg just before the egg moves into storage elsewhere on the farm. Because internal egg temperature directly influences the rate of *Salmonella* growth inside an egg, this value must be selected from a distribution before estimating growth.

*Consistency with data*

Table 3-10 shows seven *k* values for eggs that have been palletized: 0.0063, 0.0064, 0.0075, 0.0094, 0.0215, 0.0472, and 0.0524. These values are applicable to eggs in the center of pallets. For simplicity, eggs in the center of pallets are assumed to have a *k* value of 0.01.

Table 3-10 shows 11 values for eggs in cases or flats: 0.0131, two instances of 0.0628, four instances of 0.10, three instances of 0.228, and 0.275. The *k* value for "fiber filler flats or fiber cases with forced air cooling through opening in cases" is not included because it is believed to be more representative of eggs that are exposed to ambient air than eggs in the center of a case or stack of flats. For simplicity, eggs in the center of cases or flats are assumed to have a *k* value of 0.1.

No *k* values are shown in Table 3-10 for eggs exposed to ambient air or in a single carton in a refrigerator. In a layer house, eggs are generally exposed to ambient air. These eggs usually sit on an egg belt until collected. In many home refrigerators, eggs are in a single dozen container in which all eggs are outside of the container. Although these situations are not shown among the packing methods in Table 3-10, these eggs are assumed to have a *k* value at least as large as or larger than that reported for "fiber filler flat or fiber cases with forced air cooling through the openings in the cases." This is because forced air cooling provides mechanical ventilation that should move air into the container and nearly surround eggs with the ambient air. The average value of *k* for this packing method is 0.615; Annex D shows it ranged from 0.39 to 0.97. Consequently, a *k* value of 1.0 is used for eggs exposed to ambient air or in a carton in a refrigerator.

*Model predictions*

The discussion above shows that the cooling rates used are consistent with the data. This section presents the results of modeling the rate of cooling. As noted earlier, *k* values were estimated from measurements of the temperature of the eggs in the center of flats, cases, or pallets. These eggs do not represent all eggs within a pallet. They are the extreme instance. To adjust for the nonrepresentative nature of the center egg cooling rate, the rate is adjusted by the following formula for eggs not in the center of a pallet (found in Annex D).

$$\textit{Adjusted cooling constant} = \textit{Cooling constant in center of pallet} \times (\textit{Distance from perimeter to center of pallet} / \textit{distance from perimeter to specificied egg})^2 \quad (3.11)$$

A pallet measures approximately 3 ft wide x 4 ft long x 6 ft high. Given these dimensions, approximately 40% of eggs would be within 4 inches of the perimeter of the pallet and would thus have an adjusted cooling constant of at least 20 times that of an egg in the center:

$$(0.01) \times (18 \text{ inches} / 4 \text{inches})^2 \approx 0.20 \quad (3.12)$$

The calculation is the same for a case except a case measures approximately 18 inches by 12 inches by 14 inches. If we assume a cooling constant of 0.01 for pallets and a cooling constant of 0.1 for cartons, then the predicted cooling constants at varying distances from the perimeter can be calculated and are shown in Figure 3-14.

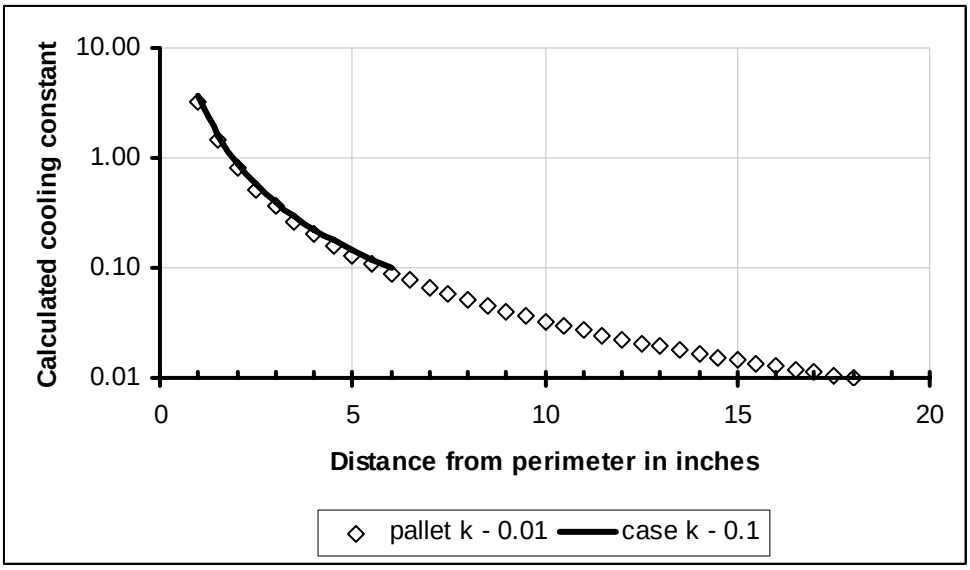



FIGURE 3-14 PREDICTED COOLING CONSTANTS FOR VARYING DISTANCES FROM PERIMETERS FOR PALLETS ASSUMING A CENTRAL EGG COOLING CONSTANT OF 0.01 AND CASES ASSUMING A CENTRAL EGG COOLING CONSTANT OF 0.1.

Figure 3-14 shows that the cooling rates for cases are very close to those for pallets over a limited range of distances. For instance, at a distance of 6 inches from the perimeter (the central egg in a case), the predicted cooling rate for the pallet is 0.09 per hour. At a distance of 2 inches from the perimeter, the predicted cooling rate for the pallet is 0.81 per hour and for a case, it is 0.9 per hour. Thus, the model predictions give consistent results across cases and pallets. Furthermore, the predictions of cooling constants around 1.0 for eggs within 2 inches of the perimeter in pallets or cases lends support to the assumption that eggs exposed to ambient air or in cartons in a refrigerator have a cooling constant of 1.0.

Distribution of Exponential Cooling Rates for Each Step

Among egg producers and processors, egg storage practices vary. For example, some producers may use pallets to store their eggs, while others prefer to use cartons or flats. The following describes the estimated fraction of production or processing facilities that use the three basic storage practices of cases within a pallet, stacks of cartons or flats within or without a case, and eggs exposed to ambient air in a carton in a refrigerator. These fractions are used to determine the applicable cooling rate for each modeled egg during its travels from the layer house to the processor.

*Layer House*

In a layer house, eggs are exposed to ambient air. These eggs usually sit on an egg belt until collected. An exponential cooling constant of 1.0 is assumed for all eggs in a layer house.

*On-Farm Storage*

Within the model, on-farm storage is assumed to apply to off-line facilities only. What might be thought of as on-farm storage for in-line facilities is modeled as pre-processing storage. The NAHMS survey of the U.S. layer industry found 81.5% of farms that were off-line facilities used reusable plastic flats to store and transport eggs off the farm. [78] The remaining 18.5% of such farms used disposable fiber flats. These findings actually highlight the fact that most commercial egg producers are likely to store and transport eggs, in line or off line, in flats that are placed on wheeled racks for ease of movement. It seems unlikely that eggs would be stored in boxes on pallets before the eggs are processed. This possibility is accounted for in eggs stored on the farm by assuming that 1% of all eggs might be transported in cases on pallets from the farm to the processor. These eggs would have a *k* value of 0.01. The other 99% of eggs would be transported in flats on racks and would have a *k* value of 0.1.

Cooling constants for each egg are adjusted to account for the egg's distance from the perimeter. Random draws are taken from three uniform distributions to represent the egg's three-dimensional location in a case or pallet. The value representing the closest outside surface is selected as representing the egg's distance to the perimeter. In this manner, a different cooling rate is chosen for each egg that passes through this processing step.

*Transportation*

Within the model, transportation applies to off-line facilities only. The same packaging used for storing eggs on the farm is assumed to be used for transportation. Thus, the same *k* values and frequencies are used for transportation that were used to model on-farm storage. For an individual egg, the *k* value is equal to the *k* value the egg had on the farm.

Pre-processing Storage

Storage before processing is common to both in-line and off-line facilities. The same packaging used for storing eggs on the farm and for transportation is used for pre-processing storage. Thus, the same k values and frequencies used for pre-processing storage for off-line eggs are used to model on-farm storage. Cooling constants for storing eggs at in-line facilities are the same as for off-line facilities with the exception that no eggs would be stored in cases and pallets. Table 3-12 summarizes the exponential cooling constants used in the model. Note that a cooling constant of 0.01 represents storage in pallets, and a cooling constant of 0.1 represents storage in individual cases or racks. These cooling constants are for the central egg; the cooling constant for a specific egg is adjusted with Equation 3.11.

TABLE 3-12 FRACTION OF THE CENTRAL EGGS AT DIFFERENT COOLING CONSTANTS IN THE STEPS BEFORE PROCESSING.

| | Location | Fraction of Central Eggs at Given *k* Value | | |
|---|---|---|---|---|
| | | **0.01** | **0.1** | **1** |
| Off line | Layer house | | | 1.00 |
| | On-farm storage | 0.01 | 0.99 | |
| | Transportation | 0.01 | 0.99 | |
| | Pre-processing storage | 0.01 | 0.99 | |
| In line | Layer house | | | 1.00 |
| | Pre-processing storage | | 1.00 | |

Functional Relationships

In this section, the relationships presented earlier are revisited to provide the detailed calculations for $G_1$. The complexities alluded to earlier are added to the model in this section. Internal egg temperature is an important input calculated from the ambient temperature and cooling rate. YMB depends on internal egg temperature and time of storage. The rate of growth of *Salmonella* inside the egg depends on YMB and internal egg temperature. Finally, the rate of growth, in conjunction with the initial number of SE and amount of time available, determines the number of bacteria in an egg serving. The algorithms for predicting internal egg temperature and for estimating YMB, growth rate, and the total bacteria inside the egg are presented in this section.

Internal Egg Temperature, $T_t$

Internal egg temperature changes with time as a function of its initial temperature, the ambient temperature, and the rate of cooling (see Table 3-13). Note that the units for time (hours) must match up with the units for the $k$ value (hours$^{-1}$).

TABLE 3-13 DETERMINATION OF INTERNAL EGG TEMPERATURE ($T_T$).

| Variable Name | Description | Estimation |
|---|---|---|
| $T_a$ | Storage temperature for applicable time | Lognormal distribution from data |
| $T_0$ | Internal egg temperature at time of lay | 40°C (104°F) |
| $k$ | Exponential cooling rate (hours$^{-1}$) | Based on Table 3-11 |
| $T$ | Storage time in hours | Lognormal distribution from data |
| $T_t$ | Internal egg temperature at time = $t$ | $e^{(-kt)} (T_0 - T_a) + T_a$ |

Yolk Membrane Breakdown, $M_t$

YMB is a concept that applies to eggs that are not initially contaminated in the yolk. For the SE inside such eggs, growth is assumed to occur slowly or not at all until the bacteria have access to the rich nutrients of the yolk. The yolk membrane provides a physical barrier to rapid bacteria growth, but the membrane's permeability increases across time as a function of the internal temperature of the egg. The likelihood that YMB occurs for a specific egg at a specific time depends on the current and past ambient temperatures that the egg has experienced. See Annex E for more detail.

Estimation of the cumulative probability of YMB, $P(M_t)$, is based on the calculations shown in Table 3-14. Although the cumulative likelihood of YMB increases monotonically with time, the actual time YMB occurs is a random occurrence for a particular egg. Therefore, two eggs handled in exactly the same conditions will have identical cumulative probability distributions across time for YMB. However, one egg's yolk membrane may break down at the 5$^{th}$ percentile of this distribution, while the other may not break down until the 95$^{th}$ percentile of this distribution.

TABLE 3-14 ESTIMATION OF THE CUMULATIVE PROBABILITY OF YMB.

| Variable name | Description | Estimation |
|---|---|---|
| $T_t$ | Internal egg temperature at time = $t$ | See Table 3-13 |
| Ω | Multiplier to account for data discrepancies | Either 1 or 2.53 |
| $S_0$ | Initial bacteria in egg at time of lay | Random value depending on egg type, $E_i$ |
| $d, f, g, k$ | Coefficients estimated from statistical fitting to data | Constants |
| $YMB_b$ | Intermediate calculation for estimating $P(M_t)$ | $\Omega e^{(e^{(F+ G \times Tt)} - K)} + [0.0032(S_0 - 500) \div (8\Omega)$ |
| $t$ | Storage time in hours | Lognormal distribution from data |
| $P(M_t)$ | cumulative probability of YMB | $1 - e^{(-e^{(D = YMB_b \times t)})}$ |

Annex E provides more detail about the input Ω in Table 3-14. It is a multiplier included to account for discrepancies in predictions from two sets of data concerning YMB. If Ω equals one, then the estimated $P(M_t)$ is consistent with one dataset. If Ω equals 2.53, then $P(M_t)$ is consistent with the other dataset. For the baseline model, Ω is assumed to equal one. For more detail about this parameter, see Annex E (section 2).

Imagine an egg that is 25 hours old. Suppose the incremental change in the probability of YMB ($P(M_t)$) during the past hour is desired. The change in cumulative probability for that egg is calculated as

$$\Delta P(M_t) = P(M_t = 1.04) - P(M_t = 1.00) \tag{3.13}$$

where we calculate $P(M)$ at time = 1.04 days and subtract from it $P(M)$ at time = 1.00 day when the time increment is 0.04 day or 1 hour.

If internal egg temperature varies, but we know $P(M)$ at time = 1.00 day, then the value for $P(M)$ at time = 1.04 days is approximated as

$$P(M_{1.04}) = P(M_{1.00}) + \Delta P(M_{0.04}) \tag{3.14}$$

where $\Delta P(M_{0.04})$ is solved for using and assuming a constant internal egg temperature during the past hour. This does not require assuming the internal egg temperature was constant before time = 1.00 day. If the internal egg temperature declined between time = 1.00 day and time = 1.04 days, then $\Delta P(M_{0.04})$ will be smaller than that predicted assuming the temperature remained constant. Alternatively, $\Delta P(M_{0.04})$ will be larger if the temperature increased during that time interval.

This example can be generalized for any value of time and sufficiently small values for the time increment. This is how $P(M_t)$ is recalculated as the age of an egg increases and internal egg temperature varies. In the model, a random value ($p$) from 0 to 1 is drawn at the beginning of the iteration. As subsequent increments are modeled, the value for $P(M_t)$ is updated and compared to $p$. When *P (Mt) exceeds p,* then YMB has occurred and $P(M_t)$ is no longer estimated.

Growth Rate

The exponential growth rate for *Salmonella* in eggs depends on the initial contamination site, level of *Salmonella*, and internal egg temperature. Annex E presents the detailed data and estimation of growth rate functions. The algorithms for predicting the exponential growth rate in albumen, VM, and yolk are shown in Table 3-15.

TABLE 3-15 EXPONENTIAL GROWTH RATES FOR YOLK-CONTAMINATED, VITELLINE MEMBRANE-CONTAMINATED, AND ALBUMEN-CONTAMINATED EGGS

| Variable name | Description | Estimation |
|---|---|---|
| $T_t$ | Internal egg temperature at time = *t* | See Table 3-14 |
| *Tmax* | Maximum temperature at which growth occurs | 45.6°C |
| *B, E, FY, W* | Coefficients estimated from statistical fitting to data | Constants, see Annex E, Table E14 |
| *Ws* | Seropositivity indicator | Is 1 if sero-positive egg, is zero if sero-negative egg |
| $\mu^{Yolk}$ | Predicted exponential growth rate in yolk | $(1 - W \times W_s) \times ((E + FY \times T_t) \times (1 - e^{(B \times (Tt - Tmax))}))^2$ |
| *V* | Coefficient estimated from data | Constant, see Annex E, Table E14 |
| $\mu^{Vitelline}$ | Predicted exponential growth rate on the vitelline membrane | $V \times \mu_{Yolk}$ |
| *K* | Constant of proportionality between vitelline and albumen growth rates | 0.07 |
| $\mu^{Albumen}$ | Predicted exponential growth rate in albumen | $K \times \mu_{Vitelline}$ |

Number of Bacteria inside Egg, $S_t$

Calculating growth inside an egg requires consideration of the initial number of bacteria inside the egg, how long the bacteria have been growing, where the bacteria reside in the egg, the exponential growth rate, and the time when YMB occurs. If an egg is albumen contaminated, then SE growth is unlikely to occur until YMB commences. The same general pattern applies to VM-contaminated eggs.

Figure 3-15 provides an illustrative example of our conception of the growth phases for an albumen-contaminated egg with a constant internal temperature of 12.5°C and initially contaminated with one SE bacterium. This bacterium in the albumen may begin to adapt to the relatively difficult environment of the albumen. This initial adaptation period, the lag phase, lasts up to 8 days after which the bacterium is able to grow exponentially at a slow rate. This particular egg's yolk membrane is assumed to break down at 42 days, the $10^{th}$ percentile of the cumulative distribution at a constant temperature of 12.5°C. Following this breakdown, the organisms adapt again to a new environment and experience an abbreviated lag phase, before growing exponentially at a fast rate in the yolk. As the bacteria population approaches the maximum population density achievable inside an egg, theoretically about 10 $\log_{10}$, growth slows and eventually ceases, or equilibrates to the death rate, inside that egg about 50 days after lay.

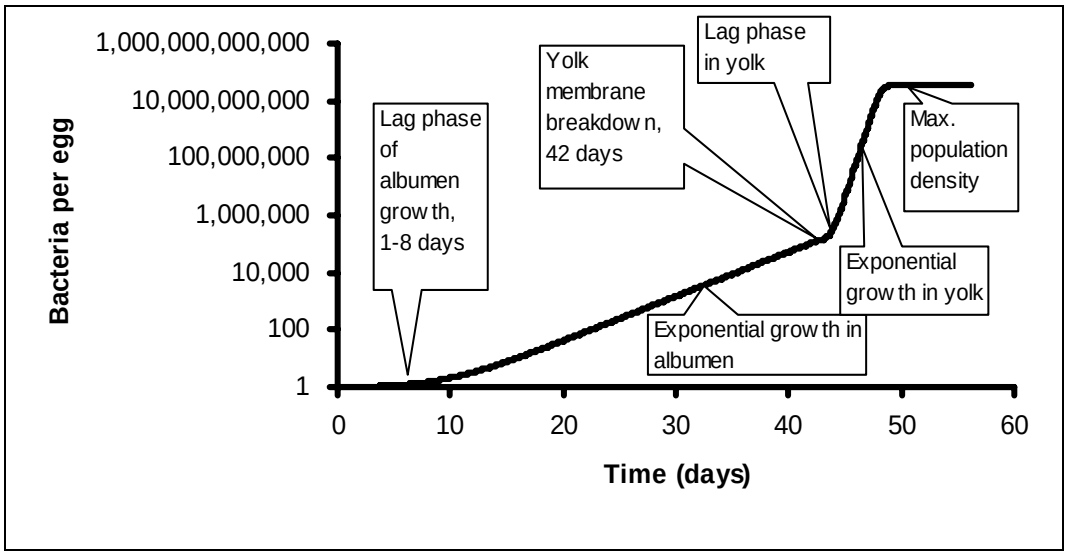



FIGURE 3-15 ILLUSTRATIVE EXAMPLE OF PHASES OF GROWTH MODELED FOR SE IN CONTAMINATED EGGS. IN THIS EXAMPLE, INTERNAL TEMPERATURE IS CONSTANT AT 12.5°C AND YMB OCCURS AT THE 10TH PERCENTILE OF THE POPULATION (I.E., APPLICABLE $P(M) = 0.10$).

For modeling purposes, the exponential growth rate in albumen is estimated according to Table 3-15. The number of days of albumen growth depends on when YMB occurs. The growth in the yolk is also estimated according Table 3-15. The number of days of yolk growth depends on the remaining time the egg is stored before it is consumed and the maximum density of organisms allowed in the egg. Growth rates and YMB depend on internal egg temperature. Internal egg temperature further depends on ambient storage temperatures, length of time in storage, and the cooling rate. The ambient temperatures, storage times, and cooling rates are described by probability distributions. Therefore, calculating the number of bacteria in an egg at any point between the times it was laid and the time it is processed requires all of the inputs and calculations previously described in this section. Given all these previous calculations, the final calculations for estimating the number of bacteria in the egg are presented here.

*Deterministic Calculations*

The amount of bacteria in an egg can be estimated using deterministic or non-random calculations. Alternatively, these estimates can be completed using stochastic or random techniques. The deterministic calculations are described first.

In the absence of any constraints, bacteria within an egg would grow according to the following differential equation:

$$dS(t) / dt = S(t)\mu \qquad (3.15)$$

where $S(t)$ = number of bacteria at time $t$ and $\mu$ = the daily exponential growth rate. The exponential growth rate per day, $\mu$, is assumed independent of time for a sufficiently small time interval.

The lag phase occurs because the bacteria are adjusting to changing environmental conditions. The consequence of the lag phase is that the bacterial growth rate is less than $\mu$ for some initial period. Baranyi and Roberts[83] proposed a variable, $\alpha$, as the adjustment function. It

is a function of time and describes the modulating effect of environmental influences on $\mu$. Therefore, $\mu$ is considered the maximum growth rate, and $\alpha$ essentially reduces the maximal rate for some period. The variable $\alpha(t)$ ranges from zero to one and exerts its influence early in the growth period of bacteria.

The adjustment factor ($\alpha(t)$) may be defined as a function of some critical substance that serves to limit or constrain growth.[83] Much complexity surrounds the notion of rate-limiting nutrients or processes. Table 3-16 describes the elements needed to calculate $\alpha(t)$and more detail is provided in Annex E.

TABLE 3-16 ESTIMATING THE NUMBER OF BACTERIA IN AN EGG.

| Variable Name | Description | Estimation |
|---|---|---|
| $\mu$ | Exponential growth rate | See Table 3-15 |
| *LPD* | Lag period duration | $\ln(1 + (1/q_0)) / \mu$ from Baranyi and Roberts[83] |
| *GT* | Time for cells to double in number (generation time) | $\ln(2) / \mu$ |
| *R* | Ratio of lag period duration to generation time | $LPD \div GT$ (Assumed to be 5) |
| $Q_0$ | Ratio of exponential lag rate ($\lambda$) to $\mu$ | $R = \ln(1 + (1/q_0)) / \ln(2)$, so $q_0 = 0.03$, see Annex E |
| *t* | Storage time in hours | Lognormal distribution from data |
| $\alpha(t)$ | Lag adjustment to $\mu$ | $q_0 / (q_0 + e^{-\mu t})$ from Baranyi and Roberts[83] |
| *MPD* | Maximum population density for SE in eggs | $10^{10.59}$ |
| $S_0$ | Initial number of bacteria in egg | Random value depending on egg type, $E_i$ |
| $\beta(t)$ | Maximum density adjustment to $\mu$ | $1 - S_t / MPD$ |
| $\Delta(t)$ | Time increment | Model setting in $days^{-1}$ |
| $S_t$ | Number of bacteria within egg at time *t* | $S_0 \times e^{\alpha \times \mu \times \beta \times \Delta}$ |

The lag adjustment is not the only consideration in modeling the growth of bacteria. The maximum population density that can be achieved by the bacteria is another consideration. While the lag phase reflects the bacteria adjusting to their new environment, the maximum population density reflects the limitations of the environment or genetic factors to support an ever-increasing population size. As the maximum population density is approached in an egg, the growth rate slows down and eventually becomes zero. Therefore, a second adjuster of $\mu$ that ranges from one to zero and exerts its effect late in the growth period is introduced, $\beta(t)$. Its estimation is also shown in Table 3-16.

Including the $\alpha(t)$and $\beta(t)$ terms, the differential equation becomes

$$dS(t) / dt = S(t)a(t)\mu\beta(t) \tag{3.16}$$

which is a complicated expression to solve. Baranyi and Roberts[83] provide a solution for the case where $\mu$ is constant, but such a solution is not easily applied to a computer model where $\mu$ is changing with time. Instead, for each sufficiently small time increment in the model the terms $\alpha$, $\mu$ and $\beta$ are assumed constant. Therefore, the solution is approximated as

$$S_{t+1} = S_t \times e^{\alpha \times \mu \times \beta \times \Delta t} \tag{3.17}$$

where $S_{t+1}$ is the number of bacteria at the end of one time increment, $S_t$ is the number of bacteria at the beginning of the time increment, and $\Delta t$ is the size of the time increment (i.e., fraction of days for this model). This calculation is completed for each egg individually throughout the time it is modeled.

Using Equation 3.17, the model steps through cumulative time increments and recalculates the bacterial levels in a contaminated egg. For example, if the egg is albumen contaminated, the model determines the growth rate in albumen for the applicable temperature and time increment, then calculates the corresponding $\alpha$ and $\beta$ terms, and finally calculates the number of SE in the egg for each point in time. This step is repeated for each successive time increment until the time when YMB occurs. Once this occurs, subsequent time increments calculate the growth rate in yolk for the temperature applicable to the time increment. Because $\alpha(t)$ for yolk growth is a different function of time relative to that for albumen growth, the calculation for this input is based on the cumulative time since YMB. Time begins again at zero when YMB occurs for the purposes of calculating $\mu(t)$. For each time increment after YMB, the number of bacteria is recalculated using with the appropriate substitutions for $\mu(t)$ and $\alpha(t)$.

*Variability in Growth*

The process described above estimates growth of SE in a deterministic fashion when in fact there could be a great deal of variability in the growth behavior of the SE cells in shell eggs. To examine these effects, an alternative algorithm for calculating the number of bacteria in an egg using stochastic theory is presented. This theory and the derivation of these equations are presented in detail in Annex E. The algorithm for estimating the number of bacteria in an egg at time *t* is shown in Table 3-17 (following page).

Modeling stochastic growth processes is computationally intensive. To examine the value of including the stochastic calculations, the results of the model using deterministic and stochastic predictions are compared as part of the risk characterization.

TABLE 3-17 NUMBER OF BACTERIA WITHIN EGG AT TIME *T* ASSUMING STOCHASTIC GROWTH PROCESSES.

| Variable Name | Description | Estimation |
|---|---|---|
| $\mu(t)$ | Exponential growth rate | See Table 3-15 |
| $q_0$ | Ratio of exponential lag rate ($\lambda$) to $\mu$ | $R = \frac{\ln\left(1+\frac{1}{q_0}\right)}{\ln(2)}$, so $q_0 = 0.03$ (see Table 3-16) |
| $\lambda(t)$ | Exponential lag rate | $q_0 \times \mu$ |
| $I$ | Integration of growth rates from time 0 to $t$ | $\sum_0^t \mu(t) \times \Delta r$ |
| $P(t)$ | Cumulative likelihood of one organism being beyond its lag period duration at time $t$ | $e^{-\sum_0^t \lambda x \Delta r} + \sum_0^t \left( e^{-1+\sum_0^t (\mu x \Delta r) - \sum_0^t (\lambda x \Delta r)} x \lambda x \Delta t \right)$ |
| $S_0$ | Number of organisms inside egg before growth begins | Initially a random value depending on egg type, $E_i$, but $S_0$ is iteratively updated during each time increment |
| $P(Growth)_t$ | Likelihood that one or more organisms begin growth at time t | $1 - P(t)^{S0}$ |
| $E[r(t)]$ | Average relative growth occurring at time $t$ for all bacteria in egg | $e^{-\sum_0^t \lambda x \Delta r} + \sum_0^t \left( e^{-1+\sum_0^t (\mu x \Delta r) - \sum_0^t (\lambda x \Delta r)} x \lambda x \Delta t \right)$ |
| $v(t,s)$ | Intermediate calculation | $I - \sum_0^t \mu x \Delta t$ |
| $\gamma(s)$ | Intermediate calculation; the integral of exponential lag rate from time 0 to t | $\sum_0^t \lambda x \Delta r$ |
| $V[r(t)]$ | Variance in relative growth occurring at time $t$ for all bacteria in egg | $\{2\int_0^t (e^{2v(t,s)} - e^{v(t,s)}) e^{-\gamma(s)} ds + E[r(t)][1 - E[r(t)]]\} \div N_0$ |
| $E[r(t)\|growth]$ | Average relative growth for cells that grow inside egg | $\frac{E[r(t)] - (1-q)}{q}$ |
| $V[r(t)\|growth]$ | Variance in relative growth for cells that grow inside egg | $\frac{V[r(t)] - (1-q)q^{-1}(E[r(t)]-1)^2}{q}$ |
| $S_t$ | Number of bacteria within egg at time $t$ | If $P(t)$<some critical value, then $S_0$; Otherwise $S_0$ *x Lognormal((E[r(t)* \| *growth], V[r(t)* \| *growth]* |

***Percentage of bacteria that survive pasteurization,* P**

Pasteurization of shell eggs involves immersing the eggs in hot water for a prescribed length of time. The process should result in destroying some or all of the bacteria inside the egg. Different levels of effectiveness are achieved by changing the water temperature or the length of time the egg is immersed. The effectiveness of any combination of time and temperature is estimated

from an equation. This effectiveness is expressed as the percentage of bacteria in an egg, *P*, that survive the pasteurization process.

One purpose of this risk assessment is to estimate the effectiveness of different pasteurization processes. Risk managers will use these estimates to determine a required level of effectiveness from pasteurization. Because the effectiveness of pasteurization will vary with the particular characteristics of the eggs being pasteurized so could any eventual performance standards.

Although pasteurization is intended to reduce or eliminate bacteria within eggs, there is potential for an increase in risk in some eggs because pasteurization increases the temperature inside eggs and hastens YMB. YMB is a critical event for contaminated eggs because once it occurs, growth rates of bacteria within the egg dramatically increase. Any bacteria remaining inside an egg after pasteurization may be more likely to multiply faster during the post-pasteurization growth period, $G_2$, than they would in an egg that was not pasteurized.

Shown in Table 3-18 is the time in, and the temperature of, the pasteurizer. The temperature inside the egg begins at some value depending on how the egg was handled before pasteurization, as predicted in $G_1$. This temperature then begins to equilibrate to the hot water temperature after egg immersion. Each egg "exits" the $G_1$ stage of the model with an internal temperature and a bacteria count. It enters the $G_2$ stage of the model with the same values.

TABLE 3-18 DETERMINING PASTEURIZATION FACTOR.

| Variable Name | Description | Estimation |
|---|---|---|
| $\alpha$ | Intercept term estimated from data | Fixed value (e.g., 67.2) |
| $\beta$ | Slope term estimated from data | Fixed value (e.g., –1.2) |
| $T$ | Ambient temperature in pasteurizer | Fixed value (e.g., 58°C) |
| $b$ | Slope term as function of ambient pasteurizer temperature | $e^{\alpha + \beta T}$ |
| $A$ | Intercept term as function of ambient pasteurizer temperature | $-e^{4.18 + \ln(b)}$ |
| $t$ | Time in pasteurizer | Simulated |
| $T_0$ | Internal egg temperature prior to pasteurization | Simulated output from $G_1$ |
| $k$ | Exponential cooling rate constant | Fixed value (e.g., 0.10 second$^{-1}$) |
| $T_t$ | Internal egg temperature at time = $t$ | $e^{(-kt)}(T_0 - T) + T$ |
| $P$ | Pasteurization factor given the time in pasteurizer and the temperature of the pasteurizer | $e^{-\sum_0^t e^{a(T)+b(T)\times EggTemp_t}\times\Delta t}$ |

The mechanics of simulating pasteurization for a single egg involve stepping through small time intervals to recalculate the internal egg temperature and the corresponding *P* value. The target value for *P* determines how long (i.e., in model terminology how many time increments) the pasteurization period is modeled. For each simulation, the target value for *P* is fixed for each pasteurized egg. The time it takes each egg to reach that *P* value will vary because the internal

egg temperature will vary from egg to egg. We assign a fixed value of 58°C for the temperature of the pasteurizer's hot water.

While the pasteurizer is working to destroy bacteria, the internal egg temperature is also influencing the integrity of the yolk membrane such that it is likely to break down sooner. The algorithm presented in the $G_1$ section for $PYMB_t$ was developed based on ambient temperatures much less extreme than the temperatures experienced during pasteurization. The algorithm does not predict meaningful results for the high temperatures and short time periods experienced during pasteurization. Therefore, an alternative approach to determine the cumulative likelihood of YMB is needed. For $P(M_t)$, see Table 3-14. This approach uses the number of days until YMB ($M$) for given internal egg temperatures.

Figure 3-16 plots the natural log of days until YMB ($M$) versus internal egg temperature. The values were generated using the algorithm in the $G_1$ section and determining the number of days when $P(M_t)$ was nearly 100%. The algorithm uses fixed internal egg temperatures and selects the time (in days) when the calculated $PYMB_t$ begins to plateau near 100% (i.e., where the cumulative likelihood of an egg's yolk membrane breaking down is about 100%).

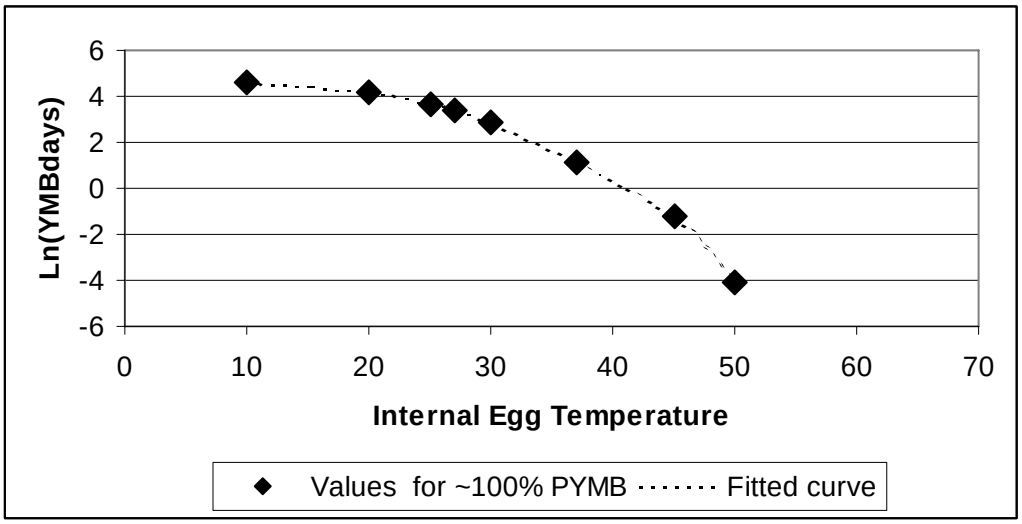



FIGURE 3-16 INTERNAL EGG TEMPERATURE VS. LN(YMB DAYS).

Given the values plotted in Figure 3-16, a function is fit to the values to allow calculation of days until YMB for any egg temperature. This function,

$$Ln(YMB\ days) = (1-e^{k(EggTemp-10)}\ x\ Ln(100) \quad (3.18)$$

was estimated by minimizing the squared deviation between the values calculated using the algorithm described above and the values predicted by this function.

During each time increment in the pasteurization model, a value for $M$ is calculated based on the internal temperature at that time. Recall that $P(M_t)$ is the cumulative probability of YMB. During pasteurization, this cumulative probability is incremented by $\Delta t$ / M, where $\Delta t$ is the size of time increment.

As an alternative to using, a published function for $M$ ($M = 10^{2.09-0.043\ x\ Tt}$)) is also available.[84] This function is easier to work with but predicts generally fewer days to YMB than that shown in

Figure 3-16. The consequence of this alternative function is to increase $P(M_t)$ at higher temperatures more slowly. Thus, YMB is less likely to occur. The different effect of this function on model outputs is considered in the sensitivity and uncertainty analysis. The baseline model uses the function shown in Figure 3-16 because that function is directly related to the $P(M_t)$ algorithm used in $G_1$ and $G_2$.

### *Growth Effect after Processing,* $G_2$

This section presents background material, mathematical concepts, derivation of inputs, functional relationships, and computer programming topics that concern growth of SE in contaminated eggs after processing ($G_2$).

In the conceptual model, the amount of SE growth per egg after processing is represented as a multiplier, $G_2$. This represents the number of SE in an egg at the time of consumption resulting from handling and storing an egg after processing until the egg is consumed.

As with growth before processing, growth in an individual egg after processing depends on storage time, storage temperature, and the cooling rates for eggs in particular storage conditions. The effect of the location of contamination and immunologic characteristics are the same as for growth before processing. The output of $G_2$ is a probability distribution reflecting the amount of growth that would be expected in the population of SE-contaminated eggs from the processor to consumption.

#### Derivation of Storage Times, Storage Temperatures, and Exponential Cooling Constants

The modeling approach for $G_2$ is similar to that for $G_1$. The number of bacteria, the location of contamination, and the internal egg temperature predicted in $G_1$ as well as the pasteurization step, $P$, are carried over to $G_2$. After predicting SE growth in $G_1$ and possible SE decline in pasteurization, the remainder of the model considers the following steps for each egg: post-processing storage; retail transportation or transportation to a distributor; retail storage or storage at a distributor, home transportation or transportation to a hotel, restaurant, or institution; and home storage or storage at a hotel, restaurant, or institution.

The number of pathways that eggs can take after processing probably exceeds the number of pathways they can take before processing. Eggs may be shipped directly to a retail store after processing or they may pass through intermediate distributors. Eggs may be stored and prepared in a restaurant setting rather than in the home. The evidence available for storage practices after processing, however, is sparse. Distributions for storage practices are inferred from recorded practices for other types of products or recommended practices for eggs. The model treats eggs as if they pass through all five steps.

Determination of internal egg temperature, YMB, and bacteria growth follows the procedures detailed for $G_1$. The principal differences between $G_1$ and $G_2$ are the storage times and temperatures for each of the new steps and the heat transfer dynamics after processing when eggs are transferred to different types of containers.

#### Storage Times

Eggs are stored after processing, during transport, at retail, during transport to the home, and in the home. The length of time any egg is stored in each of the locations can be described by a probability distribution. Data for estimating distributions for storage times at each location are presented in this section. The estimated distributions are also shown. Table 3-19 shows the available data for time inputs.

TABLE 3-19 AVAILABLE DATA FOR TIME INPUTS FOR $G_2$.

| Retail Storage (represents post-processing, retail transportation, and retail storage)[a] | | Home Transportation[b] | | | |
|---|---|---|---|---|---|
| Days Since Egg Processing when Consumer Purchased | % Frequency | Time Out of Refrigeration in Minutes | % Frequency at Listed Outside Temperatures | | |
| | | | <21.1°C | 21.1-31.7°C | 31.7°C |
| 1 – 7 | 25% | 0 – 15 | 0 | 0.4 | 0.4 |
| 8 – 14 | 45.2% | 16 – 30 | 3 | 6 | 4 |
| 15 – 21 | 16% | 31 – 45 | 15 | 14 | 17 |
| 22 – 28 | 9.2% | 46 – 60 | 25 | 27 | 24 |
| 29 – 35 | 4% | 61 – 75 | 27 | 24 | 26 |
| 36 – 42 | 0% | 76 – 90 | 16 | 13 | 16 |
| 43 – 49 | 0.6% | 91 – 105 | 11 | 10 | 7 |
| | | 106 – 120 | 3 | 4 | 3 |
| | | >120 | 1 | 3 | 2 |
| | | n = | 143 | 545 | 245 |

[a]Source: Bell et al.[85]

[b]Source: Audits International.[86]

Data were available for storage time for only two of the five steps. The data for retail storage, however, are more informative than might be apparent at first. Bell[85] reports on the total time between processing and purchase by consumers. Thus, the data in the table above represent the total storage time in the post-processing, retail transportation, and retail storage steps.

As with the data for $G_1$, these data were fit to lognormal distributions. Figure 3-17 compares the cumulative lognormal distribution with the cumulative frequency data from the retail storage data in Table 3-19.

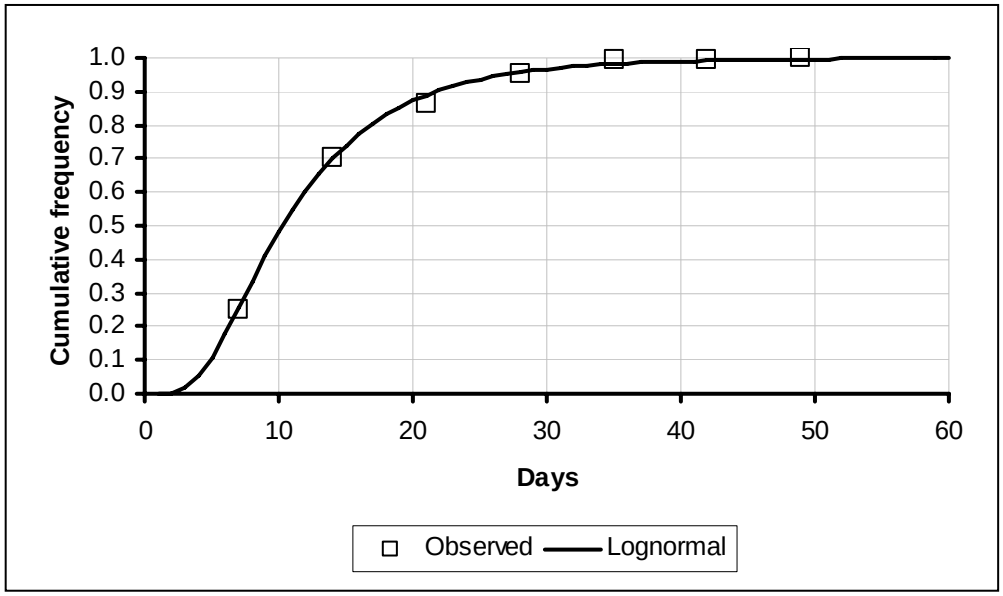



FIGURE 3-17 COMPARISON OF OBSERVED AND PREDICTED RESULTS FROM A LOGNORMAL DISTRIBUTION FOR RETAIL STORAGE TIME.

Audits International[86] reports time, in days, of transportation to the home for three different ambient temperature ranges; a chart depicting the relative frequencies of these times for each of the ambient temperature ranges is shown in Figure 3-18.

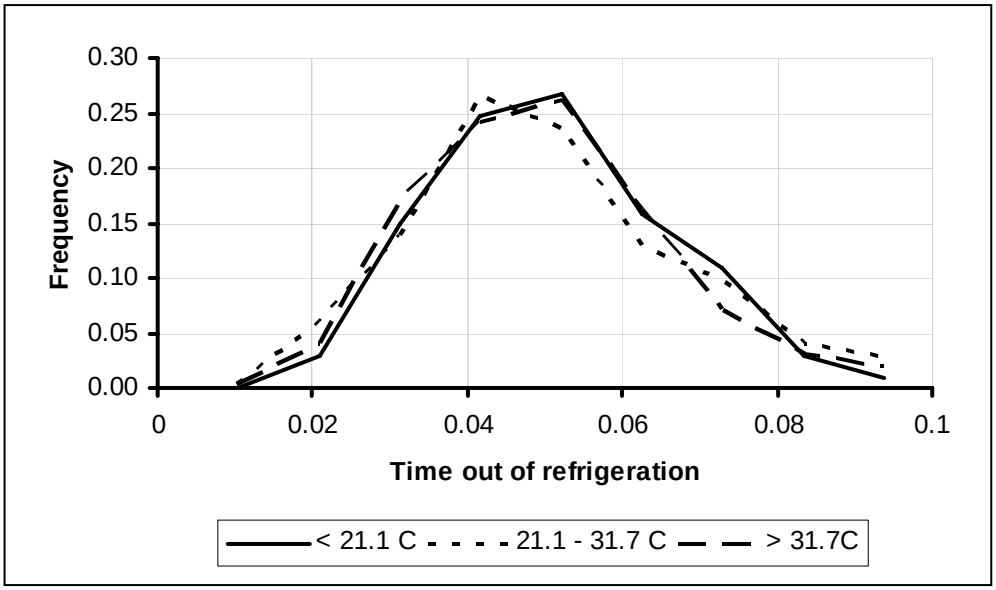



FIGURE 3-18 RELATIVE FREQUENCIES OF TIME, IN DAYS, OUT OF REFRIGERATION FOR THREE DIFFERENT TEMPERATURE RANGES.

Because there appears to be relatively little difference in the three frequency distributions, the three distributions are integrated. Figure 3-19 compares the observed data with a lognormal distribution.

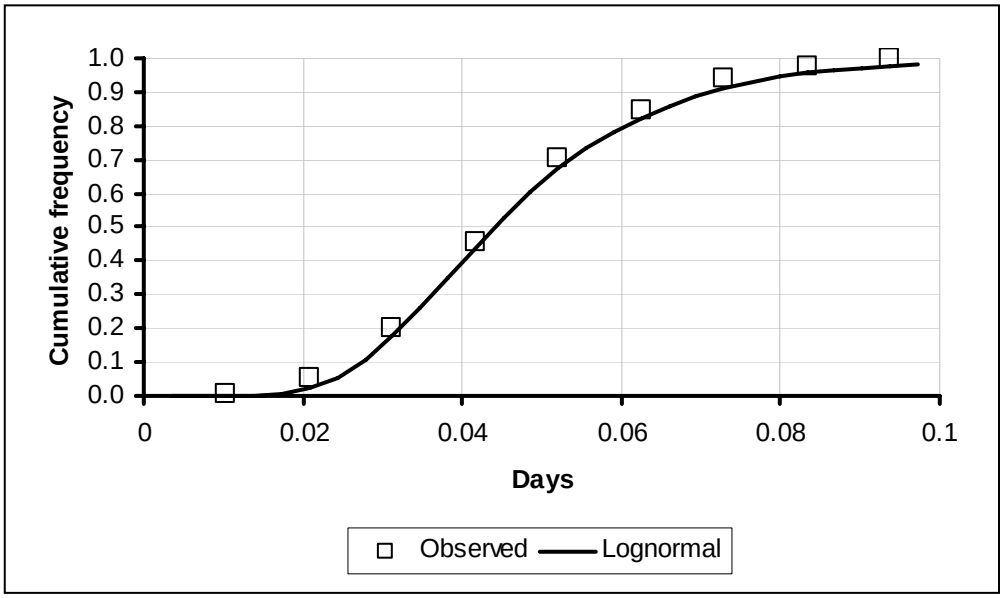



FIGURE 3-19 COMPARISON OF OBSERVED AND PREDICTED RESULTS FOR A LOGNORMAL DISTRIBUTION FOR HOME TRANSPORTATION STORAGE TIME.

Although the information above provides an estimate of the total time elapsed between the finishing of processing and the purchasing of eggs at retail, no data specifically describe post-processing storage time or the time it takes to transport eggs between the processor and retail.The post-processing storage times occur after egg processing and before the eggs are transported from the processor to retail. Therefore, default distributions for post-processing storage, and transportation times are developed and then subtracted from the total time of storage to estimate retail storage time. As a default, post-processing storage time was modeled with a lognormal distribution where the mean was equal to the weighted mean of the two pre-processing storage time distributions, and the standard deviation was equal to the larger of the two standard deviations for pre-processing storage time. The two means for pre-processing storage time are –0.04 for the 86.5% of eggs that undergo off-line processing and 0.67 for the 13.5% of eggs that undergo in-line processing. Thus, the input mean to the lognormal distribution is –0.04 x 0.865 + 0.67 x 0.0135 = 0.056. Of the two standard deviations, 1.33 and 0.89, the larger is chosen. Similarly, no data specifically describe the time for transportation to a retailer. A value of 12 hours was chosen as a default mean for a lognormal distribution. The standard deviation was set to the same as used for layer house storage, on-farm storage, and transportation to the processor.

The lognormal distribution shown in Figure 3-19 represents the total storage time for the post-processing, retail transportation, and retail storage steps. To determine the modeled times for each of these steps, the following algorithm is used during model simulation: (i) One total storage time for all three steps is sampled from the distribution; (ii) post-processing storage time is sampled from its default distribution; (iii) retail transportation time is sampled from its default distribution; (iv) retail storage time is equal to the total storage time minus the post-processing and retail transportation times; (v) if retail storage time is less than 0.5 days, then retail storage time is set to 0.5 days, and the post-processing storage time is now set to the total storage time minus the retail transportation and retail storage times.

This algorithm ensures that total storage time from processing through consumer purchase will mirror the data shown in Table 3-19. There are no data describing the length of time eggs are stored before preparation. There are, however, recommended storage practices for eggs. The mean of the lognormal distributions was set as the geometric mean of 1 day and 35 days of storage. The standard deviation was set at the value used for other steps in $G_1$ and $G_2$. Table 3-20 shows the inputs for storage time for $G_2$.

TABLE 3-20 PARAMETERS FOR LOGNORMAL DISTRIBUTIONS FOR TIME OF EGG STORAGE AT DIFFERENT MODEL POINTS.

| Input | Time (Ln(Days)) | | |
|---|---|---|---|
| | Supported by Data? | Mean | Std Dev |
| Post-processing | No | 0.05 | 1.33 |
| Retail transportation | No | -0.69 | 0.59 |
| Retail storage | Yes | 2.33 | 0.59 |
| Home transportation | Yes | -3.12 | 0.37 |
| Home storage | No | 1.78 | 0.59 |

Storage Temperatures

The ambient temperature of storage for an egg during post-processing, transportation, retail, home transportation, and home storage is used to predict the internal egg temperature that determines the amount of *Salmonella* growth in the egg. This is a vector of five values for each egg. The ambient storage temperature at each of these stages can be described by a probability

distribution. Data for estimating distributions for storage temperatures at each location are presented in this section. The estimated distributions are also shown. Table 3-21 shows the available data for temperature inputs.

TABLE 3-21 AVAILABLE DATA FOR TIME INPUTS FOR $G_2$.

| Retail Storage | | | Home Transportation | | Home Storage | |
|---|---|---|---|---|---|---|
| **Dairy Semi-solid** | **Frequency of Temps in** | | **Outside Temps** | | **Home Product Temps** | |
| Temperature (°C) | Retail Refrigerator | Backroom Refrigerator | Temperature (°C) | Frequency (%) | Temperature (°C) | Frequency (%) |
| <-2.8 | 0.004 | 0.030 | <12.8 | 1 | <0.6 | 9 |
| -2.8 to -1.7 | 0.005 | 0.010 | 12.8 to 15.0 | 2 | 0.6 to 1.7 | 10 |
| -1.1 to 0.0 | 0.039 | 0.089 | 15.6 to 17.8 | 5 | 2.2 to 3.3 | 25 |
| 0.6 to 1.7 | 0.059 | 0.099 | 18.3 to 20.6 | 7 | 3.9 to 5.0 | 29 |
| 2.2 to 3.3 | 0.167 | 0.325 | 21.1 to 23.3 | 12 | 5.6 to 6.7 | 18 |
| 3.9 to 5.0 | 0.325 | 0.276 | 23.9 to 26.1 | 12 | 7.2 to 8.3 | 5 |
| 5.6 to 6.7 | 0.236 | 0.108 | 26.7 to 28.9 | 20 | 8.9 to 10.0 | 3 |
| 7.2 to 8.3 | 0.069 | 0.020 | 29.4 to 31.7 | 15 | 10.6 to 11.7 | 0.4 |
| 8.9 to 10.0 | 0.059 | 0.030 | 32.2 to 34.4 | 14 | 12.2 to 13.3 | 0.5 |
| 10.6 to 11.7 | 0.020 | 0.008 | 35.0 to 37.2 | 8 | 13.9 to 15.0 | 0.4 |
| 12.2 to 13.3 | 0.008 | 0.002 | 37.8 to 40.0 | 4 | 15.6 to 16.7 | 0.1 |
| 13.9 to 15.0 | 0.003 | 0.002 | >40.0 | 0.6 | 17.2 to 18.3 | 0 |
| 15.6 to 16.7 | 0.004 | 0.002 | *n* = | 970 | >18.3 | 0.1 |
| 17.2 to 18.3 | 0.000 | 0.000 | | | *n* = | 939 |
| >18.3 | 0.001 | 0.000 | | | | |
| *n* = | 972 | 515 | | | | |

Source: Audits International. [86]

Data were available for storage temperatures for three of the five steps. All data came from a single source.[86] Product temperatures were reported for the following products in retail display cases: liquid dairy, semi-solid dairy, pre–packaged lunchmeat, ground beef, fish fillet, sliced meat, and potato salad or equivalent. Additionally, temperatures were recorded in semi-solid dairy product in the backroom refrigerator. Temperatures for home transportation and home storage also came from semi-solid dairy products. Because of the availability of information for semi-solid dairy products and because these products were more likely to be stored in the same cases as eggs, semi-solid dairy product temperatures were used as a proxy for egg storage temperatures.

Data for retail storage temperatures came from two locations in the store: the retail display case and, when permission was granted to the auditor, the backroom refrigerator. Frequency distributions of temperature in these two locations are shown in Figure 3-20.

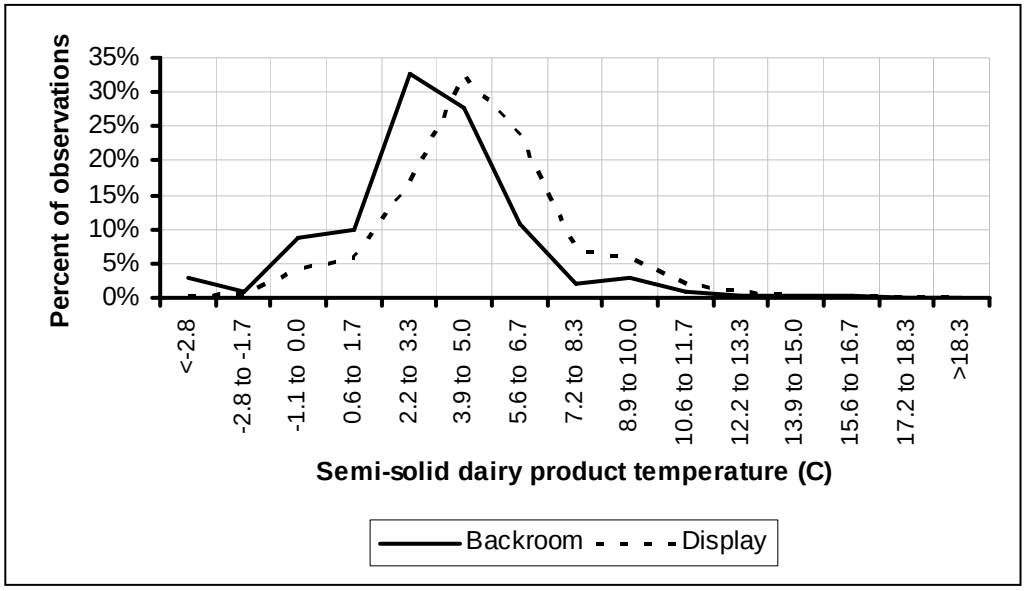



FIGURE 3-20 RECORDED TEMPERATURES FOR SEMI-SOLID DAIRY PRODUCTS.
Source: Audits International.[86]

The two frequency distributions shown in Figure 3-20 are similar with the backroom product temperature being shifted to lower temperatures. It is likely that eggs would spend some time after transportation in a backroom refrigerator and then moved to a display case as needed. Temperature is modeled as a single distribution because there is no information regarding the relative times of storage in each location and the semi-solid dairy product serves only as a proxy for eggs. Lognormal distributions were fit to the data for $G_2$ temperature distributions in the same manner as for the $G_1$ temperature distributions. Figure 3-21 compares the observed data with a lognormal distribution for retail storage temperature.

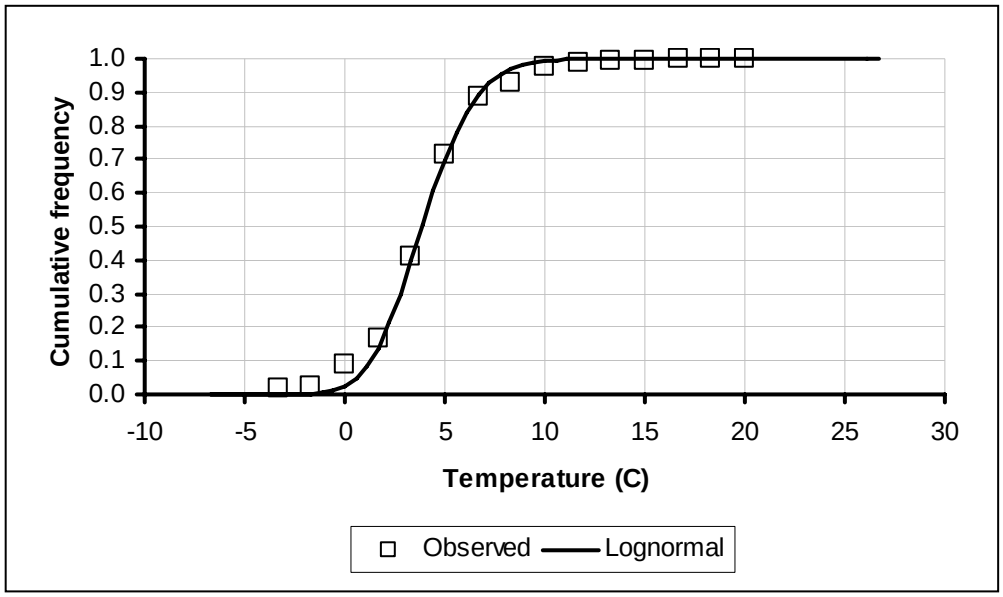



FIGURE 3-21 COMPARISON OF OBSERVED AND PREDICTED RESULTS FROM A LOGNORMAL DISTRIBUTION FOR RETAIL STORAGE TEMPERATURE.

Figure 3-22 compares observed data with a lognormal distribution for home transportation temperature.

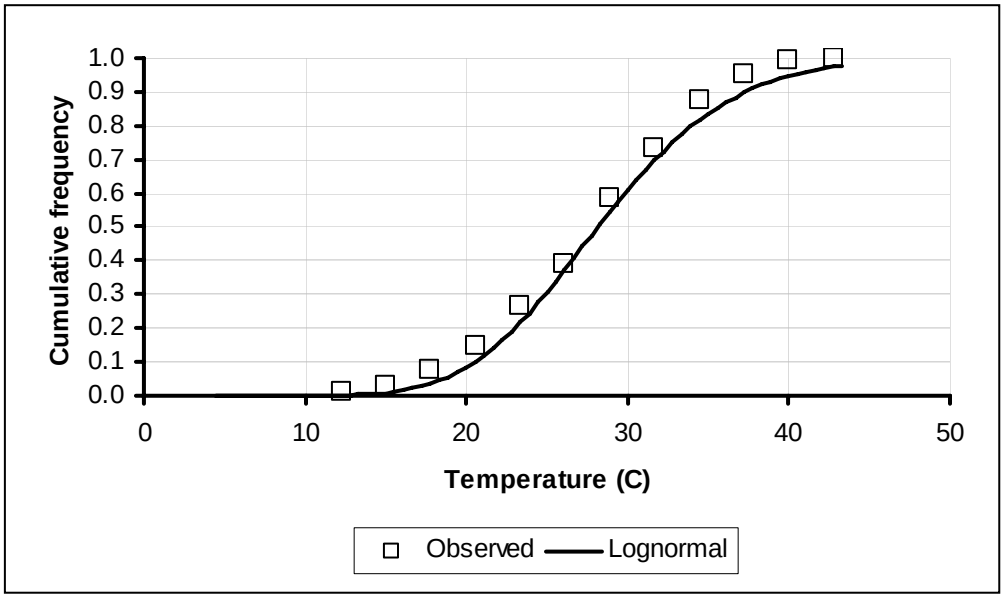



FIGURE 3-22 COMPARISON OF OBSERVED AND PREDICTED RESULTS FROM A LOGNORMAL DISTRIBUTION FOR HOME TRANSPORTATION TEMPERATURE.

The temperature measured in home refrigerators was taken in semi-solid dairy product 24 hours after the product was placed in the refrigerator. Thus, the temperature is considered an adequate representation of the ambient temperature. Figure 3-23 compares observed data with a lognormal distribution for home storage temperature.

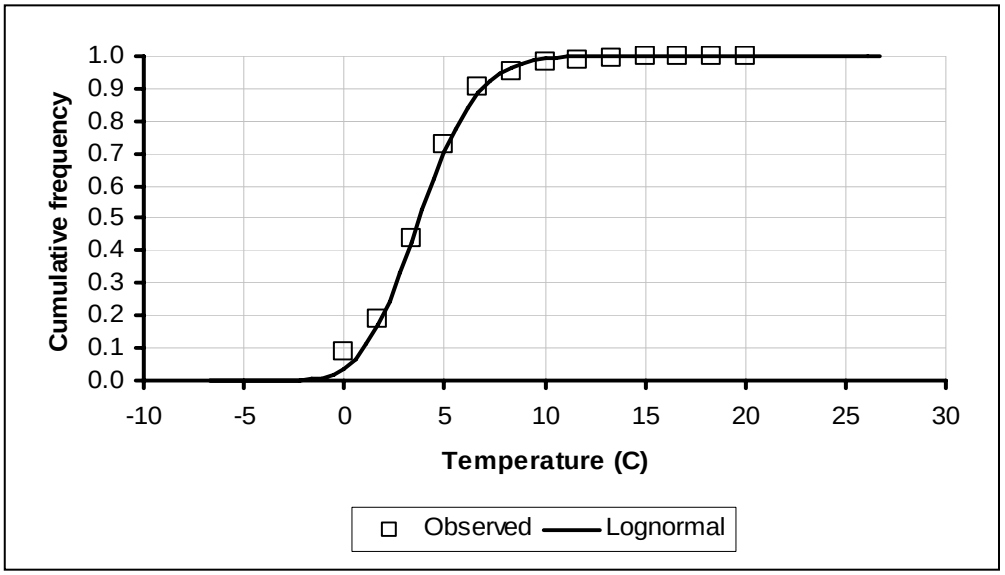



FIGURE 3-23 COMPARISON OF OBSERVED AND PREDICTED RESULTS FROM A LOGNORMAL DISTRIBUTION FOR HOME STORAGE TEMPERATURE.

There was no direct evidence describing the temperature of post-processing storage to which eggs would be exposed. Consequently post-processing storage temperature is assumed similar to pre-processing storage temperature. Nevertheless, it is easy to imagine ways in which storage temperatures for eggs before processing could be quite different from storage temperatures for eggs after processing. As with post-processing storage time, the in-line and off-line storage temperature distribution means were averaged with producers considered to represent in-line eggs and accounting for 13.5% of the distribution, while packers were considered off-line and accounted for 86.5% of the distribution. Because all of the standard deviations for storage temperatures were similar, the largest standard deviation was used for post-processing storage temperature.

No direct evidence is available that summarizes temperatures of vehicles used for transporting shell eggs to a retail establishment. It is likely that the vehicles used to transport eggs from the processor would not be the same vehicles as those used to transport eggs to the processor. Some simplifying assumptions have been made, however. It seems reasonable to assume that vehicles transporting eggs from a processor to retail or a distributor would be refrigerated. Consequently, the information on distribution of temperatures during transportation to the processor was used to develop the distribution for temperature during transportation from the processor. Table 3-22 shows the parameters for lognormal distributions for temperature of egg storage at different model points.

TABLE 3-22 PARAMETERS FOR LOGNORMAL DISTRIBUTIONS FOR TEMPERATURE OF EGG STORAGE.

| Input | Temperature (parameters in model entered as °F) | | |
|---|---|---|---|
| | Supported by Data? | Mean | Std Dev |
| Post-processing | No | 3.87 | 0.15 |
| Retail transportation | No | 3.94 | 0.15 |
| Retail storage | Yes | 3.66 | 0.10 |
| Home transportation | Yes | 4.42 | 0.14 |
| Home storage | Yes | 3.66 | 0.11 |

Exponential Cooling Rates

The exponential cooling rates applicable to stages in $G_2$ determine how fast an egg cools to the ambient storage temperature. The cooling rates reflect the manner in which eggs are stored. The manner of storage includes the packing material itself (e.g., cardboard or Styrofoam) and how an egg is stacked among all stored eggs. This section describes how exponential cooling rates are modeled during post-processing, transportation, retail, home transport, and home storage. The approach used here is similar to that described previously for $G_1$.

*Post–processing Storage*

After processing, eggs are assumed to be placed in cases and pallets for distribution. These eggs would have a cooling constant of 0.01. The model assumes that 1% of eggs would be non–palletized. These eggs would have a cooling constant of 0.1.

*Retail Transportation or Transportation to a Distributor*

All eggs are assumed to be packaged in cases with flats or cartons and placed on pallets for transportation. Thus, the cooling constant for transportation is identical to that for post-processing storage.

*Retail Storage or Storage at a Distributor*
No information describes the storage practices for eggs in retail facilities and other types of distributors. We assume that regardless of where eggs are eventually consumed they would be stored in cases or on metal racks of dozens. These would have an exponential cooling constant value of 0.1.

*Home Transportation or Transportation to a Hotel, Restaurant, or Institution*
Eggs are assumed to be transported in cases to institutional users and in sacks of groceries to home users. Consequently, an exponential cooling constant value of 0.1 is assigned for transportation from a retail store to a home.

*Home Storage or Storage at a Hotel, Restaurant, or Institution*
Eggs used in the home are assumed stored in the individual carton or in an egg tray in the refrigerator. These eggs would have an exponential cooling constant of 1.0. Eggs stored in an institutional setting would be stored in cases and thus have an exponential cooling constant of 0.1. Table 3-23 shows the exponential cooling constants used in the model. Note that a cooling constant of 0.01 represents storage in pallets, and a cooling constant of 0.1 represents storage in individual cases or racks. These cooling constants are thus for the central egg, and the cooling constant for a specific egg is adjusted in accordance with the equations provided in the description for $G_1$.

TABLE 3-23 FRACTION OF THE CENTRAL EGGS AT DIFFERENT COOLING CONSTANTS IN THE STEPS BEFORE PROCESSING.

| Location | Fraction of Central Eggs at Given *k* Value | | |
|---|---|---|---|
| | **0.01** | **0.1** | **1** |
| Post-processing storage | 0.99 | 0.01 | |
| Retail transportation | 0.99 | 0.01 | |
| Retail storage | 0.20 | 0.80 | |
| Home transportation | | 1.00 | |
| Home storage | | 0.55 | 0.45 |

***Percentage of Bacteria Surviving Cooking,* C**
After an egg has moved from the layer house, through the processor, through the retail store and has been stored at home, it is finally used to prepare a meal. Meal preparation may involve cooking. Cooking can reduce the number of bacteria in an egg. The effectiveness of cooking is measured as the percentage of bacteria that survive the cooking process, *C*. Cooking effectiveness can vary because of a multitude of factors; therefore, *C* is best described using a probability distribution. This section describes the data and analysis for estimating this distribution. The effectiveness of different cooking procedures for reducing SE is seen in Table 3-24.

TABLE 3-24 THERMAL DEATH RATES FOR SE.

| Method of Cooking | Cooking Time (minutes [± S.E.]) | Mean Inoculum ($log_{10}$ cfu/gm yolk ± S.E.) | Mean Number of Survivors ($log_{10}$ cfu/gm yolk ± S.E.) |
|---|---|---|---|
| Boiling[a] | 4 | 6.81 ± 0.06 | 5.87 ± 0.27 |
| Frying sunny side up[a] | 1.6 ± 0.2 | 6.90 ± 0.5 | 5.14 ± 0.2 |
| Frying over easy[b] | 2.4 ± 0.2 | 6.88 ± 0.4 | <1 |
| Scrambled –(high temp) | 1.2 | 6.09 ± 0.13 | 0 |
| Scrambled (at low/mod temp) | 3.1 | 5.9 ± 0.1 | <1 |

[a]Includes results from experiments with SE PT4 and *S.* Typhimurium PT110 and PT141.

[b]Eggs fried in vegetable oil at approximately 120°C until white appeared solid and opaque. Sunny-side-up eggs were cooked approximately 1.5 to 2 minutes. Over-easy eggs were cooked for up to 1 minute longer.
Source: Humphrey et al.[87]

Subtracting the mean $log_{10}$ cfu/gm of survivors from the mean cfu/gm of inoculum results in the $log_{10}$ reduction (Table 3-25). More effective cooking methods, such as frying over easy and scrambling, did not have sufficient bacteria surviving to allow enumeration. Humphrey et al.[87] state that their detection limit was about 1 $log_{10}$ cfu/gm. For the trials that did not allow enumeration but still resulted in recovery of bacteria, a 1 $log_{10}$ cfu/gm was assigned. If no bacteria were recovered, a $log_{10}$ reduction equivalent to the starting $log_{10}$ cfu/gm of bacteria was assumed. Table 3-25 shows the $log_{10}$ reduction for each cooking method. The results were weighted to account for those trials resulting in 0 or 10 cfu/gm. This resulted in an "effective $log_{10}$ reduction". Finally, each of these $log_{10}$ reductions was assigned to a fraction of all egg dishes.[88]

Only 86% of total egg dishes are accounted for in Table 3-25. The other 14% of egg dishes are reportedly hard-boiled eggs.[88] Humphrey et al.[87] state that the maximum effectiveness of cooking observed after boiling eggs for 10 minutes was about an 8-$log_{10}$ reduction. Hard-boiled eggs were assigned an effective $log_{10}$ reduction of 8.

TABLE 3-25 DETERMINING $LOG_{10}$ REDUCTIONS FOR COOKING TYPES.

| Starting $Log_{10}$ | Ending $Log_{10}$ | % Samples with Surviving Bacteria | $Log_{10}$ Reduction | Effective $Log_{10}$ Reduction | Fraction of Egg Dishes[88] | Comments |
|---|---|---|---|---|---|---|
| 6.81 | 5.87 | 100% | 0.94 | 0.94 | 0.12 | Soft boiled and poached |
| 6.9 | 5.14 | 100% | 1.76 | 1.76 | 0.135 | Sunny side up and |
| 6.88 | 1.00 | 56% | 5.88 | 6.32 | 0.135 | over easy reported as 27% |
| 6.09 | 0.00 | 0% | 6.09 | 6.09 | 0.235 | All scrambled and |
| 5.9 | 1.00 | 97% | 4.9 | 4.93 | 0.235 | omelets reported as 47% |

The frequency distribution for fraction of egg dishes ordered by the effective log10 reduction is shown in Table 3-26.

TABLE 3-26 FREQUENCY OF EFFECTIVE $LOG_{10}$ REDUCTIONS.

| Type of Dish | Effective $Log_{10}$ Reduction | Frequency |
|---|---|---|
| Soft boiled and poached | 0.9 | 0.12 |
| Sunny side up | 1.8 | 0.135 |
| Scrambled and omelets | 4.9 | 0.235 |
| Scrambled and omelets | 6.1 | 0.235 |
| Over easy | 6.3 | 0.135 |
| Hard boiled | 8.0 | 0.14 |

Three cumulative frequency distributions for effective $log_{10}$ reduction are shown in Figure 3-24. The curves were fit to the data points using a least-squares fitting algorithm. None of them provides a compelling visual fit. Consequently, this distribution is modeled as a discrete distribution using the data in Table 3-26.

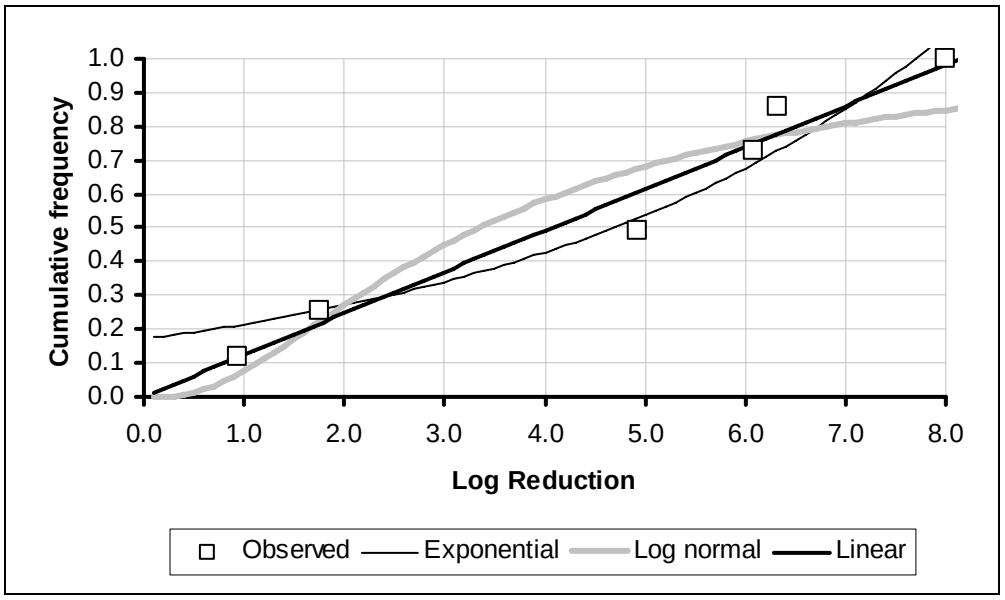



FIGURE 3-24 CUMULATIVE FREQUENCIES OF EFFECTIVE $LOG_{10}$ REDUCTION DUE TO COOKING.

To model cooking, three types of meals are considered. The consumption analysis in Annex H categorizes eggs as those served as main meals, in beverages, or as ingredients in mixtures. Additionally, that analysis further categorizes these servings as potentially higher risk or lower risk. Higher risk products are those likely to experience very limited cooking before consumption. Lower risk products are likely to be thoroughly cooked. Table 3-27 summarizes the fraction of product in each of these categories.

TABLE 3-27 FREQUENCIES OF DIFFERENT EGG SERVING TYPES.

| Type of Egg Consumption | Relative Risk | % of Shell Eggs |
|---|---|---|
| Main meal | Lower risk | 0.08% |
| | Higher risk | 44.76% |
| Beverage | Lower risk | 0.00% |
| | Higher risk | 0.33% |
| Ingredient | Lower risk | 53.04% |
| | Higher risk | 1.79% |

All eggs served as a main meal or used as ingredients in higher risk meals are assumed to have the same distribution of $\log_{10}$ reductions as those described above. All beverages are assumed to experience a 0-$\log_{10}$ reduction, and all lower risk servings of eggs as ingredients in mixtures are assumed to experience a 12-$\log_{10}$ reduction.

***Servings per Egg,* V**

Once an egg is used to prepare a meal, the bacteria remaining after cooking will be consumed. The number of individuals exposed to the bacteria in that egg is determined from the servings per egg, *V*. This value both serves to estimate the number of exposures that result from an egg containing *Salmonella* and estimates the actual dose of bacteria consumed per serving. If there are multiple servings consumed from a meal containing a contaminated egg, then these multiple servings increase the number of persons exposed but reduce the dose consumed by any one person.

The number of servings to which an egg contributes is best described using a probability distribution. This section presents the data and analysis for estimating this distribution. A single egg may feed one person or many persons. This is because eggs may be combined with other eggs to produce more than one serving. The Continuing Survey of Food Intake by Individuals (CSFII) estimates the grams of shell egg in products made from shell eggs, but it does not detail how many eggs were incorporated into individual servings.

The CSFII does, however, contain some useful information to help construct a probability distribution to represent the number of servings per egg. Lin et al.[88] report that when eggs are served as a main meal that 12% were soft boiled or poached, 27% were served sunny side up or over easy, and 14% were served hard boiled. Thus 53% of the eggs served as main meals were likely to have served just one person. If the remaining 47% of eggs were served scrambled or in omelets, then assume half of those (23.5%) also served just one person. Thus, 76.5% of shells eggs served as a main meal are assumed to have served one person.

The preceding discussion estimates the frequency of eggs used as a main meal that are eaten by one person. However, what percentage of all eggs is used as a main meal? To estimate this value the tables for consumption of shell eggs in Annex H are used. The number of eating occasions in 2 days was multiplied by the average weight of egg per serving for each category. Table 3-28 shows the percentage of total shell eggs that are consumed in main meals, in beverages, or as ingredients in a mixture.

TABLE 3-28 PERCENTAGE OF SHELL EGGS IN DIFFERENT MEAL TYPES.

| Type of Egg Consumption | % of Shell Eggs |
|---|---|
| Main meal | 44.9 |
| Beverage | 0.3 |
| Ingredient | 54.8 |

Thus, 44.9% of all eggs are used as the main meal, and 76.5% of them go to a single person. Hence, 34.3% of all eggs consumed in the home are a main meal served to only one person.

When eggs are served as an ingredient in a mixture (i.e. 54.8% of all eggs), approximately 10% of the servings have a serving size of less than 1 gram. A single egg then can contribute to about 58 servings on average. The fraction of shell eggs that contribute to 58 servings is then given by 0.10 x 0.548 / 58, or approximately 0.1%. Thus, a reasonable probability distribution for the number of servings per egg among all types of servings would include among its data points 34.3% of eggs serving just one person and about 0.1% of eggs serving 58 or more persons.

A Poisson distribution did not have a sufficient variance to model the variability in the number of servings per egg. An approximation to a lognormal distribution was used to ensure a sufficient variance. Excel Solver was used to estimate parameters for a lognormal distribution with the constraints described above. Figure 3-25 shows the subsequent distribution with a mean of 1.6 servings and a standard deviation of 3.2. The return from this lognormal distribution was rounded to the nearest integer. Any values returned that were less than one, were set to 1.

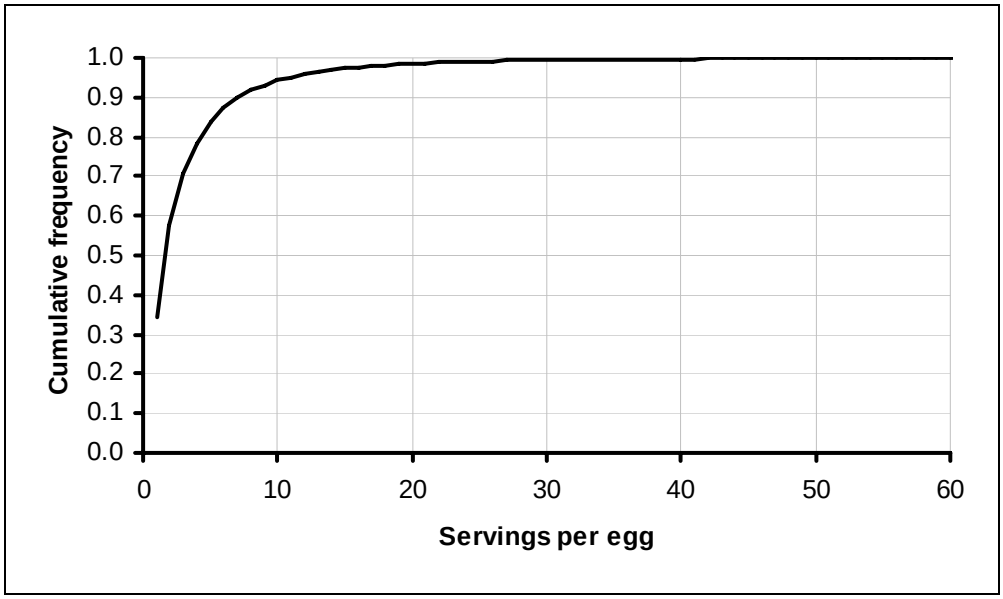



FIGURE 3-25 MODELED DISTRIBUTION OF SERVINGS PER EGG.

In the model, the bacteria remaining in an egg after cooking are divided by a random selection from the distribution for *V* shown in Figure 3-25. This determines the dose of bacteria in each serving consumed from that egg. The results of this exposure assessment are presented in the next section. The dose estimated here is the argument for the dose-response relationship described in Chapter 4. The frequency of illness is calculated using this exposure assessment and the dose-response relationship in Chapter 5.

## Exposure Assessment Results: SE in Shell Eggs

The model was run with 50,000 iterations, effectively tracking 50,000 contaminated eggs through this system. It took about 2.5 hours on a Pentium IV 1500 MHz computer. Results are summarized with reference to the conceptual model reproduced below as Figure 3-26.

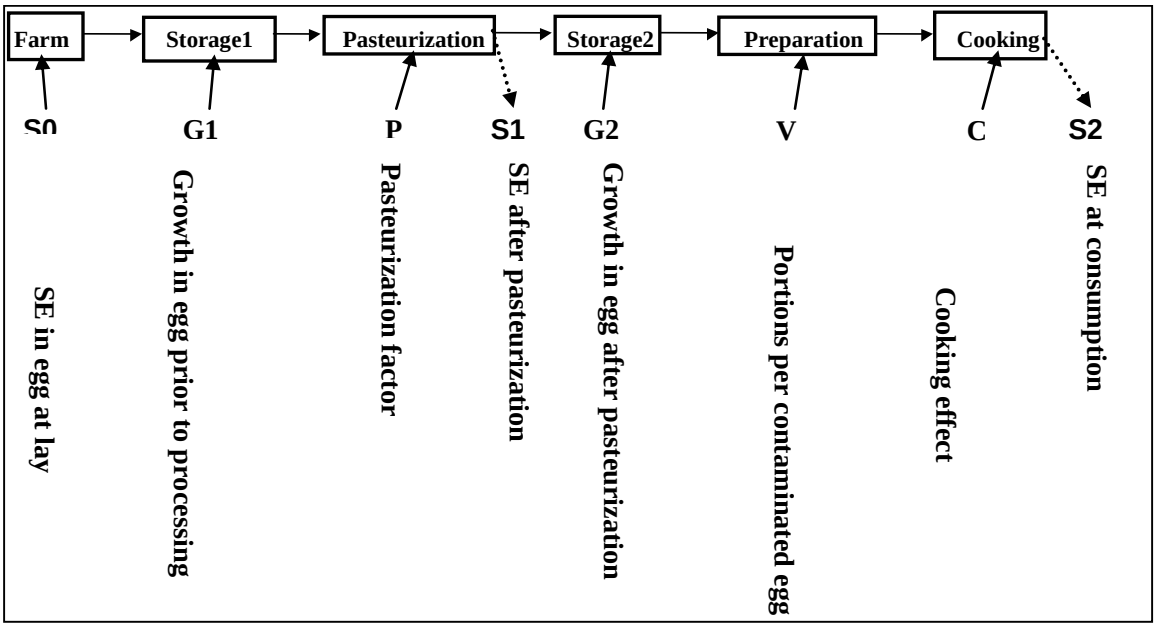



FIGURE 3-26 FLOW OF PRODUCT IN EXPOSURE ASSESSMENT.

***SE per egg at lay,* $S_0$**

Figure 3-27 shows the number of bacteria in an egg at lay given that the egg is SE contaminated. The likelihood that an egg is SE contaminated is simulated using the inputs from Table 3-1 and has an estimated value of about 0.00028 or approximately 1 in every 3,600 eggs. Thus, the frequency distribution shown in Figure 3-27 applies to only one out of every 3,600 eggs.

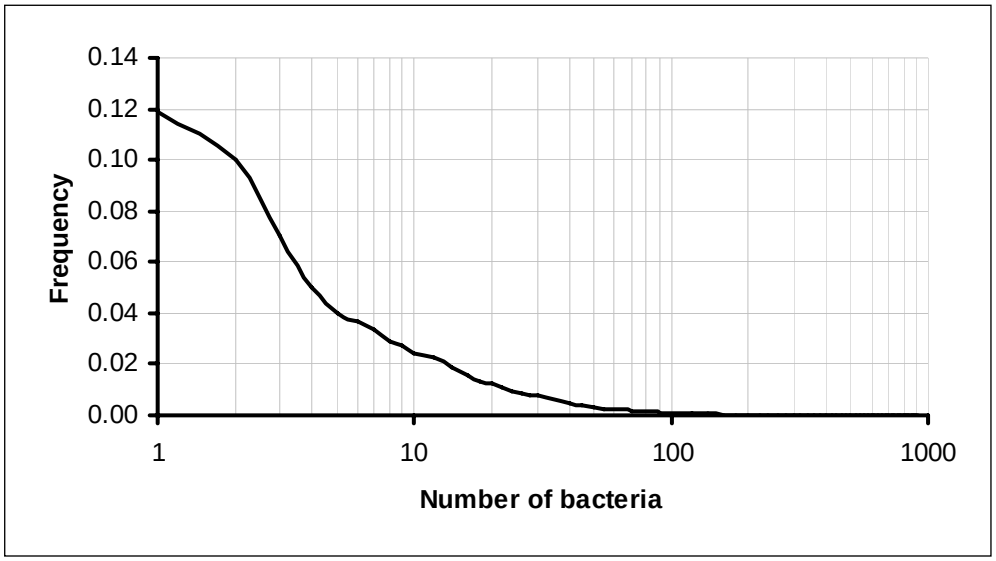



FIGURE 3-27 NUMBER OF BACTERIA IN SE-CONTAMINATED EGGS AT TIME OF LAY.

***Growth Effect before Processing,* $G_1$**

Only about half of all contaminated eggs simulated experienced any SE growth ($G_1$ >1) before processing, and only about 15% of all contaminated eggs experienced more than 1 $\log_{10}$ of SE

growth ($G_1$ >10). Figure 3-28 shows the cumulative frequency of $\log_{10}$ growth in SE-contaminated eggs before processing.

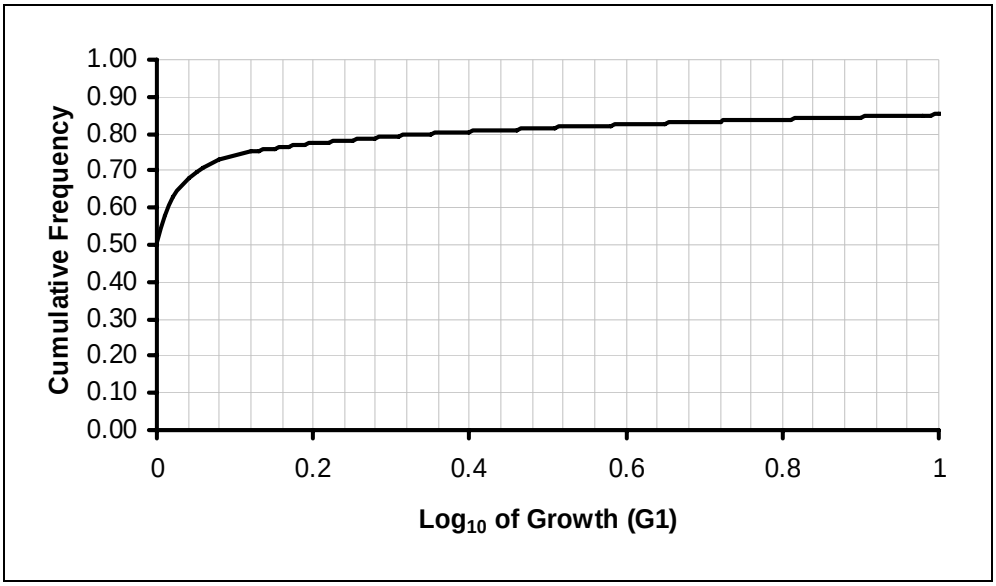



FIGURE 3-28 CUMULATIVE FREQUENCY OF $LOG_{10}$ GROWTH IN SE-CONTAMINATED EGGS BEFORE PROCESSING.

***Percentage of Bacteria that Survive Pasteurization,* P**

As noted earlier, one purpose of this risk assessment is to support the determination of a required level of effectiveness from pasteurization, and establishing the regulatory standard value of *P* is a risk management task and is not a focus of this risk assessment. To support the establishment of a performance standard, however, this risk assessment estimates the percentage of bacteria expected to survive different levels of pasteurization and from those estimates determines the resulting risk of human illness. The effect of this mitigation is given in terms of human illness in Chapter 5.

***Growth Effect after Processing,* $G_2$**

The amount of SE growth after processing is less than that before processing probably because of lower storage temperatures following processing of eggs. Though about half of contaminated eggs experience any SE growth ($G_1 > 1$) before processing, only about 4% of contaminated eggs experience more than 1 $\log_{10}$ of SE growth ($G_2 > 10$). Figure 3-29 shows the frequency distribution for $G_2$.

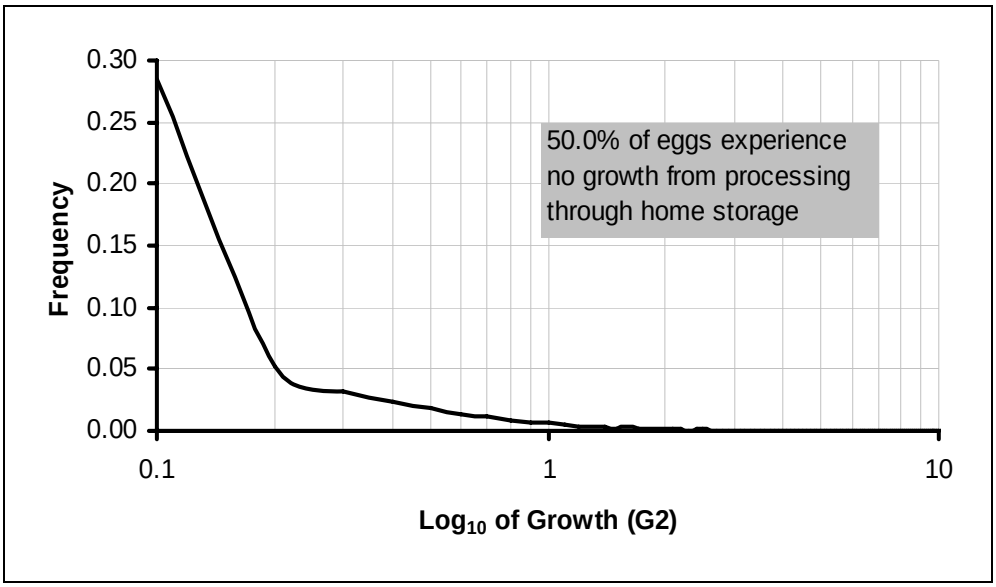



FIGURE 3-29 $LOG_{10}$ GROWTH IN SE-CONTAMINATED EGGS AFTER PROCESSING.

Figure 3-30 is a rescaling of the information in Figure 3-28.

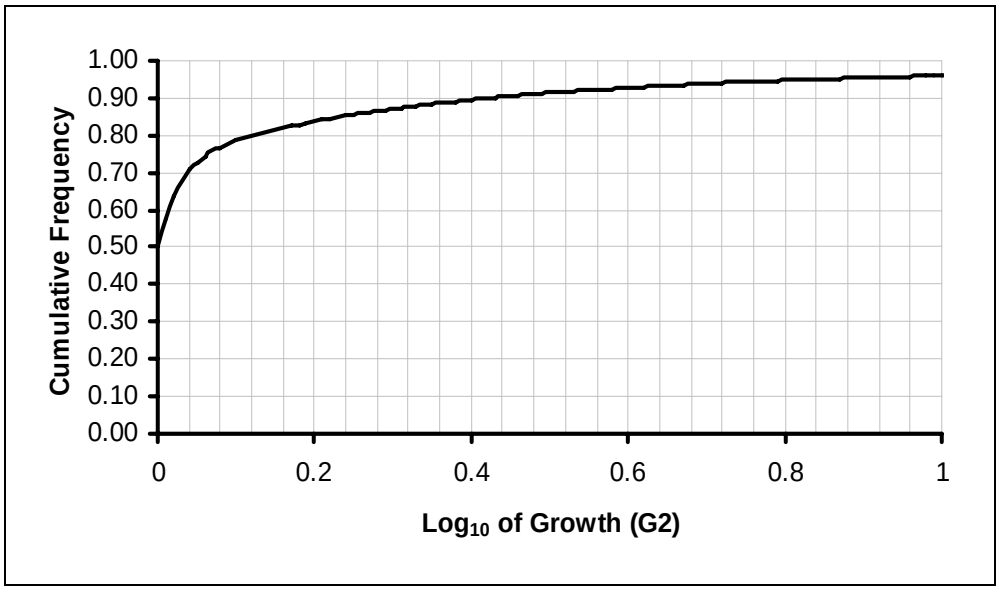



FIGURE 3-30 CUMULATIVE FREQUENCY OF $LOG_{10}$ GROWTH IN SE-CONTAMINATED EGGS AFTER PROCESSING.

***Percentage of Bacteria Surviving Cooking,* C**

Because the effect of cooking is governed by a discrete distribution, the $\log_{10}$ reductions due to cooking reflect the discrete values of the input distribution. Figure 3-31 shows the modeled $\log_{10}$ reductions due to cooking. Note that the x-axis values are given in terms of $\log_{10}$ reduction for simplicity. To convert these to values for *C* in the conceptual model, the anti-log of each value is taken. In other words, 52.7% of eggs have the contamination multiplied by $10^{-12}$ (a 12-$\log_{10}$ reduction) prior to consumption.

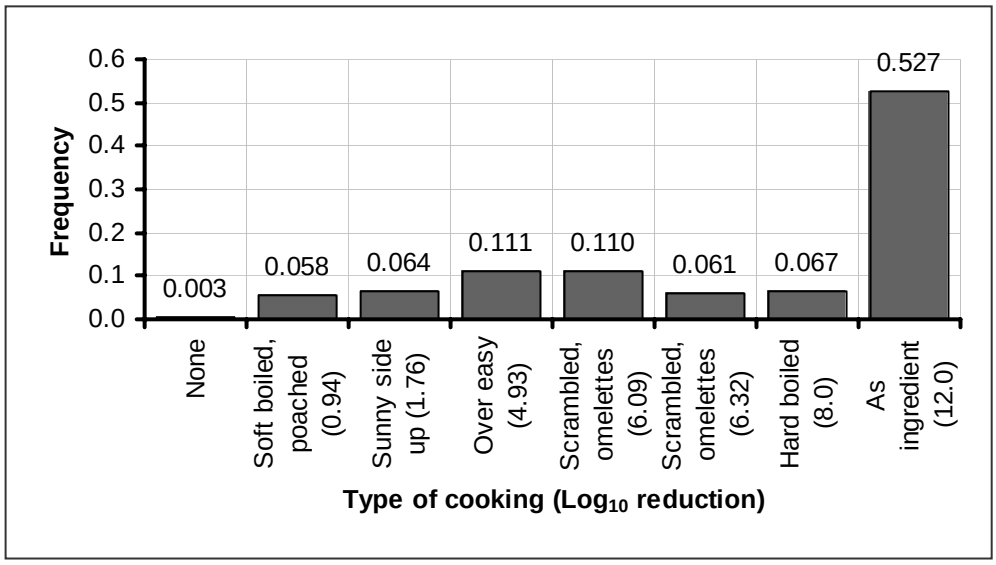



FIGURE 3-31 $LOG_{10}$ REDUCTIONS DUE TO COOKING FOR CONTAMINATED EGGS.

Cooking is an important mitigation that will decrease the number of SE by 12 $\log_{10}$ ($10^{-12}$) in over half of the contaminated eggs. This degree of cooking is associated in the model with thorough heating of mixtures incorporating shell eggs as ingredients. Less thorough cooking methods are applied to eggs served as main meals but this cooking could still eliminate moderate amounts of bacterial contamination.

***Number of SE per Consumed Serving***

The fundamental output of the exposure assessment is the number of SE per contaminated serving consumed. The model predicts that approximately 85.6% of eggs that were originally contaminated with SE would produce servings that had no SE in them after storage and cooking. Figure 3-32 shows the number of SE expected in servings made from originally contaminated eggs.

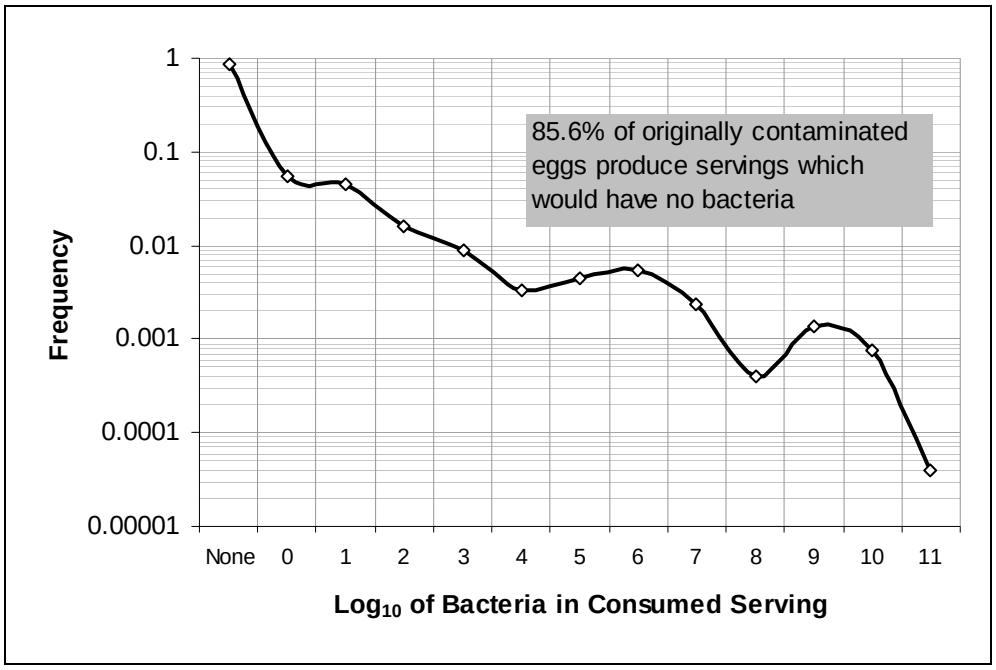



FIGURE 3-32 SE PER CONSUMED SERVING MADE FROM CONTAMINATED EGGS. OPEN CIRCLES REPRESENT THE NUMBER OF SE PER SERVING AND THE LINE A SMOOTH CURVE.

Figure 3-33 shows the same information as provided in Figure 3-32 but in a non-log scale. This emphasizes the low numbers of SE in eggs in consumed servings from eggs that were originally contaminated.

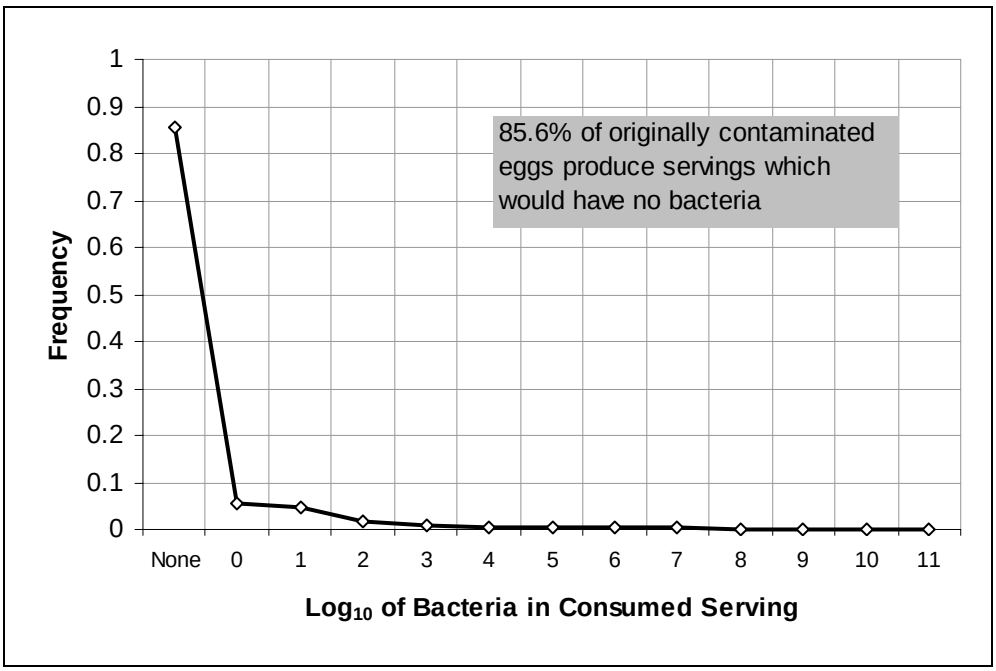



FIGURE 3-33 SE PER CONSUMED SERVING MADE FROM CONTAMINATED EGGS ON NON-LOG SCALE.

***Additional Exposure Assessment Results***

The following steps are specifically modeled for each egg in the exposure assessment results summarized above:

- laying house;
- on-farm storage (off-line only);
- transportation to the processor (off-line only);
- pre-processing storage;
- post-processing storage;
- retail transportation or transportation to a distributor;
- retail storage or storage at a distributor;
- home transportation or transportation to a hotel, restaurant, or institution; and
- home storage or storage at a hotel, restaurant, or institution.

Figure 3-35 and 3-36 show the median age of eggs, median temperature of eggs, and median bacteria in contaminated eggs, respectively, for each of the steps listed above. Additionally, the figures all present the $5^{th}$ and $95^{th}$ percentiles for each parameter. Although pasteurization is shown as a step in these charts, the effect of pasteurization is not shown until mitigations are applied in Chapter 5. Note that these charts do not include the effect of cooking just prior to consumption. Figure 3-34 shows that the median egg would reach retail facilities within a week and would be consumed within 3 weeks.

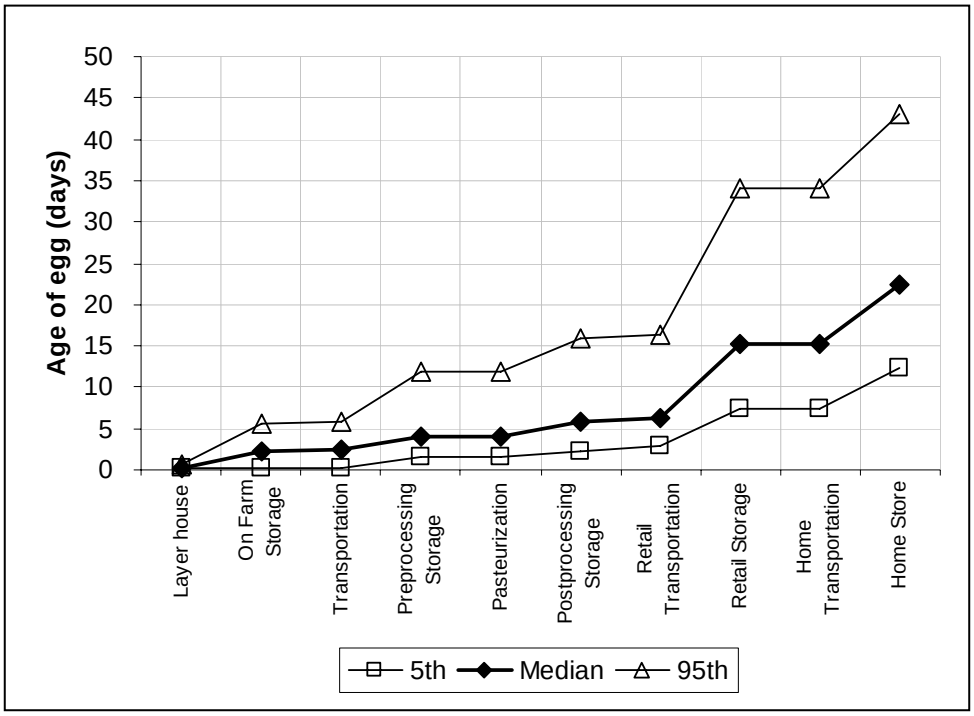



FIGURE 3-34 AGE OF EGGS AT DIFFERENT MODEL STEPS.

Figure 3-35 shows the temperature of eggs at each model step. Note that the times that correspond with the longest median storage times (retail and home) correspond with the lowest

median storage temperatures. Home transportation shows a marked increase in egg temperature, but generally for a very short time (no more than 6 hours in the model). Thus, steps after processing are expected to have less effect on bacterial numbers than steps before processing.

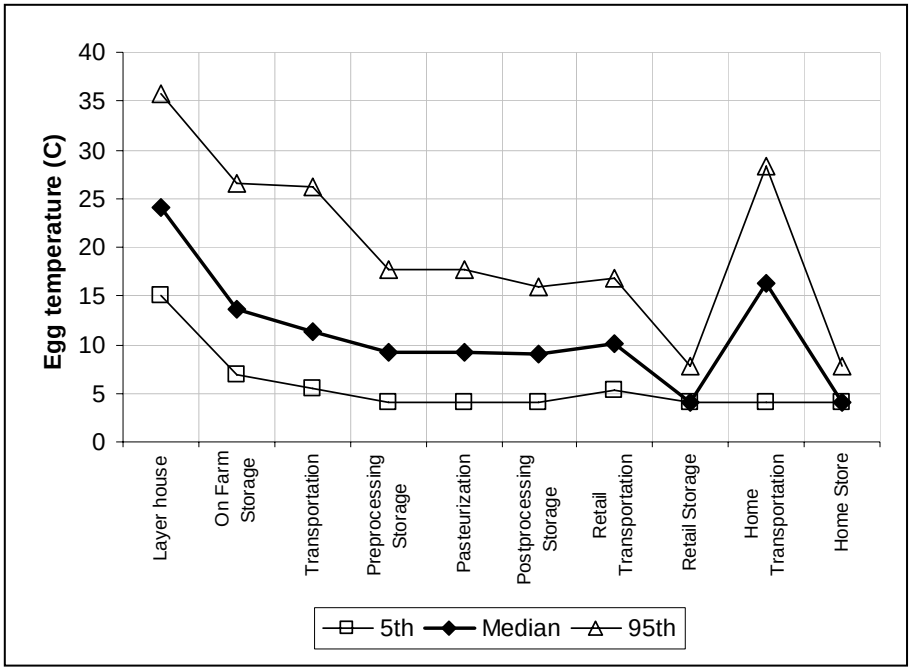



FIGURE 3-35 TEMPERATURE OF EGGS AT DIFFERENT MODEL STEPS.

The amount of growth that takes place appears to be driven more by the temperature of storage rather than the time of storage. At the 95$^{th}$ percentile, the longest storage time depicted in Figure 3-34 is for retail storage. The 95$^{th}$ percentile for the number of bacteria per contaminated egg (Figure 3-36) shows relatively little growth during this step. On the other hand, the greatest amount of bacterial growth appears to be during on-farm storage and pre-processing storage.

Figure 3-36 shows percentiles of SE bacteria in eggs at different points along the farm to table continuum. Note that at consumption most previously contaminated eggs would be expected to have no surviving bacteria (this corresponds to an expected number of less than 1. Nevertheless, about 1% of previously contaminated eggs would be expected to have 10,000 or more SE bacteria present at consumption. The median number of bacteria raises only slightly throughout the various storage steps. The 95$^{th}$ percentile, however, rises much more quickly. This effect for the top 5% of the eggs is most noticeable in the step just before processing, although it is evident in all steps. This implies that some storage conditions allow for rapid growth for a small percentage of eggs. SE-contaminated eggs are infrequent, but when they do occur in our simulations they generally contain less than 100 organisms at the time of lay. Most of these contaminated eggs will undergo little or no growth from lay through processing. Furthermore, most of these eggs undergo little or no growth all the way through home storage. However, the variability about the median number of bacteria increases over the various steps. Thus, the 95$^{th}$ percentile of bacteria per egg is only about 100 at the end of layer house storage, while it is over 10,000,000 at the end of home storage.

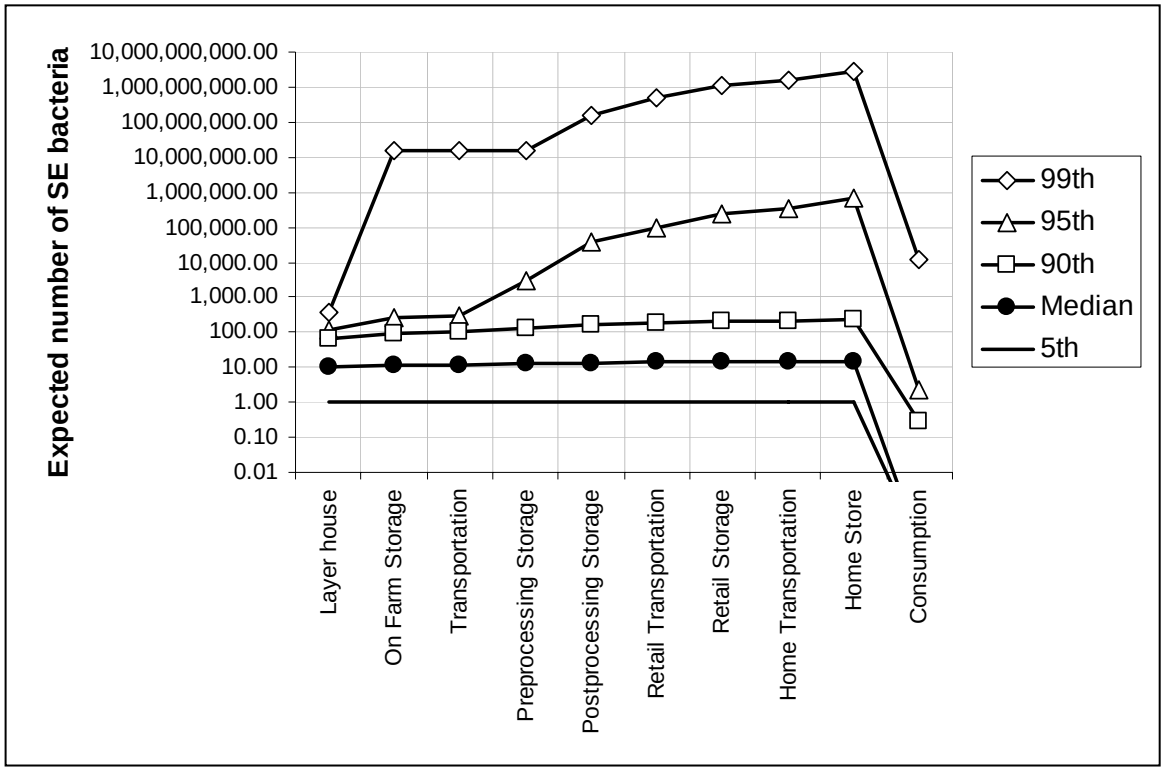



FIGURE 3-36 NUMBER OF SE IN CONTAMINATED EGGS AT DIFFERENT MODEL STEPS.

## EXPOSURE ASSESSMENT OF *SALMONELLA* SPP. IN EGG PRODUCTS

### Introduction

About one-third of all eggs produced in the U.S. are marketed as egg products (i.e., whites, yolks, or whole eggs). These eggs are sent to processing plants where they are cracked open. The internal contents of these eggs are accumulated in large vats and subsequently pasteurized. Depending on the manufacturer's needs, yolk and white material may be separated just after each egg is cracked open. These liquids are then shunted to separate holding vats. Alternatively, the entire contents of the egg may be directed to a holding vat.

In the 1960s, egg products were thought to be responsible for many human cases of *Salmonella* illness. Egg products were often sold in bulk as powdered or liquid product and were used in the commercial preparation of foods. It was discovered that an unacceptable number of these products were contaminated with *Salmonella*. Because of this discovery, USDA in 1970 developed regulations that required the pasteurization of all egg products. Since passage of those regulations, egg products have not been identified as a source of *Salmonella* illness in humans.

The current regulations are being reevaluated within this risk analysis effort. USDA periodically samples pasteurized egg products and has occasionally found evidence of *Salmonella* contamination in these samples. Such results suggest that current pasteurization practice has not been completely effective at eliminating *Salmonella* from all egg products. USDA is converting its current process standards into performance standards. Current pasteurization regulations specify times and temperatures for treating egg products. These

regulations are called process standards because they dictate the process manufacturers must follow. The outcomes from following this process are highly variable from plant to plant or even from vat to vat. For example, a heavily contaminated vat is subjected to the same heat for the same period during pasteurization as a vat that contains few *Salmonella*. The outcome of pasteurizing these two vats may differ because *Salmonella* may survive the pasteurization treatment of the heavily contaminated vat, but pasteurization would probably eliminate any *Salmonella* in a vat containing just a few cells.

To avoid these types of discrepancies in pasteurized egg product outcomes, process standards will be replaced with performance standards. These performance standards will specify the required outcome from pasteurization, but they will not specify the process to achieve this outcome. Performance standards provide for a more flexible approach. Manufacturers can adjust the process they use to suit their specific circumstances, but they must still demonstrate that they comply with the standards.

This exposure assessment determines the frequency with which people are exposed to different doses of *Salmonella* spp. in servings of foods prepared from seven categories of pasteurized egg products. The basic egg product categories are whole egg, white, and yolk. Whole egg product results from breaking shell eggs and collecting their entire contents. White and yolk egg products result from breaking shell eggs but separately collecting the white and yolk. Manufacturers of egg products may also blend whole egg and yolk with salt or sugar. Therefore, four additional categories result: whole egg with salt, whole egg with sugar, yolk with salt, and yolk with sugar (Table 3-29).

TABLE 3-29 MODELED CATEGORIES OF EGG PRODUCTS.

| Whole Egg Products | | | Yolk Products | | | White Products |
|---|---|---|---|---|---|---|
| Whole egg | Whole egg with salt | Whole egg with salt | Egg yolks | Egg yolks with salt | Egg yolks with sugar | Egg whites |

## Overview of the Egg Products Exposure Assessment Model

**Servings of Egg Products**

Just as eggs may be consumed by themselves or as ingredients in many types of recipes, egg products may be consumed in various types of products. A serving of egg product could be included in a serving of scrambled eggs, a waffle, a slice of cake, or a serving of egg nog. Sizes of servings would be expected to vary from just a few grams to hundreds of grams.

Egg products are considered in that part of the food chain from just before pasteurization to consumption of servings prepared from egg products. Figure 3-37 shows the most important components of this process. Pasteurization has special prominence in this assessment because it is the principal risk management measure being evaluated by this risk assessment. The amount of *Salmonella* in a serving of egg products depends on the amount present just prior to pasteurization, the amount of *Salmonella* destroyed during pasteurization, the amount of growth that occurs during storage after pasteurization, the amount of additional destruction of bacteria that occurs during cooking, and the size of the serving. These steps comprise the exposure assessment for egg products and provide an estimate of the number of bacteria to which a consumer is exposed in a single serving of food made with egg products. When a contaminated serving is consumed, the dose-response relationship described in Chapter 4 estimates the frequency that illness will

result. The results of combining the exposure assessment with dose-response relationship are described in Chapter 5.

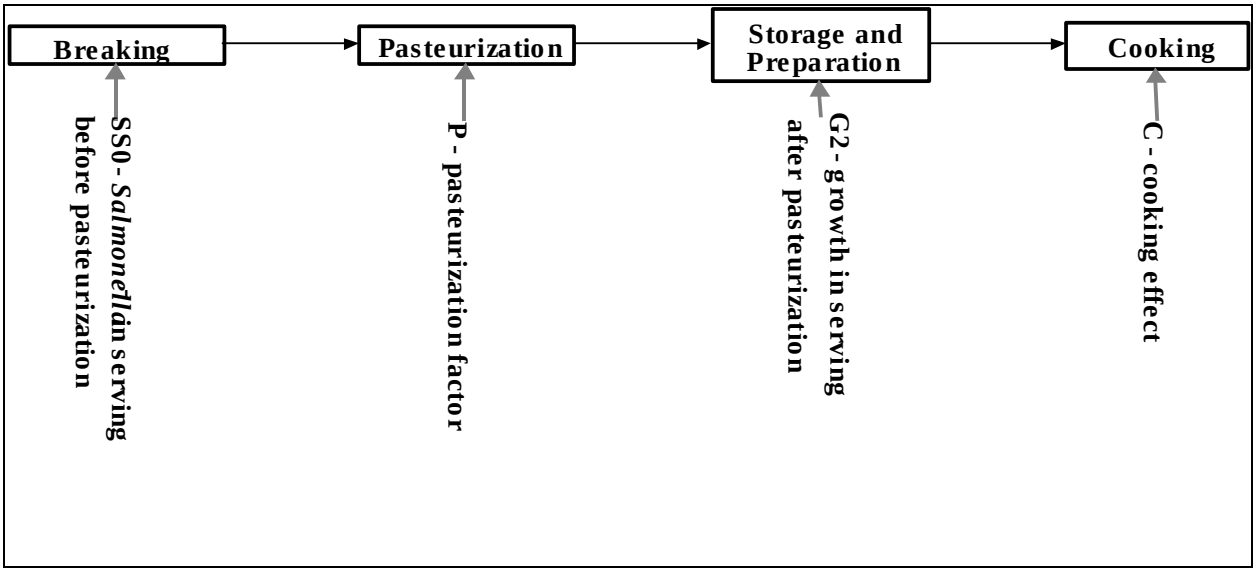



FIGURE 3-37 FLOW OF EGG PRODUCTS IN EXPOSURE ASSESSMENT.

This exposure assessment for egg products includes all *Salmonella*, whereas the shell eggs exposure assessment discussed above considers only SE. In contrast to the problem with SE in shell eggs, the origins of *Salmonella* within egg products are less well understood. Manufacturing egg products begins with the cracking of shell eggs to accumulate large volumes of liquid white or liquid yolk, or liquid whole egg. At some point in the manufacture of egg products, *Salmonella* contamination occurs. This contamination is not limited to SE, and it is likely that sources of *Salmonella* besides the internal contents of the egg are partly responsible. Alternative sources of bacteria include the shells of eggs and the breaking equipment.

This exposure assessment begins at the breaker plant rather than on the farm. *Salmonella* that are not SE account for a substantial portion of the contamination of egg products. Although the source of this contamination may be on the farm, there is no direct evidence describing the relationship between *Salmonella* spp. on the farm and *Salmonella* spp. in egg products just before pasteurization. Consequently, this exposure assessment begins just before pasteurization, accepting the fact of contamination without developing the details of its causes.

At the processing plant, or breaking plant, eggs are cracked and the liquid is accumulated from thousands of eggs. The vats, or bulk tanks, containing pre-pasteurized yolk, white, or whole egg product constitute the basic product types. Ingredients such as sugar or salt may be added to these vats. Contamination levels vary among different product types and among vats of the same product type. The amount of *Salmonella* contamination in a vat is the critical variable of interest at this stage of the exposure assessment.

Currently, during pasteurization, egg products are subjected to target temperatures for specific amounts of time. These target temperatures differ for the seven product categories. Heat destroys bacterial cells, but it must not cook the egg material to the point at which its usefulness as a foodstuff is affected. Different combinations of pasteurization time and temperature result in different levels of effectiveness in destroying *Salmonella*. If pasteurization is effective, then the

probability that *Salmonella* will survive this process is low. If pasteurization is ineffective, then *Salmonella* can survive the process and grow in numbers, and consumers may eventually become exposed.

After pasteurization, the processor, wholesaler, retailer, and consumer may store egg products. Surviving *Salmonella* may grow in the egg products during these times. The amount of growth depends on the combination of storage times and temperatures.

Meals prepared using egg products may be cooked. Like pasteurization, cooking can destroy *Salmonella*. Like pasteurization, its effect is variable. Cooking effectiveness depends on the cooking method, the cooking temperature, and the duration of cooking. Individual cooking behavior is highly variable. It depends on many factors; one of these is the food cooked. Scrambled eggs and birthday cakes prepared from egg products, for example, are typically subjected to very different temperatures for very different times.

The purposes of this exposure assessment are to (i) estimate the baseline exposure of consumers to *Salmonella* in egg products and (ii) evaluate the effectiveness of pasteurization in reducing these exposures. Data and models were developed to investigate different levels of pasteurization effectiveness that can influence human exposure to *Salmonella*s and subsequent illness.

***Mathematical Summary of the Egg Products Exposure Assessment***

The model used to estimate the numbers of *Salmonella* in egg products consumed begins with the number of *Salmonella* in a serving before pasteurization. This depends on the size of the serving and the category of egg product. The serving is pasteurized and the number of *Salmonella* remaining in the serving has to be estimated (Equation 3.19). Pasteurization's effectiveness also depends on the category of egg product.

The model next estimates the amount of growth that occurs in the serving after pasteurization. Then it estimates the effectiveness of cooking in destroying the bacteria that survived and grew after pasteurization. These steps determine the number, or dose, of *Salmonella* consumed in the serving (Equation 3.20 below).

Illness is not necessarily the outcome from consuming *Salmonella* in a serving of egg product. The frequency that illness occurs for a given dose in a serving is estimated using the dose-response relationship developed in Chapter 4 (Equation 3.21 below). Each of these relationships is developed below.

## Bacteria after Pasteurization

The number of *Salmonella* in a serving after pasteurization depends on the number of *Salmonella* per serving just before pasteurization and the effect of pasteurization on reducing *Salmonella* numbers within contaminated eggs.

$$SS_1 = SS_0 \times P \tag{3.19}$$

where

$SS_1$ = the number of *Salmonella* in a serving after pasteurization

$SS_0$ = the number of *Salmonella* in a serving before pasteurization. This number can range from zero cells to thousands of cells.

$P$ = the fraction of *Salmonella* cells that survive pasteurization.

The range in the number of *Salmonella* before pasteurization differs by egg product category and serving size. Just as the shell egg exposure assessment follows an egg through the system, this assessment follows an individual serving. Because of the mixing of large numbers of eggs together, the consumption unit of interest in egg products is the serving, which by definition would expose only one person. For each serving, the number of *Salmonella* is randomly selected from a probability distribution that reflects the natural variability in the number of bacteria found in a serving of a certain size from a certain egg product category. Equation 3.19 shows that the number of bacteria in a serving of egg product before pasteurization is reduced by the effect of pasteurization. The fraction, $P$, ranges over the [0,1] interval. Zero 0 is complete elimination of the bacteria and one is complete survival. Values of $P$ are entered into this equation as point estimates because they represent a decision variable. That is, risk managers would be responsible for establishing a desired kill rate, which effectively establishes a deterministic value for $P$. The input distributions for $SS_0$ and the point estimates for $P$ are described in their own sections below. By repeatedly considering different servings from contaminated vats, the output of Equation 3.19 is a distribution of values that capture the variability attending the estimate of this post pasteurization value, $SS_1$.

**Example**

$S_0$ = 12 *Salmonella* in a particular serving. This is determined by both the concentration of *Salmonella* per ml and the serving size, which can vary from just a few grams to hundreds of grams.

$P$ = 1.2 $\log_{10}$ reduction due to pasteurization (a multiplier of $10^{-1.2}$ = 0.063)

$S_1$ = 12 x 0.063 = 0.76, which is the expected number of *Salmonella* in a serving after pasteurization. This is input into a Poisson distribution to determine the modeled bacteria in the serving.

Bacteria after Growth and Cooking

The number of *Salmonella* per serving after cooking depends on the number of *Salmonella* after pasteurization ($SS_1$ above), the growth of these bacteria after pasteurization, and the attenuating effect of cooking.

$$SS_2 = SS_1 \times G_2 \times C \qquad (3.20)$$

where $SS_1$ is defined above and

$G_2$ = the relative growth of *Salmonella* from the time of pasteurization to the time of preparation and cooking and

$C$ = the fraction of cells that survive cooking.

Inputs $G_2$ and $C$ are the result of complex interactions of time and temperature. These inputs are further explained in their own sections below. The value of $G_2$ generally ranges over the $[1,10^{10}]$ interval. One means no growth occurred, and $10^{10}$ means one organism grew to 10 billion organisms at the time the serving was prepared. $G_2$ enters the equation as a random value selected from a distribution based on this interval. The fraction, $C$, ranges over the [0,1] interval,

**Example**

$S_1$ = 1 *Salmonella* bacterium

$G_2$ = 0.1 $\log_{10}$ of growth (a multiplier of $10^{0.1}$ = 1.26)

$C$ = 12 $\log_{10}$ reduction due to cooking (a multiplier of $10^{-12}$)

$S_2$ = 1 x 1.26 x $10^{-12}$ = 1.26 x $10^{-12}$, which is the expected number of *Salmonella* per serving.

where 0 is complete elimination of the bacteria and 1 is complete survival. *C* enters this equation as a random value selected from a distribution.

The equation begins with the *Salmonella* in a serving that survive pasteurization and allows them to grow until the egg meal is cooked. This number of bacteria is then reduced by the effect of cooking to produce the number of bacteria in the serving that are consumed. By repeatedly calculating $SS_2$ values for different egg product servings, the output of Equation 3.20 is a distribution of values that capture the variability attending the estimate of the number of *Salmonella* per serving of egg product.

Frequency of Illness per Serving

The frequency of illness per serving is calculated using a dose-response function with the number of *Salmonella* per serving as its argument.

$$I_S = DR(SS_2) \tag{3.21}$$

where

$I_S$ = the frequency of illness resulting from consuming a serving of egg product. $SS_2$ is as defined in equation 3.20.

**Example**

$S_2$ = $1.26 \times 10^{-12}$ expected *Salmonella*

$DR(222)$ = $3.1 \times 10^{-15}$ likelihood of illness given that average expected dose. Thus, the likelihood of illness would be extremely remote in this example.

Given a particular dose (i.e., number of bacteria per serving), this equation calculates the frequency that each serving might cause illness. If all possible servings of egg product are considered, the mean of the resultant distribution of frequencies can be calculated. This value can be interpreted as the expected probability that a member of the general population of egg product eaters will get ill from any given serving. Alternatively, when multiplied by the number of servings eaten in a year it yields the estimated number of illnesses in a year. Taken alone and interpreted somewhat differently, the estimated frequency of an illness is the estimated number of illnesses that result per serving of egg product consumed in the U.S. This latter value is one of the final measurements of this risk assessment and is presented in Chapter 5.

The following sections of this chapter describe how the inputs $SS_0$, $P$, $G$, and $C$ were modeled. These elemental components of the conceptual model are combined to estimate a distribution of *Salmonella* per serving. This distribution is combined with the dose-response function to assess the risk of illness from *Salmonella* in egg products in the Risk Characterization chapter.

The exposure assessment model is programmed in Visual Basic for Applications. Inputs and outputs are stored in Excel spreadsheets.

### *Number of* Salmonella *in a Serving before Pasteurization,* $SS_0$

The number of *Salmonella* in a serving before pasteurization depends on the type of egg product serving, the concentration of *Salmonella* in the vat that produced the serving, and the size of the serving. High densities of *Salmonella* per gram in vats will result in high densities of *Salmonella* per gram of serving. Larger servings will, on average, contain more *Salmonella* than smaller servings. Contamination levels in vats of white, whole egg, and yolk are different. The servings from these vats will contain different numbers of *Salmonella*. To estimate the number of

*Salmonella* in a serving of egg product, the algorithm in Table 3-30 is used. For a given egg product type, the number of *Salmonella* per gram in the egg product vat is estimated. With the number of grams in the serving, the number of *Salmonella* in the dose is determined.

TABLE 3-30 DETERMINING THE INITIAL LEVEL OF *SALMONELLA* IN A SERVING OF EGG PRODUCT.

| Input Name | Description | Estimation |
|---|---|---|
| $i$ | Index for type of egg product serving | See Figure 3-38 |
| $W_i$ | *Salmonella* per gram in vat of egg product type $i$ | White; Weibull(0.301, 9.03)<br>Whole egg, whole egg 10% salt, and whole egg 10% sugar; Weibull (2.87, 11.8)<br>Yolk, yolk 10% salt, and yolk 10% sugar; Weibull (0.236, 8.43) |
| $R$ | Size of serving in grams | Empiric distribution derived from CSFII. |
| $SS_0$ | Number of *Salmonella* in a serving before pasteurization | *Poisson*($W_i$ x $R$) |

Figure 3-38 shows the relative frequency of the seven categories of egg products based on total weight of production. These relative frequencies of product types are estimated from data from the National Agricultural Statistics Service,[66] but those data only provide the proportion of egg products for whole egg, white, and yolk, and the amount of blended whole egg and yolk with salt or sugar. They do not break the blended product out by salt or sugar content. Based on work done by Research Triangle Institute,[89] it is assumed that 66% of blended whole egg products are 10% salt and the remaining 34% of these are 10% sugar. Using the same report for blended yolk products, it is assumed that half are 10% salt products and half are 10% sugar products.

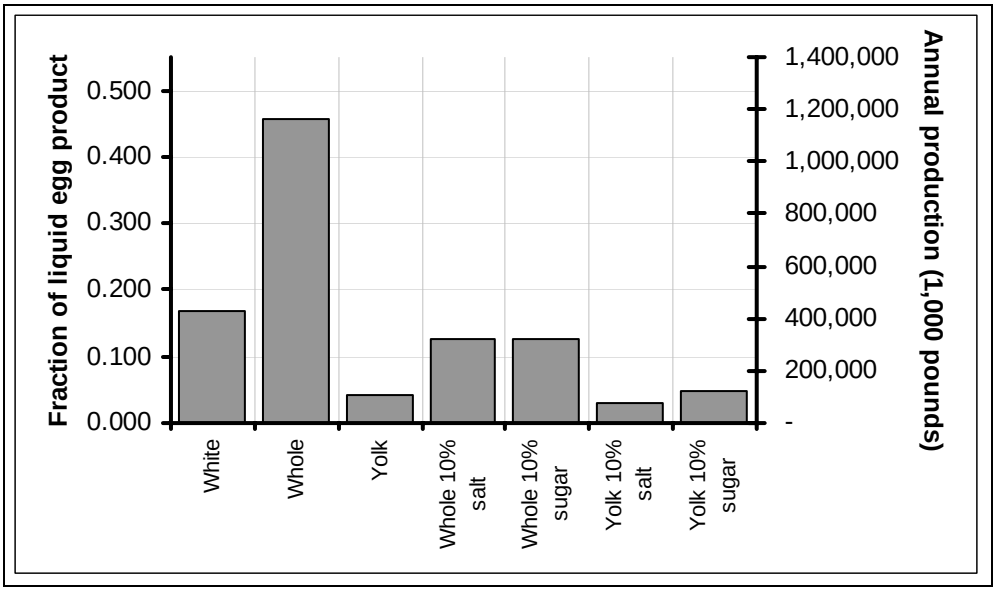



FIGURE 3-38 RELATIVE FREQUENCY AND TOTAL PRODUCTION OF VARIOUS TYPES OF LIQUID EGG PRODUCTS.

Estimates were based on data from the National Agricultural Statistics Service[66] and assumed fractions of different egg blends.[89]

The *Salmonella* per gram in vats of white, whole, and yolk egg product is based on a transformation of a Weibull distribution as explained in Annex F. Briefly, the Weibull is expressed as

$$W(x \mid b, c) = 1 - e^{-(x/c)^b} \tag{3.22}$$

The modified Weibull ($\mu$,$\sigma$) probability distribution has the following functional form:

$$P(W_i) = 1 - e^{-e((ln(W_i)-\mu) / e^{\sigma})} \tag{3.23}$$

where $b=e^{-\sigma}$ and $c=e^{\mu}$.

Different parameter values have been estimated for each egg product type, and the resultant distributions are shown in Figure 3-39. A random selection from the relevant probability distribution is the concentration of *Salmonella* per gram of egg product in a vat.

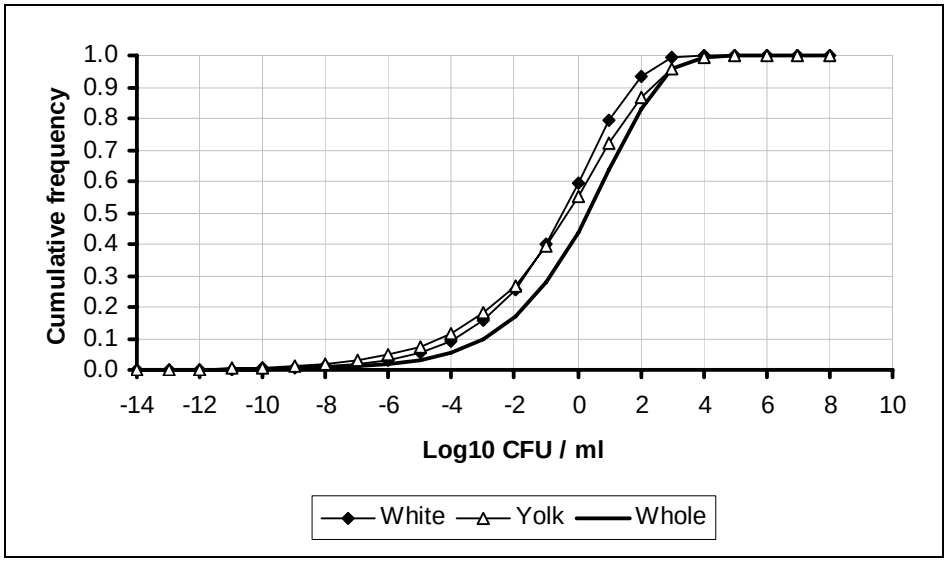



FIGURE 3-39 CUMULATIVE FREQUENCY OF LOG$_{10}$ *SALMONELLA* PER GRAM IN VATS OF WHITE, YOLK, AND WHOLE EGG PRODUCT BEFORE PASTEURIZATION.

The number of grams of egg product consumed in a serving is based on an analysis of the CSFII database, as explained in Annex H. Table 3-31 summarizes the frequencies of three types of consumed products: main meals, beverages, and ingredients. It gives percentiles for the number of grams consumed for each. Egg products may be consumed as the main meal, for example, in servings of scrambled eggs or omelets. The amount of egg product actually consumed (i.e., the serving size) varies among individuals. This variability is shown by the distribution in Table 3-31. Figure 3-40 is a graphical representation of serving sizes.

Egg products may also be consumed in beverages such as eggnog. These serving sizes tend to be large. The vast majority of egg products are used as ingredients in other foods such as pasta, bread, and cake. When used as ingredients, the serving sizes of egg products can be small.

For example, there is only a fraction of egg product, on a per-weight basis, in a piece of commercially prepared bread.

TABLE 3-31 SUMMARY OF CONSUMPTION INFORMATION FOR SERVINGS MADE FROM EGG PRODUCTS.

| | | All Egg Products | | | Potentially Undercooked Egg Products (subset of all egg products) | | |
|---|---|---|---|---|---|---|---|
| | **Meal type** | **Main Meal** | **Beverage** | **Ingredient** | **Main Meal** | **Beverage** | **Ingredient** |
| | Consumption average (g/p/d) | 77.8 | 182.5 | 36.0 | 79.1 | 182.5 | 13.6 |
| | Std Dev (g) | 49.0 | 75.1 | 71.0 | 48.9 | 75.1 | 21.6 |
| | Eating occasions | 32,345,212 | 286,428 | 226,268,156 | 28,304,347 | 286,428 | 28,312,529 |
| | Fraction | 0.125 | 0.001 | 0.874 | 0.109 | 0.001 | 0.109 |
| | *n* = | 2,594 | 17 | 16,666 | 2,291 | 17 | 2,042 |
| Percentile | 5.0% | 24 | 71 | 1 | 24 | 71 | 2 |
| | 10.0% | 34 | 95 | 1 | 38 | 95 | 3 |
| | 20.0% | 41 | 127 | 3 | 42 | 127 | 4 |
| | 30.0% | 45 | 127 | 5 | 45 | 127 | 5 |
| | 40.0% | 57 | 127 | 6 | 60 | 127 | 7 |
| | 50.0% | 76 | 191 | 9 | 77 | 191 | 8 |
| | 60.0% | 80 | 191 | 13 | 82 | 191 | 10 |
| | 70.0% | 86 | 254 | 22 | 86 | 254 | 12 |
| | 80.0% | 94 | 254 | 46 | 94 | 254 | 16 |
| | 90.0% | 138 | 254 | 105 | 138 | 254 | 25 |
| | 95.0% | 173 | 286 | 164 | 170 | 286 | 40 |
| | 97.0% | 188 | 286 | 239 | 175 | 286 | 55 |
| | 98.0% | 221 | 286 | 293 | 220 | 286 | 76 |
| | 99.0% | 281 | 286 | 320 | 293 | 286 | 111 |
| | 99.1% | 293 | 286 | 334 | 293 | 286 | 111 |
| | 99.2% | 293 | 382 | 344 | 300 | 382 | 132 |
| | 99.3% | 300 | 382 | 377 | 302 | 382 | 133 |
| | 99.4% | 312 | 382 | 402 | 315 | 382 | 167 |
| | 99.5% | 315 | 382 | 435 | 324 | 382 | 167 |
| | 99.6% | 324 | 382 | 477 | 342 | 382 | 188 |
| | 99.7% | 350 | 382 | 516 | 350 | 382 | 202 |
| | 99.8% | 350 | 382 | 557 | 350 | 382 | 209 |
| | 99.9% | 350 | 382 | 639 | 350 | 382 | 221 |
| | 100.0% | 410 | 382 | 959 | 410 | 382 | 304 |

For this analysis, it is assumed that serving size is not correlated with type of egg product. This is a simplifying assumption that may not adequately reflect reality. For instance, the amount of product in servings made with whole egg product may be larger than servings made with yolk product. Because whole egg product has a different distribution of *Salmonella* concentration than yolk egg product, this could affect the risk of human illness.

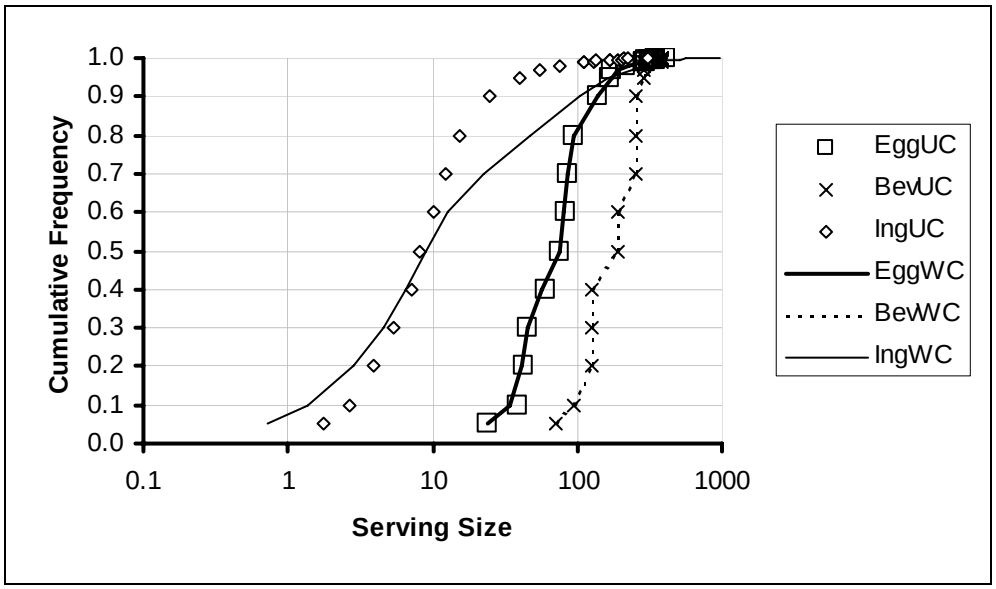



FIGURE 3-40 CUMULATIVE FREQUENCY OF SERVING SIZES BY TYPE OF SERVING CONSUMED.

The number of *Salmonella* in a serving is estimated using the serving size and the concentration of *Salmonella* per gram in a vat. The contamination of servings from a vat is assumed to follow a Poisson process. The average of the Poisson distribution is the average number of organisms per serving of fixed size from a particular vat. The $SS_0$ in a single serving is randomly sampled from this Poisson distribution. By repeatedly sampling from the probability distributions used to estimate $SS_0$ and using the algorithm in Table 3-1, a distribution of $SS_1$ values can be generated. This captures the variability attending the number of *Salmonella* in a serving of egg product.

***Pasteurization Effectiveness,* P**

*P* is the fraction of *Salmonella* that survives a pasteurization treatment. It is a regulatory variable in this analysis, and the model user can set its value. Different levels of pasteurization effectiveness are modeled to determine the resulting effect on exposures to *Salmonella* and their concomitant risks of human illness or death. In this manner, the relationship between *P* and risk of illness or death can be described in support of the determination of regulatory standards.

Annex G derives five different functions for the effect of pasteurization in the seven different products modeled. The functional relationships for these pasteurization effects are summarized in Table 3-32, Table 3-33, Table 3-34, Table 3-35, and Table 3-36. These tables present the equations used to estimate pasteurization effectiveness. The inputs required for these equations are presented as well. More details on these relationships are provided in Annex G.

TABLE 3-32 DETERMINATION OF $LOG_{10}$ REDUCTION IN LIQUID WHOLE EGG WITH 10% ADDED SALT AND LIQUID YOLK WITH 10% ADDED SALT.

| Input | Description | Value |
|---|---|---|
| $T$ | Pasteurization temperature | 62.2 |
| $t$ | Pasteurization time | 7.0 |
| $a$ | Parameter | 4.810836 |
| $b$ | Parameter | 3.263478 |
| $c$ | Parameter | –0.539650 |
| $d$ | Parameter | 0.231221 |
| $e$ | Parameter | 0.655073 |
| $f$ | Parameter | 0.701920 |
| $g$ | Parameter | 0.101009 |
| $\delta$ (whole egg) | Parameter | 1 |
| $\delta$ (yolk) | Parameter | –1 |
| $Log_{10}$ reduction | Calculation | $-\log_{10}(1 + \exp(b + c\delta + d(T - 60)) \times \ln(t) + a + e\delta + f(T - 60) + g(T - 60)^2)$ |

TABLE 3-33 DETERMINATION OF $LOG_{10}$ REDUCTION IN LIQUID WHOLE EGG WITH 10% ADDED SUGAR.

| Input | Description | Value |
|---|---|---|
| $T$ | Pasteurization temperature | 62.2 |
| $t$ | Pasteurization time | 7.0 |
| $d$ | Parameter | –3.394085 |
| $e$ | Parameter | 0.655432 |
| $w$ | Calculation | $exp(d + e(T-55))$ |
| $a$ | Calculation | $w / log_{10}(e)$ |
| $x$ | Parameter | 0.331788 |
| $y$ | Parameter | –0.070704 |
| $z$ | Parameter | 0.007454 |
| $b$ | Calculation | $exp(x = Y(T-55) + z(T-55)^2)$ |
| $\ln(p(t))$ | Calculation | $-at^b$ |
| $Log_{10}$ reduction | Calculation | $log_{10}(e^{ln(p(t))})$ |

TABLE 3-34 DETERMINATION OF $LOG_{10}$ REDUCTION IN LIQUID YOLK WITH 10% ADDED SUGAR

| Input | Description | Value |
|---|---|---|
| $T$ | Pasteurization temperature | 61.1 |
| $t$ | Pasteurization time | 7.0 |
| $e$ | Parameter | 11.65200 |
| $f$ | Parameter | –0.28275 |
| $a$ | Calculation | $e+f(T-55)$ |
| $g$ | Parameter | –46.69955 |
| $h$ | Parameter | 9.28490 |
| $k$ | Parameter | –0.29105 |
| $b$ | Calculation | $g+h(T-55) + k(T-55)^2$ |
| $Log_{10}$ reduction | Calculation | $-log_{10}(1 + exp(a \times ln(t) + b))$ |

TABLE 3-35 DETERMINATION OF $LOG_{10}$ REDUCTION IN PLAIN LIQUID WHOLE EGG AND YOLK

| Input | Description | Value |
|---|---|---|
| *T* (whole egg) | Pasteurization temperature | 60 |
| *T* (yolk) | Pasteurization temperature | 61.1 |
| *t* | Pasteurization time | 7.0 |
| *a* | Parameter | 3.8258 |
| *D* (whole egg) | *D*-value | $12.1199-0.20834T$ |
| *D* (yolk) | *D*-value | $8.1518-0.1382T$ |
| *b* | Calculation | $b = ln((10^3-1)/((3D)^a))$ |
| Ln(*k*) | Calculation | $a + b\ (T - 50) + c(pH - 7) + d(T - 50)\ x\ (pH - 7)$ |
| $Log_{10}$ reduction | Calculation | $-log_{10}(1 + exp(a(ln(t)) + b))$ |

TABLE 3-36 DETERMINATION OF $LOG_{10}$ REDUCTION IN LIQUID EGG WHITE.

| Input | Description | Value |
|---|---|---|
| *T* | Pasteurization temperature | 56.67 |
| *t* | Pasteurization time | 7.0 |
| *pH* | pH of product | 8.8 |
| *a* | Parameter | –4.76610 |
| *b* | Parameter | 0.71335 |
| *c* | Parameter | 0.52728 |
| *d* | Parameter | –0.05284 |
| ln(*k*) | Calculation | $a + b\ (T - 50) + c(pH - 7) + d(T - 50)\ x\ (pH - 7)$ |
| *k* | Calculation | $e^{ln(k)}$ |
| *e* | Parameter | –10.99275 |
| *f* | Parameter | 0 |
| *g* | Parameter | 14.46086 |
| *h* | Parameter | –1.69467 |
| *i* | Parameter | 0 |
| *j* | Parameter | 0 |
| ln(*w*) | Calculation | $e + f(T - 50) + g(pH - 7) + h(T - 50)\ x\ (pH - 7) + i(T - 50)^2 + j(pH - 7)$ |
| *w* | Calculation | $e^{ln(w)}$ |
| ln(*p*(*t*)) | Calculation | $-kt + ln(1 + (k/w)\ x\ (1 – e^{-wt}))$ |
| $Log_{10}$ reduction | Calculation | $log_{10}(e^{ln(p(t))}$ |

Current FSIS standards require that various egg product types be heated to a specific temperature for a requisite time. Table 3-37 shows the $log_{10}$ reduction for the current process standards. These values were derived by solving the equations in the preceding tables for the time and temperature requirements for each egg product type. These are used as default values for *P* in this exposure assessment, where $P = 10^{\text{LogReduction}}$.

TABLE 3-37 REQUIREMENTS AND ESTIMATED $LOG_{10}$ REDUCTIONS FOR MODELED TYPES OF EGG PRODUCTS.

| | Requirement | | |
|---|---|---|---|
| Product | Time | Temp | $Log_{10}$ Reduction |
| White | 3.5 | 56.67 | –3.3 |
| Whole | 3.5 | 60 | –5.9 |
| Yolk | 3.5 | 61.11 | –5.5 |
| Whole 10% salt | 3.5 | 62.22 | –6.0 |
| Whole 10% sugar | 3.5 | 62.22 | –42.0 |
| Yolk 10% salt | 3.5 | 63.33 | –7.2 |
| Yolk 10% sugar | 3.5 | 63.33 | –12.4 |

### *Growth Effect after Pasteurization,* $G_2$

**Modeled pasteurization times are higher than required times**

Pasteurization times for eggs products are modeled at 7 minutes. This assures that *every* particle is subjected to 3.5 minutes at the required temperature under laminar flow conditions.

Egg products are stored after pasteurization for varying times and temperatures. These products must be transported from the processor to wholesale or retail outlets and then transported to homes or commercial facilities. Depending on the places of storage, the products may at various times be frozen, refrigerated, or held at room temperature. Because of a lack of data specific to growth of *Salmonella* in egg products, this growth is assumed similar to growth of SE in shell eggs. Egg products are homogenized. For whole egg products, this means the yolk and white are mixed; therefore, the concept of YMB does not apply to *Salmonella* in whole egg products. Nor does it apply to the separated products. It is assumed that *Salmonella* in whole egg products and yolk egg products grows as if it were SE in a shell egg after YMB has occurred. *Salmonella* in egg white products is assumed to grow at rates predicted for SE in albumen in the shell egg exposure assessment. Shell eggs initially contaminated in the white can occasionally support a low rate of growth, but the growth rate increases substantially when YMB occurs. In the absence of yolk material, growth rates in white egg products are low throughout the post-pasteurization period.

*Salmonella* growth in white and yolk is described in the shell egg exposure assessment presented earlier in this chapter. Additional details can be found in Annex E. The same approach is used here for estimating growth in egg products.

Because growth of *Salmonella* in egg products depends on the time and temperature of storage of the egg product, estimates of these values are needed. Absent better data for these time and temperature relationships for egg products, distributions for storage times and temperatures were estimated in expert elicitations conducted by RTI[90] specifically for egg products. Variability in storage times and temperatures for egg products is characterized using Pert distributions with the parameters shown in Table 3-38. A distinction is made between egg products stored at room temperature and egg products stored in the refrigerator. Most egg products are stored continuously in refrigerators. A small proportion of egg products may be stored for a short time at room temperature. Table 3-38 presents distribution parameters for egg white products, Table 3-39 provides this information for whole egg products, and Table 3-40 gives it for yolk products.

For a given egg product category, a random value from the appropriate time and temperature distribution is selected and feeds into the growth equations to predict the value of $G_2$ for a serving. By repeatedly considering different times and temperatures, the output of the growth equations is a distribution of values that capture the variability attending the estimate of $G_2$. This distribution is used in Equation 3.2 to estimate the number of *Salmonella* consumed in a serving. The effect of cooking is also included in Equation 3.2 and is discussed in the next section.

TABLE 3-38 PARAMETERS FOR PERT DISTRIBUTIONS FOR STORAGE INPUTS FOR EGG WHITE PRODUCTS.

| Input | Model Abbreviation | Min | Mid | Max |
|---|---|---|---|---|
| Days product is stored in the refrigerator | RefriDays | 2.00 | 10.00 | 22.00 |
| Refrigerator temperature | RefriTemp | 0.00°C | 3.33°C | 4.44°C |
| Fraction of product stored at room temperature | FractRS | 0.02 | 0.05 | 0.10 |
| Days product is stored at room temperature | RSDays | 0.02 | 0.04 | 0.17 |
| Room temperature | RSTemp | 15.56°C | 21.11°C | 26.67°C |

TABLE 3-39 PARAMETERS FOR PERT DISTRIBUTIONS FOR STORAGE INPUTS FOR WHOLE EGG PRODUCTS.

| Input | Model Abbreviation | Min | Mid | Max |
|---|---|---|---|---|
| Days product is stored in the refrigerator | RefriDays | 2.00 | 5.50 | 13.00 |
| Refrigerator temperature | RefriTemp | 0.00°C | 3.33°C | 4.44°C |
| Fraction of product stored at room temperature | FractRS | 0.02 | 0.05 | 0.10 |
| Days product is stored at room temperature | RSDays | 0.02 | 0.04 | 0.17 |
| Room temperature | RSTemp | 15.56°C | 21.11°C | 26.67°C |

TABLE 3-40 PARAMETERS FOR PERT DISTRIBUTIONS FOR STORAGE INPUTS FOR EGG YOLK PRODUCTS.

| Input | Model Abbreviation | Min | Mid | Max |
|---|---|---|---|---|
| Days product is stored in the refrigerator | RefriDays | 2.00 | 5.50 | 11.00 |
| Refrigerator temperature | RefriTemp | 0.00°C | 2.22°C | 4.44°C |
| Fraction of product stored at room temperature | FractRS | 0.02 | 0.05 | 0.10 |
| Days product is stored at room temperature | RSDays | 0.02 | 0.04 | 0.17 |
| Room temperature | RSTemp | 15.56°C | 21.11°C | 26.67°C |

***Attenuation from Cooking,* C**

The effectiveness of cooking in destroying *Salmonella* depends only on the type of serving in this model. It is not correlated with the category of egg product. This is a simplifying assumption that may bias the estimated risk per serving if bacteria in certain egg product categories are more thoroughly or less thoroughly destroyed than in other categories.

Values for *C* for four different $\log_{10}$ reductions, shown in Table 3-41, are based on estimates for cooking shell eggs. These estimates are from the 1998 USDA risk assessment for shell eggs and egg products.[7] All egg products served as a main meal are assumed to be either scrambled or served as omelets. Consumption data support the assumption that soft boiled, poached, over-easy eggs, and so on would be made with shell eggs. The exposure assessment for shell eggs used a $\log_{10}$ reduction of 4.9 for half the eggs that are scrambled or made into omelets and 6.1 for the other half. The 1998 USDA risk assessment also estimated that about 1.7% of shell eggs consumed as ingredients are consumed raw. A similar percentage for egg products consumed as part of a main meal is assumed here. This is reasonable considering that egg products are considered a ready-to-eat item. Thus, 2% of egg products served as a main meal will not be cooked, 49% will have a $\log_{10}$ reduction of 4.9, and 49% will have a $\log_{10}$ reduction of 6.1. The same $\log_{10}$ reductions are applied to potentially undercooked egg products served as ingredients. All egg products served in beverages are served raw, and thus have a 0-$\log_{10}$ reduction. It is

further assumed that all egg products served as ingredients in mixtures that are well cooked would have a 12-$\log_{10}$ reduction. These estimates are consistent with those presented for shell eggs in Table 3-26.

The proportion of egg product servings by different meal types is given earlier in Table 3-31. By repeatedly sampling different meal types and $\log_{10}$ reductions from cooking those meal types, as shown in Table 3-31, a distribution of values that captures the variability attending the estimate of $C$ is derived; where $C = 10^{-\text{LogReduction}}$. This distribution, a discrete distribution limited to the values shown, is used in Equation 3.2 to estimate the number of *Salmonella* consumed in a serving.

TABLE 3-41 FRACTIONS, *C*, FOR DIFFERENT TYPES OF COOKING AND ASSOCIATED $\text{LOG}_{10}$ REDUCTIONS.

| Meal type | | Fractions for Possible $\text{Log}_{10}$ Reductions | | | |
|---|---|---|---|---|---|
| | | **0** | **4.9** | **6.1** | **12** |
| Potentially undercooked egg products | Main meal | 0.02 | 0.49 | 0.49 | 0.00 |
| | Beverage | 1.00 | 0.00 | 0.00 | 0.00 |
| | Ingredient | 0.02 | 0.49 | 0.49 | 0.00 |
| Well-cooked egg products | Main meal | 0.02 | 0.49 | 0.49 | 0.00 |
| | Ingredient | 0.00 | 0.00 | 0.00 | 1.00 |

## Exposure Assessment Results: *Salmonella* Spp. in Egg Products

Results are reported for the elements of the conceptual model, reproduced below as Figure 3-41.

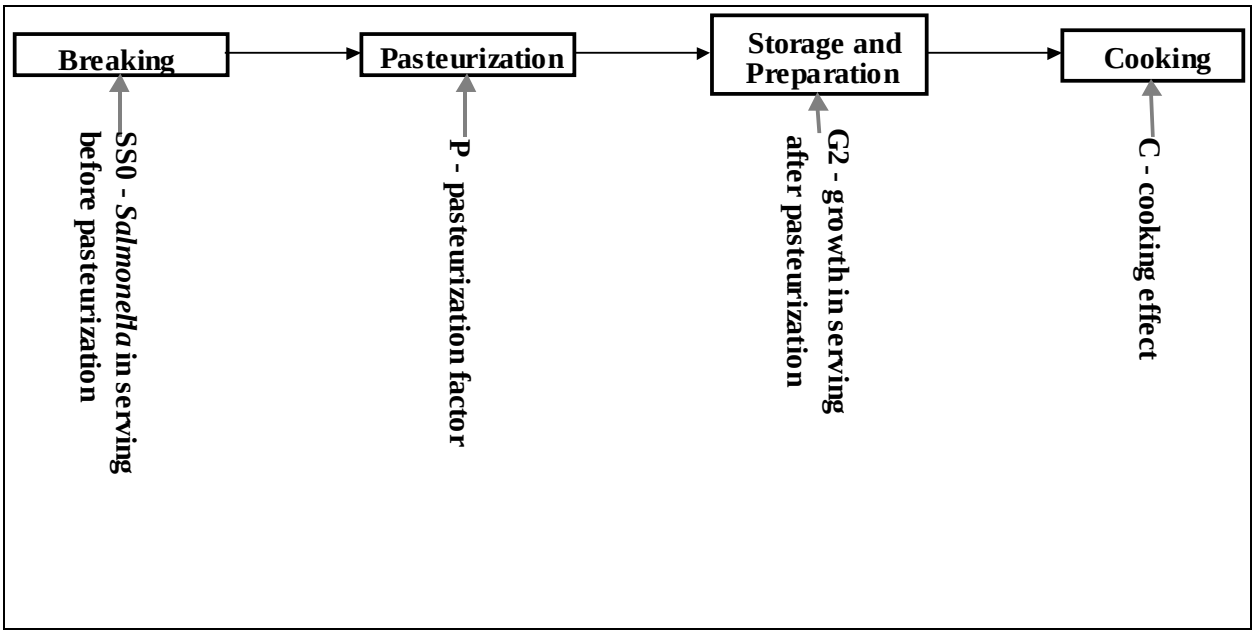



FIGURE 3-41 FLOW OF EGG PRODUCTS IN THE RISK ASSESSMENT.

Number of *Salmonella* in a Serving before Pasteurization, $SS_0$

Figure 3-42 presents the distribution of the number of *Salmonella* in servings before pasteurization, $SS_0$. The number is reflective of the concentration per gram shown in Figure 3-39

but also takes into account the variability in serving sizes. Thus, larger serving sizes result in exposure to more bacteria, on average.

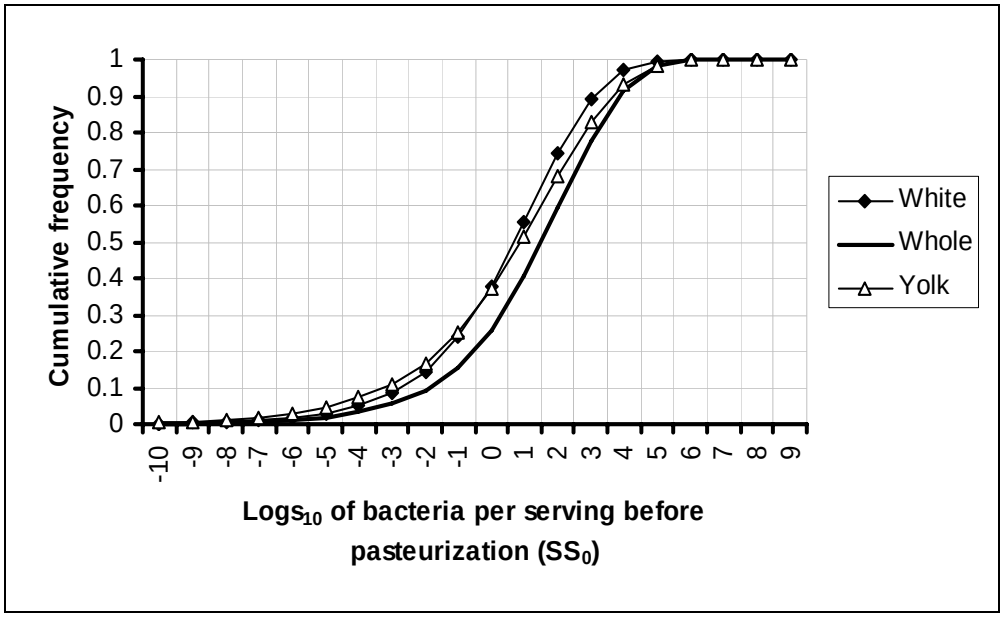



FIGURE 3-42 $LOG_{10}$ BACTERIA PER SERVING IN DIFFERENT TYPES OF EGG PRODUCTS BEFORE PASTEURIZATION.

Figure 3-43 contains the same information as in Figure 3-42 but is presented as a frequency distribution. This makes it easy to visualize that a typical serving of egg product may contain 2 $log_{10}$, or 100 bacteria before pasteurization.

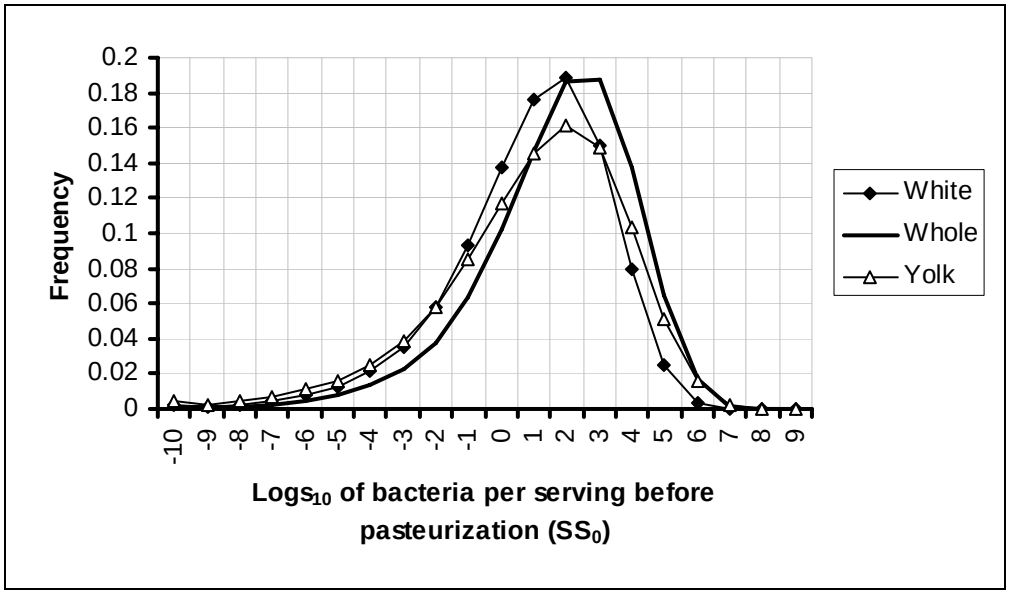



FIGURE 3-43 $LOG_{10}$ BACTERIA PER SERVING IN DIFFERENT TYPES OF EGG PRODUCTS BEFORE PASTEURIZATION.

Figure 3-44, Figure 3-45, and Figure 3-46 compare cumulative frequency distributions for $\log_{10}$ of bacteria per ml and the subsequent $\log_{10}$ of bacteria per serving for whites, wholes, and yolks, respectively.

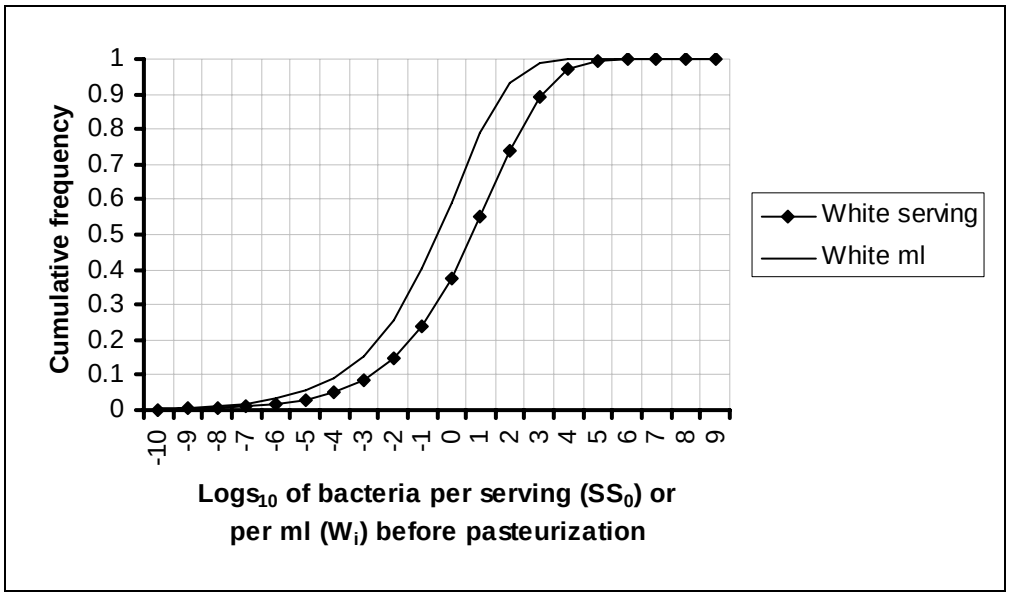



FIGURE 3-44 $\text{LOG}_{10}$ BACTERIA PER ML AND PER SERVING BEFORE PASTEURIZATION FOR EGG WHITE.

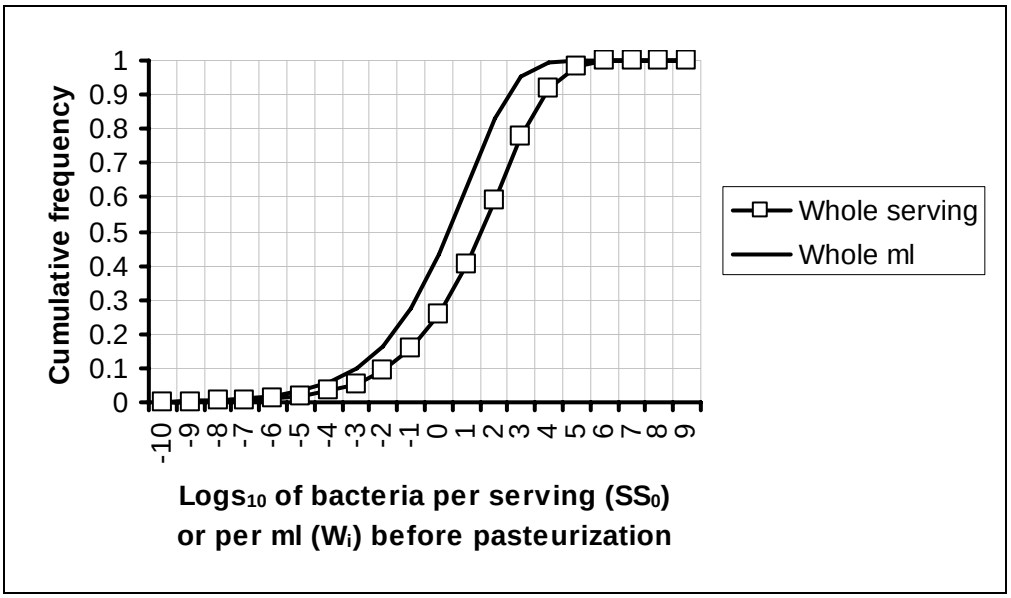



FIGURE 3-45 $\text{LOG}_{10}$ OF BACTERIA PER ML AND PER SERVING BEFORE PASTEURIZATION FOR WHOLE EGG.

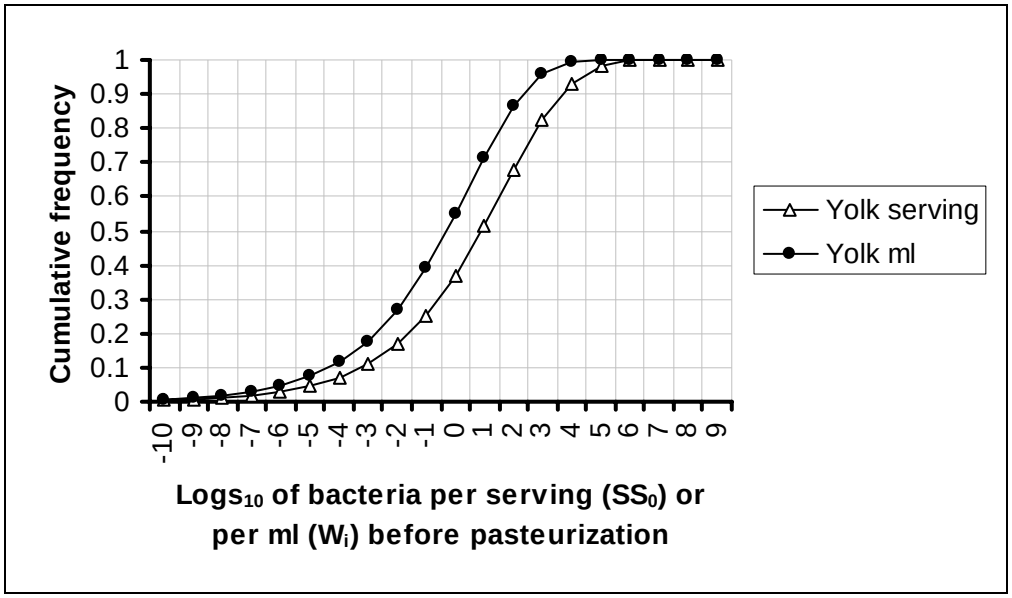



FIGURE 3-46 $LOG_{10}$ OF BACTERIA PER ML AND PER SERVING BEFORE PASTEURIZATION FOR EGG YOLK.

***Pasteurization Effectiveness,* P**

*P* was defined as the fraction of *Salmonella* that survive a pasteurization treatment. The input values for *P* for each egg product type are presented in Table 3-37 and are presented graphically below in Figure 3-47, which shows the fraction of bacteria that would survive after pasteurization.

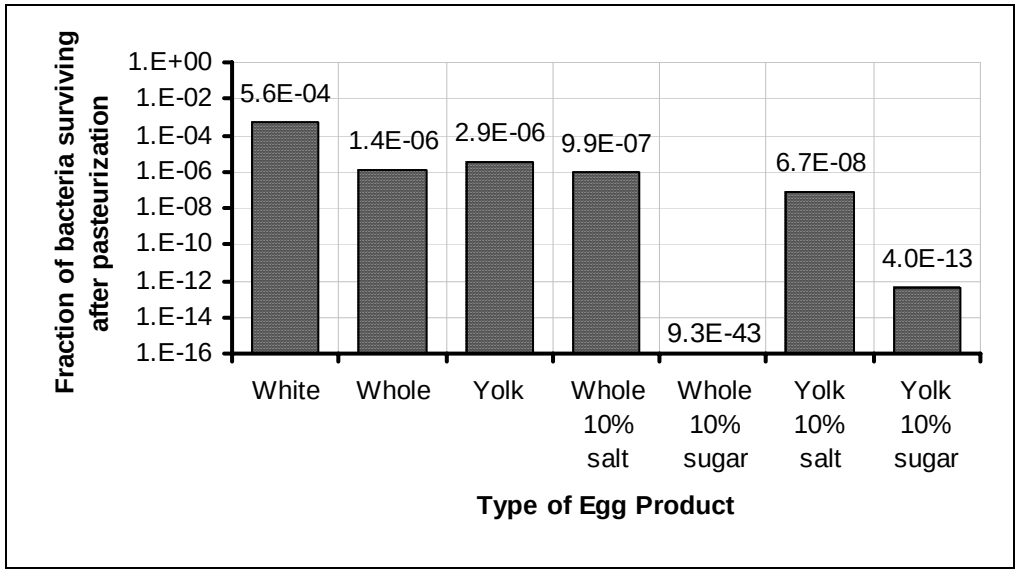



FIGURE 3-47 MODELED PASTEURIZATION EFFECTIVENESS FOR DIFFERENT TYPES OF EGG PRODUCTS.

**Why are egg products pasteurized at different temperatures?**

Egg products are pasteurized at different temperatures depending on whether the product is white, whole egg, or yolk, or whether the product has additives such as sugar or salt.

Egg white coagulates at a lower temperature than whole egg which coagulates at a lower temperature than yolk. Additives increase the temperature of coagulation so yolk product with added sugar can be pasteurized at a higher temperature than white product. Attempting to pasteurize egg whites at the temperature used for egg yolks can result in cooking rather than pasteurization.

Note that liquid white product would be expected to have a relatively large fraction of bacteria surviving pasteurization compared to the other products. In contrast, there is no probability of bacteria surviving pasteurization in whole egg product with 10% added sugar. Solely considering time and temperature requirements from Table 3-37, one would expect egg whites to have more bacteria surviving because of the lower temperature. Similarly, egg product with additives is required to be heated to a higher temperature.

Temperature is an extremely sensitive input to the calculation for the pasteurization factor for egg white. Increasing the temperature from 56.67°C to 57.0°C decreases the pasteurization factor from $5.6 \times 10^{-4}$ to about $1 \times 10^{-4}$. Increasing the temperature to 58°C decreases the pasteurization factor to about $1 \times 10^{-8}$, or an 8-$\log_{10}$ reduction due to pasteurization.

Growth Effect after Pasteurization, $G_2$

The amount of *Salmonella* growth after processing is minimal because of the low storage temperatures at which the products are expected to be held. The model reflects these temperatures. No contaminated servings experienced as much as 2 $\log_{10}$ of growth and the maximum growth simulated for liquid white was less than 0.5 $\log_{10}$. Figure 3-48 shows the frequency distribution for $G_2$ for the three main classes of egg products.

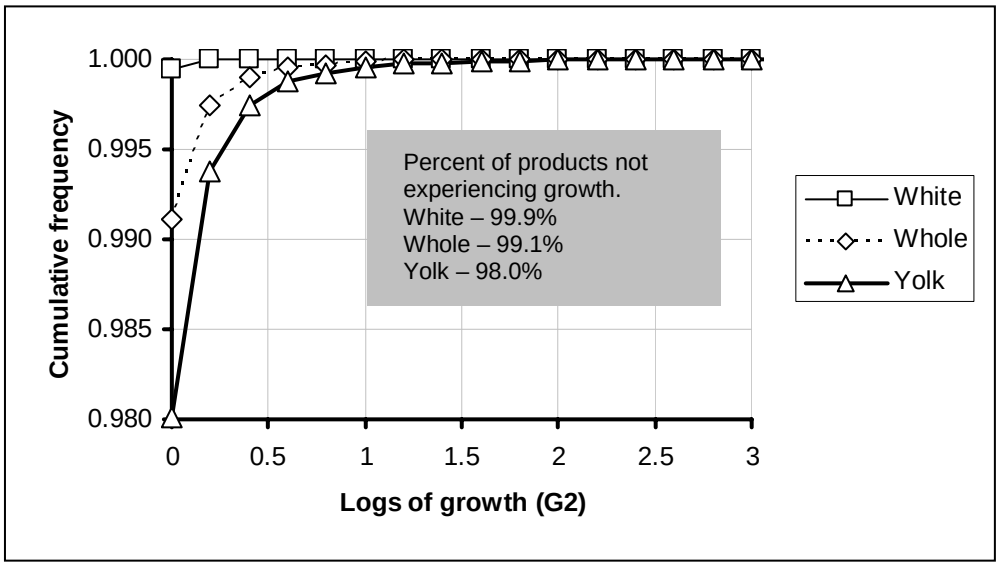



FIGURE 3-48 $\text{LOG}_{10}$ GROWTH IN YOLK, WHOLE, AND WHITE FOLLOWING PASTEURIZATION ($G_2$).

Figure 3-49 replicates Figure 3-48 in the form of a frequency distribution on a $\log_{10}$ scale. It more readily demonstrates the difference between whole egg product and egg yolk product above 1 $\log_{10}$ of growth.

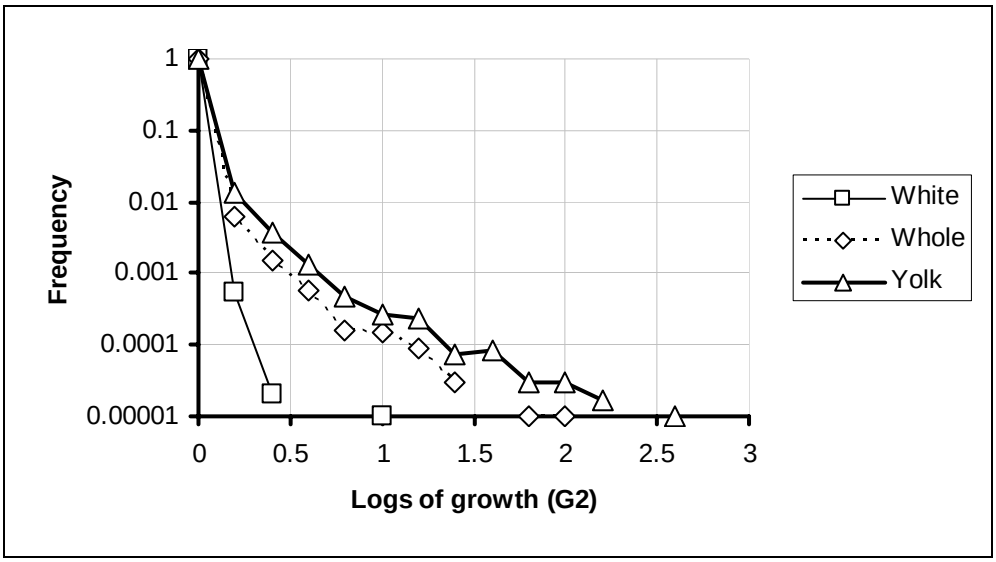



FIGURE 3-49 $LOG_{10}$ GROWTH IN YOLK, WHOLE, AND WHITE FOLLOWING PASTEURIZATION ($G_2$).

Number of *Salmonella* per Consumed Serving

The most useful output of the exposure assessment is the number of *Salmonella* consumed per serving for each of the seven different egg product types. Figure 3-50, Figure 3-51, Figure 3-52, Figure 3-53, Figure 3-54, Figure 3-55, and Figure 3-56 show the number of bacteria per serving for white, whole egg, yolk, whole egg with salt, whole egg with sugar, yolk with salt, and yolk with sugar, respectively. In each of these figures, both the x-axes and the y-axes are shown in the $\log_{10}$ scale. Frequency distributions rather than cumulative frequency distributions are shown because they allow easier viewing of the low frequencies. The y-axes are scaled from $10^{-9}$ (0.000000001), or one serving per billion servings, to 1, which represents every serving.

As might be expected, egg whites have the highest frequency distribution because of the relatively low number of $\log_{10}$ reductions due to pasteurization. Nevertheless, about 99.87% of prepared servings would be expected to have 0 bacteria present. Of the contaminated servings, over 99% would be expected to contain 1 *Salmonella*, and about 0.1% of the contaminated servings would be expected to contain 10 or more *Salmonella*.

The other six product types have fewer numbers of contaminated servings. The modeled pasteurization effectiveness is so great for whole egg product with 10% added sugar that no contaminated servings are estimated.

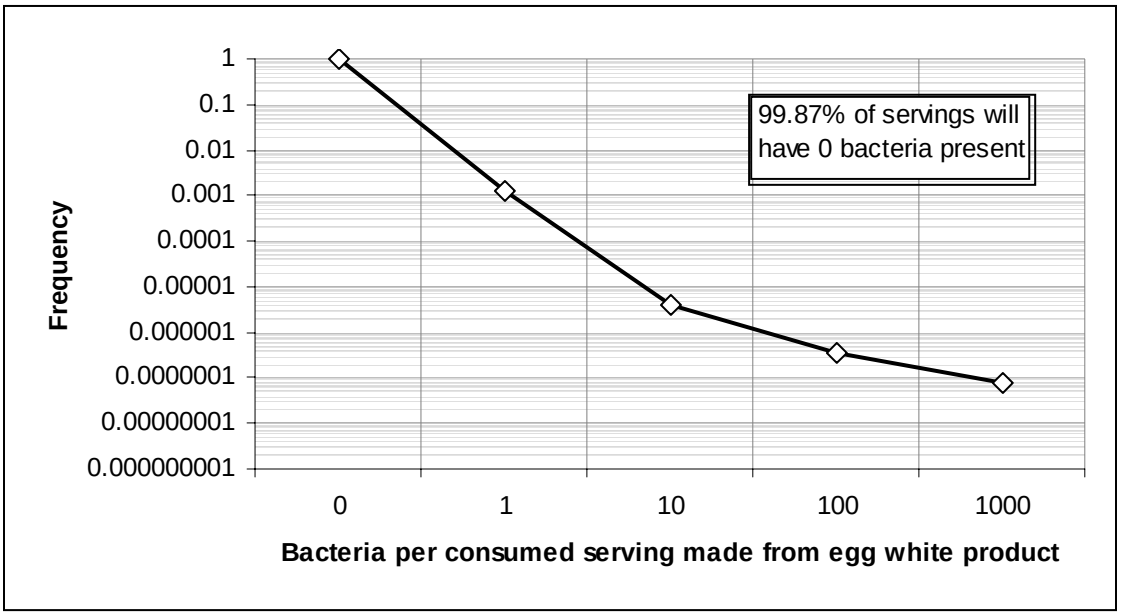



FIGURE 3-50 NUMBER OF *SALMONELLA* PER SERVING OF EGG WHITE PRODUCT AT CONSUMPTION.

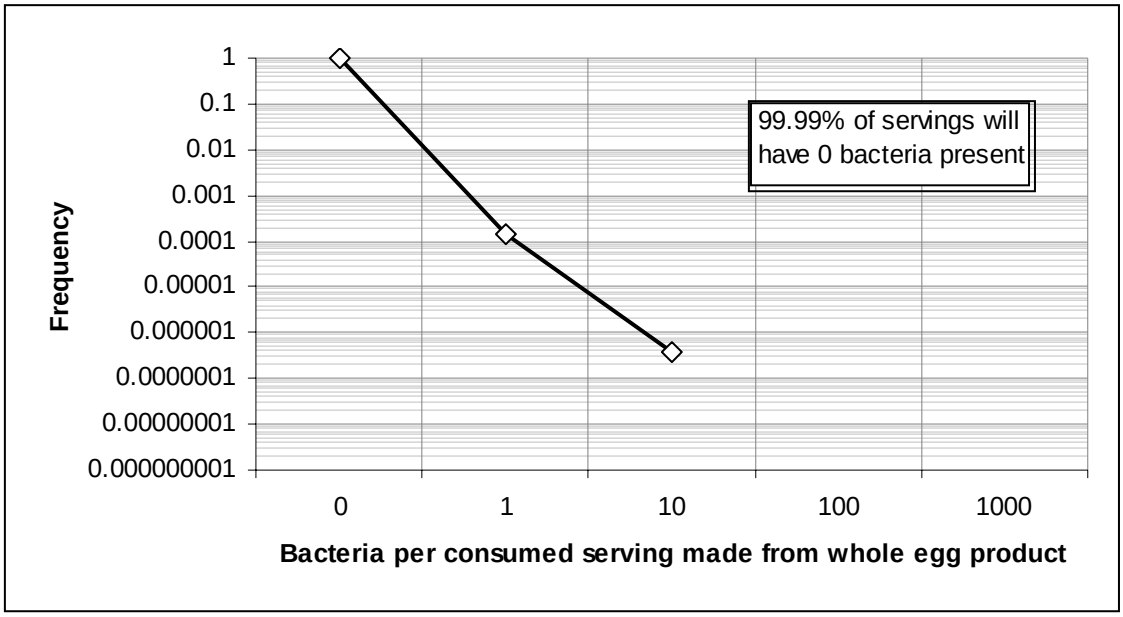



FIGURE 3-51 NUMBER OF *SALMONELLA* PER SERVING OF WHOLE EGG PRODUCT AT CONSUMPTION.

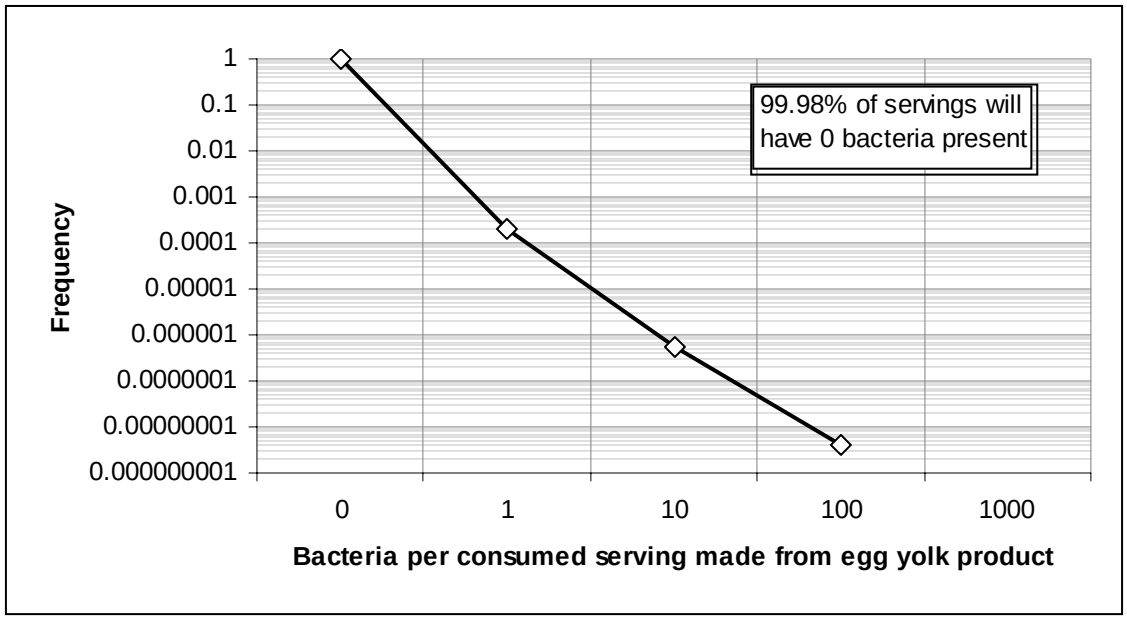



FIGURE 3-52 NUMBER OF *SALMONELLA* PER SERVING OF EGG YOLK PRODUCT AT CONSUMPTION.

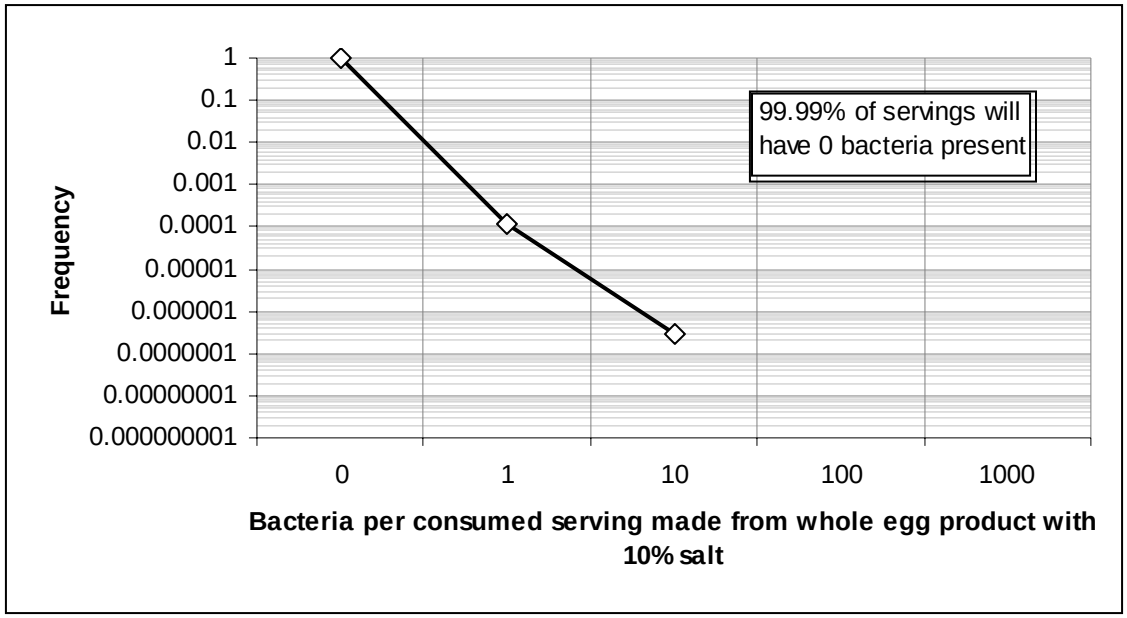



FIGURE 3-53 NUMBER OF *SALMONELLA* PER SERVING OF WHOLE EGG PRODUCT WITH 10% SALT AT CONSUMPTION.

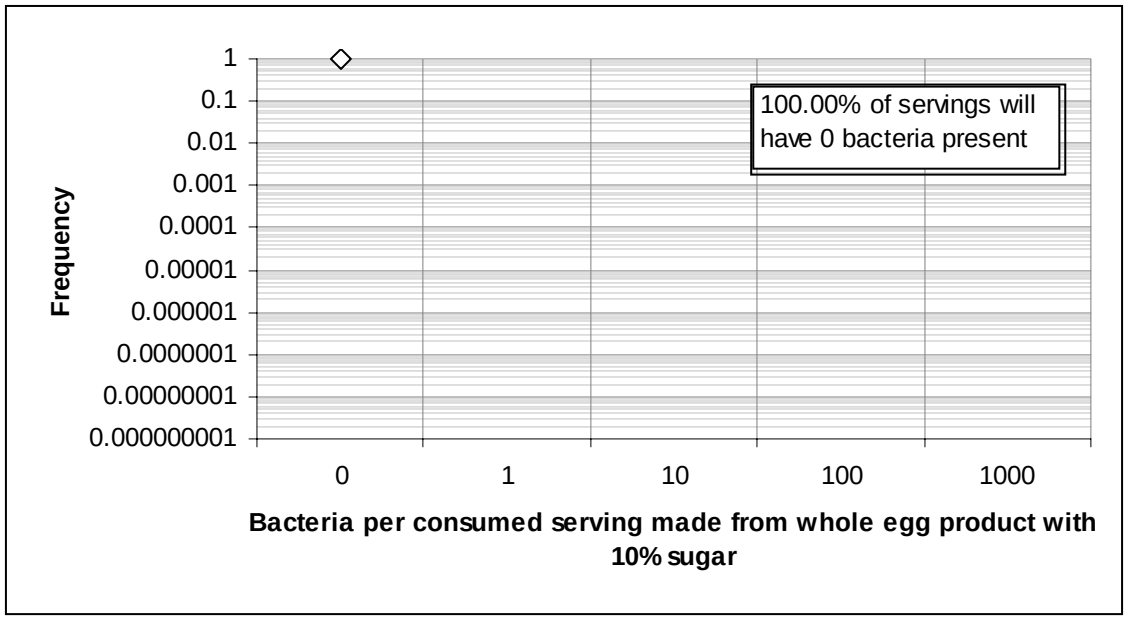



FIGURE 3-54 NUMBER OF *SALMONELLA* PER SERVING OF WHOLE EGG PRODUCT WITH 10% SUGAR AT CONSUMPTION.

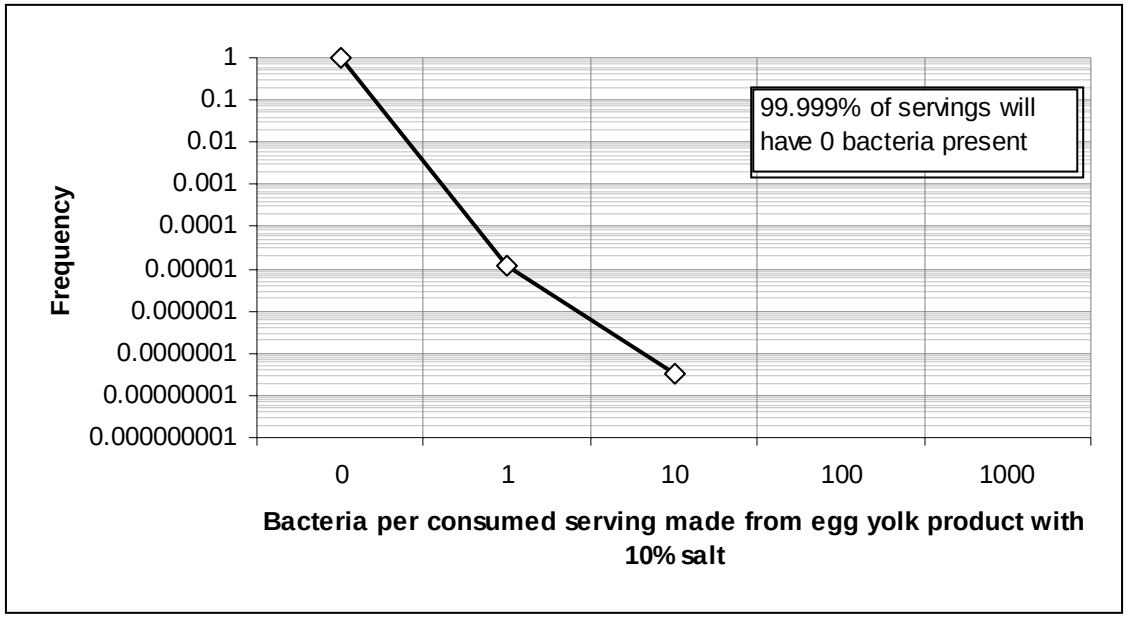



FIGURE 3-55 NUMBER OF *SALMONELLA* PER SERVING OF EGG YOLK PRODUCT WITH 10% SALT AT CONSUMPTION.

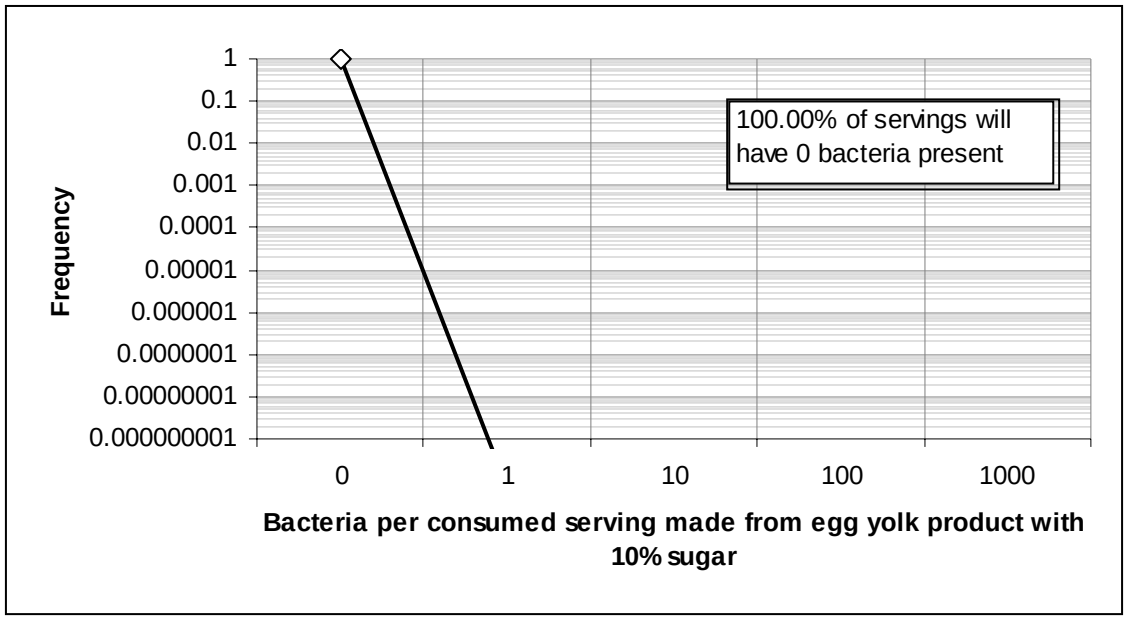



FIGURE 3-56 NUMBER OF *SALMONELLA* PER SERVING OF EGG YOLK PRODUCT WITH 10% SUGAR AT CONSUMPTION.

Table 3-42 shows the probability that a consumed serving would contain at least one *Salmonella* for each of the seven modeled egg products. Again, liquid egg white has the highest probability of exposure.

TABLE 3-42 PROBABILITY OF A CONSUMED SERVING CONTAINING AT LEAST ONE *SALMONELLA* BACTERIUM FOR DIFFERENT TYPES OF EGG PRODUCTS.

| Egg Product | Probability of a Consumed Serving Containing at Least One *Salmonella* |
|---|---|
| White | $1.3 \times 10^{-3}$ |
| Whole | $1.4 \times 10^{-4}$ |
| Yolk | $2 \times 10^{-4}$ |
| Whole 10% salt | $1.1 \times 10^{-4}$ |
| Whole 10% sugar | $<10^{-16}$ |
| Yolk 10% salt | $1.2 \times 10^{-5}$ |
| Yolk 10% sugar | $7.5 \times 10^{-11}$ |

Simulated servings frequently contained *Salmonella* prior to pasteurization for all three main product types. After pasteurization, however, contamination was infrequent and occurred only at low levels. Very little *Salmonella* growth occurs in egg products after pasteurization due to short storage times and low temperatures. Most servings are expected to be thoroughly cooked to effect a 12-$\log_{10}$ reduction. Therefore, cooking renders even heavily contaminated servings free of *Salmonella*. A small percentage of liquid egg product servings, however, will be consumed with no cooking. The contamination levels in these products at the time of consumption are generally the same as right after pasteurization.

Table 3-43 compares the expected values of each of the egg product exposure distributions with the expected values of the pre-pasteurization serving distributions. Dividing the expected value of the exposure distribution by the expected value of the pre-pasteurization distribution results in a number that represents the combined mitigation multiplier effect due to pasteurization and cooking.

TABLE 3-43 COMPARISON OF DISTRIBUTIONS FOR *SALMONELLA* PRE-PASTEURIZATION AND AT CONSUMPTION.

| Egg Product | Expected Value of Exposure Distribution | Expected Value of Pre-Pasteurization Distribution | Mitigation Multiplier Effect |
|---|---|---|---|
| White | $1.4 \times 10^{-3}$ | $8.1 \times 10^{3}$ | $1.7 \times 10^{-7}$ |
| Whole | $1.4 \times 10^{-4}$ | $4.7 \times 10^{4}$ | $3 \times 10^{-9}$ |
| Yolk | $2 \times 10^{-4}$ | $5.9 \times 10^{4}$ | $3.5 \times 10^{-9}$ |
| Whole 10% salt | $1.1 \times 10^{-4}$ | $4.7 \times 10^{4}$ | $2.4 \times 10^{-9}$ |
| Whole 10% sugar | $<10^{-16}$ | $4.7 \times 10^{4}$ | $<10^{-16}$ |
| Yolk 10% salt | $1.2 \times 10^{-5}$ | $5.9 \times 10^{4}$ | $2.1 \times 10^{-10}$ |
| Yolk 10% sugar | $7.5 \times 10^{-11}$ | $5.9 \times 10^{4}$ | $1.3 \times 10^{-15}$ |

## SUMMARY

Consumers may be exposed to *Salmonella* from egg eating eggs. The amount of *Salmonella* cells consumed depends on various factors, including whether the egg was contaminated at lay; the time and temperature at which the egg was stored; the effect of pasteurization; and the effect of cooking. The Exposure Assessment described the mathematical formulations used to model these events and estimate the number of SE in shells eggs and *Salmonella* spp. in egg products at consumption. The sensitivity of estimates to various inputs and assumptions and the effect of interventions besides pasteurization are described in Chapter 4. The effect of *Salmonella*-contaminated egg servings on human health is described in Chapter 5.

# 4 Hazard Characterization

Hazard characterization is a description of the adverse effects that may result from ingesting a microorganism and of a dose-response relationship if data are obtainable.[91] It provides a descriptive analysis of clinical and epidemiological information on the adverse effects that may result from ingesting a microorganism. A dose-response model describes the probability of a specific response in a specific population as a function of the dose. The biological basis for dose-response models results from the interactions among the pathogen, the host, and the food matrix (Figure 4-1). Each step is composed of many biological events. Infection and illness result from the successful passage of multiple barriers in the host. These barriers are not equally effective in eliminating or inactivating pathogens. Each individual pathogen has some particular probability of overcoming a barrier, which is conditional on the previous step(s) being completed successfully.[91]

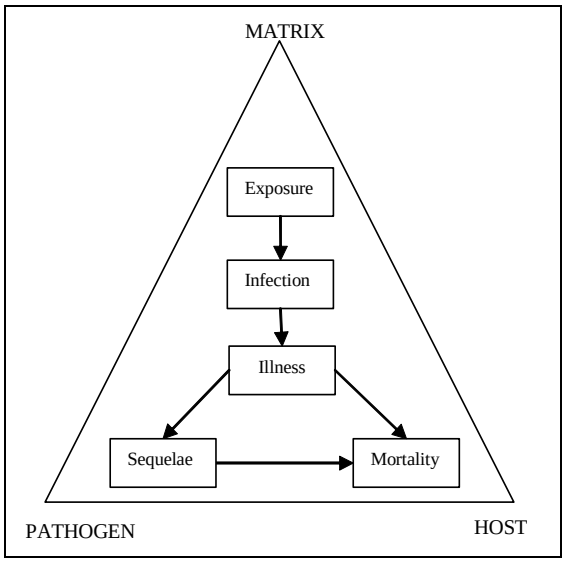



FIGURE 4-1 HAZARD CHARACTERIZATION TRIANGLE. SOURCE: FAO/WHO.[24]

**Joint Expert Meetings on Microbiological Risk Assessment (JEMRA)**

JEMRA is a joint FAO/WHO expert group organized to conduct risk assessments on microbiological hazards in foods. JEMRA generally conducts risk assessments in response to requests from the Codex Committee on Food Hygiene (CCFH). A small international group of risk analysts drafts the assessment over a two-year period. The drafts are reviewed during weeklong consultations that occur twice during the two-year process. The final report is peer reviewed. Currently, JEMRA has completed a risk assessment on *Salmonella* spp. in broilers and eggs and has several other risk assessments in process.

This chapter presents the data available to model a dose-response relationship for *Salmonella* spp. and the beta-Poisson model produced by the Joint Expert Meetings on Microbiological Risk Assessment (JEMRA—see text box for details).[24] The strengths and weakness of the JEMRA model are discussed along with reasons for selecting the JEMRA model for use in this risk assessment. This chapter refers extensively to the Joint FAO/WHO Risk Assessment of *Salmonella* spp. in Eggs and Broiler Chickens. [24] A draft of that report can be found in Annex I. This chapter also provides an estimate of yearly cases of illness, hospitalization, sequellae, and death from SE in eggs in the U.S. These estimates were derived from public health surveillance systems, and they provide a benchmark for comparing the results of a probabilistic model.

## GENERIC DATA SOURCES

A Joint FAO/WHO Consultation on Hazard Characterization identified several generic sources of data that may be useful in developing a mathematical relationship between dose and response.[91] Each of these sources contributes in varying degrees to an understanding of the pathogen host food-matrix interactions that influence the potential public health risks attributable to a disease agent. An assessment of the strengths and limitations of various data sources is critical to selecting appropriate data for use in this risk assessment.[91] The relevance of data from the sources in

Table 4-1 can be difficult to judge. However, in general, human data are preferred to animal data, which in turn are preferable to *in vitro* data. Data on the pathogen of concern are preferred to data on surrogate organisms, which should only be used on the basis of solid biological evidence such as common virulence factors.[91] The data from each of these sources that was considered most relevant for this risk assessment are summarized in the sections that follow.

## SOURCES OF DOSE-RESPONSE DATA EVALUATED BY JEMRA

One source of data available for calculating a dose and response relationship is the information collected during investigations of foodborne illness outbreaks. Table 4-1 summarizes the strengths and weaknesses of these kinds of data. The Joint Expert Group collected data from countries worldwide and identified 20 outbreaks that included sufficient information on dose and attack rate to develop a dose-response model (Table 4-2).

TABLE 4-1 EVALUATION OF OUTBREAK DATA FOR DEVELOPING A DOSE-RESPONSE MODEL.

| | |
|---|---|
| **Pros** | • Data from low dose exposures are available.<br>• Exposed population more closely resembles the population at risk; therefore, these results may be easier to generalize to the population under consideration.<br>• The strains and serotypes included are ones implicated in foodborne human illness.<br>• Data reflect a range of food chemistries associated with transmission. |
| **Cons** | • Measurements of concentration of bacteria in food can be misleading because of the non-homogenous nature of pathogens in food commodities.<br>• The quantity of food consumed is often not recorded. Consequently, an estimate of the food consumed or average serving size is often used to calculate dose.<br>• It can be difficult to assess accurately the exposed population as well as the number of ill people because of underreporting.<br>• Information on age and immunologic health of patients is often not available, making it difficult to differentiate subpopulations that are more susceptible. |

TABLE 4-2 *SALMONELLA* OUTBREAKS USED IN DEVELOPING THE JEMRA DOSE-RESPONSE RELATIONSHIP.

| Otbrk Ref # | Serotype | Country | $Log_{10}$ Dose (Uncertainty) | | Attack Rate (Uncertainty) | |
|---|---|---|---|---|---|---|
| | | | Min | Max | Min | Max |
| 1 | *S.* Typhimurium | US | 1.57 | 2.57 | 11.20% | 12.36% |
| 2 | *S.* Heidelberg | US | 1.48 | 2.48 | 28.29% | 36.10% |
| 3 | *S.* Cubana | US | 4.18 | 4.78 | 60.00% | 85.71% |
| 4 | *S.* Infantis | US | 6.06 | 6.66 | 100.00% | 100.00% |
| 5 | *S.* Typhimurium | US | 3.05 | 4.05 | 52.36% | 57.64% |
| 7 | *S.* Newport | US | 0.60 | 1.48 | 0.54% | 2.59% |
| 11 | *S.* Enteritidis | US | 4.00 | 5.00 | 100.00% | 100.00% |
| 12 | *S.* Enteritidis | US | 1.00 | 2.37 | 6.42% | 7.64% |
| 13 | *S.* Typhimurium | US | 8.00 | 8.88 | 100.00% | 100.00% |
| 18 | *S.* Enteritidis | Japan | 5.13 | 5.57 | 60.00% | 60.00% |
| 19 | *S.* Enteritidis | Japan | 6.03 | 6.48 | 87.70% | 100.00% |
| 20 | *S.* Enteritidis | Japan | 2.69 | 3.14 | 18.61% | 36.41% |
| 22 | *S.* Enteritidis | Japan | 6.02 | 6.47 | 52.17% | 61.32% |
| 23 | *S.* Enteritidis | Japan | 5.53 | 5.97 | 84.62% | 84.62% |
| 24 | *S.* Enteritidis | Japan | 1.45 | 1.89 | 12.19% | 23.96% |
| 25 | *S.* Enteritidis | Japan | 3.36 | 3.80 | 39.85% | 39.85% |
| 30 | *S.* Enteritidis | Japan | 3.53 | 3.97 | 60.14% | 70.90% |
| 31 | *S.* Enteritidis | Japan | 2.37 | 2.82 | 25.62% | 30.04% |
| 32 | *S.* Enteritidis | Japan | 1.11 | 1.57 | 26.92% | 26.92% |
| 33 | *S.* Oranienburg | Japan | 9.63 | 10.07 | 100.00% | 100.00% |

Source: FAO/WHO.[24]

**Generic Data Sources for Dose-Response (WHO/FAO Expert Consultation in Bilthoven, 1990)**

**Human illness outbreaks**—An epidemiological investigation is sometimes undertaken to identify the cause of a foodborne illness outbreak, limit its further spread, and provide recommendations on preventing the problem in the future. These data can serve as a means for deriving dose-response relations and for evaluating the plausibility of risk assessments.

**Volunteer feeding trials**—Dose-response relationships for pathogenic microorganisms have been derived from studies where humans were exposed to the agent under controlled conditions. Feeding studies using volunteers have been carried out for a limited number of pathogens. Most of these studies were conducted in conjunction with vaccine trials.

**Biomarkers**—Biomarkers are measurements of host characteristics that indicate exposure of a population to a hazard or the extent of adverse effect caused by the hazard. They are generally minimally invasive techniques that were developed to assess the status of the host.

**Animal studies**—Animal studies overcome many of the logistical and ethical limitations associated with human volunteer feeding studies. Large varieties of different animal models have been used to understand the pathogen, host, and matrix factors and develop dose-response relationships.

**Expert elicitation**—Expert elicitation is a formal approach to the acquisition and use of expert opinions, in the absence of, or to augment available data.

**In vitro studies**—The use of cell, tissue, or organ cultures and related biological samples has been used to characterize the effect of a pathogen on a host. These studies are of greatest use in qualitative characterizations of pathogen virulence, but they may also be used to evaluate the effects of defined factors on the disease process.

**Intervention studies**—Human trials where the impact of a hazard is evaluated by reducing exposure for a defined sample of a population. The incidence of disease or a related biomarker is then compared to a control population to assess the magnitude of the response differential for the two levels of exposure.

A second source of data on dose and response for *Salmonella* spp. is human feeding trial studies.[92-94] Some strengths and weaknesses of these kinds of data are presented in Table 4-3. These data were collected by dosing healthy male prisoners with a defined number of organisms in a liquid medium. The pathogen levels used were high relative to the levels generally observed in foodborne illness outbreaks.

In general, the variables of interest in human feeding study data are well controlled but less representative of real-world situations. For example, the number of organisms given to human volunteers in feeding trials is known with great accuracy, but those numbers are generally much higher than people are exposed to in reported foodborne illness outbreaks. On the other hand, data from outbreak investigations are very representative of the exposure levels and the diversity in response likely to occur in human populations. However, in outbreak studies, the variables of interest are measured after the outbreak occurred; consequently, the uncertainty in the measurement is high. Finally, though data are unavailable to inform the point, it is possible that continued bacterial evolution since the time of human volunteer studies and outbreak investigations may complicate data interpretation.

A beta-Poisson model fit to naïve human feeding trial data greatly underestimates the frequency of illness as observed in the outbreak data (Figure 4-2). Consequently, the Joint Expert Group chose to use only the outbreak dataset in developing a dose-response relationship. Similarly, accurate representation of the exposure levels and the variation in human responses to

foodborne pathogens is more important than the precision provided by the human feeding trial studies in developing a dose-response relationship.

TABLE 4-3 EVALUATION OF HUMAN FEEDING TRIAL DATA FOR DEVELOPING A DOSE-RESPONSE RELATIONSHIP.

| | |
|---|---|
| **Pros** | • The dose consumed is known with certainty.<br>• The number of people exposed and ill is known with certainty.<br>• The health status of exposed individuals is known with more certainty. |
| **Cons** | • The data were obtained exclusively from healthy male volunteers, which prohibits any assessment of susceptible populations.<br>• High doses of *Salmonella* were fed to volunteers, thus complicating extrapolation to low doses typically observed in outbreaks.<br>• A limited number of serotypes were administered, and only one of these has been observed in the top five serotypes recorded by FoodNet.<br>• The administered strains are different from those currently found in shell eggs and liquid egg products.<br>• Data are lacking for the serotype Enteritidis that accounts for the majority of sporadic illnesses and outbreaks from shell eggs. |

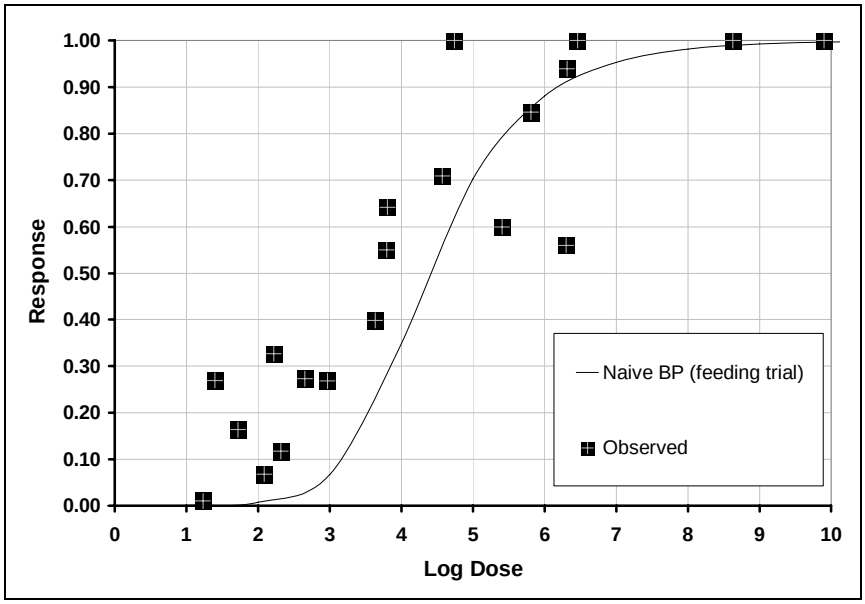



FIGURE 4-2 BETA-POISSON DOSE-RESPONSE MODEL FIT TO NAÏVE HUMAN FEEDING TRIAL DATA COMPARED WITH REPORTED OUTBREAK DATA. SOURCE: FAO/WHO.[24]

## JEMRA OUTBREAK DATASET

JEMRA collected data from countries worldwide and identified 33 outbreaks that included quantitative information from which the dose and attack rate could be estimated (Table 4-2). Twenty-three of the 33 outbreak reports contained sufficient data on the number of people exposed, the number of people who became ill, and the number of organisms in the implicated food to be used in developing a dose-response relationship. Three of these outbreaks were excluded because the immune status of the persons exposed could not be determined. In some outbreak reports, the data needed were incomplete and the number of people exposed, number of people ill, and/or the dose were/was estimated. The remaining 20 outbreaks comprise the database used to calculate a dose-response relationship.

**The Japanese Food Saving Program**

The Japanese Ministry of Health and Welfare provided data from epidemiological investigations of foodborne illness outbreaks in Japan for use in the JEMRA risk assessment. This information was especially useful because it contained enumeration data on *Salmonella* spp. present in foods that made people ill. In Japan, large-scale cooking facilities which prepare more than 750 meals per day or more than 300 servings of a single menu item at a time, are advised (in accordance with a Japanese notification released in March 1997) to save food for future possible analysis in the event of an outbreak. This advice is also applicable to smaller-scale kitchens with social responsibility such as schools, day care centers, and other child-welfare and social-welfare facilities. Fifty-gram portions of each raw food ingredient and each cooked dish are saved for at least 2 weeks at temperatures lower than minus 20ºC. If an outbreak of foodborne illness occurs, public health personnel retrieve the samples, culture the saved food, and quantify the number of bacteria present.

Several *Salmonella* serotypes were associated with the outbreaks, including *S.* Enteritidis (12), *S.* Typhimurium (3), *S.* Heidelberg, *S.* Cubana, *S.* Infantis, *S.* Newport, and *S.* Oranienburg. Several vehicles were implicated, including food (meat, eggs, dairy products, and others), water, and a medical dye capsule (carmine dye). Eleven of the 20 outbreaks in the database occurred in Japan, and nine occurred in the U.S. Outbreak investigation reports provided by the Ministry of Health and Welfare of Japan provided a valuable source of information that expanded the database considerably (see text box). JEMRA identified the most significant limitations of the dataset.

- Analysis of epidemiological reports indicates there are differences in responses (illness) between normal (between the ages of 5 and 65) and susceptible (less than 5 and greater that 65) human populations.[16] However, the outbreak dataset used by JEMRA does not contain detectable differences in response between normal and susceptible individuals. The inability of the JEMRA dose-response model to discriminate the response in these two populations may be due to the high level of uncertainty in the estimates for dose and number of people ill in the outbreak dataset. On the other hand, the association between salmonellosis and age may be due to reporting bias because children and the elderly with diarrhea may be more frequently cultured than other age groups.[71] In addition, confounding factors may be associated with behavioral characteristics of children (i.e., children eating snow, sand, or soil may be more likely to be exposed to *Salmonella* spp.).[72]

- The endpoint measured in the outbreak dataset used by JEMRA was illness, but a standard definition for illness was not applied to all outbreaks. Illness is a process of cumulative damage to the host, leading to an adverse reaction. There are usually different and simultaneous symptoms of illness in any individual, and the severity of symptoms varies among hosts infected with the same pathogen. Illness is a process that is ideally measured on a multidimensional, quantitative, and continuous scale (e.g., number of stools passed per day and body temperature).

- Analysis of data from human feeding trial studies did detect a difference in the response (infection) between some *Salmonella* serotypes. However, no difference was detected in the response (illness) between *S.* Enteritidis and other *Salmonella* serotypes in the outbreak dataset used by JEMRA. The significance of this discrepancy is uncertain given the difference in responses that were measured in the two datasets and the complex relationship between infectivity/virulence and serotype.

- The dataset used in the JEMRA dose-response model included outbreaks from both the U.S. and Japan. The U.S. population may differ from the Japanese population in susceptibility to *Salmonella* spp. Application of the JEMRA model to the U.S. population without considering differences in susceptibility at the population level could bias the results. The number of people exposed in Japanese outbreaks (~14,037, 52%) was about the same as that in U.S. outbreaks (~12,728, 48%) (Annex I, Table 3.14). The overall attack rate in the data was 21.8% (26,765 exposed, 5,636 ill). The attack rate among Japanese outbreaks (27.4%, range 16 to 100%) was higher than that of U.S. outbreaks (15.6%, range 1 to 100%). This was due in part to one large outbreak in the U.S. (8,788 people exposed) with an attack rate of 11.7% and one large outbreak in Japan (5,102 people exposed) with an attack rate of 26.9%. The overall attack rate was higher for Japanese outbreaks, but the median attack rate of U.S. outbreaks (55%) was higher than Japanese outbreaks (49%). Although differences in age and immune status between the two populations may exist, any potential effects appear to be small compared to the large amount of uncertainty in the dose-response relationship. This limitation of the JEMRA dose-response model was recognized, but we did not attempt to adjust the model for an exclusively U.S. population.

Furthermore, because the protocol of storing retained foods at –20°C would have likely reduced the numbers of salmonellae cells present and made survivors more difficult to culture, it is probable that the numbers found in the food samples may have been an underestimate.

## DOSE-RESPONSE MODELS

JEMRA evaluated three existing dose-response models for *Salmonella* spp. using criteria developed by WHO for selecting mathematical models to interpret a dataset. The first model was the beta-Poisson model fit to the human feeding trial data for *Salmonella*.[95] The second model was proposed in the U.S. SE risk assessment[7] and was based on using a surrogate pathogen to describe the dose-response relationship. The third model, introduced in the Health Canada SE risk assessment, used a Weibull dose-response relationship updated to reflect outbreak information using Bayesian techniques. JEMRA concluded "…the dose-response model based upon the observed outbreak data provides an estimate for the frequency of illness that is based on real world data. Given the assumptions associated with some of the other models the outbreak model offers the best current alternative for estimating the frequency of illness upon ingestion of a dose of *Salmonella*." (Annex I, Figure I.19). JEMRA developed a beta-Poisson model (Equation 4.1) as the mathematical form for the relationship and this was fit to the outbreak data.

$$P(ill) = 1 - (1 + (Dose / \beta)^{-\alpha} \quad (4.1)$$

The data from 34 outbreak studies provided JEMRA with the opportunity to develop a dose-response relationship. The beta-Poisson model was used for the dose-response relationship because it has been used successfully in previous risk assessments[7;95] and because it provided a good statistical fit to the data. A maximum likelihood estimation technique was used to estimate the parameters $\alpha$ and $\beta$ from reported $\log_{10}$ dose and attack ratio response values obtained from the outbreak studies.

Point estimates of $\alpha$ and $\beta$ were considered inadequate for use in the risk assessment because of the uncertainty in the outbreak data due to the uncontrolled conditions under which the data must be collected. Both the actual dose ingested and the true number of people exposed can be under- or overestimated. The uncertainty in the $\log_{10}$ dose and response data was described using a minimum and maximum value for each input for each of the 34 studies, as shown in Table 4-2.

Resampling techniques were used to generate synthetic data sets from each of the 34 ranges of $\log_{10}$ dose and response. The maximum likelihood technique was then used to estimate values of $\alpha$ and $\beta$ for that resampled data set. This $\alpha$ and $\beta$ pair was used to develop a single dose-response curve. This resampling process was repeated about 5,000 times. It generated 5,000 $\alpha$ and $\beta$ pairs and 5,000 dose-response curves. Table 4-4 presents selected descriptive statistics for the 5,000 estimates of $\alpha$ and $\beta$.

TABLE 4-4 ALPHA AND BETA PARAMETERS USED IN DOSE-RESPONSE MODEL.

| | Alpha | Beta |
|---|---|---|
| **Expected value** | 0.1324 | 51.45 |
| **Lower bound** | 0.0763 | 38.49 |
| **2.5$^{th}$ percentile** | 0.0940 | 43.75 |
| **97.5$^{th}$ percentile** | 0.1817 | 56.39 |
| **Upper bound** | 0.2274 | 57.96 |

Source: FAO/WHO.[24]

The expected values shown in Table 4-4 are used to generate the baseline. The effect of assuming upper or lower bounds of $\alpha$ and $\beta$ is shown in the sensitivity analysis (see Risk Characterization, Figure 5-16). These parameters, in essence, were used to generate the range of

dose-response curves shown in Figure 4-3. The squares indicate actual data points. The dark curve in the center represents the expected value of the dose-response relationship. The two adjacent curves represent the 2.5$^{th}$ and 97.5 percentiles, while the two outermost curves represent the lower and upper bounds on the dose-response relationship. Using the characterization of dose-response curves described here enabled risk assessors to address the uncertainty in the dose and response inputs quantitatively.

The draft reports of the Expert Group were reviewed by a group of internationally recognized experts twice during the course of work, and the final product was peer-reviewed and revised before completion. The thorough evaluation and review process is a strong point of the joint FAO/WHO dose-response model. However, all models are incomplete representations of the system they are intended to model.

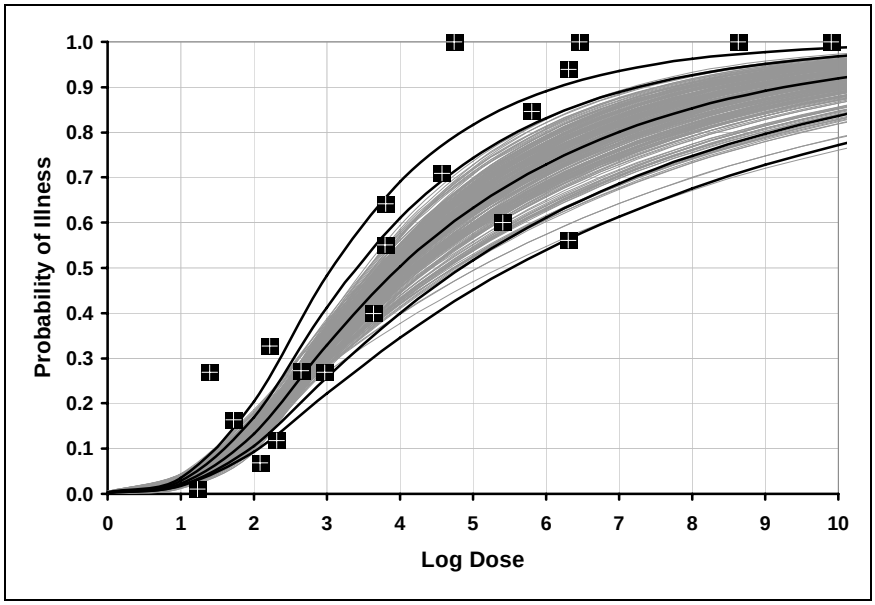



FIGURE 4-3 UNCERTAINTY BOUNDS FOR DOSE-RESPONSE CURVES, COMPARED WITH EXPECTED VALUE FOR THE OUTBREAK DATA. SOURCE: FAO/WHO.[24]

The dose-response model developed by JEMRA was selected for use in this risk assessment for the following reasons:

- The JEMRA model was developed through a process that incorporated the principles of transparency, peer review, and separation of risk assessment and risk management. The adherence to these principles provides some confidence in the results.

- The National Advisory Committee for Microbiological Contaminants in Foods (NACMCF) evaluated the model and determined it adequate for use in risk assessment.

- FDA is using the FAO/WHO model in their risk assessment of SE in shell eggs. Consistency with FDA will allow comparison of the results of the two assessments and meets Office of Management and Budget (OMB) guidelines.

The dose-response analysis presented here is combined with the exposure assessment described in the preceding chapter to develop the risk characterization in Chapter 5.

## *SALMONELLA* ILLNESS ESTIMATED FROM SURVEILLANCE DATA

This section provides an estimate of yearly cases of illness, hospitalization, sequellae, and death from SE in eggs in the U.S., derived from public health surveillance systems. These independently derived estimates provide a benchmark to evaluate the plausibility of the probabilistic risk assessment. Dose-dependency of severity of salmonellosis is not considered in this risk assessment. However, there is evidence of a relationship between dose and severity of salmonellosis and other foodborne diseases.[96-99]

Passive surveillance of illness from non-typhoid *Salmonella* has been conducted for more than three decades in the U.S. Estimates of the yearly incidence rate from passive surveillance have been useful in tracking trends over time but they significantly underestimate the level of illness. Figure 4-4 shows the series of steps that must be met for an illness to be reported to the CDC. Multipliers, ranging from 29[100] to 350,[101] have been developed to relate reported illness to total illnesses.

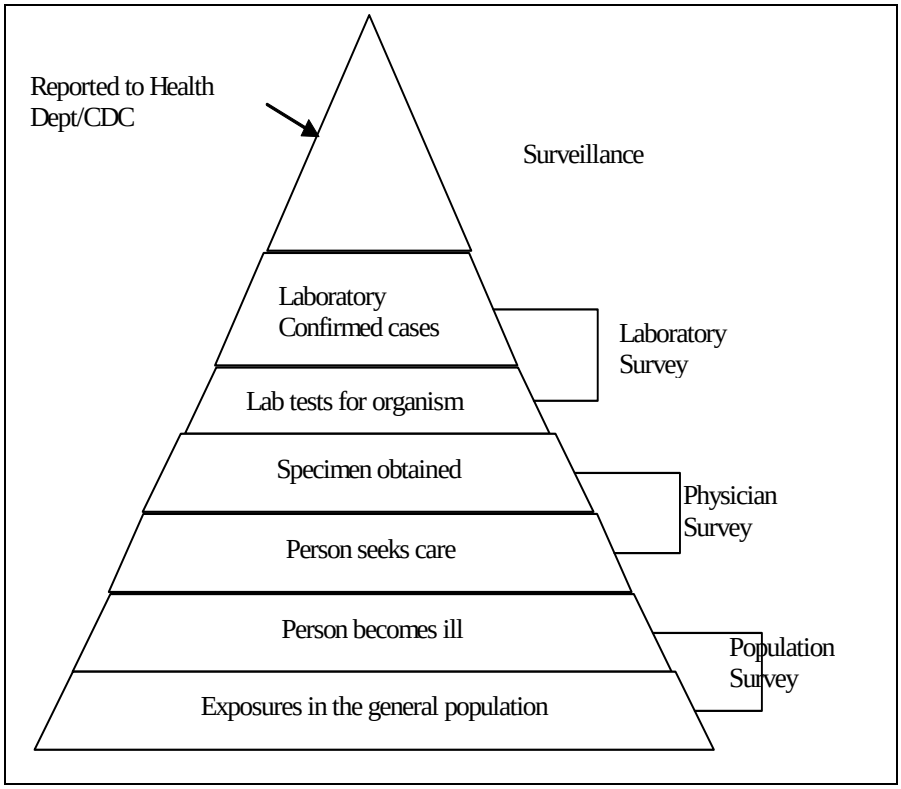



FIGURE 4-4 BURDEN OF ILLNESS PYRAMID.

In recent years, the CDC instituted FoodNet to more accurately estimate the level of illness, hospitalization, and death from foodborne illness and to better define the performance of the surveillance system at all stages from infection to reporting of cases to CDC. However, cases of foodborne illness reported through the active surveillance system of FoodNet still represent only a fraction of the total number of illnesses. People who become ill may not seek medical care, physicians may not order bacterial stool cultures for patients with diarrhea, laboratories may not order the correct test, and illness reports may not be delivered.

Chalker and Blaser[102] developed a multiplier to estimate illness based on estimates of sequential artifacts within the national Salmonella surveillance system. Mead et al.[1] refined the estimates of sequential artifacts with results from surveys of laboratories, physicians, and the general population in the FoodNet system to estimate total illness from Salmonella and other foodborne pathogens in the U.S. Mead et al.[1] also calculated multipliers for underreported illnesses, Salmonella-specific hospitalization, and a Salmonella-specific case fatality rate (Table 4-5, Table 4-6, and Table 4-7). The underreporting multiplier developed by Chalker and Blaser[102] and the *Salmonella*-specific rates for hospitalization and death determined by Mead et al.[1] were used to estimate yearly illness, hospitalization, and death from SE in eggs in the U.S.

**Foodborne Diseases Active Surveillance Network (FoodNet)**

FoodNet is a network for responding to new and emerging foodborne diseases of national importance, monitoring the burden of foodborne diseases, and identifying the sources of specific foodborne diseases. Currently, FoodNet surveillance is conducted in eight locations: California, Connecticut, Georgia, Minnesota, Oregon, New York and Maryland, Tennessee, and Colorado. The total population of the current catchment is 25.4 million persons, or about 10% of the U.S. population. In addition to ongoing active surveillance, FoodNet activities include surveys of clinical laboratory practices, physician practices, and a survey of the general population. The pyramid of Figure 4-4 shows how these surveys contribute to our understanding of the burden of foodborne illness.

TABLE 4-5 SEQUENTIAL SURVEILLANCE ARTIFACTS IN THE STEPS FROM INFECTION TO ILLNESS REPORTING FOR *SALMONELLA*.

| | Factor Range | | | | |
|---|---|---|---|---|---|
| Surveillance Step | Median Multiplying Factor | Low | High | Number of Studies | Number of Observations (all studies) |
| 1. Infected person becomes ill | 2.07 | 1.25 | 17.00 | 12 | 614 |
| 2. Patient consults a doctor | 2.21 | 1.29 | 12.06 | 6 | 843 |
| 3. Doctor obtains culture | 3.11 | 1.18 | 4.25 | 5 | 183 |
| 4. Laboratory identifies the organism | 1.43 | 1.19 | 3.58 | 11 | 5625 |
| 5. Laboratory reports to the health department | 1.50 | 1.28 | 2.2 | 3 | 336 |
| 6. Health department reports to CDC | 1.21 | 1.0 | 1.4 | 1 | Unknown |
| *Salmonella* surveillance total multiplier | 37.0 | | 9,608 | | |

Source: Based on review of Chalker and Blaser.[102]

## ESTIMATING ILLNESS FROM *SALMONELLA* ENTERITIDIS IN EGGS

The calculations for estimating the yearly number of SE cases in the U.S. are described in this section and in Table 4-6. FoodNet data from the year 2000 reported 4,330 cases of illness from *Salmonella* spp. Of these 3,964 were serotyped. Of those serotyped, 585 isolates were identified as SE. The ratio of SE isolates to all serotyped isolates (585/3964) was multiplied by the number of *Salmonella* cases (4,330). The product, 639 SE cases, is an estimate of all cases (serotyped and unserotyped) caused by SE that occurred in the eight FoodNet catchment areas. Dividing the total number of cases (639) by the total population of the catchment area (30,500,000) provides the incidence of SE in the catchment area (2.1 cases/100,000 persons). The number of cases in the U.S. was estimated by multiplying the incidence rate in the catchment area by the U.S. population (281,400,000). The result, 5,896 reported cases, is an estimate of the number of *reported* SE cases from all causes in the U.S. in 2000 (Table 4-6).

Not all cases of illness from SE are reported. We repeated the work done by Chalker and Blaser[102] to calculate a multiplier relating reported illness to total illness from *Salmonella* spp. (Table 4-5). The multiplier of 37.0 was calculated by sequentially multiplying each of the surveillance step multipliers (1 through 6, Table 4-5). The value calculated in Table 4-5 (37) is slightly less than the value of 39 calculated by Chalker and Blaser. The reasons for the difference are shown in the appendix to this chapter. The multiplier from Table 4-5 was used to estimate the total number of illnesses from SE in the U.S. (217,946 infected) from the estimate of reported cases (5,896 reported cases).

TABLE 4-6 ESTIMATED ANNUAL ILLNESS FROM *SALMONELLA* ENTERITIDIS IN EGGS

| | | Range | | |
|---|---|---|---|---|
| **Surveillance Step (see Table 4-5)** | **Estimate** | **Low** | **High** | **Source of Estimate** |
| 1. *Salmonella* illnesses reported to FoodNet | 4,330 | | | CDC[25] |
| 2. Isolates serotyped | 3,964 | | | CDC[25] |
| 3. Serotyped isolates that were Enteritidis | 585 | | | CDC[25] |
| 4. Ratio of serotyped isolates that were Enteritidis | 0.148 | | | 3 ÷ 2 |
| 5. Estimated number of illnesses from *Salmonella* attributable to Enteritidis | 639 | | | 1 × 4 |
| 6. Population of the FoodNet catchment area | 30,500,000 | | | U.S. Census 2000 |
| 7. Incidence of SE in FoodNet catchment area | 2.1/100,000 | | | (5 ÷ 6) × $10^5$ |
| 8. U.S. Population in 2000 | 281,400,000 | | | U.S. Census 2000 |
| 9. Estimated cases of SE in U.S. | 5,896 | | | 7 × 8 |
| 10. Illness underreporting multiplier | 37.0 | 3.7 | 9,608 | Table 4-5 |
| 11. Illness from SE | 254,688 | 17,088 | 5.66 × $10^7$ | 9× 10 |
| 12. Proportion of SE illness from eggs | 0.8 | 0.68 | 0.95 | Mishu et al.,[69] CDC[6;52] |
| 13. Estimated annual SE illness from eggs | 174,356 | 11,620 | 5.38 × $10^7$ | |

Not all cases of illness from SE are the result of eating eggs. Mishu et al.[69] reported that 77% to 82% of vehicle-confirmed SE outbreaks were associated with grade A shell eggs. Between 1993 and 1997, on average, 80% of vehicle-confirmed outbreaks were egg-associated, with a range of 68% to 95%. In 1998, of the 18 outbreaks for which a vehicle could be confirmed, 15 (83%) were associated with eggs.[6] In 1999, of the 19 outbreaks for which a vehicle could be confirmed, 15 (79%) were associated with eggs.[52] The proportion of SE cases that are due to consuming eggs was estimated to be 80%. The range of this proportion extends from 0.68 to 0.95. The result is an estimate of about 174,356 (range 12,000 to 54 million) yearly cases of illness from SE in eggs.

## ESTIMATING HOSPITALIZATIONS FROM *SALMONELLA* ENTERITIDIS IN EGGS

A fraction of the persons who become ill from SE in eggs are hospitalized. Mead et al.[1] calculated a *Salmonella*-specific hospitalization rate from FoodNet data of 0.221. More recent information from FoodNet suggests that hospitalization rates varied for the four major serotypes (*S.* Typhimurium, SE, *S.* Heidelberg, and *S.* Newport) isolated from human illness cases from 0.1 for *S.* Newport to 0.22 for *S.* Heidelberg.[103] The rate of hospitalization for SE was 0.15 (322 hospitalization / 2,144 cases). The annual number of hospitalizations from SE in eggs was estimated using the methodology developed by Mead et al.[1] and the SE-specific hospitalization rate provided by Finke et al.[103] (Table 4-7). The range of hospitalization rates from the most frequently isolated *Salmonella* serotypes of 0.1 to 0.22 respectively was used as lower and upper bounds for this estimate.[103]

Not all hospitalizations are reported because the condition leading to hospitalization may be a sequella that developed well after resolution of the actual infection. Mead et al.[1] used a multiplier of two to derive an estimate of the total number of hospitalizations from reported hospitalizations, correcting for underreporting. The lower bound for the estimate is 1 because it seems plausible that all hospitalizations are reported. The upper bound was arbitrarily set at 3. The estimate for hospitalizations from all SE was calculated by multiplying the reported hospitalizations by the underreporting multiplier. The product is an estimate of all hospitalizations (reported and unreported) caused by SE. Not all hospitalization caused by SE are the result of eating eggs. The estimate for hospitalization (reported and unreported) was multiplied by the proportion of SE illnesses that resulted from consuming eggs (0.8). The product is our estimate of the total yearly hospitalizations in the U.S. resulting from SE in eggs. The estimate from Table 4-7 shows between 601 and 2,519 with a most likely estimate of 1,440 hospitalizations annually due to SE in eggs.

TABLE 4-7 ESTIMATED ANNUAL HOSPITALIZATIONS FROM *SALMONELLA* ENTERITIDIS IN EGGS.

| | | Range | | |
|---|---|---|---|---|
| | **Estimate** | **Low** | **High** | **Source of Estimate** |
| 1. Estimated cases of SE in the United States | 5,896 | | | Table 4-5 |
| 2. SE-specific hospitalization rate | 0.15 | 0.1 | 0.22 | Finke et al.[103] |
| 3. Hospitalizations (reported) | 884 | 590 | 1,297 | 1 × 2 |
| 4. Hospitalization underreporting factor | 2 | 1 | 3 | Mead et al.[1] |
| 5. Hospitalizations (reported and unreported | 1,768 | 884 | 2,652 | 3 × 4 |
| 6. Proportion due to eggs | 0.8 | 0.68 | 0.95 | Mishu et al.[69] |
| Total hospitalizations from SE in eggs | 1,440 | 601 | 2,519 | 4 × 5 |

## ESTIMATING DEATHS FROM *SALMONELLA* ENTERITIDIS IN EGGS

A fraction of persons who become ill from SE in eggs die. Mead et al.[1] estimated a *Salmonella*-specific death rate from reported cases of 0.0078. The annual number of deaths from SE in eggs was estimated using Mead et al.'s[1] methodology (Table 4-8). The reported cases of illness from *Salmonella* spp. were multiplied by the *Salmonella*-specific death rate.

Deaths, like hospitalizations, are underreported because pathogen-specific surveillance systems rarely collect information on illness outcome, and outcome-specific surveillance systems (e.g., death certificates) grossly underreport many pathogen-specific conditions.[1] The multiplier used by Mead et al.[1] for underreported deaths is two. The lower bound for the estimate is one because it seems plausible that all deaths are reported. The value of 3.1 was used as an upper bound. Consequently, deaths from egg-related SE infections are estimated to be between 75 and 139, with a most likely value of 75 annually.

TABLE 4-8 ESTIMATED ANNUAL DEATHS FROM *SALMONELLA* ENTERITIDIS IN EGGS

| | | Range | | |
|---|---|---|---|---|
| | **Estimate** | **Low** | **High** | **Source of Estimate** |
| 1. Estimated cases of SE in the U.S. | 5,896 | | | Table 4-5 |
| 2. SE-specific death rate | 0.0078 | | | Mead et al.[1] |
| 3. Reported deaths | 47 | | | 1 × 2 |
| 4. Death underreporting factor | 2 | 1 | 3.1 | Mead et al.[1] |
| 5. Estimated deaths | 94 | 47 | 146 | 3 × 4 |
| 6. Proportion due to eggs | 0.8 | 0.68 | 0.95 | Mishu et al.[69] CDC[25;104] |
| 7. Total deaths from eggs | 75 | 32 | 139 | |

## ESTIMATING SEQUELLAE FROM *SALMONELLA* ENTERITIDIS IN EGGS

The sequellae reported in a review of 55 journal publications on Salmonella infection included reactive arthritis, urethritis, conjunctivitis, entesopathy, myalgia, weight loss of over 5 kg., dactylitis, erythema nodosum, oral ulcers, myocarditis, acute anterior uveitis, iritis, cholecystitis, keratitis, pharyngitis, and pneumonia.105 In an outbreak among 473 police officers, 340 responded to a questionnaire and 196 (57%) individuals reported extra-enteric symptoms.106 In another study of 210 cases, 191 responded and 143 (75%) of those reported extra-enteric symptoms.107 The results of these two studies are summarized in Table 4-9.

The most severe sequellae of *Salmonella* infection is probably reactive arthritis. Symptoms commonly develop 7 to 30 days after intestinal illness. The knee is often affected along with other peripheral joints. Reiter's syndrome, considered a special case of reactive arthritis, typically includes three symptoms: asymmetric arthritis in knees and ankles, non-specific urethritis, and conjunctivitis.[108] Roughly 2 to 3 % of people who become ill from *Salmonella* spp. develop reactive arthritis.

TABLE 4-9 RANKING OF SEQUELLAE FROM *SALMONELLA* INFECTION.

| ***Salmonella* Typhimurium PT 22**[106] | | ***Salmonella* Bovismorbificans**[107] | |
|---|---|---|---|
| Headaches | 182 (53.5%) | Articular symptoms | 66 (35%) |
| Joint pain | 106 (31.2%) | Headaches | 52 (27%) |
| Redness or soreness in the eyes | 37 (10.9%) | Eye symptoms | 8 (4%) |
| Soreness in the mouth | 15 (4.4%) | Cutaneous symptoms (one erythema nodosum) | 7 (4%) |
| Skin rash | 10 (2.9%) | | |
| Total extra-enteric symptoms | 196 | Total extra-enteric symptoms | 143 |

## SUMMARY

This chapter considered the data available to model a dose-response relationship for *Salmonella* spp. and the beta-Poisson model produced by the Joint Expert Meetings on Microbiological Risk Assessment (JEMRA).[24] The strengths and weaknesses of the JEMRA model were discussed as well as reasons for selecting the JEMRA model for use in this risk assessment. This dose-response relationship is used in this risk assessment to estimate illness from exposure.

This chapter estimates yearly cases of illness, hospitalization, and death from egg-associated SE in the U.S. as shown in Table 4-10. The median hospital stay for patients in one study was 4 days.[103] Two to three percent of ill persons, about 4,000 to 6,000 persons, could later develop reactive arthritis and 0.5 to 1.0% of ill persons, about 1,000 to 2,000 persons, could develop another sequella of infection. These independently derived estimates provide a benchmark for comparing the results of a probabilistic model and will allow testing of the plausibility of the modeling results.

TABLE 4-10 ESTIMATED YEARLY CASES OF ILLNESS, HOSPITALIZATION, SEQUELLA, AND DEATH FROM *SALMONELLA* ENTERITIDIS IN EGGS.

| | | **Range** | |
|---|---|---|---|
| **Outcome** | **Estimate (per annum)** | **Low** | **High** |
| Illness | 174,356 | 11,620 | $5.38 \times 10^7$ |
| Hospitalization | 1,440 | 601 | 2,519 |
| Chronic sequella | 6,622 | - | - |
| Death | 75 | 32 | 139 |

## APPENDIX

Synopsis and review of the rationale for the multipliers developed by Chalker and Blaser. [102]

| **Surveillance Step 1—Persons who are infected become ill (i.e., show clinical signs)** | | | | |
|---|---|---|---|---|
| Proportion | Multiplier | Number Sampled | Reference | Comments |
| 0.5 | 2.0 | 225 | Onogawa et al. 1972 | In a "large" study of children and food handlers in Tokyo, 50% of culture-proven handlers had symptoms. A total of 1,258,801 fecal samples, obtained from 816,965 pupils and 441,836 food handlers, were examined for the presence of *Salmonellae*. Of those samples collected from pupils, 1022 (0.13%) were positive for *Salmonellae*; of those samples collected from food handlers, 314 (0.07%) were positive for *Salmonellae*. In the conclusions appendix to this article, it is stated that about 50% of *Salmonella* carriers had such complaints as mild diarrhea, stomachache, and nausea. Unfortunately, it is not clear if this ~50% value was derived from information on all asymptomatic carriers, or, as presented in Figure 3 of the manuscript, this value was derived from the retrospective survey of 2,215 healthy carriers. The body of the text of the article is in Japanese; therefore, we were unable to determine if this point is clarified in the article per se. |
| 0.55 | 1.8 | 9 | Blaser et al. 1981 | In a restaurant outbreak of salmonellosis, 5 (55%) of 9 culture-positive employees had symptoms. |
| 0.69 | 1.4 | 59 | Palmer et al. 1981 | A retrospective survey of those involved in a college residence hall outbreak showed that 41 (69%) of 59 culture-positive students had symptoms. |
| 0.07 | 2.1 | 15 | CDC unpublished | One (7%) of 15 culture-positive nursing home employees had symptoms following a salmonellosis outbreak (unpublished CDC communication, no date given). |
| 0.08 | 13.0 | 13 | CDC unpublished | In a hospital outbreak, 1 (8%) of 13 culture-positive personnel surveyed had symptoms (unpublished CDC communication). |
| 0.06 | 17.0 | 17 | CDC unpublished | In a New York City hospital outbreak, 1 (6%) of 16 culture-positive dietary personnel had symptoms (unpublished CDC communication, no date given *(Chalker and Blaser point out data involving food-handling employees may be skewed by reluctance to admit having had symptoms).* |
| 0.27 | 3.7 | 11 | Rice et al. 1976 | In a nosocomial outbreak in Puerto Rico, 3 (27%) of 11 culture-positive patients had symptoms. |
| 0.8 | 1.3 | 55 | Koplan et al. 1978 | Forty-four (80%) of 55 persons were symptomatic following a summer camp outbreak in Trinidad. |
| 0.23 | 4.3 | 69 | Wilkie et al. 1977 | In an English nursing home outbreak, 16 (23%) of 69 culture-positive individuals had symptoms. |
| 0.43 | 2.3 | 7 | Ryder et al. 1977 | In a nosocomial outbreak linked to contaminated milk, 3 (43%) of 7 culture-positive infants had symptom. |
| 0.34 | 1.9 | 64 | Payne and Scudamore 1977 | Thirty-four (54%) of 64 culture-positive individuals had symptoms following an outbreak in England. |
| 0.66 | 1.6 | 70 | Gill et al. 1983 | In an outbreak linked to chocolate bars, 43 (66%) of 70 culture-positive household contacts surveyed reported symptoms. |

| 2 – Persons who are ill consult a doctor | | | | |
|---|---|---|---|---|
| Proportion | Multiplier | Number Sampled | Reference | Comments |
| 0.08 | 12.1 | 386 | CDC 1979 | During a *Salmonella* outbreak on a Caribbean cruise ship, 32 (8%) of 386 passengers who became ill sought the ship's doctor. |
| 0.77 | 1.3 | 22 | CDC 1981 | In an outbreak linked to ice cream, 17 (77%) of 22 ill patients sought a doctor ***(Chalker and Blaser point out here the dose of Salmonella ingested may have been high).*** |
| 0.58 | 1.7 | 22 | Bollegraaf 1979 | In a common-source outbreak affecting Canadian executives, 26 (58%) of 45 ill individuals consulted a doctor. |
| 0.37 | 2.7 | 232 | CDC unpublished | As determined by a retrospective questionnaire, 86 (37%) of 232 college students who became ill following a *Salmonella* outbreak sought medical aid. |
| 0.36 | 2.8 | 91 | CDC unpublished | Following a *Salmonella* outbreak on a Navajo Indian reservation, 33 (36%) of 91 ill individuals received prescriptions for paregoric (unpublished CDC report). Chalker and Blaser assumed all symptomatic persons seen as outpatients received this prescription ***Data are not provided with which to judge the strength of the authors' assumption.*** |
| 0.72 | 1.4 | 67 | Rice et al. 1976 | Following an outbreak of salmonellosis at a summer camp, 48 (72%) of 67 acutely ill patients visited a doctor. |

| 3- Doctor obtains culture | | | | |
|---|---|---|---|---|
| Proportion | Multiplier | Number Sampled | Reference | Comments |
| 0.66 | 1.5 | 32 | CDC 1979 | Of 32 people who reported being acutely ill to a cruise ship's doctor, specimens were obtained from 21 (66%). |
| 0.86 | 1.2 | 80 | McCall et al. 1966 | At a Tennessee hospital for the mentally retarded, specimens obtained from 68 (86%) of 80 patients with acute gastroenteritis were cultured. |
| 0.32 | 3.1 | 28 | Rosenberg et al. 1977 | About 40% of *Shigella*-associated diarrhea presents with gross blood in the stool, an observation that might be expected to cause an increase in the proportion of samples sent for culture |
| 0.24 | 4.3 | 17 | CDC 1981 | In an ice cream-related outbreak of salmonellosis in Georgia, 4 (24%) of 17 ill persons who visited a physician had specimens taken for culture. |
| 0.42 | 2.4 | 26 | Bollegraaf 1979 | Eleven (42%) of 26 ill Canadian executives who visited a doctor had specimens taken. |

| **4 -Laboratory identifies the organism** | | | | |
|---|---|---|---|---|
| Proportion | Multiplier | Number Sampled | Reference | Comments |
| 0.84 | 1.19 | 4,374 | Gavan 1974 | In a 1972 quality evaluation, the College of American Pathologists found that 84% of 4,374 laboratories that were one of 20 common bacterial pathogens were able to identify it correctly. |
| 0.83 | 1.20 | 800 | CDC 1975 | In 1975, the CDC evaluated approximately 800 laboratories in the U.S. and found that 83% were able to correctly isolate and identify *Salmonella*. |
| 0.34 | 1.29 | 79 | Bengtsson et al. 1955 | During an outbreak of *Salmonella* Typhimurium in Sweden, 27 (34%) of 79 people with negative stool cultures had a subsequent seroconversion to *Salmonella.* |
| 0.77 | 2.93 | 66 | Palmer et al. 1981 | *Salmonella* was isolated from stools of 77% of college students from an affected residence hall who presented with acute gastroenteritis during a common-source outbreak. |
| 0.42 | 2.35 | 54 | CDC unpublished | Twenty-three (42%) of 54 culture specimens from ill patients were positive for *Salmonella* Enteritidis following an outbreak of salmonellosis in a nursing home. |
| 0.71 | 1.43 | 63 | Koplan et al. 1978 | Forty-four (71%) of 63 acutely ill patients at a summer camp in Trinidad developed positive cultures. |
| 0.57 | 1.76 | 44 | Lowenstein 1975 | Stools from 25 (57%) of 44 ill persons were positive. |
| 0.4 | 2.50 | 85 | Armstrong et al. 1970 | Following a point-source outbreak, 34 (40%) of 85 stool specimens from acutely ill persons yielded positive cultures. |
| 0.83 | 1.20 | 6 | CDC 1981 | During a series of multiple *Salmonella* outbreaks in the northeast U.S. and linked to precooked roast beef, five (83%) of 6 stool specimens from symptomatic subjects were positive. |
| 0.28 | 3.58 | 43 | Spitalny et al. 1984 | During *Salmonella* outbreaks in Vermont, 12 (28%) of 43 cultured specimens from acutely ill subjects were positive. |
| 0.82 | 1.22 | 11 | Bollegraff 1979 | In an outbreak among Canadian men, nine (82%) of 11 cultures obtained were positive. |

| 5 -Laboratory reports to the health department | | | | |
|---|---|---|---|---|
| Proportion | Multiplier | Number Sampled | Reference | Comments |
| 0.67 | 1.50 | 42 | Vogt et al. 1986 | The value of 56% given by Chalker and Blaser only takes into account data from 1983 in which 24 of 42 cases were reported to the health department. Data from 1982 indicate 18 of 21 (86%) of salmonellosis cases were reported. If data from 1982 and 1983 are combined, we find that 42 of 63 (67%) of cases were reported; thus, the multiplier is adjusted to 1.5, and the median of the three studies is 1.5. |
| 0.42 | 2.20 | 11 | Marier 1977 | The number of samples here (11) is actually the number of hospitals surveyed and not the number of positive bacterial isolates identified by a laboratory. |
| 0.78 | 1.28 | 262 | Godes et al. 1982 | Of 262 clinical laboratories in Minnesota, 78% of *Salmonella* infections were reported to the state health department. |
| | 2.20 | ? | Thacker et al. (in press) | Upon institution of an active surveillance system in Rochester, New York, Thacker et al. (in press) report a 2.2-fold increase in the number of cases reported compared to earlier surveillance systems. |

| 6. Health department reports to CDC | | | | |
|---|---|---|---|---|
| Proportion | multiplier | Number sampled | Reference | Comments |
| 0.83 | 1.2 | 100* | Thacker et al. in press | Because only one study was reported, we assumed a range extending from 1.0 to 1.4. |

*All references cited in Chalker and Blaser.[102]

# 5 Risk Characterization

## INTRODUCTION

The World Health Organization defines risk characterization as the "integration of hazard identification, hazard characterization, and exposure assessment into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainties." (http://www.who.int/fsf/Micro/Definition_risk_analysis_terms_related_to_food_safety.pdf).

The Hazard Identification chapter of this report described qualitatively associations of human salmonellosis associated with *Salmonella* Enteritidis (SE) in shell eggs and with *Salmonella* spp. in egg products. In the Hazard Characterization chapter of the report, development of a dose-response function, in which various levels of *Salmonella* contamination were associated with frequencies of illness, was presented. In the Exposure Assessment chapter of the report, derivation of estimates of human exposure to *Salmonella* contamination in shell eggs and egg products was described. This section, Risk Characterization, draws on the information in these previous sections to estimate human illness.

At its most basic level, risk characterization is simply incorporating the exposure distribution derived in the exposure assessment with the dose-response function derived in the hazard characterization. Each point in the exposure distribution is multiplied by both its likelihood of occurrence and the likelihood of illness given that level of exposure. The resulting likelihoods are then summed to give the overall frequency of illness. Thus, the final output of each model is a single estimate of the frequency of illness from either SE in shell eggs or *Salmonella* spp. in egg products. In addition, risk characterization represents an evaluation of the risk of certain practices, procedures, or populations. Risk managers can use this feature of risk characterization to evaluate whether regulatory action may be helpful in a certain area and/or whether educational efforts should be targeted at certain subpopulations, for instance. The risk characterization also uses sensitivity analysis to identify the relative importance of specific model inputs.

## Using the Risk Characterization to Answer Risk Management Questions

The introduction to this report identified five "risk management questions" to be answered by the SE in shell eggs and and Salmonella spp. in egg products risk assessments. These questions are related to the estimates of risk of illness and risk reduction at intermediate points in the exposure assessment.

***Risk Management Questions Related to SE in Shell Eggs***

- 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?

Shell egg pasteurization scenarios

Currently, few shell eggs (less than 0.05%) processed in the U.S. are pasteurized. The goal of pasteurization is to achieve a very high likelihood of no SE in shell eggs, with a high level of confidence. Risk managers requested that the risk assessment consider the per annum risk of illness (number of illnesses per year) if 0.05%, 1%, 5%, 10%, 25%, 50%, 75%, or 100% of the industry pasteurizes shell eggs. As a result, this risk assessment has been developed with the flexibility to examine different shell egg pasteurization scenarios, and it can incorporate new information about industry practices as it becomes available. At this point, limited information on industry practices constrained the extent of the modeling of pasteurization practices.

Shell egg handling scenarios

The time at which shell eggs are pasteurized is critical. The amount of SE within a contaminated egg may increase over time, largely based on the temperature at which the egg is stored. As a result, FSIS risk managers requested that this risk assessment consider the age of shell eggs and the corresponding storage times and temperatures prior to reaching the processor (where they may be pasteurized). As a result, this risk assessment considers several egg handling and storage scenarios for eggs (e.g., the cooling of eggs commences at 24 and 36 hours for eggs that are 1 to 60 days old and stored at temperatures from 45 to 60$^{o}$F (7.2 to 15.6°C), followed by a refrigeration at 45ºF (7.2°C) until the eggs are pasteurized). By considering these "egg handling" scenarios (i.e., when shell eggs should be refrigerated and the extent of refrigeration), the risk assessment provides insight to the effectiveness of various egg handling performance standards to limit the growth of SE in shell eggs, and mitigate the subsequent risk of illness.

Egg production risk factors for SE

Risk managers requested that this risk assessment evaluate the effects of season and the molting of flocks on the production of SE-contaminated eggs and the consequent risk of illness. Unfortunately, data were not available to estimate fully the effect of season on the production of SE-contaminated eggs and the subsequent risk of illness. This risk assessment does, however, include the effects of molting of flocks on the prevalence of SE-contaminated eggs.

***Risk Management Questions Related to* Salmonella *spp. in Egg Products***

- What is the number of illnesses per serving and annual number of illnesses from *Salmonella* spp. in *pasteurized egg products* (liquid whole eggs, yolks, and egg whites)?
- What is the number of *Salmonella* in a liter of egg product (whole, yolk, albumen) *before* and *after* a specified pasteurization scenario?

Egg product pasteurization scenarios

Current command-and-control regulations for the pasteurization of egg products 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 prevalence and/or level of *Salmonella* spp. prior to pasteurization. Moreover, these prescriptive regulations do not allow industry the flexibility to implement hazard controls that are most effective for specific processes and products. Risk managers requested that this risk assessment consider egg product pasteurization scenarios in which the level of *Salmonella* spp. in egg products is reduced by 7 to 12 $\log_{10}$.

## RISK CHARACTERIZATION FOR *SALMONELLA* ENTERITIDIS IN SHELL EGGS

### Modeling Illnesses per Egg

***Frequency of Illness per Serving***

The Exposure Assessment introduced the concept of calculating illness per serving using a dose-response function with the number of SE per serving as its argument.

$$I_S = DR(S_2) \qquad (5.1)$$

Where:

$I_S$ = The frequency of illness resulting from consuming a serving of an egg meal. This frequency can range over the [0,1] interval.

$S_2$ = The number of SE in a contaminated serving.

**Multiple illnesses per egg**

The frequency of illness per serving will always be between 0 and 1. If multiple servings were generated from a contaminated egg, however, it is possible to have many illnesses that result from the consumption of that single egg. For example, consider one contaminated egg that is used to make a pitcher of eggnog. Assume the pitcher serves 10 persons and that the egg was contaminated with $10^9$ SE. Each serving thus contained $10^8$ bacteria. Conceivably, that single egg could account for 10 illnesses. This illustration represents one way many persons can become ill from a single egg.

The dose-response function was given as a beta-Poisson model in chapter 4. Thus, the frequency of illness (IS) becomes:

$$IS = 1 - (1 + (S2 / \beta))^{-\alpha} \qquad (5.2)$$

where

$\alpha$ = 0.1324 and

$\beta$ = 51.45 in the baseline model.

The specific dose-response function used for the baseline estimates is shown below in Figure 5-1.

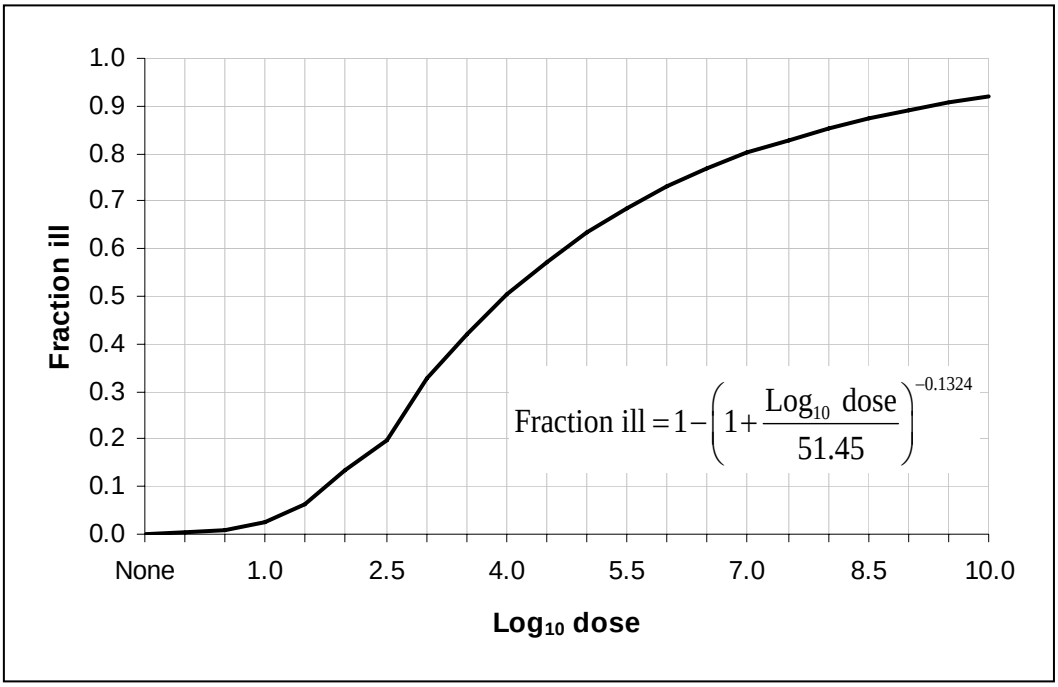



FIGURE 5-1 DOSE-RESPONSE FUNCTION USED FOR BASELINE ESTIMATES.

Given a particular dose resulting from a contaminated egg, Equation 5.1 calculates the frequency that the dose would cause illness.

***Illnesses per Egg***

As noted in the Exposure Assessment, a single egg may serve more than one person. Thus, Equation 5.1 would apply to each person that consumed a portion of the egg. Furthermore, the dose to which each person would be exposed would be effectively reduced. Consequently, the Exposure Assessment determined the contamination per serving by dividing the contamination in the egg by the number of servings. The Risk Characterization accounts for these eggs potentially serving multiple persons by multiplying the illnesses per serving by the number of servings. The number of illnesses per egg is thus the frequency of illness per serving multiplied by the number of servings per egg.

$$I_E = I_S \text{ x } V \tag{5.3}$$

where

$I_E$ = the frequency of illnesses resulting from one or more persons consuming servings generated from a single egg. This value can exceed 1.
$I_S$ as defined in equation 5.1.
$V$ = The number of servings generated from a single egg.

***Calculating Illnesses per Egg in the Model***

The model represents exposure assessment and risk characterization. The model is written in *Visual Basic for Applications* (Microsoft Corp., Redmond, WA) and inputs and outputs are stored in *Excel* (Microsoft Corp.) worksheets. A more complete description of the model structure can be found in the Exposure Assessment and Hazard Characterization chapters.

Each iteration of the model follows an egg from the farm to consumption. At consumption, the model estimates the number of bacteria per serving ($S_2$), and the number of servings per egg ($V$) is determined. These values are used in 5.1 and 5.3 above to determine the total illnesses for the egg for that iteration. These values are averaged to give the expected illnesses per egg for a given simulation.

## Generating Baseline Estimates

The term "baseline," as used in the shell egg model, refers to the scenario in which no eggs are pasteurized.

***Monte Carlo Modeling***

The baseline model contains distributions that represent variability in storage times and temperatures, initial levels of bacteria, the effect of growth parameters, serving size, the effect of cooking, and other factors. The baseline model is run using Monte Carlo methods. [80]

***Seed Values***

All draws from distributions are governed by a two-dimension array that holds a specific set of random numbers generated by Visual Basic. This array is generated each time the model is run but can be replicated each time by ensuring that the seed value in the Inputs worksheet is the same.

## Answering Risk Management Questions

***Significant changes to model output after peer and public review***

There has been a significant change in the reporting of the output of the shell egg model. After peer review and public comment it was decided to anchor the output of the model to the CDC estimates for the number of human illnesses for the year 2000.

*Background*

The original draft model gave an estimate of approximately 350,000 human illnesses of *Salmonella* Enteritidis annually in the United States. Uncertainty was generally not evaluated in this assessment, however, because the global uncertainty in the model overwhelmed the uncertainty present in the epidemiologic evidence. This was because many of the inputs were based on very limited data. Uncertainty was evaluated for the epidemiologic evidence and the estimate from the draft model when using the most likely values for parameters and distributions was within the bounds of that uncertainty. Therefore, it was believed that the estimate from the draft model was validated by the epidemiologic evidence.

Reporting an estimate of 350,000 illnesses, however, caused confusion because although this estimate was within the bounds of uncertainty given by the epidemiologic evidence, it did not match the epidemiologic estimate. Thus it was decided to anchor the model estimate to the epidemiolgic estimate.

*Anchoring the model estimate*

Based on data from CDC, an estimate for the number of human illnesses caused by *Salmonella* Enteritidis from shell eggs in the United States in 2000 may be computed as follows:

1. There were 6,224 SE isolates in the year 2000. These are reported on CDC's website: http://www.cdc.gov/ncidod/dbmd/phlisdata/salmonella.htm#2000.
2. Many illnesses are not reported. For every illness that is reported, CDC estimates that 38 illnesses occur but are not reported.[1] Thus, a surveillance multiplier of 38 is applied – 6,224 x 38 (surveillance multiplier) = 236,512.
3. Approximately 16% of infections are typically obtained outside the United States. Thus, the number of SE infections attributable to U.S. sources is 236,512 x (1 – 0.16) = 198,670.
4. The proportion of SE infections due to shell eggs is estimated from the proportion of SE outbreaks due to shell eggs. The low range estimate for this value is 53% and the high range estimate is 79%. Using the mid-range estimate of 66% there would be 198,670 x 0.66 = 131,122 illnesses due to SE from shell eggs.
5. The epidemiologic estimate of illnesses from CDC is divided by the model estimate of illnesses – 131,122 / 350,000 ~ 0.37. Thus, 0.37 is used as a multiplier for the output of the model to estimate the number of human illnesses.

*Consequences of anchoring the model estimate*

Anchoring the model ensures that the model estimate matches the epidemiologic estimate. Consequently, modeled mitigations would not be expected to estimate an effect greater than what is supported by the epidemiologic evidence.

Numeric estimates in the report have been replaced by the anchored values. Graphs have been changed to reflect the anchored values except for the graphs depicting the nominal range sensitivity analysis. For these graphs the important feature is the relative change in output. Furthermore, the difference in the estimates is not readily noticeable.

Because the model output has been anchored to the epidemiologic estimate, the section on validation is not needed and has been removed.

### *What is the number of* Salmonella *Enteritidis in shell eggs before and after a specified pasteurization scenario?*

In-shell pasteurization of eggs is meant to reduce the number of SE by a specified amount. The amount of pasteurization is given in $\log_{10}$ reduction. A 1-$\log_{10}$ reduction means that the amount of contamination is reduced by 90%; a 2-$\log_{10}$ reduction corresponds to a 99% reduction in contamination, and a 3-$\log_{10}$ reduction to 99.9%. In the model, $\log_{10}$ reductions are handled

probabilistically. For example, if an egg has 1 SE and is exposed to a 3-$\log_{10}$ reduction, there is a 99.9% probability that the organism will be killed and a 0.01% probability that it will survive.

Intuitively, 3-$\log_{10}$ pasteurization or a 3-$\log_{10}$ reduction would be expected to reduce the number of SE by 99.9%. It should be noted that most eggs are not capable of supporting bacterial growth, either in the layer house or during on-farm storage; thus most of the eggs would have the same number of bacteria with which they were contaminated, generally no more than 1,000. If just a few bacteria grow to high levels, however, the mean number of bacteria will reflect those high levels.

**Precision of Answers**

Answers to risk management questions are typically given with two or three significant digits. The model provides more precise answers, but reporting them does not portray risk more accurately. It is best to think of the answers as approximations. That said, in some cases, more than two or three significant digits will be given to show the effect of model parameters.

The number of bacteria at each model stage is actually a distribution. It may be easier to think of these distributions in terms of their ability to cause human illness. Thus we can think of the potential for human illness at various model stages if humans were to consume raw eggs at those stages. This is, of course, unrealistic, but it does show how the potential risk of eggs changes in the farm to table continuum and it shows the effect that pasteurization has on the ability of contaminated eggs to cause illness. Figure 5-2 (following page) shows the number of estimated human illnesses after each step in the model if eggs were immediately consumed. If all eggs were consumed raw in the layer house, there would be about over 200,000 human illnesses. The potential illnesses increase to about 550,000 by the time we reach the end of home storage. Finally, cooking reduces the potential illnesses to about 130,000, our baseline value.

If eggs are subjected to a 3-$\log_{10}$ pasteurization, the potential for human illness drops substantially, from about 450,000 illnesses to about 100,000 illnesses immediately after pasteurization. Furthermore, the potential for additional illness does not increase as rapidly. This is because bacteria have now been eliminated from most contaminated eggs. Cooking further reduces the risk. A 5-$\log_{10}$ pasteurization further reduces the potential for eggs to cause human illness to about 50,000 illnesses immediately after pasteurization.

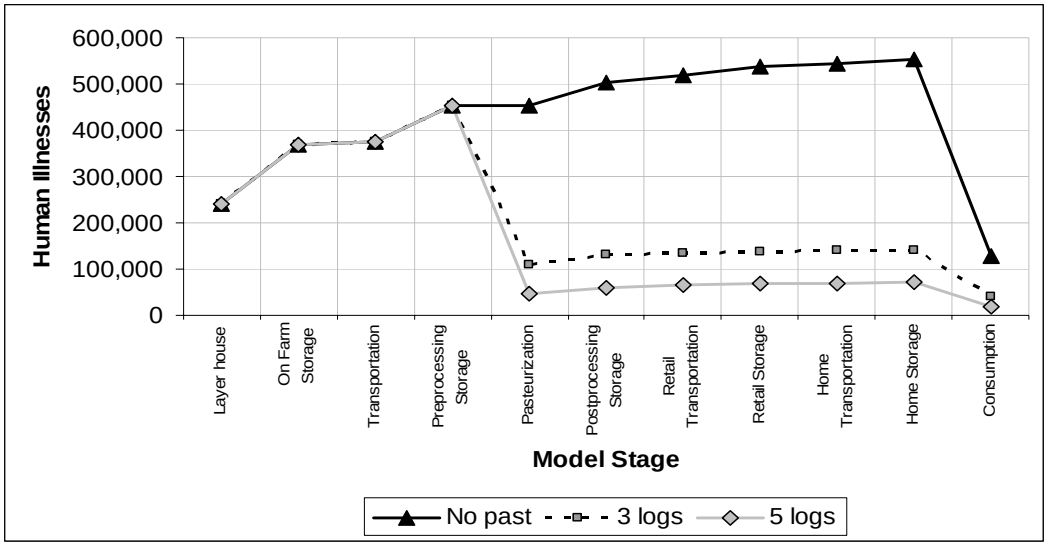



FIGURE 5-2 NUMBER OF ESTIMATED HUMAN ILLNESSES AFTER EACH STEP IN MODEL IF EGGS WERE IMMEDIATELY CONSUMED.

Figure 5-2 shows that if eggs were consumed immediately after pasteurization the numbers of illnesses would be substantially reduced. Pasteurization does not affect the way eggs are handled in subsequent steps. If eggs are handled in such a way to allow bacterial growth, then any bacteria left after pasteurization can theoretically rapidly grow to pre-pasteurization levels. Furthermore, the heat of pasteurization may have an effect on the yolk membrane, which could conceivably allow more rapid growth of bacteria following pasteurization. Figure 5-3 shows the percent of eggs estimated to have yolk membrane breakdown (YMB) at different model steps with and without pasteurization. The model estimates that, based on the temperatures necessary to achieve a 3-$\log_{10}$ reduction, YMB will always occur.

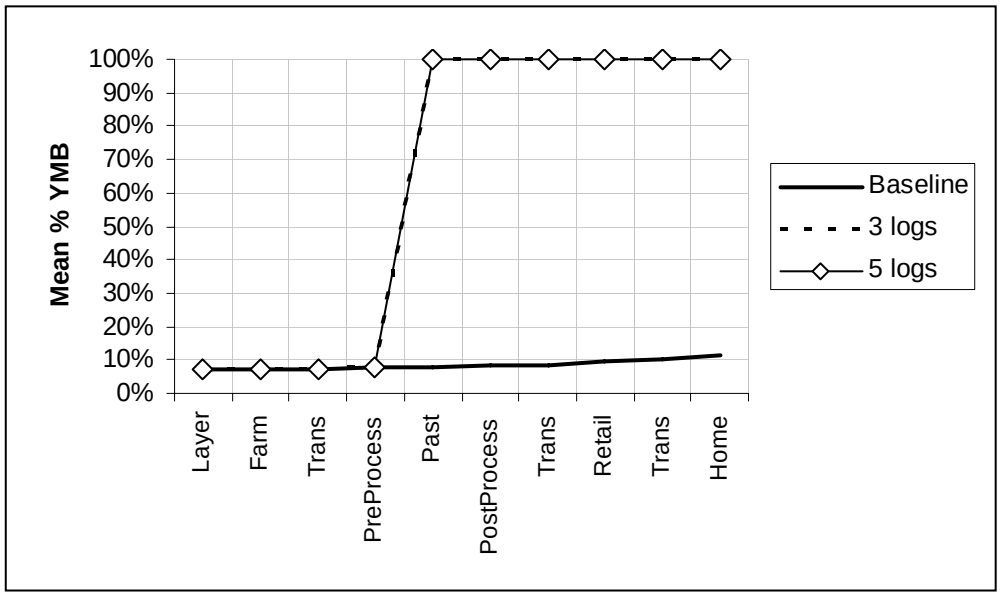



FIGURE 5-3 MEAN % YMB IN EGGS AT DIFFERENT STEPS IN THE MODEL WITH AND WITHOUT PASTEURIZATION.

Despite the opportunities for additional growth of bacteria after pasteurization as shown in Figure 5-3, Figure 5-2 shows that the increase in potential human illnesses is less following pasteurization than would normally occur in the no pasteurization scenario.

***What is the number of illnesses per serving and annual number of illnesses from* Salmonella *Enteritidis in pasteurized and non-pasteurized shell eggs*?**

Estimated illnesses per serving for non-pasteurized shell eggs

The unanchored baseline model estimates approximately 0.023 illnesses per contaminated egg. It further estimates approximately 0.0003, or about 3 eggs in every 10,000, would be contaminated at lay. Thus, the number of illnesses per egg in the unanchored baseline model is approximately 0.023 x 0.0003 ≈ 0.000007, or about 1 illness in every 150,000 eggs. As noted earlier, eggs may contribute to more than one serving. Thus, the risk per serving is equal to the illnesses per egg divided by the number of servings per egg. The mean number of servings per egg from the distribution shown in the exposure assessment is approximately 3.2. Therefore, the risk of illness per serving before anchoring is 0.000007 / 3.2 ≈ 2 x $10^{-6}$, or about 1 illness in every 470,000

servings. After anchoring the risk of illness is per serving is about $8 \times 10^{-7}$ or about 1 illness in every 1.3 million servings.

Estimated illnesses per serving for pasteurized shell eggs

As noted earlier, a particular $\log_{10}$ reduction in bacteria at pasteurization does not necessarily correspond with a similar $\log_{10}$ reduction in bacteria at consumption. Likewise, given the number of steps following processing, pasteurization does not have as large an effect on illnesses as might be thought given the data and model assumptions. A 3-$\log_{10}$ reduction at pasteurization reduces the number of illnesses per egg from approximately $2.6 \times 10^{-6}$ to $8.1 \times 10^{-7}$. A 5-$\log_{10}$ reduction at pasteurization further reduces the number of illnesses to approximately $3.7 \times 10^{-7}$. Thus, the number of illnesses per serving is approximately $7.8 \times 10^{-7}$ for the baseline scenario, $2.6 \times 10^{-7}$ for a 3-$\log_{10}$ reduction, and $1.1 \times 10^{-7}$ for a 5-$\log_{10}$ reduction. Table 5-1 shows the illnesses per egg and illnesses per serving, as well as the reciprocals of these values (eggs per illness and servings per illness). There are approximately 3.2 servings per egg; therefore, the illnesses per egg would be approximately 3.2 times greater than illnesses per serving.

TABLE 5-1 ILLNESSES PER EGG AND SERVING FOR PASTEURIZED AND NON-PASTEURIZED EGGS.

| Scenario | Illnesses per egg | Eggs per illness | Illnesses per serving | Servings per illness |
|---|---|---|---|---|
| Baseline | $2.6 \times 10^{-06}$ | 400,000 | $7.8 \times 10^{-07}$ | 1,300,000 |
| 3-$\text{Log}_{10}$ | $8.1 \times 10^{-07}$ | 1,200,000 | $2.6 \times 10^{-07}$ | 4,000,000 |
| 5$\text{Log}_{10}$ | $3.7 \times 10^{-07}$ | 2,700,000 | $1.1 \times 10^{-07}$ | 8,600,000 |

Estimating the annual number of illnesses

Estimating the total illnesses for a given year in the U.S. is accomplished by multiplying the illnesses per egg by the total number of eggs consumed. Total egg consumption is given in Table 5-2.

TABLE 5-2 ANNUAL EGG CONSUMPTION IN THE U.S.

| Year | Million dozens consumed | Eggs per capita |
|---|---|---|
| 1997 | 5,358.6 | 235.8 |
| 1998 | 5,522.2 | 240.2 |
| 1999 | 5,816.6 | 250.1 |
| 2000 | 5,926.8 | 252.1 |
| 2001 | 6,010.6 | 252.6 |
| 2002 | 6,101.1 | 253.7 |
| 2003[a] | 6,132.1 | 252.3 |
| 2004[b] | 6,159.0 | 250.9 |

[a]Preliminary data.
[b]Forecasted data.
Source: http://www.ers.usda.gov/publications/Agoutlook/AOTables/

For the purposes of this risk assessment, egg consumption data for the year 2002 were used (http://www.ers.usda.gov/publications/Agoutlook/AOTables/). This was the most recent year for which a full year's observation was available.

Only a portion of the eggs shown in Table 5-2 is consumed as shell eggs. The rest are consumed as egg products. Use of egg products has continued to rise over the past decade. The Economic Research Service states:

> *Through August 2002, 1.25 billion dozen eggs, approximately 31 percent of all eggs produced for table use, went to the breaking-egg market. This volume was up 4 percent from the same period in 2001*. (http://www.ers.usda.gov/publications/agoutlook/Nov2002/ao296a.pdf).

and:

> *Since 1996, the amount of eggs going to the breaking market has risen by about 25 percent and now uses about one-third of total table egg production.* (http://www.ers.usda.gov/publications/ldp/may03/ldpm107f.pdf)

This risk assessment thus assumes that 31 percent of the total egg consumption for 2002 was in the form of egg products. Thus, shell egg consumption was estimated at 0.69 * 6.1 billion dozen ≈ 4.2 billion dozen, or about 50.5, billion eggs.

Estimated annual number of illnesses for non-pasteurized shell eggs

The annual number of illnesses from non-pasteurized shell eggs (this assumes that all eggs in the U.S. are non-pasteurized) is given by $2.6 \times 10^{-6}$ illnesses per egg * 50.5 billion eggs ≈ 130,000 illnesses.

Estimated annual number of illnesses for pasteurized shell eggs

The annual number of illnesses for pasteurized shell eggs assumes that all eggs in the U.S. are pasteurized. Given a 3-$\log_{10}$ reduction, the annual estimate of illnesses is about 41,000. A 5-$\log_{10}$ reduction is predicted to result in about 19,000 illnesses annually (Figure 5-4).

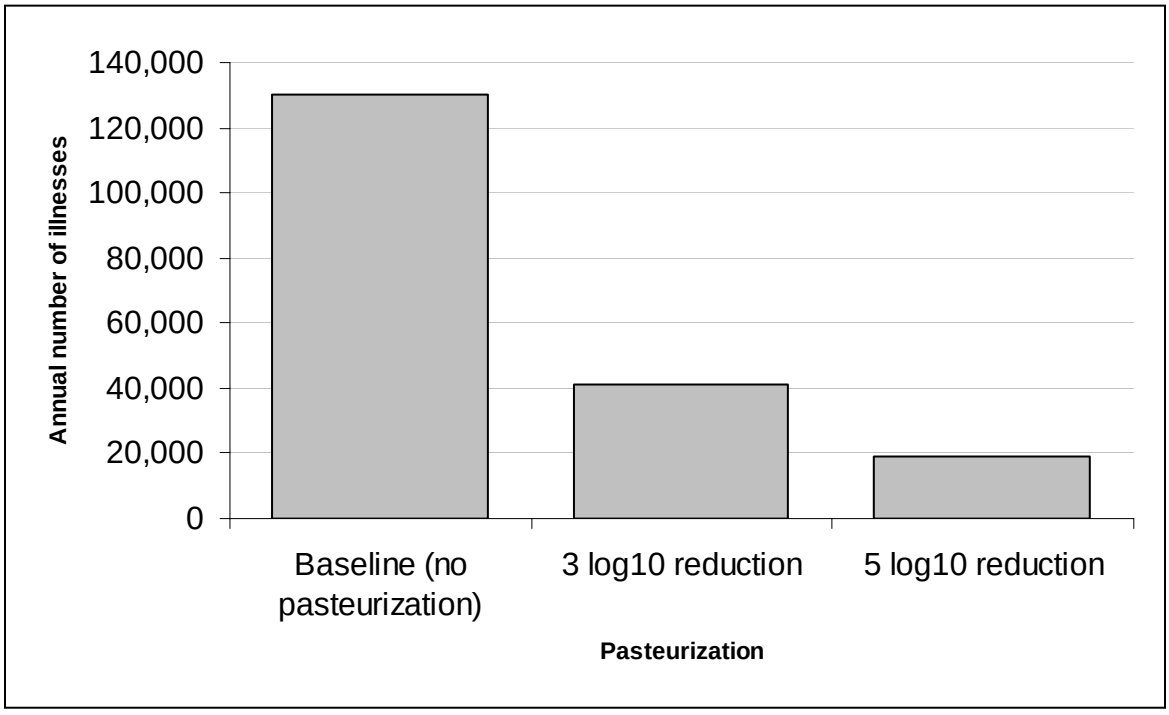



FIGURE 5-4 EFFECT OF PASTEURIZATION ON ANNUAL NUMBER OF ILLNESSES.

Estimated annual number of illnesses assuming varying proportions of pasteurized shell eggs

It is unlikely that all shell eggs in the U.S. would be pasteurized. The annual number of illnesses in such cases is directly proportional to the percent of eggs pasteurized. As an example, if no eggs were pasteurized the model estimates 130,000 annual illnesses. If all eggs were pasteurized to a 3-$\log_{10}$ reduction, the model predicts 41,000 illnesses. If 50% of the eggs were pasteurized then the number of illnesses would be halfway between 130,000 and 41,000 illnesses, or about 85,500 illnesses. (Each of these estimates assumes no differences in growth parameters for surviving SE). Table 5-3 and Figure 5-5 show this effect.

TABLE 5-3 EFFECT OF PERCENT EGGS PASTEURIZED ON ANNUAL NUMBER OF ILLNESSES.

| % Eggs Pasteurized | Pasteurization Level | |
|---|---|---|
| | 3-$\log_{10}$ | 5-$\log_{10}$ |
| 0.00 | 130,000 | 130,000 |
| 0.05 | 129,956 | 129,945 |
| 0.10 | 129,911 | 129,889 |
| 1.00 | 129,110 | 128,890 |
| 5.00 | 125,550 | 124,450 |
| 10.00 | 121,100 | 118,900 |
| 20.00 | 112,200 | 107,800 |
| 30.00 | 103,300 | 96,700 |
| 40.00 | 94,400 | 85,600 |
| 50.00 | 85,500 | 74,500 |
| 60.00 | 76,600 | 63,400 |
| 70.00 | 67,700 | 52,300 |
| 80.00 | 58,800 | 41,200 |
| 90.00 | 49,900 | 30,100 |
| 95.00 | 45,450 | 24,550 |
| 99.00 | 41,890 | 20,110 |
| 99.90 | 41,089 | 19,111 |
| 100.00 | 41,000 | 19,000 |

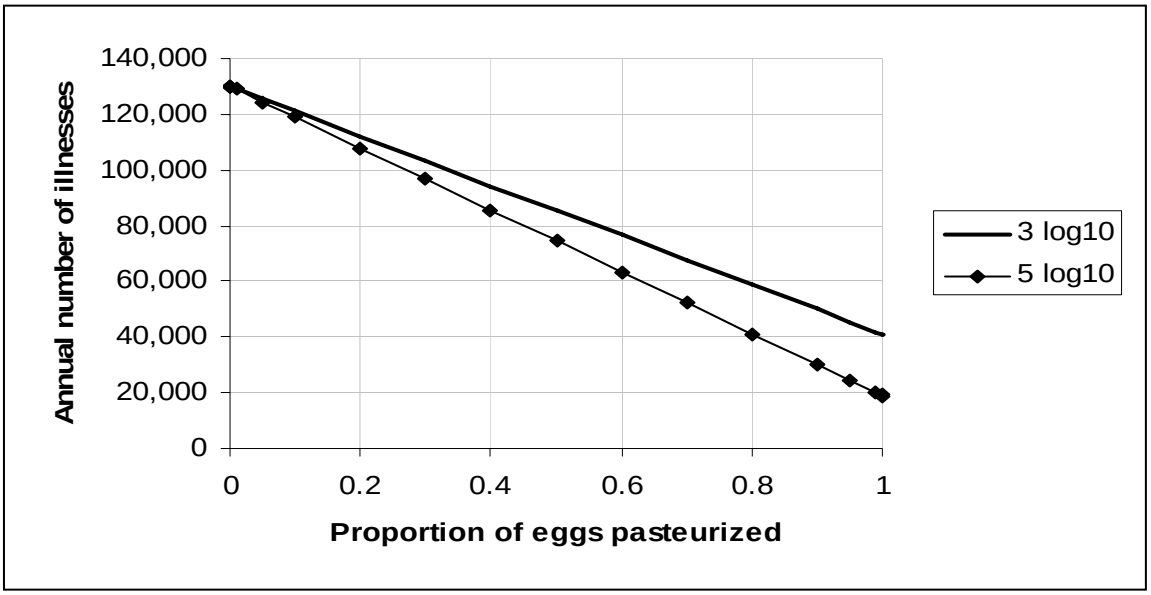



FIGURE 5-5 EFFECT OF PROPORTION OF EGGS PASTEURIZED ON ANNUAL NUMBER OF ILLNESSES.

***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?***

Eggs are collected at various intervals after lay. If eggs are collected twice a day, one would expect about twelve hours to elapse between collections. The average egg would thus be about six hours old at the time of collection. Of course, eggs are not always collected twice a day. Nor does twice a day collection necessarily correspond with collection every twelve hours. Nevertheless, after collection, eggs are stored at different temperatures for different periods until processing.

One possible way to limit the growth of SE in shell eggs is to require refrigeration of the eggs soon after lay. This is modeled by truncating the distribution for the time spent in the layer house at a set value and then subjecting all eggs to a particular temperature for the time of storage until processing. Eggs after processing are stored in the same manner as in the baseline.

Egg storage time was truncated at 3 different values: 12 hours, 24 hours, and 36 hours. This does not mean that each egg was stored for 12, 24, or 36 hours, because eggs may be laid at different times throughout the day. Rather, each egg in the scenario was stored for no more than 12, 24, or 36 hours. Since very few eggs in the baseline were stored in the layer house for as long as 36 hours, truncating the distribution at 36 hours would be expected to have relatively little effect on subsequent human illness. On the other hand, many more eggs were stored for more than 12 hours. Thus, limiting the time in the layer house to no more than 12 hours would be expected to have a greater effect.

**Storage Temperature is Ambient Temperature**

Throughout the model storage temperature is the ambient or air temperature at which eggs are stored.

Storage temperature after egg collection was set at 3 different values: 45, 53, and 60°F (7.2, 11.7, and 15.6°C). In these scenarios, eggs were stored only at those temperatures. For instance, if there is a requirement that eggs after collection must be stored at temperatures no greater than

60°F (15.6°C), it is reasonable to assume that producers currently storing eggs at 45°F (7.2°C) would wish to save money on refrigeration costs while maintaining compliance with regulations.

Thus, there are three scenarios in which eggs are refrigerated within 12, 24, or 36 hours. For each of these scenarios, there are three other scenarios in which eggs are stored at 45° F, 53° F, or 60° F (7.2, 11.7, and 15.6°C). In addition, there is the baseline scenario for ten scenarios. The total number of human illnesses is modeled for each of these scenarios with no pasteurization and with 3 and 5 $\log_{10}$ pasteurization. Results are shown in Table 5-4.

TABLE 5-4 COMPARING DIFFERENT PASTEURIZATION AND STORAGE PROTOCOLS ON ESTIMATED NUMBERS OF HUMAN ILLNESSES.

| Time and Temperature | Pasteurization | | |
|---|---|---|---|
| | None | 3 $\log_{10}$ | 5 $\log_{10}$ |
| Storage at 7.2°C (45°F) within 0.5 days | 28,000 | 5,200 | 2,700 |
| Storage at 7.2°C (45°F) within 1.0 days | 48,100 | 12,000 | 6,300 |
| Storage at 7.2°C (45°F) within 1.5 days | 89,000 | 24,000 | 12,000 |
| Baseline | 130,000 | 41,000 | 19,000 |

The bottom row in Table 5-4 refers to the baseline values for the model simulated with and without pasteurization. These are identical to the values shown in Figure 5-4. Storage of eggs at collected within 1.5 days and stored at 11.7°C (53°F) produces values similar to the baseline. In other words, a requirement to store eggs at 11.7°C (53°F) within 36 hours of lay would likely have little effect on reducing the number of human illnesses. Storage at 15.6°C (60°F) would increase the number of human illnesses, even if eggs were subsequently pasteurized with a 3-$\log_{10}$ reduction. Storage at 7.2°C (45°F) after collection reduces human illness.

Combined effect of storage and pasteurization

Storage time and temperature and pasteurization have a combined effect. In the baseline row in Table 5-4 pasteurization at 5-$\log_{10}$ results in reduction of human illness from 130,000 to 19,000 or 15% of the no pasteurization value. If eggs are stored at 7.2°C (45°F) within 12 hours of collection the model estimates 28,000 illnesses or 22% of the no pasteurization value. If eggs are stored at 7.2°C (45°F) within 12 hours of collection and subjected to a 5-$\log_{10}$ reduction from pasteurization, the total illnesses expected would be 130,000 x 15% x 22% = 4300. Instead, the model estimates only 2,700 illnesses.

Cooling eggs rapidly to 7.2°C (45°F) after processing makes pasteurization more effective. One surviving bacterium in an egg could rapidly multiply during the post-processing steps. Limiting growth of SE before pasteurization decreases the probability that there will be any surviving bacteria.

## Stability of the Baseline Model

Results from the baseline model are generated from 50,000 iterations using a particular seed value. The number of iterations was set at 50,000 because each of the inputs and outputs for each iteration can be easily saved to an Excel worksheet. This allows for both easier auditing of model results and subsequent analysis of correlations between inputs and outputs. When the seed value for the model changes, the number of human illnesses per egg and the annual number of human illnesses change.

The output from a set of 50,000 iterations can be thought of as a sample from a population of all possible output values. Thus, in addition to the mean number of illnesses per egg reported earlier (0.0000069) (unanchored model), the standard deviation (0.0001) can also be determined. The standard error can then be calculated from the mean, standard deviation, and sample size, and the size of the standard error can be compared to the size of the mean. For the baseline model with 50,000 iterations, the standard error is about 6% of the mean. This gives an idea of how much the model output will vary given different seed values.

The model was simulated twenty separate times using a different randomly generated seed value (from the *Excel* Rand() function) for each simulation. Table 5-5 shows the results of the 20 simulations using the unanchored output.

TABLE 5-5 UNANCHORED ESTIMATES OF HUMAN SE ILLNESSES PER YEAR FROM 20 BASELINE SIMULATIONS USING DIFFERENT RANDOM SEED VALUES.

| | | | |
|---|---|---|---|
| 285,219 | 317,474 | 342,432 | 345,989 |
| 289,189 | 318,063 | 342,847 | 347,129 |
| 300,389 | 324,891 | 342,882 | 350,787 |
| 303,557 | 335,180 | 343,079 | 372,016 |
| 304,454 | 337,108 | 345,518 | 382,883 |

The model has an option that allows simulation in such a way that the only value captured is the frequency of human illnesses. This allows a greater number of iterations to be conducted and results in greater stability. More iterations, however, result in greater model run times, and preclude correlation analysis of inputs and outputs. Furthermore, the model presently stores all distributions in memory. Depending on the computer, large models may require paging to virtual memory and thus, slow the simulation more than would be expected.

Because the baseline model run used a specific seed value, comparisons can easily be made with mitigation runs with the same seed value. This ensures identical draws from distributions and that the only change is in the specific mitigation modeled.

## Sensitivity Analysis

Sensitivity analysis shows the effect of changing input values on the outcome of a model, given model structure, data, and assumptions. For instance, the effect of forced molting on the likelihood of human illness from SE in shell eggs can be examined by changing the input fraction of flocks that are molted. Sensitivity analysis can thus address directly some risk management questions.

Sensitivity analysis can also identify those inputs that have the biggest effect on the model output for the current model structure. The reason for the effect may be obvious. For instance, it is intuitive that reducing the number of contaminated eggs by one half would reduce the number of human illnesses by one-half. Often, however, the reason is not obvious. Changes in equation parameters may have non-intuitive effects that can only be understood through further study. Although inputs that have a great deal of uncertainty associated with them would be expected to have a greater effect on the model output than more certainly defined outputs, this is not always the case. Some inputs may be very uncertain but have little effect on the model output. Identifying those inputs that have significant effects on model outputs is an important step in

prioritizing research needs. Little benefit is gained from additional research into unimportant variables or those variables that are already well characterized.

***Sensitivity Analysis as Proxy for Second-order Model***

In this report, sensitivity analysis serves as a proxy for conducting a second-order model in which all inputs have their uncertainties characterized probabilistically. A second-order model would then generate a series of exposure distributions and a series of dose-response functions that would all be integrated to generate a distribution that would characterize our uncertainty about the likelihood of illness. This second-order approach was not conducted for the following reasons:

**Second-order modeling**

A first-order model accounts for variability in a system by iterating through specific values and distributions. A second-order model accounts for uncertainty by iteratively choosing from sets of values and distributions to use for the first-order model. A second-order model allows characterization of the uncertainty in the output distribution.

1) The uncertainty and variability about the likelihood of human illness from SE in shell eggs are characterized in the Hazard Characterization chapter of this report. The characterization is based on epidemiologic evidence regarding the occurrence of human illness.

2) Additional uncertainties within the model have not been adequately characterized for a second-order model. In particular, uncertainties regarding producer, processor, and consumer behavior in the storage, transportation, cooking, and consumption of eggs were not characterized probabilistically. Consequently, a second-order model would not adequately show the uncertainty within the system.

3) A second-order model is computationally impractical at present and requires considerably more time to run than a first-order model. A first-order model seeks only to characterize the variability in a system. Thus, a single simulation of the model is sufficient to generate a single exposure distribution. The shell egg model takes about 1½ hours to generate a single exposure distribution (50,000 iterations) and a single estimate of the frequency of human illness due to SE from shell eggs. A second-order model of 300 uncertainty simulations would thus take more than 420 hours. This is too long to be of practical use when evaluating multiple mitigations. On the other hand, a one-time evaluation of sensitivity for the first-order model was completed in about 40 hours.

***Types of sensitivity analysis conducted***

Three types of sensitivity analysis are conducted for the model. First, a correlation analysis of the baseline model identifies those variables that are most influential in the frequency of human illness. Second, a nominal range sensitivity analysis identifies uncertainties deemed most influential. Third, a set of outputs is generated that identifies sensitivity of the model to different modeling choices.

***Correlation analysis of the baseline scenario***

Spearman rank order correlations were conducted for a number of inputs and intermediate outputs with the frequency of human illness. Rank order correlation is useful “because it makes

no assumption about the relationship between the input and the output." [80] Each input of interest is correlated with the frequency of illness per egg.

Correlation with storage variables

Time, temperature, and cooling constant inputs for specific stages do not appear to be correlated with human illness (Table 5-6). This is likely because it is only necessary for growth to occur at any step for illness to occur.

TABLE 5-6 CORRELATION OF HUMAN ILLNESS WITH INPUT FOR TIME, TEMPERATURE, AND COOLING CONSTANT AT EACH STEP.

| Model Step | Correlation with: | | |
|---|---|---|---|
| | **Time** | **Temp** | ***k*** |
| Layer | 0.023 | 0.015 | NA |
| On Farm | 0.032 | 0.042 | -0.005 |
| Transportation to Processor | -0.002 | 0.004 | -0.005 |
| Pre-processing | 0.034 | 0.038 | -0.009 |
| Post-processing | 0.021 | 0.021 | 0.002 |
| Retail Transportation | 0.010 | 0.007 | 0.002 |
| Retail Storage | -0.003 | 0.019 | -0.004 |
| Home Transportation | 0.001 | 0.003 | -0.002 |
| Home Storage | 0.003 | 0.010 | -0.002 |

Correlation with intermediate outputs

The model can capture four intermediate outputs at the end of each step. These are (i) age of the egg, (ii) internal egg temperature, (iii) the amount of yolk membrane (YMB) that has occurred, and (iv) the number of bacteria in the egg. As with the storage time and temperature variables shown in Table 5-6, the age of the egg and the internal egg temperature at the end of a step are not correlated with human illness (Table 5-7).

There is a slight correlation, however, for YMB that has occurred. The correlation increases slightly through processing, but then levels off. There is a larger correlation between the number of bacteria at the end of each step and human illness. Again, this correlation increases through processing and then plateaus. This effect is visible in Table 5-7 and the tornado charts in Figure 5-6.

**Tornado Charts**

Tornado charts are an easy way of visualizing the relative degree of correlation of an output to several variables. It consists of bars that either approach 1 (positive correlation or -1 (negative correlation).

TABLE 5-7 CORRELATION OF HUMAN ILLNESS WITH OUTPUT AT END OF EACH STEP.

| Model Step | Correlation with: | | | |
|---|---|---|---|---|
| | **Egg Age** | **Egg Temp** | **YMB** | **Bacteria** |
| Layer | 0.023 | 0.014 | 0.090 | 0.150 |
| On Farm | 0.034 | 0.048 | 0.120 | 0.326 |
| Transportation to Processor | 0.033 | 0.018 | 0.120 | 0.335 |
| Pre-processing | 0.054 | 0.041 | 0.147 | 0.402 |
| Post-processing | 0.060 | 0.041 | 0.154 | 0.426 |
| Retail Transportation | 0.061 | 0.028 | 0.156 | 0.432 |
| Retail Storage | 0.033 | 0.024 | 0.145 | 0.437 |
| Home Transportation | 0.033 | 0.007 | 0.145 | 0.438 |
| Home Storage | 0.031 | 0.015 | 0.144 | 0.441 |

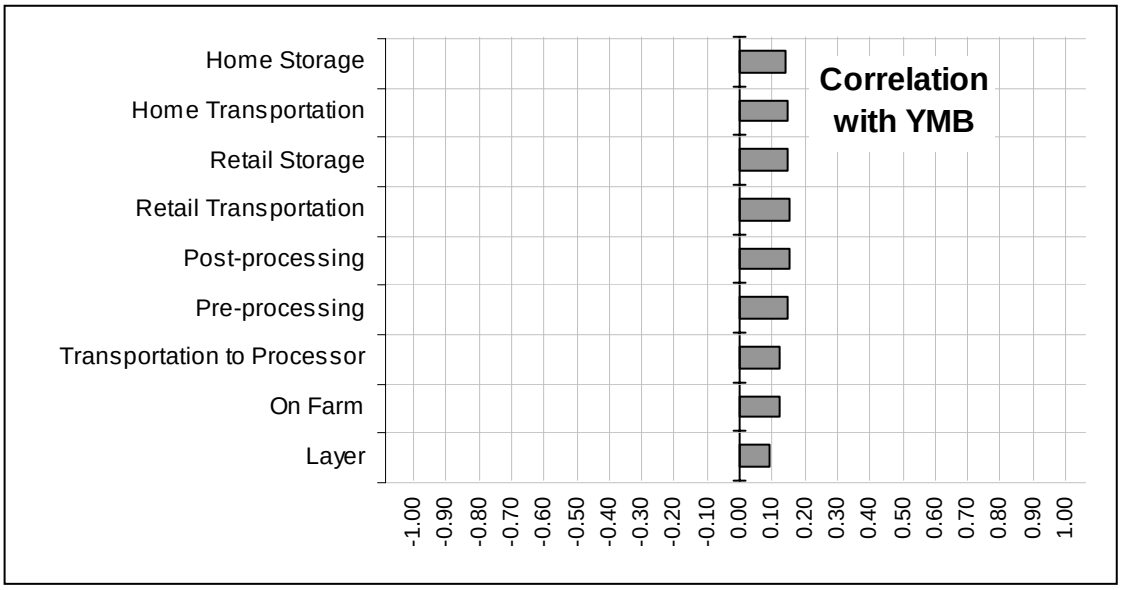



FIGURE 5-6 CORRELATION OF % YOLK MEMBRANE BREAKDOWN THAT HAS OCCURRED BY THE END OF EACH STEP WITH FREQUENCY OF HUMAN ILLNESS.

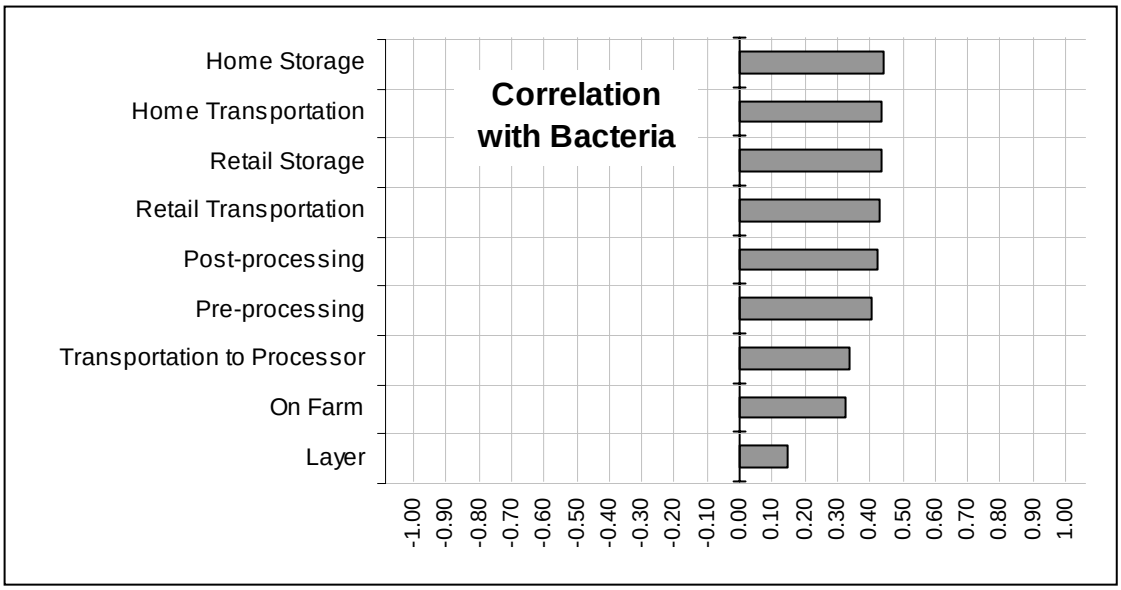



FIGURE 5-7 CORRELATION OF NUMBER OF BACTERIA AT END OF EACH STEP WITH FREQUENCY OF HUMAN ILLNESS.

Correlation with other variables

Also of interest in the model is the initial number of bacteria with which an egg is contaminated. As can be seen in Table 5-8 this is not correlated with human illness. The number of servings produced by an egg is also not correlated with human illness. The $\log_{10}$ reduction due to cooking, however, is strongly negatively correlated with the frequency of human illness. Cooking directly affects the number of bacteria consumed.

TABLE 5-8 CORRELATION OF HUMAN ILLNESS WITH OTHER MODEL VARIABLES.

| Variable | Correlation |
|---|---|
| Initial Bact | 0.064 |
| Servings | 0.001 |
| Cooking | -0.863 |

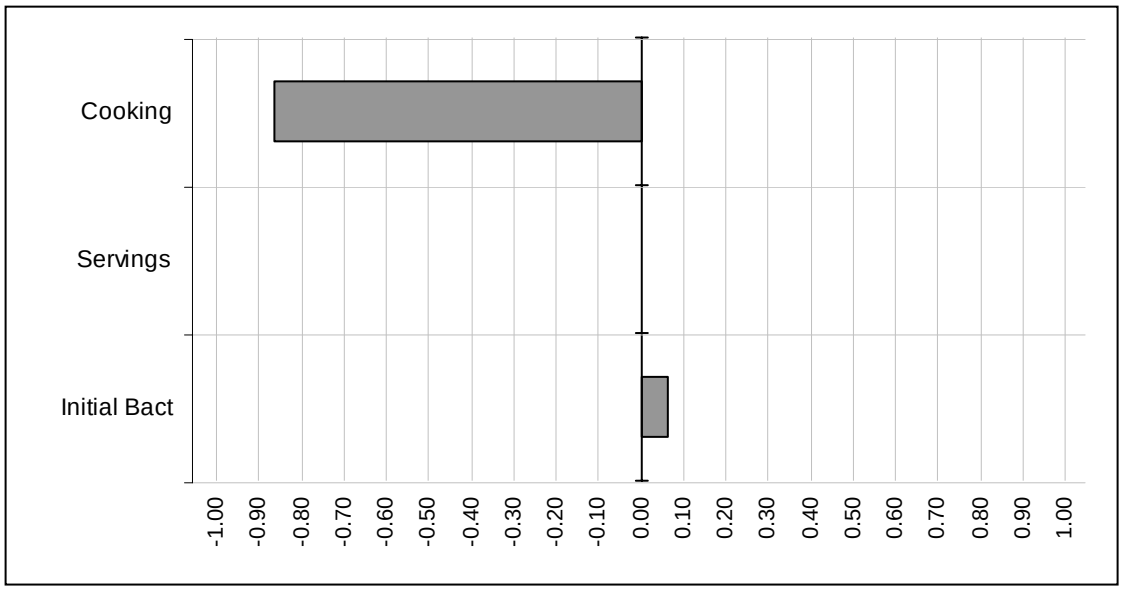



FIGURE 5-8 CORRELATION OF $\log_{10}$ REDUCTIONS DUE TO COOKING, NUMBER OF SERVINGS PER EGG, AND INITIAL BACTERIA WITH FREQUENCY OF HUMAN ILLNESS.

A reviewer of the draft risk assessment noted that

> *Although the correlation analysis does not show a correlation with serving size, serving sizes are important for the result (the illness rate). The few cases with* $I_E = p(\text{ill}) > 1$ *contribute most to the result, and they are associated with larger serving sizes. If, in the shell egg spreadsheet, you select the simulation iterations that contribute 95% of the total* $I_E$ *(i.e. the 805 out of 50000 with the highest values for p(illness)), there is a correlation: […] so serving size is important.*

The reviewer also provided a chart that demonstrated this relationship. This chart is shown below as Figure 5-9.

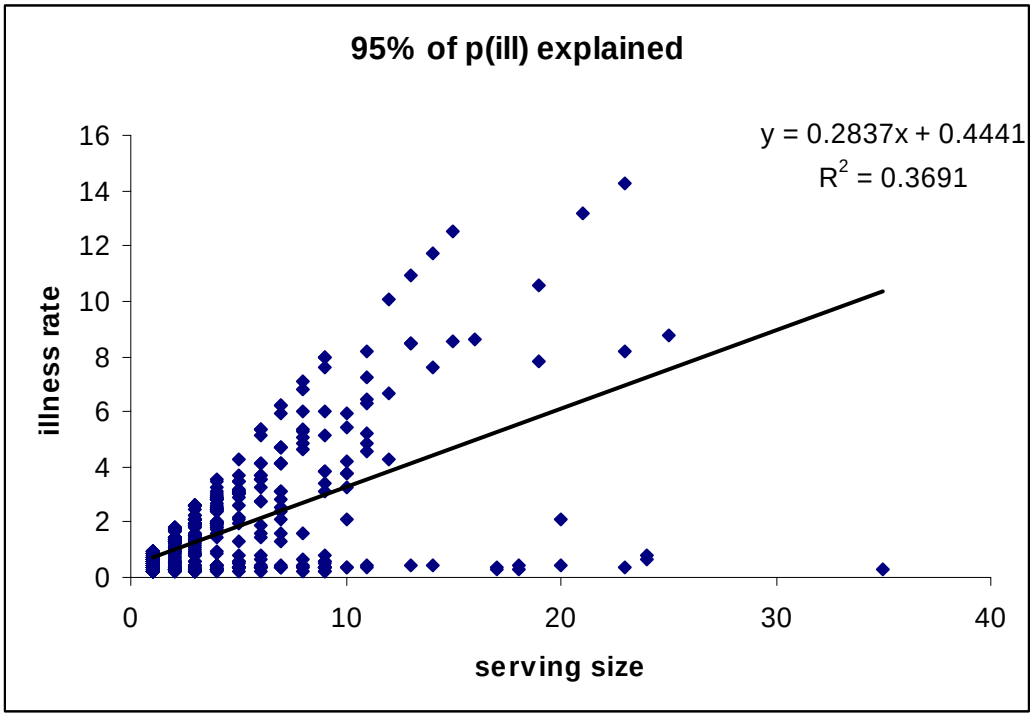



FIGURE 5-9 CORRELATION OF SERVING SIZE AND ILLNESS FROM SE IN EGGS.

***Nominal range sensitivity analysis***

Nominal range sensitivity analysis evaluates the effect of changing only one input at a time in the model while holding other inputs constant. It is a relatively simple method and is generally used with linear models rather than probabilistic models. It does not, however, capture the effect of interactions between inputs.[109]

The analysis was conducted by setting all inputs to their most likely values (baseline scenario) and running the model for 10,000 iterations. Because the baseline model used 50,000 iterations, this baseline was slightly different. Then upper and lower bounds were selected for each of the inputs. Generally, these bounds were set arbitrarily. For fixed inputs, bounds were generally selected by multiplying the input by a set factor. For distributional inputs, the distribution parameters such as the mean or standard deviation were adjusted. Some inputs were thought to be correlated with other inputs. For those inputs, if the correlation was below -0.5 or above 0.5 then the inputs were changed and evaluated separately. If the correlation was between -0.5 and 0.5 then the inputs were changed and evaluated separately.

After selecting lower and upper bounds for each input or set of inputs, the model was run for 10,000 iterations for each lower and upper bound modeled. After each input was evaluated at its lower and upper bound, the input was changed to its most likely value and the next input was evaluated.

Ninety-eight sets of inputs were changed and evaluated at the upper and lower bound. The following tables and charts show the results of the simulations. The inputs are displayed in categories. The bounds for each input are displayed in tables. Results of the analysis are shown in charts following each table.

Egg contamination

Inputs that affect the probability of contamination of an egg with SE and the number of SE contaminating the egg are shown in Table 5-9. For each of these inputs the lower bound was set to the most likely value x 0.5 and the upper bound was set to the most likely value multiplied by 2.

TABLE 5-9 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR EGG CONTAMINATION.

| Parameter | LB | ML | UB |
|---|---|---|---|
| *p(Flock infected)* | 0.099 | 0.198 | 0.396 |
| *p(Hen is infected \| flock is infected)* | 0.007 | 0.015 | 0.030 |
| *p(Egg contaminated \| hen infected, not molted)* | 0.043 | 0.086 | 0.172 |
| *p(Flock is molted)* | 0.047 | 0.094 | 0.188 |
| *molting multiplier* | 1.430 | 2.860 | 5.720 |
| *Albumen init cont (mean of lognormal)* | 1.301 | 2.602 | 5.204 |
| *Albumen init cont (st. dev. of lognormal)* | 0.648 | 1.295 | 2.591 |
| *Yolk and VM init cont (mean of Poisson)* | 0.695 | 1.390 | 2.780 |
| *Yolk and VM init cont (prob. of 0)* | 0.125 | 0.249 | 0.498 |

Some of the values in Table 5-9 were compared to values calculated for the uncertainty characterized in Annex C. Table 5-10 shows the bounds that would result from the uncertainty calculations. Since the bounds are reasonably close to those shown in Table 5-9, the bounds in Table 5-9 are used to help maintain a more consistent approach.

TABLE 5-10 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR EGG CONTAMINATION USING 5TH AND 95$^{TH}$ UNCERTAINTY LIMITS.

| Parameter | LB | ML | UB |
|---|---|---|---|
| *p(Flock infected)* | 0.018 | 0.198 | 0.454 |
| *p(Hen is infected \| flock is infected)* | 0.005 | 0.015 | 0.218 |
| *p(Egg contaminated \| hen infected, not molted)* | 0.069 | 0.086 | 0.123 |
| *molting multiplier* | 1.670 | 2.860 | 8.518 |

Results of the model runs are shown in Figure 5-10. For this chart and subsequent charts, each input is identified along the x-axis. The frequency of illness is given on the y-axis. Each input has a corresponding vertical line with a diamond in the center that gives the frequency of illness when the input is set at its most likely value (about 0.000069 in the model used to develop the charts, which differs slightly from the later model used for generating baseline results). The frequencies of illness for the upper and lower bounds of the input are given by the horizontal lines at the ends of each vertical line. The longest vertical lines represent those inputs that have the most influence on the frequency of illness.

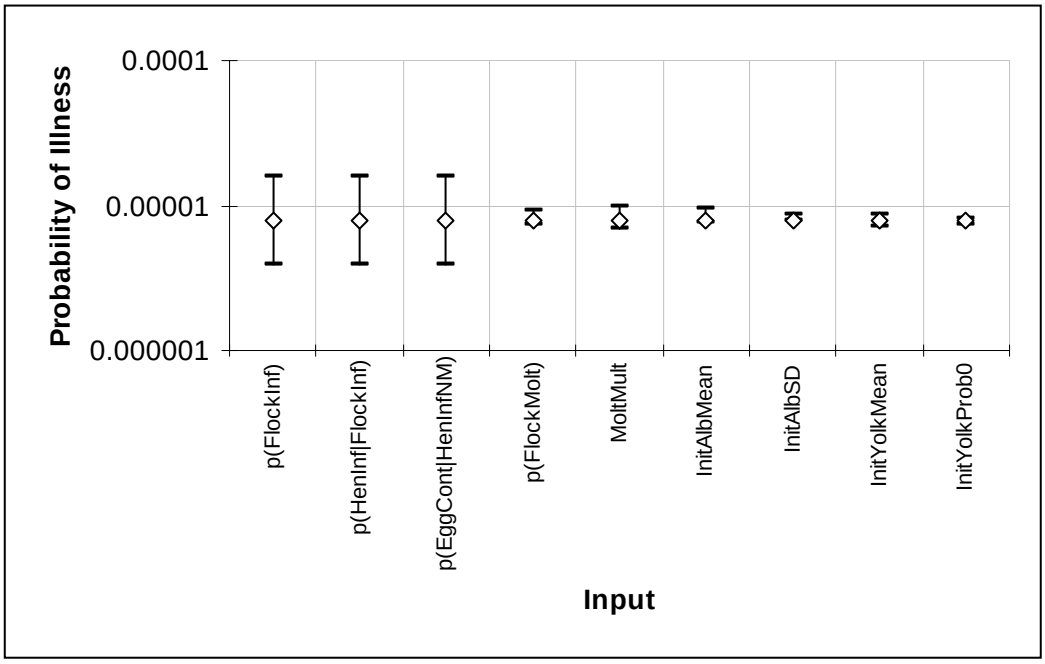



FIGURE 5-10 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR EGG CONTAMINATION INPUTS.

Fraction of contaminated eggs

The model identifies nine different types of contaminated eggs depending on where contamination occurs, the amount of contamination, and when growth takes place. Table 5-11 identifies the nine types of contaminated eggs. The nine most likely values for each of these fractions sum to 1. When the bounds are modeled, the most likely fraction is replaced by the appropriate bound and the resultant fractions are normalized. Thus, the individual bounds represent weights for each of nine egg types rather than fractions.

TABLE 5-11 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR CONTAMINATED EGG FRACTIONS.

| Parameter | LB | ML | UB |
|---|---|---|---|
| *Shell* | 0.0926 | 0.1852 | 0.3704 |
| *Alb C G* | 0.0361 | 0.0723 | 0.1446 |
| *Alb C N* | 0.0097 | 0.0194 | 0.0387 |
| *Alb F G* | 0.1024 | 0.2048 | 0.4097 |
| *Alb F N* | 0.1573 | 0.3146 | 0.6292 |
| *VM Low* | 0.0852 | 0.1704 | 0.3407 |
| *VM High* | 0.0061 | 0.0123 | 0.0245 |
| *Yolk Low* | 0.0098 | 0.0197 | 0.0393 |
| *Yolk High* | 0.0007 | 0.0014 | 0.0028 |

Figure 5-11 shows the results of the nominal range sensitivity analysis for contaminated egg fractions.

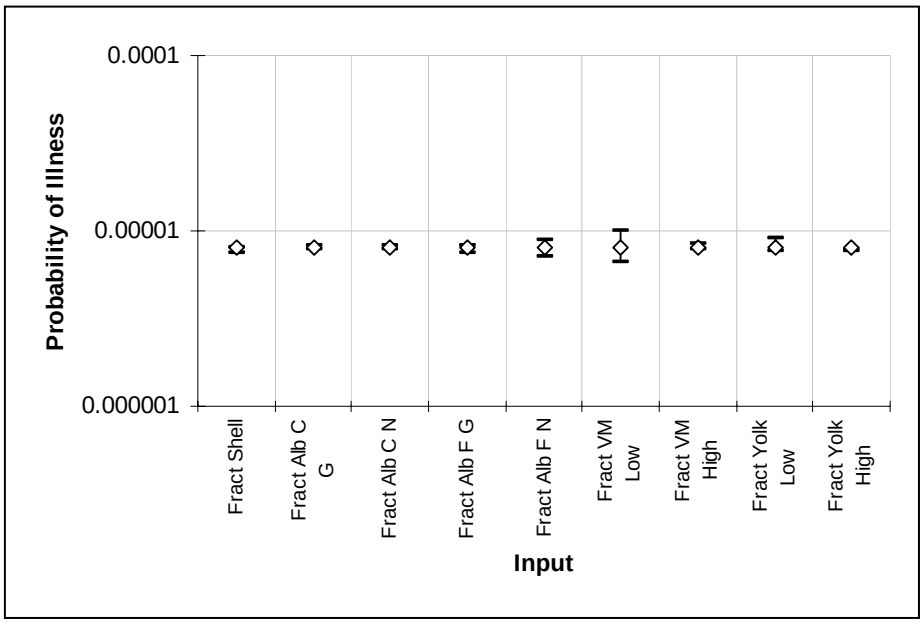



FIGURE 5-11 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR CONTAMINATED EGG FRACTIONS.

Storage temperature

Egg storage temperatures were modeled using lognormal distributions with means and standard deviations coming from fits to the data. Some steps had no data available for storage temperatures, and thus were modeled using parameters from other steps. Uncertainty in storage temperatures was not characterized. Bounds for means were established at 45 and 90°F (7.2 and 32.2°C) for each of the temperatures. For the standard deviations, the lower bounds were set at 0.01 and the upper bounds were set at Ln(*e*(most likely)*2). These values are shown in Table 5-12.

TABLE 5-12 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR PARAMETERS OF LOGNORMAL DISTRIBUTIONS FOR EGG STORAGE TEMPERATURES (PARAMETER VALUES IN LN(°F)).

| | LB | | ML | | UB | |
|---|---|---|---|---|---|---|
| **Parameter** | **Mean** | **Std Dev** | **Mean** | **Std Dev** | **Mean** | **Std Dev** |
| *Layerhouse* | 3.81 | 0.01 | 4.32 | 0.15 | 4.50 | 0.84 |
| *OnFarm* | 3.81 | 0.01 | 4.01 | 0.14 | 4.50 | 0.83 |
| *TransportationFromFarm* | 3.81 | 0.01 | 3.92 | 0.14 | 4.50 | 0.83 |
| *PreProcessingOffLine* | 3.81 | 0.01 | 3.86 | 0.15 | 4.50 | 0.84 |
| *PreProcessingInLine* | 3.81 | 0.01 | 3.97 | 0.14 | 4.50 | 0.83 |
| *PostProcessing* | 3.81 | 0.01 | 3.87 | 0.15 | 4.50 | 0.84 |
| *RetailTransportation* | 3.81 | 0.01 | 3.94 | 0.15 | 4.50 | 0.84 |
| *RetailStorage* | 3.81 | 0.01 | 3.66 | 0.10 | 4.50 | 0.79 |
| *HomeTransportation* | 3.81 | 0.01 | 4.42 | 0.14 | 4.50 | 0.84 |
| *HomeStorage* | 3.81 | 0.01 | 3.66 | 0.11 | 4.50 | 0.80 |

Figure 5-12 shows the results for this analysis. Storage temperatures in the layer house, during on farm storage, before processing at off-line facilities, at retail establishments, and at end

users have a significant effect on the frequency of illness. Temperature during transportation has less effect, probably because the time available for bacterial growth is generally much less. The lower bound for retail and home storage temperatures show a higher frequency of illness than the most likely values. This is because the most likely values for the lognormal means for the distributions of retail and home storage temperatures are below 113°C.

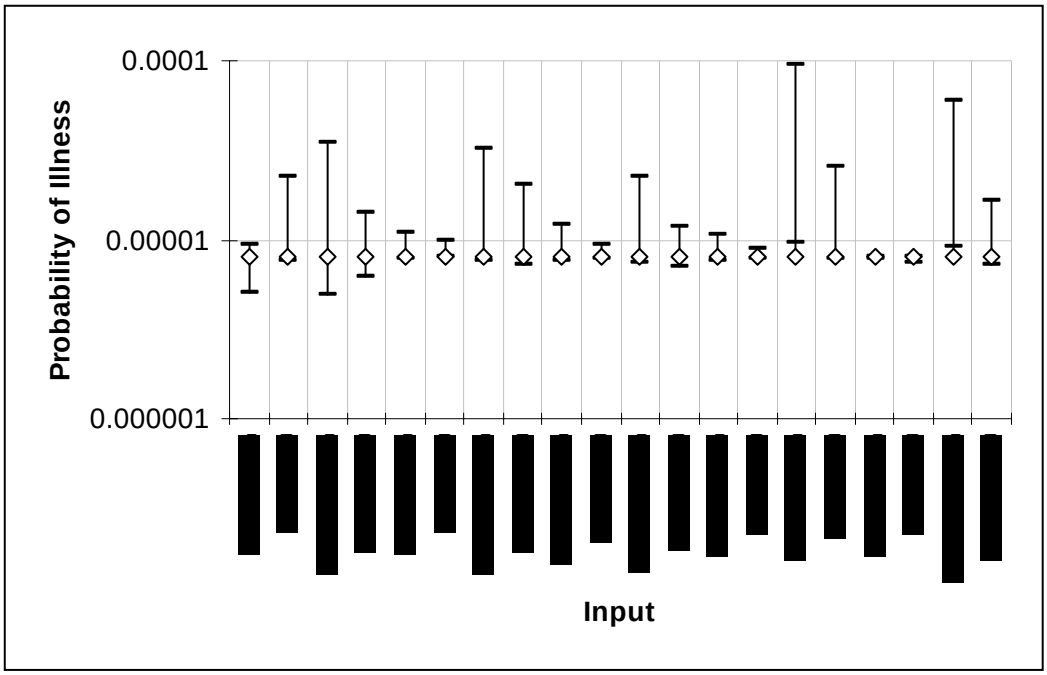



FIGURE 5-12 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR STORAGE TEMPERATURE INPUTS.

Growth parameters

Parameters for bacterial growth have their uncertainty characterized in Annex E. Bounds are based on the 5th and 95th percentiles for the yolk growth parameters (*e*, *f*, and *b*) and yolk membrane breakdown (YMB) parameters (*d*, *f*, *g*, and *k*). Two sets of these inputs are correlated. Bounds and identification of correlations are shown in Table 5-13. Results are shown in Figure 5-13.

TABLE 5-13 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR GROWTH PARAMETERS.

| Parameter | | LB | ML | UB | Correlated |
|---|---|---|---|---|---|
| Yolk growth | *e* | -1.5863 | -1.0063 | -0.4263 | 1 |
| | *f* | 0.1954 | 0.2219 | 0.2484 | 1 |
| | *b* | 0.0100 | 0.4007 | 0.8761 | |
| YMB | *d* | 1.0869 | 1.3103 | 1.5337 | |
| | *f* | -3.2745 | -1.5087 | -0.0100 | 2 |
| | *g* | 0.0299 | 0.0751 | 0.1203 | 2 |
| | *k* | 2.6227 | 3.4825 | 4.3423 | 2 |
| | *Omega* | 1 | 1 | 2.6 | |
| Albumen growth | *SD* | 0.1925 | 0.385 | 0.77 | |
| | *lag/growth* | 2 | 5 | 10 | |

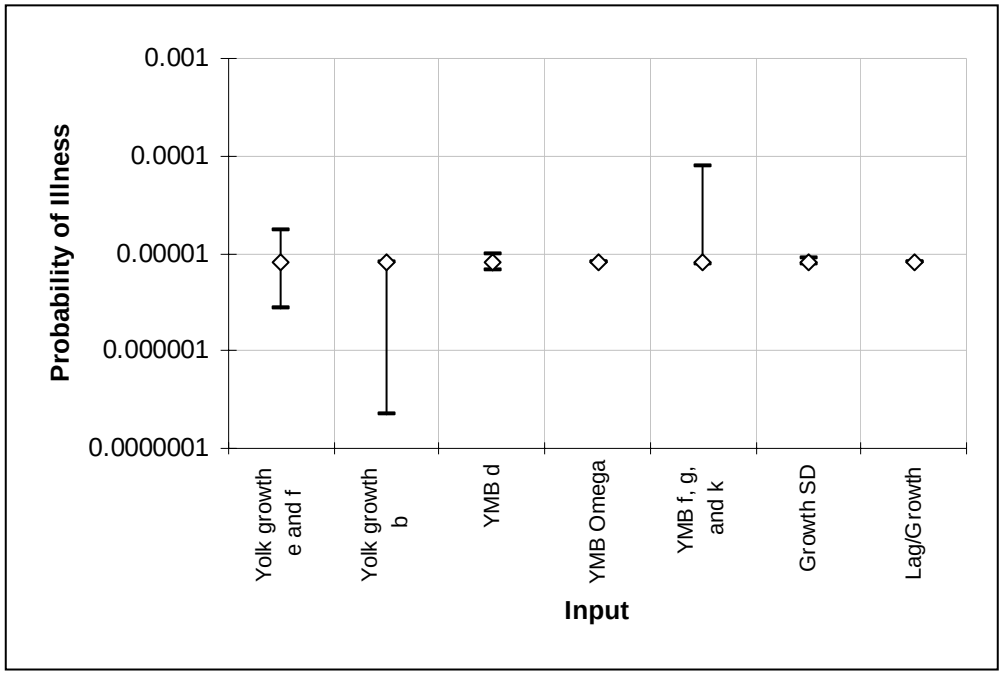



FIGURE 5-13 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR BACTERIAL GROWTH INPUTS.

Figure 5-13 shows a considerable effect on the frequency of illness from the uncertainty related to both yolk growth and yolk membrane breakdown.

Storage time

Bounds for mean storage times are set at one-half [Ln($e^{(\text{most likely})}$x0.5)] and double [Ln($e^{(\text{most likely})}$x2)] those in the most likely scenario. Bounds for standard deviations are set in a similar way to those for storage temperatures.

TABLE 5-14 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR PARAMETERS OF LOGNORMAL DISTRIBUTIONS FOR EGG STORAGE TIMES (DAYS).

| Parameter | LB | | ML | | UB | |
|---|---|---|---|---|---|---|
| | Mean | Std Dev | Mean | Std Dev | Mean | Std Dev |
| *Layerhouse* | (2.07) | 0.01 | (1.38) | 0.59 | (0.69) | 1.29 |
| *OnFarm* | 0.03 | 0.01 | 0.72 | 0.59 | 1.41 | 1.29 |
| *TransportationFromFarm* | (2.08) | 0.01 | (1.39) | 0.59 | (0.69) | 1.28 |
| *PreProcessingOffLine* | (0.74) | 0.01 | (0.04) | 1.33 | 0.65 | 2.03 |
| *PreProcessingInLine* | (0.03) | 0.01 | 0.67 | 0.89 | 1.36 | 1.58 |
| *PostProcessing* | (0.64) | 0.01 | 0.05 | 1.33 | 0.75 | 2.03 |
| *RetailTransportation* | (1.39) | 0.01 | (0.69) | 0.59 | 0.00 | 1.28 |
| *RetailStorage* | 1.64 | 0.01 | 2.33 | 0.59 | 3.02 | 1.28 |
| *HomeTransportation* | (3.81) | 0.01 | (3.12) | 0.37 | (2.43) | 1.07 |
| *HomeStorage* | 1.08 | 0.01 | 1.78 | 0.59 | 2.47 | 1.28 |

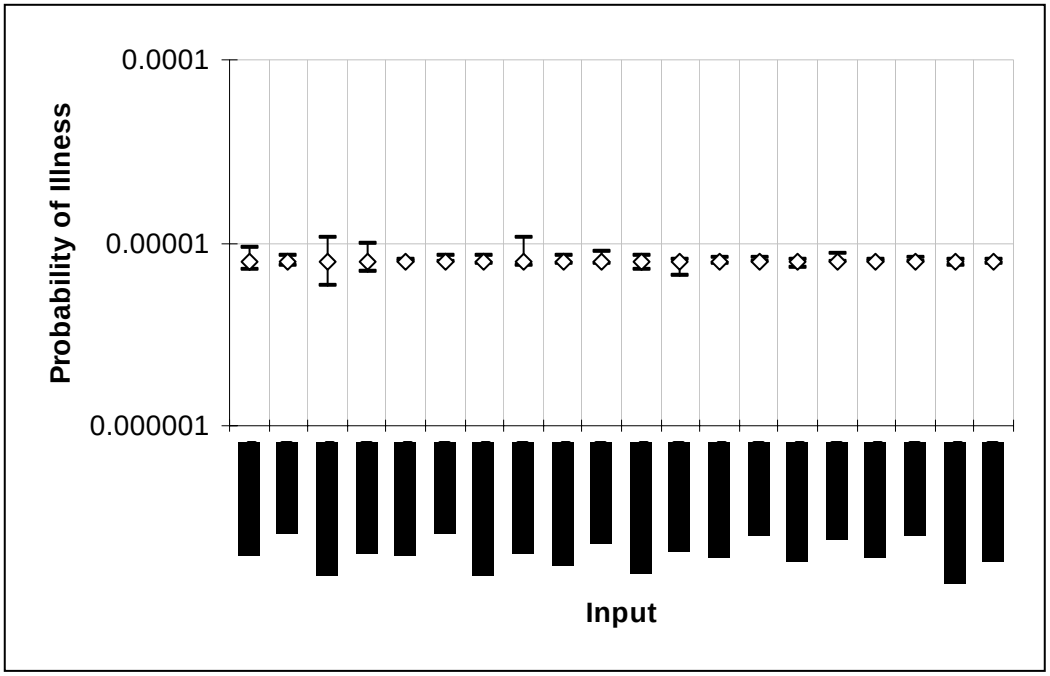



FIGURE 5-14 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR STORAGE TIME INPUTS.

Cooling constants

Bounds for cooling constants are established by setting the "central egg" cooling constant for a case or pallet to either the minimum modeled value (0.001) or the maximum modeled value (1) (Table 5-15; following page).

TABLE 5-15 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR PARAMETERS OF LOGNORMAL DISTRIBUTIONS FOR EGG STORAGE COOLING CONSTANT VALUES.

| **Parameters for *k*-values** | | ***k*-values and associated cumul fraction** | | | |
|---|---|---|---|---|---|
| **Input** | | **0.001** | **0.01** | **0.10** | **1.00** |
| *Layerhouse - off line* | | 0.00 | 1.00 | 1.00 | 1.00 |
| *Layerhouse - in line* | | 0.00 | 1.00 | 1.00 | 1.00 |
| *OnFarm* | | 0.00 | 1.00 | 1.00 | 1.00 |
| *TransportationFromFarm* | | 0.00 | 1.00 | 1.00 | 1.00 |
| *PreProcessingOffLine* | | 0.00 | 1.00 | 1.00 | 1.00 |
| *PreProcessingInLine* | | 0.00 | 1.00 | 1.00 | 1.00 |
| *PostProcessing* | | 0.00 | 1.00 | 1.00 | 1.00 |
| *RetailTransportation* | Lower bound | 0.00 | 1.00 | 1.00 | 1.00 |
| *RetailStorage* | | 0.00 | 1.00 | 1.00 | 1.00 |
| *HomeTransportation* | | 0.00 | 1.00 | 1.00 | 1.00 |
| *HomeStorage* | | 0.00 | 1.00 | 1.00 | 1.00 |
| *Layerhouse - off line* | | 0.00 | 0.00 | 0.00 | 1.00 |
| *Layerhouse - in line* | | 0.00 | 0.00 | 0.00 | 1.00 |
| *OnFarm* | | 0.00 | 0.01 | 1.00 | 1.00 |
| *TransportationFromFarm* | | 0.00 | 0.01 | 1.00 | 1.00 |
| *PreProcessingOffLine* | | 0.00 | 0.01 | 1.00 | 1.00 |
| *PreProcessingInLine* | | 0.00 | 1.00 | 1.00 | 1.00 |
| *PostProcessing* | | 0.00 | 0.99 | 1.00 | 1.00 |
| *RetailTransportation* | Most likely values | 0.00 | 0.99 | 1.00 | 1.00 |
| *RetailStorage* | | 0.00 | 0.20 | 1.00 | 1.00 |
| *HomeTransportation* | | 0.00 | 0.00 | 1.00 | 1.00 |
| *HomeStorage* | | 0.00 | 0.00 | 0.55 | 1.00 |
| *Layerhouse - off line* | | 0.00 | 0.00 | 0.00 | 1.00 |
| *Layerhouse - in line* | | 0.00 | 0.00 | 0.00 | 1.00 |
| *OnFarm* | | 0.00 | 0.00 | 0.00 | 1.00 |
| *TransportationFromFarm* | | 0.00 | 0.00 | 0.00 | 1.00 |
| *PreProcessingOffLine* | | 0.00 | 0.00 | 0.00 | 1.00 |
| *PreProcessingInLine* | | 0.00 | 0.00 | 0.00 | 1.00 |
| *PostProcessing* | | 0.00 | 0.00 | 0.00 | 1.00 |
| *RetailTransportation* | Upper bound | 0.00 | 0.00 | 0.00 | 1.00 |
| *RetailStorage* | | 0.00 | 0.00 | 0.00 | 1.00 |
| *HomeTransportation* | | 0.00 | 0.00 | 0.00 | 1.00 |
| *HomeStorage* | | 0.00 | 0.00 | 0.00 | 1.00 |

Figure 5-15 shows that the cooling constant has only a minor effect on the frequency of illness. It is important to note that the cooling constant applies only to the central egg of a case or pallet and that most eggs would be near the perimeter with a cooling constant approaching that of exposure to air.

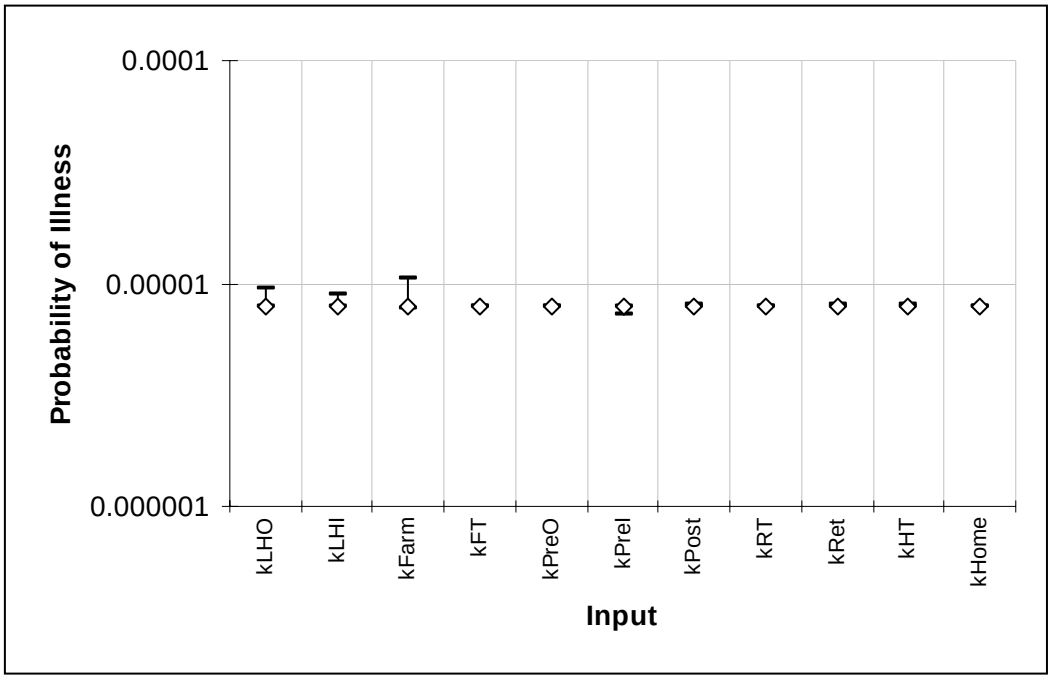



FIGURE 5-15 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR COOLING CONSTANT INPUTS.

Preparation and serving

This category includes fractions for different types of egg servings, $\log_{10}$ reductions for different types of cooking, fractions of eggs cooked in different ways, servings per egg, and dose-response parameters. Table 5-16 shows the bounds for these inputs. As with fractions for contaminated eggs, bounds for fractions in this category represent weights.

Sensitivity for $\log_{10}$ reductions is modeled by adding or subtracting one $\log_{10}$. In the case of soft-boiled eggs and beverages, the most likely value is already less than a $\log_{10}$. The most likely value for the mean of the lognormal distribution for servings per egg is 0.47, or about 1.6 servings per egg. The lower bound is 0, or 1 serving per egg and the upper bound is 1.39, or about 4 servings per egg. Dose-response bounds come from the Hazard Characterization chapter. The dose-response parameters are correlated so the results reflect changing both parameters at the same time. Results are shown on the following page in Figure 5-16.

TABLE 5-16 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR COOKING, SERVING SIZE, DOSE-RESPONSE, AND MISCELLANEOUS PARAMETERS.

| Parameter | | LB | ML | UB |
|---|---|---|---|---|
| Fraction | *Beverages* | 0.0017 | 0.0033 | 0.0067 |
| | *Mixtures* | 0.2000 | 0.5304 | 0.8000 |
| $\log_{10}$ reductions | *Soft boiled and poached* | 0.0 | 0.9 | 1.9 |
| | *Sunny side up* | 0.8 | 1.8 | 2.8 |
| | *Scrambled and omelets 1* | 3.9 | 4.9 | 5.9 |
| | *Scrambled and omelets 2* | 5.1 | 6.1 | 7.1 |
| | *Over easy* | 5.3 | 6.3 | 7.3 |
| | *Hard boiled* | 7.0 | 8.0 | 9.0 |
| | *Beverages* | 0.0 | 0.0 | 1.0 |
| | *Mixtures* | 11.0 | 12.0 | 13.0 |
| Fraction | *Soft boiled and poached* | 0.0600 | 0.12 | 0.2400 |
| | *Sunny side up* | 0.0675 | 0.135 | 0.2700 |
| | *Scrambled and omelets 1* | 0.1175 | 0.235 | 0.4700 |
| | *Scrambled and omelets 2* | 0.1175 | 0.235 | 0.4700 |
| | *Over easy* | 0.0675 | 0.135 | 0.2700 |
| | *Hard boiled* | 0.0700 | 0.14 | 0.2800 |
| Fraction | *In-line processed* | 0.0% | 13.5% | 100.0% |
| | *Consumed away from home* | 0.0% | 55.0% | 100.0% |
| Servings per egg (lognormal distribution) | *Mean* | 0.00 | 0.47 | 1.39 |
| | *SD* | 0.00 | 1.16 | 2.08 |
| Dose-response (parameters correlated) | *Alpha* | 0.0763 | 0.1324 | 0.2274 |
| | *Beta* | 38.49 | 51.45 | 57.96 |

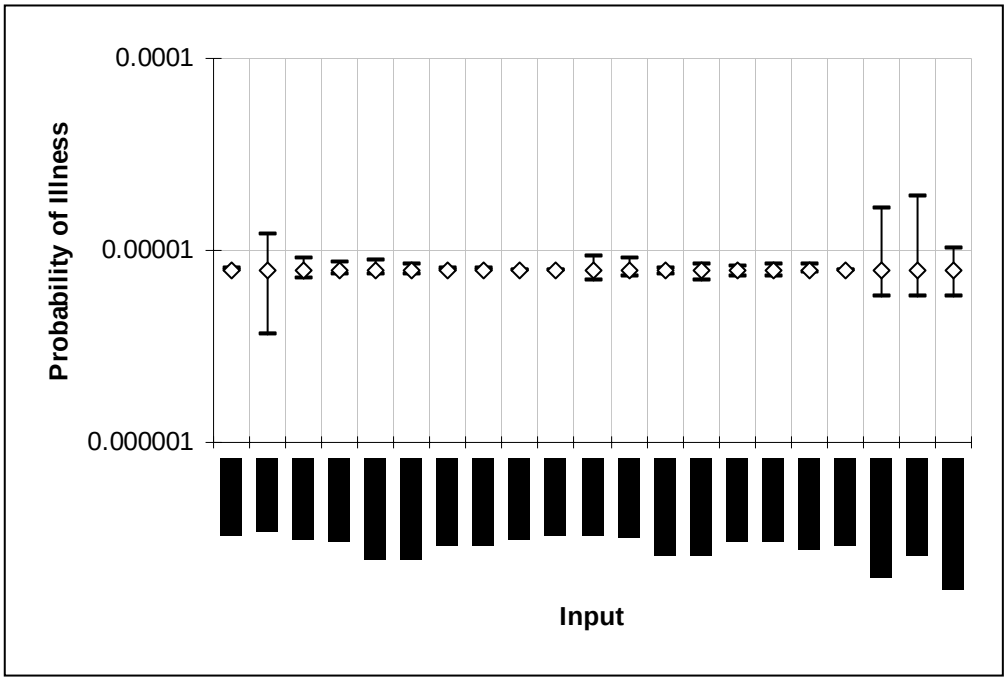



FIGURE 5-16 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR PREPARATION, SERVING, AND DOSE-RESPONSE INPUTS.

Figure 5-17 shows the effect of uncertainty in the parameters of the beta-Poisson dose-response function reported by FAO/WHO. [24]

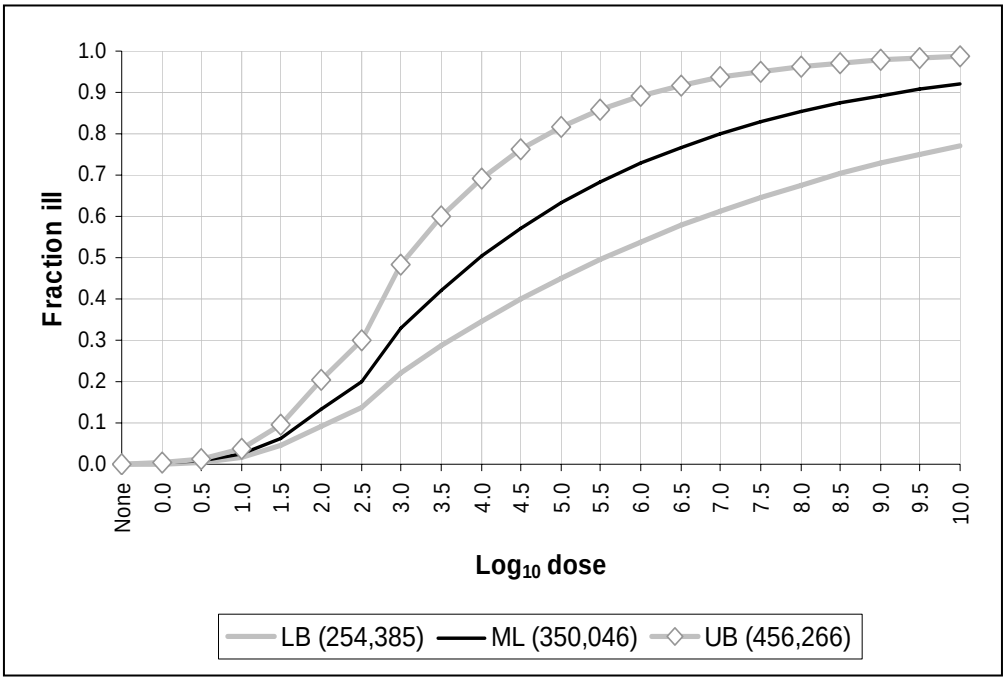



FIGURE 5-17 LOWER BOUNDS (LB), MOST LIKELY (ML), AND UPPER BOUNDS (UB) VALUES FOR THE BETA-POISSON DOSE-RESPONSE FUNCTION. [24]

The effect of this uncertainty is about 100,000 illnesses or about 29% above or below the baseline estimate.

Summary of nominal range sensitivity analysis

Figure 5-18 shows the most influential inputs identified by the nominal range sensitivity analysis. Generally, inputs related to storage temperature had the most influence. Since these inputs had relatively wide bounds, it is reasonable that they would have the most influence, given model structure, data, and assumptions.

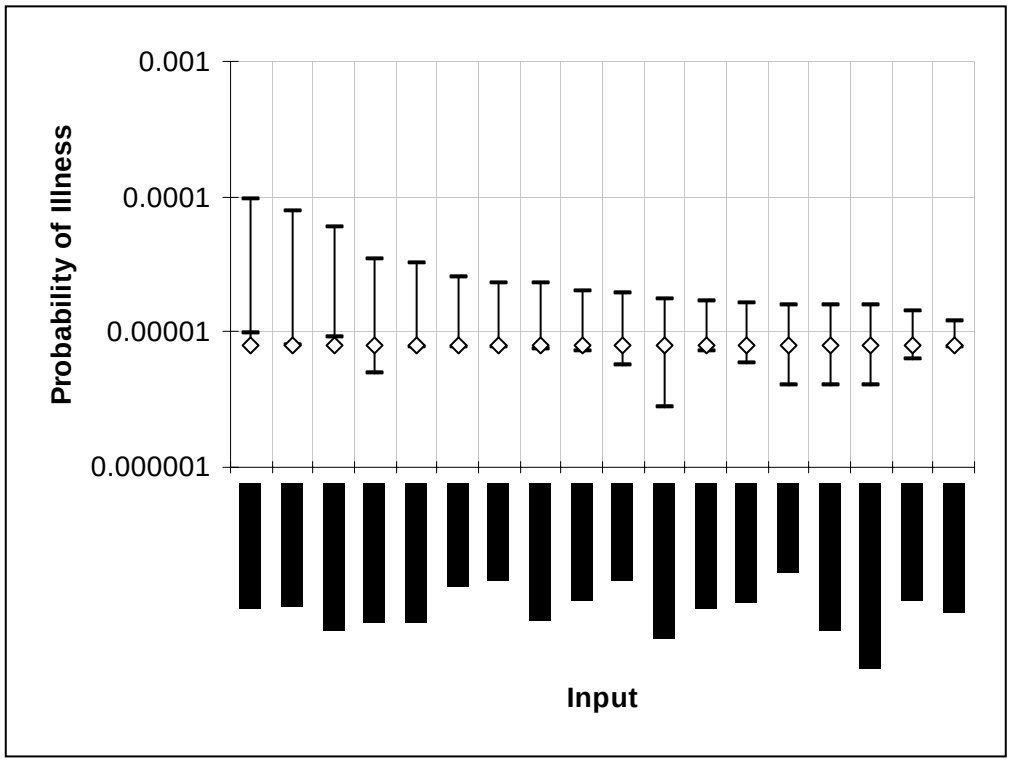



FIGURE 5-18 MOST INFLUENTIAL INPUTS IDENTIFIED BY NOMINAL RANGE SENSITIVITY ANALYSIS.

Difference in log-odds ratio

The difference in log-odds ratio is a special case of the nominal range sensitivity analysis when the model output is a probability.[109] The most influential inputs displayed in Figure 5-18 are shown below in Figure 5-19 in terms of the log-odds ratios.

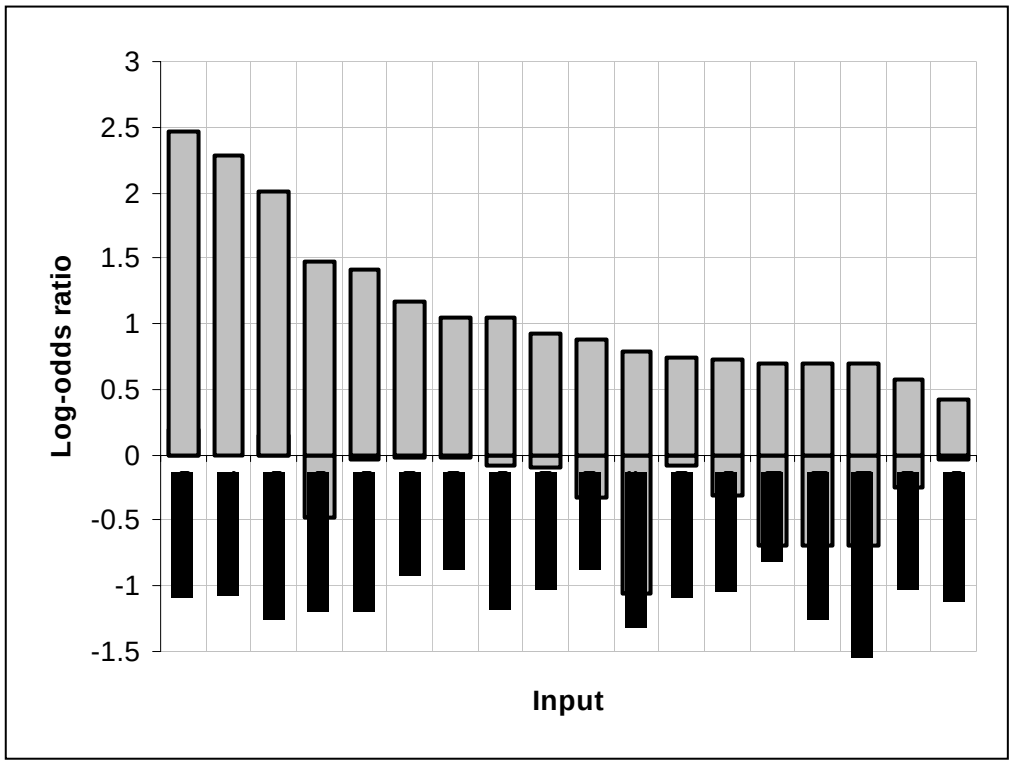


FIGURE 5-19 DIFFERENCE IN LOG-ODDS RATIO FOR MOST INFLUENTIAL INPUTS.

***Sensitivity to modeling assumptions***

As the baseline model is developed and later run, certain modeling choices influence the output. The effect of some of these modeling assumptions is discussed below.

Stochastic growth modeling versus deterministic growth modeling

The baseline uses a stochastic model in which it is assumed that the event of growth is random and that once growth commences, all bacteria in an egg grow at the same rate. The consequence of stochastic growth is that fewer cells begin to grow, but those that do can grow at faster rates than the expected values from the deterministic model. (Deterministic growth modeling is not random, but is modeled as the expected value of growth of the bacterial population, as described in Annex E). The effect of the stochastic model is that small amounts of contamination (less than 10 bacteria) in simulated eggs are less likely to allow bacterial growth sufficient to cause illness. The corresponding results are shown in Table 5-17.

TABLE 5-17 DIFFERENCES IN DETERMINISTIC VERSUS STOCHASTIC BACTERIAL GROWTH MODELING ON FREQUENCIES OF ILLNESS.

| | Deterministic | Stochastic |
|---|---|---|
| Frequency of Illness | $4.0 \times 10^{-6}$ | $2.6 \times 10^{-6}$ |
| Expected Number of Annual Illnesses | 200,000 | 130,000 |

Post-pasteurization growth of thermally injured bacteria

The baseline model assumes that SE not killed by pasteurization will be able to grow as well as any bacteria that have not been exposed to pasteurization temperatures. It is possible, however, that these bacteria may have sub-lethal injuries because of exposure to high temperatures. These

bacteria would not be expected to grow as well as wild-type bacteria. Thus, the effect of pasteurization would be greater than is modeled in the baseline.

However, the effect of pasteurization on surviving bacteria is not fully elucidated. Smelt et al.[110] demonstrated that lag phase duration increased significantly for injured bacterial cells (*Lactobacillus plantarum*). These researchers assumed that rates of growth were constant for both injured and non-injured bacteria. However, the possibility exists that the rate of growth would decrease for injured cells. Therefore, scenarios were run in which the growth rate for all bacteria after 3 and 5 $\log_{10}$ pasteurization was set to 50% of the growth rate before pasteurization. The results of this scenario were compared to the results of a baseline scenario. Figure 5-20 shows the difference in mean numbers of bacteria at each of the model steps.

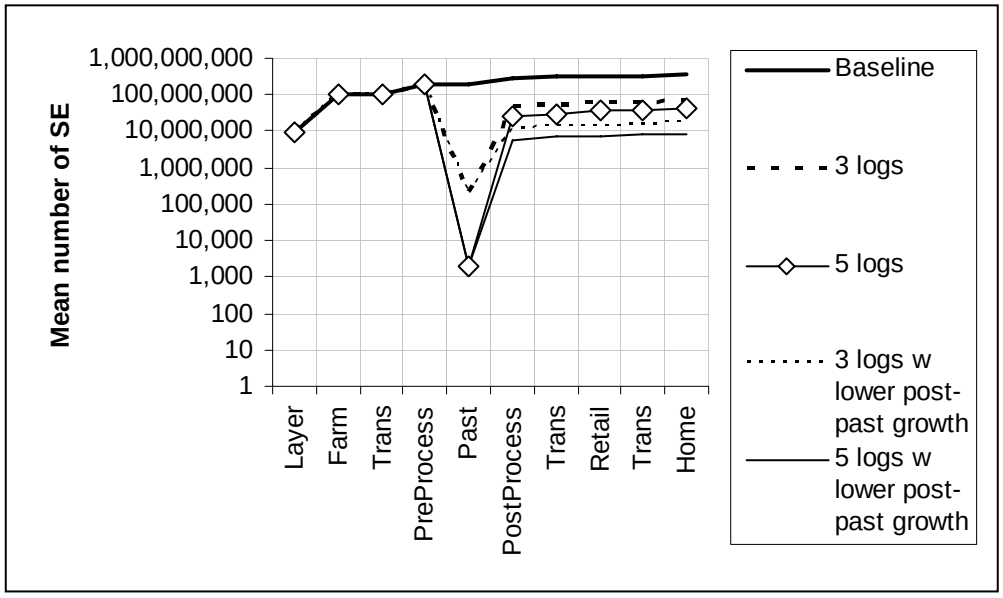



FIGURE 5-20 MEAN NUMBER OF BACTERIA IN BASELINE MODEL WITH 3 $LOG_{10}$ PASTEURIZATION USING BOTH THE NORMAL GROWTH RATE AND A POST-PASTEURIZATION GROWTH RATE OF 50% OF THE NORMAL FOR INJURED SE CELLS.

The mean number of bacteria assuming 3-$\log_{10}$ pasteurization using the 50% growth rate is about 23% of the mean number of bacteria using the normal growth rate. Assuming 3 $\log_{10}$ it is about 20% when using the 50% growth rate. The expected number of illnesses after 3 $\log_{10}$ pasteurization is about 41,000 (Table 5-4). When using the 50% post-pasteurization growth rate the expected number of illnesses drops to about 30,000 (a 26% reduction). For a 5-$\log_{10}$ reduction after pasteurization, the number of illnesses drops from 19,000 to 12,000 (a 38% reduction).

## RISK CHARACTERIZATION FOR *SALMONELLA* SPP. IN EGG PRODUCTS

### Modeling Frequency of Illness per Serving

The Exposure Assessment introduced the idea of illness per serving being calculated using a dose-response function with the number of SE per serving as its argument.

$$I_S = DR(S_2) \quad (5\text{-}4)$$

Where:

$I_S$ = the frequency of illness resulting from consuming a serving of an egg meal. This frequency can range over the [0,1] interval.
$S_2$ = The number of SE in a contaminated serving.

Estimation of the dose, $S_2$, is discussed in the Exposure Assessment. The function relating the dose to the frequency of illness (*DR*) is discussed at length in the Hazard Characterization and reproduced as equation 5-2. Given a particular dose resulting from using a contaminated egg, Equation 5-4 calculates the frequency that the dose would cause illness.

#### *Calculating Frequency of Illness per Serving in the Model*

As with the shell egg model, the same model encompasses both the Exposure Assessment and the Risk Characterization. The model is written in Visual Basic for Applications (Microsoft Corp., Redmond, WA). Inputs and outputs are stored in Excel (Microsoft Corp., Redmond, WA) worksheets. A more complete description of the model can be found in the Exposure Assessment chapter.

Each iteration of the exposure model describes a serving from the processing plant through consumption. At consumption, the model determines the number of bacteria per serving ($S_2$) and the servings per egg ($V$) are determined. These values are used in equation 5-4 above to determine the frequency of illness per serving for that iteration. These values are averaged to give the frequency of illness per serving for a given simulation.

### Generating Baseline Estimates

#### *Monte Carlo Modeling*

As with the shell egg model, the baseline model for egg products is run using Monte Carlo methods.

#### *Seed Values*

All draws from distributions are governed by a multiple-dimension array that holds a specific set of random numbers generated by Visual Basic. This array is generated each time the model is run but can be replicated each time by ensuring that the seed value is the same.

***Parallel Modeling***

The egg products model follows seven egg product types, four different levels of initial contamination, and six different types of end product use for 168 different (7 x 4 x 6) combinations on each iteration. This method oversamples low likelihood, high consequence events and makes the model more stable than the draft model sent for peer review. The draft model required 3.5 million iterations to be reasonably stable when compared with the shell egg model. This model is more stable after about 5000 iterations. The total serving combinations modeled in a simulation is 840,000 (5000 x 168).

## Anchoring the Egg Products Model

***Need for anchoring***

Initial runs of the egg products model resulted in very large estimates of human illness, which could not be supported by epidemiologic information. These large estimates were generally due to large numbers of illnesses attributed to egg white product. Because the estimates were not supported by epidemiologic data, the model was anchored to a data source that was independent of data used for model development.

***Using FSIS pasteurized egg product sampling to inform log reductions due to pasteurization***

FSIS routinely collects and cultures 100 ml samples of pasteurized egg products. Positive samples are not enumerated. Table 5-18 summarizes pasteurized egg product testing results for calendar year 2002. The number of samples collected for each product varies and thus the data representativeness may be affected. Nonetheless, the data were useful for comparing post-pasteurization *Salmonella*-positive samples to model predictions, as described below.

TABLE 5-18 RESULTS OF FSIS TESTING OF PASTEURIZED EGG PRODUCTS, 2002.

| Code | Name | Samples | + | % |
|---|---|---|---|---|
| *CAEW* | Egg Whites, Raw | 1 | 0 | 0.00% |
| *CAWE* | Whole Eggs, Raw | 2 | 0 | 0.00% |
| *CHEW* | Egg Whites (with or without added ingredients) | 352 | 3 | 0.85% |
| *CHSWE* | Whole Eggs (w/>2% salt or sugar added) | 64 | 0 | 0.00% |
| *CHSY* | Yolks (w/>2% salt or sugar added) | 282 | 1 | 0.35% |
| *CHWE* | Whole Eggs (w/<2% added ingred .besides salt/sugar) | 432 | 0 | 0.00% |
| *CHWEB* | Whole Eggs w/Added Yolks (>2% added ingred.) | 156 | 0 | 0.00% |
| *CHWEY* | Whole Eggs w/Added Yolks | 32 | 0 | 0.00% |
| *CHY* | Yolks (w/<2% added ingred. besides salt/sugar) | 29 | 0 | 0.00% |
| *CIDEW* | Spray Dried Egg Whites (w/wo added ingred.) | 125 | 0 | 0.00% |
| *CIDY* | Dried Yellow Egg Products | 159 | 3 | 1.89% |
| *CIPDEW* | Pan Dried Egg Whites | 13 | 0 | 0.00% |
| Total | | 1647 | 7 | |

There were 352 samples taken of pasteurized egg white. Of these, 3 were positive for *Salmonella*. Figure 5-21 shows the relationship of this end product testing to the flow of egg products in the risk assessment.

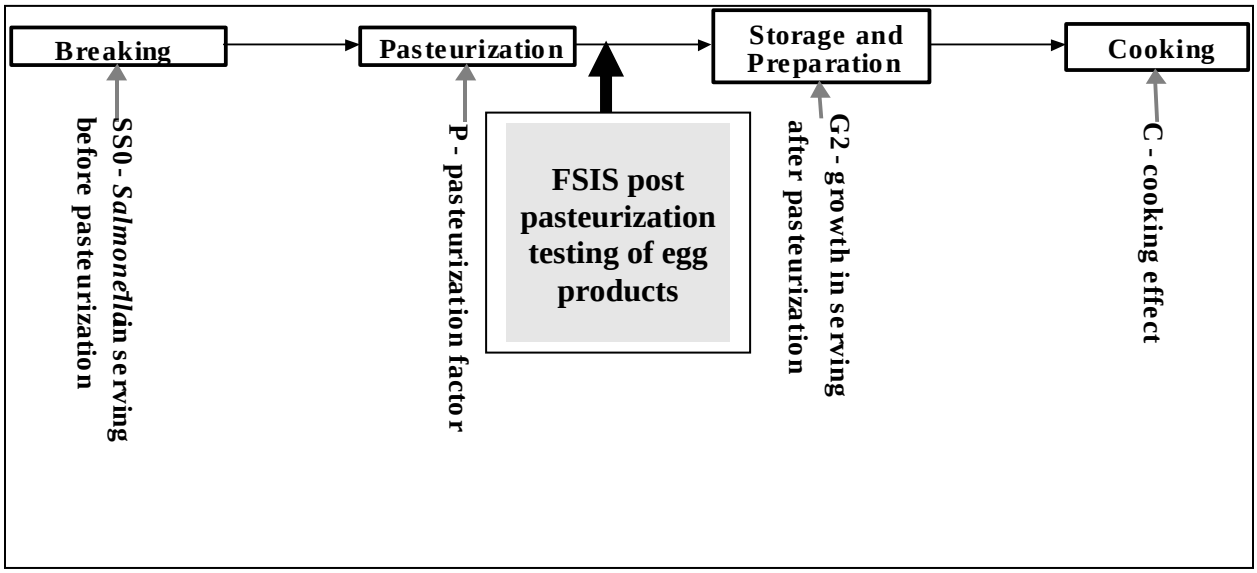



FIGURE 5-21 RELATIONSHIP OF FSIS END PRODUCT TESTING TO THE FLOW OF EGG PRODUCTS IN THE RISK ASSESSMENT.

An analysis was conducted which compared the expected number of positive *Salmonella* samples with the actual number of positive samples found during FSIS end product testing.

1. An initial number of bacteria per milliliter is assumed.
2. A given $\log_{10}$ reduction is applied.
3. The expected number of bacteria per ml is multiplied by 100 ml per sample to give the expected number of bacteria per sample.
4. The expected number of bacteria per sample is multiplied by an assumed sensitivity for the testing procedure.
5. The probability of having 0 bacteria recovered is calculated assuming a Poisson distribution.
6. The probability of recovering 0 bacteria is multiplied by the probability of the initial number of bacteria using Equation 3.23.
7. The above is repeated for all values of bacteria.

Equation 5-5 summarizes the procedure.

$$P(>0) = \sum_{i=0}^{\infty} \left(1 - e^{\left(-e^{\left[\frac{ln(B_i)-\mu}{e^{\sigma}}\right]}\right)}\right) \times \left(1 - e^{-\left(B_i \times 10^{-LR} \times 100 \times Se\right)}\right) \quad (5\text{-}5)$$

This equation is then applied for each log reduction and each sensitivity in the following tables. Table 5-19, Table 5-20, and Table 5-21 show the predicted percent positive samples for different test sensitivities and different $\log_{10}$ reductions due to pasteurization for egg white product, whole egg product, and egg yolk product respectively.

TABLE 5-19 PREDICTED PERCENT POSITIVE 100 ML SAMPLES OF EGG WHITE PRODUCT GIVEN DIFFERING PASTEURIZATION EFFECTIVENESS AND ASSUMING DIFFERENT SENSITIVITIES OF CULTURE METHOD.

| $Log_{10}$ reduction | Predicted percent positive samples Sensitivity of Testing Method | | | | |
|---|---|---|---|---|---|
| | **0.1** | **0.25** | **0.5** | **0.75** | **0.9** |
| 0 | 78.9% | 83.5% | 86.4% | 87.8% | 88.4% |
| 1 | 62.7% | 70.0% | 74.8% | 77.3% | 78.4% |
| 2 | 40.3% | 49.7% | 56.5% | 60.2% | 61.8% |
| 3 | 17.9% | 26.2% | 33.1% | 37.3% | 39.2% |
| 4 | 4.6% | 8.5% | 12.7% | 15.6% | 17.1% |
| 5 | 0.7% | 1.5% | 2.7% | 3.7% | 4.3% |
| 6 | 0.1% | 0.2% | 0.4% | 0.5% | 0.6% |
| 7 | 0.0% | 0.0% | 0.0% | 0.1% | 0.1% |
| 8 | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| 9 | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| 10 | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |

TABLE 5-20 PREDICTED PERCENT POSITIVE 100 ML SAMPLES OF WHOLE EGG PRODUCT GIVEN DIFFERING PASTEURIZATION EFFECTIVENESS AND ASSUMING DIFFERENT SENSITIVITIES OF CULTURE METHOD.

| $Log_{10}$ reduction | Predicted percent positive samples Sensitivity of Testing Method | | | | |
|---|---|---|---|---|---|
| | **0.1** | **0.25** | **0.5** | **0.75** | **0.9** |
| 0 | 80.1% | 84.2% | 86.9% | 88.2% | 88.8% |
| 1 | 65.3% | 71.9% | 76.3% | 78.6% | 79.5% |
| 2 | 44.6% | 53.4% | 59.6% | 63.0% | 64.5% |
| 3 | 22.3% | 30.8% | 37.7% | 41.7% | 43.5% |
| 4 | 6.9% | 11.8% | 16.6% | 19.8% | 21.4% |
| 5 | 1.2% | 2.6% | 4.3% | 5.7% | 6.4% |
| 6 | 0.1% | 0.3% | 0.6% | 0.9% | 1.1% |
| 7 | 0.0% | 0.0% | 0.1% | 0.1% | 0.1% |
| 8 | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| 9 | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| 10 | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |

TABLE 5-21 PREDICTED PERCENT POSITIVE 100 ML SAMPLES OF EGG YOLK PRODUCT GIVEN DIFFERING PASTEURIZATION EFFECTIVENESS AND ASSUMING 100% SENSITIVITY OF CULTURE METHOD.

| $Log_{10}$ reduction | Predicted percent positive samples Sensitivity of Testing Method | | | | |
|---|---|---|---|---|---|
| | 0.1 | 0.25 | 0.5 | 0.75 | 0.9 |
| 0 | 72.3% | 77.0% | 80.0% | 81.7% | 82.4% |
| 1 | 57.5% | 63.9% | 68.3% | 70.7% | 71.7% |
| 2 | 39.1% | 46.7% | 52.2% | 55.3% | 56.7% |
| 3 | 20.7% | 27.7% | 33.3% | 36.7% | 38.2% |
| 4 | 7.5% | 11.9% | 16.0% | 18.7% | 20.0% |
| 5 | 1.7% | 3.3% | 5.1% | 6.4% | 7.1% |
| 6 | 0.2% | 0.5% | 1.0% | 1.3% | 1.6% |
| 7 | 0.0% | 0.1% | 0.1% | 0.2% | 0.2% |
| 8 | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| 9 | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| 10 | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |

Table 5-19 shows that assuming a 3-$log_{10}$ reduction due to pasteurization and a 90% sensitivity for the testing procedure (FSIS requires the sensitivity of testing procedures for *Salmonella* in egg products to be at least 97%), then one would expect that 39.2% of all end product testing samples would be positive. Thus, the results of post-pasteurization testing by FSIS are inconsistent with modeled $log_{10}$ reductions due to pasteurization of less than 5. Table 5-22 summarizes the expected $log_{10}$ reductions for current time and temperature requirements that were given in the exposure assessment. The only product for which the expected $log_{10}$ reduction is below five is egg white. Therefore, the baseline model estimates are simulated using an expected $log_{10}$ reduction due to pasteurization of 5 for egg white only.

TABLE 5-22 EXPECTED $LOG_{10}$ REDUCTIONS FOR DIFFERENT EGG PRODUCTS.

| Product | Expected $Log_{10}$ Reduction | $Log_{10}$ Reduction Modeled for Baseline |
|---|---|---|
| White | –3.3 | –5.0 |
| Whole | –5.9 | –5.9 |
| Yolk | –5.5 | –5.5 |
| Whole 10% salt | –6.0 | –6.0 |
| Whole 10% sugar | –42.0 | –42.0 |
| Yolk 10% salt | –7.2 | –7.2 |
| Yolk 10% sugar | –12.4 | –12.4 |

## Answering Risk Management Questions

***Significant changes to model output after peer and public review***

The liquid egg products model has undergone significant changes after both peer review and public comment. Table 5-23 shows the original estimates for human illnesses after 3.5 million iterations of the draft model.

TABLE 5-23 BASELINE NUMBER OF ILLNESSES ASSOCIATED WITH EGG PRODUCT TYPES IN DRAFT MODEL.

| Egg Type | Number ill |
|---|---|
| White | 22,917 |
| Whole | 18,019 |
| Yolk | 5,672 |
| Whole 10% salt | 3,707 |
| Whole 10% sugar | 0 |
| Yolk 10% salt | 127 |
| Yolk 10% sugar | 0 |
| Total | 50,443 |

The following tables show the effect of making changes to the model in response to peer review and public comments.

- The model was made more stable by oversampling low likelihood, high consequence pathways. This resulted in a slightly lower estimate of illnesses when compared with draft model runs of 500,000 iterations per product, but a higher estimate with the draft model run of 100,000 iterations per product. Table 5-24 shows the estimated number of illnesses in the stabilized model with 5,000 iterations.

TABLE 5-24 BASELINE NUMBER OF ILLNESSES ASSOCIATED WITH EGG PRODUCT TYPES IN DRAFT MODEL AFTER STABILIZING.

| Egg Type | Number ill |
|---|---|
| White | 21,374 |
| Whole | 14,293 |
| Yolk | 5,743 |
| Whole 10% salt | 3,303 |
| Whole 10% sugar | 0 |
| Yolk 10% salt | 90 |
| Yolk 10% sugar | 0 |
| Total | 44,803 |

- An assumption was made in the draft model that recovery of a single colony-forming unit in the baseline survey should represent recovery of three bacteria, each of which would be capable of causing illness. This had the effect of tripling the number of illnesses that would otherwise have been estimated. It was noted in

review that there was not sufficient data to warrant modeling this multiplication factor. Furthermore, the information from which the dose-response function is derived assumes that one colony-forming unit represents one bacterium. Therefore, the multiplication factor was inconsistent with the methodology used to determine the dose-response function. Table 5-25 shows the new estimates for illnesses after removing the multiplication factor.

TABLE 5-25 BASELINE NUMBER OF ILLNESSES ASSOCIATED WITH EGG PRODUCT TYPES IN DRAFT MODEL AFTER STABILIZING AND REMOVING MULTIPLICATION FACTOR FOR CLUSTERING.

| Egg Type | Number ill |
|---|---|
| White | 7,125 |
| Whole | 4,764 |
| Yolk | 1,914 |
| Whole 10% salt | 1,101 |
| Whole 10% sugar | 0 |
| Yolk 10% salt | 30 |
| Yolk 10% sugar | 0 |
| Total | 14,934 |

- The CDC noted that there was nearly a three times overestimate in the number of human illnesses estimated in the shell egg model compared to epidemiologic data. The results from the shell egg model were anchored to the epidemiologic data by applying a multiplier of 0.37 to the estimated number of human illnesses. Thus, CDC believed it appropriate to apply a similar multiplier to the estimate provided by the egg products model. Multiplying the values in Table 5-25 by 0.37 gives the values shown in Table 5-26.

TABLE 5-26 BASELINE NUMBER OF ILLNESSES ASSOCIATED WITH EGG PRODUCT TYPES IN DRAFT MODEL AFTER STABILIZING, REMOVING MULTIPLICATION FACTOR FOR CLUSTERING AND APPLYING AN OVERESTIMATION ADJUSTMENT.

| Egg Type | Number ill |
|---|---|
| White | 2,636 |
| Whole | 1,763 |
| Yolk | 708 |
| Whole 10% salt | 407 |
| Whole 10% sugar | 0 |
| Yolk 10% salt | 11 |
| Yolk 10% sugar | 0 |
| Total | 5,526 |

- Additionally, there has been increased concern about whether the log reduction values modeled truly represent industry practices. Consequently, the effect of different combinations of log reduction values has been modeled and is presented later in this chapter. Baseline estimates, however, are assumed consistent with the assumptions and values presented in Table 5-26.

This section presents baseline estimates after making changes in the liquid egg products model as described above and presented in Table 5-26.

***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)?***

Illnesses per serving for egg products (baseline)

The baseline model provides estimates for seven different types of egg products: white, whole, yolk, whole with 10% added salt, whole with 10% added sugar, yolk with 10% added salt, and yolk with 10% added sugar. These seven products are used to represent all possible types of egg products. Table 5-27 shows the baseline model results for the seven different types of egg products. Yolk has the highest frequency of illness per serving at $3.5 \times 10^{-7}$. Whole egg product has a frequency of illness per serving of $8.2 \times 10^{-8}$. White has a frequency of illness of $3.3 \times 10^{-7}$. Products with added ingredients tended to have lower estimates. Whole egg product with salt had a frequency of illness per serving of $6.8 \times 10^{-8}$ and yolk product with salt had a frequency of $7.6 \times 10^{-9}$. Sugar added product had even lower frequencies of illness. Whole egg with added sugar and yolk with added sugar a frequency of illness per serving of less than $10^{-12}$. The reciprocals of these values give the servings per illness. Thus, there are about than 3.0 million servings of white per illness, about than 12 million servings of whole egg product per illness and about 2.9 million servings of yolk product per illness. Whole egg product with added salt takes more than 14 million servings per illness while yolk product with salt takes more than 132 million.

TABLE 5-27 BASELINE MODEL RESULTS FOR SEVEN EGG PRODUCT TYPES.

| | Baseline Model Results | | | | | | |
|---|---|---|---|---|---|---|---|
| Product | White | Whole | Yolk | Whole 10% salt | Whole 10% sugar | Yolk 10% salt | Yolk 10% sugar |
| Frequency of illness | $3.3 \times 10^{-7}$ | $8.2 \times 10^{-8}$ | $3.5 \times 10^{-7}$ | $6.8 \times 10^{-8}$ | $<10^{-12}$ | $7.6 \times 10^{-9}$ | $<10^{-12}$ |

Calculating baseline annual number of illnesses

Calculating the total illnesses for a given year in the U.S. is accomplished by multiplying the frequency of illness per serving by the total number of servings consumed. Table 3-31 in the exposure assessment chapter gives the number of eating occasions for two days from the 1994-1996, 1998 Continuing Survey of Food Intakes by Individuals (CSFII). Table 5-28 reproduces the first part of the table and shows the total number of eating occasions observed for two days.

TABLE 5-28 TOTAL NUMBER OF SERVINGS FOR EGG PRODUCTS FOR 2 DAYS FROM CSFII 1994-1996, 1998.

| | All Egg Products | | |
|---|---|---|---|
| Meal type | Main meal | Beverage | Ingredient |
| Consumption average (g/p/d) | 77.8 | 182.5 | 36.0 |
| Std Dev (g) | 49.0 | 75.1 | 71.0 |
| Eating occasions | 32,345,212 | 286,428 | 226,268,156 |

The total number of eating occasions is multiplied by 182.5 (365/2) to give the number of eating occasions for a year. This is estimated to be about 47 billion per year. The fraction of production represented by each egg product type is also shown in a chart in the exposure assessment chapter. These fractions are shown in Table 5-29 and Figure 5-22.

TABLE 5-29 FRACTION OF SERVINGS REPRESENTED BY EACH EGG PRODUCT TYPE.

| Egg Product | Fraction |
|---|---|
| White | 0.169 |
| Whole | 0.456 |
| Yolk | 0.043 |
| Whole 10% salt | 0.127 |
| Whole 10% sugar | 0.127 |
| Yolk 10% salt | 0.031 |
| Yolk 10% sugar | 0.047 |

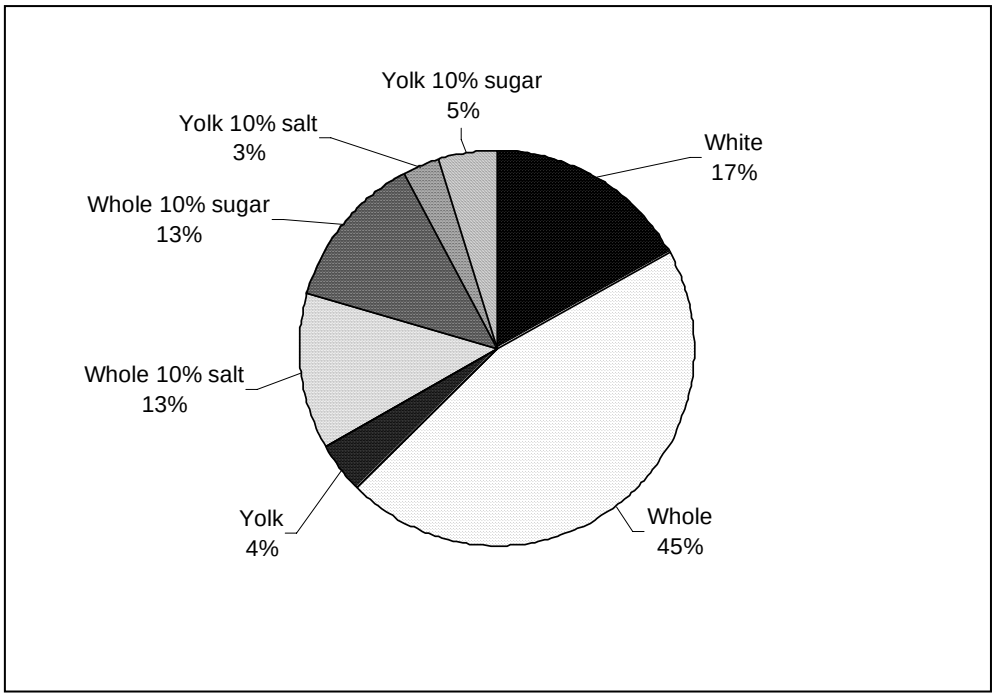



FIGURE 5-22 FRACTION OF SERVINGS REPRESENTED BY EACH EGG PRODUCT TYPE. ESTIMATES WERE BASED ON USDA-NASS DATA[66] AND ASSUMED FRACTIONS OF DIFFERENT BLENDS.[79]

Illnesses for each product type are calculated by multiplying the frequency of illness by the number of servings per year for that product type.

$$Illnesses_{product} = I_S \times Servings \times F(product) \quad (5\text{-}6)$$

Where:

*Illnesses*$_{product}$ = the illnesses resulting from consuming servings made with a particular egg product
$I_S$ = the frequency of illness resulting from consuming a serving of an egg meal.
*Servings* = the total servings of egg products
*F*(product) = the fraction of servings for a particular egg product

**Precision of Answers for Egg Products Model**

Numbers of human illnesses in the egg products model are generally reported with more significant digits than in the shell egg model. This is because the differences between scenarios are often small. The appearance of more significant digits should not be taken as a more accurate portrayal of risk.

Table 5-30 shows the number of illnesses associated with each of the egg product types. Note that these are the values after adjusting the draft model in response to peer review and public comments and were first given in Table 5-26.

TABLE 5-30 BASELINE NUMBER OF ILLNESSES ASSOCIATED WITH EGG PRODUCT TYPES.

| Egg Type | Number ill |
|---|---|
| White | 2,636 |
| Whole | 1,763 |
| Yolk | 708 |
| Whole 10% salt | 407 |
| Whole 10% sugar | 0 |
| Yolk 10% salt | 11 |
| Yolk 10% sugar | 0 |
| Total | 5,526 |

Annual number of illnesses for different pasteurization scenarios

The model was run with log reductions ranging from 3 $\log_{10}$ to 12 $\log_{10}$ in 0.1 $\log_{10}$ intervals. Table 5-31 shows the number of illnesses predicted for all egg products when they are pasteurized at various fixed levels. It can be used to estimate the effect of different performance standards for pasteurization.

TABLE 5-31 ESTIMATED ILLNESSES FOR FIXED $LOG_{10}$ REDUCTIONS AT THE PASTEURIZATION STEP FOR ALL EGG PRODUCTS.

| Illnesses associated with each of the following log reductions and product types | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Log reductions** | **White** | **Whole** | **Yolk** | **Whole 10% salt** | **Whole 10% sugar** | **Yolk 10% salt** | **Yolk 10% sugar** |
| -3 | 140,551 | 545,757 | 59,613 | 159,632 | 166,766 | 41,550 | 63,462 |
| -3.1 | 118,776 | 471,441 | 52,119 | 137,116 | 143,445 | 36,538 | 55,494 |
| -3.2 | 100,842 | 405,617 | 45,321 | 117,466 | 122,719 | 31,878 | 48,516 |
| -3.3 | 84,526 | 346,668 | 39,292 | 99,542 | 105,566 | 27,843 | 41,999 |
| -3.4 | 71,185 | 296,539 | 33,977 | 84,342 | 89,512 | 24,065 | 36,277 |
| -3.5 | 59,541 | 251,449 | 29,191 | 71,735 | 76,118 | 20,812 | 31,227 |
| -3.6 | 49,258 | 211,295 | 25,016 | 59,854 | 64,033 | 17,943 | 26,785 |
| -3.7 | 40,719 | 178,022 | 21,483 | 50,323 | 54,212 | 15,337 | 22,904 |
| -3.8 | 33,383 | 149,028 | 18,294 | 41,598 | 45,016 | 13,121 | 19,447 |
| -3.9 | 27,531 | 124,780 | 15,538 | 34,608 | 37,660 | 11,089 | 16,527 |
| -4.0 | 22,656 | 103,794 | 13,138 | 28,781 | 31,005 | 9,388 | 13,901 |
| -4.1 | 18,443 | 86,073 | 11,081 | 23,911 | 25,757 | 7,938 | 11,716 |
| -4.2 | 15,072 | 71,015 | 9,304 | 19,710 | 21,301 | 6,674 | 9,835 |
| -4.3 | 12,170 | 58,128 | 7,773 | 16,192 | 17,500 | 5,606 | 8,228 |
| -4.4 | 9,821 | 47,555 | 6,469 | 13,307 | 14,322 | 4,670 | 6,863 |
| -4.5 | 7,893 | 38,673 | 5,379 | 10,801 | 11,715 | 3,884 | 5,718 |
| -4.6 | 6,418 | 31,441 | 4,444 | 8,850 | 9,526 | 3,217 | 4,699 |
| -4.7 | 5,154 | 25,309 | 3,674 | 7,190 | 7,797 | 2,673 | 3,870 |
| -4.8 | 4,108 | 20,479 | 3,024 | 5,864 | 6,308 | 2,196 | 3,168 |
| -4.9 | 3,276 | 16,562 | 2,473 | 4,750 | 5,060 | 1,800 | 2,605 |
| -5.0 | 2,636 | 13,229 | 2,023 | 3,851 | 4,072 | 1,462 | 2,140 |
| -5.1 | 2,106 | 10,541 | 1,648 | 3,102 | 3,291 | 1,191 | 1,728 |
| -5.2 | 1,667 | 8,486 | 1,340 | 2,497 | 2,620 | 969 | 1,414 |
| -5.3 | 1,327 | 6,792 | 1,080 | 2,007 | 2,064 | 782 | 1,152 |
| -5.4 | 1,062 | 5,415 | 871 | 1,610 | 1,676 | 636 | 922 |
| -5.5 | 845 | 4,336 | 708 | 1,240 | 1,333 | 517 | 752 |
| -5.6 | 667 | 3,460 | 570 | 996 | 1,080 | 418 | 610 |
| -5.7 | 532 | 2,775 | 456 | 800 | 867 | 334 | 490 |
| -5.8 | 424 | 2,209 | 382 | 640 | 686 | 264 | 392 |
| -5.9 | 339 | 1,763 | 307 | 510 | 526 | 213 | 313 |
| -6.0 | 270 | 1,407 | 246 | 407 | 419 | 170 | 252 |
| -6.1 | 214 | 1,112 | 197 | 324 | 335 | 136 | 203 |
| -6.2 | 169 | 881 | 156 | 258 | 268 | 107 | 160 |
| -6.3 | 135 | 703 | 126 | 207 | 213 | 86 | 127 |
| -6.4 | 107 | 563 | 99 | 166 | 167 | 68 | 102 |
| -6.5 | 85 | 447 | 79 | 131 | 134 | 54 | 81 |
| -6.6 | 68 | 357 | 63 | 105 | 107 | 43 | 65 |
| -6.7 | 54 | 280 | 50 | 82 | 85 | 34 | 52 |
| -6.8 | 43 | 222 | 39 | 65 | 68 | 27 | 41 |
| -6.9 | 34 | 177 | 31 | 52 | 54 | 22 | 33 |
| -7.0 | 27 | 140 | 25 | 41 | 43 | 17 | 26 |
| -7.1 | 21 | 112 | 20 | 33 | 34 | 14 | 21 |
| -7.2 | 17 | 88 | 16 | 26 | 27 | 11 | 16 |
| -7.3 | 14 | 70 | 13 | 21 | 21 | 9 | 13 |
| -7.4 | 11 | 55 | 10 | 16 | 17 | 7 | 11 |
| -7.5 | 9 | 44 | 8 | 13 | 14 | 5 | 8 |
| -7.6 | 7 | 35 | 6 | 10 | 11 | 4 | 7 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| -7.7 | 5 | 28 | 5 | 8 | 9 | 3 | 5 |
| -7.8 | 4 | 22 | 4 | 6 | 7 | 3 | 4 |
| -7.9 | 3 | 18 | 3 | 5 | 5 | 2 | 3 |
| -8.0 | 3 | 14 | 2 | 4 | 4 | 2 | 3 |
| -8.1 | 2 | 11 | 2 | 3 | 3 | 1 | 2 |
| -8.2 | 2 | 9 | 2 | 3 | 3 | 1 | 2 |
| -8.3 | 1 | 7 | 1 | 2 | 2 | 1 | 1 |
| -8.4 | 1 | 6 | 1 | 2 | 2 | 1 | 1 |
| -8.5 | 1 | 4 | 1 | 1 | 1 | 1 | 1 |
| -8.6 | 1 | 4 | 1 | 1 | 1 | 0 | 1 |
| -8.7 | 1 | 3 | 0 | 1 | 1 | 0 | 1 |
| -8.8 | 0 | 2 | 0 | 1 | 1 | 0 | 0 |
| -8.9 | 0 | 2 | 0 | 1 | 1 | 0 | 0 |
| -9.0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| -9.1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| -9.2 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| -9.3 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| -9.4 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| -9.5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -9.6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -9.7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -9.8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -9.9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -10.0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -10.1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -10.2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -10.3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -10.4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -10.5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -10.6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -10.7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -10.8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -10.9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -11.0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -11.1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -11.2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -11.3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -11.4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -11.5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -11.6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -11.7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -11.8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| -11.9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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

Pasteurization of egg products is meant to reduce the number of *Salmonella* by a specified amount. As with shell eggs, the amount of pasteurization is given in $\log_{10}$ reduction. A 1-$\log_{10}$

reduction means that the amount of contamination is reduced by 90%; a 2-$\log_{10}$ reduction corresponds to a 99% reduction in contamination, and a 3-$\log_{10}$ reduction to 99.9%.

Graphically, these $\log_{10}$ reductions due to pasteurization can be represented by shifting the distribution of the incoming concentration to the left. The following figures show the effect of pasteurization for egg whites, whole egg product, and egg yolk under the baseline scenario. For these figures, the effect of pasteurization is rounded to the nearest whole number. Thus, pasteurization of egg whites is shown as a 5-$\log_{10}$ reduction, pasteurization of whole egg product as a 6-$\log_{10}$ reduction, and pasteurization of egg yolk as a 5-$\log_{10}$ reduction. Figure 5-23 compares the pre- and post-pasteurization levels of *Salmonella* in a liter of liquid egg white product given a 5-$\log_{10}$ reduction due to pasteurization.

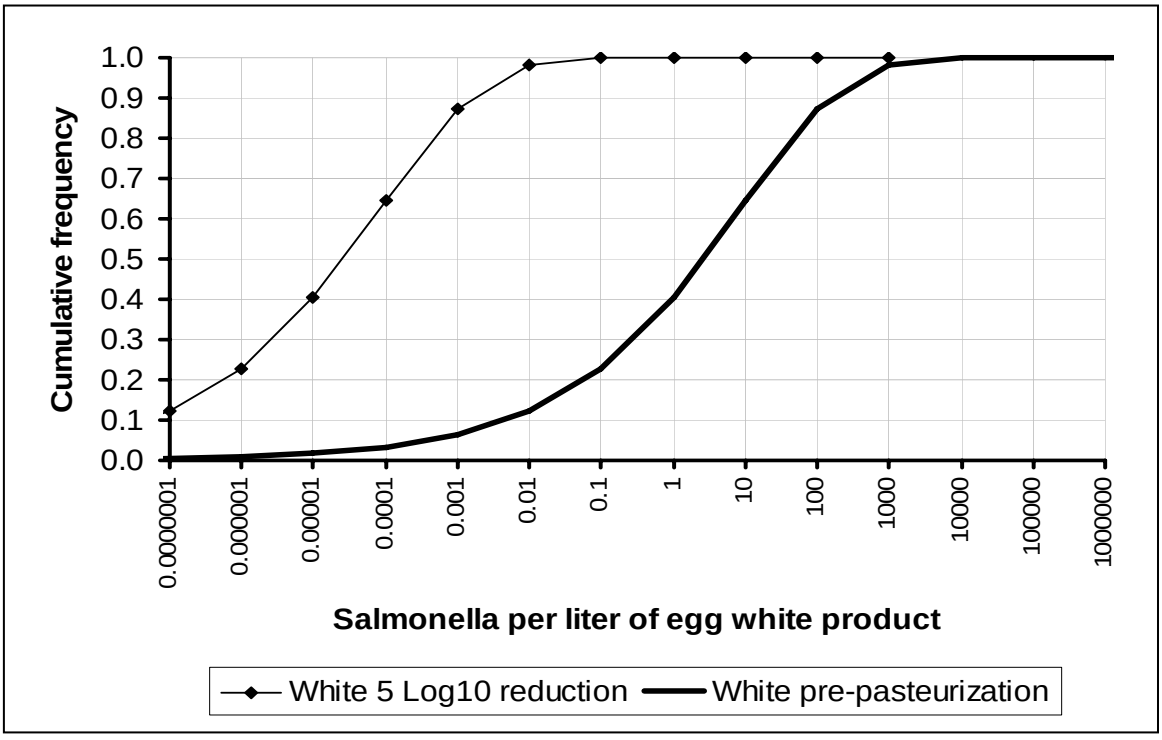



FIGURE 5-23 COMPARISON OF PRE- AND POST-PASTEURIZATION LEVELS OF *SALMONELLA* IN A LITER OF LIQUID EGG WHITE PRODUCT GIVEN 5-$\log_{10}$ REDUCTION DUE TO PASTEURIZATION.

The x-axis shows the number of *Salmonella* per liter. Given a 5-$\log_{10}$ reduction due to pasteurization, Figure 5-23 shows that nearly 100% of liters of egg white product would have 1 or less *Salmonella*. Figure 5-24 shows the effect of a 6-$\log_{10}$ reduction on the number of *Salmonella* in a liter of whole egg product. Given a 6-$\log_{10}$ reduction, nearly 100% of liters would have an expected number of *Salmonella* of 1 or less. Figure 5-25 shows the effect of a 5-$\log_{10}$ reduction in egg yolk product.

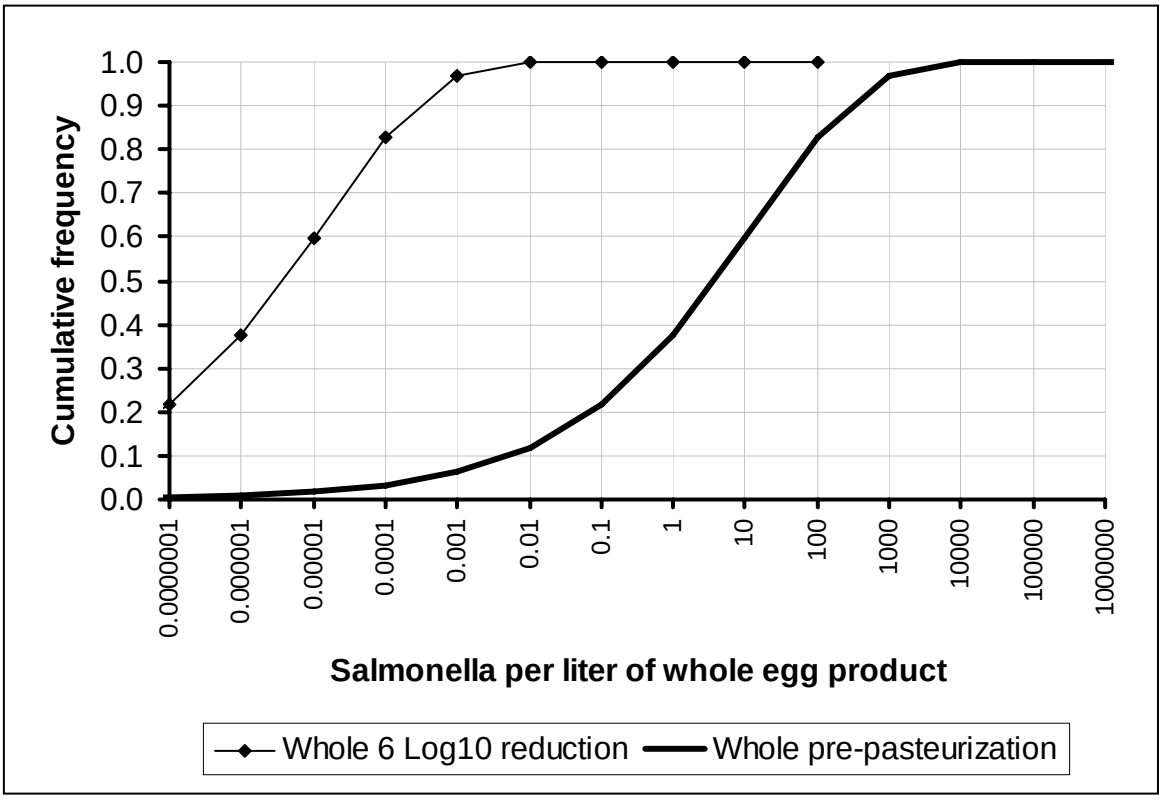



FIGURE 5-24 COMPARISON OF PRE- AND POST-PASTEURIZATION LEVELS OF *SALMONELLA* IN A LITER OF LIQUID WHOLE EGG PRODUCT GIVEN A 6-$LOG_{10}$ REDUCTION DUE TO PASTEURIZATION.

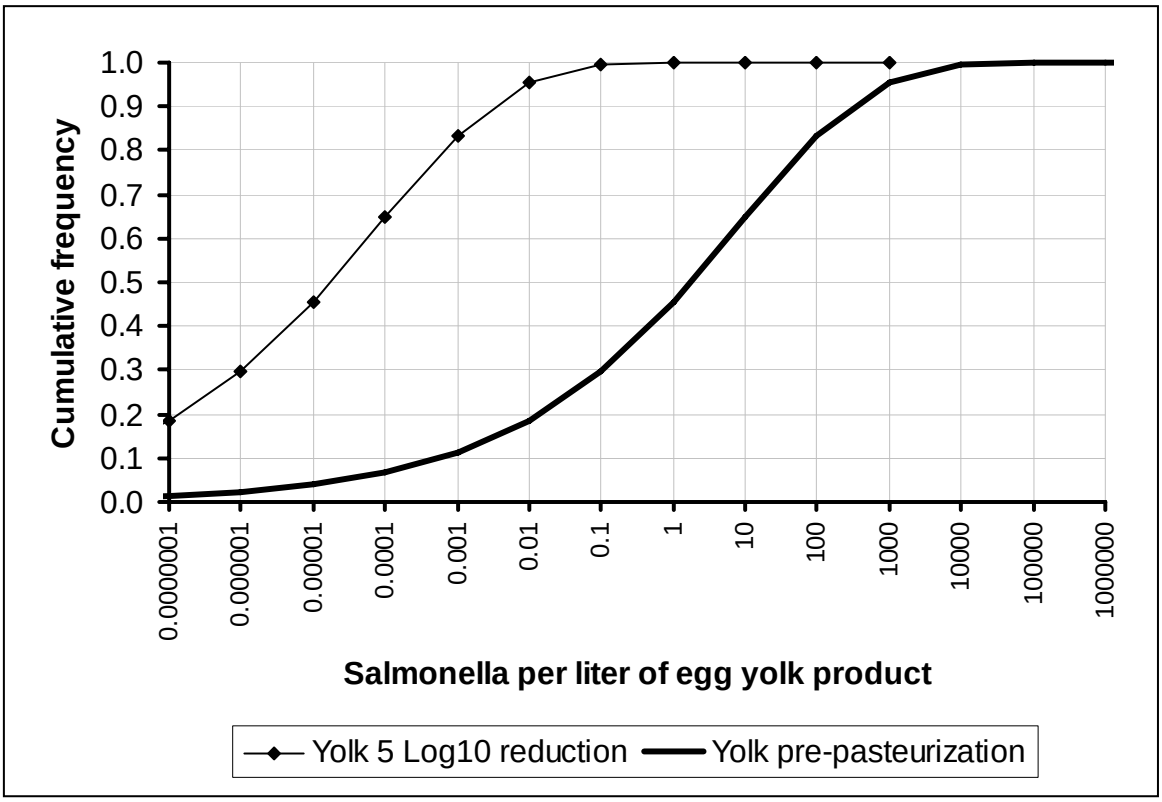



FIGURE 5-25 COMPARISON OF PRE- AND POST-PASTEURIZATION LEVELS OF *SALMONELLA* IN A LITER OF LIQUID EGG YOLK PRODUCT GIVEN A 5-$LOG_{10}$ REDUCTION DUE TO PASTEURIZATION.

### Stability of the Baseline Model

Results from the baseline model are generated from 5,000 iterations using a particular seed value. This ensures identical draws from distributions and that the only change is in the specific mitigation modeled. The number of iterations was set at 5,000 because this number of iterations gives about the same stability as 50,000 iterations of the shell egg baseline model. The standard error is less than 6% of the mean value. Figure 5-26 shows how the model becomes stable relatively quickly. After each iteration, the estimated number of illnesses is computed. Thus, the graph shows what the model estimated assuming anywhere from 1 to 30,000 iterations were conducted.

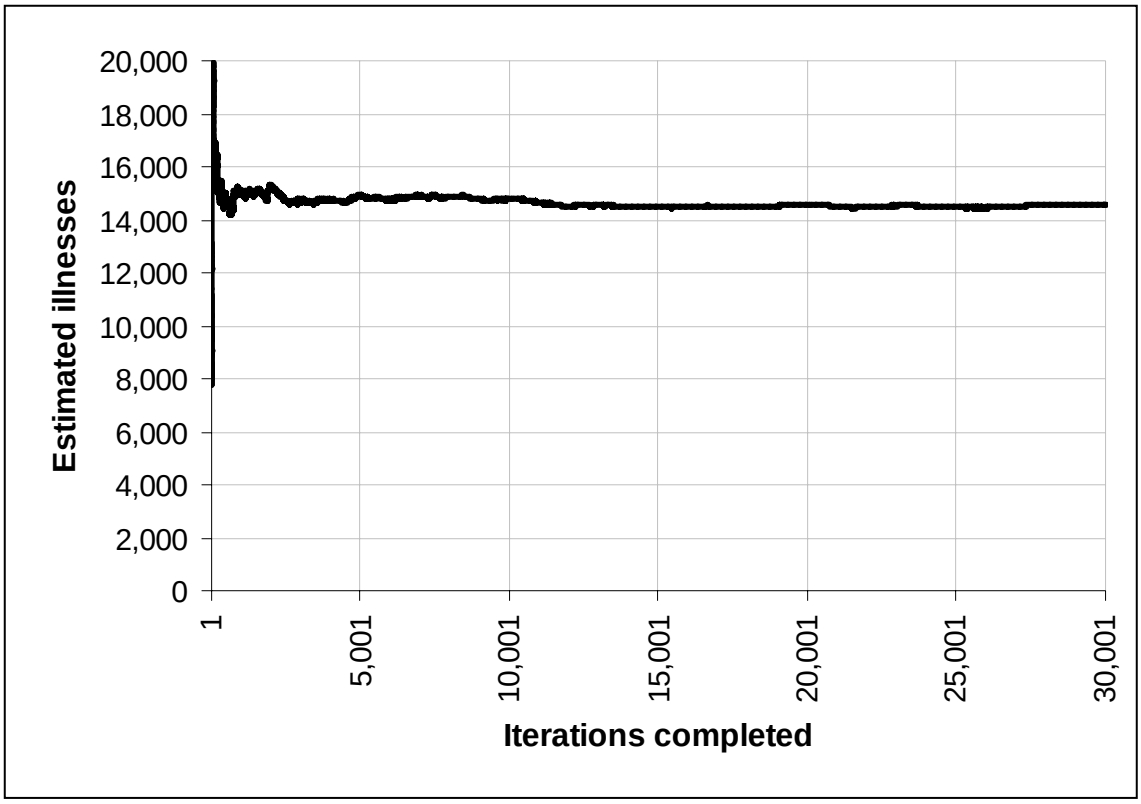



FIGURE 5-26 ILLNESSES ESTIMATED FROM BASELINE MODEL BASED ON 1 TO 30,000 ITERATIONS.

## Sensitivity Analysis

***Types of sensitivity analysis***

Three types of sensitivity analysis are conducted for the model. First, a correlation analysis of the baseline model identifies those variables that are most influential in the frequency of human illness. Second, a nominal range sensitivity analysis identifies the most influential parameters. Third, a set of outputs is generated that identifies sensitivity of the model to different modeling choices. Sensitivity analysis is based on the unanchored baseline model.

***Correlation analysis of the baseline scenario***

Unlike the shell egg model, Spearman rank order correlations were not conducted due to the difficulty of ordering the large data sets in Excel. Rather, standard correlation coefficients using the Excel function Correl(input array, output array) were calculated for different inputs and intermediate outputs with the probability of negative servings (servings with no *Salmonella*) or of human illness for servings made with white, whole egg, or yolk. Table 5-32 shows the correlation of the probability of a negative serving before pasteurization with various intermediate outputs. The table shows that the probability of a negative serving is negatively correlated with the concentration of bacteria in the raw product. In other words, lower concentrations in raw product are more likely to be associated with negative servings. At first glance, it might be expected that the correlation should be more pronounced. Because most raw

product have generally low concentrations of bacteria and servings sizes are relatively small, a less pronounced correlation makes sense.

TABLE 5-32. CORRELATION OF THE PROBABILITY OF A NEGATIVE SERVING BEFORE PASTEURIZATION WITH VARIOUS INTERMEDIATE OUTPUTS.

| Parameter | White | Whole | Yolk |
|---|---|---|---|
| *BegBacConc* | -0.289 | -0.517 | -0.410 |
| *ServSize* | -0.258 | -0.228 | -0.196 |
| *BacServMean* | -0.178 | -0.516 | -0.313 |

Table 5-33 shows the correlation of the probability of a negative serving just at the point of consumption with various intermediate outputs.

TABLE 5-33 CORRELATION OF THE PROBABILITY OF A NEGATIVE SERVING AT CONSUMPTION WITH VARIOUS INTERMEDIATE OUTPUTS.

| Parameter | White | Whole | Yolk |
|---|---|---|---|
| *BegBacConc* | -0.017 | -0.031 | -0.021 |
| *ServSize* | -0.034 | -0.021 | -0.020 |
| *BacServMean* | -0.018 | -0.038 | -0.023 |
| *NegServ* | 0.082 | 0.089 | 0.087 |
| *InitBac* | -0.018 | -0.040 | -0.022 |
| *RefTemp* | -0.001 | 0.003 | 0.003 |
| *RefDays* | 0.006 | 0.008 | 0.009 |
| *RefBac* | -0.018 | -0.015 | -0.014 |
| *RoomTempFlag* | -0.002 | 0.002 | 0.002 |
| *RoomTemp* | -0.003 | 0.001 | 0.003 |
| *RoomDays* | -0.008 | -0.005 | -0.007 |
| *RoomBac* | -0.018 | -0.040 | -0.022 |
| *AttFac* | 0.150 | 0.068 | 0.073 |
| *BacServFinal* | -0.362 | -0.358 | -0.573 |

Although there was some moderate correlation between the beginning bacterial concentration (*BegBacConc*) and the probability of a negative serving at pasteurization, there is no correlation between *BegBacConc* and the probability of a negative serving at consumption. Table 5-34 shows the correlations between the listed intermediate outputs and the frequency of human illness from the draft baseline model with 100,000 iterations.

TABLE 5-34 CORRELATION OF HUMAN ILLNESS WITH VARIOUS INTERMEDIATE OUTPUTS.

| Parameter | White | Whole | Yolk |
|---|---|---|---|
| *BegBacConc* | 0.035 | 0.035 | 0.028 |
| *ServSize* | 0.010 | 0.010 | 0.008 |
| *BacServMean* | 0.035 | 0.035 | 0.029 |
| *NegServ* | -0.070 | -0.070 | -0.061 |
| *InitBac* | 0.048 | 0.048 | 0.034 |
| *RefTemp* | -0.003 | -0.003 | -0.004 |
| *RefDays* | -0.007 | -0.007 | -0.007 |
| *RefBac* | 0.021 | 0.021 | 0.022 |
| *RoomTempFlag* | -0.002 | -0.002 | -0.002 |
| *RoomTemp* | -0.003 | -0.003 | -0.003 |
| *RoomDays* | 0.006 | 0.006 | 0.004 |
| *RoomBac* | 0.052 | 0.052 | 0.032 |
| *AttFac* | -0.045 | -0.045 | -0.038 |
| *BacServFinal* | 0.458 | 0.458 | 0.762 |
| *TProbNeg* | -0.848 | -0.848 | -0.769 |

***Nominal range sensitivity analysis***

Nominal range sensitivity analysis was conducted in manner similar to that used for the shell egg model. All inputs were set to their most likely values (baseline scenario) and the model was run for 100,000 iterations using the draft model. Because the relative effect of different inputs was the item of interest, nominal range sensitivity analysis was not conducted using the new assumptions presented earlier. These assumptions had an effect on the estimated number of human illnesses but not on the relative effect of different inputs. In addition, the sensitivity analysis was based on the unanchored baseline model. Upper and lower bounds were selected for each of the inputs. For fixed inputs, bounds were generally selected by multiplying the input by a set factor. For distributional inputs, the distribution parameters such as the mean or standard deviation were adjusted. Some inputs were thought to be correlated with other inputs. For those inputs, if the correlation was below -0.5 or above 0.5 then the inputs were changed and evaluated separately. If the correlation was between -0.5 and 0.5 then the inputs were changed and evaluated separately.

After selecting lower and upper bounds for each input or set of inputs, the model was run for 100,000 iterations for each lower and upper bound modeled. After each input was evaluated at its lower and upper bound, the input was changed to its most likely value and the next input was evaluated.

Setting upper and lower bounds

Twenty-seven sets of inputs were changed and evaluated at the upper and lower bound. Two sets were specific to growth of *Salmonella* in whites and two to growth in other products. Table 5-35 shows bounds for parameters for the distributions that determine the initial levels of *Salmonella* in white, whole, or yolk egg products. Bounds are based on the uncertainty of the parameters estimated in Annex F. Upper and lower bounds are two standard deviations away from the most likely estimates presented.

TABLE 5-35 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR WEIBULL DISTRIBUTION FOR EGG PRODUCT CONTAMINATION.

| Parameter | LB | ML | UB |
|---|---|---|---|
| *Initial levels μ – white* | -0.14 | 0.44 | 1.02 |
| *Initial levels s – white* | 1.30 | 1.42 | 1.54 |
| *Initial levels μ – whole* | 1.73 | 2.27 | 2.81 |
| *Initial levels s – whole* | 1.30 | 1.40 | 1.50 |
| *Initial levels μ – yolk* | 0.41 | 1.13 | 1.85 |
| *Initial levels s – yolk* | 1.48 | 1.60 | 1.72 |

Table 5-36 shows bounds for growth parameters. Upper bound parameters and lower bound parameter, *f*, to estimate growth of bacteria in yolk or whole egg product are based on uncertainty estimates. Lower bounds are set arbitrarily for *e* and *b*.

TABLE 5-36 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR GROWTH PARAMETERS.

| Parameter | LB | ML | UB | Corr |
|---|---|---|---|---|
| *Yolk growth e* | -1.3000 | -1.0063 | -0.4263 | 1 |
| *Yolk growth f* | 0.1954 | 0.2219 | 0.2484 | 1 |
| *Yolk growth b* | 0.0100 | 0.4007 | 0.8761 | |
| *Albumen growth SD* | 0.1925 | 0.3850 | 0.7700 | |
| *Albumen growth lag/growth* | 2 | 5 | 10 | |

Table 5-37 shows bounds for parameters for the Pert distributions that are used to model storage times and temperatures. The Pert distributions are each characterized with a min (or minimum value), a mid (or midpoint value), and a max (or maximum value). Either the lower bound min is set at 0 for days of storage or refrigerator temperature in $^{o}$C or it is set at 10 for room storage temperature in $^{o}$C.

TABLE 5-37 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR PARAMETERS FOR PERT DISTRIBUTIONS FOR EGG PRODUCT STORAGE TIMES AND TEMPERATURES.

| | | LB | | | ML | | | UB | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | *Pert Parameter* | **min** | **mid** | **max** | **min** | **mid** | **max** | **min** | **mid** | **max** |
| **Parameter** | | | | | | | | | | |
| White | *Time and Temp RefriDays* | 0.00 | 2.00 | 10.00 | 2.00 | 10.00 | 22.00 | 10.00 | 22.00 | 44.00 |
| | *Time and Temp RefriTemp* | 0.00 | 0.00 | 3.33 | 0.00 | 3.33 | 4.44 | 3.33 | 4.44 | 8.89 |
| | *Time and Temp RSDays* | 0.00 | 0.02 | 0.04 | 0.02 | 0.04 | 0.17 | 0.04 | 0.17 | 0.33 |
| | *Time and Temp RSTemp* | 10.00 | 15.56 | 21.11 | 15.56 | 21.11 | 26.67 | 21.11 | 26.67 | 35.00 |
| | *Time and Temp FractRS* | 0.00 | 0.02 | 0.05 | 0.02 | 0.05 | 0.10 | 0.05 | 0.10 | 0.20 |
| Whole | *Time and Temp RefriDays* | 0.00 | 2.00 | 5.50 | 2.00 | 5.50 | 13.00 | 5.50 | 13.00 | 26.00 |
| | *Time and Temp RefriTemp* | 0.00 | 0.00 | 3.33 | 0.00 | 3.33 | 4.44 | 3.33 | 4.44 | 8.89 |
| | *Time and Temp RSDays* | 0.00 | 0.02 | 0.04 | 0.02 | 0.04 | 0.17 | 0.04 | 0.17 | 0.33 |
| | *Time and Temp RSTemp* | 10.00 | 15.56 | 21.11 | 15.56 | 21.11 | 26.67 | 21.11 | 26.67 | 35.00 |
| | *Time and Temp FractRS* | 0.00 | 0.02 | 0.05 | 0.02 | 0.05 | 0.10 | 0.05 | 0.10 | 0.20 |
| Yolk | *Time and Temp RefriDays* | 0.00 | 2.00 | 5.50 | 2.00 | 5.50 | 11.00 | 5.50 | 11.00 | 22.00 |
| | *Time and Temp RefriTemp* | 0.00 | 0.00 | 2.22 | 0.00 | 2.22 | 4.44 | 2.22 | 4.44 | 8.89 |
| | *Time and Temp RSDays* | 0.00 | 0.02 | 0.04 | 0.02 | 0.04 | 0.17 | 0.04 | 0.17 | 0.33 |
| | *Time and Temp RSTemp* | 10.00 | 15.56 | 21.11 | 15.56 | 21.11 | 26.67 | 21.11 | 26.67 | 35.00 |
| | *Time and Temp FractRS* | 0.00 | 0.02 | 0.05 | 0.02 | 0.05 | 0.10 | 0.05 | 0.10 | 0.20 |

Upper and lower bounds for fractions of different types of servings made from egg products are developed using the number of eating occasions from CSFII. The bounds are set by either doubling or halving the eating occasions for the type of serving.

Upper and lower bounds for serving sizes are developed from summaries of serving size from the CSFII. All of the inputs for a cumulative distribution for a particular serving type are either doubled (upper bound) or halved (lower bound).

Table 5-38 shows the bounds for discrete distributions for the $\log_{10}$ reductions due to cooking for the different types of egg servings. As with the Pert distributions for time and temperature, these boundary distributions are developed by shifting the most likely distribution up or down.

TABLE 5-38 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR PARAMETERS FOR DISCRETE DISTRIBUTIONS REPRESENTING $LOG_{10}$ REDUCTIONS DUE TO COOKING.

| | LB | | | | ML | | | | UB | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **$Log_{10}$ Reductions** | 0 | 4.9 | 6.1 | 12 | 0 | 4.9 | 6.1 | 12 | 0 | 4.9 | 6.1 | 12 |
| **Parameter** | | | | | | | | | | | | |
| *Cooking EggUC* | 0.51 | 1 | 1 | 1 | 0.02 | 0.51 | 1 | 1 | 0 | 0.02 | 0.51 | 1 |
| *Cooking BevUC* | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 1 |
| *Cooking IngUC* | 0.51 | 1 | 1 | 1 | 0.02 | 0.51 | 1 | 1 | 0 | 0.02 | 0.51 | 1 |
| *Cooking EggWC* | 0.51 | 1 | 1 | 1 | 0.02 | 0.51 | 1 | 1 | 0 | 0.02 | 0.51 | 1 |
| *Cooking BevWC* | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 |
| *Cooking IngWC* | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 |

Table 5-39 shows the bounds for the parameters for the dose-response function. These bounds are identical to those presented in the hazard characterization chapter and Table 5-16.

TABLE 5-39 LOWER BOUNDS (LB), MOST LIKELY VALUES (ML) AND UPPER BOUNDS (UB) FOR PARAMETERS TO THE BETA-POISSON DOSE-RESPONSE FUNCTION.

| Parameter | | LB | ML | UB |
|---|---|---|---|---|
| *Dose-response* | *Alpha* | 0.0763 | 0.1324 | 0.2274 |
| *(parameters correlated)* | *Beta* | 38.49 | 51.45 | 57.96 |

Results of nominal range sensitivity analysis

Results of the model runs are shown in the following figures. Each input is identified along the x-axis. The frequency of illness is given on the y-axis. Each input has a corresponding vertical line with a diamond in the center that gives the frequency of illness when the input is set at its most likely value. The frequencies of illness for the upper and lower bounds of the input are given by the horizontal lines at the ends of each vertical line. The longest vertical lines represent those inputs that have the most influence on the frequency of illness.

Each egg product type is presented in a separate figure. Results for whole egg product with 10% added sugar are not shown because after pasteurization the simulated frequency of illness results in 0 cases regardless of other factors.

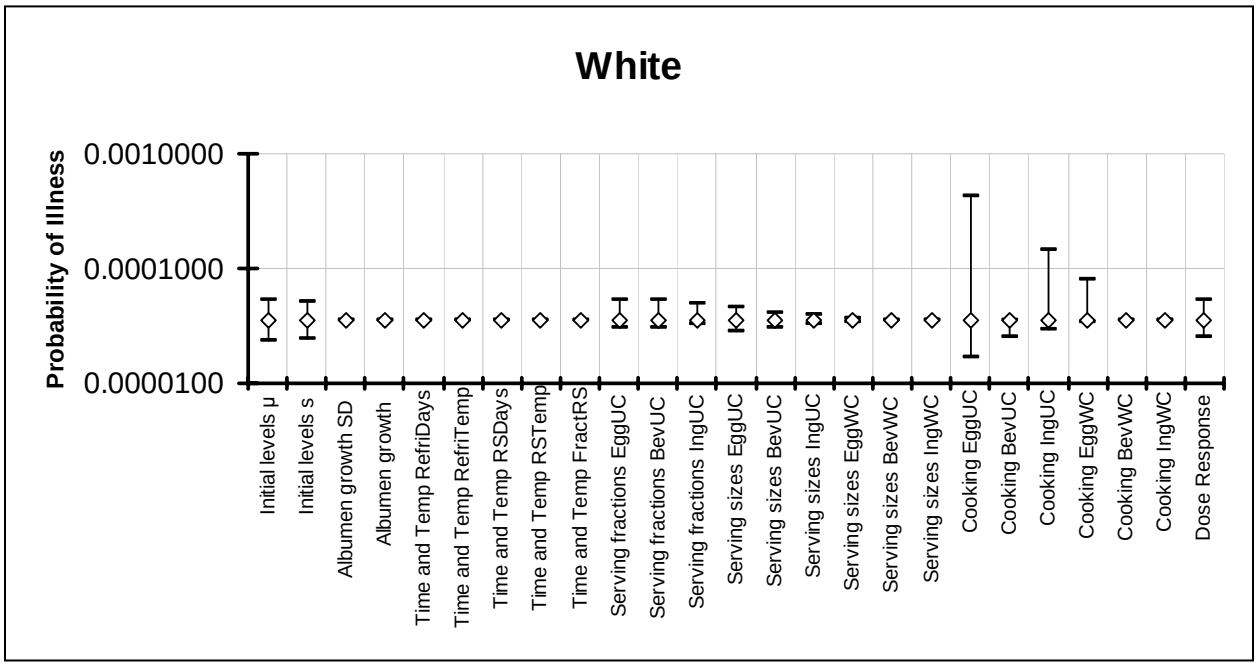



FIGURE 5-27 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR EGG WHITE PRODUCT.

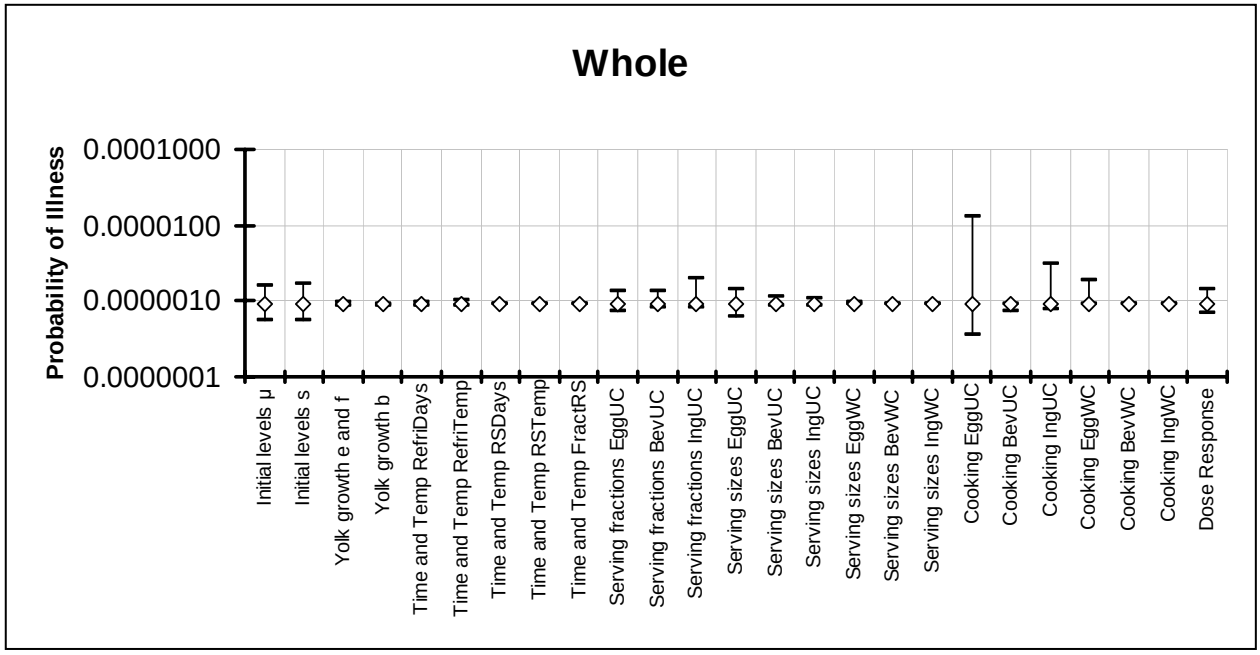



FIGURE 5-28 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR WHOLE EGG PRODUCT.

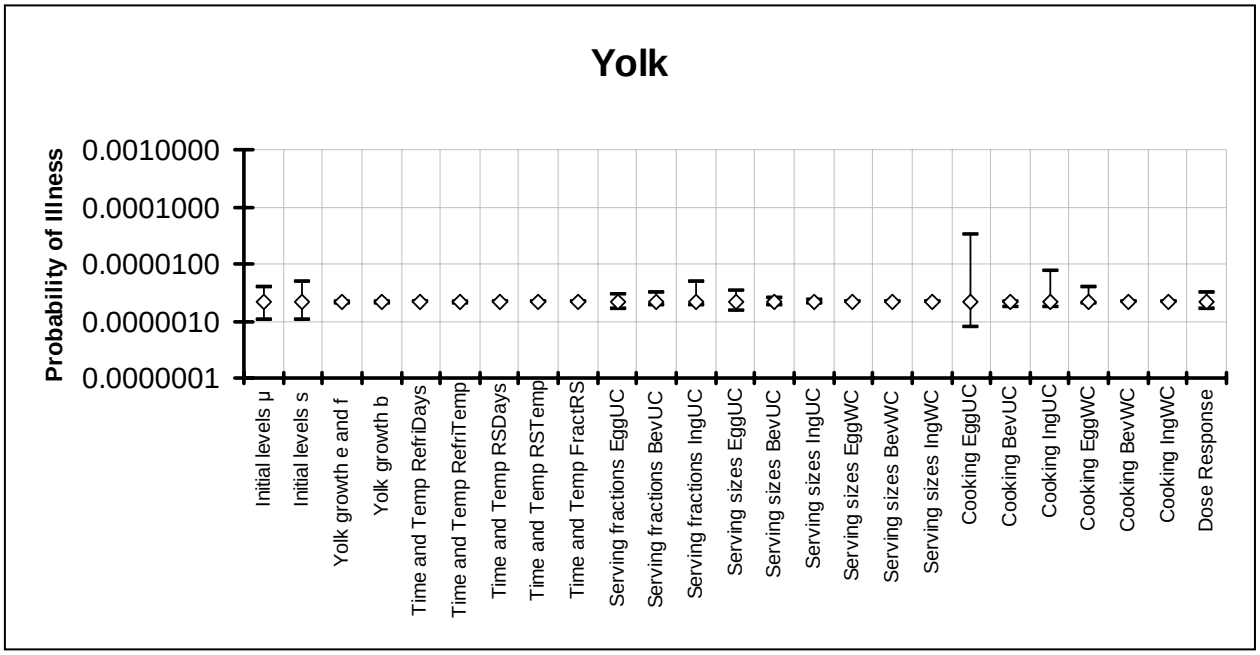



FIGURE 5-29 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR YOLK EGG PRODUCT.

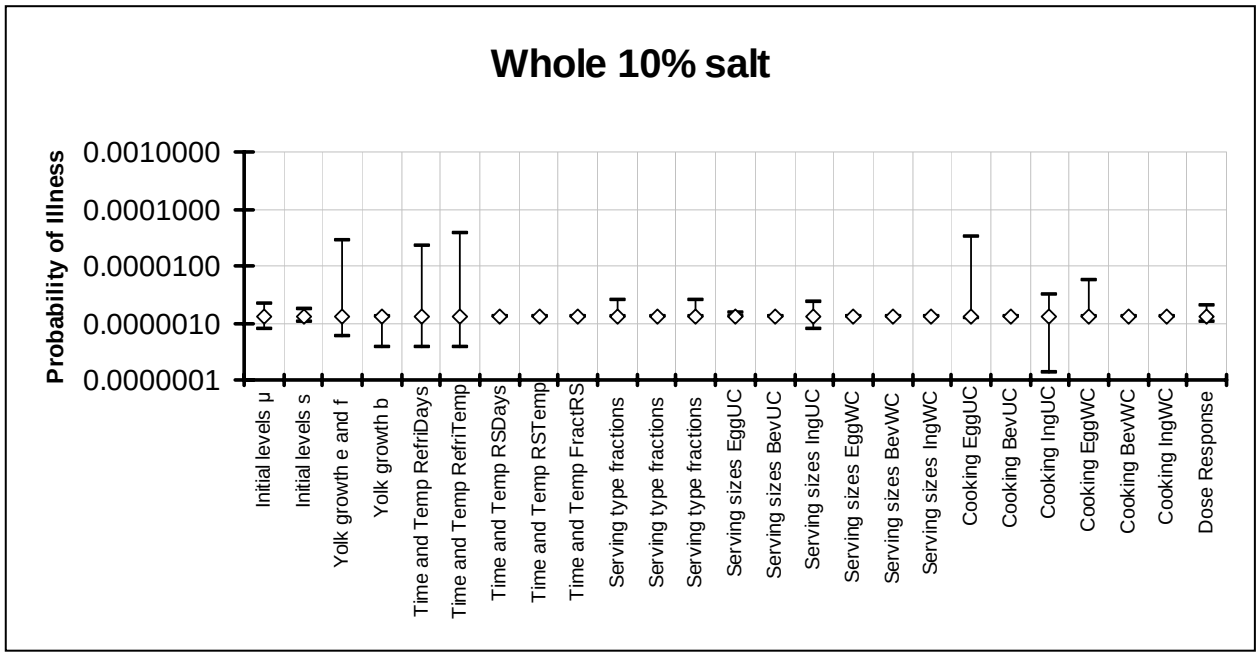



FIGURE 5-30 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR WHOLE EGG PRODUCT WITH 10% ADDED SALT.

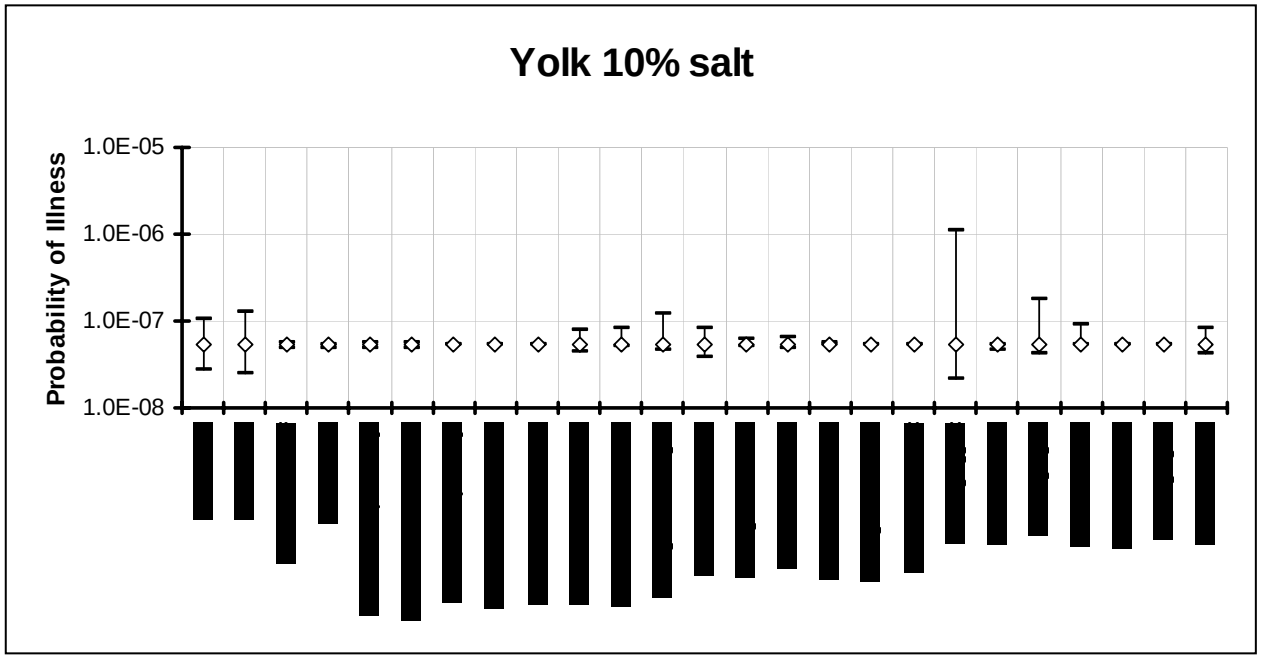



FIGURE 5-31 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR EGG YOLK PRODUCT WITH 10% ADDED SALT.

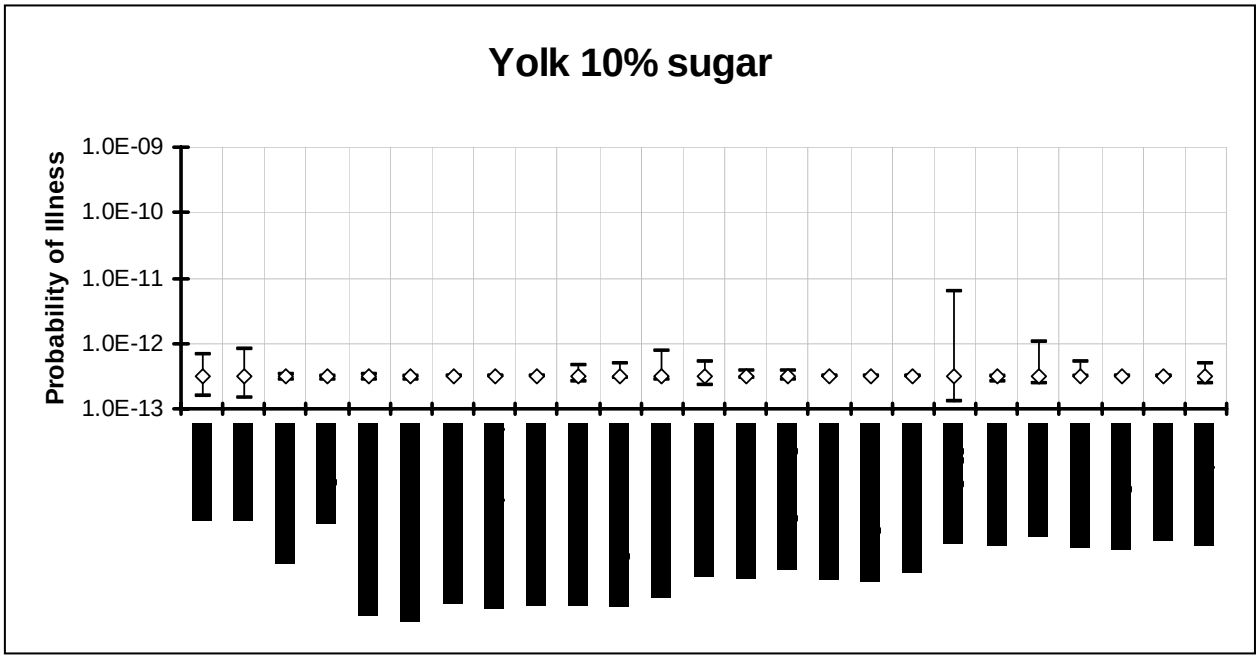



FIGURE 5-32 RESULTS OF NOMINAL RANGE SENSITIVITY ANALYSIS FOR EGG YOLK PRODUCT WITH 10% ADDED SUGAR.

Summary of nominal range sensitivity analysis

The effect of upper and lower bounds for the various inputs was similar across all egg product types. Cooking is noted to have a large potential effect. The uncertain parameters for the Weibull

distribution that predicts the amount of contamination in egg products prior to pasteurization also had a relatively large effect. Little effect was noted from time and temperature of storage. This is due primarily to the relatively narrow range of times and temperatures which was informed by expert opinion. Furthermore, given the low temperatures modeled for egg product, storage time of storage would have a small effect.

***Sensitivity to modeling assumptions***

Stochastic growth modeling versus deterministic growth modeling

As with shell eggs, the difference between stochastic growth modeling and deterministic growth modeling was evaluated. There was much less difference between the two modeling assumptions than was noted for shell eggs in Table 5-17. This is likely due to the small amounts of growth modeled in the baseline model.

Post-pasteurization growth of thermally injured bacteria

Because all modeled egg products are subjected to pasteurization, the question of post-pasteurization growth of thermally injured bacteria is important. The effect of sub-lethal injury to bacteria that would affect the growth parameters was modeled similar to the method used to evaluate the same question for shell eggs. The draft baseline model was run with 100,000 iterations. These results were then compared with the results from running the model when the growth rate was set at one-half the expected growth rate after pasteurization. The modeled difference between these two assumptions was negligible. This was also likely due to the small amount of growth that takes place in the baseline model due to the time and temperature assumptions used.

Effect of pH on pasteurization of egg white

The lethality equation for egg white shown in Table 3-36 is based on experimental studies of lethality in which the pH was 8.8. This value may be too low. Experimental studies have also been conducted for egg white with a pH of 9.3. The suggested model for lethality of *Salmonella* in eggwhite with pH = 9.3 is

$$\log_{10}\left(p(t)\right) = -\log_{10}(e)kt + \log_{10}\left(1+\frac{k\left(e^{-wt}\right)}{w}\right) \quad (5\text{-}7)$$

where

$T$ is temperature ºC

$k = \exp(a + b(T\text{-}50))$

$w = \exp(c)$, for specified constants, $a$ = -2.74273, $b$ = 0.566244, and $c$ = 0.229781.

At this pH, the expected $\log_{10}$ reduction due to pasteurization in egg white is about 8.2. The expected number of illnesses due to egg white drops from 2,636 to 2 (Table 5-31). The overall number of expected illnesses for all egg product types drops from 5,526 to 2,892. Thus, if egg white has a lower pH than modeled, the estimated number of illnesses is lower than the anchored model would estimate.

## Scenario Analysis

***Scenarios examined***

The draft liquid egg products model assumed that all pasteurized egg products experienced pure laminar flow during pasteurization. Laminar flow refers to a layering effect that takes place within tubes. In the center of the tube, product moves the fastest. The product moves slowest next to the walls of the tube due to the friction from the walls. Given laminar flow, the average dwell time for product would be twice that for the fastest moving particle. The baseline estimates presented above were modeled assuming pure laminar flow.

Since presentation of the draft report at the public meeting in October 2004, FSIS has considered scenarios other than pure laminar flow. Because pure laminar flow would require product next to the tube wall to be nearly stationary, this is not likely to represent reality. On the other hand, it is unlikely that processors are able to achieve purely turbulent flow in which every particle would achieve the same velocity. Thus, scenarios were evaluated in which the slowest particle was assumed to have 100% of the velocity of the fastest particle (turbulent flow), 50% of the velocity, 25% of the velocity, or 0% of the velocity of the fastest particle (laminar flow). See Annex G for a more complete explanation.

In addition, since the public meeting, FSIS has conducted a survey of pasteurization practices. This survey noted that some processors were pasteurization egg product at higher times or temperatures than required. Furthermore, much of the product was formulated product and was subjected to times and temperatures higher than had been modeled in the draft risk assessment. Annex G contains more information about the survey and about the effect of formulation on log reductions.

Table 5-40 and Table 5-41 show net lethalities for different product types, with different assumptions for velocity of the slowest particle and for different mixes of formulated product. Eight different scenarios (4 velocity assumptions x 2 product formulation assumptions) were modeled.

TABLE 5-40 NET LETHALITIES FOR DIFFERENT PRODUCT TYPES, WITH DIFFERENT ASSUMPTIONS FOR VELOCITY OF SLOWEST PARTICLE, ASSUMING PRODUCT-TYPE MIX OF 50% PLAIN AND 50% FORMULATED ($W = ½$) FOR LIQUID WHOLE EGG, EGG YOLK, AND EGG WHITE.

| Product Type | Slowest particle = 100% fastest particle | Slowest particle = 50% fastest particle | Slowest particle = 25% fastest particle | Slowest particle = 0% fastest particle |
|---|---|---|---|---|
| *other white* | 4.72 | 5.39 | 5.48 | 5.51 |
| *other whole* | 5.36 | 5.72 | 5.81 | 5.84 |
| *other yolk* | 4.95 | 5.3 | 5.39 | 5.42 |
| *10% salt added whole* | 6.33 | 6.68 | 6.77 | 6.8 |
| *10% sugar added whole* | 9.1 | 10.1 | 10.2 | 10.23 |
| *10% salt added yolk* | 6.1 | 6.53 | 6.63 | 6.66 |
| *10% sugar added yolk* | 9.8 | 10.42 | 10.52 | 10.54 |

TABLE 5-41 NET LETHALITIES FOR DIFFERENT PRODUCT TYPES, WITH DIFFERENT ASSUMPTIONS FOR VELOCITY OF SLOWEST PARTICLE, ASSUMING PRODUCT-TYPE MIX OF 75% PLAIN AND 25% FORMULATED ($W$ = ¼) FOR LIQUID WHOLE EGG, EGG YOLK, AND EGG WHITE.

| Product Type | Slowest particle = 100% fastest particle | Slowest particle = 50% fastest particle | Slowest particle = 25% fastest particle | Slowest particle = 0% fastest particle |
|---|---|---|---|---|
| *other white* | 4.56 | 5.22 | 5.32 | 5.34 |
| *other whole* | 5.19 | 5.54 | 5.63 | 5.66 |
| *other yolk* | 4.78 | 5.13 | 5.22 | 5.24 |
| *10% salt added whole* | 6.33 | 6.68 | 6.77 | 6.8 |
| *10% sugar added whole* | 9.1 | 10.1 | 10.2 | 10.23 |
| *10% salt added yolk* | 6.1 | 6.53 | 6.63 | 6.66 |
| *10% sugar added yolk* | 9.8 | 10.42 | 10.52 | 10.54 |

***Results***

Table 5-42 shows the estimated illnesses for each of the eight modeled scenarios. Of the eight scenarios modeled, the combination of 50% formulated product and assuming the slowest particle moves at 0% of the velocity of the fastest particle is closest to the baseline value of 5526. Five of the modeled scenarios are above the baseline value and three of the scenarios are below the baseline value.

TABLE 5-42 ESTIMATED ILLNESSES FOR DIFFERENT PRODUCT FORMULATION MIXES, WITH DIFFERENT ASSUMPTIONS FOR VELOCITY OF SLOWEST PARTICLE, ASSUMING PRODUCT-TYPE MIX OF 50% PLAIN AND 50% FORMULATED ($W$ = ½) FOR LIQUID WHOLE EGG, EGG YOLK, AND EGG WHITE.

| Product Formulation | Slowest particle = 100% fastest particle | Slowest particle = 50% fastest particle | Slowest particle = 25% fastest particle | Slowest particle = 0% fastest particle |
|---|---|---|---|---|
| *25% formulated* | 12,935 | 5,053 | 4,033 | 4,024 |
| *50% formulated* | 18,272 | 7,787 | 6,236 | 5,542 |

## Validation and limitations of the egg products model

***Lack of epidemiologic data***

Historically, pasteurized egg products have been a very safe food. There have been no outbreaks linked to the consumption of egg products and consumption of pasteurized egg products does not appear as a risk factor in case control studies of foodborne illness. This is in contrast to shell eggs, which have been linked to about 80% of SE outbreaks in the U.S. The consumption of shell eggs, particularly lightly cooked shell eggs, appears as a risk factor in case control studies of SE. Thus, unlike shell eggs, there is no published estimate of human illness with which to validate the egg products model. Furthermore, an anchoring approach was used to adjust the $\log_{10}$ reduction due to pasteurization of egg white. Thus, the idea of validating the model is questionable. Nevertheless, possible sources of error (e.g., survey bias) are associated with data for incoming *Salmonella* spp. concentration, the effect of pasteurization, cooking, and consumption of foods containing egg products, and the dose-response function.

Incoming concentration
The distribution for incoming concentration is based on analysis of the FSIS egg product baseline survey. If the sampling procedure did not adequately represent the concentration within the vats, the results could be biased.

$Log_{10}$ reductions due to pasteurization
The effect of pasteurization was based on a single study. If the study was not representative, the results would not represent all egg products.

Cooking and consumption of specific egg product types
All seven egg product types were assumed to have been cooked in the same way and used in the same types of products. If the various products were used in distinctly different ways from that modeled, this would affect the results. For instance, if egg white is always cooked thoroughly, there would be fewer illnesses than predicted by the model.

Dose-response function
The dose-response function reported in the hazard characterization is based on a single set of dose-response functions developed by the Joint Expert Meetings on Microbiological Risk Assessment organized by the WHO and FAO. This dose-response function may not be applicable to all of the *Salmonella* serotypes recorded in the FSIS baseline survey. In addition, the dose-response function may not be applicable to bacteria that have a sub-lethal injury because of pasteurization.

## SUMMARY

### Risk Estimates in Response to Management Questions Related to SE in Shell Eggs

***What is the number of SE in shell eggs* before *and* after *a specified pasteurization scenario?***
After pasteurization resulting in a 3-$log_{10}$ reduction, the mean number of SE drops by 3 $log_{10}$ or 99.9%. Similarly, a 5-$log_{10}$ reduction results in a drop in the mean number of SE by 5 $log_{10}$ or 99.999%. The potential for human illness drops after pasteurization although not by a similar amount. Before shell eggs are pasteurized, they have the potential to cause about 450,000 human illnesses. Immediately after pasteurization to effect a 3- $log_{10}$ reduction these eggs would have the potential to cause only about 100,000 illnesses. A 5-$log_{10}$ reduction results in eggs having a potential to cause only 50,000 illnesses. The number of illnesses estimated at the end of the farm to table continuum are, of course, different due to the possibilities of multiplication of bacteria that exist during storage and the decrease in bacteria due to cooking prior to consumption.

***What is the number of illnesses per serving and annual number of illnesses from SE in* pasteurized *and* non-pasteurized shell eggs?**
The model predicts about 1 illness in every 400,000 eggs. Because eggs may contribute to more than one serving, the risk per serving is about 1 illness in every 1.3 million servings. A 3-$log_{10}$ reduction due to pasteurization reduces the risk of SE to about 1 illness in every 4.0 million servings. A 5-$log_{10}$ reduction reduces the risk to about 1 illness in every 8.7 million servings. The

anchored baseline model estimates about 130,000 SE illnesses. A 3-$\log_{10}$ reduction due to pasteurization reduces the number of illnesses to 41,000 illnesses. A 5-$\log_{10}$ reduction results in a prediction of 19,000 illnesses. These predictions assume that all shell eggs would be pasteurized.

***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?***

Quick refrigeration of shell eggs has a significant effect on reducing the number of human illnesses. If eggs are stored and held at 45°F (7.2°C) within 36 hours of lay, the estimated number of human illnesses drops from 130,000 to 89,000. Storage time and temperature and pasteurization have a combined effect. Cooling eggs rapidly to 45°F (7.2°C) makes pasteurization more effective. One surviving bacterium in an egg can rapidly multiply during the post-processing steps. Limiting growth of SE before pasteurization decreases the probability that there will be any surviving bacteria.

## Risk Estimates in Response to Management Questions Related to *Salmonella* spp. in Egg Products

***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)?***

The baseline model provides estimates for seven different types of egg products: white, whole, yolk, whole with 10% added salt, whole with 10% added sugar, yolk with 10% added salt, and yolk with 10% added sugar. These seven products are used to represent all possible types of egg products. The frequency of illness per serving ranged from $3.5 \times 10^{-7}$ for egg yolk product to less than $10^{-12}$ for whole egg product with added sugar. The baseline model estimates about 5500 illnesses. The seven egg products are pasteurized to varying amounts depending on current regulatory requirements. Differences in assumptions about the application alone of pasteurization on egg products results of in a range of human illness from about 4,000 to about 18,000. Pasteurization to effect a 6-$\log_{10}$ reduction results in an estimation of about 3,200 annual illnesses. Pasteurization of all egg products to effect a 7-$\log_{10}$ reduction results in an estimation of about 320 annual illnesses.

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

Pasteurization of egg products is meant to reduce the number of *Salmonella* by a specified amount. As with shell eggs, the amount of pasteurization is given in $\log_{10}$ reduction. A 1-$\log_{10}$ reduction means that the amount of contamination is reduced by 90%; a 2-$\log_{10}$ reduction corresponds to a 99% reduction in contamination, and a 3-$\log_{10}$ reduction to 99.9%. Given a 5-$\log_{10}$ reduction due to pasteurization, about 90% of liters of egg white product would have 1 or less *Salmonella*. On the other hand, given the baseline $\log_{10}$ reductions, nearly 100% of liters of whole egg product would be expected to have no *Salmonella*.

# 6 Research Needs

The strength of risk assessment modeling is its iterative nature. Models can be built with incomplete data and assumptions, and updated as new scientific studies are completed. The revised SERA model is based on the best available data, but also includes as inputs many assumptions and some ambiguous data and principles from scientific theory. Key uncertainties were identified for the current body of evidence and addressed as described in the various Annexes to this risk assessment and other chapters. Good risk assessment differentiates what is known from what is not known, so that future research initiatives can be directed toward filling the data gaps that would most enhance the scientific basis for food safety regulations. Thus, the goal of this Chapter is to describe ongoing studies and new research initiatives that could target the most important research needs for risk assessment modeling. Filling these research needs would improve our understanding of the farm-to-table system modeled in this assessment by identifying the variability of the variables that affect risk reducing the uncertainty in the model.

An overview of the presentation of the major research needs for the SERA revision is presented in Table 6-1 below. The specific discussion is organized in four sections:

1) studies already in progress that might fill research needs;
2) additional research needs for Exposure Assessment;
3) other research needs for Hazard and Risk Characterization; and
4) research priorities from sensitivity analysis of the draft simulation model.

Some research needs are likely to require long-term commitments from multi-disciplinary teams and may require expert consultations before more explicit applications in risk assessment modeling are possible. The potential usefulness of new research initiatives to risk assessment and public health protection is addressed.

TABLE 6-1 OVERVIEW OF RESEARCH NEEDS.

| Origin | Annex or Chapter | Research needs |
|---|---|---|
| Farm | B. Prevalence in shell eggs<br>C. Initial levels in shell eggs<br>D. Cooling of shell eggs | Prevalence and levels by site of contamination<br>Probability of hens infected given young infected flocks |
| Farm<br>Establishment<br>Retail and Home | E. Growth<br>Exposure Assessment | Growth kinetic parameters by site of contamination, and previous history of storage<br>Time and temperature assumptions for storage |
| Establishment | F. Levels in egg products | Paired pre- and post-pasteurization data<br>Storage practices of liquid<br>Growth of *Salmonella* in liquid product pre and post pasteurization |
| Establishment And HRI or Home Kitchen | G. Lethality | Data at additional temperatures by site of contamination for shell egg pasteurization<br>Data of liquid products with and without additives<br>Time and temperature assumptions for cooking<br>Extent of undercooking |
| Home or HRI | H. Consumption Hazard Characterization | Classifications of high risk foods<br>Fractions of eggs consumed undercooked<br>Variability in host and *Salmonella* populations<br>Data depicting relationships between dose and severity<br>Progression of infection to adverse effects and severity<br>Methodology for expanded epidemiologic investigations, particularly for reconstruction of doses causing and not causing illnesses in outbreaks |

## STUDIES IN PROGRESS

The data analysis for the draft revision of the SERA risk assessment in shell eggs and egg products was completed in the fall of 2002. The following studies already proposed or in progress appear relevant to FSIS data needs for the SERA revision. As raw data from these studies become available in the coming years, FSIS could conduct data analysis and update the SERA model to determine the impact of the new data on model predictions. The need for additional studies addressing other aspects of these topics may be considered upon completion of the work in progress.

- A preliminary dataset from the FSIS baseline survey for liquid egg products was used to determine the distribution of the initial levels of *Salmonella* spp. in liquid egg products before pasteurization. This study is important, as the usefulness of the pasteurization process is dependent on the starting level of bacteria present within the raw liquid eggs. In this risk assessment, preliminary data from a portion of this survey was used to determine this distribution from the partial dataset available in December 2002. Upon completion of the FSIS baseline survey for liquid egg products expected in March 2003, the full dataset will be analyzed and compared to the derived distribution. In addition, data for serotypes identified from egg product samples from this study will also be summarized and considered in the final risk assessment upon completion of the FSIS

dataset. These data are important for consideration of the fraction of isolations attributable to SE versus other *Salmonella* spp. relevant to the mechanisms of contamination and potentials interventions to reduce risk.

- FSIS/RTI web-based Consumer Behavior survey questionnaire is currently under review by the Office of Management and Budget (OMB). If this survey is approved and funded, it could provide information permitting reliable quantification of consumer handling and preparation of eggs for future risk assessment models. The times and temperatures of egg storage and the methods and efficiencies of cooking eggs prepared in households are important predictors of the levels of SE surviving within a contaminated egg serving. The fractions of egg handling and preparation attributable to given scenarios might also determined from this questionnaire. The sensitivity analysis in Section 4 identified the following as priorities for data needs relevant to this item: times and temperatures of eggs and egg products under home storage; and fractions of undercooked eggs and egg ingredients. Future models could be updated to determine the impact of these data relative to the assumptions used in the current model.

- The American Egg Board has funded research to measure times and temperatures that eggs might experience from the farm to the processing plant and ultimately to the consumer's table. This time and temperature information is important, as these variables will strongly influence the potential and the extent of SE growth. Future models could be updated to determine the impact of these data relative to the assumptions or expert opinions from academia and industry for times and temperatures of egg storage used in the current model.

  - Dr. Paul Patterson of The Pennsylvania State University is conducting a study entitled "Temperature sequence of an egg from oviposition through retail distribution". This study will encompass 7 states representing different regions, winter and summer seasons, in-line and off-line processing, and open sided and forced ventilation houses. This study will:
    - determine ambient and internal temperatures of eggs from farm to retail;
    - identify variables associated with US production and processing that influence times and temperatures of egg storage; and
    - model the various time and temperature sequences of processing and handling to predict resulting egg temperature under many scenarios.

    This study is expected to be completed by the end of 2003. From the sensitivity analysis described in the Risk Characterization Chapter and summarized in Section 4, times and temperatures on farm and temperatures in retail are likely to be influential data gaps for updating the assumptions used in the risk assessment model with scientific data.

  - Dr. Charles Benson of the University of Pennsylvania and Dr. Tom Humphrey of the United Kingdom are conducting a study entitled "SE concentration in shell eggs in the U.S. as determined by time and temperature." This study will:

- Develop an experimental inoculation model for the reliable production of eggs from laying hens containing SE;
- Confirm the intra egg location of SE from experimentally inoculated laying hens;
- Determine the impact of time and temperature abuse on the intra-egg concentration of SE;
- Define the impact of aging on the intra-egg growth of SE under ideal and abusive storage conditions; and
- Address five targeted sampling locations: hen house, processing plant, cartooned storage, distribution, and retail supermarket.

This study is expected to be completed by the end of 2003. From the sensitivity analysis described in the Risk Characterization Chapter and summarized in Section 4, the fraction of eggs that are contaminated on the vitelline membrane of the yolk is likely to be an influential data gap for updating the risk assessment model with additional scientific data.

- The Agricultural Research Service has funded Dr. Richard Gast of the SE Poultry Research Laboratory to conduct a study entitled: Detection and control of SE in Poultry (planed for 2001-2006). This study will focus on the following research needs.

  - Improved methods for detecting SE infections in laying flocks and SE contamination in eggs. This will help to reduce false-negative rates associated with current methodology. From the sensitivity analysis described in the Risk Characterization Chapter and summarized in Section 4, the likelihood of hen positives given flock positives is likely to be an influential data gap for updating the risk assessment model with additional scientific data.

  - Characterizing how, where, when, and in what numbers egg contamination by SE occurs. From the sensitivity analysis described in the Risk Characterization Chapter and summarized in Section 4, the fraction of eggs that are contaminated on the vitelline membrane of the yolk is likely to be an influential data gaps for updating the risk assessment model with additional scientific data.

  - Reducing airborne dust and SE in poultry hatching cabinets and breeder houses using an electrostatic space charge system (ESCS), and determine the mechanism by which ESCS kills airborne and surface SE. This aspect of the study could identify effective interventions to reduce transmission of SE within a flock, thereby reducing the risk to the consumer.

## NEW RESEARCH NEEDS FOR EXPOSURE ASSESSMENT

Numerous research needs were identified during the data analysis for the exposure assessment described in Annexes B through H. The research needs for exposure assessment are presented below by annex. An additional entry for this section relates to time and temperature assumptions

for storage, including post-processing behaviors of consumers and preparers of egg servings, discussed in the Exposure Assessment Chapter rather than in an Annex.

## Annex B. Distribution of *Salmonella* prevalence within shell eggs

- The site or location of *Salmonella* contamination within the egg is important because the potential and the extent of SE growth differ by site. To determine this, a nationally representative survey conducted over all seasons to estimate the fraction of annual shell egg-positives for *Salmonella* in yolk, on vitelline membrane, in albumen close to and far from the yolk, and on inner shell is needed. This study should include variables for molting status, age, and breed of hen and *Salmonella* strain as these factors may affect *Salmonella* survival and recovery from different compartments of intact shell eggs. In this risk assessment, these estimates are either assumed or identified from several different studies. A survey analyzing these issues would decrease the uncertainty associated with many of the above estimates. From the sensitivity analysis described in the Risk Characterization Chapter and summarized in Section 4, the site and level of contamination is likely to be an influential data gap for updating the risk assessment model with additional scientific data.

- *Salmonella* present on the eggshell surface prior to washing can penetrate the outer shell, persist in the pores of the shell, and gain internal access to the egg contents. Studies using experimentally infected hens and artificially contaminated eggshell surfaces were used to estimate the prevalence of eggshell contamination and the likelihood of penetration, respectively. However, it is unclear to what extent this takes place in hens naturally infected with *Salmonella* and processed under commercial conditions. To estimate the prevalence of eggshell contamination and the likelihood of shell penetration, eggs produced by hens naturally infected with *Salmonella* should be investigated for *Salmonella* on the eggshell surface and evidence of shell penetration. This should include SE and other *Salmonella* spp., as shell penetration is not exclusive for SE. These data are needed to verify assumptions in the model for shell eggs and to better elaborate the mechanisms of contamination of egg products.

- This draft risk assessment used data from surveys conducted with hens at the time of slaughter (i.e., spent hens) to identify the proportion of individually infected hens within a SE-infected flock. Because the relationship between egg-producing hens and spent hens is unclear, a nationally representative baseline survey is needed for SE and other *Salmonella* spp. within-flock prevalence over all seasons utilizing rigorous *Salmonella* isolation techniques to minimize potential bias in methods associated with high false-negative rates. From the sensitivity analysis described in the Risk Characterization Chapter and summarized in Section 4, the fractions of flocks positive and of hens positive within positive flocks are likely to be influential data gaps for updating the risk assessment model with additional scientific data.

- A priority research need beyond the scope for the current model regards data depicting how farm management practices may influence flock or egg positive fractions and levels. Data demonstrating the impact of manure management, flock size, feeding practices,

rodent control, and biosecurity would likely be informative. These issues could be important for future modeling efforts targeting potential interventions for egg contamination on the farm.

## Annex C. Initial levels of contamination in shell eggs

- The level of *Salmonella* spp. initially deposited within the egg is important for determining the potential and extent of SE growth. A nationally representative survey conducted over all seasons to estimate the counts of *Salmonella* in yolk, on the vitelline membrane, in albumen close to and far from the yolk, and on the inner shell is needed. Variables for molting status, age, and breed of hen and *Salmonella* strain should be considered. In this risk assessment, SE-contaminated eggs produced by experimentally infected hen studies were used to estimate the levels of SE within an egg. However, due to the low samples numbers and potential of SE to have grown before analysis, there is a large amount of uncertainty associated with some of the above estimates. A survey analyzing these issues would decrease the uncertainty associated with many of the above estimates, in particular the level of SE within the yolk. The studies proposed by the American Egg Board and Agricultural Research Service may partially fulfill this research need. From the sensitivity analysis described in the Risk Characterization Chapter and summarized in Section 4, the initial levels are likely to be influential data gaps for updating the risk assessment model with additional scientific data.

## Annex D. Exponential cooling rates for storage of shell eggs

- During the processing of shell eggs, eggs are cooled to prevent microbial growth and preserve egg quality. In this risk assessment, cooling rates were applied to various levels of egg processing to predict the internal egg temperature. However, it is unclear what fraction of eggs in US production is applicable to each cooling rate. To determine this, a study of the fractions of U.S. egg production applicable to each cooling rate model from available studies of eggs within pallets of selected materials used in commercial egg packing is needed.

- A validation study for the derived adjustment for the effect of location of shell eggs within pallets is also needed. Data were available to describe the worst-case for cooling of an egg in the center of the pallet. Although adjustments were developed for eggs in other locations of pallets based on theoretical equations of heat transfer, experimental studies are needed to describe the actual cooling behavior of eggs in pallets to determine the appropriateness of the theoretical adjustments.

## Annex E. Modeling growth of *Salmonella* in shell eggs

- The potential for, the rate of, and the extent of SE growth within a contaminated egg will largely determine risk of illness to the consumer. A large body of experimental evidence was considered in the data analysis phase of this risk assessment to model the growth of

SE in shell eggs. However, data were sparse for estimating growth parameters for SE. In particular, there are no data for the lag phase duration times. Other *Salmonella* spp. contaminations in some specific compartments of intact shell eggs. These sites included on inner shell (*Es*), in albumen close to (*Eac*) and far from the yolk (*Eaf*), and on the vitelline membrane (*Ev*). In contrast, data were more extensive for estimation of growth parameters for yolk contaminations (*Ey*) from experimentally inoculated eggs. While albumen is recognized as a sub-optimal environment for SE growth compared to yolk, little data is available from controlled studies describing the likelihood of growth/no growth events for any compartments of intact shell eggs. However, multiple researchers have developed theoretical approaches to model growth as a stochastic or random process. This scientific theory was applied in the absence of data for modeling SE growth in shell eggs in stages, first as likelihood of growth and approximations for the extent of growth. Therefore, studies validating these theoretical stochastic growth models for SE are needed. An additional line of research could involve development of alternative methods for estimating and modeling the key events of pathogen growth more mechanistically. From the sensitivity analysis described in the Risk Characterization Chapter and summarized in Section 4, growth parameters in yolk and yolk membrane breakdown are likely to be influential data gaps for updating the risk assessment model with additional scientific data.

- The current model predicts risk for given scenarios of pasteurization efficacy. Further, the current model assumes that growth after pasteurization is consistent with kinetics of growth before pasteurization. One study reported that the extent of growth in reconstituted dried albumen was substantially higher than that of untreated albumen. In addition, in-shell pasteurization could have profound effects on the time to yolk membrane breakdown, and subsequent enhancement of growth. Quantitative data are needed to measure the impact of these factors on growth after pasteurization. Specifically, data are needed to determine the likelihood and extent of growth for low numbers of SE or other *Salmonella* spp. surviving shell egg pasteurization.

## Annex F. Levels of *Salmonella* spp. in liquid product

- Upon completion, the FSIS baseline study will provide data for prevalence and levels of *Salmonella* spp. in egg product samples collected immediately before pasteurization. However, additional studies may be needed to resolve questions about valve effects and other factors that might confound the survey results. From the sensitivity analysis described in the Risk Characterization Chapter and summarized in Section 4, the initial levels, particularly in yolk products, may be an influential data gap.

## Annex G. Lethality models for liquid egg products and contents within shell egg

- While the ongoing FSIS baseline study will provide data for prevalence and levels of *Salmonella* spp. in egg product samples collected immediately before pasteurization, data are needed after pasteurization as well. Paired data from pre- and post-processing at commercial plants (and perhaps at end-user establishments?) are needed to quantify the

magnitude of the lethality achieved in commercial pasteurization processes. The available data on decline after pasteurization may not be representative of the commercial processes used currently. The current model predicts risk for given scenarios of pasteurization efficacy. Data for modeling more explicitly the efficacy of various commercial pasteurization processes are needed for the full range of egg products produced in the US. These data could be incorporated in future risk assessment models and also could serve as validation for the efficacy of commercial processes to achieve lethality performance standards in future regulatory initiatives for *Salmonella* spp. in egg products.

- Data are also needed determining the growth potential for *Salmonella* spp. that survive pasteurization processes for egg products. These data are needed to replace assumptions in the current model predicting growth after pasteurization from the data for growth in raw egg matrices.

- Some experimental data are available to estimate lethality curves for both in-shell and egg product pasteurization. In the case of lethality for shell eggs, the experimental data used in this risk assessment provided the $\log_{10}$ reduction only at two different temperatures. Thus, it was not possible to model lethality accurately over a range of temperatures as was possible for modeling growth in yolk. In addition, the experiments for shell eggs were conducted by inoculating SE in the center of yolk in an egg. Because high levels of SE contamination can occur within the albumen, information concerning the lethality of *Salmonella* within the albumen is needed. These data could be incorporated in future risk assessment models and also could serve as validation for the efficacy of commercial processes to achieve lethality performance standards in future regulatory initiatives SE and other *Salmonella* spp. in eggs.

## Annex H. Consumption

- The data available from the Continuing Survey for Food Intake by Individuals (CSFII) for servings of eggs as ingredients and main dishes are well represented. The survey includes few observations of consumption of eggs as beverages. However, from the sensitivity analysis described in the Risk Characterization Chapter and summarized in Section 4, serving sizes of beverages do not seem to be an influential data gap in the draft simulation model.

- The classification of high-risk foods and the fraction of egg servings consumed undercooked and the extent of undercooking are not well characterized. Research needs for experimental data on lethality for cooking procedures are discussed below. Data from nationally representative surveys are desirable to replace the assumptions used in the model. From the sensitivity analysis described in the Risk Characterization Chapter and summarized in Section 4, the fraction of egg ingredient servings is likely to be an influential data gap.

- The CSFII data do not address questions for batch scrambling of eggs. For example, the number of individuals consuming an egg and the number of eggs contributing to a serving are unknown. The impact of the assumptions in the model may warrant further data collection.

## EXPOSURE ASSESSMENT CHAPTER: POST-PROCESSING BEHAVIOR OF CONSUMERS AND PREPARERS

- Although studies are proposed and funded that might address some research needs for this topic, the time and temperature assumptions about storage and preparation of eggs will be strong drivers of growth and decline in the model. The high importance and uncertainty associated with post-processing behavior might warrant additional research initiatives. Primary research into these practices is needed to ensure that risk managers have sufficient information about actual levels of protection achieved by various consumer practices. From the sensitivity analysis described in the Risk Characterization Chapter and summarized in Section 4, the times and temperatures of storage, the fraction of mixed ingredients, and the cooking and undercooking of eggs and egg ingredients are likely to be an influential data gaps for updating the risk assessment model with additional scientific data.

## OTHER RESEARCH NEEDS: ANNEX I AND HAZARD CHARACTERIZATION

Extrapolation is needed to predict from epidemiologic studies to the likelihood and severity of illness in the US population. Variability is incompletely characterized, and uncertainty might be reduced with additional research. A more mechanistic understanding of the host, pathogen, and food matrix factors influencing the likelihood and severity of illness is needed, particularly for low doses of SE and other *Salmonella* spp. in eggs and egg products. The research needs are extensive and may require long-term systematic and collaborative studies, as well as development of new methodology and models. The need for analytical-deliberative process for mechanistic modeling is commonly acknowledged. The topic is on the agenda for future WHO/FAO expert consultations and for other groups in professional societies and the European Union (http://www.cost920.com/00012.html).

- Data from case-control studies to determine the fraction of US salmonellosis cases attributable to egg and egg products consumption are needed. Such studies would be helpful to anchor the model predictions of magnitude of the public health impact and the effectiveness of future risk management strategies in reducing egg-associated salmonellosis cases in the US.

- When enhanced epidemiologic investigations are possible (see Foodborne Disease Outbreak Questionnaire, http://www.foodriskclearinghouse.umd.edu/dose_resp.htm), data on possible doses consumed and responses resulting could be estimated and used to re-construct a dose-response relationship. However, additional methodology is needed for formal dose-reconstruction that accounts for measurement and sampling errors for food

microbiology methods. Various intrinsic and extrinsic factors of foods, eggs in particular, are associated with methodological limitations of recovery, detection, and enumeration of pathogens typically expected to be clustered or non-homogeneously distributed in foods. For example, study designs to address this research need could target repeated sampling to describe distributions of pathogens in lots of suspect foods. Such data would increase the confidence in estimates of ingested doses that resulted in illness or no adverse effects.

- Additional strategies might be considered to generate data relating ingested doses of foodborne pathogens and likelihood of illness, such as the following.
  - Food microbiology studies could be established through collaborations between government, industry, and academia. When positive lots or positive flocks are identified, the distribution of levels of *Salmonella* in naturally contaminated foods could be determined to verify or refute the assumption of homogeneous distribution in foods. These data would enhance the understanding of the food system and provide risk managers a more direct measure of the potential effectiveness of sampling plans in detecting pathogens that may not be distributed homogeneously in foods.

- Mechanistic data for salmonellosis dose-response modeling is needed to characterize the variability in host, pathogen strain, and environment, as well as interactions influencing predictions of illness likelihood and severity. These data would better inform risk assessors and risk managers about the relative impact of exposures to the strains in servings of eggs and egg products. This research is needed for:
  - Normal and susceptible subpopulations
  - Serotype and strain differences in pathogenesis and virulence
  - Progression to more severe or systemic complications of salmonellosis, including factors associated with more severe illness such as high doses

These data are needed for cost-benefit analysis of interventions to reduce illnesses and for future development of food safety objectives linked to public health endpoints.

## RESEARCH NEEDS IDENTIFIED FROM SENSITIVITY ANALYSIS OF SIMULATION MODEL

Results of the sensitivity analysis for the simulation model described in the Risk Characterization Chapter are summarized below. Small changes in the values of the most influential input variables resulted in 10-100-fold changes in the prediction of illness, with other variables constant. Variables that result in 10-fold or lower changes in the prediction of illness may be important, but appear of lesser influence given the current model structure and assumptions. Variables are also identified that are not influential, given the current model structure.

- For the shell egg model, the time and temperature assumptions were most influential in predictions of illness. The most important variables were storage times and temperatures on farm and in homes, times for eggs produced off-line, and temperatures at retail. The following variables were also influential in predicting illness: probability of infected flocks; the probability of infected hens within infected flocks; the fraction of eggs SE-positive on the vitelline membrane at low levels; the initial density in albumen; the

growth parameters for yolk and yolk membrane breakdown; the fraction of servings with egg ingredients; and the lethality for boiled eggs. Variables that are not influential for this model include assumptions for cooking methods, cooling rates, and serving sizes.

- For the egg products model, the assumptions for storage times and temperatures and undercooking were most influential in predictions of illness from all the egg products modeled. For yolk and whole egg products, the growth parameters in yolk were also important. Initial levels may be important for egg products. Variables that are not influential for this model include serving type fractions and serving sizes.

## SUMMARY

The new research initiatives identified in this chapter will improve the scientific basis of future iterations of the risk assessment model.

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