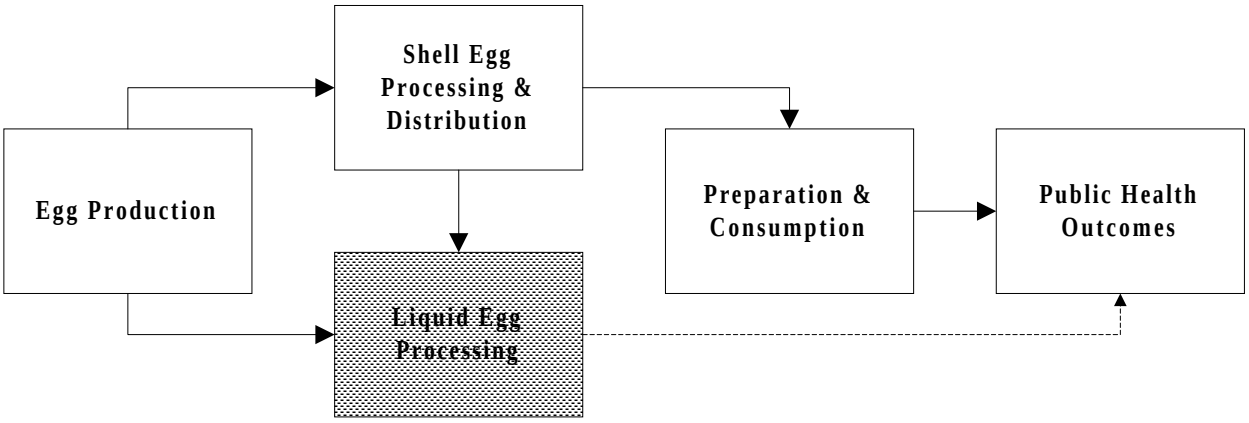
Egg Products Processing and Distribution Module



A. Summary of Egg Products Processing and Distribution Module

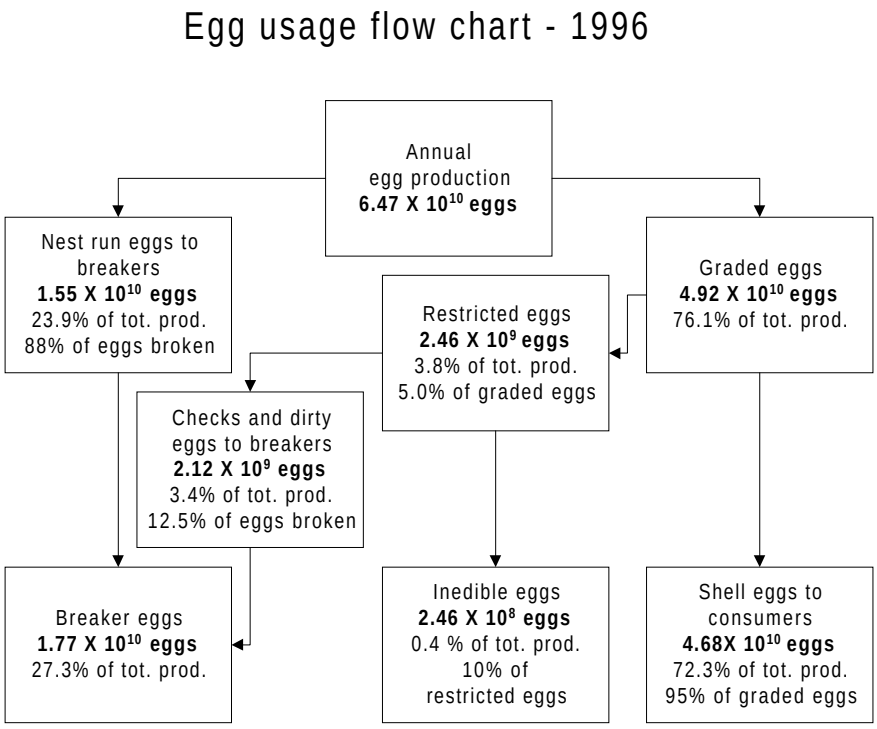
The purpose of this module is to calculate the number of *Salmonella* Enteritidis bacteria in six different egg products: liquid whole egg, liquid yolk, liquid albumen, frozen whole egg, frozen yolk, and frozen albumen. This is done by tracking the change in numbers of *Salmonella* Enteritidis through the production processes of egg products plants.

The egg products industry processed 17 billion eggs or 27% of the U.S. production of eggs in 1996 (Figure C-1). Eggs arriving at egg products plants originate from two sources. Nest run eggs from poultry layer flocks constituted 88% of all eggs processed in 1996. Restricted eggs sent from egg grading plants constituted 12% of all eggs processed in 1996 (Figure C-1). The six products modeled here (liquid and frozen forms of whole egg, albumen, and yolk) constitute about 44% (32% + 12%) of the egg products produced (Table C-1). The remaining 56% of egg products shown in Table C-1 are not simulated in this module. The estimates of the amounts of product in Table C-1 are based on data collected by the Egg Products Inspection Division, Food Safety and Inspection Service for 1996. The amount and type of egg product formulations change significantly from year to year.

Figure C-2 illustrates the processes simulated in this module. In modeling frozen products the assumption is made that freezing does not change the number of SE bacteria present. A simulation result for a liquid egg product is directly applied to the frozen product counterpart. We did not simulate SE in blended, dried, or blended and dried egg products (Figure C-3).

Although many *Salmonella* serotypes are found in egg products prior to pasteurization, this module considers only *Salmonella* Enteritidis. *Salmonella* Enteritidis from **egg contents** is modeled independently from *Salmonella* Enteritidis from **all sources**. The prevalence and level of SE contamination of egg contents is an input to this module from the production module. SE from all sources is modeled as a variable that begins at the breaking process (Figure C-2). SE from all sources includes SE from cross contamination as well as SE from egg contents. Cross

Figure C-1



contamination from equipment, egg shells, machine operators, and airborne spread during breaking are significant sources of SE in liquid egg prior to pasteurization. This contamination of liquid egg is incorporated into the variable "SE in liquid egg" (see page 126).

Restricted eggs (i.e. cracked or dirty eggs) are not modeled independently, but the contribution of SE from restricted eggs to the load of SE is reflected in the estimates of SE in liquid egg prior to pasteurization. Restricted eggs are at increased risk to have *Salmonella* of different species (Humphrey, 1989).

The per cent of U.S. egg production used by the egg products industry has risen steadily in recent years. Consequently, the percent of eggs that come from grading operations as restricted eggs has declined. Restricted eggs are checked (cracked shell but intact shell membrane) and dirty eggs that are diverted from the shell egg market during grading. An estimated 2 billion eggs (12.5% of eggs broken) received at egg product plants were restricted in 1996 (figure C-1). The remaining 15.5 billion eggs (87.5% of eggs broken) came directly from production as nest run eggs.

Specialty egg products are not included in this module. In the last few years there has been an increase in the usage of convenience products and products for immediate consumption. This includes ready-to-eat scrambled eggs; hard-cooked eggs in the shell; hard-cooked and peeled eggs (plain or pickled); omelets; and frozen, fried eggs. Egg substitute and low-cholesterol products are perhaps the newest of these convenience products and their formulation includes a number of added ingredients such as vegetable oil, non-fat milk powder, soy protein, gums, food coloring, minerals and vitamins. Some specialty egg products present a potential risk in that they may be eaten with little or no additional heat treatment. Each of these products should be modeled individually because the processing steps involved are unique.

Egg Products Processing and Distribution Module

The number of SE bacteria in a lot (a lot is composed of 10,000 pounds of egg product) is determined for SE from egg contents and SE from all sources. Ten thousand pound lots of liquid whole egg, albumen, and yolk are modeled through pasteurization (Figure C-2). Results reported for this module are the number of SE bacteria from **all sources** for pasteurized liquid whole egg, albumen and yolk (Figure C-2).

FSIS regulates the minimum time and temperature requirements for pasteurization of egg products. Our model assumes that all egg products plants meet but do not exceed the FSIS time and temperature requirements for pasteurization. We determined the reduction in the number of SE bacteria from pasteurization by combining the data from all recent publications on experimental studies of SE reduction from pasteurization of egg products. A single regression equation was formulated based on this combined data, and an estimated log D-value with associated uncertainty was calculated.

The pH of albumen has a significant effect on the reduction of SE, when liquid egg white is pasteurized. Pasteurization is more effective at higher pH levels. Egg albumen has a bicarbonate buffer system which allows the pH to rise very rapidly. The pH of a freshly laid egg is about pH 7.8 and rises to pH 8.7 or 8.8 over 3 days of storage. After that, the pH increases much more slowly over time to a maximum pH of 9.3 to 9.4 (Froning). The time and temperature requirements of the pasteurization regulations were based on a pH of about 9 for egg white which was the case in 1969 when the regulations were written and eggs did not arrive at the egg processing plant before 3 - 5 days. Since that time conditions have changed. Eggs reach the egg processing plant sooner now than in 1969, and the pH of the albumen is lower in eggs. For these reasons pasteurization today may be less effective than in 1969 because of the lower pH of eggs at the time of processing in 1998.

Several processes are used to pasteurize egg white but a hydrogen peroxide process and pasteurization without the use of added chemicals are the most commonly used. We modeled only pasteurization without chemicals. About 60% of albumen in the U.S. is pasteurized in this manner.

Egg Products Processing and Distribution Module

Figure C-2

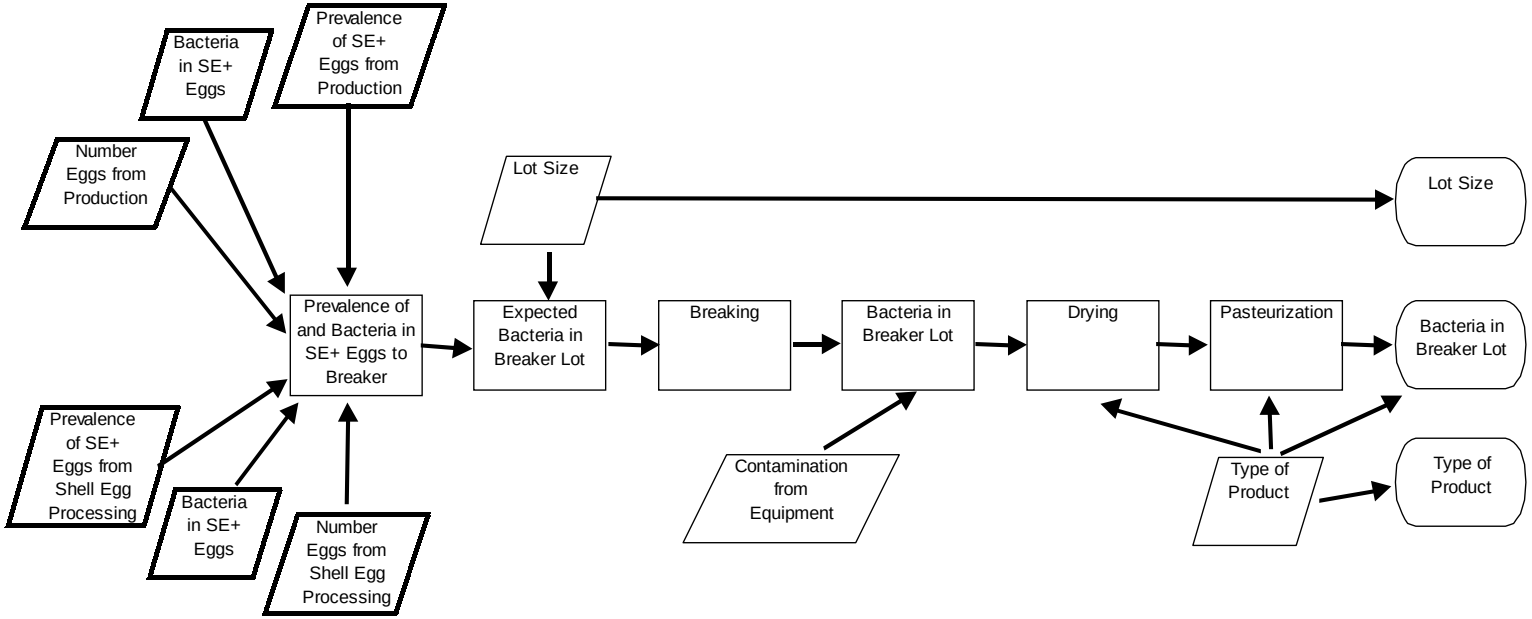


Figure C-3

Liquid egg product flow FY 1996

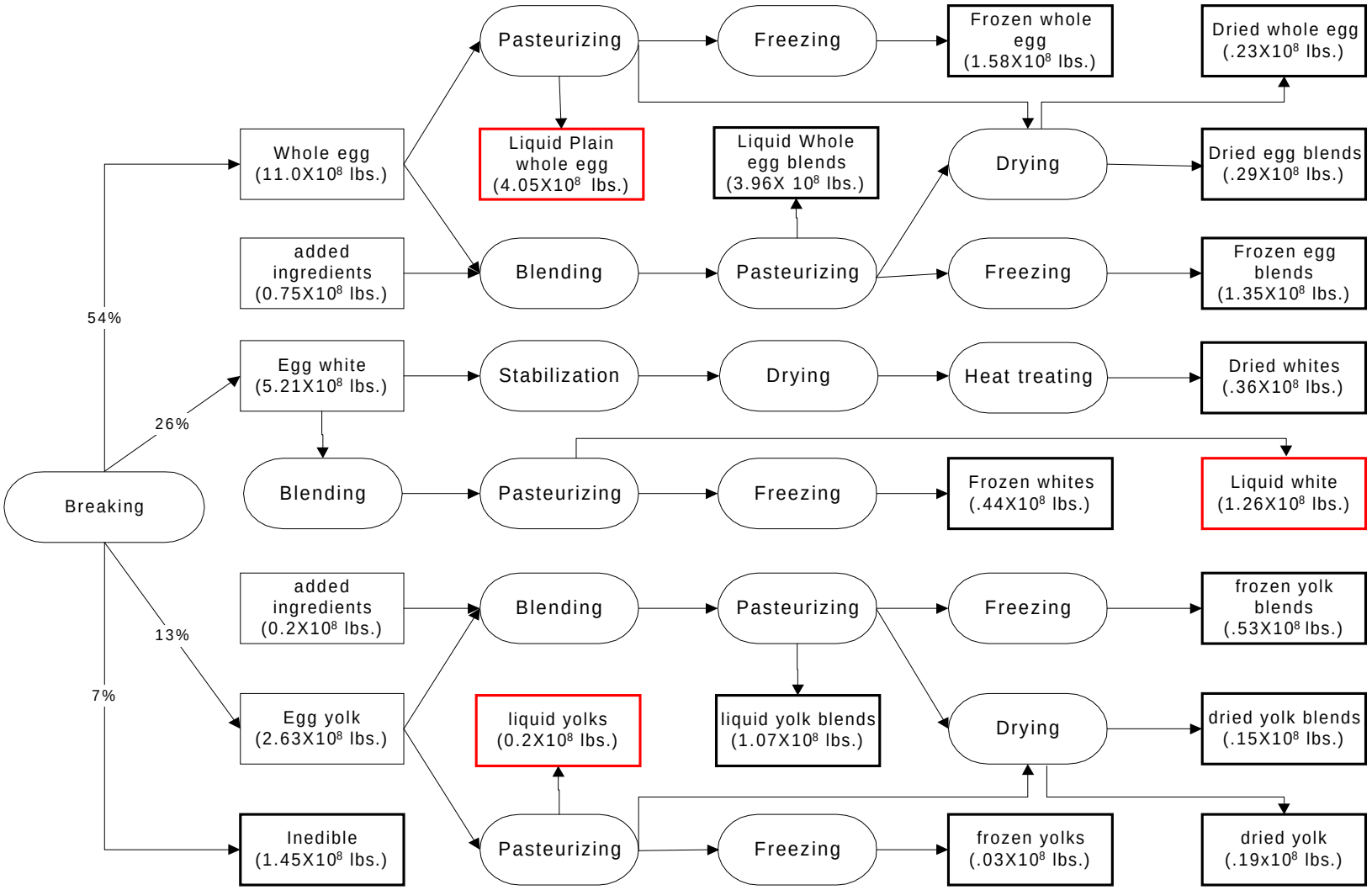


Table C-1. Amount of Egg Products Produced in the US in 1996

	Product	Pounds	Percent	Percent
liquid	whole egg	405,000,000	24%	32%
	albumen	126,000,000	7%	
	yolk	20,000,000	1%	
frozen	whole egg	158,000,000	9%	12%
	albumen	44,000,000	3%	
	yolk	3,000,000	0%	
blended	whole egg	396,000,000	23%	29%
	yolk	107,000,000	6%	
blended and frozen	whole egg	135,000,000	8%	11%
	yolk	53,000,000	3%	
dried	whole egg	23,000,000	1%	5%
	albumen	36,000,000	2%	
	yolk	19,000,000	1%	
blended and dried	whole egg	29,000,000	2%	3%
	yolk	15,000,000	1%	
inedible		145,000,000	8%	8%
Total		**1,714,000,000**	**100%**	**100%**

Conversions

Number of milliliters per pound of liquid egg = 438.25

To convert from pounds into milliliters of liquid egg multiply the number of pounds by 453.59 (equivalent in grams of 1 avoirdupois pound); then divide the product by 1.035 (the specific gravity of whole egg, albumen, and yolk) (Siegmund, 1979).

Ounces of egg to milliliters of egg

Multiply the number of ounces by 28.35 (equivalent in grams of 1 avoirdupois ounce): then divide the product by the specific gravity of the substance, to obtain its volume in milliliters (Siegmund, 1979).

B. Inputs to the Egg Products Processing and Distribution Module

1. Number of birds in a flock

Flocks are stratified by size to account for variability in egg production between flock size strata. The number of birds in a flock that contributes eggs to a lot (10,000 lbs.) of liquid egg is estimated from the distribution of birds per flock in the U.S. (See page 31 in production module).

a. Evidence

Table C-2. Number of egg-type laying birds per flock

Number of flocks	Birds per flock	frequency
1,892	11,470	0.38
1,134	27,222	0.23
519	68,691	0.10
1,483	110,000	0.30
5,028		1.0

Census of Agriculture, 1992

b. Distribution

Discrete (11,470, 27,222, 68,691, 110,000, .38, .23, .1, .3)

2. Frequency of *S*. Enteritidis positive flocks

The frequency of *S*. Enteritidis positive flocks is determined in the Production Module (see page 32). This module uses the Production Module calculations to determine the number of positive eggs in a lot (10,000 pounds of liquid).

3. Positive eggs per infected flock (see outputs of the Production Module page 60).

4. Number of SE bacteria per positive egg at lay (see page 80 in the Shell Egg Module)

C. Egg Products Module Variables

1. Number of eggs produced per bird per day

   a. Evidence

      The average hen in a flock produces 0.72 eggs per day (i.e., a hen will produce 72 eggs during a 100 day period). This average daily egg production is based on a published egg production curve (Rahn, 1997), which was adjusted for improved egg production - using annual USDA-NASS statistics.

   b. Value: 0.72 eggs per bird per day

   c. Distribution: Eggs produced per day is a constant in the model.

2. Proportion yolk and proportion albumen

   a. Evidence

   b. Value: An egg is 55% albumen and 45% yolk by volume or weight.

   c. Distribution: Proportion yolk and proportion albumen are constants in the model.

3. Weight of eggs in ounces

a. Evidence

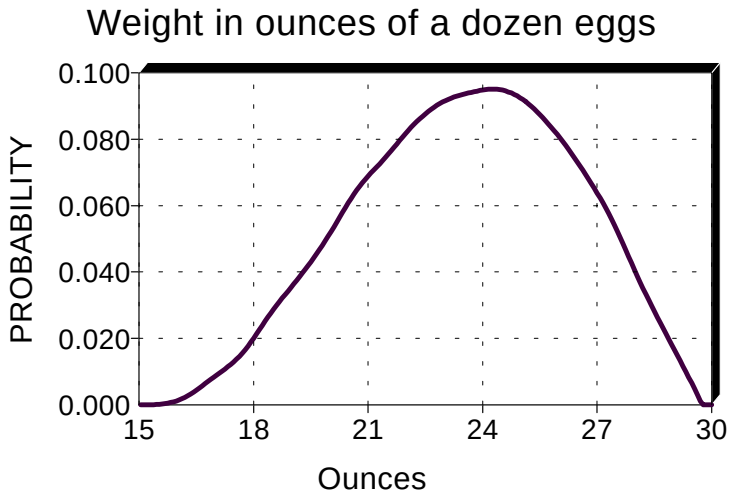
Table C-3. U.S. Weight Classes for Consumer Grades for Shell Eggs 7 CFR 56.218

Size or weight class	Minimum net weight per dozen (ounces)	Minimum net weight for individual eggs at rate per dozen (ounces)
Jumbo	30	29
Extra large	27	26
Large	24	23
Medium	21	20
Small	18	17
Peewee	15	--

b. Distribution - Pert(30,24,15)

This distribution assumes 15 ounces is the minimum weight of a dozen eggs, 24 ounces is the most likely and 30 ounces is the maximum. The value selected from this distribution is applied to all eggs from a flock.

Figure C-4



4. SE bacteria (from egg contents) in albumen and yolk

The mechanism of infection in birds determines the site of contamination within eggs. Research suggests *S.* Enteritidis colonizes the pre-ovulatory follicles of infected birds. SE can attach to granulosa cells resulting in the organisms becoming closely attached to the outside of the yolk membrane (Thiagarajan D., 1994). However, the isolation of *S.* Enteritidis from white of some eggs suggests that contamination can also occur after the ovulation process. This could occur through colonization of the oviduct or reverse peristalsis from the cloaca.

a. Evidence

SE was never isolate from aseptically collected yolk contents (Gast, 1990) but SE is frequently isolated from the yolk portion when the yolk is mechanically separated from the albumen. In a study of naturally infected eggs from two flocks SE was cultured from the yolk of 4 eggs and the albumen of 2 (Humphrey, 1989). In a second study on naturally infected eggs Humphrey found 2 of 14 yolks positive and 12 of 14 albumens positive (Humphrey, 1991). In experimentally infected laying hens, SE was cultured from the albumen of 153 of 855 (17.9%) eggs laid over a period of a month. SE was cultured from the yolk of 143 of 835 (17.1%) eggs (Gast, 1990). In a number of eggs *S.* Enteritidis was cultured from both the yolk and albumen of an egg. From this information it appears that although SE is rarely found in yolk contents, the probability of S. Enteritidis organisms being located in the albumen when eggs are separated is about the same as the probability of them being in the yolk portion.

When eggs are separated after breaking *Salmonella* Enteritidis organisms are distributed between yolks and albumens. This occurs only for SE from the internal contents of the eggs. After breaking an additional load of *Salmonella* is added to the egg. We assume that contamination added after breaking is equally likely to affect the yolks as the albumens.

b. Distribution:

The SE bacteria within an egg at the time of breaking are assigned to one of the following three outcomes: (1) all of the SE bacteria within the egg are associated with the yolk, or (2) all of the SE bacteria within the egg are associated with the albumen, or (3) 50% of the SE bacteria within the egg are associated with the yolk and 50% are associated with the albumen. Each of these three outcomes is assigned the same probability of 0.33. This assignment is used to calculate the level of SE in a lot (i.e. 10,000 pounds) of liquid egg product.

5. Pasteurization times, temperatures, and scenarios

The USDA currently regulates the minimum temperature and holding time for pasteurization of egg products. We used these values as constants and assumed that all breaker plants meet but do not exceed the requirements of the regulation. For the three products modeled, the regulation specifies two scenarios for albumen and yolk, and one for whole egg (Table C-4).

a. Evidence

Table C-4. USDA minimum time and temperature requirements for three egg products.

Liquid egg product	Minimum temperature requirements (° F)	Minimum holding time requirements (Minutes)
Albumen	134	3.5
	132	6.2
Whole egg	140	3.5
Plain yolk	142	3.5
	140	6.2

From: Regulations Governing the Inspection of Eggs and Egg Products (7 CFR Part 59). May 1, 1991, USDA, FSIS, Washington, D.C. 20250.

b. Distribution

We assumed the probability of pasteurization by the higher temperature shorter time scenario is the same as the lower temperature longer time scenario. Thus, a discrete distribution of 0 and 1 are used with a probability of 0.5 for both outcomes (discrete {0,1},{0.5,0.5}). If the result is 0 the log reduction from pasteurization is based on the lower temperature longer time scenario. If the result is 1 the log reduction is based on the higher temperature shorter time scenario.

6. Number of *Salmonella* Enteritidis in a lot (10,000 lbs.) of unpasteurized liquid egg

A number is selected by simulated sampling from the distribution of organisms per ml. shown below and multiplied by the number of ml. in a lot (10,000 lbs.) of liquid egg.

a. Evidence

The distribution of *Salmonella* Enteritidis in unpasteurized liquid egg across breaker plants nationwide was estimated from two surveys (table C-6). The first is an APHIS survey of 10 plants conducted in 1991 and repeated in 1995. Ten ml. of liquid whole egg were cultured for the presence or absence of *Salmonella* Enteritidis and other *Salmonella* serotypes. The second is a 1969 survey by Garibaldi that quantifies the level of *Salmonella* in liquid egg (Garibaldi, 1969).

Table C-6. *Salmonella* in unpasteurized liquid eggs

Reference	*Salmonella* species			*Salmonella* Enteritidis		
	pos.	samples	percent	pos.	samples	percent
Garibaldi, 1969	100	287	35%			
Ebel, 1993	524	1002	52%	132	1002	13%
Hogue, 1997	451	935	48%	179	937	21%

Comparison of results from the two surveys is problematic because of differences in methodology. Garibaldi used a Most Probable Number method and reported the number of *Salmonella* (all serotypes) per ml. of liquid egg while the APHIS surveys cultured 10 ml. of liquid egg for the presence or absence of *Salmonella* Enteritidis and all other *Salmonella* serotypes.

Evidence suggests that the use of data from Garibaldi's 1969 survey overestimates the number of organisms in a lot (10,000 lbs.) of liquid egg: 1) Garibaldi's survey reported the number of *Salmonella* species but *Salmonella* Enteritidis is one of many serotypes present in unpasteurized liquid egg (Hogue, 1997). 2) The highest level of *Salmonella* found in Garibaldi's survey was 100 organisms per ml. Controls over sanitation have improved since passage of the Egg Products Inspection Act of 1970 and its unlikely that levels in raw product today are as high as the highest level found in 1969.

b. Distribution

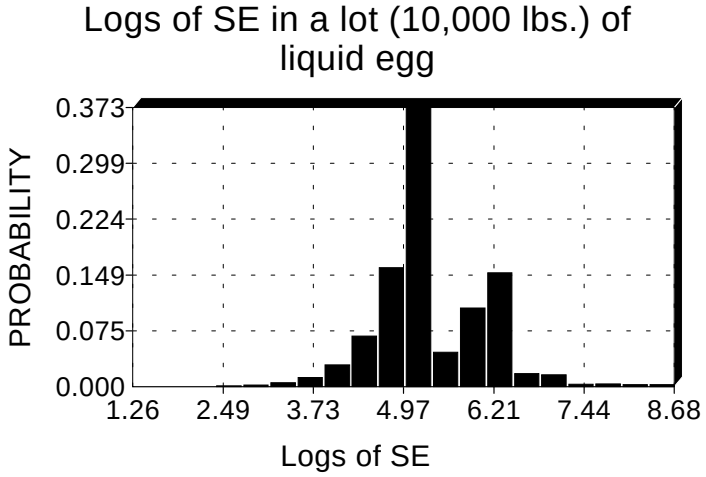
The data in Table C-7 was used to develop a distribution. A maximum value of 150 and a minimum value of 0.000001 were specified.

Table C-7. Number of *Salmonella* in Commercially Broken Eggs before Pasteurization

Number of Samples	MPN *Salmonella*	Frequency
187	0	0.6538
85	0.5	0.0411
10	2.25	0.0050
1	5.3	0.0005
2	24	0.0010
1	110	0.0005

Garibaldi, 1969

Mean	5.3
Standard Deviation	0.7
5th Percentile	4.2
95th Percentile	6.3



7. Pounds of liquid egg in a bulk egg holding tank

The bulk egg holding tank volume is the unit used in the liquid egg products module. The distribution of SE is calculated per tank and reductions in bacteria during pasteurization are applied to the entire tank.

a. Value

10,000 pounds

b. Evidence

unpublished data from the 1995 liquid egg survey

c. Distribution - none

The pounds of egg in holding tanks vary from 1,000 pounds to 100,000 pounds but we assumed a constant value of 10,000 pounds per tank.

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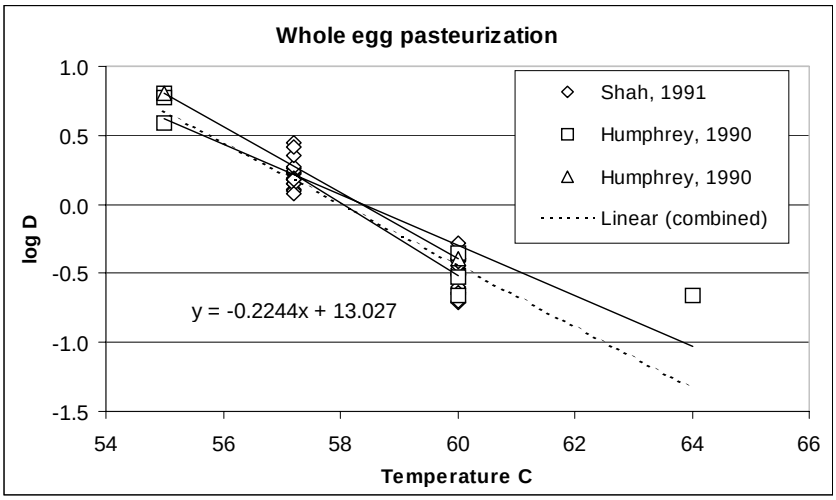
8. Log_{10} reduction of *Salmonella* Enteritidis in liquid whole eggs from pasteurization at 60° C (140° F) for 3.5 minutes.

a. Assumptions

All whole egg is pasteurized at the time and temperature combinations specified in the Egg Products Regulation (60° C [140° F] for 3.5 minutes).

All egg products plants meet but do not exceed the pasteurization requirements of the Egg Products Regulation (USDA, 1991).

Figure C-6



b. Evidence

Data from recent experimental studies by Shah and Humphrey were combined to calculate a single least squared regression equation to estimate log-D = 13.03 + (-0.22 × T) + E, where T is temperature in degrees Centigrade and E is the variability of the estimate: E = normal(μ = 0, σ = 0.16) (Figure C-6).

The log of D for *Salmonella* Enteritidis from pasteurization according to FSIS regulation (60° C for 3.5 minutes) is determined as follows:
First, determine the log-D from pasteurization at 60°C for one minute, by solving the regression equation (13.03 + (-0.22 × T) + E for T = 60°C:
$Log\text{-}D_{60}$ = 13.03 + (-0.22 × 60) = -0.44.
Then, determine the log of D for pasteurization at 60°C for 3.5 minutes:
$Log\text{-}D_{60\text{-}3.5}$ = log(3.5) - (-0.44) + E = 0.544 + 0.44 + E = 0.983 + E

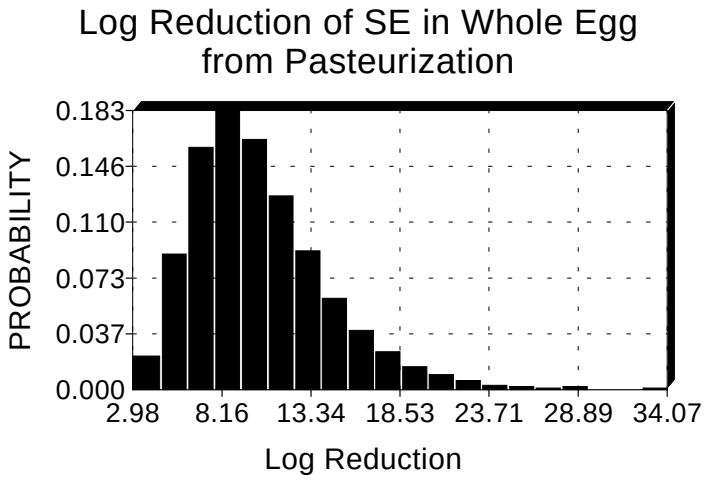
The log of the decimal reduction (log-D) for *Salmonella* Enteritidis from pasteurization according to FSIS regulation (60° C for 3.5 minutes) can be represented by a log normal distribution with a mean of 0.983 and a standard deviation of 0.16. The log reduction (D) is the antilog of log-D: $10^{log\text{-}D} = D$.

c. Distribution - $10^{\text{log normal } (\mu = 0.983,\ \sigma = 0.16)}$

Figure C-7 is a distribution for the log reduction of *Salmonella* Enteritidis in whole egg pasteurized at the minimum time and temperature requirements of the egg products regulation (60° C [140° F] for 3.5 minutes).

Figure C-7

Mean	10.3
Standard Deviation	4.0
5th Percentile	5.2
95th Percentile	17.8



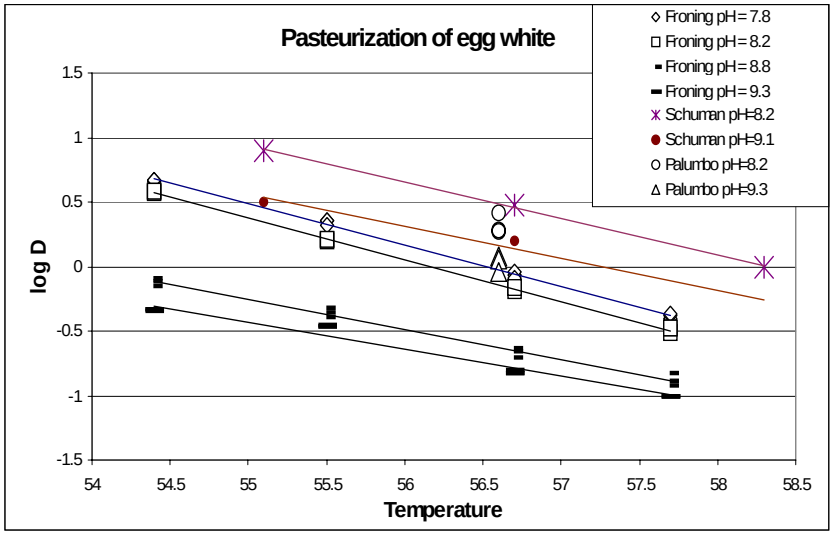
9. Log reduction of *Salmonella* Enteritidis in liquid egg white from pasteurization.

a. Assumptions

All liquid egg white is pasteurized at one of the two time and temperature combinations specified in the Egg Products Regulation (56.7° C [134° F.] for 3.5 minutes or 55.6° C [132° F.] for 6.2 minutes) and either time-temperature scenario is equally likely to occur.

All egg products plants meet but do not exceed the pasteurization requirements of the Egg Products Regulation (USDA, 1991).

Figure C-8



b. Evidence

Data from experimental studies by Froning (1997), Schuman (1997), and Palumbo (1996) were combined to calculate a single least squared regression equation: log-D = 64.0 + (-1.1 × T) + (-6.1 × pH) + (0.1 × T × pH) + E, where T is temperature in degrees Centigrade, E is the variability of the estimate: E = normal(μ = 0, σ = 0.16) and pH is a pert distribution with a minimum value of 7.8, most likely value of 8.2 and a maximum of 9.1 (see page 135). pH is inversely correlated with the reduction of bacteria during pasteurization and there is a significant interaction between pH and temperature.

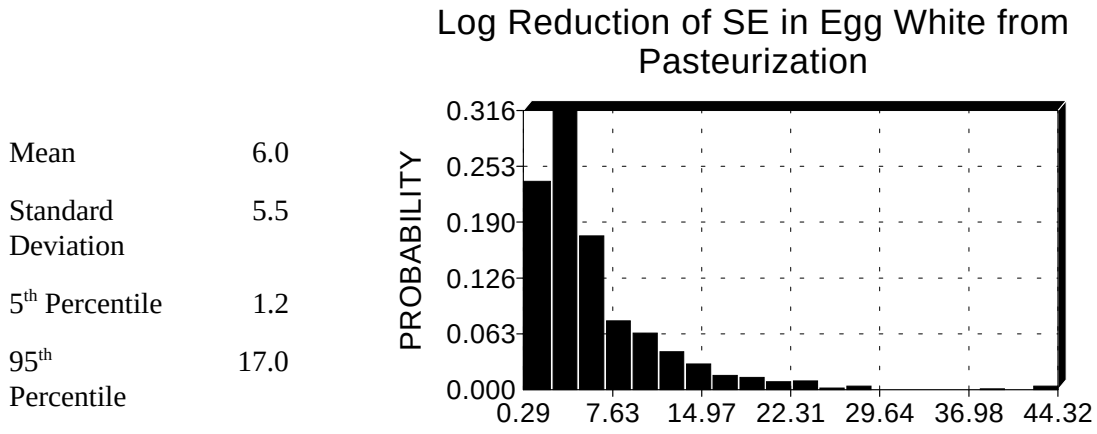
Variation of the estimate for the log of D within an experimental study, at a specified pH, is small (Figure C-8). However, there is a large variation in the results of experimental pasteurization studies by different investigators (Figure C-8). The reduction of bacteria calculated from a least squared regression

formula from data collected by Schuman for egg white pasteurized at 56.67 C for 3.5 minutes at a pH of 8.2 is 1.2 logs (Schuman, 1997). Under the same conditions Froning's data indicates a 5.1 log reduction; a difference of nearly 4 logs. The standard error of the Y estimate (log-D) calculated by combining the current data is large (0.33) because of this discrepancy in experimental results. This standard error is larger than that calculated by combining the data available for yolk (0.18) or whole egg (0.16). Possible explanations for the discrepancy are that Froning used a selective media which may have reduced the recovery of bacteria following pasteurization. A second explanation is that another confounding variable may be present.

c. Distribution - Log Normal

Figure C-9 is a distribution for the log reduction of *Salmonella* Enteritidis in egg white pasteurized at the minimum time and temperature requirements specified in the Egg Products Regulation (56.7° C [134° F.] for 3.5 minutes or 55.6° C [132° F.] for 6.2 minutes). Data from experimental studies by Froning, Palumbo, and Schuman were combined to calculate the regression equation used.

Figure C-9



Mean	6.0
Standard Deviation	5.5
5th Percentile	1.2
95th Percentile	17.0

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10. pH of liquid egg white at breaker plants

pH has a significant effect on the D-value when liquid egg white is pasteurized. The time and temperature requirements of the pasteurization regulations were based on a pH of about 9 for egg white which was the case in 1969 when the regulations were written. Since that time conditions have changed. Egg reach the market faster now than in 1969 and the pH of albumen is lower in fresher eggs. Pasteurization however is less effective at lower pH levels.

The effort here is to describe the distribution of pH in liquid egg white at breaker plants across the United States.

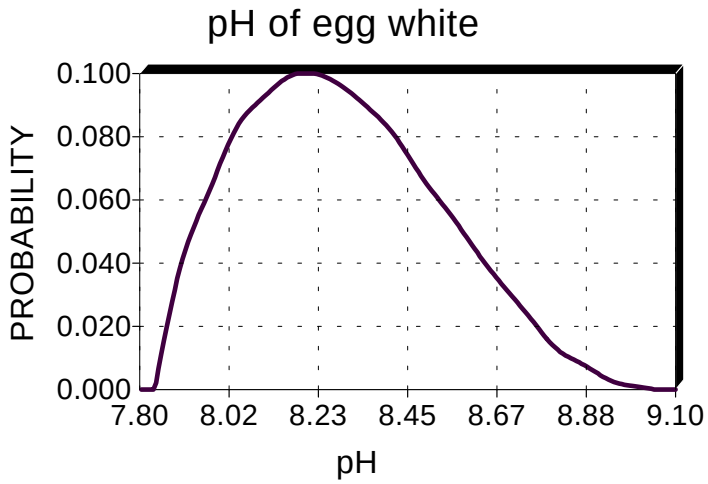
a. Evidence

Egg albumen has a bicarbonate buffer system which allows the pH to rise very rapidly. The pH of a freshly laid egg is about 7.8 and rises to 8.7 or 8.8 in about 3 days storage. After that, the pH increases much more slowly over time to a maximum of 9.3 to 9.4 (Froning).

In-line processed eggs reach the breaker plant within 24 hours of lay. Eggs that are broken in one plant and transported to another for processing are usually pasteurized within three days of lay. Eggs that are diverted from the shell egg market to breaking spend additional time in transport and storage before they are processed. The pH of eggs will reflect the time spent in transportation and storage.

b. Distribution - pert(7.8, 8.2, 9.1)

Figure C-10



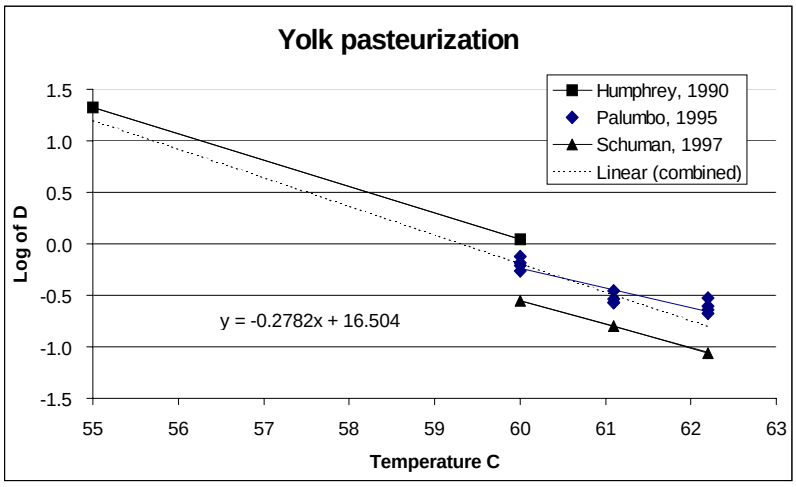
11. Log reduction of *Salmonella* Enteritidis in liquid egg yolk from pasteurization.

a. Assumptions

All liquid egg yolk is pasteurized at one of the two time and temperature combinations specified in the Egg Products Regulation (61.1° C [142° F] for 3.5 minutes or 60° C [140° F] for 6.2 minutes) and that either time-temperature scenario is equally likely to occur.

All egg products plants meet but do not exceed the pasteurization requirements of the Egg Products Regulation (USDA, 1991).

Figure C-11



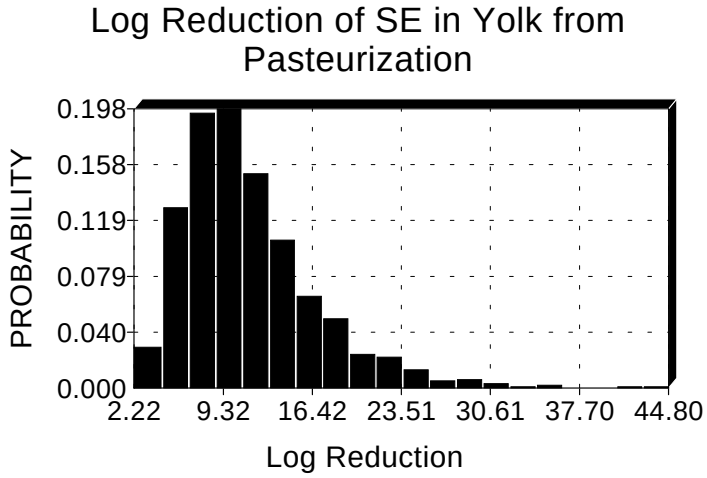
b. Evidence

Data from recent experimental studies (Humphrey, 1990; Palumbo, 1995; and Schuman, 1997) were combined to calculate a single least squared regression equation: log D = 16.50 - (0.28 × T), where T is temperature in degrees Centigrade (Figure C-12).

c. Distribution -

Figure C-12

Mean	11.3
Standard Deviation	5.3
5th Percentile	4.8
95th Percentile	21.6



D. Sensitivity Analysis

Table C-8. Correlation of input variables with *Salmonella* Enteritidis from all sources in product after pasteurization

Product	Input variable	Correlation Coefficient
Yolk	Number of SE before pasteurization	0.63
	Log reduction of SE (60 ° C)	0.34
	Log reduction of SE (61.1° C)	0.31
Whole egg	Number of SE before pasteurization	0.66
	Log reduction of SE (60° C)	0.65
Albumen	Number of SE before pasteurization	0.57
	Log reduction of SE (56.7° C)	0.41
	Log reduction of SE (55.6° C)	0.40
	pH	-0.19

The number of *Salmonella* Enteritidis bacteria remaining after pasteurization is more closely associated with the number of SE bacteria before pasteurization than with any other variable in the model. This relationship is true for yolk, whole egg, and albumen. Control of the bacterial load that goes into the pasteurizer is important in assuring the final product is free of SE. Knowledge of the distribution of SE in liquid egg across egg product plants in the U.S. is essential to predicting the number of bacteria that will remain after pasteurization.

The log reduction achieved through pasteurization according to FSIS time and temperature requirements is the second most strongly associated variable with the number of bacteria remaining after pasteurization. There is a great deal of uncertainty in the actual reduction achieved depending on the experimental study used to determine the D-value.

pH is inversely correlated with the final number of SE in pasteurized egg white. When time and temperature of pasteurization are held constant the number of bacteria decreases as the pH of albumen increases. This association is the weakest of those compared.

E. Module Validation

The FSIS monitoring program detected *Salmonella* species in 0.6% (25/4064) of the samples of egg product tested from January 1996 through December 1977 (Table C-9). Whole eggs with added yolk (88 samples), is the only product category in which no *Salmonella* species were detected. The FSIS monitoring program for egg products is not random. The skip lot program used by FSIS targets plants with a history of positive results for increased testing. Blended egg products had a greater proportion of samples positive for *Salmonella* species (1.0% or 13/1336), than dried (0.5% or 3/661), or liquid non-blended products (0.5% or 9/1979). An analysis of variance indicates that the proportion of *Salmonella* species positive blended samples is significantly higher than the proportion of *Salmonella* species positive liquid unblended products (at $p<0.05$). *Salmonella* Enteritidis was the most frequently isolated serotype (5 isolates); Typhimurium, Braenderup, Give, and Heidelberg were second (2 isolates each); Infantis, Agona, Hadar, and Montevideo were third (one isolate each). Serotyping was not done on six isolates and one isolate was untypable (Table C-9). All five *S*. Enteritidis isolates were cultured from blended egg products: four from yolk with more than 2% added salt or sugar and one from whole egg with more than 2.0% added salt or sugar (Table C-9).

The FSIS monitoring program detected five *Salmonella* Enteritidis isolates in pasteurized egg products from 1996 to 1997. *Salmonella* Enteritidis was not detected in any of the unblended liquid products modeled (yolk, whole egg, or albumen). Simulated testing was done to produce results from the model comparable with results from the FSIS monitoring program. Simulated testing of liquid whole egg and liquid yolk using FSIS methods (100 mls. of product tested with a detection sensitivity of 0.5 organisms per ml.) did not predict any SE-positive samples. These simulation results are consistent with the results of FSIS monitoring.

Simulated testing of albumen predicts that 5% of liquid albumen samples would be positive but the FSIS monitoring program did not find any *Salmonella* Enteritidis positive albumen samples. The discrepancy between the results of the FSIS monitoring program and the results of the simulation for liquid albumen may result from one or more of the following: 1) About 60% of the liquid albumen is produced without the use of added chemicals; the process modeled. The other 40% is produced with a process that uses peroxide to provide a greater reduction of bacteria at a lower temperature. The simulated results do not reflect the level of *Salmonella* Enteritidis in the 40% of albumen pasteurized using the peroxide process. 2) The pH of 8.3 which was used in the modeling of albumen may not accurate reflect conditions in the industry. 3) The model is incorrect in some other assumption.

Table C-9. Results of FSIS monitoring for *Salmonella* in pasteurized liquid egg products from 1996 and 1997

	year	pos	samples	percent	serotypes
egg whites - with or without added ingredients	1996	1	414	0.2%	Typhimurium
	1997	1	408	0.2%	Not serotyped*
whole eggs (<2% added ingredients)	1996	2	557	0.4%	Give Typhimurium
	1997	4	541	0.7%	Agona Hadar*
yolks (<2% added ingredients)	1996	1	36	2.8%	Braenderup
	1997	0	23	0%	
whole eggs with added yolks	1996	0	29	0%	
	1997	0	30	0%	
blended whole egg (>2% added ingredients)	1996	2	121	1.7%	Enteritidis
	1997	0	111	0%	
blended yolk (>2% added ingredients)	1996	4	331	1.2%	Enteritidis (2) Heidelberg*
	1997	5	338	1.5%	Enteritidis (2) Braenderup Heidelberg*
blended whole eggs with added yolks	1996	1	242	0.4%	Infantis
	1997	1	223	0.4%	Not serotyped*
Dried yolk and whole egg	1996	1	153	0.7%	Untypable
	1997	1	145	0.7%	Montevideo
Dried white	1996	1	186	0.5%	Give
	1997	0	176	0	

Serotyping was not done for all *Salmonella* species isolated

Table C- 10. Rank Order Comparison of *Salmonella* Serotypes Found in Liquid Egg Products Before and After Pasteurization

***Salmonella* serotypes in liquid egg before pasteurization - 1989 testing**		
Serotype	**number**	**percent**
Cerro	23	20%
Heidelberg	18	16%
Enteritidis	12	10%
Infantis	9	8%
Braenderup	8	7%
Mbandaka	7	6%
Montevideo	7	6%
Ohio	7	6%
Kentucky	4	3%
Thompson	3	3%
Agona	3	3%
Hadar	3	3%
Havana	2	2%
Typhimurium	2	2%
Livingstone	2	2%
London	1	1%
Oranienburg	1	1%
Poona	1	1%
Brandenburg	1	1%
Albany	1	1%
Haardt	1	1%
Total	116	100%

***Salmonella* serotypes in pasteurized liquid egg - 1996 to 1997 testing**		
Serotype	**number**	**percent**
Enteritidis	5	21%
Typhimurium	2	8%
Braenderup	2	8%
Give	2	8%
Heidelberg	2	8%
Infantis	1	4%
Agona	1	4%
Hadar	1	4%
Montevideo	1	4%
Untypable	1	4%
not serotyped	6	25%
Total	24	100%

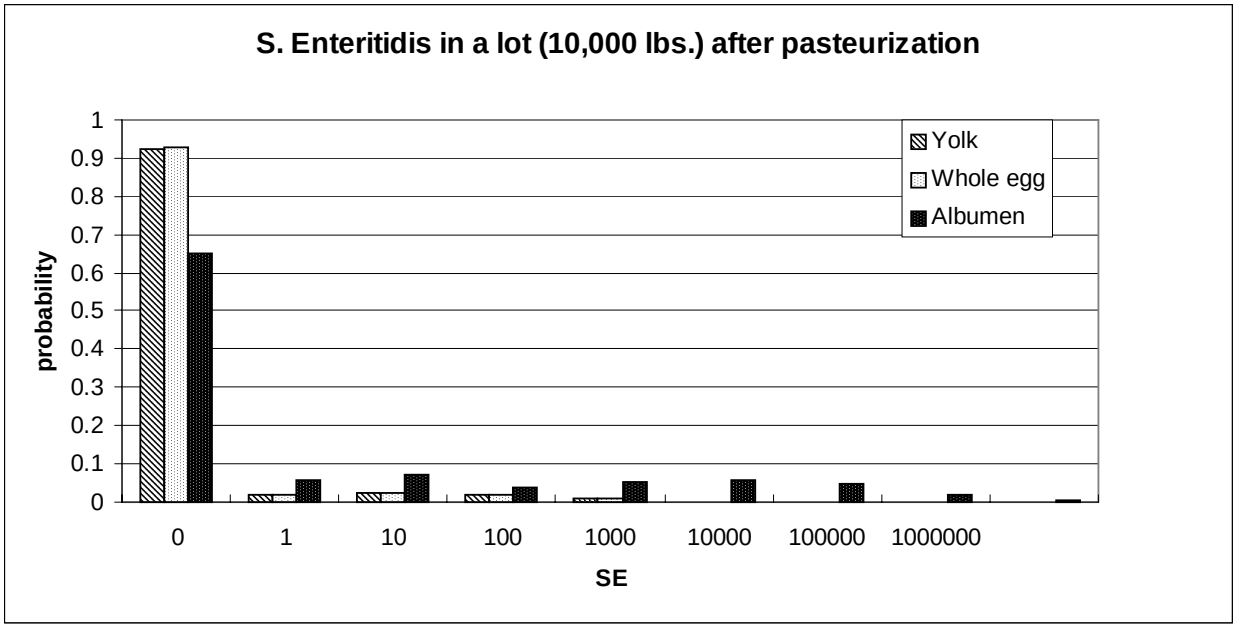
F. Results and Conclusions

The results of simulation of the module are shown in Figure C-13. The module predicts the probability that a single lot (a lot is composed of 10,000 lbs. of product) of liquid yolk or whole egg will not contain any *Salmonella* Enteritidis is larger than 0.9. The probability that liquid albumen will not contain any *Salmonella* Enteritidis in about 0.65.

The scope of this risk assessment for egg products is to evaluate the risk from a single *Salmonella* serotype (*Salmonella* Enteritidis) in a portion of the egg products produced in the U.S. annually. This module does not consider the possibility of post-pasteurization contamination of liquid egg products with *Salmonella* species but there is anecdotal evidence that this may occur. This module also does not consider the risk from out-of-date eggs returned to egg processing plants from grocery stores or from shell egg grading operations. Although this module is not a comprehensive coverage of the risk to human health from egg products it does provide insight into ways that FSIS can improve the controls in egg products processing.

Salmonella species are occasionally detected in pasteurized egg products (see Table C-10), but outbreaks of SE from egg products have not been reported since the Egg Productions Inspection Act was passed in early 1970. Two explanations may account for the lack of reported *Salmonella* outbreaks from pasteurized egg products: 1) Much of the egg product produced is used in further processing, either in an institution setting or in a consumer's home. Often this involves an additional heating process which kills any remaining *Salmonella*. 2) The number of *Salmonella* Enteritidis remaining after pasteurization is below the dose required to cause disease. If the egg product remains refrigerated, then *Salmonella* species will not multiply and the few remaining bacteria are diluted in a large volume of product. The exposure hazard for an

Figure C-13



individual under these circumstances is very small.

This baseline Egg Products Processing and Distribution Module describes the usual situation in the egg products processing industry and does not account for the possibility of process failure. Process failure can occur if the eggs used by breaker plants have very high levels of *Salmonella* or if equipment failure results in inadequate pasteurization. If current process controls fail, then a large number of people may be exposed to SE as a result. It is expected that failure in the pasteurization process is a rare event, but such an event has the potential to produce a significant number of cases of human illness.

A major portion of the load of *Salmonella* Enteritidis in liquid egg prior to pasteurization is introduced at the egg breaking step of egg processing.

Many *Salmonella* serotypes are found in liquid egg products before and after pasteurization (Table C-10). *Salmonella* Enteritidis was the serotype most frequently isolated by the FSIS monitoring program of pasteurized egg products between 1996 and 1997, and *Salmonella* Enteritidis was the third most frequently isolated serotype found by AMS testing of liquid egg product prior to pasteurization in testing conducted in 1989. With the exception of *Salmonella* Give, all the serotypes recovered from pasteurized product were also found in unpasteurized product, in spite of the fact that the testing was done 7 to 8 years apart.

Salmonella Enteritidis is the only serotype, of those listed in Table C-10, commonly isolated from the contents of intact eggs. Therefore, the other serotypes found in egg products before and after pasteurization must originate from a source located after the eggs are broken. Cantor made the same observation in 1948 before *Salmonella* Enteritidis was identified as a contaminant in eggs: "The majority of *Salmonella* types in egg powder do not originate in egg meat" (Cantor, 1948). Cantor's statement was based on the observation that many *Salmonella* serotypes were found in egg powder but *Salmonella* Pullorum was the most common serotype transmitted within eggs at that time in 1948.

Similarly, simulation results suggest that ovarian transmitted SE (SE from the contents of eggs) is less than 1% of the total SE load in liquid eggs prior to pasteurization. Most SE present in liquid egg prior to pasteurization originates from sources other than egg contents. These sources include: contamination from the shell of eggs as bits of shell fall into the liquid product or the egg contents contact the outside surface of the shell in the breaking process, contamination from the breaking machinery, machine operators, and airborne *Salmonella*.

Sensitivity analysis indicates that the number of SE bacteria before pasteurization is positively correlated with the number of SE bacteria remaining in liquid egg after pasteurization. This suggests that reduction of the number of bacteria in liquid egg prior to pasteurization will result in a reduction of bacteria after pasteurization. Plant sanitation is the most promising means of reducing *Salmonella* in the final product. Sanitation techniques include washing and sanitizing of incoming eggs, preventing cross contamination from breaking machinery, preventing contamination from machine operators, preventing contamination from airborne *Salmonella*, and preventing contamination from the surface of the shell during the breaking process.

Egg Products Processing and Distribution Module

The current FSIS minimum time and temperature requirements for pasteurization of egg products are not adequate to ensure that no *Salmonella* will survive pasteurization.

Current FSIS controls of egg product processing include minimum time and temperature requirements for pasteurization. These requirements are based on experimental pasteurization studies on egg products. This SE Risk Assessment model suggests reasons why these controls are not adequate to ensure that no human exposure occurs from *Salmonella* species remains in egg products after pasteurization:

1) The uncertainty in this module's estimate of the log of the reduction of bacteria in liquid egg which has been pasteurized according to FSIS regulations is large (see Table C-11). The 95% confidence interval for whole egg and yolk ranges from about five to more than 17 and the 95% confidence interval for albumen is about one to 16. This large uncertainty is a result of the large variation between the experimental studies upon which the estimates are based. Variation within a study is generally low, but variation between studies is large (see regression charts for whole egg, yolk, and albumen). Minor differences in methods between studies do occur, but no single variable has been identified as responsible for the lack of repeatability of these pasteurization studies conducted at different laboratories. Egg may, by its composition (high fat and globular), provide less repeatable results, or the conditions under which bacteria are grown prior to inoculation may influence experimental results.

Table C-11. Estimates of the reduction in *Salmonella* Enteritidis from pasteurization

Product	FSIS minimum pasteurization requirements	Log of reduction in SE expected	95% confidence interval
whole egg	60°C for 3.5 minutes	8.1	5.2-17.8
yolk	60°C for 6.2 minutes	7.8	4.7-19.6
	61.1°C for 3.5 minutes	8.2	5.4-22.5
albumen (pH=8.3)	55.6°C for 6.2 minutes	3.6	1.1-15.7
	56.7°C for 3.5 minutes	3.7	1.1-16.0

2) The number of *Salmonella* Enteritidis remaining after pasteurization is more closely associated with the number of bacteria before pasteurization than with any other variable in the module. This relationship is true for yolk, whole egg, and albumen. Control of the bacterial load that goes into the pasteurizer is important to insure that the final product is free of SE.

3) The intended use of the final product is an important factor in determining whether human exposure occurs from *Salmonella* species in egg products. The use of egg products can be placed in one of three categories: 1) Egg products may be further processed involving a controlled heat treatment. 2) Egg products may be part of a ready to eat product. 3) Egg products may be sold as products intended for cooking where a final heat treatment may or may not occur (i.e. liquid whole eggs to be cooked as scrambled eggs).

Egg Products Processing and Distribution Module

The risk of human exposure to *Salmonella* Enteritidis from egg products may be reduced by basing the minimum time and temperature requirement for pasteurization on the level of *Salmonella* species in raw product and the intended use of the final product.

Blended whole egg product and blended yolk product may pose a greater risk to consumers than other types of egg products.

This risk assessment does not model *Salmonella* Enteritidis in blended egg products, however the results of the FSIS egg products monitoring program suggest that blended products should be included in future modeling efforts. The FSIS egg products monitoring program found a greater proportion of samples positive for *Salmonella* species in blended egg products (1.0% or 13/1336) than dried (0.5% or 3/661) or liquid non-blended products (0.2% or 9/4034). An analysis of variance indicates that the proportion of *Salmonella* species positive blended samples is significantly higher than the proportion of *Salmonella* species positive liquid unblended products ($p<0.05$). *Salmonella* Enteritidis was the most frequently isolated serotype in blended egg products (5 isolates). All five *Salmonella* Enteritidis isolates were cultured from blended egg products: four from blended yolk with more than 2% added salt or sugar and one from blended whole egg with more than 2.0% added salt or sugar (Table C-9). The FSIS egg products monitoring program is not a random sampling program. The skip lot program used by FSIS targets those plants with a history of positive test results for more frequent testing.

Ingredients such as salt and sugar lower the a_w (water activity) of liquid egg and increase the thermal resistance of *Salmonella* species in the product. Pasteurization studies indicate that the log reduction of *Salmonella* species achieved by pasteurization of egg yolk blended with **10% added sugar** at the minimum time and temperature required in the egg products regulation (63.3° C or 146° F for 3.5 minutes) is about 4.9 logs (Palumbo, 1995). The log reduction of *Salmonella* species in yolk blended with **10% added salt** was 0.3 logs. Pasteurization at the minimum time and temperature requirements of the egg products regulation would not kill all of the 5.3 logs of SE expected to be present in these two blended yolk products prior to pasteurization (expected SE - see page 127).

In conclusion the current FSIS time and temperature regulations do not provide sufficient guidance to the egg products industry for the large range of products it produces. Time and temperature standards based on the amount of bacteria in the raw product, how the raw product will be processed, and the intended use of the final product will provide greater protection to the consumers of egg products.

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