Public Health Risk-Based Inspection System

for

Processing and Slaughter

Appendix A – Public Health Attribution and Performance Measures Methods

APPENDIX A – PUBLIC HEALTH ATTRIBUTION AND PERFORMANCE MEASURES METHODS

The Food Safety and Inspection Service (FSIS) is proposing a public health risk-based inspection system (PHRBIS) for meat and poultry processing and slaughter establishments. The components of the proposed PHRBIS are science-based and are being designed with input from stakeholder groups and expert peer review. One component of the PHRBIS is an algorithm for categorizing processing and slaughter establishments with respect to their potential impact on public health. A basic element of prioritizing and allocating resources to reduce the level of foodborne illness is the ability to identify which FSIS-inspected food products are major contributors to human foodborne illness. This Appendix gives an overview of an approach for performing microbial foodborne disease attribution, and for relating FSIS inspection activities to public health impacts and public health goals. FSIS acknowledges that no system of estimating foodborne disease attribution is perfect. The best current estimates come from combined consideration of illness outbreak data, illness case-control studies, risk assessments, pathogen serotype data, and expert elicitation (Batz et al. 2005). FSIS has adopted this approach and considered the best information currently available. FSIS, in conjunction with CDC and FDA is investigating methods, such as using serotypes and subtypes of pathogens to improve attribution estimates. FSIS will use these and other advances to improve foodborne disease attribution estimates as better information becomes available.

PRINCIPLE CAUSES OF FOODBORNE DISEASE OF ANIMAL ORIGIN

More than 250 different microbial foodborne diseases have been described (CDC 2007). Most of these diseases are infections, caused by a variety of bacteria, viruses, and parasites. The most commonly recognized foodborne infections in the United States are those caused by the bacteria *Campylobacter*, *Salmonella*, and *Escherichia coli* O157:H7 (*E. coli* O157:H7), and by a group of viruses known as Norwalk-like viruses (CDC 2007). Among bacterial agents, 47 percent of foodborne illnesses are caused by *Campylobacter*, 32 percent by *Salmonella*, and less than 0.06 percent are caused by *Listeria monocytogenes* (*Lm*) (CDC 2007).

The most definitive study on the burden of foodborne disease in the United States and attribution to known foodborne pathogens was performed by the Centers for Disease Control and Prevention (CDC) in 1999 (Mead et al. 1999). Foodborne diseases cause approximately 76 million illnesses in the United States each year (CDC 2007). CDC estimates there are 325,000 hospitalizations and 5,000 deaths related to foodborne diseases each year (Mead et al. 1999). Six pathogens account for 95 percent of estimated food-related deaths: *Salmonella* (31 percent), *Listeria monocytogenes* (28 percent), *Toxoplasma* (21 percent), Norwalk-like viruses (7 percent), *Campylobacter* (5 percent), and *E. coli* O157:H7 (3 percent) (**Table A-1**).

Table A-1. Estimated Annual Illnesses, Hospitalizations, and Deaths Caused by Foodborne Bacterial Agents in the United States

Agent	Total Illnesses	Foodborne Illnesses	Estimated % Foodborne	Foodborne Hospitalizations	Foodborne Deaths
Campylobacter	2.5 million	2.0 million	80	10,500	100
Salmonella	1.4 million	1.3 million	95	16,100	550
E. coli O157	73,500	62,500	85	1,800	50
E. coli non-O157	195,600	110,600	57	940	30
Listeria monocytogenes	2,520	2,490	99	2,300	500
Vibrio	7,900	5,100	65	1,200	30
Yersinia	96,400	87,000	90	1,100	2

Source: Mead et al. 1999, Based on data from 1996-1998.

CDC HEALTHY PEOPLE 2010 GOALS

The overall goal of a public health risk-based inspection system (PHRBIS) for meat and poultry processing and slaughter establishments is to improve the ability to protect public health. When considering how to reallocate resources, it is important to consider the Agency's public health goals. In Healthy People 2010, for which FSIS and the Food and Drug Administration (FDA) are the food safety co-leads, the CDC set a goal of reducing *Salmonella* species, *Campylobacter* species, *E. coli* O157:H7, and *Lm* infections each by 50 percent from the period 1996–1998. Subsequent to the publication of Healthy People, President William J. Clinton established the Council on Food Safety which set forth a Food Safety Strategic Plan that established similar targets. The Healthy People 2010 objectives are given in **Table A-2**.

Table A-2. CDC Healthy People 2010 Food Safety Objectives (Laboratory-Confirmed Cases of Foodborne Illness per 100,000 Population)

Pathogen	Laboratory-Confirmed Cases per 100,000	
	1997 Baseline	**2010 Target**
Campylobacter species	24.6	12.3
Escherichia coli O157:H7	2.1	1.0
Listeria monocytogenes	0.47	0.24
Salmonella species	13.7	6.8

Source: CDC http://www.healthypeople.gov/data/midcourse/comments/faobjective.asp?id=10

FSIS' efforts have focused on three microorganisms that can severely impact public health—*E. coli* O157:H7, *Salmonella*, and *Lm*. *Campylobacter* will be added in the near future. While good progress has been made toward those goals, FSIS must continuously evaluate how to most effectively use its resources to meet those goals.

FOODBORNE DISEASE ATTRIBUTION

No single source of information is currently able to provide a comprehensive picture of the food attribution issue. The best estimates come from combined consideration of multiple data sources including disease outbreak data, illness case-control studies, risk assessments, pathogen serotype data, and expert elicitation (Batz et al. 2005). FSIS has adopted this approach and reviewed the best information currently available.

- <u>Outbreak data</u> – The PHRBIS ranking algorithm employs the Centers for Disease Control and Prevention (CDC) outbreak data in developing estimates for food attribution. Reported data on foodborne disease outbreaks can be valuable in establishing a link between foodborne illness and the food sources that cause them. A strength of disease outbreak data is that the specific food sources causing the outbreak have generally been identified. While only a small fraction of total foodborne disease is caused by outbreaks, this does not automatically mean that attribution estimates derived from outbreak data disagree with those derived from sporadic disease data. For example, as demonstrated below, attribution estimates for the major FSIS-inspected food categories of beef, poultry, pork, and deli derived from CDC outbreak data agree closely with estimates from two expert elicitations which account for sporadic illness. This increases confidence in using the outbreak data for these pathogens. In addition, outbreak data represents the largest epidemiological dataset available for attribution studies and is a valuable source of information linking foodborne human illness with specific food sources.

- <u>CDC case-control studies</u> – CDC has conduced 18 twelve month population-based case control studies over the period 1996 to 2007 (Patrick 2007). The purpose of these studies was to identify risk factors (food sources) associated with sporadic illnesses. FSIS has reviewed CDC case-control studies relevant to identification of food types contributing to human cases of *Salmonella, E. coli* O157:H7, and *Listeria monocytogenes* illnesses. Unfortunately the utility of these studies is limited in that (1) there are very few studies, and (2) they are only able to identify the one or two major foodborne sources of human exposure. For example, for *Salmonella* CDC identified chicken and undercooked ground beef prepared outside the home, undercooked eggs, international travel, and exposure to birds and lizards as risk factors. For *Listeria monocytogenes*, CDC identified melons and hummus eaten at a commercial establishment, and living on a cattle farm as risk factors. Because of the limitations of this data, CDC case-control studies were not used for the attribution approach presented below.

- <u>Risk assessments</u> – The value of current risk assessments for developing food attribution studies is limited since they are generally focused on a single food product or process and therefore, do not provide attribution estimation across a range of food types, including both UDSA and FDA inspected foods. For example, FSIS has conduced risk assessments on *Salmonella* Enteritidis in shell eggs and *Salmonella* spp. in egg products (FSIS 2005), *E. coli* O157:H7 in ground beef (FSIS 2001), *E. coli* O157:H7 in intact (non-tenderized) and non-intact (tenderized) beef (FSIS 2002), *Listeria monocytogenes* in deli meat (FSIS 2003). Because these studies focused on a single food product they are not used for the attribution approach presented below. Various efforts are underway to use risk assessments in attribution studies including using meta-analysis of multiple studies and developing new exposure models that consider multiple pathways to human exposure. As these efforts develop they will be incorporated.

- <u>Pathogen serotype</u> – A CDC/FDA/FSIS effort is underway to use *Salmonella* serotype data to estimate attribution for meat and poultry products (Guo 2007). This effort is characterizing the relative contribution of specific broad categories of meat and poultry products to total human *Salmonella* illness for these meat and poultry products. Currently, because of a lack of data, it does not include FDA-inspected products except for eggs. FSIS has initiated a program of collecting *Salmonella* serotype data on chicken broilers and this data will be available in the future to improve attribution estimates.

- <u>Expert elicitation</u> – The use of expert elicitation in determining food attribution has been endorsed by the National Academy of Sciences (IOM/NRC 2003). FSIS will employ two different expert elicitations on food attribution: (1) An expert elicitation sponsored by FSIS (Karns et al. 2007) using a panel of 12 food safety experts to attribute foodborne illnesses of *Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes* and *Campylobacter* to handling and consuming foods in 25 processed meat and poultry product categories, and (2) An expert elicitation performed by Resources for the Future (RFF) and Carnegie Mellon University (Hoffmann et al. 2007), which used a panel of 42 food safety experts to estimate food attribution for each of 11 pathogens. A valuable contribution of the Hoffmann et al. (2007) study is that it includes both FSIS- and FDA-inspected food categories. It thus provides a more complete picture of disease attribution than the FSIS expert elicitation. However, the FSIS expert elicitation provides more detail on specific FSIS-inspected meat and poultry food categories. Thus, both elicitation studies provide different, but valuable perspectives on the food attribution problem.

- <u>Combined Approach</u> – As described below, the FSIS attribution methodology relies on two expert elicitations (FSIS 2007, Hoffmann et al. 2007) and the CDC outbreak data. After review of all currently available approaches, FSIS has determined that these three data sources are the most comprehensive currently available datasets for use in estimating foodborne disease attribution. As additional datasets and other approaches (like serotype for *Salmonella* sporadic disease) are developed, they will be incorporated.

The remainder of the Appendix will focus on using a combination of disease outbreak data and expert elicitation to arrive at estimates of foodborne disease attribution for FSIS-inspected food products.

EXPERT ELICITATION

One frequently used approach to foodborne disease attribution is the use of expert elicitation. During expert elicitation, a group of experts is asked, based on their professional judgment, to either rank food groups as to their relative important as sources of foodborne disease or to estimate the percent contribution of food groups to foodborne disease. The reliability of expert opinion regarding foodborne disease attribution has been questioned since it is based on opinion and not quantifiable data (Batz et al. 2005). However, by selecting experts with first-hand knowledge of different aspects of foodborne attribution (e.g., experts working in academia, the food industry, and public health) it is possible to obtain an informed and integrated judgment of the impact of different food types of human illness. Moreover, expert judgment is often the best source for guidance when scientific and epidemiologic data are sparse (Batz et al. 2005; National Academy of Sciences 2003). We briefly review the results of two recent expert elicitations.

FSIS Expert Elicitation

Karns et al. (2007) conducted an expert elicitation for FSIS to determine foodborne disease illness attribution for 25 meat and poultry food categories. The expert panel consisted of 12 experts equally divided among scientists from the public health community, industry, and academic institutions. The expert panelists were asked to attribute foodborne illnesses of *Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes*, and *Campylobacter* to handling and consuming foods in 25 processed meat and poultry product categories. The attributions developed represent the percentage that each product category contributes to the overall disease rate from all 25 FSIS meat and poultry product categories. The attributions thus sum to 100 percent for each pathogen. The attributions obtained for the Karns et al. (2007) study are presented in **Table A-3**.

Table A-3. FSIS Expert Elicitation (Karns et al. 2007) on the Percentage of Foodborne Illness Attributable to Each of 25 Processed Meat and Poultry Product Categories

Finished Product Type	***Salmonella***	***E. coli* O157:H7**	***L. monocytogenes***
Raw ground, comminuted, or otherwise nonintact chicken	8.9	0.4	1.3
Raw ground, comminuted, or otherwise nonintact turkey	6.8	0.3	1.2
Raw ground, comminuted, or otherwise nonintact poultry – other than chicken or turkey	2.8	0.4	0.9
Raw ground, comminuted, or otherwise nonintact beef	8.4	57	1.9
Raw intact chicken	22.0	1.1	1.3
Raw intact turkey	14.1	0.3	0.8
Raw intact poultry – other than chicken or turkey	3.7	0.7	1.4
Raw otherwise processed poultry	5.6	0.6	1.4
Raw ground, comminuted, or otherwise nonintact meat – other than beef or pork	2.7	13.8	0.8
Raw otherwise processed meat	3.5	2.9	1.5
Raw ground, comminuted, or otherwise nonintact pork	4.3	1.4	0.9
Raw intact beef	4.6	8.4	1.4
Raw intact meat – other than beef or pork	2.2	2.6	0.4
Raw intact pork	2.8	1.3	0.6
RTE acidified/fermented poultry (without cooking)	1.6	0.3	4.4
RTE acidified/fermented meat (without cooking)	1.0	4.2	6.4

Finished Product Type	***Salmonella***	***E. coli* O157:H7**	***L. monocytogenes***
RTE fully cooked poultry	1.0	0.2	25.0
RTE salt-cured poultry	0.6	0.2	4.0
RTE salt-cured meat	0.5	0.8	3.6
RTE dried meat	0.9	1.3	3.2
RTE dried poultry	1.0	0.2	3.2
RTE fully cooked meat	0.5	1.1	30.2
RTE meat fully cooked without subsequent exposure to the environment	0.3	0.3	2.1
RTE poultry fully cooked without subsequent exposure to the environment	0.3	0.3	2.0
Thermally processed, commercially sterile	0.0	0.0	0.1

Source: Karns et al. 2007.

Resources for the Future/Carnegie Mellon Expert Elicitation

Resources for the Future (RFF) in conjunction with Carnegie Mellon University conducted an expert elicitation attribution study to determine the relative contribution of different foods to foodborne illness in the United States (Hoffmann et al. 2007). In what follows this study is referred to as the RFF expert elicitation. The authors of the study used a panel of 42 food safety experts to perform a separate food attribution relative ranking for each of 11 pathogens. For each pathogen, respondents were asked to provide their best estimate of the proportion of cases of foodborne illness caused by a specific pathogen in a typical year associated with consumption of each of 11 food categories. While the RFF study (Hoffmann et al. 2007) looked at 11 different pathogens, we present their results for only three pathogens: *Salmonella*, *E. coli* O157:H7, and *L. monocytogenes*. Resources for the Future and Carnegie Mellon University have followed up this study with additional valuable investigations on attribution estimates (Hoffmann et al. 2007a, Hoffmann et al. forthcoming)

A valuable contribution of the Hoffmann et al. study is that it includes both FSIS- and FDA-inspected food categories. It thus provides a more complete picture of disease attribution than the FSIS expert elicitation. However, the FSIS expert elicitation provides more detail on specific meat and poultry food categories. Thus, both elicitation studies provide slightly different perspectives on the food attribution problem.

Table A-4 presents data from the RFF elicitation of the percent contribution (attribution) of 11 food types to foodborne illness in the United States. Hoffman et al. (2007) also used the percent attributions in Table A-4 to estimate the number of illnesses from each food type. These estimates are presented in **Table A-5**.

Table A-4. RFF Expert Elicitation (Hoffman et al. 2007) Estimate of Percent Contribution of Listed Food Types to Foodborne Illness in the United States

Food Type	***Salmonella***	***E. coli* O157:H7**	***L. monocytogenes***
Beef	10.90	67.90	1.60
Poultry	35.10	0.86	2.70
Pork	5.70	0.59	1.30
Deli meats	1.90	1.78	54.00
Eggs	21.80	0.03	0.32
Seafood	2.04	0.05	7.10
Produce	11.70	18.40	8.70
Breads and bakery	0.03	0.00	0.16
Dairy	7.30	4.00	23.60
Beverages	1.70	3.20	0.20
Wild game	1.60	3.20	0.30

SOURCE: Hoffmann et al. (2007)

Table A-5. RFF Estimates of Foodborne Illnesses using Expert Elicitation to Attribute Mead et al. Illness Estimates

Food Type	***Salmonella***	***E. coli* O157:H7**	***L. monocytogenes***
Beef	146,781	42,418	39
Poultry	471,391	539	67
Pork	76,527	368	32
Deli meats	25,075	1,113	1,346
Eggs	292,463	18	8
Seafood	27,377	33	178
Produce	156,463	11,507	216
Breads and bakery	3,833	0	4
Dairy	97,439	2,477	589
Beverages	23,232	1,987	5
Wild game	21,292	1,998	8
Total Illnesses	1,341,873	62,458	2,493

SOURCE: Hoffmann et al. (2007)

Comparison of RFF and FSIS Expert Elicitations

The food categories used in the RFF attribution study are different than those used in the FSIS expert elicitation attribution study. However, the FSIS food categories may be collapsed into the four meats and poultry food categories considered in the RFF study. Note that the correspondence is not perfect since the FSIS has two categories (raw intact meat-other and beef or pork, and raw ground, comminuted, or otherwise nonintact meat – other than beef or pork) that are not included in the RFF beef category. **Table A-6** presents the correspondence used to compare the two studies.

Table A-6. Correspondence between Meat and Poultry Categories used in the RFF and FSIS Expert Elicitation Studies

RFF Meat and Poultry Categories	FSIS Food categories
Beef	Raw ground, comminuted, or otherwise nonintact beef Raw intact beef Raw ground, comminuted, or otherwise nonintact meat – other than beef or pork Raw otherwise processed meat Raw intact meat – other than beef or pork
Poultry	Raw ground, comminuted, or otherwise nonintact chicken Raw ground, comminuted, or otherwise nonintact turkey Raw ground, comminuted, or otherwise nonintact poultry – other than chicken or turkey Raw intact chicken Raw intact turkey Raw intact poultry – other than chicken or turkey Raw otherwise processed poultry
Pork	Raw ground, comminuted, or otherwise nonintact pork Raw intact pork
Deli meats	All RTE categories

Using the mapping in Table A-6, food attribution for the four meat and poultry food categories can be calculated. **Table A-7** presents the results of the calculation.

Table A-7. Attribution (percentages) to Four Meat and Poultry Food Categories for the FSIS and RFF Expert Elicitation Studies

Finished Product Type	Salmonella		*E. coli* O157:H7		*Listeria* M	
	FSIS	RFF	FSIS	RFF	FSIS	RFF
Beef	21.4	20.4	84.7	95.5	4.6	2.7
Poultry	64.1	65.5	3.8	1.2	8.3	4.5
Pork	7.1	10.6	2.7	0.08	1.5	2.2
Deli meats	7.7	3.5	8.9	2.5	84.2	90.6

As can be seen from Table A-7, the two expert elicitation attribution studies produce very similar results. A linear regression of the two data sets yields a correlation coefficient (R^2) of 0.989 for *Salmonella*, 0.998 for *E. coli* O157:H7, and 0.998 for *Listeria monocytogenes*. Thus, the attribution statistics derived from the RFF and FSIS studies are highly correlated. These correlations provide additionally validation of the FSIS expert elicitation study. It is noted by FSIS that there may have been some information exchange between the two studies since, while the RFF expert elicitation had 47 members and the FSIS study had 12 members, the two committees had a few members in common. In addition, as might be expected, the members of the two groups may have relied on common sources of information to arrive at their estimates.

Nevertheless, these two expert elicitations represent the best current expert opinion regarding estimates of foodborne disease attribution.

FOODBORNE DISEASE OUTBREAKS

Data on foodborne disease outbreaks can provide a useful source of information concerning some aspects of the food attribution problem. An outbreak is defined as the occurrence of two or more cases of a similar illness resulting from the ingestion of a food in common. The CDC maintains a database of foodborne illness outbreaks that covers the years 1990 to 2006. Reported data on foodborne disease outbreaks can be valuable in establishing a link between foodborne illness and the specific food sources that cause them. As pointed out above, while only a small fraction of total foodborne disease is caused by outbreaks, this does not automatically mean that attribution estimates derived from outbreak data disagree with those derived from sporadic disease data. For example, attribution estimates for the major FSIS-inspected food categories of beef, poultry, pork, and deli derived from CDC outbreak data agree closely with estimates from two expert elicitations which account for sporadic illness. This increases confidence in using the outbreak data for these pathogens. In addition, outbreak data represent the largest epidemiological dataset available for attribution studies and provide an important source of information linking foodborne illness with specific food sources. **Table A-8** presents attribution information related to outbreaks of *E. coli* O157:H7, *Salmonella*, and *L. monocytogenes.*

Table A-8. CDC Outbreak Data for *Salmonella*, *E. coli* O157:H7, and *L. monocytogenes* by Specific Food Category

Food Type	***Salmonella***		***E. coli* O157:H7**		***Listeria monocytogenes***	
	Cases	**Percent**	**Cases**	**Percent**	**Cases**	**Percent**
Beef	2,253	8.9	2,105	44.3	0	0.0
Poultry	5,633	22.3	49	1.0	3	0.8
Deli Meats	320	1.3	59	1.2	251	69.9
Pork	1,121	4.4	0	0.0	0	0.0
Seafood	773	3.1	26	0.5	0	0.0
Produce	6,144	24.3	2042	43.0	0	0.0
Eggs	4,309	17.0	0	0.0	0	0.0
Dairy	2,748	10.9	319	6.7	105	29.3
Breads, Bakery	1,154	4.6	0	0.0	0	0.0
Game	0	0.0	4	0.1	0	0.0
Beverages	818	3.2	149	3.1	0	0.0
Total	25,273	100	4,753	100	359	100

One value of the CDC outbreak database is that it presents attribution data of both FSIS- and FDA-regulated foods. Another source that estimates attribution for both FSIS- and FDA-regulated foods is the Resources for the Future expert elicitation (Hoffman et al. 2007). **Table A–9** compares food type attributions from these two sources.

Table A-9. Comparison of Attribution Estimates Derived from the RFF and CDC Datasets

Food Type	***Salmonella***		***E. coli* O157:H7**		***L. monocytogenes***	
	RFF	**CDC**	**RFF**	**CDC**	**RFF**	**CDC**
Beef	10.9	8.9	67.9	44.3	1.6	0.0
Poultry	35.1	22.3	0.9	1.0	2.7	0.8
Pork	5.7	4.4	0.59	0.0	1.3	0.0
Deli meats	1.9	1.3	1.78	1.2	54	69.9
Eggs	21.8	17.0	0.03	0.0	0.32	0.0
Seafood	2.0	3.1	0.05	0.5	7.1	0.0
Produce	11.7	24.3	18.4	43.0	8.7	0.0
Breads and bakery	0.03	4.6	0	0.0	0.16	0.0
Dairy	7.3	10.9	4.0	6.7	23.6	29.3
Beverages	1.7	3.2	3.2	3.1	0.2	0.0
Wild game	1.6	0.0	3.2	0.1	0.3	0.0

In general, agreement between the two studies is good. The CDC outbreak database attributes a larger percentage of *Salmonella* cases to FDA regulated foods than does the RFF expert elicitation. The main difference for *Salmonella* is that the CDC outbreak database attributes a larger percentage of *Salmonella* cases to produce consumption and a smaller percentage to poultry consumption than does the RFF study. For *E. coli* O157:H7, the CDC outbreak database attributes a larger percentage of *E. coli* O157:H7 cases to produce consumption and a smaller percentage to beef consumption than does the RFF study. Nevertheless, the two studies produce remarkably good agreement given that the CDC data reflects only outbreak data, while the RFF study reflects expert opinion regarding the impact of both outbreak and sporadic disease. Together, the two studies provide complementary perspectives on disease attribution.

All three of the FSIS, RFF, and CDC datasets cover FSIS meat and poultry food categories. We can thus compare all three studies with respect to meat and poultry food categories. To accomplish this, we collapse the food categories used in the three studies to four meat and poultry food categories as described by Table A-6 above. We then normalize the percentage so they add to 100 percent for these four food categories. This is necessary because the FSIS study only considered FSIS regulated meat and poultry categories, while the RFF and CDC datasets considered both FSIS and FDA food categories. **Table A-10** presents a comparison of the three studies.

Table A-10 Comparison of Normalized Attribution (Percentage) Developed by the FSIS, RFF, and CDC Studies

Finished Product Type	*Salmonella*			*E. coli* O157:H7			*L. monocytogenes*		
	FSIS	**RFF**	**CDC**	**FSIS**	**RFF**	**CDC**	**FSIS**	**RFF**	**CDC**
Beef	21.4	20.4	24.2	84.7	95.5	95.3	6.0	2.7	0.0
Poultry	63.9	65.5	60.4	3.8	1.2	2.1	8.3	4.5	1.1
Pork	7.1	10.6	12.0	2.7	0.08	0.0	1.5	2.2	0.0
Deli meats	7.7	3.5	3.4	8.9	2.5	2.6	84.2	90.6	98.9

As can be seen from Table A-10, the three attribution studies (one of which is an actual count of outbreak illness) produce very similar estimates of attribution for FSIS-inspected beef, poultry, pork, and deli meat products. This result provides an independent validation of the attribution results of the FSIS 2007 expert elicitation (Karns et al. 2007). The above methodology has been peer reviewed and is supported by CDC.

ATTRIBUTION FOR 25 FSIS MEAT AND POULTRY PRODUCT CATEGORIES

The Karns et al. (2007) expert elicitation study (Table A-3) is the only study that gives attribution estimates for each of the 25 meat and poultry product categories of interest to FSIS. The Karns et al. (2007) study can be used along with results of the RFF expert elicitation and the CDC outbreak data to provide attribution estimates for the 25 FSIS meat and poultry product categories. The basic approach is as follows:

- The average normalized attribution estimates from Table A-10 are assumed to represent the most reasonable estimate of attribution for the four major FSIS product categories.

- The average normalized attribution estimates from Table A-10 are used to adjust attribution estimates from the Karns et al (2007) study so that the study agrees with the average Table A-10 attribution estimates for the four major FSIS product categories.

MICROBIAL SEROTYPES

A serotype is a grouping of microorganisms or viruses based on their cell surface antigens. Serotypes allow organisms to be classified at the sub-species level; an issue of particular importance in epidemiology. Phage typing is a subtyping method used to monitor trends within a given serotype of bacteria. A phage (also called bacteriophage) is a small virus that infects only bacteria. Serotyping has also proved useful for foodborne disease attribution. The CDC tracks serotype information through its PulseNet database. PulseNet is a national network of public health and food regulatory agency laboratories coordinated by the CDC. The network consists of: state health departments, local health departments, and federal agencies (CDC, USDA/FSIS, and FDA). PulseNet participants perform standardized molecular subtyping (or "fingerprinting") of foodborne disease-causing bacteria by pulsed-field gel electrophoresis (PFGE). PFGE can be used to distinguish strains of organisms such as *E. coli* O157:H7, *Salmonella*, *Shigella*, *Listeria*, or *Campylobacter*.

Salmonellae are divided into more than 2300 serotypes, although the majority of human disease is caused by 5 serotypes. *Salmonella* serotypes can be used to quantify to contribution of *Salmonella* to human disease from different food groups. This is accomplished by comparing the serotypes identified in human infections with the prevalence of the serotypes isolated from the different food sources, weighted by the amount of food source consumed (Hald et al. 2004). The Netherlands and Denmark have used serotyping methods to produce annual estimates of the number of human *Salmonella* infections attributable to various food sources (Hald et al. 2004; Havelaar et al. 2007).

A CDC/FDA/FSIS effort is underway to use *Salmonella* serotype data to estimate attribution for meat and poultry products (Guo 2007). However, the project is not yet complete.

DISTRIBUTION OF ILLNESSES BETWEEN FSIS- AND FDA-INSPECTED FOODS

Two data sources contain information upon which to base an estimate of the distribution of illnesses between FSIS- and FDA-inspected foods: the Resources for the Future expert elicitation and the CDC Outbreak Database (see **Table A-11** through **Table A-13**).

Table A-11 Percent of Foodborne *Salmonella* Illnesses Attributable to FSIS- and FDA-Inspected Food Products.

Source	RFF	CDC	Average
FSIS Regulated Foods	54	37	46
FDA Regulated Foods	46	63	54

Based on these data, 46 percent of *Salmonella* foodborne illnesses are attributable to FSIS and 54 percent are attributable to FDA regulated foods.

Table A-12 Percent of Foodborne *E. coli* O157:H7 Illnesses Attributable to FSIS- and FDA-Inspected Foods

Source	RFF	CSPI	Average
FSIS Regulated Foods	71	47	59
FDA Regulated Foods	29	53	41

Based on these data, 59 percent of *E. coli* O157:H7 foodborne illnesses are attributable to FSIS and 41 percent are attributable to FDA-inspected foods

Table A-13 Percent of Foodborne *Listeria monocytogenes* Illnesses Attributable to FSIS- and FDA-inspected Foods

Source	RFF	CDC	Average
FSIS-Regulated Foods	60	71	66
FDA-Regulated Foods	40	29	34

PERFORMANCE OBJECTIVES RELATED TO PUBLIC HEALTH GOALS

FSIS has developed performance measures and objectives for *Salmonella* on broilers, *Listeria monocytogenes* in ready-to-eat products, and *E. coli* O157:H7 in ground beef, as seen in Table A-14. FSIS has based its goals for these pathogen product pairs on the CDC Healthy People 2010 goals. CDC plans to establish updated Food Safety Public Health goals for 2020. Once those goals are established, FSIS performance objectives will also be updated.

FSIS assesses its progress toward meeting the Healthy People 2010 goals using the volume adjusted percent positive rates from FSIS laboratory verification testing data and the expected human case rate based upon this percent positive rate. Beginning in 2008, FSIS began using volume adjusted percent positive rates as opposed to non volume adjusted percent positive rates to measure its progress toward meeting the Healthy People 2010 goals. FSIS believes that volume adjusting provides a better estimate of population exposure to pathogens because it gives more weight to positive pathogen test results in high volume establishments.

Previously, performance measures and objectives were calculated by dividing the total number of samples positive for *Lm* and *E. coli* O157:H7 by the total number of samples tested for each pathogen. That method, however, is not representative of the potential exposure to the pathogens, because it does not take into account differences in production volume across the establishments being sampled. For example, an *E. coli* O157:H7 positive at a production facility producing a small amount of ground beef would cause fewer *E. coli* O157:H7 illnesses than a positive at a large production facility. Therefore, adjusting for production volume provides measures and objectives that are more representative of FSIS' progress towards preventing cases of human illness. Formula A- 1 presents the calculation used to adjust for production volume and any possible over-sampling of production volume classes. The number 4 in the formula represents the number of volume classes used for establishments producing ground beef and n_i is the number of establishments in each volume category.

The sections below provide an overview of FSIS' performance goal, objective and measurement development using the Agency's foodborne illness attribution methodology and volume adjustment.

Formula A-1 Calculation of Volume-Weighted Proportion of Adulterated Sample Units

$$\text{Proportion of adulterated sample units} = \frac{\sum_{i=1}^{4}\left(\left(\frac{\text{Production lbs}}{\text{Day}}\right)_i \times \text{Days}_i \times n_i \times \frac{\sum_{j=1}^{n_i}\frac{\text{Positives}_j}{\text{Samples}_j}}{n_i}\right)}{\sum_{i=1}^{4}\left(\left(\frac{\text{Production lbs}}{\text{Day}}\right)_i \times \text{Days}_i \times n_i\right)}$$

Health-Based Performance Goals and Objective for Salmonella on Broilers

The CDC Healthy People 2010 goal for *Salmonella* illnesses is 6.8 cases/100,000 U.S. population (Table A-2). The FSIS expert elicitation (Table A-3) indicates that about 22.0 percent of *Salmonella* illnesses are attributable to intact chicken consumption. However, this estimate assumes all *Salmonella* illnesses result for consuming one of the 25 FSIS product categories. Adjusting this number by the 46 percent of *Salmonella* foodborne illnesses attributable to FSIS (Table A-11) yields an estimate of 10.1 percent of *Salmonella* illness attributable to intact chicken consumption. The CDC outbreak data indicate that about 10 percent of *Salmonella* illnesses result from consumption of intact chicken. Thus a health-based performance goal for *Salmonella* in broilers can be established as follows:

- Health-based performance objective for *Salmonella* on broilers
  = 6.8 case/100,000 × 0.10 attributable to broilers
  = 0.68 cases/100,000.

As seen in Table A-12, FSIS had not met the Healthy People 2010 goal for *Salmonella* in broilers as of FY 2007.

As of June 2006, FSIS began employing a “category” system to measure establishments’ *Salmonella* performance due to a change in how the establishments were selected for testing. FSIS compares how many establishments are in “Category 1” from one quarter to the next and from one year to the next. Category 1 represents establishments that have achieved 50 percent or less of the performance standard or baseline guidance, for two consecutive FSIS test sets. Category 2 represents establishments that have achieved greater than 50 percent on at least one of the two most recent FSIS test sets without exceeding the performance standard or baseline guidance. Category 3 represents establishments that have exceeded the performance standard or baseline guidance on either or both of the two more recent FSIS test sets. For example, for broiler slaughter establishments, the performance standard is constructed such that the standard is met if there are 13 or fewer positive samples in 51 daily tests. Consequently, a Category 1 establishment would have six or fewer positive results in the two most recent 51 sample sets.

FSIS set a goal of having 90 percent of establishments achieve Category 1 status by 2010 and 95 percent of establishments in Category 2 by 2013. By 2013, FSIS will have completed one or more new baseline studies. The results of these new baselines would be to establish new performance standards or baseline guidance and to re-set Category 1, Category 2, and Category 3 criteria.

Health-Based Performance Objective for E. coli O157:H7 in Ground Beef

The CDC Healthy People 2010 goal for *E. coli* O157:H7 illness is 1.0 case/100,000 U.S. population (Table A-2). The CSPI outbreak data indicate that 34 percent of *E. coli* O157:H7 illnesses result from consumption of ground beef. Thus a health-based performance objective for *E. coli* O157:H7 in ground beef can be established as follows:

- Health-based performance objective for *E. coli* O157:H7 in ground beef
  = 1.0 case/100,000 × 0.34 attributable to ground beef
  = 0.34 cases/100,000.

Further Adjustment of *E. coli* O157:H7 Objective

When FSIS performance objectives and measures for *E. coli* O157:H7 in ground beef were adjusted for attribution and volume, the estimates indicated that FSIS was currently meeting its CDC Public Health 2010 Goal for *E. coli* O157:H7. In order to continually improve its program and better protect public health, FSIS decreased the calculated Healthy People 2010 Goal an additional 50 percent. That is, rather than having 0.34 cases per 100,000 people from ground beef as its goal, FSIS set a new goal of 0.17 cases per 100,000.

Health-Based Performance Objective for Listeria monocytogenes on RTE Meat and Poultry

The CDC Healthy People 2010 goal for *Listeria monocytogenes* illnesses is 0.24 cases/100,000 U.S. population (Table A-2). Table A-13 indicates that 66 percent of *Listeria monocytogenes* illnesses results from consumption of meat and poultry products. Table A-10 indicates that 91.2 percent of *Listeria monocytogenes* illnesses from meat and poultry products results from consumption of deli meats. Thus, 66 × 0.912 = 60 percent of *Listeria monocytogenes* illnesses result from consumption of deli meats. Thus a health-based performance objective for *Listeria monocytogenes* in deli meats can be established as follows:

- Health-based performance objective for *Listeria monocytogenes* in deli meats
  = 0.24 case/100,000 × 0.60 attributable to deli meats
  = 0.14 cases/100,000.

Further Adjustment of *Listeria monocytogenes* Goal

As of FY 2007, FSIS had met the volume weighted percent positive Healthy People 2010 goal for *Listeria monocytogenes* in RTE products (See Table A-12). Consequently, FSIS has set its FY 2010 goals by decreasing the FY 2007 volume weighted percent positive rate by one percent each year.

FSIS Performance Goals, Objectives, and Measures for 2007 through 2010

The CDC and Prevention provides the most comprehensive assessment of the national burden of foodborne illness. The CDC estimates that there were 76 million total foodborne illnesses in 1997. Based upon its foodborne illness attribution work, FSIS estimates that 588,000 *Salmonella*, 29,700 *E. coli* O157:H7, and 1,150 *Lm* foodborne illnesses are attributable to FSIS regulated meat and poultry products in CY 2006. FSIS has developed public health based performance measures targeted at reducing the rate of human foodborne illness from FSIS regulated food products. The Healthy People 2010 goals for illnesses due to *Salmonella*, *E.coli* O157:H7, and *Lm* are 6.8 cases per 100,000, 1.0 cases per 100,000, 0.24 cases per 100,000, respectively (see Table A-2).

FSIS estimates based upon its public health attribution work above that the Healthy People 2010 goals for illnesses from consumption of broilers, ground beef, and RTE products are:

- *Salmonella* illnesses from broilers -- 0.68 cases per 100,000,
- *E.coli* O157:H7 illnesses from ground beef -- 0.34 cases per 100,000,
- Listeriosis illnesses from RTE products -- 0.14 cases per 100,000.

Table A-14 presents a summary of FSIS performance measures for 2006 and 2007 and FSIS performance objectives for 2008 through 2010.

Table A-14. FSIS Performance Objectives for 2007 - 2010

	Performance Measures		Performance Objectives		
	FY2006	**FY2007**	**FY2008**	**FY2009**	**FY2010**
***Salmonella* on Broilers**					
Percent of Establishments in Category I	45%	73%	80%	85%	90%
Not Volume Adjusted Percent Positive Rate	12.6%	9.1%	8.8%	8.7%	8.5%
Volume Adjusted Percent Positive Rate	11.1%	7.37%	7.2%	7.1%	6.8%
Human Cases / 100,000	1.4	0.9	0.81	0.72	0.68
***Listeria monocytogenes* in ALLRTE**					
Not Volume Adjusted Percent Positive Rate	0.59%	0.37%	0.35%	0.33%	0.30%
Volume Adjusted Percent Positive Rate	0.33%	0.29%[4]	0.27%	0.25%	0.24%
Human Cases / 100,000	0.19	0.17	0.16	0.15	0.14
***E. coli* O157:H7 on Ground Beef**					
Not Volume Adjusted Percent Positive Rate	0.17%	0.20%	0.20%	0.20%	0.19%
Volume Adjusted Percent Positive Rate	0.40%	0.28%[4]	0.23%	0.22%	0.20%
Human Cases / 100,000	0.44	0.29	0.27	0.25	0.23

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