Letter Report on the Review of the Food Safety and Inspection Service Proposed Risk-Based Approach to and Application of Public-Health Attribution

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Committee for Review of the Food Safety and Inspection Service Risk-Based Approach to Public-Health Attribution, National Research Council

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Board on Environmental Studies and Toxicology

Division on Earth and Life Studies

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April 20, 2009

Dr. Carol Maczka
Assistant Administrator
Office of Food Defense and Emergency Response
Food Safety Inspection Service
United States Department of Agriculture
South Agriculture Building
1400 Independence Avenue SW, Room 3130
Washington, DC 20201

Dear Dr. Maczka:

At the request of the Food Safety and Inspection Service (FSIS), the National Academies Division on Earth and Life Studies established the ad hoc Committee for Review of the Food Safety and Inspection Service (FSIS) Risk-Based Approach to Public-Health Attribution. This ad hoc National Research Council committee is one of three independent committees charged to examine the use of public-health data in FSIS food-safety programs. The committee was selected to include expertise in food science, food safety, meat processing, microbiology, biostatistical sampling, microbial-risk assessment, foodborne-disease epidemiology, and disease attribution.

The committee was tasked with evaluating the proposed FSIS methodology and the adequacy of the data used to estimate foodborne-disease attribution for the purpose of ranking slaughtering and processing establishments according to public-health risk. The statement of task is discussed further below.

The committee held two meetings, each with a public session in which FSIS staff presented their proposed approach to public-health risk-based inspection, including the calculation and use of attribution estimates to link foodborne illnesses to specific FSIS-regulated products and application of the model by Hald et al. (2004) to calculate *Salmonella* attribution estimates. In addition, the committee heard from stakeholders regarding their concerns with the proposed FSIS risk-based approach.

This letter report first provides background information on the FSIS approach to attribution and its method of estimating attribution. The strengths and limitations of approaches used for estimating attribution are discussed next. The proposed FSIS approach to estimating attribution for risk ranking and determination of performance objectives is then assessed, and the report closes with conclusions and recommendations regarding future steps that FSIS should take to ensure that attribution estimates and related public-health goals make use of the best available science and enhance protection of public health. Several attachments are included: Attachment A, a verbatim statement of the task; Attachment B, the committee roster and biographies; Attachment C, a bibliography; Attachment D, acknowledgment of

reviewers; Attachment E, Agendas for Public Meetings, Attachment F, the form from the Electronic Foodborne-Outbreak Reporting System, and Attachment G, a paper prepared by FSIS, Foodborne Disease Attribution.

Sincerely,

John C. Bailar III, *Chair*
Committee for Review of the Food Safety
and Inspection Service Risk-Based Approach
to Public-Health Attribution

LETTER REPORT ON THE REVIEW OF THE FOOD SAFETY AND INSPECTION SERVICE PROPOSED RISK-BASED APPROACH TO AND APPLICATION OF PUBLIC-HEALTH ATTRIBUTION

SUMMARY

The committee applauds FSIS's efforts to develop a Public Health Risk-Based Inspection System (PHRBIS) for the purpose of improving and facilitating priority-setting and resource allocation for FSIS-inspected products that are the major contributors to human-foodborne illness. However, the committee concludes that the algorithm for ranking slaughtering and processing establishments needs to be made more transparent (that is clear and understandable) to clearly present the rationale behind the agency's approach and to ensure that the system prioritizes resources according to public-health risk. In addition, uncertainty characterization should be included in the inputs into the risk-ranking algorithm, including the attribution estimates. The committee considers that FSIS should use additional data beyond the Centers for Disease Control and Prevention (CDC) outbreak data and expert elicitations to develop better-informed attribution estimates. For example, the CDC outbreak database can be mined further to obtain additional information on sources of contamination. However, the committee acknowledges that it struggled with evaluating the attribution estimates alone, independent of their use in risk ranking, since FSIS's primary use for these attribution data are for ranking the slaughtering and processing establishments. Because of the limitations of the attribution estimates, the committee considers that it is premature for FSIS to develop performance measures to evaluate the PHRBIS system. The committee concludes that *Salmonella* serotyping will be critical for improved subtype-based attribution efforts but the *Salmonella* serotype-based and subtype-based attribution models are not currently ready for policy decision-making.

Recognizing the difficulty in estimating foodborne-disease attribution, the committee recommends that FSIS should consider alternative prioritization methods to allocate and prioritize inspection resources, including ranking methods that do not rely on attribution data per se or risk-ranking models that approach the attribution issue differently. Once FSIS selects a risk-ranking approach, it should provide clear and transparent documentation for how it conducted its analyses, including characterization of uncertainty. To the extent practicable, the risk ranking should consider the importance of differences in disease severity associated with different pathogens. Recognizing the value of food-attribution data to many agencies, FSIS should work collaboratively with CDC, FDA, and other federal and state agencies to develop a common set of definitions for microbial foodborne-disease attribution and a coordinated approach to improve the quality and consistency of data used among agencies in determining food-attribution estimates. FSIS should continue to support the collection of serotype and molecular subtype data for *Salmonella* and perhaps other relevant pathogens, and the development of mathematical models that use these serotype and subtype data for understanding food (and source) attribution of human *Salmonella* infections.

BACKGROUND

The Food Safety and Inspection Service (FSIS) is the regulatory arm of the U.S. Department of Agriculture (USDA) responsible for ensuring the safety of the nation's commercial supply of meat, poultry, and egg products. FSIS is proposing a PHRBIS for all slaughtering and processing establishments. The PHRBIS has been designed to improve the ability of FSIS to protect public health by using data-driven approaches to target inspection resources toward establishments that pose the greatest health risk (Hurd 2008). The PHRBIS is intended to ensure that the basis of proposed decisions is "clearly delineated, transparent, and scientifically-driven" (FSIS 2008a, p. 1).

In 2003, the Institute of Medicine and the National Research Council published *Scientific Criteria to Ensure Safe Food,* which provided guidance to FSIS and other relevant U.S. regulatory agencies on the development of science-based performance standards and food-safety criteria to protect public health (IOM/NRC 2003). In 2004, FSIS began to develop a risk-based inspection program for identifying slaughtering and processing establishments that pose the greatest risk to food safety and for developing rankings that enable efficient, targeted use of FSIS inspection resources. In 2007, the USDA Office of Inspector General (OIG) completed an audit of the FSIS risk-based inspection program (OIG 2007). The OIG found that FSIS lacked the infrastructure needed to oversee and support a timely and reliable risk-based inspection program. Among the OIG's concerns was the lack of FSIS procedures to set priorities for and schedule food-safety assessments, the "fundamental building block for assessing establishment risk" (OIG 2007, p. 32). The OIG stated that FSIS, as it moves forward with the development and implementation of a risk-based inspection program, "should ensure that components of the selected algorithm are thoroughly documented and evaluated with limitations mitigated and are transparent (i.e., clear and understandable) to all stakeholders" (p. vii).

In response to the OIG's report, comments from industry and consumer groups, and previous work by FSIS to develop a PHRBIS to focus inspection resources on the greatest food-safety risks, FSIS is again seeking ways to improve its ability to protect public health. Food may be contaminated by disease-causing pathogens at many points between production (farm) and consumption (fork), so epidemiologic and microbiologic data are used to identify the points of contamination along the farm-to-fork continuum. In many cases, however, it is still difficult to attribute a specific pathogen to a specific food commodity definitively. For example, it is widely known that *Salmonella* is associated with poultry products, but we do not know what proportion of human salmonellosis cases are caused by chicken, turkey, eggs, or nonpoultry sources, so we do not know how much disease FSIS actions could theoretically prevent. Similarly, we do not know what proportion of cases are associated with undercooking, cross-contamination, or other means of transmission. Without such information, it is difficult to design the most effective strategies to control *Salmonella* contamination in poultry to reduce the pathogen level in the end product or to evaluate the efficacy of FSIS control strategies after they have been implemented.

FSIS asked the National Academies to evaluate the strengths and limitations of the methods that FSIS intends to use to attribute microbial disease to food contamination and to investigate whether the limitations and assumptions in FSIS's methods hinder their use in policy development. FSIS also asked for comments on the adequacy of *Salmonella* serotype data for use in informing FSIS attribution estimates. The task undertaken by this committee is part of a broader effort by the National Academies to evaluate data and methods used by FSIS in risk assessment and in planning for risk-based inspection. The charge to the committee is presented in Appendix A.

This committee's evaluation was undertaken in parallel with two companion efforts to evaluate aspects of FSIS's risk-based inspection system. The Institute of Medicine's Food and Nutrition Board evaluated the use of process indicators for ranking slaughtering and processing establishments (IOM 2009), and the National Research Council Board on Agriculture and Natural Resources reviewed FSIS's proposed methods for risk-based regulation of in-commerce activities (NRC 2009).

OVERVIEW OF ATTRIBUTION

The findings and recommendations of IOM/NRC (2003) stated, "the Committee concludes that science-based food safety criteria must be clearly linked to the public health problem they are designed to address. To accomplish this, a cause/effect relationship needs to be established between contaminants in foods and human disease, that is, to allocate the burden of foodborne disease among foods and food groups" (p. 250). That statement underlines the need for foodborne-disease attribution.

The first work on the development of food-attribution estimates was undertaken by Mead et al. (1999), who attempted to attribute the proportions of pathogen-associated illnesses, hospitalizations, and

deaths in the United States transmitted by food. They addressed transmission routes but not specific food vehicles. Batz et al. (2005) provided a more specific definition for food attribution: "the capacity to attribute cases of foodborne disease to the food vehicle or other source responsible for illness" (p. 993). They emphasized that identifying the food vehicles and other sources responsible for illness is critical for designing and setting priorities for "effective food safety interventions" (p. 993). Similarly, the European Food Safety Authority (EFSA) discussed "efforts to quantify the (relative) importance of specific food sources and animal reservoirs for human cases of food-borne illness" (EFSA 2008, p. 5). Both Batz et al. and EFSA clearly focused on attributing specific pathogens to specific foods, with both addressing the issue of attribution at the point of production and at the point of consumption.

On the basis of FSIS-provided documentation, the committee finds that the focus of FSIS efforts is on the proportion of foodborne illnesses or cases attributable to FSIS-regulated foods—meat, poultry, and processed egg products. For example, FSIS estimates that about 60% of all *Salmonella* illnesses transmitted via FSIS products in 2007 are attributable to poultry products (FSIS 2008b). Because of the heavy reliance on epidemiologic data associated with outbreaks to determine its estimates, FSIS is inherently assessing attribution at the point of consumption.

It is important to emphasize that estimating attribution is extraordinarily difficult and ideally takes into account all phases of the farm-to-fork continuum. For example, imagine that a passing starling drops feces on a farm that results in *Salmonella* infection in a chicken. The microorganism is then transferred to another chicken after slaughter during the chilling process. Cross-contamination in the kitchen results in contamination of lettuce used to make a salad; ultimately, consumption of the salad results in human illness. To what is the illness attributed? If "point-of-consumption" attribution is the intent, the illness is attributed to the lettuce, if it is "point-of-processing," the illness is attributed to the chicken, and if it is the "reservoir" the illness might be attributed to the starling. The point is that the answer differs depending on at what level the question is being asked, and this underscores the need to clearly define attribution. The only steps under clear FSIS control are the slaughtering and chilling processes, but other circumstances contributed to the occurrence of disease.

DEVELOPMENT AND USE OF ATTRIBUTION ESTIMATES BY THE FOOD SAFETY AND INSPECTION SERVICE

FSIS has developed food-attribution estimates for *Salmonella, Escherichia coli* O157:H7, and *Listeria monocytogenes* by combining two types of data: information from CDC on reported outbreaks of food-related illness, including the products reported to have caused the illnesses; and two separate expert elicitations, one produced by FSIS (Karns et al. 2007) and the other by Resources for the Future (Hoffmann et al. 2007a). FSIS also intends to develop attribution estimates for *Campylobacter*, although this was not considered in the committee's deliberations (Dreyling 2008). FSIS considers that those three data sources "are the most comprehensively available datasets for use in estimating foodborne disease attribution" (FSIS 2008c, p. A-4). The committee notes that FSIS conducted an earlier expert elicitation (Karns et al. 2005), which produced results similar to those presented in Karns et al. (2007).

FSIS (2008c) and Dreyling (E. Dreyling, FSIS, unpublished material,[1] January 6, 2009) provide detailed discussions of how the three data sources are combined to estimate attribution. The committee notes that CDC outbreak data used as an input to estimate attribution by FSIS (2008c) and Dreyling (E. Dreyling, FSIS, unpublished material, January 6, 2009) are not consistent, so attribution estimates based on the two documents differ.[2]

FSIS presented the attribution estimates derived from the two expert elicitations and the CDC outbreak data and then compared them; finding excellent agreement among the three estimates. In fact,

[1]Food Disease Attribution.

[2]All unpublished materials cited in this report are available through the National Academies Public Access Records Office, paro@nas.edu.

when attribution estimates derived from Karns et al. (2007) and Hoffmann et al. (2007a) were compared, correlation coefficients were 0.989, 0.998, and 0.998 for *Salmonella*, *E. coli* O157:H7, and *L. monocytogenes*, respectively (FSIS 2008c). FSIS acknowledges that part of this agreement among the estimates may result from the fact that the members of the expert elicitation may have relied on common sources of information in developing their estimates (FSIS 2008c), in particular the CDC outbreak data.

FSIS combined the three data sets to develop their attribution estimates. Karns et al. (2007) provided detailed information on specific meat and poultry categories, while Hoffmann et al. (2007a) included attribution data on both FSIS- and FDA-inspected food products. The attribution estimates from the three data sets were first normalized for the same four product categories (meat, poultry, pork, and deli meats), and the average attribution estimates were calculated for *Salmonella*, *E. coli* O157:H7, and *Listeria monocytogenes*. These average attribution estimates were adjusted by the percent contribution of FSIS-inspected foods, and then further adjusted for the percent contribution to each of the individual FSIS food-product categories (see E. Dreyling, FSIS, unpublished material, January 6, 2009.)

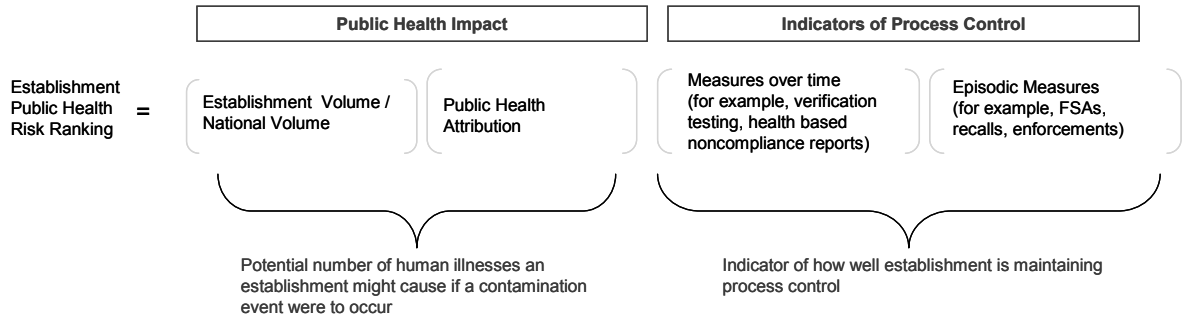
Attribution Estimates for Developing a Public-Health Risk-Ranking Algorithm

FSIS intends to use the food-attribution estimates for two purposes: to develop a public-health risk-ranking algorithm and to develop performance objectives. (The use of attribution estimates for developing performance objectives is not in the committee's formal charge but is discussed briefly because FSIS requested the committee to address this at the committee's first public session [Travis 2008]). The algorithm would be used to rank establishments according to public-health risk for focusing "FSIS inspection resources on those establishments and points within slaughter and processing that can have the greatest impact on the microbial growth and contamination of products" (FSIS 2008b, p. 2).

The risk-ranking algorithm consists of two factors, "public-health impact" and "indicators of process control," that together produce a "public-health risk ranking" (FSIS 2008b, p. 11). (See Box 1 for the Conceptual Approach for the Risk-Ranking Algorithm.) FSIS considers that "public-health impact" is a measure of the effect if the hazard occurs and that "indicators of process control" are measures of the probability of the hazard.

With regard to "indicators of process control," FSIS first places a slaughtering or processing establishment into one of three "levels of inspection" (LOI 1, LOI 2, or LOI 3) on the basis of the establishment's ability to satisfy a list of process-control indicators, such as recalls, enforcements, and

BOX 1 Conceptual Approach for Risk-Ranking Algorithm



Source: Dreyling 2008.

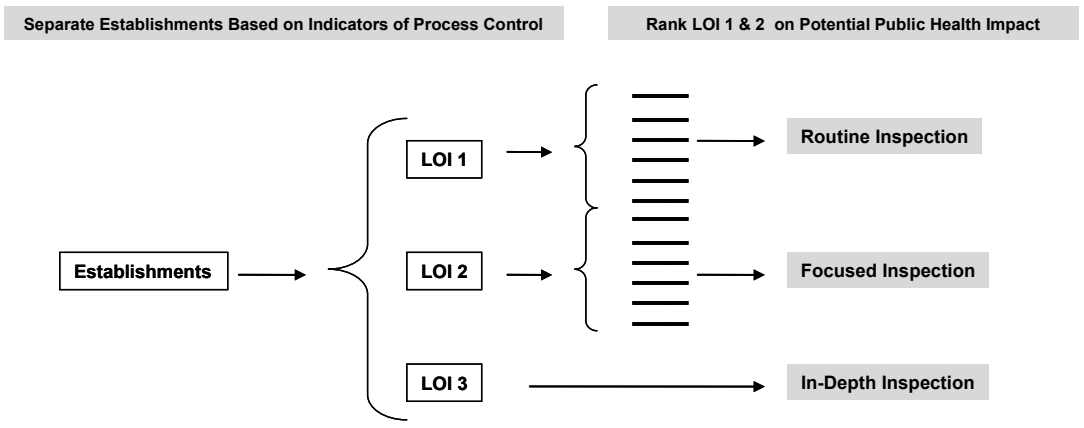
verification testing. (The appropriateness of placing an establishment into LOI 1, LOI 2, or LOI 3 was examined by the Institute of Medicine Committee on Review of Use of Process Indicators in FSIS Public Health Risk-Based Inspection System and was not within the present committee's charge.) In theory, establishments in LOI 1 are maintaining the greatest level of process control and thus pose the lowest probability of a hazard, whereas establishments in LOI 3 have the lowest level of process control, have the highest probability of a hazardous contaminant, and are subject to immediate in-depth inspection. With regard to "public-health impact," FSIS intends to rank establishments within LOI 1 and LOI 2 to set priorities for food-safety assessments and to determine the frequency of particular inspection procedures (such as comprehensive verification). (Box 2 provides an overview of the risk-ranking algorithm and illustrates ranking of establishments in LOI1 or LOI2 based on public-health impact.)

To rank the potential public-health impact of each establishment in LOI 1 or LOI 2, FSIS multiplies the attribution estimate for each pathogen-product pair by the product fractional volume (see Box 1). The product fractional volume is the volume of a particular product (such as raw ground chicken) generated by an establishment divided by the national volume of the product (that is across all establishments). FSIS (2008a) states, "if the establishment produces more than one product with the same pathogen of concern, select the maximum potential public impact" (p. 29) and goes on to state, "sort the ranked establishments into one of four pathogen categories—*Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, *Campylobacter*—or place in fifth category of establishments not susceptible to any of those pathogens" (p. 29). However, data analysis provided by FSIS (E. Dreyling, FSIS, unpublished material,[3] January 7, 2009) shows that FSIS sums the fractional attribution-volume estimates for an establishment across all of the pathogen-product pairs to obtain a ranking in a given LOI that is designated "public-health risk ranking." Therefore it appears that the methods presented by FSIS in FSIS 2008a and in Dreyling (E. Dreyling, FSIS, unpublished material, January 7, 2009) may be inconsistent.

Attribution Estimates for Developing Performance Objectives

FSIS also intends to use public-health attribution data to develop performance objectives on the basis of CDC Healthy People 2010 goals for *E. coli* O157:H7 in ground beef, *L. monocytogenes* in ready-to-eat (RTE) products, and *Salmonella* in broiler chickens. A performance objective, which is calculated

BOX 2 Overview of Risk-Ranking Algorithm



Source: Dreyling 2008.

[3]Data analysis to calculate risk ranking.

as the product of the FSIS foodborne-illness attribution estimate (fraction attributable to an FSIS-regulated food product) and the CDC Healthy People 2010 goal for illness (number of cases of illness per 100,000 people), estimates the proportion of the Healthy People 2010 goal for which FSIS is responsible. FSIS intends to evaluate the success of the PHRBIS system based on the performance objectives (FSIS 2008a, p. 35).

STRENGTHS AND LIMITATIONS OF ATTRIBUTION METHODS

Overview

There are five generally recognized approaches to attributing foodborne disease (EFSA 2008):

- Foodborne-disease surveillance, including pathogen-specific surveillance and outbreak investigations, from which population-level aggregated data on foodborne-disease outbreaks are analyzed to identify relationships between agents and sources.
- The case-control study, an epidemiologic method designed to identify relevant risk factors, including sources of infection, for sporadic cases of disease identified through pathogen-specific surveillance. The relative importance of risk factors can be estimated by calculating population-attributable fractions.
- Microbiologic subtyping, which applies strain-typing methods to microorganisms (usually pathogens) isolated from animal and food sources and from human clinical specimens. The subtyping information is often collated with results of epidemiologic surveillance programs and mathematical modeling to estimate attribution.
- Quantitative microbial risk assessment (QMRA), which uses a combination of data, expert opinion, and mathematical modeling to estimate the overall probability of illness associated with a food product along the entire farm-to-fork continuum. QMRA can be used to identify the steps in production, processing, and handling of a food product that affect the foodborne-disease risk associated with consumption of the product. One component of QMRA is a comparative exposure assessment in which mathematical modeling is used to estimate exposure to all relevant foods.
- Expert elicitation (also termed expert judgment), which poses a series of attribution-related questions to a set of experts. The experts are usually provided with extensive briefing material, training activities, and calibration exercises to assist in estimating attribution, along with their degree of confidence or certainty in those estimates.

Each of those five approaches has strengths and limitations, which are summarized in Table 1 and discussed in more detail below in relation to FSIS's proposed approach to attribution. Some of the important overriding themes are considered briefly here. First, foodborne-disease surveillance and microbial subtyping are supported by evidence obtained from foodborne-disease outbreak investigations. The CDC defines a foodborne-disease outbreak as an incident in which two or more persons experience a similar illness resulting from the ingestion of a common food (Lynch et al. 2006). Outbreak investigations are inherently biased toward point sources of contamination or to continuous outbreaks confined to well-defined populations, so they usually do not account for multisource or diffuse outbreaks and sporadic cases. But it is well documented that the vast majority of cases of foodborne disease are sporadic and that outbreaks caused by many infectious agents, particularly ones that cause milder illness, are not investigated (Samuel et al. 2001; Widdowson et al. 2005; CDC 2008). In addition, there are many instances in which the etiologic agent of an outbreak is never definitively identified or in which several foods (possibly multicomponent foods) are implicated. Case-control studies are useful in the identification of sources of sporadic disease, but they, too, are subject to limitations, including bias and

confounding. Consequently, reliance solely on outbreak data for estimating foodborne-disease attribution associated with one or more agent-vehicle combinations results in an incomplete picture.

Second, foodborne-disease attribution can be estimated at various degrees of resolution with respect to food source and microbial strain. Ideally, one would attribute specific pathogens (species and serotypes or strains) to specific foods (for example, a specific package of ground beef, steak, or pot roast). In reality, because of the complex nature of food contamination, microbiologic subtyping, outbreak investigation, case-control studies, and expert elicitation rarely achieve that degree of resolution but instead categorize food into general groups (for example, beef and chicken). In some cases, the species or strain of the pathogen is not delineated. The only method of foodborne-disease attribution that is amenable to a greater degree of resolution with respect to food source is QMRA, because it can take into account detailed information from human-consumption databases. However, these methods can be subject to substantial uncertainty, and no single approach to attribution is ideal. The choice of attribution method or methods for disease attribution will depend on the specific questions to be addressed and the available data and resources.

Foodborne-Disease Surveillance

Background

Public-health disease surveillance, an application of epidemiology, is the continuing systematic collection, analysis, interpretation, and dissemination of data on public-health events for use in reducing morbidity and mortality and hence improving public health. The "health event" in foodborne-disease surveillance is typically an individual case of disease, which may appear as an isolated event or may be aggregated as part of a foodborne-disease "outbreak." Surveillance of foodborne diseases is conducted to control and prevent outbreaks, determine the causes of foodborne disease, monitor trends in occurrence of disease, and measure the magnitude of disease. Acquisition of foodborne-disease surveillance data can be "passive" or "active." Passive surveillance is typically characterized by state or local medical reporting on diseased people. Active surveillance generally involves widespread screening of a target population to identify cases of illness or disease.

In the United States, much of the foodborne-disease surveillance is conducted under the authority of individual states' communicable-disease reporting laws and regulations. Responsibility for disease reporting and investigation varies by state. In the 50 states, more than 3,000 local health departments act with various degrees of autonomy. A 2007 survey of the states regarding the structure and practices of foodborne-disease surveillance programs found that gastrointestinal-disease surveillance was the responsibility of local agencies in about half the states, was centralized in a single state office in about one-fourth of the states, and was distributed among regional state offices in most of the remainder (Keene and Kanwat 2007).

Individual cases of illness caused by *E. coli* O157:H7, *Listeria*, and *Salmonella* are reported to CDC by state epidemiologists through the National Notifiable Disease Surveillance System (NNDSS) and are summarized and analyzed from time to time in *Morbidity and Mortality Weekly Report*. CDC aggregates surveillance data on a national level in the National Outbreak Reporting System and provides consultation and coordination for multistate investigations of outbreaks.

CDC also supports the Foodborne Diseases Active Surveillance Network (FoodNet), which, in addition to active surveillance, conducts case-control studies of sporadic illnesses and population surveys to determine background rates of diarrheal illness and exposure to various food items. Trends in the occurrence of foodborne diseases under active surveillance by FoodNet since 1996 have been important in establishing consistent methods for capturing data on foodborne illness. Those data, with the results of various passive surveillance systems, provided the basis for estimating the total number of cases of foodborne disease attributable to different microbiologic agents, as reported by Mead et al. (1999). Theoretically, such information can be used to evaluate the effects of regulatory changes made by FSIS.

TABLE 1 Summary of Approaches to Food Attribution Compiled by the Committee

Approach	Data Needs	Advantages	Limitations	Examples
Foodborne-disease surveillance Based on the use of aggregate data from epidemiologic investigation of outbreaks	Coordinated surveillance systems with similar data-collection efforts throughout specified location, region, country. Takes many years to accumulate sufficient data. Must contain food vehicle information.	Usually applied to multiple foods and pathogens; outbreak data are a measure of attribution at the point of consumption; able to take into account other routes of transmission (such as travel, contact with animals); addresses a broad range of microbes and foods; data are collected routinely on a national basis for a large number of pathogens over many years.	Assumes equivalence in pathogen-specific contributions of each food type to disease; a challenge to adequately classify multicomponent foods; serious gaps in databases	Adak et al. 2005; Batz et al. 2004; DeWaal et al. 2006
Case-control study Analytic epidemiologic study that compares diseased (cases) with nondiseased (controls) persons with respect to previous exposures; relative role of exposure is determined by comparing frequencies in cases and controls	Systematic review of published case-control studies, case series to identify relevant risk factors for disease; calculation of population-attributable to estimate relative importance of different exposures	Identification of sources of sporadic infections; classic strengths of case-control study design, including ability to explore multiple exposures (specific foods, food-preparation practices, cross-contamination, travel, other risk factors)	Classic weaknesses of case-control studies, including misclassification, recall bias, limited resolution for commonly consumed foods, establishing temporality; many cases required for adequate statistical power; usually limited to single microorganism rather than multiple agents; expensive	Multiple examples, but specific applications to food attribution are sparse (see EFSA 2008)
Microbial subtyping Based on combination of strain typing collated with epidemiologic-surveillance data and mathematical modeling; underlying hypothesis is that control of ultimate reservoir (usually occurring before harvest) will prevent human exposure	Integrated, active surveillance of most major sources (food, animals); reliance on extensive collection of representative strains for comparison; information on amount of animal or food product available for consumption	Best suited for pathogens that are clonally disseminated through food chain; useful in identification of original reservoir, setting priorities for interventions when contamination occurs during production	Usually applied to single pathogen; in current use, not well suited for organisms that have relatively unstable DNA; does not take into account effects of other contamination risk factors (human handling, cross-contamination); assumes equivalence in relative pathogen-specific contribution of each food type to disease; expensive; requires extensive libraries of isolates from a range of foods or reservoirs.	Hald et al. 2004, 2007; van Pelt et al. 2003

Quantitative microbial risk assessment Yields mathematically derived estimates of risk	Information on estimates for parameters to use in model and uncertainty distributions for estimates; logic model of how parameters are related to each other	Allows high level of detail with respect to specific food commodities; theoretically, can integrate data obtained from national surveillance programs	Serious data gaps; substantial uncertainty (should be accompanied by uncertainty analysis); resource-intensive	CFSAN/FSIS/CDC 2003 (*Listeria monocytogenes);* Evers et al. 2008
Expert elicitation Experts combine and weigh data from different sources to estimate attribution	More explicit, structured, quantitative methods—including well-calibrated methods, performance-based weighting—are being used and are increasing resolution and transparency	Best suited for filling in data gaps; able to combine information from multiple sources (different experts with different knowledge bases)	Subjective in nature; potential for bias (based on respondent background, personal bias) although use of structured approaches decreases bias; best methodologic approaches (calibrated, highly structured) require high degree of expertise and are resource-intensive	Hoffmann et al. 2007a,b; Havelaar et al. 2008

Another outbreak database is maintained by the Center for Science in the Public Interest (CSPI). The CSPI database uses the CDC definition of *outbreak,* which includes both the identification of the food source and the pathogen, but is broader than the CDC database and includes information obtained from CDC, state health departments, and scientific journals (Dewaal et al. 2006). FSIS chose not to use the CSPI outbreak data in its attribution estimates (Travis 2008).

Strengths of Foodborne-Disease Surveillance Data

Although the definition of a foodborne-illness outbreak does not appear to be very stringent, in practice two additional criteria are usually imposed in accounting for outbreaks: cases should not have shared multiple exposures other than the common food, and consumption of the common food should be associated with the illness through epidemiologic evaluation. Those criteria substantially increase the specificity of the definition of an outbreak and help to reduce the number of foodborne-illness complaints that are reported as outbreaks.

Because epidemiologic investigation is needed to confirm a food-related outbreak, outbreak databases constitute a useful source of information, because the grouping of cases as part of an outbreak allows the comparison of exposure histories (that is, information on who is being exposed and the level of exposure) between persons with illness and persons not involved in the outbreak. Exposures that are disproportionately shared by outbreak-associated cases are likely to be part of the causal pathway, if not the cause itself. The power of epidemiology in this regard has been empirically demonstrated time and again during outbreak investigations.

Relationships between reported illnesses and confirmed food-related outbreaks can be demonstrated for *E. coli* O157:H7 and *Salmonella* (CDC 2006a, 2007; McNabb et al. 2008). During 2006, 4,432 cases of *E. coli* O157:H7 infections were reported to the NNDSS (McNabb et al. 2008); 510 (11.5%) of the cases were associated with 27 confirmed food-related outbreaks of *E. coli* O157:H7 infection (CDC 2006a). A vehicle was identified for 16 (59%) of the outbreaks (CDC 2006a). Similarly, 15% of *E. coli* O157:H7 cases detected by FoodNet active surveillance were associated with outbreaks (CDC 2007). Of 45,808 cases of salmonellosis reported to the NNDSS (McNabb et al. 2008), 2,760 (6%) cases were associated with 116 confirmed food-related outbreaks. A vehicle was identified for 63 (54%) of the outbreaks (CDC 2006a). Of salmonellosis cases detected by FoodNet, 6% were outbreak-associated (CDC 2007). The consistency between national passive surveillance and FoodNet active surveillance for those pathogens suggests that passive surveillance is reasonably comprehensive for the two diagnosed illnesses.

Although diagnosed cases account for only a small fraction of illnesses, they probably represent the more severe end of the clinical spectrum, so identifying the sources of these cases can be assumed to address the highest priority food-safety concerns. In that regard, it is important to remember that epidemiology involves the surveillance of populations and does not always lead to a link between a specific source and an individual inasmuch as an individual case may have many potential sources of exposure. Thus, although sporadic cases constitute the vast majority of illnesses, they cannot currently contribute much information for the attribution of foodborne illnesses in the population.

Limitations of Foodborne-Disease Surveillance Data

Outbreak investigations can provide useful information for linking a source of exposure to an outbreak, but there are two principal limitations in applying such data to estimate population-based attribution. First, outbreaks caused by such bacterial pathogens as *Salmonella* usually occur as the result of failures in the food-safety system that lead to contamination and possible amplification of the organism in the implicated food or to cross-contamination of another food. For example, commercial ice cream was identified as the vehicle for a nationwide outbreak of *Salmonella* Enteritidis infection in 1994

(Hennessy et al. 1996). However, the ice cream had been contaminated from unpasteurized liquid egg, and the contamination occurred when raw grade A shell eggs were the leading cause of *Salmonella* Enteritidis infection in the population. Thus, food items that lead to detectable outbreaks may differ from the food items that result in more widespread exposure among sporadic cases. In addition, high-volume distribution of food items with a low level of contamination may cause many cases of illness without the clustering needed to lead to their detection as outbreaks. In the absence of epidemiologic or microbiologic (subtyping) data from small outbreaks or sporadic cases, attribution can be underestimated or overestimated, depending on the number of specific food sources, homogeneity of the agent in the sources, and the proportion of cases that arise from such unrecognized disease.

A second concern is the tendency toward systematic vehicle-detection bias in outbreak investigations, that is, bias toward collecting data on foods already perceived as posing high risk. For example, in an *E. coli* O157:H7 outbreak, investigators may be biased toward ground beef as a suspect food. Likewise, eggs in the shell may be targeted in a *Salmonella* serovar Enteritidis outbreak. In those outbreaks, investigators biased toward an expected vehicle may be slow to identify or even fail to recognize a new vehicle.

Epidemiologic data, specifically data from outbreak investigations, are most reliable when they come from active, rather than passive, surveillance systems. Countries (and even states) vary in the degree of rigor applied to the collection of such surveillance data.

Case-Control Studies

Background

Several other epidemiologic approaches can be used in estimating foodborne-disease attribution; the most common is the case-control study. In case-control studies, ill people (cases) and nonill people (controls) are questioned about their behaviors and recent food-consumption patterns, and associations between particular food choices and illnesses are calculated in cases and controls. The method has often been used in outbreak investigations to identify the most likely source of an infection. CDC, along with the other state health departments within FoodNet have conducted at least 15 case-control studies on a variety of foodborne pathogens based primarily on sporadic cases, including *Campylobacter* spp., *S. enteritidis*, *L. monocytogenes*, and *E. coli* O157:H7 (Kimura et al. 2004; Fullerton et al. 2007; Scallan 2007; Varma et al. 2007; Voetsch et al. 2007).

Strengths and Limitations of Case-Control Studies

Case-control studies compare a sample of subjects who already have the outcome of interest with a sample of subjects who do not have the outcome to see whether there is a difference in exposure. That is effective for investigating rare and sporadic disease events, and studies can be completed in a relatively short period. Case-control studies are useful for identifying sources of sporadic disease. Many case-control studies also collect data on host factors (for example, age and immune status), behaviors (for example, hygiene practices), and nonfood exposures (such as environmental exposures or animal exposures).

Results from case-control studies from FoodNet data on sporadic cases of *E.coli* O157:H7, *L. monocytogenes*, and *Salmonella* infections (Kimura et al. 2004; Fullerton et al. 2007; Varma et al. 2007; Voetsch et al. 2007) generally support the use of outbreak data for attribution purposes in large part because the primary vehicles associated with the outbreaks are also identified as contributors to the occurrence of the sporadic infections. If samples are drawn and analyzed without bias, case-control and cohort studies should lead to the same estimates of relative risk. However, there are several instances of disagreement as to the primary source of infection in outbreaks and sporadic cases. For example, most

Campylobacter outbreaks are attributed to contaminated, unpasteurized dairy products or water (CDC 2008a), whereas case-control studies have identified poultry as the primary source of sporadic cases (Friedman et al. 2004). In another case, outbreak data point to RTE meat and dairy products as the primary source of listeriosis cases, whereas a case-control study identified consumption of melons or hummus (Varma et al. 2007). Interestingly, a QMRA (CFSAN/FSIS/CDC 2003) also identified RTE delicatessen meats as constituting the predominant exposure risk for listeriosis. The degree to which any of these three sources of information may be biased is unknown; regardless, the studies yielded conflicting results.

A limitation of case-control studies from FoodNet (CDC 2006b) is that many of the high-risk food items are also the most frequently consumed food items. Because calculating population-attributable fractions of cases involves both the strength of an association and the frequency of exposure, food items with high exposure in the population account for a high proportion of attributable cases even if the relative risk posed by them is low. In contrast, for very uncommon food exposures, small samples may prevent potentially important sources from achieving statistical significance.

Case-control studies are subject to other limitations, including substantial misclassification (recall) bias, confounding, and the fact that risk (and temporality) can be measured only indirectly. Biases are associated with participants' ability to remember foods that they consumed and with heavy reliance on food questionnaires (people are less likely to identify novel foods). Confounding due to consumption of several common food items can improperly implicate a particular food as a source of disease. For example, if *E. coli* O157:H7 is found on a cheeseburger, the ground beef may be initially implicated, when in fact it is the lettuce that was contaminated.

Use of Molecular Subtyping Information on *Salmonella* to Enhance Attribution Efforts

Background

Serotyping, a method used to classify microorganisms on the basis of their cell-surface antigens, has been used for several decades to characterize *Salmonella* isolates. More than 2,500 *Salmonella* serotypes have been reported, but only about 20 are responsible for about 70% of cases of human salmonellosis in the United States (CDC 2008b). Some serotypes are associated with specific animal hosts, so serotype information can sometimes provide important information on the source of human *Salmonella* infections. For example, the serotype *Salmonella* Enteritidis is associated with poultry. Although human infections with this serotype appear to be typically caused by exposure to undercooked poultry or eggs, it also occurs in other foods, particularly if they contain poultry ingredients or are cross-contaminated by poultry-associated sources. Recently, data on the prevalence of specific *Salmonella* serotypes in different animal sources have been used to develop a serotype and phage-subtyping-based attribution model, which is discussed below (Hald et al. 2004).

Strengths and Limitations of the Use of Molecular Subtyping Information on *Salmonella*

Serotyping and phage typing have been used for salmonellosis surveillance and outbreak identification, but routine application of standardized molecular subtyping tools, such as pulse field gel electrophoresis (PFGE), has considerably improved the ability of public-health systems worldwide to detect foodborne-disease outbreaks and to define outbreak sources. PFGE patterns for *Salmonella* and other disease-causing agents can be determined by public-health laboratories and included in CDC's PulseNet database. Phenotypic and newer molecular subtyping methods also have helped in the identification and characterization of new and emerging *Salmonella* strains, including multiple-drug-resistant strains. Although PFGE is considered the current "gold standard" subtyping method for *Salmonella*, and standardization of PFGE protocols allow comparisons across laboratories through

PulseNet (Ribot et al. 2006), it is also well established that some *Salmonella* types identified by PFGE are common and widely distributed, both spatially and temporally. That observation reduces the value of PFGE in surveillance and outbreak investigations, particularly investigation of outbreaks that are caused by common PFGE types. There is a continuing need to develop and implement improved and more discriminatory molecular subtyping methods for *Salmonella*, such as multiple-loci variable-number tandem-repeat analysis (MLVA) (for example, Malorny et al. 2008). (MLVA is used for the genetic analysis of particular microorganisms, such as pathogenic bacteria; this method has been shown to improve subtype discrimination in comparison to PFGE for some pathogens, including some common *Salmonella* serotypes. However, assembling sufficiently large datasets for alternate subtyping methods for source attribution may be time and cost intensive.)

Because both food and nonfood vehicles can be sources of human *Salmonella* infections, there is considerable interest in developing accurate estimates of the relative contributions of different exposures to the total number of human cases. That information is important for optimal priority-setting for control and intervention strategies, for example, among different food commodities. While *Salmonella* serotype data are often used in initial identification of case clusters, few efforts to use *Salmonella* serotype data for population-based attribution of human *Salmonella* infections to different sources have been reported (reviewed by Ridgon 2007). Hald et al. (2004) have developed an in-depth approach to use *Salmonella* serotype and phage-typing data for source attribution in Denmark. The approach relies on "detailed knowledge on the distribution of *Salmonella* types in relevant food animals and food types, generated through intensive and continuous monitoring" (p. 256). As pointed out by Ridgon (2007, p. 39), the "Danish model" represents a "point-of-reservoir" attribution approach. The model specifically attributes human salmonellosis cases to primary animal reservoirs (for example, pigs and cattle) and thus cannot readily attribute human cases to more specific food items (such as ground meat and poultry and RTE products) or to other animal-associated contamination routes, as might occur during the production of fresh fruits and vegetables. Use of this model to assist in *Salmonella* control efforts requires an integrated farm-to-fork approach to control foodborne pathogens, as increases in certain *Salmonella* serotypes among human cases signals the need to improve interventions at the farm level.

The FSIS, in coordination with CDC and the Food and Drug Administration (FDA), has applied the Danish approach to characterize the relative contributions of specific FSIS food-product categories to total human *Salmonella* illness. Because of lack of data, the analysis does not include FDA-inspected products, except eggs in the shell (Guo 2007; Schroeder 2009). Although the effort has produced some initial estimates, the suitability of using the approach to attribute illnesses to food products (rather than "point-of-reservoir") remains to be validated. This modeling effort is undergoing interagency review.

Quantitative Microbial-Risk Assessment

Background

QMRA is a method used to organize and analyze relevant data to estimate the public-health consequences associated with microbiologic risk. QMRA considers some of or all of the various stages in the food-production process, and its main outcome is an estimate of the probability of illness caused by the consumption of the food product under study. The method has provided valuable information on the effects of specific steps in food production, processing, distribution, and handling on the risk of human disease posed by various foodborne pathogens (Cassin et al. 1998). Once a risk model is developed, different scenarios can be analyzed by varying the inputs of particular modules; this allows the user to evaluate individual process steps and risk-mitigation strategies to determine their effect on the overall risk (Vanderlinde 1998). The results of these risk-assessment simulations provides a scientific basis for the evaluation of risk-management alternatives. In QMRA, the identification of factors that contribute the most to risk is often referred to as sensitivity analysis (Cassin et al. 1998). Examples of risk-mitigation

strategies that may be considered within QMRA for meat products are reduction of on-farm prevalence of a pathogen, reduction in storage temperature, and inclusion of a decontamination step.

QMRA consists of four stages: hazard identification, in which the pathogenic microorganisms potentially present in the food product are identified; hazard characterization, defined as the qualitative or quantitative evaluation of the nature of the adverse health effects associated with biologic, chemical, and physical agents that may be present in food (FAO/WHO 2001, p. 2); exposure assessment, which provides an estimated frequency of consumption of the food product and the probable number of microorganisms per serving; and risk characterization, in which hazard characterization and exposure assessment are integrated to provide an estimated risk of disease associated with the consumption of the food product. In the case of meat products, a farm-to-fork approach would theoretically provide the most comprehensive estimation of risk; however, the lack of crucial data often makes the task difficult and the results uncertain. Furthermore, the scope of the QMRA should suit the purpose of the assessment and the questions it intends to answer; in some cases, a farm-to-fork approach may not be appropriate (Kelly et al. 2003). In general terms, the distribution of pathogens in the raw material and changes in pathogen population during manufacturing, distribution, storage, and preparation at home or in retail establishments need to be integrated with dose-response models to estimate the probability of illness. On-farm factors that ultimately affect contamination or colonization of animals before slaughter may be included in a QMRA, but these are usually modeled separately, and the results used as inputs for later processing and consumption modules.

Strengths and Limitations of Quantitative Microbial-Risk Assessment

QMRA applied to pathogens in meat or poultry products can provide valuable information for risk managers. In addition to providing estimates of the overall probability of illness or infection associated with a food product, QMRA helps to identify food processing and handling steps that affect the overall risk associated with the consumption of a particular food product. For example, FSIS developed a QMRA for *L. monocytogenes* in delicatessen meats (Gallagher et al. 2003) in response to risk-management questions regarding the effectiveness of food-contact surface testing and sanitation regimes in reducing the risk of contamination by *L. monocytogenes*. Results showed that a decline in the concentration of *L. monocytogenes* may be achieved by increasing surface testing and sanitation efforts. Another FSIS-sponsored risk assessment, for *Clostridium perfringens* in RTE and partially cooked meat and poultry products (Crouch and Golden 2005), demonstrated that retail and consumer storage temperature had a significant effect on the estimated risk of disease caused by this organism.

The quality of the data sources used to develop a QMRA is critical in that it determines the accuracy of the risk estimates produced. How closely the QMRA model describes the actual scenario being studied will also affect the accuracy of the conclusions. QMRA risk estimates may be validated by using epidemiologic data; however, the usefulness of epidemiologic data is often limited, especially if QMRA considers specific food products in a larger food-product category (such as ground beef in the beef category) or if specific food-handling conditions (such as consumer behaviors) are being evaluated. Data gaps can increase the uncertainty of QMRA results. For example, data on the dynamics and mechanisms of cross-contamination suitable for risk assessment were limited prior to the publication by Chen et al. (2001), so many early QMRAs have not included this event. However, it is acknowledged that cross-contamination may have a significant effect on the risk estimates, and more recent risk assessments have included cross-contamination (Nauta et al. 2005).

Expert Elicitation

Background

Quantitative data on risk probabilities are often needed to inform decision-making. However,

empirical datasets are frequently incomplete, unreliable, or inappropriately analyzed, so it can be difficult to use the datasets alone in predicting outcomes with a given level of confidence. In such cases, expert elicitation can be used to help in quantifying risks. Expert elicitation is a formal synthesis of expert judgments. It is based on the premise that an expert or small group of experts in a discipline can provide valuable insight into interpretation and quantification of available data. Given that most decisions are complex and involve multiple aspects, obtaining input from a large, heterogeneous group of multidisciplinary experts reduces the influence of individual biases (van der Fels-Klerx et al. 2002). The results of expert elicitation must be interpreted cautiously. Havelaar et al. (2008) state that "an expert opinion may not be expected to provide an unbiased estimate of the relative importance of different transmission routes. Rather it should be regarded as a structured way to obtain consensus opinion, based on available data" (p. 9).

Considerable care must be taken in collecting expert opinion. Well-defined procedures—including the identification of target, query, and performance variables; appropriate selection of experts; and a systematic combination or synthesis of expert judgment—can yield valuable information on the questions posed (Cooke and Goosens 1999). Formal (and sometimes complex) methods should be used to determine overall probabilities with classical or Bayesian approaches to data aggregation (Clemen and Winkler 1999). Whatever method is used to assess overall probabilities, it is critical that expert elicitation contains some estimate of uncertainty.

Expert elicitation has been used in combination with other tools to estimate the relative importance of particular routes of exposure (for example, food, water, environmental, and human-to-human) for infectious-disease transmission in different countries (VanDuynhoven et al. 2002; Cressey and Lake 2004; Hall et al. 2005; Vaillant et al. 2005; Havelaar et al. 2007). The estimated attributable proportions of infections caused by specific pathogens in specific food sources (or other transmission vehicles) may vary considerably from country to country, depending on such factors as geographic differences in contamination frequency or magnitude, food choices and cooking habits, hygiene, environment and climate, population susceptibility, and agricultural and food production and processing practices. Therefore, although estimates obtained from other regions may demonstrate similar trends or patterns of disease transmission, it is imperative that population-specific estimates be obtained.

Recently, Hoffmann (Hoffmann et al. 2007a) used structured expert elicitation to estimate the association of pathogens with specific food commodities, and Karns et al. (2007) described the results of an expert elicitation that focused on the role of meat and poultry products in foodborne illness. Those two studies present the only publicly available data on the application of expert elicitation to food-source attribution and public health in the United States.

Strengths and Limitations of Expert Elicitation

Using a written survey instrument, Hoffmann et al. (2007a,b, 2008) asked 42 expert panelists to provide source-attribution estimates for 11 pathogens commonly transmitted in food—*Campylobacter* spp., nontyphoidal *Salmonella*, *Shigella* spp., *Yersinia enterocolitica*, *E. coli* O157:H7, *Vibrio* spp., *L. monocytogenes*, *Cyclospora cayetanensis*, *Cryptosporidium parvum*, *Toxoplasma gondii,* and "Norwalk-like" viruses—in association with 12 foods, including one "other" category. Participants were asked to include confidence bounds around their estimates. Karns et al. (2007) explored the perceived role of meat and poultry in the transmission of four bacterial pathogens—*Salmonella* (nontyphoidal and multiple-drug-resistant), *E. coli* O157, *L. monocytogenes*, and thermotolerant *Campylobacter* spp. (*C. jejuni* and *C. coli*)—associated with foodborne disease by asking 17 panelists to rank the likelihood of disease in healthy adult consumers and vulnerable consumers (defined as "very young, the elderly, pregnant women and their fetuses, and those with compromised immune systems") from consumption or handling of 25 processed meat and poultry products. Experts were asked to provide their estimates about the percentages of illness that would be attributed to each food category, including their degree of confidence in their

estimates—1 (little or no confidence) to 3 (very confident)—for each pathogen. However, different information was elicited for different pathogen-food combinations.

Although these two studies are among the first to provide important information on food attribution in the U.S., there are some notable limitations. Neither Hoffmann et al. nor Karns et al. used control or "seed" variables with known distributions, which are increasingly included in expert elicitations to assess how closely the expert judgment corresponds with known parameters (Cooke and Goossnes 1999). Self-reported measures of certainty were recorded in both studies, and preliminary reports from Hoffmann et al. (2007b, 2008) describe how these data may be qualitatively analyzed to understand the magnitude of uncertainty in expert elicitation estimates; however, a full analysis of the data was not provided.

Some differences between the findings of Hoffmann et al. (2007a) and Karns et al. (2007) were noted. For example, poultry was identified by both studies as responsible for the largest fraction of cases of foodborne illness, but Hoffmann et al. found that "luncheon and other meats" were considered to be a more significant source of illness than eggs, beef, or pork, whereas Karns et al. (2007) found that the experts considered the same RTE products to be the smallest contributor to foodborne illness. That may be due to differences in RTE product definitions used in the two elicitations, specifically, the presence or absence of preservatives and postlethality treatment. (Postlethality treatment includes high-pressure processing, post pasteurization, or bactericidal surface treatments to reduce the presence or limit the growth of microorganisms after processing.) Karns et al. asked participants to assume that no additives were included in RTE products to inhibit the growth of *L. monocytogenes* and that no postlethality treatment was applied to products—two assumptions that do not reflect current practices of many commercial processors.

Although only two people served on both panels, the two studies may not constitute independent observations and are likely to be subject to common cognitive biases introduced through heuristics related to members of each group. For example, the most readily available data on foodborne-disease attribution are those reported by Mead et al. (1999), and it is likely that all panelists relied on them; this illustrates the problem of availability bias. Other potential biases may also be of concern. Anchoring bias, or focalism, is the tendency to rely on a single point or reference from which other estimates are made; participants in the Hoffmann et al. study were instructed to start their responses with a food category that they knew best, which potentially introduced anchoring bias. Representativeness bias can be introduced if people rank two products similarly because the two products themselves are somewhat similar; in the Karns et al. study, the inclusion of two similar product categories—"raw ground, comminuted, or otherwise nonintact pork" and "raw ground, or otherwise nonintact meat other than beef or pork"—may have introduced representativeness bias.

In both expert-elicitation studies, the experts were asked to attribute illness to specific food commodities consumed and not to consider sources of cross-contamination. For example, someone may become ill by eating a salad that was contaminated on a cutting board that had been used to cut raw beef, but the experts were expected to consider such an illness as arising from produce, not beef (Hoffmann et al. 2007a, p. 1223). However, raw-meat products can contribute to the contamination of a variety of other foods in many ways. Interventions that reduce the likelihood and magnitude of contamination in raw meats would also reduce cross-contamination risks, but these were not considered in either expert-elicitation study.

Comparisons of Expert Elicitation and Outbreak Data

Descriptions of how well expert opinion correlated with outbreak data are provided by Hoffmann et al. (2008). When the attributable fractions are multiplied by correction factors to account for underreporting and the expected number of illnesses, the resulting estimates of numbers of cases of illness, hospitalizations, and deaths predicted by expert elicitation and the outbreak data sometimes agree and sometimes do not. For example, the correlation of expert elicitation and outbreak data for attribution

of illness to beef, poultry, luncheon meats, and pork was 0.81, 0.71, 0.55, and 0.53, respectively. However, the estimates of cases attributable to eggs did not correlate ($r = 0.00$). This may result from the fact that eggs are often used as an ingredient in complex dishes, and may be typically undercounted in outbreaks (Adak et al. 2005).

EVALUATION OF THE PROPOSED FOOD SAFETY AND INSPECTION SERVICE APPROACH TO ATTRIBUTION AND USE OF ATTRIBUTION ESTIMATES

Attribution Estimates

Foodborne pathogens have different biologic and environmental niches in animals and in the environment, and they may enter or change their level in the food chain (farm-to-fork) at different points. Thus, pathogens have many potential source pathways, and this makes the attribution of human illness to foods challenging. Developing accurate estimates of attribution of foodborne illness to specific foods requires a comprehensive program that combines many methods and datasets. Harmonization and structured categorization of food items based on both the foods themselves and the combined effects of their production, processing (preservation), and handling methods are crucial for accurate source attribution, particularly when data are collected from various sources and when results from more than one source are to be compared or integrated.

Scientific Criteria to Ensure Safe Food (IOM/NRC 2003) stated that "depending on the quality of available data, food safety regulatory agencies could use controlled studies, expert opinion, or a combination thereof to develop science-based food safety criteria. Because of common gaps in available data and scientific knowledge, the combination strategy is the optimal science-based procedure to develop food safety criteria" (IOM/NRC 2003, p. 7). FSIS (2008c), likewise, acknowledges that no single source of information can provide a comprehensive picture of food-source attribution and has identified several datasets that could be used to establish improved attribution estimates, including CDC outbreak data; results of FoodNet case-control studies; FSIS and FDA risk assessments; CDC, FDA, and FSIS *Salmonella* serotype data; and expert elicitation. It also stated that "FSIS will use these and other advances to improve foodborne disease attribution estimates as better information becomes available" (FSIS 2008c, p. A-1). Nonetheless, the proposed approach was limited to the combination of CDC outbreak data and the two expert elicitations. The committee finds that additional data are available and can be exploited. Examples are described below. However, the committee acknowledges that they struggled with evaluating attribution alone, independent of its use for public-health-risk ranking of processing and slaughtering establishments.

The CDC outbreak database (the Electronic Foodborne Outbreak Reporting System; see Attachment F) can be mined further to obtain additional information on sources of contamination. This database provides information on contributing factors (contamination, survival, and amplification) that may be helpful in refining attribution estimates. For example, a produce-associated outbreak with documented cross-contamination by raw meat or poultry might be considered an outbreak attributed to an FSIS-regulated product. It may be possible to investigate contributing factors by using the additional data in the CDC outbreak database and to prevent misattribution while improving the accuracy of current attribution estimates. To that end, the committee finds that additional use of the CDC outbreak data for food-attribution modeling may provide further incentive to state and local agencies to report their outbreak data more accurately and quickly for use by CDC.

Currently foodborne-illness information available to local and state public-health agencies might not be included in the national CDC outbreak database, because reports from state health departments on some illnesses might not be received or because the illnesses do not meet CDC criteria for foodborne outbreaks due to specific pathogens (Batz et al. 2005).

CDC outbreak data do not include sporadic cases of foodborne illness. Consequently, pathogens that rarely cause outbreaks are underrepresented. A possible solution for that limitation is to use data

from population-based FoodNet case-control studies to refine food-attribution estimates so that they reflect the effects of sporadic illness better. FoodNet has conducted at least 15 population-based case-control studies of a variety of pathogens, including *Salmonella*, *E. coli* O157:H7, *Campylobacter*, and *L. monocytogenes* (CDC 2006b). Although the studies were not designed specifically for source attribution, but rather to examine risk factors, they should be relevant in refining source-attribution estimates. In addition to individual case-control studies, systematic review of published studies of sporadic foodborne illness could provide information on population-attributable fractions for each exposure. Such information would be valuable in estimating the relative burden of illness caused by a pathogen attributed to multiple exposures.

Quantitative data on exposure to pathogens from a multitude of sources may be obtained by application of risk-assessment methods, and FSIS and FDA have conducted several QMRAs. Those studies have focused on single food products or processes and do not necessarily provide attribution estimates, but some of the resulting data—for example, related to *E. coli* O157:H7 in ground beef (FSIS 2001) or *L. monocytogenes* in delicatessen meat (CFSAN/FSIS/CDC 2003)—may be relevant to food attribution inasmuch as the QMRAs provided data on how many human cases were linked to these foods.

Outbreak data yield information for attribution at "point of consumption" because outbreak investigations link illness to the food that was consumed. Attribution at that point is necessarily the sum of the effects of contamination at pre-harvest, processing, and final preparation in the kitchen. By relying on outbreak data, FSIS includes all of the chain, even though they are only responsible for part of it. Therefore, the use of outbreak data in this capacity does not translate directly into the attribution at the point of processing. Another major consideration is that, unlike the work of Evers et al. (2008), who estimated that foodborne sources accounted for less than 33% of all *Campylobacter* exposures, non-foodborne sources of infections (such as travel-related cases, and "unknown" sources) are not always fully considered in the disease attribution estimates. Taken together, the current FSIS approach to attribution may under or over-estimate the proportion of illnesses attributable to specific FSIS-inspected foods.

Algorithm for Public-Health Risk Ranking

The committee acknowledges FSIS's efforts to develop a public-health risk-ranking method for meat and poultry establishments. However, FSIS should provide greater justification and clear documentation to explain fully the rationale for the ranking method and to enable an independent reviewer to duplicate the risk-ranking calculations.

Although the committee was tasked with examining only the "public-health impact" calculation that feeds into the public-health risk ranking, it considers that because the "indicators of process control" and the LOI categorization are intimately linked with the "public-health impact" (the product of attribution and fractional volume), it is difficult to evaluate the effectiveness of ranking by attribution and fractional volume without also evaluating the LOI categorization. The product of attribution and fractional volume does not incorporate the totality of the public-health impact of the equation; rather, much of the impact is captured in the LOI categorization.

The documentation provided to the committee by FSIS did not explain why and how the proposed approach for ranking establishments was selected from among other potential methods for risk ranking. The committee is aware of other risk-ranking approaches, such as those of Ross and Sumner (2002) and Batz et al. (2004). For example, one alternative means of conducting risk-based inspection would be to rank all facilities according to public-health risk without prior categorization by LOI.

The committee is concerned that FSIS provided no estimates of uncertainty in the public-health attribution estimates and the public-health risk ranking. Rather, the attribution fractional-volume estimates were calculated to five decimal places; they inappropriately reflected substantially greater precision than the data warrant. For example, FSIS reported that the total fractional attribution of the

plant in LOI 2 with the highest rank is 0.02595; however, the uncertainty associated with this estimate was never given (E. Dreyling, FSIS, unpublished material,[4] January 7, 2009).

Box 3 illustrates the importance of conducting a sensitivity analysis of the attribution estimates to explore the effect of the uncertainty in the attribution estimates on the stability and reliability of the public-health rankings. As described in Box 3, a relatively small change in an attribution estimate can exert widespread change on the public-health rankings of establishments. An understanding of the uncertainty can help inform the level of "comfort" with the results and provide information on the plausible alternative values that fall within the bounds of the uncertainty.

BOX 3 Illustration of Change in Public-Health Risk Ranking Based on Change in Attribution Estimate of *E. coli* O157:H7 from 35.9% to 39.2% for Ground Beef and from 8.7% to 9.5% for Other Raw Ground Meat, for Top 50 Plants in Each Category

Change in Public-Health Risk Ranking	All Establishments		LOI 2	
	Number	Percent	Number	Percent
+ 4	20	40	1	2
+3	3	6	3	6
+2	1	2	5	10
+1	0	0	9	18
No change	18	36	12	24
-1	3	6	13	26
-2	1	2	3	6
-3	0	0	2	4
-5	0	0	1	2
-6	0	0	1	2
> -20	4	8	0	0
Total	50	100	50	100

Source: E. Dreyling, FSIS, Data Analysis to Calculate Risk Ranking, unpublished material, December 31, 2008, and January 7, 2009.

FSIS provided the committee with two versions of its public-health risk ranking of slaughtering and processing establishments (E. Dreyling, FSIS, Data Analysis to Calculate Risk Ranking, unpublished material, December 31, 2008, and January 7, 2009). The fraction of *E. coli* O157:H7 cases attributable to specific FSIS product categories was revised in the January 7 version; the greatest changes were in ground beef and other raw ground meat. The public-health risk ranking of establishments changed with the change in attribution estimates. In the ranking of all establishments, 36% of the 50 top-ranked establishments retained their original ranking, 40% moved up four places, and four dropped more than 20 places. Only 24% of LOI 2 plants retained their original ranking, and two dropped five or more places. This example demonstrates that relatively small changes in attribution estimates can exert widespread changes in the public-health risk rankings of establishments. Because the attribution estimates contain considerable uncertainty, systematic sensitivity analyses are needed to explore the effect of that uncertainty on the stability and reliability of the public-health risk rankings.

[4]Data analysis to calculate risk ranking.

The committee is also concerned that the proposed risk-ranking method may not be appropriate for ranking establishments and assigning resources across plants, and further validation of the model is needed. FSIS considers that production volume is important in estimating public-health attribution—the larger the production volume, the higher the potential public-health impact. For each plant, FSIS calculates the potential public health impact as, $PPHI_i = \frac{V_i}{V} \times PHA$, where $\frac{V_i}{V}$ is the fraction of the total national volume of product produced by a specified establishment (i), and PHA is the public health attribution estimate for the specified product-pathogen pair (for example, *Salmonella* in raw poultry). FSIS estimated the public-health attribution as the fraction of illnesses attributed to all FSIS-regulated establishments for the corresponding pathogen-product pair.

Fractional volume serves as a proxy for the fraction or proportion of consumers exposed to a given product with the assumption that contamination is randomly dispersed throughout the supply of the product independent of the establishment. The efficacy of the algorithm requires the assumption that the probability of illness, given consumption of contaminated product, does not depend on the product source (the establishment) or the specific product. This is implicitly addressed by categorizing by LOI.

Therefore, for those establishments producing the same product, the ranking related to a specific pathogen reflects differences in the fractional volume ($\frac{V_i}{V}$) of product produced. Comparisons across product-pathogen pairs depends critically on the relative differences in the two components (public-health attribution and fractional volume) of the algorithm.

Box 4 provides an illustration of how the fractional volume and pathogen attribution estimates interact using data from FSIS (E. Dreyling, FSIS, unpublished material, January 7, 2009) for a specific establishment (plant #2). The three largest public-health attribution estimates are for *L. monocytogenes* in RTE products (59%), *E. coli* O157:H7 in ground beef (39.2%) and *E. coli* O157:H7 in other ground meat (9.5%). Box 4 indicates that the corresponding fractional volumes are 0.002, 0.006, and 0.142, while the potential public health impacts are 0.0012, 0.0024, and 0.0135, respectively. Box 4 shows that for plant #2, the relative importance of the attribution estimates is the inverse of the overall public-health impact for the three pathogen-product pairs. This reflects the need for FSIS to validate the algorithm's ability to capture the potential public health impact for each plant and assign resources accordingly. The validity of the algorithm depends on an evaluation of the assumptions in the model, which includes an evaluation of the LOI categorization and how it interacts with the potential public health impact.

BOX 4 llustration of Interaction of Fractional Volume and Pathogen Attribution Estimates in Estimating Public Health Impact for Plant Number 2

	RTE			Ground Beef			Other Ground Meat		
	Salm.	*E. Coli*	*Listeria*	*Salm.*	*E. Coli*	*Listeria*	*Salm.*	*E. Coli*	*Listeria*
Fractional Volume (V_2/V)	0.002	0.002	0.002	0.006	0.006	0.006	0.142	0.142	0.142
Attribution Estimate (PHA)	0.022	0.031	*0.589*	0.039	*0.392*	0.003	0.013	*0.095*	0.001
Potential Impact ($PPHI_2$)	0.00004	0.00006	*0.0012*	0.00023	*0.0024*	0.00002	0.0018	*0.0135*	0.00014

Source: E. Dreyling, FSIS, Data Analysis to Calculate Risk Ranking, unpublished material, January 7, 2009.

In addition, FSIS currently does not consider the severity of illness associated with a given pathogen in estimating attribution and public-health risk-ranking of establishments. Nonetheless, disease severity is an important consideration in many other risk-ranking methods, and its impact can be characterized using measures such as Disability-Adjusted Life Years (DALYs), Quality-Adjusted Life Years (QALYs) and willingness-to-pay (WTP), among others. These integrated measures of disease burden are detailed elsewhere (Batz 2007; Havelaar et al. 2007). It is likely that the rankings of establishments would differ if disease severity were considered in calculating them. Overall, the committee considers that severity of disease is an important component as FSIS seeks to measure "public health impact."

The committee is also concerned that FSIS needs to adequately evaluate and consider the rationale and implications of its risk-ranking algorithm. FSIS did not provide the committee with the algorithm and supporting data until well into its last meeting, and FSIS had to resubmit the algorithm to the committee afterward because its original submission contained calculation errors and was not adequately documented. It is important that FSIS present to the public a well-documented and transparent model to illustrate the algorithm. The algorithm (model) should be updated as new data and methods are developed. FSIS (2008a, p. 15) "recognizes that development of a health-based inspection model will be an ongoing process, and that the proposed algorithm may continue to evolve as more information about the risks associated with particular products and about the predictive indicators of food safety process controls at processing and slaughter establishments becomes available."

Performance Objectives

The committee recognizes the importance of performance objectives as FSIS seeks to continuously evaluate its efforts in reducing foodborne illness and improving public health. However, the committee is concerned that the method that FSIS used to calculate performance objectives in the current report (FSIS 2008c) needs to be better documented, transparent, and readily reproducible and that the validity of such measures is hampered by limitations in attribution estimates (discussed above). In addition, FSIS does not present any uncertainty bounds surrounding its performance-objective estimates. It is important for performance objectives to be responsive to changes in attribution estimates that result from natural variations in disease incidence. Natural variations in disease incidence may result from changes in nonfood transmission sources and in food production, processing, and preparation practices, among others. The current attribution estimates remain constant when projecting performance objectives.

FSIS (2008a) states that "prior to implementation of the proposed PHRBIS system, FSIS will develop its evaluation plan. The plan will include the types of outcome analyses to be conducted. The results of those analyses will be used to refine the PHRBIS" (FSIS 2008a, p. 34). The committee concludes that an integral part of the PBHRBIS should be an evaluation plan that contains specific metrics with which to evaluate the reduction in foodborne illness and with which to judge the success of the system. The data sources used to evaluate the metrics should be independent of those generated by FSIS. An example of such an approach could be one that uses FoodNet, PulseNet, and outbreak data to evaluate whether FSIS's risk ranking is resulting in measurable improvements to public health.

Use of *Salmonella* Serotype Data for Estimating Attribution

Comprehensive *Salmonella* surveillance—including characterization of human, food, animal, and environmental isolates with a combination of serotyping and molecular subtyping methods—is critical for improving our understanding of *Salmonella* transmission and facilitating, in the long term, science-based approaches to *Salmonella* attribution. In particular, population and commodity-specific subtype data are required for the development of mathematical models for attribution of *Salmonella* to either different reservoirs (for example specific animal-host species) or possibly to specific commodities. FSIS has

adapted one subtype-based model developed in Denmark (the "Danish model") to attribute public-health risk to different FSIS-regulated food sources. The committee applauds that effort to innovate; however, the committee is concerned about the ability of this particular approach to provide appropriate attribution to different FSIS-regulated foods. Specifically, there is limited biologic justification for associating *Salmonella* serotypes and different food items (except for *Salmonella* Enteritidis PT4, which is associated with transmission via intact eggs) other than their well-documented association with specific host species. Therefore, mathematical source attribution estimates based on subtype data for food isolates will largely reflect the underlying biologic association of subtypes with specific (animal) reservoirs and, as transmission of a specific host-associated serotype to humans can be achieved by different routes, this may prove unreliable for food-group attribution. For example, a particular serotype could be transmitted by consumption of contaminated meat or poultry products, by contamination of fruits and vegetables by manure runoff, or as a consequence of direct contact between humans and reservoir hosts.

Subtype-based attribution efforts, such as the Danish model, also require large comprehensive data sets on *Salmonella* subtypes associated with different reservoirs and food commodities. Thus, application of subtype-based attribution to only a fraction of the food supply (FSIS-regulated foods) increases the chances of inaccurate attribution estimates. In addition, association of specific serotypes with certain reservoirs and foods may change over time; for example, while *Salmonella* Enteritidis was overwhelmingly associated with egg and egg products when it initially emerged, prevalence of this serotype in poultry products appears to have increased over time. Subtype-based attribution estimates thus need to be updated regularly to be accurate and useful. Finally, the Danish model used both serotype data and phage-typing data for a subset of serotypes, while the proposed FSIS approaches only use serotype data, thus relying on more limited subtype discrimination, particularly among the common *Salmonella* serotypes (for example, Typhimurium). Use of the modified Danish model to allow for appropriate subtype-based source-attribution estimates for the US thus will require additional data (for example, subtype data in addition to serotyping data), validation, and probably further improvements in subtype characterization to define clonal groups that may be associated with specific food types.

On a broader scale, the data will also be critical for completion of an all-encompassing subtype-based *Salmonella* attribution effort for all foods and non-food-associated transmission pathways (for example, direct zoonotic transmission). The committee appreciates that the PulseNet database already provides a comprehensive subtype data set for human clinical *Salmonella* isolates but believes that further efforts are needed to enhance coverage of animal, food, and environmental *Salmonella* isolates in molecular typing databases, including design of data collection and analysis systems that are consistent among agencies. Other federal agencies (for example, the Animal Plant Health Inspection Service and FDA) and state agencies should be involved and integrated into those efforts. While FSIS appears to attempt an attribution to food source rather than reservoir, these collaborations are needed to provide serotype and PFGE data for *Salmonella* isolates associated with a variety of sources. These collaborations will be critical for accurate reservoir attribution, which, as detailed above, may be more feasible than food-source attribution.

The committee also concludes that there are opportunities for better integration of FoodNet and PulseNet data in conjunction with subtype data to facilitate estimation of population-based attribution of sporadic cases to specific agents. For example, combining serotype (from the Public Health Laboratory Information System) and PFGE data (from PulseNet) on isolates from sporadic cases can facilitate estimation of population-based attribution of sporadic cases to specific agents; this would be similar to what has been done in the Danish model (Hald et al. 2004). In addition, comparing data from sporadic cases to that obtained from outbreaks should provide a better understanding of attribution differences between outbreak and sporadic cases, if such differences exist. While collection of subtype data for other foodborne-disease agents will provide for improved outbreak detection, subtype-based attribution may not necessarily be possible for other pathogens, particularly if there is no biologic basis for associations between pathogen subtypes and specific reservoirs and/or foods.

While there are concerns whether the Danish model, which is a "reservoir" attribution effort, can be used as a model for "food-source attribution," as proposed by FSIS, continued efforts using improved

subtyping methods and data sets may yield insights into the feasibility and reliability of subtype-based food-source attribution. However, it is important to recognize that even with improved subtype data for *Salmonella* strains associated with different food and animal sources, reliable food-source attribution may not be feasible, and instead only point-of- reservoir attribution will be possible.

Consideration of Analysis in a Broader Context

The foodborne-disease attribution model put forth by FSIS is to be used to categorize slaughtering and processing establishments with respect to their potential effects on public health. The purpose is to improve and facilitate priority-setting and resource allocation with respect to FSIS-inspected products that are the major contributors to human-foodborne illness. FSIS intends to use this approach, at least initially, for priority-setting among particularly risky pathogen-commodity pairs or promising mitigation strategies. It is expected that the approach will also be used to inform the development of new microbiologic criteria and related public-health goals and to document the efficacy of control strategies in reducing the overall foodborne-disease burden and improving public health. Indeed, as policy-makers move toward promulgating food-safety regulations in the framework of risk assessment, they are increasingly faced with the challenge of linking public-health goals with scientifically valid criteria, such as performance standards. However, there remain questions about how to achieve this. For instance, Can a performance standard be designed to fit a stated public-heath goal? How will the effectiveness of a regulation be measured in terms of specific public-health outcomes? Food attribution plays an important role in answering such questions.

The committee considers that a more integrated approach to evaluating FSIS's risk-based inspection system would be more effective. For example, the committee was tasked specifically with addressing attribution for the purposes of ranking establishments, and another committee addressed only process-control indicators. Understanding how these two components influence one another is vital in addressing the primary question about FSIS's risk-based inspection system: Is it leading to improved public health? That is, does the risk-based inspection system enhance FSIS's ability to detect and respond to food-safety hazards? Does it ensure that establishments that pose a risk to public health receive more attention? These are the questions that should be addressed to ensure that FSIS's risk-based inspection system is enhancing public-health protection.

CONCLUSIONS

- The committee applauds FSIS's efforts to develop a Public Health Risk-Based Inspection System; however, FSIS should present a more transparent algorithm to rank slaughtering and processing establishments according to public-health risk. Despite considerable effort, the committee had great difficulty in understanding the rationale behind the proposed approach and in precisely reproducing FSIS's calculations because of a lack of transparency in the model. In addition, failure to characterize the uncertainty in the attribution estimates and other inputs of the risk-ranking algorithm is a critical weakness in the proposed PHRBIS.
- The precision implied in FSIS's public-health risk ranking, produced in part by using attribution estimates and production volume, appears to be quite low. Because FSIS estimates public-health effects on the basis of a small number of observations, the estimates have large uncertainties that should be communicated in the ranking algorithm. FSIS should also recognize that attribution estimates will need to be updated as disease incidence in humans changes to retain their relevance when used for risk-based inspection.
- The data sources currently available for assessing attribution are insufficient to be used independently. FSIS has not used some data that are readily available to supplement the CDC outbreak data and expert elicitations. This could help in the development of better-informed attribution estimates.

- In the proposed public-health risk-based ranking algorithm, FSIS's method of categorizing facilities on the basis of their LOI (indicators of process control) before incorporating public-health attribution (public-health effect) ranks facilities according to inspection-based risk (for example, recalls, enforcements, and verification testing). This ranking may not reflect public-health risk. In the current system, attribution has little influence on an establishment's rank, inasmuch as rank is determined primarily by LOI categorization, which pinpoints hotspots, and the system then ranks establishments with a given LOI primarily according to the product of attribution and fractional volume. It is unclear how the public-health effect component of the algorithm will improve the ability to set priorities among high-risk facilities.
- Attribution estimates based on outbreak data which reflect disease occurring at the "point of consumption" do not directly translate to attribution at the point of slaughter and processing. In fact, other points along the farm-to-fork continuum that are outside of FSIS's jurisdiction (for example, the farm and the end-user) contribute substantially to disease associated with FSIS-regulated products. Because the risk-ranking algorithm does not explicitly consider the contribution of non-regulated attribution sources to FSIS-regulated products, it can under or over-estimate the proportion of illnesses actually attributable to slaughter and processing. This oversight may result in inappropriate risk-based allocation of resources.
- The development of performance measures is premature, given the limitations of the attribution estimates and the lack of uncertainty characterization. That is of particular concern because imprecise estimates of attribution are being used to support specific performance objectives, and the proposed system may not reflect the changing or uncertain nature of the attribution estimates.
- *Salmonella* serotyping and molecular subtyping not only will be critical for improved attribution efforts but will enhance the agency's ability to monitor pathogen trends, such as emergence of new subtypes. *Salmonella* serotype-based and subtype-based attribution models are not yet at a stage where they should be used for policy decision-making.

RECOMMENDATIONS

- Recognizing that it is difficult to estimate food attribution given the small amount of available data and its relatively poor quality, FSIS should consider alternative prioritization methods for their PHRBIS. This might include ranking methods that do not rely on attribution data per se or risk-ranking models that approach the attribution problem in an alternative manner.
- Once FSIS has selected a means of ranking, it should provide transparent documentation that describes the primary data used in the risk-ranking calculations; step-by-step instructions on how to perform the calculations, with examples; characterization of uncertainty in the data; sensitivity analysis of the risk-ranking algorithm; and strengths, limitations, and clear justification of the approach selected. To the extent practicable, the risk ranking should consider the importance of differences in disease severity associated with different pathogens. Documentation should be provided to allow interested stakeholders to reconstruct FSIS's approach.
- FSIS should state that it will update the risk-ranking algorithm and reevaluate the PHRBIS every 1-3 years, and the agency should specify how this will be done. The periodic evaluations should use newly available data and methods (for example, methods for risk ranking used by other regulatory agencies worldwide) and should evaluate model inputs and the model itself. A main focus of the regular evaluations should be to ensure that the dynamic nature of attribution is factored into the model. In addition, FSIS should articulate the metrics that it will use to demonstrate public-health outcomes; the metrics should be evaluated by using data sources that are independent of those generated by USDA.
- If FSIS continues to include attribution as a component in its PHRBIS, FSIS in conjunction with CDC staff and others, should review the CDC outbreak database, including information not considered in the initial FSIS attribution model, to improve attribution of illnesses to regulated food products. Routine

use of the CDC outbreak data for purposes of food-attribution modeling may provide further incentives to state and local jurisdictions to report outbreaks accurately and quickly for use by CDC.

- If FSIS continues to include attribution as a component in its PHRBIS, FSIS staff should work collaboratively with FoodNet and PulseNet staff to use sporadic-case and outbreak data in conjunction with subtype data more effectively to facilitate estimation of population-based attribution of sporadic cases to specific agents.
- Recognizing that food-attribution data are of interest to many agencies, FSIS should work collaboratively with CDC, FDA, and other federal and state agencies to develop a common set of definitions for microbial foodborne-disease attribution; a coordinated approach to improve the quality and consistency of data used among agencies in determining food-attribution estimates; a process that allows for regular updating of attribution estimates; and a standardized coding scheme for food vehicles, including multi-component foods.
- FSIS should continue to collaborate with CDC and other appropriate organizations in the serotyping and molecular subtyping of all *Salmonella* isolates, with emphasis on those obtained from specific food products. To the extent feasible, subtype data should also be collected for isolates from environmental samples and other sources of human exposure to *Salmonella* (for example, reptiles and pets). Recognizing that *Salmonella* serotyping and molecular subtyping will not only be critical for improved subtype-based attribution efforts, but will also enhance the agency's ability to monitor pathogen trends (for example, emergence of new subtypes), FSIS should try to include serotyping and/or molecular subtyping in all of its future baseline studies. As part of these efforts, FSIS should establish and support collaborative arrangements with FDA to assure that *Salmonella* isolates obtained by USDA or FDA are characterized using the same molecular subtyping approaches and that results are available in a comprehensive database with harmonized nomenclature of human, animal, food, and environmental *Salmonella* isolates. In the future, it may be appropriate to expand such studies to other pathogens.
- FSIS should continue to support the collection of serotype and molecular subtype data for *Salmonella* and perhaps other relevant pathogens, and the development of mathematical models that use these serotype and subtype data for understanding food (and source) attribution of human *Salmonella* infections. These efforts need to include research on developing new models, evaluating and validating existing models, and developing better quality data to populate the models.

Attachments:
A – Statement of Task
B – Committee Membership
C – References
D – Acknowledgment of Reviewers
E – Public Agendas for Meetings
F – Electronic Foodborne Outbreak Reporting System
G – Foodborne Disease Attribution

Attachment A

STATEMENT OF TASK

An ad hoc committee will evaluate FSIS's proposed methodology and adequacy of data used for calculating microbial food-borne disease attribution for ranking processing and slaughtering establishments according to public health risk. The ad hoc committee's evaluation will be based on available information, including the approach and data presented in *Appendix A – Public Health Attribution and Performance Measure Methods* of the technical reports, *Public Health Risk-Based Inspection System for Processing and Slaughter* (FSIS 2008a) and *Improvements for Poultry Slaughter Inspection* (FSIS 2008b) and on supporting information contained in these two reports. In its assessment the adequacy of data for calculating attribution, the committee will also evaluate and provide recommendations on FSIS's proposed approach for using their *Salmonella* serotype data for assessing attribution. (The committee's evaluation of the *Salmonella* serotype information will be based on available information, including a presentation given to the committee by FSIS). The Ad hoc Committee will produce a letter report.

Attachment B

COMMITTEE MEMBERSHIP

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MARGARET DONOHUE HARDIN, Texas A&M University, TX
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BIOGRAPHIES

John C. Bailar III *(Chair)* (IOM) is professor emeritus in the Department of Health Studies of the University of Chicago and scholar-in-residence at the National Academies. He is a retired commissioned officer of the U.S. Public Health Service and worked for the National Cancer Institute for 22 years. He has also held academic appointments at Harvard University and McGill University. Dr. Bailar's research interests include assessing health risks posed by chemical hazards and air pollutants and interpreting statistical evidence in medicine with emphasis on cancer. He was editor-in-chief of the *Journal of the National Cancer Institute* for 6 years and statistical consultant and member of the Editorial Board of the *New England Journal of Medicine*. Dr. Bailar is a member of the International Statistical Institute and was elected to the Institute of Medicine in 1993. He served as chair of several National Research Council committees, including the Committee to Ensure Safe Food from Production to Consumption, the Committee on Estimating the Health-Risk-Reduction Benefits of Proposed Air Pollution Regulations, and the Committee on Estimating Mortality Risk Reduction Benefits from Decreasing Tropospheric Ozone Exposure. He received his MD from Yale University and his PhD in statistics from American University.

Margaret Donohue Hardin is an associate professor of food microbiology in the Department of Animal Science of Texas A&M University. She conducts a research program in food microbiology that includes research on product safety, security, and quality, encompassing deterioration, spoilage, and public-health hazards caused by bacterial growth and survival in foods of animal origin. Previously, Dr. Hardin was employed in the meat industry as director of food safety at Sara Lee Foods, director of food safety at Smithfield, and director of food safety and quality assurance at Boar's Head Brand. She also worked as director of pork safety with the National Pork Producers Council and as a research scientist and Hazard Analysis and Critical Control Point instructor with the National Food Processors Association. Dr.

Hardin's professional memberships include the American Society for Microbiology, the International Association for Food Protection, the Institute for Food Science, the Society for Applied Microbiology, and the American Meat Science Association. She is a member of the Editorial Board of the *International Journal of Food Microbiology* and of the Editorial Advisory Board of *Food Safety Magazine*. Dr. Hardin has served as a member of the National Advisory Committee on Microbiological Criteria for Food and the National Advisory Committee for Meat and Poultry Inspection. She received her PhD in food microbiology from Texas A&M University.

Craig Hedberg is a professor of environmental and occupational health at the University of Minnesota School of Public Health. His research focuses on foodborne-disease surveillance, surveillance of environmental factors associated with foodborne disease, the role of food workers in the occurrence of foodborne disease, the use of epidemiologic methods in outbreak investigations and disease control, and environmental contamination by enteric pathogens. He previously served as supervisor of the Foodborne, Vectorborne, and Zoonotic Disease Unit at the Minnesota Department of Health. Dr. Hedberg served on the National Research Council Subcommittee II on Produce and Related Products, Seafood, and Dairy Products. He received his PhD in epidemiology from the University of Minnesota.

Lee-Ann Jaykus is a professor in the Departments of Food Science and Microbiology at North Carolina State University. Her research efforts focus on the development of molecular methods to detect human enteric viruses in foods and investigation of foodborne viral disease outbreaks with a molecular epidemiologic approach. Additional research efforts include evaluation of nucleic acid amplification techniques for the detection of bacterial pathogens (*Salmonella*, *Listeria monocytogenes*, and *E. coli* O157:H7) in a variety of food products and the application of quantitative microbial risk assessment in the evaluation of foodborne microbiologic hazards. Dr. Jaykus has collaborated in large, multi-institutional projects to investigate the prevalence of pathogens and their association with production and processing practices in fresh produce, poultry, and shellfish. Her professional memberships include the International Association for Food Protection, the Carolinas Association for Food Protection, and the American Society for Microbiology. She earned a PhD in environmental science and engineering from the University of North Carolina at Chapel Hill.

Jeffrey LeJeune is an associate professor in the Department of Veterinary Preventive Medicine in the food-animal health research program at Ohio State University. His research involves preharvest control of human foodborne pathogens, control of antimicrobial-resistant bacteria in the animal host and the environment, and the effects of diet composition on the magnitude and prevalence of *E. coli* O157 in cattle. Dr. LeJeune has also investigated practical, on-farm methods to reduce bacterial contamination of livestock drinking water. He has served as an expert consultant to the joint Food and Agriculture Organization and World Health Organization on control of microbiologic contamination of leafy greens and to the International Water Management Institute on water reuse in agriculture and public health. Dr. LeJeune received his DVM from the University of Prince Edward Island and his PhD in veterinary microbiology from Washington State University, and he did postdoctoral work in epidemiology.

Jianghong Meng is a professor in the Department of Nutrition and Food Science of the University of Maryland and interim director of the Joint Institute for Food Safety and Applied Nutrition with the Food and Drug Administration. Dr. Meng is interested in molecular identification, antimicrobial resistance, and pathogenicity of major foodborne pathogens, including Shiga toxin-producing *E. coli, Campylobacter, Salmonella*, and *Listeria monocytogenes*. Dr. Meng is an appointed member of the National Advisory Committee on Microbiological Criteria for Foods of the U.S. Department of Agriculture and is on the Editorial Board of *Applied and Environmental Microbiology*. He received his DVM from Sichuan Agricultural University, China, and his PhD in comparative pathology from the University of California, Davis.

William H. Ross is a bureau director in the Food Directorate of the Health Products and Foods Branch of Health Canada. Dr. Ross oversees four programs related to food-safety regulatory, statistical, and epidemiologic analysis: the Food Regulatory Program, Outreach and Engagement, Food Policy and Issues Management, and Biostatistics and Epidemiology. Those programs focus on national and international regulatory policies concerning food safety, nutrition, decision analysis, and risk modeling. Dr. Ross has also served as bureau director of biostatistics and computer applications in the Food Directorate and director of the Risk Management Framework at Health Canada. Dr. Ross has published extensively and given many invited presentations on toxicity and growth models for foodborne pathogens, including *Listeria, Clostridium*, *Enterococcus*, and *E. coli*; quantitative risk analysis and decision-making; and food attribution. Dr. Ross received his PhD in mathematics from Queens University in Ontario, Canada.

Donald Schaffner is a professor of food science at Rutgers, the State University of New Jersey. His research is on quantitative microbial risk assessment and predictive food microbiology, including mathematical models of the growth of *Clostridium* spp. in meat products under changing temperatures and risk-modeling techniques to understand and manage the risk posed by deliberate contamination of the food supply. Dr. Schaffner has served on expert committees for the World Health Organization (WHO), and the Food and Agriculture Organization (FAO) of the UN and has chaired two expert workshops on microbial risk for WHO/FAO. He is serving a 5-year term as editor of *Applied and Environmental Microbiology*. He is a member of the National Advisory Committee on Microbial Criteria for Foods. Dr. Schaffner has served on the National Research Council Committee on Review of the Use of Scientific Criteria and Performance Standards for Safe Food. He received his PhD in food science and technology from the University of Georgia.

Martin Wiedmann is an associate professor of food science at Cornell University. His research focuses on molecular pathogenesis and evolution of bacterial and foodborne diseases, the role of alternative sigma factors in bacterial pathogens, molecular epidemiology of human foodborne and animal diseases, detection of bacterial and viral pathogens by molecular biology, preharvest food safety, and *Listeria monocytogenes*. Dr. Wiedmann serves as co-coordinator of the Cornell Food and Water Safety Program, and he participates in the Infection and Pathobiology Program and in the Cornell Genomics Initiative. He is also the director of the Cornell Laboratory of Molecular Typing. Dr. Wiedmann serves on the editorial boards of several journals, including the *Journal of Food Protection*, *Applied and Environmental Microbiology*, and *Foodborne Pathogens and Disease*. He is a member of the American Dairy Science Association, the American Veterinary Medicine Association, and the American Association for the Advancement of Science. He has served as a consultant and expert witness on a variety of food-safety issues, including *Listeria monocytogenes* contamination and ecology in food-processing plants, the link between *L. monocytogenes* recall and foodborne-illness cases, the link between *E. coli* O157:H7 cases and food recalls, and issues of food and water safety on fairgrounds. He received his PhD in food science from Cornell University and his DVM and PhD in veterinary medicine from the University of Munich, Germany.

Attachment C

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Attachment D

ACKNOWLEDGMENT OF REVIEWERS

This report has been reviewed in draft form by persons chosen for their diverse perspectives and technical expertise in accordance with procedures approved by the Report Review Committee of the National Research Council. The purposes of the independent review are to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards of objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We thank the following for their review of the report: Douglas Archer, University of Florida; Michael Batz, University of Florida; Robert Buchanan, University of Maryland; Ian Gardner, University of California at Davis; Emma Hartnett, Risk Sciences International; Joseph Rodricks, ENVIRON International Corporation; Robert Tauxe, Centers for Disease Control and Prevention.

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of the report was overseen by the review coordinator, John Erdman, University of Illinois at Urbana-Champaign, and the review monitor, Harley Moon, Iowa State University. Appointed by the National Research Council, [they] were responsible for making certain that an independent examination of the report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of the report rests entirely with the committee and the institution.

Attachment E

PUBLIC AGENDAS FOR MEETINGS

First Meeting: November 6-7, 2008

November 6, 2008

Room 100
Keck Center of the National Academies
500 5th Street, NW
Washington, DC

8:15 a.m.	Welcome, Introductions, Plans for the two days, Statement of Task *Committee chair and NRC staff*
9:00 a.m.	FSIS Overview *Carol Maczka, Assistant Administrator, Office of Food Defense and Emergency Response*
9:10 a.m.	USDA Perspective on Charge to the Committees *Scott Hurd, Deputy Under Secretary of the Office of Food Safety*
9:25 a.m.	How FSIS Does Inspection *William Shaw, Senior Food Technologist, Office of Food Defense and Emergency Response*
9:55 a.m.	FSIS Public Health Risk Ranking Algorithm *Erin Dreyling, Deputy Director, Data Analysis and Integration Group, Office of Food Defense and Emergency Response, FSIS* Handout: Technical Report ("Public Health Risk-Based Inspection System for Processing and Slaughter")
10:40 a.m.	Break
11:00 a.m.	Information on FSIS Risk-Based Approach to Public Health Attribution *Dr. Curtis Travis, Science Applications International Corporation* *Erin Dreyling, Deputy Director, Data Analysis and Integration Group, Office of Food Defense and Emergency Response, FSIS* *Lynda Kelley, Senior Advisor for Food Defense, Office of Food Defense and Emergency Response, FSIS* Handout: Appendix A of Technical Report ("Public Health Attribution and Performance Measures Methods")
12:35 p.m.	Lunch
1:35 p.m.	Proposed Methodology for Risk-Based Regulation of In-Commerce Activities *Don Anderson, Staff Officer, Program Evaluation and Improvement Staff, Office of Program Evaluation, Enforcement and Review*

2:25 p.m. Public Comment Period

3:15 p.m. Adjourn Public Session

November 7, 2008

9:30 a.m. Discussion of FSIS' approach to attribution and serotyping
Erin Dreyling, Deputy Director, Data Analysis and Integration Group, Office of Food Defense and Emergency Response, FSIS
Lynda Kelley, Senior Advisor for Food Defense, Office of Food Defense and Emergency Response, FSIS
Dr. Curtis Travis, Science Applications International Corporation

10:30 a.m End of public session

Second Meeting: January 5, 2009

Room 201
Keck Center of the National Academies
500 5th Street, NW
Washington, DC

3:30 a.m. Presentation by FSIS on the Use of the Danish Model to Calculate Attribution
Carl Schroeder, Deputy Director, Risk Assessment and Residue Division, Office of Public Health Science
Chuanfa Guo, Senior Risk Analyst, Risk Assessment and Residue Division, Office of Public Health Science

4:00 p.m. Questions and Discussion with Committee

4:45 p.m. Public Comment Period

5:00 p.m. Adjourn Public Session

Attachment F

ELECTRONIC FOODBORNE OUTBREAK REPORTING SYSTEM[5]

Form approved OMB No. 0920-0004

Electronic **F**oodborne **O**utbreak **R**eporting **S**ystem

Investigation of a Foodborne Outbreak

This form is used to report foodborne disease outbreak investigations to CDC. It is also used to report *Salmonella* Enteritidis and *E. coli* O157:H7 outbreak investigations involving any mode of transmission. A foodborne outbreak is defined as the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food in the United States. This form has 6 parts. Part 1 asks for the minimum or basic information needed and must be completed for the investigation to be counted in the CDC annual summary. Part 2 asks for additional information for any foodborne outbreak, while Parts 3 – 6 ask for information concerning specific vehicles or etiologies. Please complete as much of all parts as possible.

CDC Use Only

State Use Only

Part 1: Basic Information

1. Report Type

A.
□ Please check if this a final report

B.
□ Please check if data does not support a FOODBORNE outbreak

2. Number of Cases

Lab-confirmed cases_____(A)
Including _____secondary cases

Probable cases_____(B)
Including _____secondary cases

Estimated total ill_____
If greater than sum A + B)

3. Dates
Please enter as many dates as possible

Date first case became ill __/__/__ __ __ __
Month Day Year

Date last case became ill __/__/__ __ __ __
Month Day Year

Date first known exposure ___/___/___
Month Day Year

Date last known exposure ___/___/___
Month Day Year

4. Location of Exposure

Reporting state _____

If multiple states involved:
□ Exposure occurred in multiple states
□ Exposure occurred in single state, but cases resided in multiple states
Other states: _____

Reporting county _____

If multiple counties involved:
□ Exposure occurred in multiple counties
□ Exposure occurred in one county, but cases resided in multiple counties
Other counties: _____

5. Approximate Percentage of Cases in Each Age Group

<1 year ____% 20-49 yrs ____%
1-4 yrs ____% ≥50 yrs ____%
5-19 yrs ____% Unknown ____%

6. Sex
(Estimated percent of the total cases)

Male_____%

Female_____%

7. Investigation Methods (Check all that apply)

□ Interviews of only cases
□ Case-control study
□ Food preparation review
□ Cohort study
□ Investigation at factory or production plant
□ Investigation at original source (farm, marine estuary, etc.)
□ Food product traceback
□ Environment / food sample cultures

8. Implicated Food(s): (Please provide known information)

Name of Food	Main Ingredient(s)	Contaminated Ingredient(s)	Reason(s) Suspected (See codes just below)	Method of Preparation (See attached codes)
e.g., Lasagna	e.g., Pasta, sauce, eggs, beef	e.g., Eggs	e.g., 4	e.g., M1
1)				
2)				
3)				

□ Food vehicle undetermined

Reason Suspected (List above all that apply)
1 - Statistical evidence from epidemiological investigation
2 - Laboratory evidence (e.g., identification of agent in food)
3 - Compelling supportive information
4 - Other data (e.g., same phage type found on farm that supplied eggs)
5 - Specific evidence lacking but prior experience makes it likely source

CDC 52.13 revised November, 2004

Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0004).

[5]Form can be found at http://www.cdc.gov/foodborneoutbreaks/documents/ob_Form5213.pdf.

9. Etiology: (Name the bacteria, virus, parasite, or toxin. If available, include the serotype and other characteristics such as phage type, virulence factors, and metabolic profile. Confirmation criteria available at http://www.cdc.gov/foodborneoutbreaks/guide_fd.htm or MMWR2000/Vol. 49/SS-1/App. B)

Etiology		Serotype	Other Characteristics (e.g., phage type)	Detected In (See codes just below)
1)	☐ Confirmed			
2)	☐ Confirmed			
3)	☐ Confirmed			

☐ Etiology undetermined

Detected In (List above all that apply)

1 - Patient Specimen(s) **3 -**Environment specimen(s)

2 - Food Specimen(s) **4 -** Food Worker specimen(s)

10. Isolate Subtype

State Lab ID	PFGE (PulseNet designation)	PFGE (PulseNet designation)	
1)			
2)			
3)			

11. Contributing Factors (Check all that apply. See attached codes and explanations)

☐ **Contributing factors unknown**

Contamination Factor

☐C1 ☐C2 ☐C3 ☐C4 ☐C5 ☐C6 ☐C7 ☐C8 ☐C9 ☐C10 ☐C11 ☐C12 ☐C13 ☐C14 ☐C15 (*describe in Comments)* ☐ N/A

Proliferation/Amplification Factor (bacterial outbreaks only)

☐P1 ☐P2 ☐P3 ☐P4 ☐P5 ☐P6 ☐P7 ☐P8 ☐P9 ☐P10 ☐P11 ☐P12 (*describe in Comments)* ☐ N/A

Survival Factor (microbial outbreaks only)

☐S1 ☐S2 ☐S3 ☐S4 ☐S5 (*describe in Comments)* ☐N/A

☐ **Was food-worker implicated as the source of contamination?** ☐ Yes ☐ No

If yes, please check **only one** of following

☐ laboratory *and* epidemiologic evidence

☐ epidemiologic evidence (w/o lab confirmation)

☐ lab evidence (w/o epidemiologic evidence)

☐ prior experience makes this the likely source (*please explain in Comments*)

CDC 52.13 revised November, 2004

Part 2: Additional Information

12. Symptoms, Signs and Outcomes

Feature	Cases with outcome/ feature	Total cases for whom you have information available
Healthcare provider visit		
Hospitalization		
Death		
Vomiting		
Diarrhea		
Bloody stools		
Fever		
Abdominal cramps		
HUS or TTP		
Asymptomatic		
*		
*		
*		

13. Incubation Period

(Circle appropriate units)

Shortest_____(Hours, Days)
Longest_____(Hours, Days)
Median _____(Hours, Days)
□ Unknown

14. Duration of Illness

(Among those who recovered)
(Circle appropriate units)

Shortest_____(Hours, Days)
Longest_____(Hours, Days)
Median _____(Hours, Days)
□ Unknown

• Use the following terms, if appropriate, to describe other common characteristics of cases

Anaphylaxis	Headache	Tachycardia
Arthralgia	Hypotension	Temperature reversal
Bradycardia	Itching	Thrombocytopenia
Bullous skin lesions	Jaundice	Urticaria
Coma	Lethargy	Wheezing
Cough	Myalgia	
Descending paralysis	Paresthesia	
Diplopia	Septicemia	
Flushing	Sore throat	

15. If Cohort Investigation Conducted:

Attack rate* = _____ / _____ x 100 = _____%
(Exposed and ill / Total number exposed for whom you have illness information)

* The attack rate is applied to persons in a cohort who were exposed to the implicated vehicle. The numerator is the number of persons who were exposed and became ill; the denominator is the total number of persons exposed to the implicated vehicle. If the vehicle is unknown, then the attack rate should not be calculated.

16. Location Where Food Was Prepared

(Check all that apply)

□ Restaurant or deli
□ Day care center
□ School
□ Office setting
□ Workplace cafeteria
□ Banquet Facility
□ Picnic
□ Caterer
□ Grocery Store
□ Nursing home
□ Prison, jail
□ Private home
□ Workplace, not cafeteria
□ Wedding reception
□ Church, temple, etc
□ Camp
□ Contaminated food imported into U.S.
□ Hospital
□ Fair, festival, other temporary/ mobile services
□ Commercial product, served without further preparation
□ Unknown or undetermined
□ Other (Describe) _____

17. Location of Exposure or Where Food Was Eaten

(Check all that apply)

□ Restaurant or deli
□ Day care center
□ School
□ Office Setting
□ Workplace cafeteria
□ Banquet Facility
□ Picnic
□ Grocery Store
□ Fair, festival, temporary/ mobile service
□ Unknown or undetermined
□ Other (Describe) _____
□ Nursing Home
□ Prison, jail
□ Private home
□ Workplace, not cafeteria
□ Wedding Reception
□ Church, temple, etc.
□ Camp
□ Hospital

18. Trace back

□ Please check if trace back conducted

Source to which trace back led:

Source (e.g., Chicken farm, Tomato processing plant)	Location of Source State	Country	Comments

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19. Recall

☐ Please check if any food product recalled

Recall Comments

_____

_____

_____

_____

_____

20. Available Reports (Please attach)

☐ Unpublished agency report

☐ Epi-Aid report

☐ Publication (please reference if not attached)

_____

_____

21. Agency reporting this outbreak

_____

Contact person:

Name _____

Title _____

Phone _____

Fax _____

E-mail _____

22. Remarks

Briefly describe important aspects of the outbreak not covered above (e.g., restaurant closure, immunoglobin administration, economic impact, etc)

_____

_____

_____

_____

_____

Part 3: School Questions

1. Did the outbreak involve a single or multiple schools?

☐ Single

☐ Multiple (*If yes*, number of schools ____)

2. School characteristics (for all involved students in all involved schools)

a. Total approximate enrollment

_____ (number of students)

☐ Unknown or Undetermined

b. Grade level(s) (Please check all grades affected)

☐ Preschool

☐ Grade School (grades K-12)

Please check all grades affected: ☐K ☐1st ☐2nd ☐3rd ☐4th ☐5th ☐6th ☐7th ☐8th ☐9th ☐10th ☐11th ☐12th

☐ College/University/Technical School

☐ Unknown or Undetermined

c. Primary funding of involved school(s)

☐ Public ☐ Private ☐ Unknown or Undetermined

3. Describe the preparation of the implicated item:

☐ Heat and serve (item mostly prepared or cooked off-site, reheated on-site)

☐ Served a-la-carte

☐ Serve only (preheated or served cold)

☐ Cooked on site using primary ingredients

☐ Provided by a food service management company

☐ Provided by a fast food vendor

☐ Provided by a pre-plate company

☐ Part of a club/ fundraising event

☐ Made in the classroom

☐ Brought by a student/teacher/parent

☐ Other _____

☐ Unknown or Undetermined

4. How many times has the state, county or local health department inspected this school cafeteria or kitchen in the 12 months before the outbreak?*

☐ Once

☐ Twice

☐ More than two times

☐ Not inspected

☐ Unknown or Undetermined

5. Does the school have a HACCP plan in place for the school feeding program?*

☐ Yes

☐ No

☐ Unknown or Undetermined

*If there are multiple schools involved, please answer according to the most affected school

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6. Was implicated food item provided to the school through the National School Lunch/Breakfast Program?

- ☐ Yes
- ☐ No
- ☐ Unknown or Undetermined

***If Yes*, Was the implicated food item donated/purchased by :**

- ☐ USDA through the Commodity Distribution Program
- ☐ Purchased commercially by the state/school authority
- ☐ Other_____
- ☐ Unknown or Undetermined

Part 4: Ground Beef

1. What percentage of ill persons (for whom information is available) ate ground beef raw or undercooked? _____%

2. Was ground beef case ready? (Ground beef that comes from a manufacturer packaged for sale and not altered or repackaged by the retailer)

- ☐ Yes
- ☐ No
- ☐ Unknown or Undetermined

3. Was the beef ground or reground by the retailer?

- ☐ Yes
- ☐ No
- ☐ Unknown or Undetermined

If yes, was anything added to the beef during grinding (e.g., shop trim or any product to alter the fat content)_____

Part 5: Mode of Transmission

(Enterohemorrhagic *E. coli* or *Salmonella* Enteritidis only)

1. Mode of Transmission (for greater than 50% of cases)

Select one:

- ☐ Food
- ☐ Person to person
- ☐ Swimming or recreational water
- ☐ Drinking water
- ☐ Contact with animals or their environment
- ☐ Unknown or Undetermined

Part 6: Additional Egg Questions

1. Were Eggs: (Check all that apply)

- ☐ in-shell, un-pasteurized?
- ☐ in-shell, pasteurized?
- ☐ liquid or dry egg product?
- ☐ stored with inadequate refrigeration during or after sale?
- ☐ consumed raw?
- ☐ consumed undercooked?
- ☐ pooled?

2. If eggs traced back to farm, was *Salmonella* Enteritidis found on the farm?

- ☐ Yes
- ☐ No
- ☐ Unknown or Undetermined

Comment:_____

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Contamination Factors:[1]

C1 - Toxic substance part of tissue (e.g., ciguatera)
C2 - Poisonous substance intentionally added (e.g., cyanide or phenolphthalein added to cause illness)
C3 - Poisonous or physical substance accidentally/incidentally added (e.g., sanitizer or cleaning compound)
C4 - Addition of excessive quantities of ingredients that are toxic under these situations (e.g., niacin poisoning in bread)
C5 - Toxic container or pipelines (e.g., galvanized containers with acid food, copper pipe with carbonated beverages)
C6 - Raw product/ingredient contaminated by pathogens from animal or environment (e.g., *Salmonella* Enteriditis in egg, Norwalk in shellfish, *E. coli* in sprouts)
C7 - Ingestion of contaminated raw products (e.g., raw shellfish, produce, eggs)
C8 - Obtaining foods from polluted sources (e.g., shellfish)
C9 - Cross-contamination from raw ingredient of animal origin (e.g., raw poultry on the cutting board)
C10 - Bare-handed contact by handler/worker/preparer (e.g., with ready-to-eat food)
C11 - Glove-handed contact by handler/worker/preparer (e.g., with ready-to-eat food)
C12 - Handling by an infected person or carrier of pathogen (e.g., *Staphylococcus*, *Salmonella*, Norwalk agent)
C13 - Inadequate cleaning of processing/preparation equipment/utensils B leads to contamination of vehicle (e.g., cutting boards)
C14 - Storage in contaminated environment B leads to contamination of vehicle (e.g., store room, refrigerator)
C15 - Other source of contamination (*please describe in Comments*)

Proliferation/Amplification Factors:[1]

P1 - Allowing foods to remain at room or warm outdoor temperature for several hours (e.g., during preparation or holding for service)
P2 - Slow cooling (e.g., deep containers or large roasts)
P3 - Inadequate cold-holding temperatures (e.g., refrigerator inadequate/not working, iced holding inadequate)
P4 - Preparing foods a half day or more before serving (e.g., banquet preparation a day in advance)
P5 - Prolonged cold storage for several weeks (e.g., permits slow growth of psychrophilic pathogens)
P6 - Insufficient time and/or temperature during hot holding (e.g., malfunctioning equipment, too large a mass of food)
P7 - Insufficient acidification (e.g., home canned foods)
P8 - Insufficiently low water activity (e.g., smoked/salted fish)
P9 - Inadequate thawing of frozen products (e.g., room thawing)
P10 - Anaerobic packaging/Modified atmosphere (e.g., vacuum packed fish, salad in gas flushed bag)
P11 - Inadequate fermentation (e.g., processed meat, cheese)
P12 - Other situations that promote or allow microbial growth or toxic production (*please describe in Comments*)

Survival Factors:[1]

S1 - Insufficient time and/or temperature during initial cooking/heat processing (e.g., roasted meats/poultry, canned foods, pasteurization)
S2 - Insufficient time and/or temperature during reheating (e.g., sauces, roasts)
S3 - Inadequate acidification (e.g., mayonnaise, tomatoes canned)
S4 - Insufficient thawing, followed by insufficient cooking (e.g., frozen turkey)
S5 - Other process failures that permit the agent to survive (*please describe in Comments*)

Method of Preparation:[2]

M1 - Foods eaten raw or lightly cooked (e.g., hard shell clams, sunny side up eggs)
M2 - Solid masses of potentially hazardous foods (e.g., casseroles, lasagna, stuffing)
M3 - Multiple foods (e.g., smorgasbord, buffet)
M4 - Cook/serve foods (e.g., steak, fish fillet)
M5 - Natural toxicant (e.g., poisonous mushrooms, paralytic shellfish poisoning)
M6 - Roasted meat/poultry (e.g., roast beef, roast turkey)
M7 - Salads prepared with one or more cooked ingredients (e.g., macaroni, potato, tuna)
M8 - Liquid or semi-solid mixtures of potentially hazardous foods (e.g., gravy, chili, sauce)
M9 - Chemical contamination (e.g., heavy metal, pesticide)
M10 - Baked goods (e.g., pies, éclairs)
M11 - Commercially processed foods (e.g., canned fruits and vegetables, ice cream)
M12 - Sandwiches (e.g., hot dog, hamburger, Monte Cristo)
M13 - Beverages (e.g., carbonated and non-carbonated, milk)
M14 - Salads with raw ingredients (e.g., green salad, fruit salad)
M15 - Other, does not fit into above categories *(please describe in Comments)*
M16 - Unknown, vehicle was not identified

[1] Frank L. Bryan, John J. Guzewich, and Ewen C. D. Todd. Surveillance of Foodborne Disease III. Summary and Presentation of Data on Vehicles and Contributory Factors; Their Value and Limitations. Journal of Food Protection, 60; 6:701-714, 1997.
[2] Weingold, S. E., Guzewich JJ, and Fudala JK. Use of foodborne disease data for HACCP risk assessment. Journal of Food Protection, 57; 9:820-830, 1994.

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Attachment G

FOODBORNE DISEASE ATTRIBUTION[6]

1.0 Introduction

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 a set of criteria 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 report gives an overview of an approach for performing microbial foodborne disease attribution. 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.

The Centers for Disease Control and Prevention (CDC) in its Healthy People 2010 program, for which Food Safety Inspection Service (FSIS) and the Food and Drug Administration (FDA) are the food safety co-leads, has set to goal of decreasing *Salmonella* species, *Campylobacter* species, *E. coli* O157:H7, and *Listeria monocytogenes* infections each by 50% by the year 2010 from the period 1996-1998. It is generally agreed that the best manner of achieving these goals is to focus regulatory attention on those food types that contribute the largest burden of illness for each of these pathogens. This necessitates knowledge of what fraction of foodborne human illness results from consumption of specific food items. This knowledge is called foodborne disease attribution. Estimates of foodborne attribution are pathogen specific, that is, the percentage of disease attributable to a particular food type (i.e., consumption of beef, chicken, eggs or produce) will vary from pathogen to pathogen.

The Food Safety Inspection Service (FSIS) has, through contractors, elicited the opinion of experts to rank the contribution of various types of processed meat and poultry products to disease caused by *Salmonella*, *Listeria monocytogenes*, and *E. coli* O157:H7. The last two elicitations (Karns et al. 2005, 2007) produced similar attribution results. Nevertheless, there has been some hesitation in using these attribution estimates in a regulatory framework since they are based on expert opinion rather than empirical data.

The purpose of this report is two fold. The first is to compare the attribution estimates obtained from the FSIS 2007 expert elicitation with those from two other sources: an independent expert elicitation performed by Resources for the Future (RFF)/Carnegie Mellon and those derived from a disease outbreak database complied by the Centers for Disease Control and Prevention (CDC). The second purpose is to use these three studies to develop more informed estimates of foodborne disease attribution for 25 meat and poultry food categories of interest to FSIS.

[6]E. Dreyling, FSIS, unpublished material, January 6, 2009.

2.0 Foodborne Disease Attribution

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 perception 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.

2.1 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. In what follows this study is referred to as the FSIS expert elicitation. 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, and *Listeria monocytogenes* to handling and consuming foods in 25 processed meat and poultry product categories. The attributions obtained for the Karns et al. (2007) study are presented in Table 2-1.

TABLE 2-1 Attribution of Foodborne Illness (Percentages) for 25 Processed Meat and Poultry Product Categories Based on the 2007 FSIS Expert Elicitation

Finished Product Type	*Salmonella*	*E. coli O157*	*Listeria M*
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

(Continued)

TABLE 2-1 Continued

Finished Product Type	*Salmonella*	*E. coli O157*	*Listeria M*
RTE acidified/fermented poultry (without cooking)	1.6	0.3	4.4
RTE acidified/fermented meat (without cooking)	1.0	4.2	6.4
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.

2.2 Resources for the Future Expert Elicitation

Resources for the Future 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 *Listeria monocytogenes.*

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 much more detail on specific meat and poultry food categories. Thus, both elicitation studies provide slightly different perspectives on the food attribution problem.

Table 2-2 presents data from the RFF elicitation of the percent contribution (attribution) of 11 food types to foodborne illness in the United States.

2.3 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 (CDC 2008). 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. As will be seen 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 the two above 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 2-3 presents attribution information related to outbreaks of *E. coli* O157:H7, *Salmonella*, and *L. monocytogenes.* With respect to FSIS-inspected products, the RFF and CDC studies considered the general food categories of beef/meat, poultry, pork, and deli meats, while the FSIS expert elicitation covered 25 specific FSIS-inspected food categories. To compare the results of all three studies with respect to meat and poultry food categories, we collapse the 25 food categories to four meat and poultry food categories. Table 2-4 presents the correspondence used to compare studies.

TABLE 2-2 Attribution of Foodborne Illnesses (Percentages) from RFF Expert Elicitation

Food Type	*Salmonella*	*E. coli O157*	*Listeria M*
Beef	10.9	67.9	1.6
Poultry	35.1	0.9	2.7
Pork	5.7	0.6	1.3
Deli meats	1.9	1.8	54
Eggs	21.8	0.03	0.3
Seafood	2.04	0.05	7.1
Produce	11.7	18.4	8.7
Breads and bakery	0.03	0	0.2
Dairy	7.3	4.0	23.6
Beverages	1.7	3.2	0.2
Wild game	1.6	3.2	0.3

Source: Hoffmann et al. 2007.

TABLE 2-3 CDC Outbreak Data for *Salmonella*, *E. coli* O157:H7, and *L. monocytogenes* by Specific Food Category

	Salmonella		*E. coli O157:H7*		*Listeria M*	
Food Type	Cases	Percent	Cases	Percent	Cases	Percent
Meat	2,444	9.6	2,030	54.1	0	0.0
Poultry	5,681	22.3	0	0.0	3	0.8
Deli Meats	284	1.1	49	1.3	251	69.9
Pork	1,121	4.4	0	0.0	0	0.0
Seafood	791	3.1	14	0.4	0	0.0
Produce	6,096	23.9	1190	31.7	0	0.0
Eggs	4,309	16.9	0	0.0	0	0.0
Dairy	2,748	10.8	301	8.0	105	29.3
Breads, Bakery	1,154	4.5	0	0.0	0	0.0
Game	0	0.0	15	0.4	0	0.0
Beverages	841	3.3	153	4.1	0	0.0
Total	25,469	100	3,752	100	359	100

Using the mapping in Table 2-4, food attribution for the four meat and poultry food categories can be calculated. It is necessary to normalize the percentages so they add to 100 percent for these four food categories. Normalization is necessary because the FSIS study only considered FSIS regulated meat and poultry categories, while the RFF and CDC studies considered both FSIS and FDA food categories. Table 2-5a presents a comparison of the three studies.

TABLE 2-4 Correspondence between FSIS Expert Elicitation Categories and General Meat and Poultry Categories

FSIS Food categories	Meat and Poultry Categories
Raw ground, comminuted, or otherwise nonintact beef	Meat
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	
Raw ground, comminuted, or otherwise nonintact chicken	Poultry
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	
Raw ground, comminuted, or otherwise nonintact pork	Pork
Raw intact pork	
All RTE categories	Deli meats

TABLE 2-5a Comparison of Normalized Attribution (Percentage) Developed by the FSIS, RFF, and CDC Studies

Finished Product Type	*Salmonella*				*E. coli O157*				*Listeria M*			
	FSIS	RFF	CDC	Av[a]	FSIS	RFF	CDC	Av[a]	FSIS	RFF	CDC	Av[a]
Meat	21.4	20.4[b]	25.7	22.5	84.7	95.3	97.6	92.5	6.0	2.7	0.0	2.9
Poultry	63.9	65.5	59.6	63.0	3.8	1.2	0.0	1.7	8.3	4.5	1.1	4.6
Pork	7.1	10.6	11.8	9.8	2.7	0.8	0.0	1.2	1.5	2.2	0.0	1.2
Deli meats	7.7	3.5	2.9	4.7	8.9	2.5	2.4	4.6	84.2	90.6	98.9	91.3

[a]Average of three studies.
[b]Beef only.
Note: As can be seen from Table 2-5a, the three attribution studies (one of which is an actual count of CDC 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 RFF and CDC studies provide attribution estimates for both FSIS and FDA-inspected foods. These can be used to estimate the average contribution of FSIS-inspected food categories to the total illness impact of *Salmonella*, *E coli* O157, and *Listeria* M in the United States. Table 2-5b presents these estimates.

3.0 Attribution for 25 FSIS Meat and Poultry Product Categories

We are now in a position to use the above foodborne disease attribution results to estimate attribution for the 25 meat and poultry product categories defined by FSIS in the Karns et al. (2007) study. We accomplish this in a two-step process:

- First, the average normalized attribution estimates in Table 2-5b are adjusted by the percent contribution of FSIS-inspected foods to U.S. foodborne illness rates (Table 2-5b) to arrive at an estimate of the percent contribution of each of the four food type categories to U.S. foodborne illness rates.
- Second, attribution estimates in Table 2-1 for each of the four food type categories are normalized so that they total the percent contribution for that specific food type.

Figure 3-1 illustrates the process for estimating the percent contribution of meat products to total foodborne disease *Salmonella* illnesses.

TABLE 2-5b Estimate of Average Percent Contribution of FSIS-Inspected Products to U.S. Foodborne Illness

	Salmonella			*E. coli O157*			*Listeria M*		
	RFF	CDC	Av	RFF	CDC	Av	RFF	CDC	Av
FSIS Inspected Foods	53.6	37.4	45	71.3	55.4	63	59.6	70.7	65
FDA Inspected Foods	46.4	62.6	55	28.7	44.6	37	40.4	29.3	35

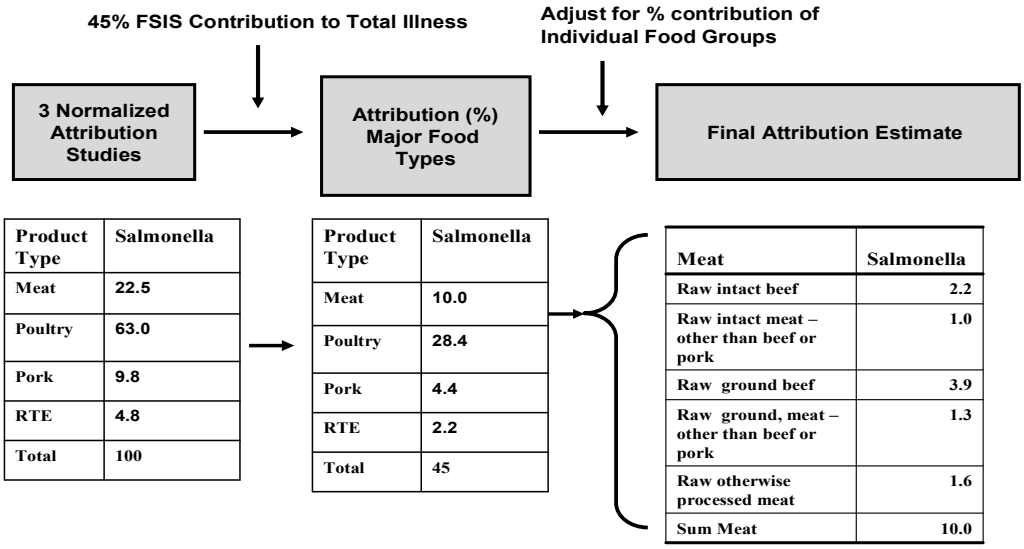

FIGURE 3-1 Example of process for estimating attribution for 25 FSIS food categories.

The results are presented in Table 3-1.

TABLE 3-1 Foodborne Disease Attribution Estimates for 25 FSIS Food Categories

Finished Product Type	*Salmonella*	*E. coli O157*	*Listeria M*
Meat			
Raw intact beef	2.2	5.8	0.2
Raw intact meat—other than beef or pork	1.0	1.8	0.1
Raw ground, comminuted, or otherwise nonintact beef	3.9	39.2	0.3
Raw ground, comminuted, or otherwise nonintact meat—other than beef or pork	1.3	9.5	0.1
Raw otherwise processed meat	1.6	2.0	0.2
Sum Meat	10.0	58.3	0.8
Poultry			
Raw intact chicken	9.8	0.5	0.27
Raw intact turkey	6.3	0.1	0.15
Raw intact poultry—other than chicken or turkey	1.7	0.3	0.30
Raw otherwise processed poultry	2.5	0.2	0.30
Raw ground, comminuted, or otherwise nonintact chicken	4.0	0.2	0.27
Raw ground, comminuted, or otherwise nonintact turkey	3.0	0.1	0.27
Raw ground, comminuted, or otherwise nonintact poultry—other than chicken or turkey	1.3	0.2	0.19
Sum Poultry	28.4	1.6	1.75
Pork			
Raw intact pork	1.7	0.4	0.31
Raw ground, comminuted, or otherwise nonintact pork	2.7	0.5	0.47
Sum Pork	4.4	0.9	0.78
RTE			
RTE acidified/fermented poultry (without cooking)	0.4	0.1	3.1
RTE acidified/fermented meat (without cooking)	0.3	1.4	4.5
RTE fully cooked poultry	0.3	0.1	17.5
RTE salt-cured poultry	0.2	0.1	2.8
RTE salt-cured meat	0.1	0.3	2.5
RTE dried meat	0.3	0.4	2.2
RTE dried poultry	0.3	0.1	2.2
RTE fully cooked meat	0.1	0.4	21.2
RTE meat fully cooked without subsequent exposure to the environment	0.1	0.1	1.5
RTE poultry fully cooked without subsequent exposure to the environment	0.1	0.1	1.4
Thermally processed, commercially sterile	0.0	0.0	0.1
Sum RTE	2.2	2.9	59

4.0 Discussion

The CDC outbreak database and two expert elicitations were used to derive foodborne disease attribution estimates for meat and poultry products. The three different approaches produce consistent estimates of attribution.

5.0 References

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