Data-Driven Inspection for Processing and Slaughter Establishments

Public Health Decision Criteria

United States Department of Agriculture
Food Safety and Inspection Service

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1.0 INTRODUCTION

The Food Safety and Inspection Service (FSIS) is the public health regulatory Agency that ensures the safety and wholesomeness of meat, poultry, and processed egg products. FSIS is transitioning to a public health-based, data-driven approach to FSIS inspection, sampling, and foreign country auditing. This data-driven approach will be supported by the Agency's enhanced data infrastructure, known as the Public Health Information System (PHIS). FSIS is using a set of public health-based decision criteria and a decision tree to select meat and poultry establishments for additional inspection activities. The public health decision criteria are intended to ensure that establishments that do or may lack control of their processes receive more inspection attention.

Egg product establishments are not currently included in the proposed approach because the establishments are not currently operating under HACCP and compliance/non-compliance data is documented manually and not collected under an automated data tracking system such as the Agency's Performance Based Inspection System (PBIS). In addition, egg establishments are not included in the current phased approach to PHIS implementation for meat and poultry establishments. Egg inspection is expected to be incorporated into PHIS and HACCP after implementation of PHIS for meat and poultry establishments is complete.

The public health decision criteria are intended for use in identifying establishments that may pose a greater risk to the public than other establishments and thus warrant increased attention by FSIS inspection program personnel. These criteria are being used to identify establishments that have an increased probability of causing human illness because: they have produced product that tested positive for pathogens known to cause human illness; are not in compliance with specific Federal laws and regulations; or are performing worse than their peers with respect to FSIS inspection findings. Establishments with these characteristics need to receive increased scrutiny because they may lack process control and thus may produce adulterated product and pose a greater risk to public health.

Under the decision criteria approach, all federally-inspected establishments receive at least the same level of daily inspection that they currently receive. In addition, establishments that do or may lack control will receive additional, comprehensive inspection procedures by in-plant personnel and FSIS Enforcement Investigation and Analysis Officers (EIAOs). The less control an establishment has over its process, the greater the risk that it will introduce into commerce a product that may be injurious to public health. Risk is defined by a set of decision criteria (delineated in Section 2.0), and it is used to select establishments for additional inspection activities. The approach addresses the Office of the Inspector General (OIG) December 2007 audit finding that FSIS should develop a timely and reliable data-driven inspection system supported by an integrated data infrastructure.

The decision criteria described in this report evolved from earlier FSIS work to develop a risk-based inspection program to rank processing establishments for the purpose of resource allocation. Based on input from industry, consumer groups, the National Academy of Sciences (NAS), and independent external peer reviewers, FSIS decided to replace the risk-based

inspection approach it was developing with a decision tree that utilizes public health decision criteria. The decision criteria were published in January 2008 and reviewed by the National Advisory Committee on Meat and Poultry Inspection (NACMPI) in February 2008. In September 2008, FSIS requested that NAS conduct an independent scientific peer review of key components of the decision tree approach and associated decision criteria. The NAS letter report dated March 13, 2009, concurs with the overall technical approach taken by FSIS to use decision criteria to identify establishments for additional inspection activities. NAS recommended that FSIS refine the terminology used in its report, improve the transparency and clarity of the description of the proposed inspection system approach, and investigate for future iterations of the decision criteria the value of statistical analyses to establish predictive relationships between its decision criteria and outcomes at FSIS-regulated meat and poultry establishments.

At the suggestion of stakeholders, FSIS has also developed a strategic data analysis plan that lays out the Agency's approach to improve data-driven decision-making. This will be an iterative process that occurs in phases. Phase 1 presents the decision criteria and planned improvements in data collection and data utilization. Phase 2 will be an evaluation of the success of the current proposed criteria and other data collection improvements in identifying establishments that pose a significant risk to public health and will use statistical analyses to evaluate predictive relationships between decision criteria and future health-related outcomes. Based upon these analyses, FSIS may add to or modify its decision criteria. The phases will be cyclical and continuous with the Agency learning from the lessons of the previous iteration. Essentially, each step seeks to build upon the last to produce the best possible decision criteria for focusing Agency resources on those establishments that pose the greatest risk to public health, while maintaining a standard in all FSIS-regulated establishments to ensure the safety and wholesomeness of all meat and poultry products in the United States. As the Agency considers revisions to its decision criteria, FSIS intends to communicate those changes publicly and seek stakeholder input.

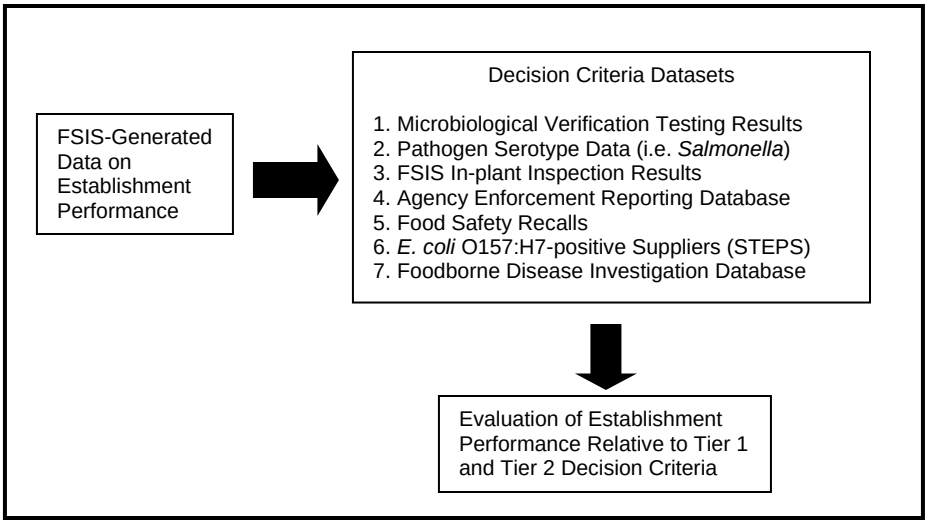
In the context of the phased-strategic data analysis plan described above, this report describes in detail the Phase 1 implementation of the public health decision criteria. The purpose of the this report is to incorporate suggestions from the NAS and other stakeholders and to present FSIS' current thinking with regard to the application of public health decision criteria for improving the Agency's processing and slaughter inspection activities and protecting public health. An important aspect of implementing this data-driven decision criteria approach is to ensure that the basis for allocation of FSIS inspection resources is clearly delineated, transparent, data-driven, and scientifically sound. The report consists of six sections with appendices. Section 1.0 is the introduction. Section 2.0 describes the proposed decision framework and associated decision criteria. Section 3.0 describes the implications of the proposed decision criteria. Section 4.0 describes an application of the decision criteria to identify establishments for additional inspection activities as of January 2010, and Section 5.0 introduces the strategic data analysis plan. Finally, the references are listed in Section 6.0, followed by six appendices.

2.0 DECISION FRAMEWORK AND DECISION CRITERIA

FSIS is utilizing a public health-based decision framework that is an integral component of the Agency's data-driven inspection system. The framework will be automated in the Public Health Information System (PHIS). PHIS will monitor data streams that characterize establishment performance and identify those establishments that may pose an increased risk to public health. This section presents an overview of the decision criteria and the framework for their application.

FSIS inspection program personnel and other Agency personnel, in verifying an establishment's compliance with FSIS regulations, collect data that can be used in evaluating an establishment's performance. These data are stored in the Agency's data warehouse and are retrieved and analyzed using the public health decision criteria to identify establishments for additional inspection activities reflecting different degrees of an establishment's potential lack of process control and thus potential risk to public health. A summary of the datasets supporting the decision criteria used to select establishments for more immediate inspection attention is in Figure 2, and a detailed description of the datasets is presented in Appendix B.

Figure 2: Decision Criteria Datasets to Select Establishments for Additional Inspection Activities



2.1 Public Health Decision Criteria

FSIS is using nine public health-based decision criteria for identifying establishments for more immediate inspection activities. Not all decision criteria apply to all establishments. For example, criterion 6 in Figure 2 only applies to establishments that supply raw ground beef components. The additional verification activities will consist of specially directed Food Safety Assessments (FSAs), intensified sampling, and a new verification activity termed a Hazard Analysis Verification (HAV). These activities are discussed in greater detail in Section 3 and in Appendix A.

FSIS is exploring options for the application of two additional Tier I criteria. These are

- Establishment has reoccurring *Salmonella* serotype positives of human health concern.
- FSIS positive *Salmonella* in heat-treated, not fully cooked, not shelf-stable stuffed poultry product.

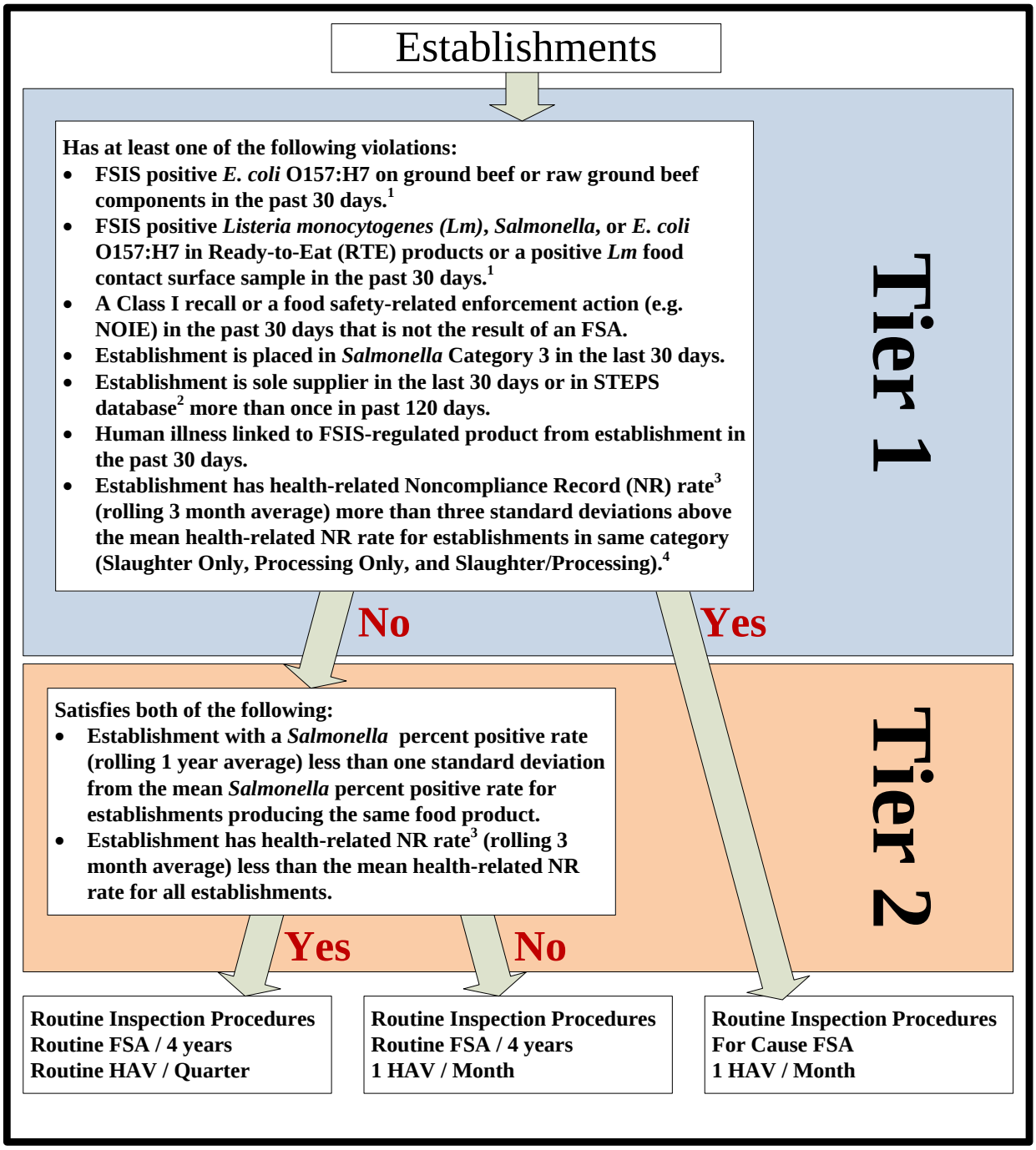
For further information on the definition of serotypes of human health concern see Appendix B. Using the proposed public health decision criteria, FSIS applies a decision tree approach to identify processing and slaughter establishments for additional inspection activities. The FSIS decision tree is shown in Figure 3.

Any establishment that violates one or more of the decision criteria in Tier 1 will require a for cause FSA and one HAV per month. Any establishment that does not violate any of the Tier 1 decision criteria will be evaluated using Tier 2 criteria. Any establishment that satisfies both criteria for Tier 2 will continue to receive routine inspection procedures, a routine FSA every four years, and a HAV every quarter. Establishments that do not satisfy both of the Tier 2 decision criteria will receive a routine FSA every four years and a HAV every month.

2.1.1 Basis for Decision Criteria

Table 1 provides a listing of rationale for why each proposed decision criterion is appropriate. The basis for selection of the decision criteria is that they identify establishments that: (1) have produced product that tested positive for pathogens known to cause human illness, (2) are not in compliance with specific Federal laws and regulations, or (3) are performing worse than their peers with respect to FSIS HACCP inspections. Establishments with these characteristics receive increased scrutiny because they have demonstrated a potential decrease in the level of process control and thus may produce adulterated product and pose a greater risk to public health.

Figure 3: FSIS Decision Tree



[1] Includes microbiological testing results for the National School Lunch Program and could be expanded to include other Federal, State, Local, Foreign government, or industry positive samples once data are available and can be analyzed.
[2] System for Tracking *E. coli* O157:H7 Positive Suppliers (STEPS) based on FSIS *E. coli* O157:H7 positive test results.
[3] Health-related Noncompliance Records (NRs) are those NRs considered most strongly related to public health. A list of the public health significant NRs is presented in Appendix C
[4] This decision criterion is continually being monitored, and it may be modified in the future as new information becomes available. This criterion is not applied to establishments with less than 40 inspections in a 3 month period. FSIS is currently investigating the impact using three standard deviations as well as integrating data from the SIP program.

Table 1: Justification for Selection of Decision Criteria

Criteria	Rationale for Selection of the Decision Criteria
Positive *E. coli* O157:H7 in Raw Ground Beef or Raw Ground Beef Components[1]	• *E. coli* O157:H7 is an adulterant in ground beef and other non-intact beef products or beef products intended for use in non-intact products, and its presence in these products is evidence an establishment may lack process control. • A positive for *E. coli* O157:H7 is a rare occurrence. An establishment with such an occurrence is performing worse than its peers. • The presence of *E. coli* O157:H7 in non-intact beef products or components intended for use in such products is a hazard that is reasonably likely to occur and thus should be prevented by the establishment's prerequisite program or controlled by its HACCP system. A positive test result is evidence that the establishment's food safety system may not be designed and/or implemented properly. • The FSIS Risk Assessment on *E. coli* O157:H7 in ground beef (FSIS 2001) found that even one or two *E. coli* O157:H7 positives in raw ground beef or raw ground beef components increases the risk of illness and death from *E. coli* O157:H7, especially among children aged 0 to 5. • CDC outbreak data indicate that *E. coli* O157:H7 in raw non-intact beef products can cause *E. coli* O157:H7 disease outbreaks. • The NAS (2009) concludes that the use of *E. coli* O157:H7 testing results for non-intact beef products and their components as a public health decision criterion is justified based on the potential direct health risk of the pathogen.
Establishments in *Salmonella* Category 3 or establishments that have a higher *Salmonella* percent positive (1 year average) than other establishments producing same product[2]	• Establishments in *Salmonella* Category 3 are performing worse than their peers. • Establishments in *Salmonella* Category 3 are exceeding the HACCP *Salmonella* performance standard indicating the establishment's food safety systems may not be designed or implemented properly. • Based upon the WHO (2002[3]) risk assessment, it can be estimated that broiler establishments in *Salmonella* Verification Category 3 have at least 2 times greater risk of causing an illness than establishments in *Salmonella* Category 1. • Based on FSIS attribution studies, *Salmonella* on FSIS-inspected meat and poultry products cause about 590,000 illnesses each year. *Salmonella* is the most common cause of foodborne bacterial illness associated with meat and poultry products. • The NAS (2009) concluded that the use of *Salmonella* testing results as a public health decision criterion is justified because a positive test result for *Salmonella* is an indicator of potential loss of process control.

Criteria	Rationale for Selection of the Decision Criteria
Positive *Salmonella, E. coli* O157:H7, or *Listeria monocytogenes* on RTE product or *Lm* positive on food contact surface[1]	• A *Salmonella, E. coli* O157:H7, or *Listeria monocytogenes* positive in a RTE product is a rare occurrence. An establishment with such an occurrence is performing worse than its peers. • FSIS has a "zero tolerance" for bacterial pathogens in RTE products and the presence of *Salmonella, E. coli* O157:H7, *Listeria monocytogenes,* or any other bacterial pathogen in a RTE product is thus an indication an establishment may lack process control. • Under 9 CFR Part 430, post-lethality exposed RTE products are adulterated if they test positive for *Listeria monocytogenes (Lm)* or come into direct contact with a food contact surface that tests positive for *Lm.* • The presence of *Salmonella, E. coli* O157:H7, or *Listeria monocytogenes* in an RTE product or *Lm* positive on a food contact surface means that the establishment is out of compliance with Federal laws and regulations. • *Salmonella, E. coli* O157:H7, *Listeria monocytogenes,* or any other bacterial pathogen in RTE products is a hazard reasonably likely to occur and thus must be prevented by the establishment's prerequisite program or controlled by its HACCP plan. Thus a positive test result for one of these pathogens is evidence that the establishment's food safety system may not be designed and/or implemented properly. • The 2003 FSIS *Listeria* Risk assessments (FDA/FSIS 2003, FSIS 2003) found that o Increased levels of *Lm* in RTE products at retail increase risk of illness and death from *Lm*; o A food contact surface positive for *Listeria* species greatly increases the likelihood of finding RTE product lots positive for *Lm*; and o A lower level of *Listeria* species and *Lm* positives on food contract surfaces results in a lower risk of death from listeriosis. • The FSIS risk assessment on *Salmonella* on RTE products (Decisionalysis Risk Consultants and FSIS 2005) found that increased levels of *Salmonella* on RTE products increases the risk of *Salmonella* illnesses. • Based on FSIS attribution studies, *Lm* in RTE products causes about 1,300 illnesses and 260 deaths each year. *Salmonella* in RTE products causes 53,000 illnesses and *E. coli* O157:H7 in RTE products causes 700 illnesses. • The NAS (2009) concluded that the use of *Lm* testing results in RTE foods as a public health decision criterion is justified based on the potential direct health risk of the pathogen.
Public Health-Related (Class I) Food Safety Recalls not the Result of an FSA	• An establishment with a Class I recall is performing worse than its peers. • An establishment with a Class I recall has produced a product with a reasonable probability of causing serious, adverse public health problems or death. This is evidence the establishment's food safety systems may not be designed or implemented properly.
Establishments Linked to Human Illness Outbreaks	• An establishment linked to a human illness outbreak is performing worse than its peers since the establishment may be having a direct impact on human health. • Illness outbreaks linked to the establishment indicates that the establishment is out of compliance with Federal laws and regulations. • An establishment must maintain a food safety system that produces a safe and wholesome product. An illness outbreak linked to establishment indicates that its food safety system may not be designed or implemented properly.

Criteria	Rationale for Selection of the Decision Criteria
Food Safety-Related Enforcement action not the Result of an FSA	• An enforcement action indicates that the establishment is not in compliance with Federal laws and regulations. • An establishment against which FSIS has brought an enforcement action is performing worse than its peers. • FSIS believes that products not produced under appropriate food safety control systems, as evidenced by an enforcement action against the producing establishment, have a higher probability of causing human illnesses or death.
High Rate of Public Health Significant Regulatory Noncompliance Records (NRs)	• A high rate of public health-related NRs indicates that an establishment is frequently out of compliance with federal health-related laws and regulations. • An establishment with a high rate of public health-related NRs is performing worse than its peers. • FSIS believes that products not produced under appropriate food safety control systems, as evidenced by a high rate of public health-related NRs, have a higher probability of causing human illness or death. • FSIS analyses have demonstrated the predictive ability of public health-related NRs as indicators of *Salmonella* contamination. Specifically, an establishment that produces raw products and has a public health-related NR in a given 7-day period is three times more likely to have a positive *Salmonella* verification test result in the next 14 days than an establishment without a public health-related NR.

[1] FSIS recognizes that there are Type I and Type II errors for each of its sampling programs. The Agency is working to improve its sampling methodologies to reduce these errors.
[2] In May 2010, FSIS announced new performance standards for *Salmonella* and *Campylobacter* in young chickens and turkeys. Once these standards go into effect, they will also be used in the decision criteria.
[3] The WHO risk assessment does not directly address FSIS *Salmonella* Verification Categories. It does give relative risk levels associated with different levels of *Salmonella* on broiler carcasses from which the relative risk levels of *Salmonella* Categories 1 and 3 can be calculated.

2.1.2 Cut-Points for Salmonella and Health-Related NR Criteria

Some of the proposed public health decision criteria depend on affirming that a certain event has occurred in an establishment, while the *Salmonella* and NR criteria are based on cut-points applied to a range of values. The value of these criteria is that they provide continuous monitoring of the mean and standard deviation of *Salmonella* and NR levels in establishments and allow for FSIS to continuously establish performance standards as industry performance improves. This section will discuss the derivation of the cut-points for the *Salmonella* and public health-related NR criteria.

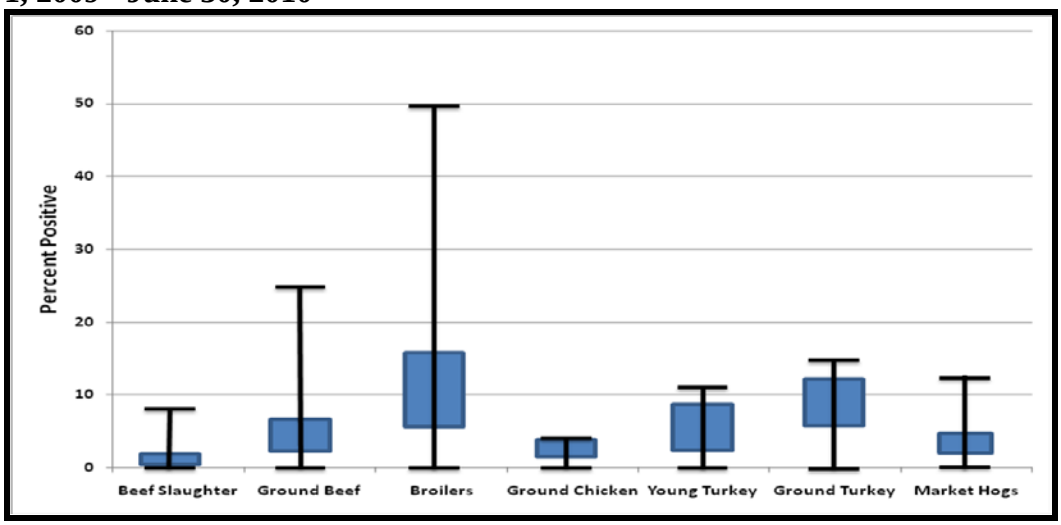
2.1.2.1 Salmonella

FSIS performs *Salmonella* verification testing at establishments that produce one or more of the eight categories of raw meat and poultry products (see Appendix B). Establishments are placed into one of three categories based on the rate of positives in sample sets. *Salmonella* Category 3 has the highest rate of positives. Establishments in *Salmonella* Category 3 within the past month will be scheduled for an FSA within 30 days.

A *Salmonella* cut-point is used to further separate the establishments that do not violate any of the Tier 1 criteria. The cut-point between these two sets of establishments is determined using the most recent year of *Salmonella* verification testing data for the establishment. The cut-point is defined at one standard deviation above the mean *Salmonella* percent positive rate for a raw product category (the raw product categories are listed in Figure 2-3 below, and are further clarified in Appendix B). Any establishment for which the *Salmonella* percent positive rate is less than one standard deviation above the mean for each raw product category will receive routine inspection procedures, routine FSAs every 4 years, and routine HAVs every quarter. In a normal distribution, 84 percent of all observations lie below one standard deviation above the mean; FSIS believes this is an appropriate cut-point to define well-performing establishments. Establishments with a *Salmonella* percent positive rate greater than one standard deviation above the mean and not in *Salmonella* Category 3 will have an increase in the frequency of HAVs to one per month and would be prioritized for their routine FSA.

Figure 4 presents box plots of the *Salmonella* percent positives for raw product categories. The upper and lower whiskers (ends of the lines) represent the upper and lower ranges of the data, while the upper edge of each solid box represents one standard deviation above the mean and the lower edge of each box represents the mean of the data. Thus, the upper edge of each box represents the cut-point for that raw product category.

Figure 4: Box Plots of Percent *Salmonella* Positives for Raw Food Products for July 1, 2009 - June 30, 2010



Note: While there are eight total raw product categories, only seven are represented by the box plot because "Steers/heifers" and "Cows/bulls" are collapsed into a single category called "Beef slaughter."

Table 2 shows the range, mean and median of the percent *Salmonella* positives for the one year time period May 1, 2009 – June 30, 2010 for establishments operating during the time period April 1, 2010 – June 30, 2010.

Table 2: Range, Mean and Median of Salmonella Rates for the Time Period July 1, 2009 – June 30, 2010 by Product

Product	Salmonella Rate Range	Mean Salmonella Rate	Median Salmonella Rate
Broilers	0.0-50.00%	17.39%	2.86%
Ground Chicken	0.0-4.00%	4.00%	0.00%
Beef Slaughter	0.0-8.00%	8.00%	0.00%
Ground Beef	0.0-25.00%	6.66%	0.00%
Turkey Slaughter	0.0-10.81%	8.33%	0.00%
Ground Turkey	0.0-14.63%	14.29%	6.70%
Market Hogs	0.0-12.00%	4.88%	0.00%

In May 2010, FSIS announced revised *Salmonella* and new *Campylobacter* performance standards for young chickens and turkeys. Once these standards go into effect, they will also be used in the decision criteria. The criterion will operate in a similar manner as the *Salmonella* verification testing criterion; however, the specific method to determine the cut-point needs to be developed taking into consideration the specific aspects of the *Campylobacter* program.

2.1.2.2 Public Health-Related NRs

Under 9 CFR Part 417, all meat and poultry slaughter and processing establishments are required to implement a HACCP system of process controls for preventing or controlling food safety hazards. FSIS inspection program personnel are present for all slaughter operations and on a daily basis at processing establishments to verify compliance with FSIS regulations, including HACCP requirements. When violations are observed, FSIS inspectors issue findings of regulatory noncompliance, or Noncompliance Records (NRs), which are an important indication that an establishment may not be maintaining effective food safety process controls. Data from NRs will be captured in PHIS using FSIS' new NR instrument. The NR instrument uses standardized fields to capture the noncompliance findings in a more analyzable format.

Noncompliance Records can vary from non-food safety issues to serious breakdowns in food safety controls. An FSIS expert panel categorized each regulatory requirement into one of four categories based on its public health significance (see Appendix C). Sixty-one out of over 564 possible regulatory citations were considered most strongly related to public health and are referred to as public health-related NRs or W3NRs. If a public health-related noncompliance occurs, it indicates an establishment's food safety system may not be in control and may not be able to prevent adulterated product from entering commerce. The list of the public health significant regulations is presented in Appendix C. FSIS is continually evaluating its public health-related NR classification.

The public health-related NR rate is calculated by the following formula using the most recent three months of establishment noncompliance data:

$$\textbf{Health-Related NR Rate} = \frac{\textbf{Number of Health-Related NRs}}{\textbf{Total Number of Inspection Procedures}}$$

The public health-related NR cut-points are defined as follows for each of the three plant types (Slaughter Only, Processing Only, and Slaughter/Processing):

- Any establishment with a public health-related NR rate that is less than the mean public health-related NR rate for all establishments with the same establishment type would continue to receive routine inspection procedures, routine FSAs every 4 years, and routine HAVs every quarter. These establishments are performing better on average than their peers with respect to compliance with FSIS regulations.
- Establishments with a public health-related NR rate between the mean public health-related NR rate for all establishments with the same establishment type and three standard deviations above the mean would continue to receive routine inspection procedures and, in addition, have the frequency of HAVs increased to one per month and be prioritized for routine FSAs.

- Establishments with a public health-related NR rate greater than three standard deviations above the mean for establishments with the same establishment type would continue to receive routine inspection procedures plus a for cause FSA and an increase in the frequency of HAVs to one per month.

Table 3 shows the range, mean and median of the public health-related NR rates for the time period April 1, 2010 – June 30, 2010. Most establishments do not receive any public health-related NRs in a given three month period. However, a few establishments do receive a significant number of public health-related NRs and these are the establishments that will receive a for cause FSA and an increase in the frequency of HAVs to one per month.

Table 3: Range, Mean and Median of the Public Health-Related NR Rates for the Time Period April 1, 2010 – June 30, 2010 by Establishment Type

Establishment Type	NR Rate Range	Mean NR Rate	Median NR Rate
Slaughter Only	0.0-2.17%	0.130%	0.00
Processing Only	0.0-4.08%	0.057%	0.00
Slaughter/Processing	0.0-5.7%	0.099%	0.00

In a normal distribution, 99.7 percent of all observations are within three standard deviations of the mean; therefore, if an establishment is three standard deviations above the mean, it can be considered to be an outlier. Since the public health-related NRs are not normally distributed, the actual percentage of establishments below the 3 standard deviation cut point differs slightly from 99.7 percent. Table 4 shows the actual cut points based on three standard deviations above the mean for the public health-related NR rates for the period April 1, 2010 to June 30, 2010. The fact that the percentages are less than 99.7 percent indicates that slightly more establishments are selected for a for cause FSA than if the NR distribution was normal.

Table 4: Percentage of Establishments with Public Health-Related NR Rates Less than the Public Health-Related NR Cut-Point

Establishment Type	Public Health-Related NR Cut-Point	Percentage of Establishments Below NR Cut-Point
Slaughter Only	1.53%	96.40%
Processing Only	0.73%	97.90%
Slaughter/Processing	1.03%	98.30%

3.0 IMPLICATIONS OF THE PUBLIC HEALTH DECISION CRITERIA

The proposed decision criteria approach in part formalizes the Agency's current criteria for identifying establishments that warrant closer attention. For example, under current FSIS Directives, an FSA will be scheduled at a Ready-to-Eat (RTE) establishment within 30 days of a *Listeria monocytogenes* positive or a raw ground beef establishment with an *E. coli* O157:H7 positive. PHIS will automate the public health decision criteria and will enhance FSIS' ability to monitor data on a near real-time basis in order to identify establishments that may pose an increased risk to public health. PHIS will analyze Agency data and automatically identify establishments based on the public health decision criteria.

The decision criteria will determine when for cause and routine Food Safety Assessments (FSAs) and a new inspection procedure called the Hazard Analysis Verification (HAV) will be performed. FSAs and HAVs are two overall assessments of an establishment's HACCP system, with FSAs providing a more comprehensive review and HAVs focusing on the hazard analysis (see Appendix A for a definition of a hazard analysis). FSAs are performed by Enforcement Investigation and Analysis Officers (EIAOs). An FSA is a comprehensive look at the design and implementation of an establishment's food safety system. FSIS conducts for cause FSAs in establishments that may pose a risk to public health, and FSIS conducts routine FSAs every four years in all meat and poultry slaughter and processing establishments. The data from FSAs will be captured in PHIS using FSIS' new FSA instrument, which uses standardized fields to capture the findings in a more analyzable format. The HAV is an additional inspection procedure that will be performed by in-plant Inspection Program Personnel (IPP). The HAV will serve as a screening process to identify issues of concern in the design of establishments' food safety systems. IPP performing a HAV evaluate an establishment's hazard analysis to verify that: (1) the hazard analysis addresses all hazards for the process, product, and intended use [9 CFR 417.2(a)]; (2) the establishment has support for hazard analysis decisions [9 CFR 417.5 (a) (1 & 2)]; and (3) all prerequisite programs are implemented as designed (see Appendix A for definition of prerequisite programs). Figure 3 in the previous section describes the frequency of FSAs and the HAVs, and additional descriptions are provided in Appendix A. Routine inspection activities, the regular actions FSIS performs as part of normal inspection duties, also are described in Appendix A. These routine activities will remain the same for all establishments.

As further data becomes available, PHIS will have the flexibility to adjust the frequencies of inspection activities, both HAVs and routine and for cause FSAs, based upon whether or not an establishment meets certain public health decision criteria.

Establishments in need of more immediate additional inspection attention will have a for cause Food Safety Assessment scheduled within 30 days and a HAV would also be scheduled and performed by in-plant personnel monthly as long as the establishment

continues to violate at least one of the Tier 1 decision criteria for the additional inspection activities.

All establishments receive an FSA every four years; however, establishments that violate any of the Tier 1 decision criteria and do not satisfy both of the Tier 2 decision criteria will be prioritized for routine FSAs over all other establishments that require a routine FSA. These establishments will be scheduled for routine FSAs according to production volume and relative health hazards in the products that the establishment produces as described in Section 3.2. Also, these establishments will receive a HAV that will be scheduled and performed by in-plant personnel on a monthly basis.

Establishments that do not violate any of the Tier 1 decision criteria and do satisfy both Tier 2 decision criteria will also receive a routine FSA once every four years. Routine FSAs for these establishments will be performed on a random basis over the four-year period. In addition, HAVs will also be scheduled and performed by in-plant personnel on a quarterly basis.

The HAVs will also be scheduled in all establishments if certain public health events, or "prompts," occur in the establishment. FSIS intends to use prompts to identify establishments that may have modified their HACCP system or may have failed to change their HACCP plan in response to a significant change in the establishment process. The list of public health prompts is presented in Tables 5 and 6.

HAV prompts are situations that warrant assessment of an establishment's hazard analysis. Many of these are noncompliance records that cite specific regulatory violations (see Table 5); however two additional prompts look at events not necessarily related to specific NRs but that also warrant assessment of the hazard analysis (see Table 6). For example, an establishment may make a change in its operations, such as adding a slaughter class or a product species that indicates it should have reassessed or modified its hazard analysis. Or an establishment may have an updated HACCP plan signature date indicating an annual reassessment or other modification of the HACCP system that warrants a HAV.

The occurrence of a prompt will not necessarily change the nature and frequency of inspection activities at an establishment. Only one HAV would be carried out in an establishment per month.

Table 5: Noncompliance Record Regulatory Citations that Prompt a HAV

Reg. Citation	Prompt	Justification
9 CFR 417.2(a)(1)	Incomplete hazard analysis	Noncompliance related to incomplete hazard analysis may indicate need for the establishment to change the hazard analysis. The NR might also indicate other design problems.
417.2(a)(2)	Omission from hazard analysis flowchart	Noncompliance related to omissions from the flowchart may indicate the need for an establishment to reconsider the hazard analysis. The NR might also indicate other design problems.
417.2(c)(2)	Failure to include Critical Control Points (CCPs) for all hazards	Noncompliance related to the failure to include CCPs for all hazards identified as reasonably likely to occur may require revision of the establishment's HACCP system.
417.2(c)(3)	Failure to specify Critical Limits for CCPs	Enforcement action related to the failure to include appropriate critical limits for one CCP may indicate broader problems with an establishment's HACCP system.
417.3(b)	Failure to address corrective actions or unforeseen hazards	Noncompliance related to corrective actions in response to deviations or unforeseen hazards not addressed in the HACCP plan may require reassessment and/or enforcement action.
417.4(a)(1)	Failure to validate the HACCP system	Noncompliance related to the failure to validate HACCP system may require revision or reassessment.
417.4(a)(3)	Failure to reassess HACCP plan	Noncompliance or enforcement action related to the failure to reassess when changes occur requires reassessment.
417.4(b)	Failure to reassess hazard analysis	Noncompliance or enforcement action related to the failure to reassess when changes occur requires reassessment.
417.5(a)(1)	Inadequate supporting documentation	Noncompliance related to the failure to provide supporting documentation (including failure to implement prerequisites) may indicate other problems with the hazard analysis.
417.5(a)(2)	Failure to support the design of the HACCP system.	Noncompliance related to the failure to support design of a CCP, critical limit, or monitoring or verification procedure may indicate other problems with the design of the HACCP system.
416.12(a)	Failure to describe/design SSOP procedures	Enforcement action related to problems with the description/design of the SSOPs. This might affect hazard analysis which typically relies on SSOP as a fundamental prerequisite.
416.12(c)	Failure to describe/design SSOPs to address cleaning of food contact surfaces	Noncompliance related to problems with the description/design of the Sanitation Standard Operating Procedures (SSOP). This might affect hazard analysis which typically relies on SSOP as a fundamental prerequisite.

Reg. Citation	Prompt	Justification
318.303 – 381.303	Failure to establish and apply critical thermal processing factors	Noncompliance related to meeting the critical factors of the canning regulations might require a reassessment or modification of the hazard analysis.
318.308 - 381.308	Deviations in thermal processing	Noncompliance related to processing deviations in canning might require a reassessment or modification of the hazard analysis.

Table 6: Other Events that Prompt a HAV

Prompt	Justification
Major change in establishment profile.	A HAV should be performed when major changes in the profile indicate that the establishment should have reassessed and modified its hazard analysis (such as an added slaughter class, added product risk class, added HACCP category, added product or species, added/modified intervention)
Updated HACCP signature date	A HAV should be performed when an annual reassessment or other modification of HACCP plan occurs.

3.1 Reevaluation of Establishments Using the Decision Criteria

PHIS will apply the decision criteria on a daily basis to identify establishments that may need more immediate inspection attention and will automatically schedule for cause FSAs and HAVs for these establishments. On a monthly basis PHIS will generate a routine FSA schedule based on the decision criteria and prioritize establishments that do not satisfy the Tier 2 decision criteria over those establishments that do satisfy the Tier 2 decision criteria.

Establishments will be reevaluated based on the decision criteria as described below.

- If an establishment is currently receiving a for cause FSA and one HAV per month, it will be reevaluated when the following conditions are met:
    - The for cause FSA is completed.
    - Any follow-up sampling required is completed, and any necessary corrective actions are completed and verified. If a positive test result occurs during follow-up sampling, the establishment will continue to receive one HAV per month until inspection program personnel have verified that the appropriate corrective actions have been taken.
    - Any enforcement action associated with the FSA is closed.
- If an establishment is currently receiving a routine FSA, it is automatically reevaluated monthly in PHIS unless it meets a Tier 1 decision criterion. If the establishment meets a Tier 1 decision criteria, PHIS will immediately schedule the establishment for a for cause FSA and a HAV will occur once per month.

- If an establishment has had a for cause FSA in the past six months, the establishment will be referred to District personnel to determine if the establishment should receive another for cause FSA.

3.2 Scheduling Routine FSAs for Establishments That Do Not Violate Any Tier 1 Criteria, but Do Not Satisfy Both Tier 2 Decision Criteria

Routine FSAs for establishments that do not violate any of the Tier 1 decision criteria, but do not satisfy both of the Tier 2 decision criteria will be scheduled with respect to the potential public health risk of the products they produce. FSIS defines potential public health impact using the *relative health hazard* of the food products an establishment produces and the total *volume* of its food products (see Appendix D).

3.2.1 Scheduling Process for FSAs

Plants are placed in one of six categories based on the food products they produce. The list of six categories in order of priority is as follows:

1. RTE products regardless of species
2. Raw Ground Beef
3. Raw Poultry (including Intact Chicken, Ground Chicken, Intact Turkey, Ground Turkey, Other Intact Poultry and Other Ground Poultry)
4. Raw Meat (including Intact Beef, Other Intact Meat and Other Ground Meat)
5. Raw Pork (including Intact Pork and Ground Pork)
6. All Other Products (products that do not fit into one of the above categories)

The order of priority reflects the relative potential health hazard of the six product categories. RTE products and raw ground beef are given the highest priority since they may contain the zero-tolerance pathogens *Listeria monocytogenes* and *E. coli* O157:H7 respectively, with RTE placed highest since *Listeria monocytogenes* illnesses cause more deaths. The remaining categories are listed in the relative order of their *Salmonella* attribution estimates (see Appendix D). If an establishment produces more than one of the six product categories, it is placed in the highest category for the products it produces.

Once all establishments are placed into one of the six product categories, the establishments within all categories *except* RTE are scheduled for FSAs in the order of the total volume of all products (processing and slaughter) the establishment produces.

RTE establishments are prioritized in the following order:

1. RTE Alternative (highest to lowest – 3, 2.2, 2.1, 1)
2. Deli Meat Plant (yes to no)
3. Total Volume (of all products produced highest to lowest).

Routine FSAs are scheduled for all establishments that produce RTE products first in the order above. Establishments that do not produce RTE products, but produce ground beef are scheduled next in the order of their total volume, and so forth.

4.0 APPLICATION OF PUBLIC HEALTH DECISION CRITERIA

To verify that the proposed public health decision criteria can be effectively applied to identify processing and slaughter establishments that will receive more immediate inspection activities, the decision criteria were applied to the 5,133 FSIS-inspected establishments (excluding import establishments) that were in operation during the period of April 1, 2010 – June 30, 2010. In June 2010, 126 establishments (about 2 percent) were identified as requiring a for cause FSA and 1 HAV per month, 510 (about 10 percent) a routine FSA with 1 HAV per month, and 4,497 (about 88 percent) a routine FSA with 1 HAV per quarter.

Table 7 summarizes the number of establishments selected for additional inspection activities based on each of the individual decision criterion. For example, 5 establishments had *E. coli* O157:H7 positives in ground beef or raw ground beef components. In total 4,497 establishments were identified to receive a routine FSA and a HAV every quarter, 510 establishments were identified to receive a routine FSA and a HAV every month, and 126 establishments were identified to receive a for cause FSA and a HAV every month. The number 4,497 is less than the number 4,536 in Table 7 of establishments that satisfied the criterion for health-related NRs since some of the 4,536 establishments violated other decision criteria that caused them to receive more frequent HAVs or a for cause FSA.

Note that totals for the columns in Table 7 may differ from the number of establishments in each of the three categories of type and frequency of inspection since establishments can violate more than one criterion. For example, the total number of violations in the forth column of Table 7 (For Cause FSAs) is 133, while the actual number of establishments identified to receive for cause FSAs for this time period, as noted above, was 126.

Based on the criteria in Table 7, each of the 5,133 establishments was successfully assigned the type and frequency of inspection activities it should receive (see Table 8). Approximately 2 percent of establishments would receive a for cause FSA and one HAV per month, 10 percent would receive a routine FSA and one HAV per month, and 88 percent would receive a routine FSA and one HAV per quarter. All establishments will continue to receive routine inspection procedures.

Table 7: Summary of Results for Individual Decision Criterion

Decision Criteria[1]	Routine Inspection Procedures, 1 FSA/4 yr, 1 HAV/Quar.	Routine Inspection Procedures, 1 FSA/4 yr, 1 HAV/Month	Routine Inspection Procedures, For Cause FSA, 1 HAV/Month
E. coli O157:H7 positive in ground beef or raw ground beef components	-	-	5
Listeria, *Salmonella*, *E. coli* O157:H7 postive in RTE or positive *Listeria* on food contact surface	-	-	-
Establishment with Class I recall or a food safety-related enforcement action	-	-	17
Salmonella Category 3	-	-	-
Salmonella percent positive rate[2]	272	38	-
Establishment identified as sole supplier or repeat supplier in STEPS database	-	-	7
Establishment Linked to Human Illness	-	-	-
Rate of health-related noncompliance records (NRs)[3]	4,536	493	104

[1]Decision criteria as defined by the timeframes identified in Figure 2-2 and if applicable the cut-points discussed in Section 2.1.2.
[2]The *Salmonella* cut points for the time period July 1, 2009 to June 30, 2010 are: Chicken broilers 17.39%; Ground chicken 4.00%; Beef Slaughter 8.00%; Ground beef 6.66%; Turkey Slaughter 8.33%; Ground turkey 14.29%; and Market Hogs 4.88%. These numbers are slightly higher than the cut-points in Figure 2-3 because they represent the percent positive rate of the first establishment above the cut-point.
[3]Based on data for April 1, 2010 to June 2010, the mean public health-related NR rate for Processing Only Plants was 0.06%, with a standard deviation of 0.22% and three standard deviations of 0.73%; for Slaughter Only Plants the mean was 0.13% with a standard deviation of 0.40% and three standard deviations of 1.52%; for Slaughter/Processing Plants the mean was 0.10% with a standard deviation of 0.31% and three standard deviations of 1.03%

Table 8: Number and Percentage of Establishments Receiving Each Type and Frequency of Inspection Activity for June 30, 2010

Type and Frequency of Inspection Activities	Number of Establishments	Percentage of Establishments
Routine Inspection 1 FSA/4 yr 1 HAV/Quarter	4,497	87.61%
Routine Inspection 1 FSA/4 yr 1 HAV/Month	510	9.94%
Routine Inspection For Cause FSA 1 HAV/Month	126	2.45%
TOTAL	5,133	100%

A summary of the percentage of establishments receiving each type and frequency of inspection activity stratified by establishment type is given in Table 9. For each establishment type, most establishments satisfy the decision criteria for a routine FSA and one HAV per quarter, fewer satisfy the decision criteria for a routine FSA and one HAV per month, and the fewest satisfy the decision criteria for a for cause FSA and one HAV per month.

Table 9: Summary of Establishments Receiving Each Type and Frequency of Inspection Activity by Establishment Type for June 30, 2010

Establishment Type	Number of Est.	Percent of Est. 1 FSA/ 4 yr 1 HAV/Quar	Percent of Est. 1 FSA / 4 yr 1 HAV / Month	Percent of Est. For Cause FSA 1 HAV / Month
Processing Only	4,090	89.85%	7.90%	2.25%
Slaughter/Processing	928	77.91%	19.07%	3.02%
Slaughter Only	115	86.09%	8.70%	5.22%
TOTAL	5,133	87.61%	9.94%	2.45%

A summary of the percentage of establishments receiving each type and frequency of inspection activity stratified by slaughter class/food product is given in Table 10.

Table 10: Summary of Establishments Receiving Each Type and Frequency of Inspection Activity by Slaughter Class/Food Product for June 30, 2010

Slaughter Class/Food Product	Number of Ests*	Percent of Est. 1 FSA/ 4 yr 1 HAV/Quarter	Percent of Est. 1 FSA / 4 yr 1 HAV / Mon.	Percent of Est. For Cause FSA 1 HAV / Mon.
Beef Slaughter	625	80.48	15.52	4.00
Pork Slaughter	593	82.63	15.51	1.85
Goat/Sheep Slaughter	476	83.82	14.08	2.10
Other Meat Slaughter	140	75.71	20.71	3.57
Chicken Slaughter	221	74.21	23.53	2.26
Turkey Slaughter	79	78.48	21.52	0.00
Other Poultry Slaughter	73	75.34	19.18	5.48
Raw Ground Beef	1,335	87.79	10.19	2.02
RTE	2,234	86.26	11.15	2.60
Intact Beef	1,616	87.56	10.15	2.29
Intact Pork	1,543	88.66	10.11	1.23
Other Intact Meat	704	87.64	10.65	1.70
Ground Pork	1,241	89.04	9.51	1.45
Other Ground Meat	277	85.92	10.11	3.97
Intact Chicken	1,044	86.88	11.11	2.01
Intact Turkey	231	85.28	12.55	2.16
Other Intact Poultry	80	87.50	8.75	3.75
Ground Chicken	230	82.17	15.65	2.17
Ground Turkey	147	87.07	10.20	2.72
Other Ground Poultry	42	88.10	9.52	2.38
Partial Cooked Meat or Poultry	823	88.21	9.48	2.31
Thermally-Processed, commercially sterile meat or poultry	89	87.64	10.11	2.25
Raw Beef Trimmings	798	87.34	10.90	1.75

* The number of establishments totals to more than 5,133 since many establishments make more than one product.

5.0 STRATEGIC DATA ANALYSIS PLAN FOR IMPROVING FSIS' DATA-DRIVEN DECISION-MAKING

FSIS recognizes that the development of an inspection system that is data-driven is an ongoing iterative process. The proposed decision criteria laid out in this report are the first step in the Agency's approach to use data to allocate inspection resources. The strategic data analysis plan, which is presented in another document, lays out the Agency's approach to enhance the effectiveness and efficiency of Agency programs through enhanced data collection, data utilization, and predictive analyses.

6.0 REFERENCES

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3. Food Safety and Inspection Service (FSIS), 2001. Risk Assessment of *E. coli* O157:H7 in Ground Beef. Available at: http://www.fsis.usda.gov/Science/Risk_Assessments/index.asp#RTE
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6. Office of Inspector General USDA (OIG) 2007. Audit Report: Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments. Report No. 24601-07-Hy. http://www.usda.gov/oig/webdocs/24601-07-HY.pdf
7. World Health Organization (WHO), Risk Assessments of *Salmonella* in Eggs and Broiler Chickens, 2002. http://www.fao.org/docrep/005/y4392e/y4392e0r.htm#bm27.3.2

APPENDICES

APPENDIX A
Definitions

An establishment's ***Food Safety Process Control System*** is the totality of all programs, measures, or processes an establishment implements to prevent or eliminate food safety hazards in its products. It is an establishment's responsibility to develop and maintain a food safety process control system that complies with Federal laws and regulations and ensures production of a safe and wholesome food product. Establishments are responsible to find and correct deficiencies and to use the information they gain when checking their systems to strengthen preventive process controls.

Hazard Analysis and Critical Control Points (HACCP) is a systematic preventive approach to food safety that relies on identification and control of physical, chemical, radiological, and biological hazards as a means of prevention rather than problem detection during finished product inspection. HACCP is used in the food industry to identify potential food safety hazards, so that key actions at Critical Control Points (CCPs) can be taken to reduce or eliminate the risk of the hazards being realized. The HACCP approach has been endorsed by the National Academy of Sciences, the Codex Alimentarius Commission (an international food standard-setting organization), and the National Advisory Committee on Microbiological Criteria for Foods. For the purposes of HACCP, an establishment's food safety system is composed of three components:

- A hazard analysis and supporting documentation which identifies potential hazards;
- Prerequisite programs or procedures used to prevent food safety hazards from occurring; and
- HACCP plans implemented to control food safety hazards that are not controlled through prerequisite programs.

The ***Hazard Analysis*** portion of a food safety system identifies the biological, physical, and chemical hazards that may be encountered in the production of a food product and develops measures to control those hazards that are reasonably likely to occur. The hazards associated with a particular product depend on the raw materials, the production steps, and the characteristics of the finished product. For example, Ready-to-Eat products are associated with different hazards than raw products.

Prerequisite Programs are conditions and practices intended to prevent food safety hazards from occurring. They frequently function across product lines and are often managed as facility-wide programs rather than being process or product specific. Prerequisite programs can include Sanitation Standard Operating Procedures (SSOPs), Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs), or any other program that an establishment uses to support decisions in the hazard analysis. A

single instance of failure of a prerequisite program may not necessarily create a food safety concern or necessitate action on the product.

HACCP Verification is defined as those activities, other than monitoring, that provide a level of confidence that the plan is based on solid scientific principles, is adequate to control the hazards associated with the product and process, and ensure that the HACCP system is operating according to the plan. Verification is done to determine whether

- the HACCP plan is being implemented properly;
- practices used are consistent with the HACCP plan;
- the HACCP system is working to control significant hazards; and
- modifications of the HACCP plan are required to reduce the risk of recurrence of deviations.

FSIS Inspection Activities are all actions the Agency may take to examine the establishment and its processes, products, and systems to verify that the establishment is fully implementing it food safety system**.** FSIS accomplishes this by

- Conducting daily inspection verification activities at operating establishments;
- Conducing periodic HACCP pathogen verification testing for *Salmonella*, *E. coli* O157:H7, and *Listeria monocytogenes* and Intensified Verification Testing (IVT) for *Listeria monocytogenes* to verify that the establishment's food safety system is controlling microbial pathogens;
- Conducting routine and for cause Food Safety Assessments (defined below); and
- Taking enforcement action when needed to ensure food safety compliance.

FSIS inspectors carry out the FSIS public health mission by verifying that each establishment produces meat or poultry products using an effective food safety system. As long as an establishment maintains its systems properly — including identifying, documenting, and correcting deficiencies — the HACCP system is functioning as designed, and there is no need for FSIS to take enforcement action.

A ***Food Safety Assessment*** (FSA) is a comprehensive look at an establishment's entire food safety system. It covers the hazard analysis, the HACCP plan and supporting documentation, sanitation standard operating procedures (SSOPs), prerequisite programs, microbiological testing procedures, sanitation performance standards (SPS), establishment documentation, and other information that relates to the establishment's products and processes. FSAs are conducted by Enforcement, Investigations, and Analysis Officers (EIAOs), who are FSIS employees trained to conduct FSAs. The methodology and documentation for conducting an FSA is specified in FSIS Directive 5100.1, and FSIS' new FSA instrument uses standardized fields to capture the findings of FSAs. The OIG (2007) believes that FSAs yield the Agency's best evidence about the design and implementation of an establishment's food safety system.

Under current FSIS Directive 5100.4, all meat and poultry slaughter and processing establishments receive an FSA at least once every four years. Establishments that violate at least one of the Tier 1 decision criteria will be scheduled for an FSA within 30 days.

A ***Hazard Analysis Verification*** (HAV) is a newly proposed inspection procedure that examines an establishment's hazard analysis. The HAV will serve as a screening process to identify issues of concern in the design of the establishments' food safety systems. HAVs will be performed when certain prompts identify establishments that may have modified their HACCP system or may have failed to change their HACCP plan in response to a significant change in the establishments' process.

A HAV will verify that the establishment's hazard analysis addresses the applicable food safety hazards for the process, product, and intended use. It will also verify that there is at least one CCP for the hazards that are reasonably likely to occur and that there is support for any decisions that applicable hazards are not reasonably likely to occur. It will also verify that prerequisite programs (such as an SOP, GMP, purchase specifications, etc.) are adequately justified and being implemented.

Prerequisite programs are used to control food safety hazards, thereby eliminating the need for CCPs. This necessitates that on a regular basis FSIS verifies that the decisions made in establishments' hazard analyses, and the data generated by prerequisite or other programs, do in fact support establishments' decisions that prerequisite programs are controlling food safety hazards.

The HACCP regulations require establishments to maintain documentation to support the decisions made in the hazard analysis (9 CFR 417.5(a)(1)) and to verify the ongoing effectiveness of the HACCP plan (9 CFR 417.4(a)). As part of inspection verification activities, FSIS verifies that each establishment meets these requirements in order to determine whether products have been produced in accordance with an effective food safety system. To that end, FSIS continues to train inspection program personnel and give them the tools to verify that establishment prerequisite programs demonstrate ongoing support for the decisions in the hazard analysis and that they are implementing their food safety systems effectively.

APPENDIX B
DATASETS AND THEIR USE IN THE PUBLIC HEALTH DECISION CRITERIA APPROACH

List of Active, FSIS-Inspected Establishments

The first step in selecting establishments for additional inspection activities is to assemble a list of active, Federally-inspected HACCP establishments. The set of active Federally/Talmadge-Aiken inspected HACCP establishments is assembled monthly. Any liquid and processed egg establishments or import houses on the list are removed. Also any establishments without inspection activity or HACCP process codes are removed from the list. Finally, establishments without a HACCP designation, but with 03 HACCP process codes are added to the list.

Microbiological Verification Testing Results

One of the public health decision criteria is the level of microbiological pathogens on meat and poultry products. As part of HACCP verification, FSIS randomly collects microbiological samples of meat and poultry products to verify that HACCP system controls are working properly and to track trends. By tracking microbiological data, FSIS can identify when food safety production processes are not being properly controlled or verify that prevention efforts undertaken by the establishment are successfully reducing bacterial levels. FSIS intends to take steps to refine existing pathogen testing programs to develop new pathogen testing programs that provide ongoing baseline measures of pathogens in FSIS-regulated products. FSIS is also characterizing the Type I and Type II error associated with its pathogen testing programs and plans to report the data publicly. FSIS has three main microbiological verification testing programs:

- *E coli* O157:H7 in ground beef, beef trim, and other components;
- *Listeria monocytogenes* (Lm) in Ready-to-Eat products; and
- *Salmonella* on eight categories of raw meat and poultry products and heat-treated, not fully cooked, not shelf-stable stuffed poultry products.

E. coli O157:H7 Verification Testing Results

FSIS performs *E. coli* O157:H7 verification testing at the approximately 1,400 Federally-inspected establishments that produce raw ground beef products or raw ground beef components. In 2007, FSIS identified an increased number of *E. coli* O157:H7 positive tests in beef, as well as a larger number of recalls and illnesses caused by this pathogen than in recent years. In response, FSIS has accelerated implementation of initiatives and improvements to its sampling methodology, including implementation of a risk-based approach to *E. coli* O157:H7 sampling and testing. In 2007, FSIS began routine sampling and testing of beef manufacturing trimmings for *E. coli* O157:H7 and follow-up testing of trimmings and other ground beef components. FSIS also intends to begin

gathering information on the production of mechanically tenderized or injected raw beef products. Establishments that test positive for this "zero tolerance" pathogen are considered to have lost food safety system process control.

Presumptive and potential entries are discarded and only positive entries for the current month under review are used to identify establishments for more immediate inspection attention. If an establishment has a raw ground beef or trim *E. coli* O157:H7 positive in the month being reviewed, the establishment will receive a for cause FSA and one HAV per month.

Listeria monocytogenes Positive Test Results in an RTE Product or on a Food Contact Surface

All establishments that produce Ready-to-Eat (RTE) products that are exposed to the environment after cooking must have written programs to control *Listeria monocytogenes* (*Lm*) and to verify the effectiveness of those programs through testing. FSIS verifies the effectiveness of these programs by collecting microbiological samples of RTE products and testing for the presence of *Listeria monocytogenes* and *Salmonella*. Dry and semi-dry fermented sausages and cooked beef patties are also analyzed for *Escherichia coli* O157:H7. Establishments that test positive for the "zero tolerance" pathogens *Listeria monocytogenes* and *Escherichia coli* O157:H7 are considered to have lost food safety system process control.

Presumptive and potential *Listeria monocytogenes* positive entries are discarded and only positive entries for the current month under review are used to identify establishments for more immediate inspection attention. If an establishment has a positive *Listeria monocytogenes, Salmonella,* or *Escherichia coli* O157:H7 test result in an RTE product or a positive *Listeria monocytogenes* on a food contact surface in the current month being reviewed, the establishment will receive a for cause FSA and one HAV per month.

Salmonella Test Results

FSIS performs *Salmonella* verification testing at establishments that produce eight categories of raw meat and poultry products. In addition, FSIS plans to sample for *Salmonella* in heat-treated, not fully cooked, not shelf-stable stuffed poultry products. The appropriate number of samples within a test set for a given product is collected from an establishment over successive days, with the goal of one sample collected each day of operation. For example, for an establishment processing raw ground beef, 53 samples would be collected on 53 successive days when the establishment is processing. Depending on the frequency of production, product type, and availability of resources, the time to complete a sample set ranges from two months to over a year. In establishments that produce more than one product subject to *Salmonella* verification testing, only one product is tested at a time. FSIS considers *Salmonella* verification testing a direct indicator of the effectiveness of process control. Annual reports summarizing results for calendar years are available on the FSIS web site (http://www.fsis.usda.gov/Science/Microbiology/index.asp).

Salmonella performance standards for establishments are defined in the PR/HACCP rule. Raw products with established performance standards are carcasses of cows/bulls, steers/heifers, market hogs, broilers, and turkeys. Processed products with performance standards are raw ground beef, ground chicken, and ground turkey. The performance standards are based on the prevalence of *Salmonella* as determined from the Agency's nationwide microbiological baseline studies. An acceptable number of positives is determined for each food product sample set, and any establishment with a number of positives higher than the acceptable positive in the most recent set of testing is placed in *Salmonella* Category 3. In May 2010, FSIS announced new performance standards for *Salmonella* and *Campylobacter* in young chickens and turkeys. Once these standards are implemented, they will be used in the decision criteria.

All establishments that move into *Salmonella* Category 3 will receive a for cause FSA and one HAV per month. The remaining establishments will be selected for additional inspection activities according to the Tier 2 decision criteria which are based on their percent positive rate relative to product specific cut-points. The percent positive rate for each establishment is determined by the following formula:

$$\textit{Salmonella}\ \%\ \text{Positive Rate} = \frac{\#\ \text{FSIS Food Product Positives}}{\#\ \text{FSIS Food Product Samples per Set}} \times 100$$

Steers/Heifers and Cows/Bulls are combined to create the Beef Carcass *Salmonella* Category. If an establishment has both Steer/Heifer and Cow/Bull data, the highest *Salmonella* Category and highest percent positive rate is used for each establishment. Table B-1 shows the estimated nationwide prevalence of *Salmonella*, number of samples collected per set, and the number of positives that exceed the standard for each food product.

Table B-1: Estimated Nationwide Prevalence of *Salmonella*, the Number of Samples Collected per *Salmonella* Set, and the Number of Positives that Exceed the Standard

Product	Baseline Prevalence (%)	Number of Samples per Set	Number of Positives to Exceed the Standard
Steers/heifers	1.0	82	2 or more
Cows/bulls	2.7	58	3 or more
Ground Beef	7.5	53	6 or more
Market Hogs	8.7	55	7 or more
Broilers	20.0	51	13 or more
Ground Chicken	44.6	53	27 or more
Ground Turkey	49.9	53	30 or more
Young Turkeys	19.6	56	14 or more

Source: HACCP/ PR rule Section 310.25 (b) 2 (meat), Section 381.94 (b) 2 (poultry)
Note: Recent baselines for Broiler and Turkeys have been completed by FSIS.At the time of this printing, new standards based on that data have not yet been implemented.

The *Salmonella* cut-point to separate establishments that will receive a routine FSA and one HAV per quarter from establishments that will receive a routine FSA and one HAV per month will be determined by calculating the z-score of each establishment based on the percent positive rate. The percent positive rate is calculated by using the following formula

$$\% \text{ Positive Rate} = \frac{\text{\# of FSIS Positive Samples}}{\text{Total \# of FSIS Samples}} \times 100$$

Once the establishment's percent positive rate has been calculated, the mean and standard deviation for each product are calculated. These are used to calculate the z-score for each establishment. The z-score formula is

$$\text{z-score} = \frac{\% \text{ Positive Rate} - \text{Mean}}{\text{Standard Deviation}}$$

If the z-score is greater than or equal to one, the establishment will receive a routine FSA and one HAV per month. If the z-score is less than one, the establishment will receive a routine FSA and one HAV per quarter.

Salmonella Serotypes

FSIS performs serotyping and pulsed-field gel electrophoresis (PFGE) analysis on all *Salmonella* positives identified through its pathogen verification testing of eight raw products classes plus Ready-to-Eat products. Isolates of *Salmonella*-positive samples are serotyped through the VetNet program at the USDA Animal and Plant Health Inspection Service's National Veterinary Services Laboratories in Ames, Iowa, while PFGE analysis is performed at the FSIS Eastern Laboratory in Athens, Georgia. *Salmonella* serotype and PFGE data provide an opportunity to examine the association among serotypes and PFGE patterns isolated from FSIS-inspected meat and poultry products with those from human cases of salmonellosis.

Through a network of State and regional laboratories, the Centers for Disease Control and Prevention (CDC) collects information on serotypes and PFGE types for *Salmonella* isolates from human cases of salmonellosis. This information is stored in the PulseNet database. CDC also assembles a listing of the most commonly identified *Salmonella* serotypes causing human infection in the United States.

In the future, FSIS intends to use *Salmonella* serotype and PFGE information from positive PR/HACCP verification samples as a public health decision criterion. The Agency is exploring how the occurrence of repetitive *Salmonella* serotypes of human health concern, as defined by CDC, and PFGE pattern matches to human illness

outbreaks can be used to identify establishments for more immediate inspection attention. FSIS is analyzing data to examine trends and patterns in *Salmonella* serotypes of human health concern and the occurrence of PFGE pattern matches to human outbreaks. The results will be used to define how serotype and PFGE information will be used as a public health decision criterion. Beginning in January 2011, FSIS plans to provide information about the occurrence of *Salmonella* serotypes of human health concern and linkage to human outbreak investigations in its End of Set Letter to establishments. To support the use of serotyping and subtyping, the Agency is developing a memorandum of agreement (MOA) with CDC and USDA's Agricultural Marketing Service for nightly exchange of subtyping and PFGE data for human cases and product testing.

FSIS In-Plant Inspection Results

FSIS inspection program personnel perform thousands of inspection procedures each day in federally-inspected establishments to determine whether inspected establishments are in compliance with regulatory requirements. Each time inspection program personnel make a noncompliance determination, they complete a noncompliance record. A noncompliance record (NR) is a written record that documents noncompliance with FSIS regulations. An NR notifies the establishment of (1) the noncompliance and (2) that it should take action to remedy the situation and prevent its recurrence. Noncompliance records vary from non-food safety issues to serious breakdowns in food safety controls. When noncompliance occurs repeatedly, or when an establishment fails to prevent adulterated product from being produced or shipped, FSIS takes action to control products and may take enforcement action under the FSIS Rules of Practice (9 CFR Part 500), such as to suspend inspection. Data from NRs will be captured in PHIS using FSIS' new NR entry form. The new NR entry form uses standardized fields to capture the findings of NRs.

Public Health Significant Noncompliance Records (NRs)

FSIS inspection program personnel document a regulatory noncompliance record (NR) at an establishment by reporting an NR in the Agency's Performance Based Inspection System (PBIS). When inspectors issue an NR, they cite one or more applicable regulatory requirements from a list of over 565citations. The rate at which an establishment fails to meet these requirements and receives an NR is considered by FSIS to be an indication of the establishment's inability to control risk. An FSIS panel has categorized each regulatory requirement into one of four categories based on its public health significance, as measured by a potential loss of process control. Specifically, each regulatory requirement was categorized into one of four categories according to how strongly each indicated a potential loss of an establishment's food safety system process control. The regulatory requirements that were considered most strongly related to public health, 61 out of over 565 possible regulatory citations, are referred to in this report as health-related or "W3NRs." About 12 percent of all possible NRs have been identified as indicative of a loss of process control.

FSIS evaluated the predictive ability of subsets of NRs as indicators of *Salmonella* contamination. Three classes of NRs were considered: all NRs, all public health-related NRs as defined by an industry coalition, and all W3NRs. This analysis provides insight

as to whether NRs or subsets of NRs are indicators of the likelihood that an establishment may have a loss of food safety process control and, therefore, provides further justification for the use of public health-related noncompliance records as a decision criterion. FSIS found that an establishment with a W3NR in a given 7-day period is three times more likely to have a positive *Salmonella* verification testing result in the next 14 days than an establishment without a W3NR. An establishment with an industry coalition-defined NR is about 2.3 times more likely to have a positive *Salmonella* verification test result, while an establishment with any type of NR is about 1.8 times more likely. All of these results are statistically significant and statistically different from each other. Thus, (1) the occurrence of an NR from any of the three sets of NRs is a statistically significant predictor of an increased probability of a positive *Salmonella* test result in the following 14 days, and (2) W3NRs are better predictors than the industry coalition NRs, which are better predictors than all types of NRs. Thus, the risk of failing a test for *Salmonella* is significantly elevated at establishments that recently were found to be noncompliant. FSIS plans to have an expert panel further evaluate the public health-related NRs to ensure they will identify establishments that may produce adulterated product. As PHIS is implemented and further data becomes available, FSIS plans to conduct predictive analyses to validate the utility of the public health-related NR decision criterion.

The NR Rate is calculated by summing the number of noncompliant procedures and dividing it by the total number of procedures performed, both compliant and noncompliant.

$$\text{NR Rate} = \frac{\text{Number of Noncompliant Procedures}}{\text{Total Number of Procedures}}$$

The above z-score formula is used to calculate the NR rate z-score and determines the cut-points to identify the establishments for more immediate inspection attention. The z-score is calculated using only the establishments that have 40 or more total tests. The establishments are then subdivided into three groups based on the type of product they produce. The three groups are Processing Only, Slaughter Only and Both Slaughter and Processing. The z score is calculated using the group mean and group standard deviation of the NR rates of each of the three groups separately. The cut-point for receiving a for cause FSA and one HAV per month is three standard deviations above the mean. The cut-point for receiving a routine FSA and one HAV per quarter is being below the mean for all establishments. Establishments that are not in operation are removed from the calculation. Plants with less than 40 inspections in a 3 month period that are not tested for *Salmonella* and pass all the Tier 1 criteria will receive quarterly HAVs and Routine FSAs.

Agency Enforcement Reporting Database
Enforcement actions are a measure of an establishment's ability to implement and maintain corrective action once a noncompliance is observed and documented. FSIS can take a variety of enforcement actions (e.g., notice of intended enforcement (NOIE), suspension, and inspection under consent order) against establishments that fail to sufficiently comply with applicable requirements.

If an establishment has a food-safety related enforcement action in the last month being reviewed that is not the result of a FSA, the establishment will receive a for cause FSA and one HAV per month.

Food Safety Recalls Database
A food recall is a voluntary action by a manufacturer or distributor to protect the public from products that may cause health problems. FSIS monitors recalls of meat, poultry, and processed egg products produced by Federally-inspected establishments and publishes summary data on the FSIS web site.

FSIS classifies recalls based on relative health risk, as follows:

- Class I: Reasonable probability of serious, adverse health problem or death;
- Class II: Remote probability of adverse health problem; or
- Class III: No adverse health consequences.

FSIS proposes to use Class I recalls as an indicator that an establishment may have lost process control.

Only Class I recalls from the last month will be used to identify establishments for more immediate inspection attention. If an establishment has a recall in the last month, the establishment will receive a for cause FSA and one HAV per month.

STEPS Database
FSIS has developed the "System for Tracking *E. coli* O157:H7 Positive Suppliers" (STEPS) database. The STEPS database captures slaughter establishments that have supplied raw ground beef components to an establishment with a positive laboratory test for *E. coli* O157:H7 in ground beef. The database allows FSIS to identify repeat offenders that have been in STEPS more than once in the past 120 days and sole suppliers that have been in STEPS in the past 30 days.

If an establishment is a sole supplier in the STEPS database in the past 30 days or if it is in the STEPS database more than once in the last 120 days, it will receive a for cause FSA and one HAV per month. If the establishment does not appear in the STEPS database in the last 120 days it will be eligible to receive a routine FSA and one HAV per quarter.

FSIS Foodborne Disease Investigation Database
FSIS investigates reports of foodborne illnesses potentially associated with FSIS-regulated products. The Foodborne Disease Investigations Branch (FDIB)) of the Office of Public Health Science is responsible for evaluating surveillance data or other information gathered by public health officials that suggests a potential association between human illness and an FSIS-regulated product.

The data are sorted so only establishments that meet the following criteria are shown: positive USDA Sample match, establishment number listed, and the earliest/recent onset date is within the time period being analyzed. If an establishment is linked to human illness within the time period being analyzed, the establishment will receive a for cause FSA and one HAV per month.

APPENDIX C
PUBLIC HEALTH-RELATED NONCOMPLIANCE RECORDS

FSIS inspection program personnel perform thousands of inspection procedures each day to determine whether inspected establishments are in compliance with regulatory requirements. Each time inspection program personnel make a noncompliance determination they complete a record explaining the nature of the regulatory action (a noncompliance record, NR) and inform the establishment management. Once issued, an establishment must take action to remedy the situation and should take measures to prevent its recurrence. Some NRs indicate the consistency with which establishments control food safety risks, whereas others cite non-food safety requirements (e.g., standard of identity, moisture content, etc.). Others document noncompliance with recordkeeping. Data from NRs will be captured in PHIS. When inspection program personnel document a noncompliance record for a procedure, they cite one or more pertinent regulatory requirements from a list of 565 in PBIS. High rates of noncompliance, certain patterns of noncompliance, or certain individual instances or types of noncompliance suggest an establishment may be losing or has lost adequate food safety system process control. FSIS believes that some NRs are more indicative than others of a potential loss of process control and thus food safety risk. The Agency has categorized NRs based upon their significance to adverse public health outcomes. This categorization was performed by nine FSIS subject matter experts using four categories. In the future, FSIS plans to have an expert panel further evaluate the public health-related NRs to ensure they will identify establishments that may produce adulterated product. As PHIS is implemented and further data becomes available, FSIS plans to conduct predictive analyses to validate the utility of the public health-related NR decision criterion. The four categories and their definitions are presented below. The public health related NRs are those in Category 3.

Category 3 Regulations

Category 3 regulations are provisions of 9 CFR that indicate a loss of the food safety system's process control if found in noncompliance. These are the public health-related NRs listed below in Table C-1. The loss of process control may not prevent adulterated product from entering commerce. Such conditions include an establishment failing to implement documented features of their HACCP or prerequisite system or failing to meet explicit regulatory requirements, including corrective action requirements. Examples: 416.15(a) "Appropriate corrective actions" and 417.3(a) "Corrective action after deviation from CCP."

Table C-1: Public Health Noncompliances (W3NRs)

Regulation	Description
309.3	HACCP-Based Inspection Models Project (HIMP) only Dead, dying, disabled or diseased and similar livestock.
309.4	(HIMP ONLY) Livestock showing symptoms of metabolic, toxic, nervous, or diseases
309.9	(HIMP ONLY) Swine erysipelas

Regulation	Description
311.16	(HIMP ONLY) Carcasses so infected that consumption of the meat may cause food poisoning.
311.17	(HIMP ONLY) Necrobacillosis, pyemia, septicemia.
318.303	Critical factors and the application of the process schedule
318.308	Deviations in processing
381.78	Condemnation of carcasses held for further examination
381.83	(HIMP ONLY) Septicemia or toxemia
417.6	Inadequate HACCP Systems
301.2(1)_Adulterated	Bears or contains poisonous or deleterious substance
301.2(1)_*E.coli*_O157:H7	FSIS verification sampling for *E. coli* O157:H7
301.2(1)_L.*monocytogenes*	FSIS verification sampling for *L. monocytogenes*
301.2(1)_*Salmonella*	FSIS verification sampling for *Salmonella* for RTE
301.2(2)_Adulterated	Bears or contains added poisonous or added deleterious substance
301.2(3)_Adulterated	Consists of any filthy, putrid, or decomposed substance
301.2(4)_Adulterated	Prepared, packed, or held under unsanitary conditions
301.2(4)_Foreign_Material	Foreign Material
301.2(6)_Adulterated	Container composed of any poisonous or deleterious substance
301.2(9)_Adulterated	Margarine containing raw material consisting of any filthy, putrid, or decomposed substance
310.22(b)	Inedible Specified Risk Material (SRM)
310.22(d)(2)	SRM, appropriate corrective action
310.25(a)	Verification criteria for generic *E. coli* testing meat
310.25(b)	Pathogen reduction performance standards; *Salmonella*
318.14(a)	Product and ingredients rendered adulterated by polluted water shall be condemned
318.14(c)	Hermetically sealed contaminated containers shall be examined/rehandled under FSIS supervision
318.17(a)(1)(2)	Lethality and Stabilization requirements for cooked beef
318.23(b)(1)	Time/Temperature for heat-processing combinations of fully-cooked meat patties
318.23(b)(3)	Heat deviations for meat patties
318.23(c)(1)	Stabilization requirements for meat patties

Regulation	Description
318.23(c)(2)	Stabilization processes for meat patties other than HACCP
381.1(i)_Adulterated	Bears or contains poisonous or deleterious substance
381.1(i)_E.coli_0157:H7	FSIS verification sampling for *E. coli* O157:H7
381.1(i)_L.monocytogenes	FSIS verification sampling for *L. monocytogenes*
381.1(i)_Salmonella	FSIS verification sampling for *Salmonella* for RTE
381.1(ii)_Adulterated	Bears or contains added poisonous or added deleterious substance
381.1(iii)_Adulterated	Consists of any filthy, putrid, or decomposed substance
381.1(iv)_Adulterated	Prepared, packed or held under unsanitary conditions
381.1(iv)_Foreign_Material	Foreign Material
381.1(vi)_Adulterated	Container composed of any poisonous or deleterious substance
381.144(a)	Packaging materials not to be composed of any poisonous or deleterious substance
381.150(a)	Lethality and Stabilization requirements for cooked poultry
381.150(c)	Lethality and Stabilization processes other than HACCP for cooked poultry
381.150(d)	Validation of new or altered process schedules by scientifically supportable means (cooked poultry)
381.151(a)	Product and ingredients rendered adulterated by polluted water shall be condemned
381.91(a)	Certain contaminated carcasses to be condemned
381.94(b)(3)(ii)	PR Poultry - Failure to maintain adequate HACCP Plan
416.15(a)	Appropriate corrective actions
416.15(b)	Corrective action, procedures for
417.3(a)(1)	Identify and eliminate the cause
417.3(a)(2)	Critical Control Point (CCP) is under control
417.3(a)(3)	Establish measures to prevent recurrence
417.3(a)(4)	No adulterated product enters commerce.
417.3(b)(1)	Segregate and hold the affected product
417.3(b)(2)	Determine the acceptability of the affected product
417.3(b)(3)	No adulterated product enters commerce
417.3(b)(4)	Reassessment
417.3(c)	Document corrective actions

Regulation	Description
417.4(a)	Adequacy of HACCP in controlling food safety hazards
430.4(b)(2)	Alternative 2
430.4(b)(3)	Alternative 3

Category 2 Regulations

Category 2 regulations are provisions of 9 CFR that indicate reasonable probability of a loss of the food safety system process control if found in noncompliance. Examples: 416.13(a) “Conduct pre-op procedures” and 416.14 “Evaluate effectiveness of SSOP's & maintain plan.”

Category 1Regulations

Category 1 regulations are provisions of 9 CFR that indicate remote probability of a loss of the food safety system process control if found in noncompliance. Examples: 416.2 (a) “Establishment Grounds and Facilities” and 416.2 (b)(1) “Sound construction, good repair & sufficient size.”

Category Zero (0) Regulations

Conditions present that do not comply with 9 CFR regulations that are not placed in Categories 1, 2, or 3. Noncompliance with these non-food safety regulatory requirements is not considered to cause adverse health effects. Examples: Product standards of identity in 319.15(a) “Chopped beef, ground beef” and 319.307 “Spaghetti sauce with meat.”

APPENDIX D
Volume Data

Routine FSAs for establishments that do not violate any Tier 1 decision criteria, but also do not satisfy both Tier 2 decision criteria will be scheduled with respect to the potential public health risk of the products they produce. FSIS defines potential public health impact using the *volume* of each food product an establishment produces and the *foodborne disease hazard* associated with the product. This appendix describes the data sources used to obtain the volumes estimates used in the scheduling process.

FSIS uses the electronic Animal Disease Reporting System (eADRS) database to estimate slaughter volume for meat and poultry products. For processed products, FSIS uses the following sources to obtain volume estimates:

- The FSIS M2K database is used to estimate raw ground beef volumes, which are recorded every time a raw ground beef sample is collected by FSIS,
- The industry generated 10,240 forms are used to estimate post-lethality exposed Ready-to-Eat (RTE) production volumes, and
- The Performance Based Inspection System (PBIS) Extension Survey contains FSIS inspector-generated volume estimates for each of 19 HACCP product categories and is used to estimate the volume of processed meat and poultry products.

Establishments are placed in one of six categories based on the food products they produce. The list of six categories in order of priority is as follows:

1. RTE
2. Raw Ground Beef
3. Poultry (including Intact Chicken, Ground Chicken, Intact Turkey, Ground Turkey, Other Intact Poultry and Other Ground Poultry)
4. Meat (including Intact Beef, Other Intact Meat and Other Ground Meat)
5. Pork (including Intact Pork and Ground Pork)
6. All Other Products

The order of priority reflects the relative potential health hazard of the six product categories. RTE and ground beef are given the highest priority since they may contain the zero-tolerance pathogens *Listeria monocytogenes* and *E. coli* O157:H7, with RTE placed highest since *Listeria monocytogenes* illnesses cause more deaths than *E. coli* O157:H7. The remaining categories are listed in the relative order of their *Salmonella* attribution estimates. If an establishment produces more than one of the six product categories, it is placed in the highest category for the products it produces.

Once all establishments are placed into one of the six product categories, the establishments within a category are ranked in order of the total volume of all products (processing and slaughter) they produce. Routine FSAs are scheduled for all establishments that produce RTE products first in the order of their total production volume. Establishments that do not produce RTE products, but produce ground beef are scheduled next in the order of their total volume, and so forth.

Slaughter Volume

Slaughter volume estimates are obtained from the eADRS database. For cattle, swine, and sheep, the eADRS database provides estimates of number of animals slaughtered. The number of animals slaughtered can be converted to dressed weight using the conversion factors shown in Table D-1.

Table D-1: Conversion Table for Heads to Dressed Weight

Animal class	Pounds dressed weight per head
Cattle	776
Steers	830
Heifers	764
Cows	617
Bulls	893
Hogs	202
Sheep	69

Source: USDA National Agricultural Statistics Service

For poultry, eADRS provides total poultry live weigh in pounds per establishment. The conversion factors shown in Table D-2 are used to convert from live weight to dressed weight.

Table D-2: Conversion Table for Poultry Live Weight to Dressed Weight

Animal class	Pounds dressed weight per pound live weight
Chicken	0.735
Turkey	0.793
Duck	0.716
Other Poultry	0.716

Source: USDA National Agricultural Statistics Service

As of June 30, 2010, there were 1,043 active federally-inspected slaughter establishments in the United States. Of these, 89 percent also process products from the meat and poultry they slaughter. Of the total, 115 establishments only slaughter animals and send the meat and poultry to other establishments to be processed. Slaughter production volumes at Federally-inspected slaughter establishments totaled 90.5 billion pounds in the year ending June 30, 2010. Tables D-3 presents slaughter volumes for the major slaughter classes.

A total of 774 establishments have eADRS data for sheep, goat, pork, or beef or other meat slaughter. Of these, 90 establishments produce 95 percent of total meat slaughter volume by weight. The total estimate of meat slaughter dressed weight is 48.93 billion pounds in the year ending June 30, 2010.

Table D-3: Slaughter Total Volume in the Year Ending June 30, 2010

Slaughter Class	Total Volume in billion pounds
Beef Slaughter	26.30
Pork Slaughter	22.38
Sheep/Goat Slaughter	0.20
Other Meat Slaughter	0.05
Chicken Slaughter	35.37
Turkey Slaughter	5.57
Other Poultry Slaughter	0.68

A total of 292 establishments have eADRS data for poultry. Of these, 165 establishments produce 95 percent of total volume by weight. The total estimate of chicken broiler dressed weight production is 35.37 billion pounds and turkey dressed weight production is 5.57 billion pounds. Other poultry slaughter accounted for 0.68 billion pounds dressed weight. The total estimate of poultry slaughter dressed weight was 41.61 billion pounds.

Processing Volume

As of June 30, 2010, a total of 4,636 establishments were processing meat and poultry products. Of these, 1,247 establishments produce 95 percent of total processing volume. The total estimate of processing volume is 60.08 billion pounds in the year ending June 30, 2010. Table D-4 shows the total volume for each of the processing classes. The following section describes how volume is derived for ground beef, Ready-to-Eat products, and other processed food products.

Table D-4: Processing Total Volume in the Year Ending June 30, 2010

Food Class	Total Volume(in billions of pounds)
Ground Beef	6.96
RTE	19.24
Intact Beef	5.99
Intact Pork	4.45
Other Intact Meat	0.45
Ground Pork	1.90
Other Ground Meat	0.23
Intact Chicken	9.40
Intact Turkey	1.48
Other Intact Poultry	0.26
Ground Chicken	0.37
Ground Turkey	0.70
Other Ground Poultry	0.01
Partial Cooked Meat or Poultry	5.29
Thermally-Processed, commercially sterile meat or poultry	1.39
Raw Beef Trimmings	1.96

Ground Beef Volume
Ground beef volume is determined using the FSIS database. The FSIS database provides estimates of average daily volume produced by each establishment. The volume is recorded in the database using the four ranges shown in Table D-5. If more than one production volume category is given for an establishment, the most frequently recorded category (the mode) is used. Table D-5 gives the average number of production days per year assumed for each production volume category. Total ground beef volume is calculated as the product of the daily production (in pounds) times the production days as shown in Table D-5.

Table D-5: Total Annual Ground Beef Volume for Each Production Category

Production Volume Category	Daily Production (in pounds)	Production Days	Total Ground Beef Volume (in pounds)
1	375,000	250	93,750,000
2	150,000	250	37,500,000
3	25,000	250	6,250,000
4	500	150	75,000

If an establishment is active, but no volume estimate is recorded in the FSIS database, the PBIS ground beef volume estimate is used.

As of June 30, 2010, there were a total of 1,335 active establishments producing ground beef. Of these, 309 establishments produce 95 percent of total ground beef volume. The total estimate of ground beef volume is 6.96 billion pounds in the year ending June 30, 2010.

Ready-to-Eat (RTE) Volume
Ready-to-Eat production volume estimates for post-lethality exposed product are taken from the 10,240 database. If an establishment is active, but does not produce post-lethality exposed product or does not have a 10,240 database RTE volume estimate, the sum of the PBIS volume estimates for RTE Fully Cooked 100 Percent Meat, Other RTE Fully Cooked Meat, RTE Not Fully Cooked Meat and Poultry, and RTE 100 Percent Poultry are used.

A total of 2,234 establishments were producing RTE products as of June 30, 2010. Of these, 421 establishments produce 95 percent of total RTE volume. The total estimate of RTE volume is 19.24 billion pounds in the year ending June 30, 2010.

Other Processed Food Products
The PBIS Extension Survey contains FSIS inspector-generated volume estimates for 19 product classes (see Table D-6). The inspectors determine approximately how many pounds of finished product are typically produced and shipped by the establishment in a day across all shifts, and how many days in the last 30 days this product was produced. The inspector then inputs that information into PBIS by filling out, for each product class, a menu of ranges for the pounds produced and/or shipped and days for each product class. This is illustrated in Table D-7.

Table D-6: PBIS Extension Survey Volume Product Classes

Product Class
Raw intact beef
Raw intact pork
Raw intact meat – other than beef or pork
Raw ground, comminuted, or otherwise nonintact beef
Raw ground, comminuted, or otherwise nonintact pork
Raw ground, comminuted, or otherwise nonintact meat – other than beef or pork
RTE Fully Cooked 100 Percent Meat
Other RTE Fully Cooked Meat
RTE not fully cooked meat or poultry
Raw intact chicken
Raw intact turkey
Raw poultry
Raw ground, comminuted, or otherwise nonintact chicken
Raw ground, comminuted, or otherwise nonintact turkey
Raw ground, comminuted, or otherwise nonintact poultry – other than chicken or turkey
RTE 100% poultry
Partially-cooked meat or poultry products
Thermally-Processed, commercially sterile meat or poultry
Beef trimmings

Table D-7: PBIS Extension Survey Volume and Production Day RangesVolume Range (in pounds produced/shipped)	**Production Days (in number of days in the last 30 days product produced)**
None	None
1 – 50	1 – 5
51 – 250	6 – 10
251 – 500	11 – 15
501 – 2,000	16 – 20
2,001- 10,000	More than 20
10,001 – 50,000	Don’t Know
More than 50,000	
Don’t Know	

The processing volume estimate is determined by multiplying the average volume produced/shipped in a typical day and the average number of days per month the product is shipped. The product of these two variables provides an estimate of the average pounds of a product shipped in a month. The monthly volume is multiplied by 12 to obtain an estimate of annual processed volume in pounds.

To estimate annual volume it is necessary to select a single number to represent each of the ranges in Table D-7. The midpoint of each range is used except for the largest category which does not have a range. The upper volume range is "more the 50,000 pounds." Large establishments can produce more than 50,000 pounds in a single day and thus using this maximum volume range can result in an underestimate of processed volume in the very large establishments. To obtain a better estimate of the volume of processed product produced by large establishments, an increased volume estimate of 180,000 pounds per day is used. Factors used to calculate volume for other processed food products are presented in Table D-8.

Table D-8: Factors Used to Calculate Volume of Other Processed Food Products

Volume Category		Production Days	
Pounds produced/shipped per day	**Average Pounds produced/shipped per day**	**Number of Days in the last 30 days product produced**	**Average days in the last 30 days product produced**
None		None	
1 – 50	25	1 – 5	2.5
51 – 250	150	6 – 10	7.5
251 – 500	375	11 – 15	12.5
501 – 2,000	1,250	16 – 20	17.5
2,001- 10,000	6,000	More than 20	25
10,001 – 50,000	30,000	Don't Know	
More than 50,000	180,000		
Don't Know			

A total of 3,405 establishments produce other processed food products excluding ground beef and RTE. Of these, 812 establishments produce 95 percent of total other processed food products, excluding ground beef and RTE, volume. The total estimate of volume for other processed food products, excluding ground beef and RTE, is 33.76 billion pounds for the year ending June 30, 2010. Table D-9 presents volumes for the other processed food products excluding ground beef and RTE products.

Table D-9: PBIS Volume Estimates for Other Processed Food Products Excluding Ground Beef and RTE Products in the Year Ending June 30, 2010

Product Class	Total Volume (in billions of pounds)
Intact Beef	5.99
Intact Pork	4.45
Other Intact Meat	0.45
Ground Pork	1.90
Other Ground Meat	0.23
Intact Chicken	9.40
Intact Turkey	1.48
Other Intact Poultry	0.26
Ground Chicken	0.37
Ground Turkey	0.70
Other Ground Poultry	0.01
Partial Cooked Meat or Poultry	5.29
Thermally-Processed, commercially sterile meat or poultry	1.39
Raw Beef Trimmings	1.96

APPENDIX E
Foodborne Disease Attribution

Introduction

A basic element of prioritizing and allocating resources to reduce the level of foodborne illness is the ability to identify which FSIS-inspected food products are major contributors to human foodborne illness. This appendix gives an overview of an approach for performing microbial foodborne illness attribution. FSIS acknowledges that no system of estimating foodborne illness attribution is perfect. The Agency has considered the following sources in its development of an attribution methodology: illness outbreak data, illness case-control studies, risk assessments, pathogen serotype data, and expert elicitation. FSIS is working with the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) to investigate methods to include serotype and subtype information of pathogens to improve attribution estimates, to better estimate foodborne illness from complex food products, and to include sporadic and outbreak data in attribution estimates. FSIS will use these and other advances to improve foodborne illness attribution estimates as additional information becomes available.

The Healthy People 2010 program, for which FSIS and FDA are the food safety co-leads, has set a goal of decreasing *Salmonella* species, *Campylobacter* species, *E. coli* O157:H7, and *Listeria monocytogenes* infections each by 50 percent by the year 2010. By Executive Order the Federal agencies were directed to achieve by 2005 the Healthy People 2010 goal for *Listeria monocytogenes*. CDC, FSIS, and FDA are in the process of developing Healthy People goals for 2020. 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 illness attribution. Estimates of foodborne attribution are pathogen specific, that is, the percentage of illnesses attributable to a particular food type (i.e., consumption of beef, chicken, eggs, or produce) will vary from pathogen to pathogen.

The purpose of this appendix is twofold. The first is to use an illness outbreak database complied by CDC to derive foodborne disease attribution estimates for *Salmonella*, *E. coli* O157:H7, and *Listeria monocytogenes.* The second is to compare attribution estimates obtained from two recent expert elicitations (FSIS 2007 expert elicitation, Karns et al.2007 and Resources for the Future (RFF)/Carnegie Mellon expert elicitation, Hoffmann et al. 2007) with attribution estimates derived from the CDC illness outbreak database.

Attribution Estimates Based on CDC Foodborne Disease Outbreak Data

Foodborne disease outbreak data provides useful information for deriving foodborne illness attribution estimates. An outbreak is defined as the occurrence of two or more

cases of a similar illness resulting from the ingestion of a common food source. The CDC maintains a database of foodborne illness outbreaks that covers the years 1990 to 2007 (CDC 2008). Reported data on foodborne illness outbreaks can be valuable in establishing a link between foodborne illness and the specific food sources that cause them. In addition, outbreak data represent the largest epidemiological dataset available linking foodborne illness with specific food sources.

The foodborne disease attribution estimates for *Salmonella, E. coli* O157:H7 and *Listeria monocytogenes* are derived from the CDC outbreak data from the seven year period 2001-2007. The 2007 outbreak data are the most recent CDC outbreak data available. While outbreak data are available from 1990, data from 2001 forward was used so that current attribution estimates would not be unduly influenced by outbreaks in the distant past. Seven years of outbreak data were used to damp out the influence of year-to-year fluctuations in outbreak data. Table E-1 presents attribution estimates based on the CDC outbreak data for time periods through 2007 for *Salmonella, E. coli* O157:H7, and *Listeria monocytogenes*.

Table E-1: Attribution Estimates Based on CDC Outbreak Data for *Salmonella, E. coli* O157:H7, and *Listeria monocytogenes* by Specific Food Type

	Category	*Salmonella*	*E. coli* O157:H7	*Listeria monocytogenes*
USDA Products	**Beef**	6.42	27.15	0.00
	Poultry	16.90	0.00	2.86
	Pork	7.82	0.00	2.86
	Deli	3.07	1.15	63.81
FDA Products	**Breads and Bakery**	0.25	0.00	0.00
	Dairy	6.19	16.59	30.48
	Eggs	7.66	0.00	0.00
	Fruits-Nuts	8.59	10.95	0.00
	Game	0.00	0.17	0.00
	Grains-Beans	11.71	3.35	0.00
	Leafy	3.54	25.33	0.00
	Root	3.01	0.00	0.00
	Other Produce	3.32	14.72	0.00
	Seafood	2.27	0.59	0.00
	Tomato	19.29	0.00	0.00

The attribution estimates in Table E-1 are based on illnesses associated with the simple food products in the CDC outbreak database. Simple foods are defined as those that are made from a single food category, while complex foods are those whose ingredients come from more than one food category. For example chicken or a cut of beef are simple food products. A beef burrito or a chicken salad is complex food product. The illnesses

from outbreaks associated with the complex category are not used in calculating the above attribution numbers.

The approach used in estimating attribution is as follows:

- CDC outbreak data is obtained from the CDC Web site for *Salmonella*, *Listeria monocytogenes*, and *E. coli* O157:H7 for the years 2001-2007.
- For each pathogen, simple food outbreaks are separated into those originating from one of the following simple food categories:
  - Meat
  - Poultry
  - Pork
  - Deli/Other Meats
  - Breads and Bakery
  - Dairy
  - Eggs
  - Fruits-Nuts
  - Grains-Beans
  - Leafy
  - Other Produce
  - Root
  - Seafood
  - Tomato

- The total number of illnesses associated with each simple food category is determined and an attribution estimate obtained for each simple food category by dividing the total number of illnesses for each simple food category by total number of illnesses from all simple food categories.

Expert Elicitation

Because of the gaps in available data on foodborne illness attribution, expert elicitation has been used to develop estimates. During expert elicitation, a group of experts is asked, based on their professional judgment, to rank food groups as to their relative important as sources of foodborne illness and/or to estimate the percent contribution of food groups to foodborne illness. The reliability of expert opinion regarding foodborne disease attribution has been questioned since it is based on judgment and not empirical data. However, by selecting experts with firsthand 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 on human illness. Moreover, expert judgment is often the best source for guidance when scientific and epidemiologic data are sparse (National Academy of Sciences 2003). This section briefly reviews the results of two recent expert elicitations.

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 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, their results are presented for only three pathogens: *Salmonella, E. coli* O157:H7, and *Listeria monocytogenes.*

Table E-3 presents data from the RFF elicitation of the percent contribution (attribution) of 11 food types to foodborne illness in the United States.

Table E-3: Attribution of Foodborne Illnesses.

Food Type	***Salmonella***	***E. coli* O157:H7**	***L. monocytogenes***
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

Estimates are based on RFF Expert Elicitation and shown in percentages.
Source: Hoffmann et al. (2007)

FSIS Expert Elicitation

Karns et al. (2007) conducted an expert elicitation for FSIS to determine foodborne 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. 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 types. To compare the results of all three studies with respect to meat and poultry food categories, the 25 food types are collapsed into four meat and poultry food categories. The attributions obtained for the Karns et al. (2007) study for the four general food categories are presented in Table E-4.

Table E-4: Attribution of Foodborne Illness for 4 Processed Meat and Poultry Product Categories.

Food Type	*Salmonella*	*E. coli* O157:H7	*L. monocytogenes*
Meat	21.4	84.7	6.0
Poultry	63.9	3.8	8.3
Pork	7.1	2.7	1.5
Deli meats	7.7	8.9	84.2

Estimates are based on the 2007 FSIS Expert Elicitation and shown as percentages.
Source: Karns et al. (2007)

Foodborne Disease Outbreaks

When comparing attribution estimates derived from the CDC outbreak data with the two attribution studies, the CDC outbreak data available at the time of the elicitation studies (the years 1990 to 2005) were utilized. Table E-5 presents attribution estimates based on the CDC outbreak data from 1990-2005 for *E. coli* O157:H7, *Salmonella*, and *Listeria monocytogenes*.

Table E-5: Attribution Estimates Based on CDC Outbreak Data for *Salmonella*, *E. coli* O157:H7, and *Listeria monocytogenes* by Specific Food Type

	Salmonella		*E. coli* O157:H7		*Listeria monocytogenes*	
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

Based on data from 1990-2005

Comparison of FSIS, RFF, and CDC Outbreak Attribution Estimates

The purpose of this section is to demonstrate that the attribution estimates derived from FSIS and RFF expert elicitations agree closely with the estimates derived from the CDC outbreak data averaged over the 15-year period, 1990 to 2005. 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 types. To compare the results of all three studies with respect to meat and poultry food categories, 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 E-6 presents a comparison of the three studies.

Table E-6: Comparison of Normalized Attribution based on FSIS, RFF, and CDC Data

Meat and Poultry Categories	*Salmonella*			*E. coli* O157:H7			*Listeria monocytogenes*		
	FSIS	RFF	CDC	FSIS	RFF	CDC	FSIS	RFF	CDC
Meat	21.4	20.4*	25.7	84.7	95.3	97.6	6.0	2.7	0.0
Poultry	63.9	65.5	59.6	3.8	1.2	0.0	8.3	4.5	1.1
Pork	7.1	10.6	11.8	2.7	0.8	0.0	1.5	2.2	0.0
Deli meats	7.7	3.5	2.9	8.9	2.5	2.4	84.2	90.6	98.9

Estimates are shown as percentages.
**Beef only*

As can be seen from Table E-6, the three attribution studies (one of which is an actual count of CDC outbreak illnesses over a 15-year period) produce similar estimates of normalized attribution for FSIS-inspected beef, poultry, pork, and deli meat products. There are differences for E. coli O157:H7 in deli meats and Lm in meat and poultry.

Data on foodborne illness outbreaks can be valuable in establishing a link between foodborne illness and the specific food sources that cause them. It should be emphasized that, while only a small fraction of total foodborne illnesses are caused by outbreaks, this does not automatically mean that attribution estimates derived from outbreak data disagree with those derived from sporadic illness data. As shown in Table E-6, attribution estimates for FSIS-inspected food categories of beef, poultry, pork, and deli derived from 1999 to 2005 CDC outbreak data agree closely with estimates from the two above expert elicitations which account for sporadic illness. Such an agreement is not totally surprising however given that experts by necessity derive their opinions from general awareness of the level of illness in the population caused by different pathogens.

Conclusion

The CDC outbreak database was used to derive foodborne disease attribution estimates for meat and poultry products. When the outbreak data are averaged over longer time periods, the two recent expert elicitations produce attribution estimates that are very similar to those obtained from the CDC outbreak data.

References

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APPENDIX F
LIST OF ACRONYMS

CCP – Critical Control Point
CDC – Centers for Disease Control and Prevention
CFR – Code of Federal Regulations
E. coli - *Escherichia coli*
EIAO – Enforcement Investigation and Analysis Officer
FDIB – Foodborne Disease Investigations Branch
FSA – Food Safety Assessment
FSIS – Food Safety and Inspection Service
HACCP/PR – Hazard Analysis Critical Control Point/Pathogen Reduction
HAV – Hazard Analysis Verification
HIMP – HACCP-Based Inspection Models Project
IPP – Inspection Program Personnel
IVT – Intensified Verification Testing
Lm – Listeria monocytogenes
NACMPI – National Advisory Committee on Meat and Poultry Inspection
NAS – National Academy of Sciences
NOIE – Notice of Intended Enforcement
NR – Noncompliance Record
OIG – Office of Inspector General (USDA)
PBIS – Performance Based Inspection System
PHIS – Public Health Information System
RLM – Risk-based *Listeria monocytogenes*
RTE – Ready-to-Eat
SOP – Standard Operating Procedure
SPS – Sanitation Performance Standards
SRM – Specified Risk Material
SSOP – Sanitation Standard Operating Procedure
STEPS – System for Tracking *E. coli* O157:H7 Positive Suppliers
USDA – United States Department of Agriculture
W3NR – Public Health Noncompliance Record (Listed in Appendix C, Table C-1)
WHO – World Health Organization