Use of FSIS Regulatory Verification Sampling to Generate Prevalence Estimates

DCC Prevalence Estimate Workgroup

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Executive Summary

Background

In the past, the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) has been criticized for asserting that some types of percent positive data were representative of pathogen prevalence. Further, FSIS is aware that some stakeholders have used pathogen testing data to make their own assertions about the prevalence of pathogens on regulated products. However, at the present time, FSIS only estimates pathogen prevalence when conducting baseline studies.

To address these issues, FSIS conducted an evaluation the Agency's current pathogen verification testing programs to determine whether they provide sufficient data to calculate prevalence estimates for pathogens in FSIS-regulated product at a given point in the production process. The three pathogens of interest were: *Escherichia coli* (*E. coli*) O157:H7, *Salmonella*, and *Listeria monocytogenes* (*Lm*) and *Salmonella* in Ready-To-Eat (RTE) products, consistent with FSIS' current major verification testing programs. The evaluation was performed by a new FSIS workgroup formed through the Agency's Data Coordination Committee (DCC) and included representatives from the Office of Data Integration and Food Protection (ODIFP), the Office of Public Health Science (OPHS) and the Office of Policy and Program Development (OPPD).

The purpose of this evaluation was to 1) construct a working definition of pathogen prevalence and identify data and statistical elements required to yield prevalence estimates, 2) review current pathogen verification testing programs in light of the data and statistical elements required to estimate prevalence and 3) identify what barriers or limitations exist to utilizing current programs to estimate prevalence. The following report provides a description of this evaluation and FSIS' findings by pathogen.

Overall Findings

At this time, given the current construction of the FSIS Pathogen Verification Sampling Programs, the Agency believes that it is only possible to utilize the existing *E. coli* O157:H7 pathogen verification testing project in raw ground beef (MT43) to estimate the national prevalence. Due to a variety of methodological and sampling related issues, FSIS does not believe it is possible to utilize existing pathogen verification testing projects to estimate prevalence for *E. coli* O157:H7 in beef trim and components, *Salmonella* in all raw products, or *Lm* and/or *Salmonella* in RTE and post-lethality exposed products.

Chapter 1: Background, FSIS Definition of Prevalence and Data and Statistical Requirements

FSIS Prevalence Estimates

The United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) recognizes the importance of timely and accurate estimates of pathogen prevalence in order to better understand how contamination rates change over time, set performance standards to reduce product contamination, develop targeted interventions and policies and measure the Agency's performance towards meeting FSIS strategic planning goals, as well as the Healthy People 2020 goals. FSIS also uses prevalence estimates in economic analyses and risk assessments and routinely updated prevalence estimates would allow the Agency to more rapidly and effectively update existing analyses. Finally, prevalence estimates provide FSIS with a proxy measure of the Agency's public health impact, in situations where direct illness outcome measures are lacking.

Historically, FSIS has used Agency's traditional microbiological baseline studies to derive estimates of pathogen prevalence in FSIS-regulated products at a given point in the production process. This data is then utilized to establish performance standards for the regulated industry. However, baseline studies are usually targeted at a specific commodity-pathogen pair to answer specific questions and are not repeated annually. Similarly, although volume-weighted calculations produced from some of FSIS' pathogen verification testing programs provide the Agency with important public health measures, not all of these programs produce data that support the calculation of true pathogen prevalence estimates. Further, FSIS has been criticized for asserting that some types of percent positive data were representative of pathogen prevalence and the Agency is aware that some stakeholders have used pathogen testing data to make their own assertions about the prevalence of pathogens on regulated products. Therefore, the overall, primary purpose of this report is to evaluate the possibility of using current FSIS pathogen verification testing data to provide on-going estimates of the national prevalence of pathogens in FSIS-regulated product at the point of processing.

Relationship to FSIS Strategic Planning Efforts

This report also builds on and supports FSIS' strategic planning efforts in a number of ways. In September 2010, FSIS released the *Strategic Data Analysis Plan for Domestic Inspection*, which identified the need for "on-going" baselines to measure prevalence and described changes to pathogen sampling programs required to achieve this goal.[1] In September 2011, FSIS released the Agency's *Strategic Plan for 2011-2016*, which included the goals that align with an evaluation of prevalence:[2]

- *Goal 1: Ensure that food safety inspection aligns with existing and emerging risks*
- *Goal 5: Effectively use science to understand foodborne illness and emerging trends*

FSIS also released the *Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs* in December, 2011 which identifies all of FSIS' sampling programs

[1] Please see the following website for more information: http://www.fsis.usda.gov/OPPDE/NACMPI/Sep2010/2010_Strategic_Data_Analysis_Plan.pdf.

[2] Please see the following website for more information: http://www.fsis.usda.gov/PDF/Strategic_Plan_2011-2016.pdf.

and discusses the statistical and policy basis for the programs.[3] Finally, FSIS released the *FY2012 Sampling Program Plan* in February 2012, which continues the Agency's efforts to comprehensively identify FSIS activities and consider them in light of data-driven strategic planning efforts.[4]

FSIS Public Health Information System (PHIS)

On April 11, 2011, FSIS launched its dynamic, comprehensive data analytics system called the Public Health Information System (PHIS). PHIS is a web-based application that integrates and automates FSIS' paper-based business processes into one comprehensive and fully automated data-driven inspection system. As a result of implementing PHIS, many of FSIS' existing systems, such as the Performance Based Inspection System (PBIS), will be phased out and replaced by PHIS. Consequently, while the way in which sampling information is scheduled, shared and stored will change under PHIS, none of the fundamental elements of FSIS' sampling activities, such as the sampling frame, methodology or collection methodology, will change. It is important to note, however, that at the time this report was developed, PHIS was not fully implemented.

Evaluation of Pathogen Testing Programs

To conduct this evaluation, FSIS formed a new Prevalence Workgroup through the Agency's Data Coordination Committee (DCC)[5] to study using verification testing data to produce national pathogen-specific prevalence estimates in FSIS-regulated products. Pathogen-specific subgroups were also formed. The workgroup/subgroups were charged with the following tasks:

- Step 1: Construct a working definition of pathogen prevalence.
- Step 2: Formulate a list of data and statistical requirements that would need to be met in order for FSIS' pathogen verification testing programs to yield prevalence estimates, as defined in Step 1.
- Step 3: Evaluate the suitability of each pathogen verification program, based on the data and statistical requirements defined in Step 2, to yield estimates of pathogen prevalence.

In addressing task 3, the workgroup focused on three pathogens: *Escherichia coli* (*E. coli)* O157:H7, *Salmonella,* and *Listeria monocytogenes (Lm)* and *Salmonella* in Ready-to-Eat (RTE) products, consistent with FSIS' current major verification testing programs.

The remaining subsections of Chapter 1 present the definition of pathogen prevalence developed by the workgroup and describe the data and statistical elements required to utilize pathogen verification testing programs for measurement of pathogen prevalence in FSIS-regulated product. Chapters 2 through 4 provide, by pathogen, an evaluation of the feasibility of using FSIS pathogen verification testing programs to estimate prevalence. Sample collection data provided in the tables within these chapters are those data that were available at the time of this

[3] Please see the following website for more information: http://www.fsis.usda.gov/PDF/FSIS_Sampling_Programs_Report.pdf.

[4] Please see the following website for more information: http://www.fsis.usda.gov/PDF/Sampling_Program_Plan_FY2012.pdf

[5] For more information regarding the FSIS Data Coordination Committee, please see the following website: http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5800.1.pdf.

assessment and therefore are not official, FSIS end-of-year data. A glossary of relevant terms has also been developed and is included as Appendix A. A summary of the DCC Pathogen Subgroup's evaluation of current sampling programs in light of the data and statistical requirements is provided in Appendix B. Appendix C provides more detailed information on FSIS' *Salmonella* sampling projects.

The purpose of this report is to evaluate the suitability of using FSIS' current pathogen verification testing programs to estimate prevalence. Moving forward, if FSIS determines that the Agency's pathogen verification testing programs should be modified to estimate prevalence based on the findings of this report, a workgroup will be established and appropriate statistical analyses will be conducted to determine the most appropriate way to change pathogen testing programs to yield estimates of prevalence. The results of these analyses, once completed, will also be shared publicly.

FSIS Definition of Pathogen Prevalence

FSIS defines prevalence as the proportion of population units that would test positive for a given pathogen if the entire population were sampled and analyzed during a specified time period. To further clarify this definition, the following additional definitions are necessary.

- A population may be defined as a species, an animal part, a product, or an environmental source (e.g. cows, chickens, turkeys, ground beef, sausage, deli meats, processed egg products and/or food contact surfaces) that is in an FSIS-regulated establishment.
- A population unit is defined as the population element of interest, as described below:
    - A population unit may be a carcass in a population of animals (e.g., a young chicken carcass in the population of federally-inspected, slaughtered young chickens).
    - Alternatively, a population unit may be a specified quantity of product (e.g., a pound of raw ground turkey from the population of federally-inspected raw ground turkeys).
- A sample is defined as the portion of the product that is collected for analysis.

In developing this definition of prevalence, FSIS has identified the following factors that are relevant when computing a prevalence estimate. Any FSIS estimate of prevalence:

- Will not directly measure or describe risk of illness.
- Will not directly measure or estimate the actual presence of contamination within an individual product.
- Will vary by sampling program.
- Will be dependent on the location at which the sample is collected (e.g., post-chill sampling compared to re-hang sampling).
- Will require adjustments to account for production volume and/or other characteristics.
- Will be affected by laboratory and collection methods.
- Will be affected by information used to define the sampling frame (e.g. inaccurate production information, inaccurate Hazard Analysis and Critical Control Points (HACCP) categorization).
- Will be affected by the number of samples in the analysis.
- Will have a varying degree of error based upon these factors.

Further, although analysis of non-methodological factors was not part of the DCC workgroup's task, several of these issues are noted below to guide future considerations of prevalence estimation.

- A prevalence estimate is only one measure of a population. To be meaningful, a prevalence estimate typically warrants detailed discussion within a broader exposure assessment, as FSIS does when it presents prevalence estimates derived from baseline studies or utilized in risk assessments.

- Prevalence may most commonly be used to portray stable characteristics in closed populations. Prevalence estimates may be difficult to interpret when used to describe complex properties of dynamic populations.
- Estimating the prevalence of rare characteristics, such as the presence of *E. coli* O157:H7 adulteration, is challenging at best. Survey methodologies developed to assess hard-to-reach populations may be applicable, but may require significant modifications to FSIS' current sampling projects.
- Because some types of pathogen contamination, such as *E coli* O157:H7 adulteration, is very rare and because of the differences across slaughter and processing establishments, prevalence estimates are poor measures of both establishment process control and FSIS program performance.

In the future, FSIS would consider estimating pathogen prevalence on a quarterly and annual basis using a year of rolling data. For example, for the calculation of the first quarter of Fiscal Year (FY) 2012, FSIS would use data from January 2011 through December 2011. Final Fiscal Year and Calendar Year (CY) estimates would also be computed using a full year of rolling data.

Limitations of Prevalence Definition

As the formulation and construction of FSIS pathogen verification programs vary significantly across pathogens, it is not possible to compare prevalence estimates across FSIS regulated products.

Assumptions

Additionally, many testing or estimation procedures are subject to the validity of the assumptions made in producing the statistical results. Once specific estimation procedures are identified for producing prevalence estimates for individual products or projects, the associated assumptions will need to be examined to determine if any further modifications to the estimation procedures are needed. Assumptions associated with all samples include:

- The sample is representative of an identifiable subset of the total collection population.
- Laboratory analyses provide consistent results across all samples tested.
- Organisms are spread throughout the product being tested, such that the sampled area or product is representative of the population.
- No additional contamination was added during sample collection or shipping.
- Shipment procedures limit any recovery, outgrowth, or reproduction of the pathogen so that the estimated presence and levels are similar to the presence and levels at the sample collection point. However, further processing, partitioning, growth and cooking ensure that a proportional relationship might exist between tested product and actual servings.

The assumptions above may not hold in all cases, which can introduce bias and therefore provide further limitations on the resulting estimates.

FSIS Data and Statistical Requirements

FSIS has identified the following data and statistical requirements for the use of verification data to compute prevalence estimates:

- Define the Population
    - The population is the universe of units for which the characteristic of interest is being assessed.
    - The population may be defined as a species, an animal part, a product, or an environmental source (e.g., cows, chickens, turkeys, ground beef, sausage, deli meats, processed egg products and/or food contact surfaces) that is sampled by FSIS.
- Define the Population Unit
    - A population unit is defined as the population element of interest. A population unit may be a carcass in a population of animals (e.g., a young chicken carcass in the population of federally-inspected, slaughtered young chickens), or a population unit may be a specified quantity of product (e.g., a pound of raw ground turkey from the population of federally-inspected raw ground turkey).
- Define the Sampling Frame
    - The sampling frame is a listing of all the units in the defined population.
    - Alternatively, the sampling frame may be an aggregated listing of enumeration units, where each population unit (e.g., chicken carcass or pound of ground beef) is associated with one and only one enumeration unit (e.g., slaughter/processing establishment) in the sampling frame.
    - For a national prevalence estimate of a given pathogen-product pair, the sampling frame would typically be a complete listing of FSIS-regulated establishments that produce a given product in that year and their associated production volume.
- Define the Collection Frame
    - This could be the entire sampling frame, or this could be a listing of establishments (or other enumeration units) selected for sampling from the sampling frame.
    - The selection procedure used to establish the collection frame must also be defined.
- Limitations on Unit Choice
    - Random unit choice is preferred.
    - Clustered samples are acceptable, but the effect of clustered choice must be addressed.
    - Announced sampling is discouraged as they may make clustered choice not acceptable.
- Limitations on Product Choice[6]
    - One hundred percent judgment based selection is not acceptable.
    - Product is stratified based on a risk characteristic (e.g. product type), and then chosen randomly within each stratum.
- Limitations on Establishment Choice

[6] Occurs when a product class is comprised of several different types. For example, for *E. coli* O157:H7, trim and components can be comprised of beef heart, lymph and cheek meat, but for *Salmonella*, the only product choice available is broiler carcasses.

- Establishments are stratified based on a characteristic (e.g. risk, production volume), and then chosen randomly within each stratum.

Additional required data and statistical considerations:

- These factors will be used to determine the probability of selection for each unit of product for each establishment:
  - Day of week and time of day should be randomly chosen.
  - The production volume for each establishment for each product is required.

Additional useful, but not required data points:

- Interventions being used
- HACCP size
- Product production volume
- Monthly total
- Daily total for sample collection day

Additional useful, but not required sample characteristics:

- Sample weight
- Shift sample collected
- Date
- Time elapsed since last cleanup

Chapter 2: *E. coli* O157:H7 Verification Sampling Program

Overview

Calculating an *E. coli* O157:H7 prevalence estimate using the current verification data **is possible** for MT43 (raw ground beef verification project). However, the *E. coli* O157:H7 Prevalence subgroup cautions that the power to detect anything less than a drastic change in prevalence is small. In other words, FSIS could only declare a statistically significant difference in prevalence when the change is substantial. In contrast, calculating a prevalence estimate using the current verification data is **not possible** for MT50, MT54 and/or MT55 (beef manufacturing trimmings, other components to raw ground beef, and bench trim) without substantial changes to the current sampling projects. Table 1 provides an overview of the data requirements evaluated and the findings of the *E. coli* O157:H7 subgroup in terms of current *E. coli* O157:H7 pathogen verification testing projects.

The current *E. coli* O157:H7 verification projects (MT43, MT50, MT54 and MT55) test intermediate and final beef products before they are available to the consumer. Because of this, the relationship between the verification projects for trim, components and raw ground beef are complex and dynamic. It is also important to note at the beginning of this discussion that *E. coli* O157:H7 adulteration is very rare, which is an important factor to consider in the calculation of prevalence estimates, their confidence intervals, and for determining when a significant change in prevalence has occurred. As such, data from the various *E. coli* O157:H7 projects should not be combined in an effort to calculate a comprehensive *E. coli* prevalence estimate.

Table 1: Overview of FSIS Findings Regarding Evaluation of Data Requirements of *E. coli* O157:H7 Pathogen Verification Testing Projects

Data and Statistical Requirements	***E. coli* O157:H7**			
	MT43	**MT50**	**MT54**	**MT55**
Population	Yes	Yes	Yes	Yes
Sampling Frame	Yes	Yes	Yes	Yes
Collection Frame	Yes	Yes	Yes	Yes
Enumeration Unit Selection	Yes	Yes	Yes	Yes
Population Unit Selection	Yes	Yes	Yes	Yes
Product Type Selection	N/A, Yes	N/A, Yes	Yes	N/A, Yes
Probability of Selection	Yes	Yes	Yes	Yes
Production Volume	Yes	Yes	Yes	Yes
Sampling representative of population	Yes	**No**	**No**	**No**
Sampling provides desired precision	Yes	**No**	**No**	**No**
CONCLUSION	Yes	**NO**	**NO**	**NO**

Background: FSIS' *E. coli* O157:H7 Verification Sampling Projects

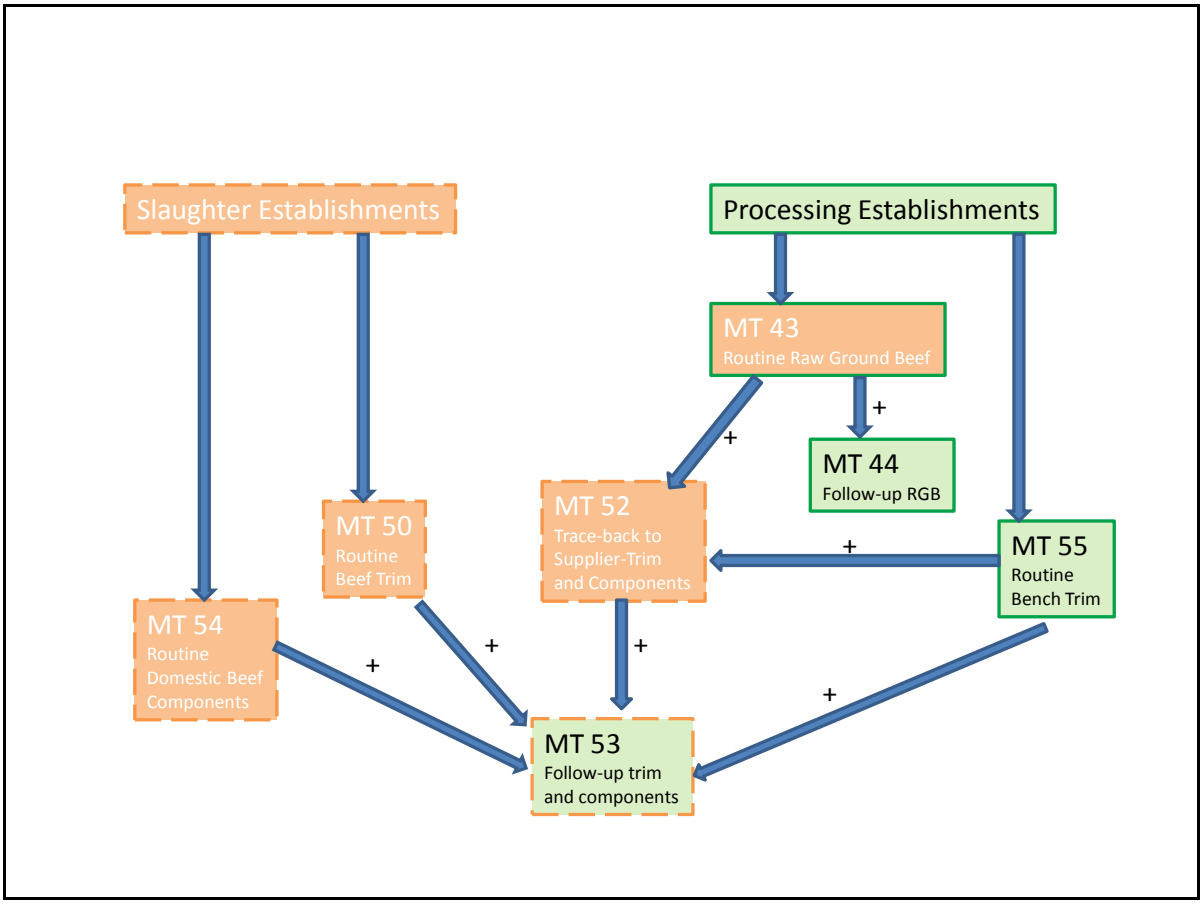
The *E. coli* O157:H7 verification sampling program formally began on October 17, 1994. The program was originally instituted to detect *E. coli* O157:H7 in raw ground beef as a means to verify process control under HACCP. The original objective of this program was to stimulate industry testing and other actions to reduce the presence of the pathogen in raw ground beef. The testing program has evolved over time and now there are verification programs for other commodities, such as beef trim and other raw ground beef components. Table 2 describes the various FSIS *E. coli* O157:H7 sampling verification projects. The projects that are in bold letters and highlighted in blue were evaluated in this project. Finally, Figure 1 displays a flow-chart which includes both verification projects and follow-up/trace-back projects.

Table 2: FSIS *E. coli* O157:H7 Verification Sampling Projects.

Product Type	**Project Code**	**Sample Size**	**Number of Analyzed Samples (CY2010)**	**Regulatory Purpose of Sampling Project**	**Type of Sampling Algorithm**
Raw ground beef	**MT43**	**15,600**	**11,291**	**Verify non-detectable standard**	**Risk-Based**
Follow up testing to a raw ground beef positive	MT44	NA	309	Verify corrective measures	Targeted Consecutive
Beef trim (slaughter establishments)	**MT50**	**2,600**	**1,274**	**Verify HACCP compliance**	**Random**
Raw ground beef components (other than trim)	**MT54**	**780**	**169**	**Verify HACCP compliance**	**Random**
Bench trim	**MT55**	**1,800**	**547**	**Verify HACCP compliance**	**Random**
Follow up testing at supplier establishments following MT43, MT44, or MT55 positive	MT52	NA	636	Verify corrective measures	Targeted Consecutive
Follow up testing to a MT50, MT54, MT55, MT53, or MT52 positive	MT53	NA	125	Verify corrective measures	Targeted Consecutive

*CY= Calendar year. HACCP: Hazard Analysis and Critical Control Point program.

Figure 1. Flow chart of all FSIS' *E. coli* O157:H7 sampling projects.



Additionally, an extensive overview of the four *E. coli* O157:H7 verification projects under consideration—MT43, MT50, MT54 and MT55—for generating prevalence estimates, including a discussion of the purpose of each project, their sampling properties and methodologies, as well as information about the FSIS collection methodology, mean response rates and analyzed samples is provided in the FSIS Sampling Program Report released in December 2011.[7]

[7] The FSIS Sampling Program Report was publicly released in December 2011 and can be accessed at the FSIS website at: http://www.fsis.usda.gov/PDF/FSIS_Sampling_Programs_Report.pdf.

Data Requirements

Prevalence can be estimated using a number of analytical approaches with a range of assumptions and varying degrees of complexity in calculation and maintenance. The following text summarizes the specific data requirements developed by the *E. coli* O157:H7 subgroup for prevalence estimation, together with a short discussion of whether the requirement is met for each of the four projects under consideration for use in deriving prevalence estimates (MT43, MT50, MT54 and MT55).

Population

Requirement

The universe of units for which the characteristic of interest is being assessed is required.

Requirement Met?

MT43: Information is available to estimate the annual production volume of raw ground beef in pounds for FSIS-inspected establishments. This information is available by volume category and is sufficient for deriving prevalence estimates. **Hence, this requirement is satisfied.**

MT50: Information is available to estimate the annual production volume of beef manufacturing trimmings in pounds for FSIS-inspected establishments. This information is available by volume category, and is sufficient for deriving prevalence estimates. **Hence, this requirement is satisfied.**

MT54: Information is available to estimate the annual production volume of raw ground beef components other than trim in pounds for FSIS-inspected establishments. This is an estimation of the group of products as a whole; this data is not available at the specific-component level. This information is available by volume category, and is sufficient for deriving prevalence estimates. **Hence, this requirement is satisfied.**

MT55: Information is available to estimate the annual production volume of bench trim in pounds for FSIS-inspected establishments. This information is available by volume category, and is sufficient for deriving prevalence estimates. **Hence, this requirement is satisfied.**

Sampling Frame

For all these projects, the population units are pounds of product and the enumeration units are establishments.

Requirement

A listing of all the units in the defined population is required. Alternatively, an aggregated listing of enumeration units could be used, provided that each population unit is associated with only one enumeration unit in the frame.

Requirement Met?

MT43: The sampling frame includes all establishments that report production of raw ground beef, as well as all establishments from which FSIS has collected and analyzed an MT43 sample in the past 12 months. There is an exclusion list that, at the time this evaluation was conducted, contained approximately 40 establishments. These establishments generally are

those from whom FSIS has collected a sample in the previous 12 months, but that are no longer producing ground beef. This list may sometimes also include establishments that have temporarily or seasonally stopped producing raw ground beef. These are all valid exclusions from the frame and do not affect the Agency's ability to meet the requirement. **Hence, this requirement is satisfied.**

MT50: The sampling frame includes all establishments that slaughter beef or their identified sister establishments. Sister establishments are those that are directly, physically next door to or across the street from a slaughter establishment and both establishments are under common ownership. FSIS does not store data on corporate affiliations, so sister establishments are difficult to identify. Those identified by field inspectors are hard-coded as inclusions to the frame. Because not all beef slaughter establishments make trim intended for raw ground beef, FSIS recognizes that the defined frame is imprecise. For this reason, when a sample collection form is returned with a discard code indicating that the product is not produced, the establishment is removed from the sampling frame for 12 months. Also, FSIS maintains an exclusion list populated from communication with field inspectors indicating that the establishment does not belong in the frame. Some justifiable reasons to put an establishment on the exclusion list are that it produces seasonally and is not currently producing, the establishment does not produce any trim, the establishment diverts all of its trim to cooking, etc. At the time of this evaluation, there were approximately 12 establishments on the exclusion list. These are all valid exclusions from the frame, but the ability to estimate prevalence would be improved by a more accurately defined frame. **Hence, this requirement is satisfied.**

MT54: The sampling frame includes all establishments that slaughter beef. Also, ammoniated beef establishments are included in this frame. Because not all beef slaughter establishments make components intended for raw ground beef, FSIS recognizes that the defined frame is imprecise. For this reason, when a sample collection form is returned with a discard code indicating that the product is not produced, the establishment is removed from the sampling frame for 12 months. Also, FSIS maintains an exclusion list populated from communication with field inspectors indicating that the establishment does not belong in the frame. Some justifiable reasons to put an establishment on the exclusion list are that it produces seasonally and is not currently producing, the establishment does not produce any components, the establishment diverts all of its components to cooking, etc. At the time of this evaluation, there were approximately 12 establishments on the exclusion list. These are all valid exclusions from the frame, but the ability to estimate prevalence would be improved by a more accurately defined frame. **Hence, this requirement is satisfied.**

MT55: The sampling frame includes establishments with indicators that they might produce bench trim in either the PBIS extension profile survey or the 2007 FSIS *E. coli* Checklist.[8] Both of these are now relatively outdated data sources, but there are currently no other identifiers in the FSIS data that could improve this frame. FSIS recognizes that the defined frame is imprecise. For this reason, when a sample collection form is returned with a discard code indicating that the product is not produced, the establishment is removed from the sampling frame for 12 months. Also, FSIS maintains an exclusion list populated from

[8] Alvares, C., Lim, C., & Green, K. (August 2008). Results of checklist and reassessment of control for *Escherichia coli* in O157:H7 in beef operations. Accessed at: http://www.fsis.usda.gov/PDF/Ecoli_Reassement_&_Checklist.pdf on March 26, 2012.

communication with field inspectors indicating that the establishment does not belong in the frame. Some justifiable reasons to put an establishment on the exclusion list are that it produces seasonally and is not currently producing, the establishment does not produce any bench trim, the establishment diverts all of its products to cooking, the establishment only grinds, etc. At the time of this evaluation, there were approximately 30 establishments on the exclusion list. Field inspectors can request that an establishment be added to the frame. Ammoniated beef establishments are excluded because they are included with certainty in the MT54 frame. These are all valid exclusions from the frame, but the ability to estimate prevalence would be improved by a more accurately defined frame. **Hence, this requirement is satisfied.**

Collection Frame

Requirement

A listing of units in the collection frame is required. The collection frame could be the entire sampling frame or the set of establishments (or other enumeration units) from which samples are selected. The procedure used to set the frame must be defined.

Requirement Met?

MT43: Establishments are selected based on their production volume and their hazard score. FSIS has determined how the sampling algorithm should be utilized in calculating the hazard score to define the collection frame. If establishments are chosen with a definable probability from all hazard categories, then this requirement is met. The sampling frame currently equals the collection frame, less valid exclusions, **hence this requirement is satisfied.**

MT50: Establishments are selected by simple random sampling. The sampling frame currently equals the collection frame, less valid exclusions, **hence this requirement is satisfied.**

MT54: Establishments are selected by simple random sampling. At the time of this evaluation, the four ammoniated beef establishments regulated by FSIS were selected with certainty. FSIS maintains is a list of products that are eligible for collection, and this is not assigned by the sampling algorithm. Rather, the inspector is instructed to select the product for collection at random from the components available for selection on the day of collection. The sampling frame currently equals the collection frame, less valid exclusions, **hence this requirement is satisfied.**

MT55: Establishments are selected by simple random sampling. The sampling frame currently equals the collection frame, less valid exclusions, **hence this requirement is satisfied.**

Enumeration Unit Selection (Establishments)

Required

The procedure used to select enumeration units (establishments) from the collection frame must be defined. Establishments may be stratified based on a characteristic (e.g. risk, production volume) and then chosen based on an identifiable probability of selection within each stratum. Random unit choice is preferred.

Requirement Met?

MT43: Under the MT43 project, product samples are selected with replacement from the sampling frame by an algorithm that employs scaling factors. Inputs to calculating the scaling factors are annual production volume group and history of positive pathogen testing. The current project has four volume groups.[9] The algorithm also includes sampling ceilings for each volume group and sampling floors. Establishments with a history of positive test results are sampled more frequently. **Hence, this requirement is satisfied.**

MT50: Under the MT50 project, establishments are selected without replacement from the sampling frame by an algorithm that employs simple random sampling. There is no stratification or weighting by establishment production volume; there are no ceilings or floors. **Hence, this requirement is satisfied.**

MT54: Under the MT54 project, there were four establishments that could be identified with certainty when this evaluation was conducted. The remaining sample is selected without replacement from the sampling frame by an algorithm that employs simple random sampling. There is no stratification or weighting by establishment production volume; there are no ceilings or floors. **Hence, this requirement is satisfied.**

MT55: Under the MT55 project, establishments are selected without replacement from the sampling frame by an algorithm that employs simple random sampling. There is no stratification or weighting by establishment production volume; there are no ceilings or floors. **Hence, this requirement is satisfied.**

Population Unit Selection

Requirement

The procedure used to select population unit(s) from a given enumeration unit must be defined. Clustered samples are acceptable, but effect of clustered choice must be addressed through statistical analysis undertaken as part of the prevalence estimation. Announced sampling is not preferred. Announced samples may make clustered choice not acceptable. Day of week and time of day when sample is taken should be randomly chosen.

Requirement Met?

MT43: Sample collection is done by collecting 325 grams of raw ground beef. Each establishment is sampled a maximum of four times per month and at least three times per year. Because FSIS recommends that establishments hold sampled lots until FSIS laboratory tests confirm, field inspectors have to announce sample collection to allow the establishment to prepare to hold product.[10] Although there is an element of announcement required for practical implementation purposes, the subgroup does not feel that it precludes the possibility

[9] Volume groups were developed by a multi-disciplinary team of scientists and technical staff within the FSIS prior to 2003. There are currently more volume groupings for MT43 sampling within PHIS, but they map exactly to the Agency's existing PBIS categories.

[10] While FSIS does not currently mandate that establishments hold product until negative test results are received, the Agency requested comments on a Federal Register Notice that would change the Agency's procedures and withhold a determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received. Please see the following website for more details: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2005-0044.pdf.

of producing a prevalence estimate. This area may need further investigation. **Hence, this requirement is satisfied.**

MT50: Sample collection is done by N60 method.[11] An N60 sample can vary in weight, but generally is between 325 grams (the goal) and 700 grams. Because FSIS recommends that establishments hold sampled lots until FSIS laboratory tests confirm, field inspectors have to announce sample collection to allow the establishment to prepare to hold product.[12] **Hence, this requirement is satisfied.**

MT54: Sample collection is done by N60 method when appropriate; otherwise, 325 grams of components are collected.[13] An N60 sample can vary in weight, but generally is between 325 grams (the goal) and 700 grams. More than one type of product qualifies for MT54 collection, and field inspectors are instructed to select randomly from those being produced on the day of collection. Because FSIS recommends that establishments hold sampled lots until FSIS laboratory tests confirm, field inspectors have to announce sample collection to allow the establishment to prepare to hold product.[14] **Hence, this requirement is satisfied.**

MT55: Sample collection is done by N60 method.[15] An N60 sample can vary in weight but generally is between 325 grams (the goal) and 700 grams. Because FSIS recommends that establishments hold sampled lots until FSIS laboratory tests confirm, field inspectors have to announce sample collection to allow the establishment to prepare to hold product. **Hence, this requirement is satisfied.**

Product Type Selection

Requirement

The procedure used to select the product type for sampling for a given product class must be defined. This applies to instances where various components make up the product class (e.g. components for raw ground product), or the final product itself varies. One hundred percent judgment based selection is not acceptable.

Requirement Met?

MT43: MT43 involves sampling of a single product (raw ground beef). **Therefore, this requirement is not applicable to the MT43 project**.

MT50: MT50 involves sampling of a single product (manufacturing trimmings). **Therefore, this requirement is not applicable to the MT50 project.**

MT54: Field inspectors are directed to select at random from the products available for collection on the date of collection. If it is one of the four ammoniated beef establishments producing at the time of this evaluation, then the product collected is ammoniated beef. **Hence, this requirement is satisfied.**

MT55: MT55 involves sampling of a single product (bench trim). **Therefore, this requirement is not applicable to the MT55 project.**

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[11] FSIS is in the process of identifying changes to the N60 sampling program in light of Office of Inspector General (OIG) audit recommendations. Changes made to the trim and component sampling programs to satisfy OIG requirements will be published on the FSIS website for public comment.

[12] Supra footnote 10.

[13] Supra footnote 11.

[14] Supra footnote 10.

[15] Supra footnote 11.

Probability of Selection

Requirement

The probability of selection for each population unit (e.g., unit of product) in each enumeration unit (establishment) must be determined. To do this, every enumeration unit (establishment) in the collection frame must have some probability of being sampled during a defined time period. Selection probabilities do not have to be equal.

Requirement Met?

MT43: The probability of selection for each population unit can be estimated from available FSIS data. **Hence, this requirement is satisfied.**
MT50: The probability of selection for each population unit can be estimated from available data. **Hence, this requirement is satisfied.**
MT54: The probability of selection for each population unit can be estimated from available data. **Hence, this requirement is satisfied.**
MT55: The probability of selection for each population unit can be estimated from available data. **Hence, this requirement is satisfied.**

Production Volume

Requirement

Production volume for each establishment for the time period in which prevalence is being calculated is required for an accurate estimate.

Requirement Met?

MT43: Production volume is available only in categories. These categories are sufficient for deriving a prevalence estimate. However, the breadth of these categories, as they are currently defined, may limit the precision of the prevalence estimates that can be derived from current information. Additional product volume categories will be included in PHIS, and may support more precise prevalence estimates. **Hence, this requirement is satisfied.**
MT50: Production volume is available only in categories. These categories are sufficient for deriving a prevalence estimate. However, the breadth of these categories, as they are currently defined, may limit the precision of the prevalence estimates that can be derived from current information. Additional product volume categories will be included in PHIS, and may support more precise prevalence estimates. **Hence, this requirement is satisfied.**
MT54: Production volume is available only in categories. These categories are sufficient for deriving a prevalence estimate. However, the breadth of these categories, as they are currently defined, may limit the precision of the prevalence estimates that can be derived from current information. Additional product volume categories will be included in PHIS, and may support more precise prevalence estimates. **Hence, this requirement is satisfied.**
MT55: Production volume is available only in categories. These categories are sufficient for deriving a prevalence estimate. However, the breadth of these categories, as they are currently defined, may limit the precision of the prevalence estimates that can be derived from current information. Additional product volume categories will be included in PHIS, and may support more precise prevalence estimates. **Hence, this requirement is satisfied.**

Analysis of Data Limitations

Based on review of the information outlined above, the *E. coli* O157:H7 subgroup has concluded that prevalence estimates can be developed for *E. coli* O157:H7 in raw ground beef (MT43). However, because of the small sample sizes and other factors, *E. coli* O157:H7 prevalence estimates cannot be developed for beef trim and components under the current verification projects. Key data, resource, and operational limitations are described below.

1. *Risk-Based Sampling*

   The current scheduling algorithm for MT43 raw ground beef is risk-based, which is critical in monitoring establishment performance. The primary effect of this approach on prevalence estimation is that the risk categories have varying degrees of precision. The separate category variances affect the overall variance estimate because it is estimated by mathematically combining the separate variances. The ability to calculate a prevalence estimate remains, as long as all categories in a given time period are represented, though the precision of the estimate may be lower than if another design was employed.

2. *Prior Notification*

   It is possible that prior notification affects FSIS' ability to collect representative samples. However, policy constraints require that notification be given to establishments so that they can plan for holding product until FSIS laboratory test results are confirmed in an effort to prevent recalling product.[16] To create an appropriate prevalence estimate, every attempt at representative sampling should be made.

3. *Sample Sizes for MT50, MT54, MT55 Projects*

   The most important aspect of creating a prevalence estimate is for the sampling to be done in a manner representative of the characteristics to be estimated. In addition, the precision of the estimate may provide an indicator of its reliability.

   Precision usually improves as sample sizes increase. That is, larger sample sizes typically lead to smaller variances. In particular, rare event sampling requires large sample sizes to obtain reasonable precision. The MT50 project detected four positive trim samples out of 1,274 analyzed samples in 2010, which gives an indication that this is rare event testing. Likewise, there were no positives out of the 169 analyzed MT54 samples in 2010 and no positives out of the 574 analyzed in MT55 samples in 2010, which indicates that these sample sizes may be too small to yield an accurate prevalence estimate in these products.

4. *Representativeness of the Samples*

   For MT50, MT54 and MT55, the sampling results are representative of sampling in establishments, but prevalence estimates require representative sampling of the product in question. Because the sample designs do not incorporate stratification or weighting by production volume, the samples may not be adequately representative of product from each production class.

[16] Supra footnote 10.

5. *Industry Testing Affecting FSIS Estimates*
   Industry test and divert practices may result in a lower prevalence estimate obtained by FSIS verification testing than would be obtained through baseline testing, because a portion of positive product would already be removed.[17] While this product is not a threat to consumers because it is not sent into commerce, test and divert could result in FSIS verification prevalence estimates that are lower than baseline prevalence estimates.

Conclusions

The *E. coli* O157:H7 subgroup has concluded the following with respect to the estimation of the prevalence of *E. coli* O157:H7 in raw ground beef, beef trim and beef components:

- *Raw ground beef:* It is possible to develop national prevalence estimates for *E. coli* O157:H7 in raw ground beef using the currently available data. Improved prevalence estimates might be obtained through implementation of changes to the current verification testing project.

- *Beef trim and beef components:* Development of national prevalence estimates for *E. coli* O157:H7 in beef trim and components using current FSIS pathogen testing data is not possible at the current time. Prevalence estimates could be developed, but would require substantial increases in sample size during a period of fiscal restraint. In addition, any changes to these sampling projects to support the development of prevalence estimates will need to be coordinated with other possible changes to the current MT50/MT54/MT55 projects, such as FSIS' activities in relation to the OIG N60 audit recommendations.

[17] Supra footnote 10.

Chapter 3: *Salmonella* Verification Sampling Program

Overview

Calculating an accurate prevalence estimate using the current *Salmonella* verification data is **not possible** because certain key elements in the data requirements are not being met. Table 4 provides an overview of the data requirements evaluated and the findings of the *Salmonella* subgroup in terms of current *Salmonella* pathogen verification testing projects.

Table 4: Overview of FSIS Findings Regarding Evaluation of Data Requirements of *Salmonella* Pathogen Verification Testing Projects[18]

Data and Statistical Requirements	*Salmonella*	
	Raw Intact Product	**Raw Ground Product**
Population	Yes	**No**
Sampling Frame	Yes	
Collection Frame	Yes	
Enumeration Unit Selection	**No**	
Population Unit Selection	**No**	
Product Type Selection	Yes	
Probability of Selection	**No**	
Production Volume	Yes	**No**
CONCLUSIONS	**NO**	**NO**

Background

The *Salmonella* verification sampling program formally began with FSIS Final Rule on Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems that issued on July 25, 1996 (61 FR 38805– 38989). Among other things, the PR/HACCP rule set *Salmonella* performance standards for establishments that slaughter selected classes of food animals or that produce selected classes of raw ground products. FSIS uses the *Salmonella* performance standards to ensure that each establishment is consistently achieving an acceptable level of performance with regard to controlling processes and reducing harmful bacteria on raw meat and poultry products.[19]

This section presents a brief overview of FSIS *Salmonella* sampling projects, specific data requirements for possible prevalence estimation, and a summary of the *Salmonella* subgroup's conclusions regarding the suitability of using verification data to estimate prevalence.

Table 5 describes the various FSIS *Salmonella* sampling verification projects. Additionally, an extensive overview of the *Salmonella* sampling projects under consideration for generating prevalence estimates, including a discussion of the purpose of the project, their sampling properties and methodologies, as well as information about the FSIS collection methodology,

[18] Sampling for *Salmonella* through the MT43S project was not included in this assessment.
[19] Federal Register, Vol. 73, No. 18, July 25, 1996.

mean response rates, and counts of analyzed samples is provided in the FSIS Sampling Program Report.[20]

Table 5: FSIS *Salmonella* Verification Sampling Projects.

Product class	***Salmonella* Sampling Projects**	**Number of *Salmonella* Samples Analyzed FY2010**	**Regulatory Purpose of Sampling Project**	**Type of Sampling Project**
Steers/heifers[21]	HC01	6,550	Verify consistent process control	Risk Based
Cows/bulls[22]	HC01	1,688	Verify consistent process control	Risk Based
Raw Ground beef[23]	HC01	8,982	Verify consistent process control	Risk Based
Market hogs[24]	HC01	305	Verify consistent process control	Risk Based
Broilers[25, 26]	HC01	762	Verify consistent process control	Risk Based
Ground chicken[27]	HC01	3,913	Verify consistent process control	Risk Based
Ground turkey[28]	HC01	3,811	Verify consistent process control	Risk Based
Turkeys[29]	HC01	1,303	Verify consistent process control	Risk Based
Raw Ground beef	MT43S	2,957	Verify consistent process control	Random
RTE meat and poultry products	ALLRTE	2,990	Verify adequacy of an establishment's ability to prevent microbiological contamination	Random
RTE meat and poultry products	RTE001	8,700	Verify adequacy of an establishment's ability to prevent contamination from *Salmonella* and *Lm*	Risk Based

[20] Supra footnote 7.
[21] Sample sets for Market Hogs, Cows/Bulls, or Steers/Heifers were not scheduled in the latter half of FY 2011.
[22] Supra footnote 21
[23] Sampling for *Salmonella* through the FSIS MT43S sampling program (*Salmonella* sampling in raw ground beef product) was not included in this assessment.
[24] Supra footnote 21.
[25] No longer being scheduled for HC01 (but being scheduled under HC11) with the implementation of the new *Salmonella* and *Campylobacter* performance standards in July 2011.
[26] FSIS initiated sampling with enumeration for *Campylobacter* in July 2011 in turkeys and broilers. FSIS will assess the ability to estimate prevalence using *Campylobacter* sampling results once data collection and analysis has been in place for at least a year period.
[27] In CY2012, FSIS anticipates issuing a Federal Register Notice informing stakeholders that the Agency intends to begin sampling comminuted and ground poultry products for *Salmonella* and *Campylobacter* during CY2012.
[28] Supra footnote 27.
[29] Supra footnote 25

Product class	*Salmonella* Sampling Projects	Number of *Salmonella* Samples Analyzed FY2010	Regulatory Purpose of Sampling Project	Type of Sampling Project
Egg whites with or without added ingredients	EM-31	292	Verify adequacy of an establishment's ability to prevent contamination from *Salmonella*	Random
Whole eggs/yolks with <2% added ingredients other than salt or sugar	EM-32	389	Verify adequacy of an establishment's ability to prevent contamination from *Salmonella*	Random
Whole eggs/yolks with ≥2% added ingredients other than salt or sugar	EM-33	141	Verify adequacy of an establishment's ability to prevent contamination from *Salmonella*	Random
Whole eggs/yolks with ≥2% salt or sugar added	EM-34	287	Verify adequacy of an establishment's ability to prevent contamination from *Salmonella*	Random
Dried yellow egg products	EM-35	114	Verify adequacy of an establishment's ability to prevent contamination from *Salmonella*	Random
Spray dried egg whites (with or without added ingredients)	EM-36	104	Verify adequacy of an establishment's ability to prevent contamination from *Salmonella*	Random
Pan dried egg whites	EM-37	10	Verify adequacy of an establishment's ability to prevent contamination from *Salmonella*	Random
Domestic liquid, frozen or dried egg products	EGGDOM	61	Verify adequacy of an establishment's ability to prevent contamination from *Salmonella*	Random

Data Requirements

The *Salmonella* subgroup established that certain key elements are necessary in order to accurately estimate prevalence. These requirements must be met for any calculations to be statistically valid.

Population

Required

The universe of units for which the characteristic of interest is being assessed is required.

Requirement Met?

The population of interest for raw intact products is the number of carcasses of a certain product class (broilers, turkeys, cows/bulls, steer/heifer, and market hog) at post-chill produced at non-exempt FSIS regulated establishments.[30, 31] This volume data is readily available from the FSIS Electronic Animal Disposition Reporting System (eADRS) slaughter database, **which sufficiently satisfies this requirement for raw intact products.**

The population of interest for raw ground products is the volume of a certain product class (ground beef, chicken, or turkey) produced at non-exempt FSIS regulated establishments.[32] Accurate volume data is not available for these products at this time. However, a rough estimate for raw ground beef can be calculated. **Therefore, this requirement is not met for raw ground products.**

Sampling Frame

Required

A listing of all the units in the defined population is required. Alternatively, an aggregated listing of enumeration units can be used, provided that each population unit is associated with only one enumeration unit in the frame. For example, if the population unit is an individual FSIS inspected steer or heifer carcass, then the list of non-exempt federally inspected establishments that slaughter steers and heifers is an appropriate listing of enumeration units.

Requirement Met?

The set of all non-exempt federally inspected establishments that produce a given product class during a given period of interest can be rapidly assembled from data currently existing in the FSIS data warehouse; **hence this requirement is satisfied**.

Collection Frame

Required

A listing of units in the collection frame is required. This could be the entire sampling frame, or a subset of enumeration units from which samples are selected. The methodology used to set the frame must be defined and statistically valid for a prevalence calculation.

Requirement Met?

The current collection frame does not include all the establishments from the sampling frame. For example, low volume producers have traditionally been excluded for sampling rate reasons. Please see the FSIS Standard Operating Procedure (SOP) for Eligibility.[33] Since low volume establishments comprise such a small percentage of industry production, the statistical impact of excluding them is minimal (this method was also used in the 2007-2008

[30] Some FSIS inspected establishments have a religious exemption and are not sampled, so carcasses produced at these establishments should be excluded from the population.

[31] Supra footnote 21

[32] Supra footnote 30.

[33] Please see the following website for more information: http://www.fsis.usda.gov/PDF/SOP_Salmonella_Eligibility_Testing_092211.pdf.

FSIS Nationwide Microbiological Baseline Data Collection Program: Young Chicken Survey).[34] **Hence, this requirement is satisfied.**

Enumeration Unit Selection

Required

The procedure used to select enumeration units (establishments) from the collection frame must be defined. Establishments may be stratified based on a characteristic (e.g. risk, production volume) and then chosen based on an identifiable probability of selection within each stratum. Random unit choice is preferred.

Requirement Met?

Establishments are currently chosen for sampling based on risk and past performance. New establishments and those in the highest risk category are selected first. All product classes are part of the same scheduling algorithm so establishments producing certain product classes are given higher priority in scheduling over other products. Please see criteria for selection and product class priority.[35] Thus, FSIS does not control the number of verification samples for specific product classes over the course of time. **This method is not ideal for prevalence estimation, so the requirement is not fulfilled.**

Population Unit Selection

Required

The procedure used to select population unit(s) from a given enumeration unit must be defined. Clustered samples are acceptable, but effect of clustered choice must be addressed. Announced sampling is not preferred. Announced samples may make clustered choice unacceptable. Day of week and time of day when a sample is collected should be randomly chosen.

Requirement Met?

Current policy specifies that HC01 samples are to be collected in sets. Once an establishment is chosen for sampling, it is sent 75 sample forms.[36] Field inspectors are instructed to collect one sample per day for each day that the establishment is producing the product. Sample collection ends when the number of samples successfully analyzed reaches the number required to complete a set—see Appendix C for a complete description. Thus, samples are both clustered and announced. The day of the week when the sample is collected is not random or varied because once a sample set is started, an establishment is aware samples will be collected consecutively every day it is producing that product for a given length of time. Nevertheless, FSIS field inspectors are instructed to collect samples at varied times of the day, though information regarding the distribution of collection times is not available. **Given the information above, this element does not meet the requirement necessary for prevalence estimation.**

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[34] Please see the following website for more information: http://www.fsis.usda.gov/PDF/Baseline_Data_Young_Chicken_2007-2008.pdf.

[35] Please see the following website for more information: http://www.fsis.usda.gov/Science/Scheduling_Criteria_Salmonella_Sets_092211/index.asp.

[36] Historically, steer/heifer establishments were sent 90 forms.

Product Type Selection

Required

The procedure used to select the product type for sampling for a given product class must be defined. This applies to instances where various components comprise the product class. For example, trim and components for raw ground beef (which are not currently sampled under *Salmonella* verification testing) might consist of cheek meat, weasand meat and/or heart meat, etc. This requirement could also apply if the final product itself varies.

Requirement Met?

Each class of raw intact product is sampled separately and consists of only one type, not parts. Also, all ground products are sampled after grinding (not components), so no sample selection procedure is necessary. **Thus, this data requirement is met.**

Probability of Selection

Required

The probability of selection for each population unit in every enumeration unit must be determined. To do this, every enumeration unit in the collection frame must have some probability of being sampled each sampling period. Probabilities do not have to be equal across enumeration units or over time.

Requirement Met?

These probabilities cannot be calculated in the current risk-based sampling algorithm because not all establishments (enumeration units) in the sampling frame have a probability of being selected each sampling period (month). **Therefore, this element is not satisfactory for calculating prevalence.**

Production Volume

Required

Production volume for each enumeration unit for the time period in which prevalence is being calculated is required for an accurate estimate.

Requirement Met?

The eADRS slaughter database contains detailed volume data of carcasses slaughtered for each product class for every establishment in the sampling frame. Volume totals are available for any time period (daily, weekly, monthly, annually, etc.) **so this requirement is met for raw intact products.** Unfortunately, exact volume data is not available for ground products, **so the requirement is not satisfied for those product classes.**[37]

Analysis of Data Limitations

After reviewing all available information, the *Salmonella* subgroup determined that prevalence cannot be estimated using the current verification data. There were several significant reasons for this assessment.

[37] For raw ground beef, the *E. coli* O157:H7 subgroup decided that the production volume groups were not ideal, but satisfactory for calculating prevalence.

1. *Risk-based Sampling*
   The current scheduling algorithm is risk-based, which is critical in positively affecting public health, but disproportionately focuses sample collection. This means that there is a large differentiation between well-performing establishments (Category 1) and poor, or potentially poor ones (Category 3), in that the former might not be scheduled for sampling for a year or more, whereas the latter could be scheduled quite often.[38] For this reason, not all establishments in the collection frame have a known probability of selection each month.

2. *Product Priority*
   Establishments producing certain products are scheduled ahead of others. This prevents those establishments/products with lower priority from being sampled regularly because only a given number of sample sets can be scheduled each month. This results in insufficient data that is not representative of certain product classes. Furthermore, some product classes that have been completely excluded during certain months would not have a probability of selection for sampling for that period.

3. *Announced Sampling*
   Once a sample set begins, an establishment is aware that it will be sampled every day the product is being produced over the next few months (or longer for smaller establishments that produce less frequently) until the set is completed. This knowledge might create a bias because establishments may, intentionally or not, be more conscientious in adhering to proper sanitary procedures during this time. This could result in an abnormally low number of positive *Salmonella* results than would occur otherwise, and any prevalence calculation would be underestimated.

4. *Sample Sets*
   Salmonella samples are scheduled in sets, which results in a high degree of clustering. That is, establishments are sampled intensively and then not at all for a period of time. Moreover, with regard to the above analysis of the risk-based sampling algorithm, this is problematic from a process control perspective because there are no available data over a long period for so-called well-performing (Category 1) establishments. Thus, it is unknown whether these establishments are consistently maintaining good process control, or if their good performance was a temporary result of announced sampling.

[38] In June 2006, FSIS began employing a "category" system to measure establishments' *Salmonella* performance due to a change in how the establishments were selected for testing. Category 1 represents establishments that have achieved 50 percent or less of the performance standard or baseline guidance, for two consecutive FSIS test sets. Category 2 represents establishments that have achieved greater than 50 percent on at least one of the two most recent FSIS test sets without exceeding the performance standard or baseline guidance. Category 3 represents establishments that have exceeded the performance standard or baseline guidance on the most recent FSIS test set. FSIS has developed new tightened performance guidance based on results from the year long Nationwide Young Chicken Microbiological Baseline completed in mid- 2008. A Federal Register Notice announcing the new guidance policies was published in May 2010 and the standards were implemented in July 2011 and the "Category 1" performance standard was modified to reflect the new standards.

5. *Production Volume*
   The major difference between the sampling data for intact and ground products is that volume information is not available at the establishment level for ground chicken or ground turkey, and only a rough estimate can be determined for ground beef. This data must be obtained to calculate a prevalence estimate in those product classes.

Conclusion

The *Salmonella* subgroup has determined that calculating an accurate prevalence estimate using the current verification data is **not possible** because certain key elements in the data requirements are not met.

Chapter 4: Ready-To-Eat (RTE) Sampling Program
Pathogen Verification for *Lm* and *Salmonella*

Overview

Calculating an accurate *Lm* or *Salmonella* prevalence estimate using the current RTE testing project verification data it is **not possible** because certain key elements in the data requirements are not being met. Table 6 provides an overview of the data requirements evaluated and the findings of the RTE subgroup in terms of current RTE pathogen verification testing program.

Table 6: Overview of FSIS Findings Regarding Evaluation of Data Requirements of Current RTE Pathogen Verification Testing Projects

Data and Statistical Requirements	**RTE**	
	RTE001	ALLRTE
Population	Yes	**No**
Sampling Frame	Yes	
Collection Frame	**No**	Yes
Enumeration Unit Selection	**No**	Yes
Population Unit Selection	**No**	Yes
Product Type Selection	**No**	Yes
Probability of Selection	**No**	Yes
Production Volume	Yes	**No**
CONCLUSION	**NO**	**NO**

Note: RTE001 and ALLRTE are being considered as separate sampling projects.

Background

FSIS has conducted a regulatory microbiological testing program in RTE meat and poultry products since 1983. From 1983 until 2004, establishments were randomly selected for regulatory samples from different sub-populations or from the total population of establishments producing RTE products.[39] *Lm* has been implicated in illness outbreaks since the early 1980s. In 1987, FSIS increased testing for *Lm* in regulated products, including domestic cooked meat and poultry and imported cooked products.[40] In 1989, after a confirmed human listeriosis case linked to cooked poultry, FSIS identified *Lm* as an adulterant subject to recall if found in commerce.[41] After the implementation of FSIS PR/HACCP regulations in 1996,[42] FSIS organized *Lm* testing around the four HACCP processes of 1) fully cooked, not shelf stable products, 2) heat-treated, shelf stable products, 3) not heat-treated, shelf stable products and 4) products with secondary inhibitors that are not shelf stable. Thus, FSIS began random testing of RTE product samples in the 1990s, while risk-based testing of RTE products for *Lm* began in 2005. Since the inception of the *Lm* verification testing program for RTE meat and poultry products, FSIS has also sampled packaged RTE products for the presence of *Salmonella*.

[39] Please see the following website for more information: http://www.fsis.usda.gov/Science/Micro_Testing_RTE/index.asp.
[40] Federal Register, Volume 52, No. 47, March 11, 1987.
[41] Federal Register Volume 54, No. 98, Tuesday May 23, 1989.
[42] Pathogen Reduction/Hazard Analysis and Critical Control Point System final rule (61 FR 38806, July 25, 1996).

The ALLRTE sampling project for *Lm*, which began in 2004, was designed to obtain random samples across the full range of RTE products and across all establishments producing a RTE product, regardless of risk, with the intention of estimating the prevalence of *Lm*. The risk-based sampling project (RTE001) began in 2005 with the intention of identifying and sampling RTE establishments according to risk as defined by the interim final *Lm* rule (9 CFR 430). Only RTE establishments with exposure of products to the environment subsequent to a lethality treatment (i.e., cooking, fermentation, curing or drying), otherwise known as post-lethality exposure, are sampled in the RTE001 sampling project. An *Lm* risk-ranking algorithm is used to select establishments with the highest risk rankings for risk-based RTE001 sampling each month. Field inspectors are instructed to collect the riskiest RTE product samples produced in the establishment at the time of collection.

Beginning in FY2008, FSIS began using the volume weighted *Lm* percent positive from the RTE001 project as a performance measure RTE001 collects more samples than ALLRTE. The *Lm* percent positive estimate from the ALLRTE project continued to be estimated as before. However, because of the judgmental selection procedure of establishments and products, the estimates derived from the RTE001 data could be biased with respect to the percent positive over all RTE products. Consequently, the decision was made to continue both projects, unchanged from FY2008, for comparative purposes.

Also, beginning in FY2008, FSIS began sampling all establishments in the RTE001 program so that no establishment producing post-lethality exposed RTE products would miss a sample result over single year. This was accomplished by retaining the same sample allocation, but reducing the number of risk-based samples by approximately 25% and allocating the difference to random sampling of establishments not selected for risk-based sampling.

This document presents a brief overview of FSIS RTE sampling projects, specific data requirements for possible prevalence estimation, and a summary of the RTE subgroup's conclusions regarding the suitability of using verification data to estimate prevalence. Sampling projects for *Lm* and *Salmonella* in domestic establishments that produce RTE meat and poultry products are summarized in Table 5. Additionally, an extensive overview of the RTE sampling projects under consideration for generating prevalence estimates, including a discussion of the purpose of each project, sampling properties and methodologies, as well as information about the FSIS collection methodology, mean response rates and analyzed samples is provided in the FSIS Sampling Program Report.[43]

[43] Supra footnote 7.

Table 5: FSIS RTE Domestic Sampling Projects

Product class	RTE Sampling Projects	Pathogens Tested	Number of FY2010 Samples collected	Regulatory Purpose of Sampling Project	Type of Sampling Project
Post-lethality exposed and non-post-lethality exposed RTE products	ALLRTE	*Lm, Salmonella*[44]	2,990	Monitor industry performance	Random
Post-lethality exposed RTE products	RTE001	*Lm, Salmonella*	8,700	Verify non-detectable standard	Risk Based
RLm product samples	RLMPRO	*Lm*	1,960	Monitor industry performance	Risk Based
RLm food contact surface samples	RLMCONT	*Lm*	6,600	Monitor industry performance	Risk Based
RLm non-food contact environ. samples (Composit. 5-sample Units; *Lm*)	RLMENVC	*Lm*	690	Monitor industry performance	Risk Based
Intensified Verification Testing (IVT) product samples	INTPROD	*Lm* or *Salmonella*	225	Response to positive ALLRTE, RTE001, RLMPROD and/or RLMCONT sample	For Cause
IVT food contact surface samples	INTCONT	*Lm* or *Salmonella*	550	Response to positive ALLRTE, RTE001, RLMPROD and/or RLMCONT sample	For Cause
IVT non-food contact environmental samples	INTENV	*Lm* or *Salmonella*	275	Response to positive ALLRTE, RTE001, RLMPROD and/or RLMCONT sample	For Cause

Data Requirements

The following provides a summary of the RTE subgroup's evaluation of the current *Lm* and *Salmonella pathogen* testing projects in light of the data and statistical requirements identified by the DCC Prevalence Workgroup.

Population

Required

The universe of units for which the characteristic of interest is being assessed is required.

[44] In addition to *Lm* and *Salmonella*, testing for *E. coli* O157:H7 was performed for specific product types, notably, dry and semi-dry fermented sausages and fully cooked meat patties until April, 2011. This testing was discontinued after an analysis showed that testing over 10,000 such products for *E. coli* O157:H7 over a nine-year period yielded no positive samples.

Requirement Met?

The population of interest for RTE meat and poultry products is the volume of a certain product produced at non-exempt FSIS regulated establishments. Presently, the individual annual product distributions for such product groups as deli meat, hot dogs, and fermented sausage can be derived from the FSIS Form 10,240-1, which contains product volume data for establishments producing post-lethality exposed RTE products. RTE establishments without these data must use production volume estimates based on HACCP establishment size. However, when PHIS is fully implemented, comparable data needs to be readily available for all RTE establishments. Estimates of inspector generated and certified daily production volumes must be determined for each establishment. In order to estimate prevalence on a per pound product basis, it is necessary to know the number of pounds corresponding to positive results, as well as the total number of pounds produced. The lot size in pounds should provide this information (which also should be inspector-certified). With these data, the selection probabilities for these products can be determined for each establishment. Since it is required that field inspectors report production volumes as predetermined range values, there will likely be increased uncertainty in prevalence estimates performed using PHIS data, as compared to estimates made from FSIS Form 10,240-1 annual point estimates. **Consequently, the requirement is met for the RTE001 project, but not for the ALLRTE project. This is because RTE001 establishments (all those with post-lethality exposure) have production volume data from FSIS Form 10,240-1, whereas ALLRTE establishments with no post-lethality exposed products are not required to report production volume data. However, the requirement will be met for both projects once inspection in all RTE establishments will be able to report production volume data through PHIS.**

Sampling Frame

Required

A listing of all the units in the defined population is required. Alternatively, an aggregated listing of enumeration units can be used, provided that each population unit is associated with only one enumeration unit in the frame. For example, if the population unit is an RTE meat or poultry product, then the list of non-exempt federally inspected establishments that produce RTE products is an appropriate listing of enumeration units. In a multiple stage sampling plan, these establishments will be the primary sampling units in the first sampling stage.

Requirement Met?

The current *Lm* risk ranking algorithm probabilities that encompass listeriosis cases at product consumption can be used as the basis for establishment selection over the entire RTE establishment sampling frame, provided appropriate data are available. Furthermore, within the establishment, second stage random selection of products sampling can be made based on the distribution of products produced.[45] Monthly sampling frames may be combined to make

[45] FSIS defines first stage sampling as including those establishments that are selected for Agency sampling in any given month, while second stage sampling is defined as including those products that are selected within establishments that are selected for Agency sampling.

quarterly and annual prevalence estimates using appropriate statistical models.
Consequently, the requirement is met for both projects, with the understanding that the sampling frame for RTE001 is only for establishments with post-lethality exposure.

Enumeration Unit Selection

Required

The procedure used to select enumeration units (establishments) from the collection frame must be defined. Establishments may be stratified based on a characteristic (e.g. risk, production volume) and then chosen based on an identifiable probability of selection within each stratum. Random unit choice is preferred, but risk-based sampling is acceptable if all selection probabilities can be determined. The enumeration units should come from the population of establishments from which all RTE products are produced.

Requirement Met?

Establishments are currently chosen for *Lm* sampling based on random selection for the ALLRTE and based on risk for the RTE001 project so the selection method is acceptable. However, since the ALLRTE collection frame includes the RTE001 collection frame the enumeration units cannot be the same because RTE001 lacks enumeration units present in ALLRTE which contains all the enumeration units. **Consequently, the requirement is not met for the RTE001 project, but is met for the ALLRTE project.**

Collection Frame

Required

A listing of units in the collection frame is required. This could be the entire sampling frame, or a subset of enumeration units from which samples are selected. The methodology used to set the frame must be defined and statistically valid for a prevalence calculation.

Requirement Met?

Presently, for the risk-based RTE001 sampling project, field inspectors are instructed to collect the riskiest RTE product samples produced in the establishment at the time of collection. These second stage collection procedures within a given establishment will need to be changed, eliminating the judgmental sample selection and implementing random sampling of different products over time, though there could still be some dependence on product risk. The ALLRTE sampling project is already established as a random sampling project. **Consequently, the requirement is not met for the RTE001 project, but is met for the ALLRTE project.**

Population Unit Selection

Required

The procedure used to select population unit(s) from a given enumeration unit must be defined. Day of week and time of day when a sample is collected should be randomly chosen. Clustered samples are acceptable, but effect of clustered choice must be addressed. Announced sampling is not preferred. Announced samples may make clustered choice unacceptable.

Requirement Met?
Current FSIS policy specifies that ALLRTE and RTE001 samples are to be collected individually and independently. **Consequently, this requirement is met for ALLRTE, but not for RTE001 because RTE001 sample selection is risk-based and not random.**

Product Type Selection

Required
The procedure used to select the product type for sampling for a given product category must be defined.

Requirement Met?
There have been seven RTE product categories being used in PBIS for both ALLRTE and RTE001 sampling (deli sliced, deli unsliced, hot dogs, cooked products, fermented products, dried products, salt-cured products, frozen products, and pate/meat spreads). Under PHIS, there are four basic product categories: 1) Acidified/fermented, 2) salt-cured, 3) dried and 4) fully cooked. The first three categories are divided into unsliced and deli sliced product types, for a total of six product types among these three categories. Within the category of fully cooked, there are eight product types:

1. RTE Fully Cooked Hotdog Products
2. RTE Fully Cooked - Other/Unsliced at establishment
3. RTE Fully Cooked - Deli Sliced
4. RTE Fully Cooked Salad/Spread/Pate
5. RTE Fully Cooked Meat and Non-meat Multi-component
6. RTE Fully Cooked Sausage Products
7. RTE Fully Cooked Diced/Shredded
8. RTE Fully Cooked Patties/Nuggets

Thus, there are a total of four PHIS product categories and 14 PHIS product types within those categories that require sampling for *Lm*. Each type of RTE meat and poultry product is sampled separately and consists of only intact packages. **Consequently, the requirement is not met for the RTE001 project (because it is not presently random), but is met for the ALLRTE project.**

Probability of Selection

Required
The probability of selection for each population unit in every enumeration unit must be determined. To do this, every enumeration unit in the collection frame must have some probability of being sampled each sampling period. Probabilities do not have to be equal across enumeration units or over time.

Requirement Met?
In the existing risk-based sampling algorithm, these probabilities cannot be calculated because not all establishments (enumeration units) in the sampling frame including all RTE establishments have a probability of being selected each sampling period (month).

Consequently, the requirement is not met for the RTE001 project, but is met for the ALLRTE project.

Production Volume

Required

Production volume for each enumeration unit for the time period in which prevalence is being calculated is required to estimate prevalence for the population of interest.

Requirement Met?

When changing from FSIS' PBIS data to PHIS, future volume data to be collected for all RTE establishments will need to be converted to annual or monthly total pounds production. Ideally, estimates of actual volume, not a range are needed, but this is not possible because of the proprietary nature of the actual production volumes within each establishment. Thus, future information may not be sufficient for making estimates of prevalence without a high degree of uncertainty. **Consequently, the requirement is met for the RTE001 project, but is not met for the ALLRTE project.**

Analysis of Data Limitations

FSIS believes that it is not possible to use the Agency's RTE sampling program data to estimate a statistically derived national *Lm* prevalence. To accomplish this, certain changes in the selection procedure, particularly for the RTE001 project, are needed. However, certain limitations must be acknowledged:

1) *Sample collection instructions*
   Current sampling instructions to FSIS field personnel influence the types of RTE samples that are collected and therefore the ability to estimate prevalence from current sampling data. Further, the modifications needed to achieve random product sampling, such as instructing field inspectors regarding probability proportional to size sampling.

2) *Announced sampling*
   Establishments are aware that they will be sampled for particular RTE products, which might create a bias because establishments may, intentionally or not, be more conscientious in adhering to proper sanitary procedures during this time. This could result in an abnormally low number of positive *Lm* and/or *Salmonella* results than would occur otherwise, and any prevalence calculation would be underestimated.

3) *Point estimates of actual volume (not a range).* When changing from PBIS data to PHIS the volume data that will be collected for all RTE establishments is in daily volume ranges and not readily convertible to annual, or monthly total pounds production. The information being planned for will not be sufficient for making estimates of prevalence without hard to quantify uncertainty.

Conclusion

The *Lm* RTE subgroup has determined that calculating an accurate prevalence estimate using the current verification data is **not possible** because certain key elements in the data requirements are not met.

Appendix A: Definition of Terms

Data Warehouse: FSIS collects numerous types of data from a variety of different sources. This data is stored in an electronic "warehouse," known as the FSIS Data Warehouse (DW).

Discard Code: When FSIS inspectors are not able to collect a specific sample for a pathogen verification testing project, particular discard codes are used on sampling forms returned to FSIS laboratories indicating when the sample was not collected.

Exclusion Criteria: Exclusion criteria are the standards FSIS uses to determine whether an establishment should be included in the sampling frame. For example, establishments that produce a very low volume of product may be excluded from the sampling frame. Therefore, producing low volume is the exclusion criterion.

Random Sampling: A random sample is one chosen by a method involving an unpredictable component. Random sampling can also refer to taking a number of independent observations from the same probability distribution, without involving any real population.

Replacement: When a sampling unit is drawn from a finite population and is returned to that population, after its characteristic(s) have been recorded, but before the next unit is drawn, the sampling is said to be "with replacement." In the contrary case, the sampling is "without replacement." A different usage occurs in sample surveys when samples are taken on successive occasions. If the same members are used for successive samples there is said to be no replacement; but if some members are retained and others are replaced by new individuals there is said to be "partial replacement".[46]

Risk Based Sampling: A sampling plan in which establishments are sampled at a greater or lesser frequency based on the risk the establishment poses. For example, establishments that have fewer positive pathogen test results might be considered to be low risk and are therefore sampled less frequently than establishments that have more positive pathogen test results.

Percent Positive: The percentage of positive samples is expressed as a percentage, determined as the number of positive samples for the pathogen per the total number of samples tested, multiplied by 100. The expected value of this percentage in this document is called "the percent positive."[47]

Performance Based Sampling: A sampling plan in which establishments are sampled at a greater or lesser frequency based on their performance. For example, establishments that have fewer positive pathogen test results might be considered to be high performers and are therefore sampled less frequently than establishments that have more positive pathogen test results.

Sample Ceiling: The maximum number of samples in a sampling frame.

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[46] Please see the following website for more information: http://stats.oecd.org/glossary/detail.asp?ID=3835.
[47] Please see the following website for more information: http://www.fsis.usda.gov/PDF/Draft_Guidelines_Sampling_Beef_Trimmings_Ecoli.pdf.

Sampling Frame[48]: Sampling frame is the actual set of units from which a sample has been drawn. In the case of a simple random sample, all units from the sampling frame have an equal chance to be drawn and to occur in the sample. In the ideal case, the sampling frame should coincide with the population of interest.

Sample Floor: The minimum number of samples in a sampling frame.

Sample Size: The sample size of a statistical sample is the number of observations that constitute it. It is typically denoted *n*, a positive integer. The sample size is an important feature of any empirical study in which the goal is to make inferences about a population from a sample. In practice, the sample size used in a study is determined based on the cost of data collection, and the need to have sufficient statistical power. In a census, data are collected on the entire population; hence the sample size is equal to the population size. Larger sample sizes lead to increased precision when estimating unknown parameters. For example, to know the proportion of cattle that is infected with a pathogen, a more accurate estimate of this proportion will result from a sample of 200, rather than 100 cattle.

Time Series: A time series is a set of regular, time-ordered observations of a quantitative characteristic of an individual or collective phenomenon taken at successive, in most cases equidistant, periods/points of time. Breaks in statistical time series occur when there is a change in the standards for defining and observing a variable over time. Such changes may the result of a single change or the combination of multiple changes at any one point in time of observation of the variable.[49] For example, changes to the way in which the *E. coli* O157:H7 sampling frame is constructed over time disrupts the time series and makes it difficult to compare results from year to year.

[48] Please see the following website for more information: www.statistics.com.
[49] Please see the following website for more information: http://stats.oecd.org/glossary/search.asp.

Appendix B

***E. coli* O157:H7 Raw Ground Beef (MT43)**

	Required	Available
Population	The universe of units for which the characteristic of interest is being assessed	Estimated annual production volume of raw ground beef in pounds at FSIS inspected establishments.
Sampling Frame	A list of all FSIS inspected establishments that produce raw ground beef	All establishments that produce raw ground beef product (CFR 9) or for whom FSIS has analyzed an MT43 sample in the last 12 months are included in the sampling frame. There is an exclusion list.
Collection Frame	Entire sample frame - perhaps excluding establishments that have a history component (HS=hazard score)	Establishments are chosen based on volume weight and HS. Whether HS is still being used in the algorithm needs to be determined by translating the visual basic code.
Enumeration Unit Selection	Define the procedure used to select enumeration units (establishments) from collection frame. Random selection is preferred. Establishments can be stratified on a characteristic (e.g. risk, production volume) and then chosen randomly within each strata	MT 43 samples selected with replacement from sampling frame by an algorithm employing scaling factors, which act like weights; inputs to calculating the scaling factors are annual production volume group and history of positive tests. Current project has 4 volume groups and algorithm includes sampling ceilings for each volume group. Establishments with a history of + test results will be sampled more frequently.
Population Unit Selection	Define the procedure used to select population unit(s) from a given enumeration unit. Clustered samples are acceptable, but effect of clustered choice must be addressed. Announced sampling is not preferred and may make clustered choice not acceptable.	MT43 sample collection is done by collecting 325 g of raw ground beef. Each establishment is sampled a maximum of 4 times per month.
Product Type Selection	Define the procedure used to select the product type for sampling for a given product class. 100% judgment based selection is not acceptable.	We are only looking at MT 43 raw ground beef sampling.
Collection Date/Time	Day of week and time of day when sample is taken should be randomly chosen	
Other Data	Production volume for each establishment is required.	Production volume is obtained in categories.
Other Factors	Determine the probability of selection for each unit of product for each establishment	The probability of selection may already exist in a column in each Excel sheet containing sampling frames

***Salmonella* Raw Intact Products**

	Required	**Available**
Population	The universe of units for which the characteristic of interest is being assessed.	All carcasses of a certain product class (broilers, turkeys, cow/bull, steer/heifer, and market hog) produced at FSIS regulated establishments.
Sampling Frame	A listing of all the units in the defined population. Alternatively, an aggregated listing of enumeration units provided that each population unit is associated with only one enumeration unit in the frame.	The set of all establishments that produce a given product class during the period of interest.
Collection Frame	This could be the entire sampling frame, or this could be the set of establishments (or other enumeration units) selected for sampling. Define the procedure used to set the frame.	Not all establishments in the sampling frame are included in the collection frame (low volume producers are excluded).
Enumeration Unit Selection	Define the procedure used to select enumeration units (establishments) from the collection frame. Random unit choice is preferred. Establishments can be stratified based on a characteristic (e.g. risk, production volume) and then chosen randomly within each strata.	Establishments are chosen for sampling based on risk. New establishments and those in the highest risk category are selected first.
Population Unit Selection	Define the procedure used to select population unit(s) from a given enumeration unit. Clustered samples are acceptable, but effect of clustered choice must be addressed. Announced sampling is not preferred. Announced samples may make clustered choice not acceptable.	HC01 samples are collected in sets. Once an establishment is chosen for sampling, it is sent 75 sample forms (steer/heifer establishments are sent 90). Field inspectors are instructed to collect one sample per day for each day that the establishment is producing the product being sampled. Only the first 50-56 successfully analyzed samples count towards the overall pass/fail result of the set depending on the product class being sampled. Thus, samples are both clustered and announced.
Product Type Selection	Define the procedure used to select the product type for sampling for a given product class. 100% judgment based selection is not acceptable.	N/A Each class of raw intact product consists of only one type (not parts).
Collection Date/Time	Day of week and time of day when sample is taken should be randomly chosen	Day of the week is not random or varied because once a sample set is started, an establishment knows it will be sampled every day it is producing that product for the next 51-75 days. Field inspectors are instructed to collect samples at varied times of the day.
Other Data	Production volume for each establishment is required.	The eADRS slaughter database contains detailed volume data for each product class at every establishment in the sampling frame. Volume totals are available for any time period (daily, weekly, monthly, yearly, etc.).
Other Factors	Determine the probability of selection for each unit of product for each establishment	TBD

	Required	**Available**
Useful Characteristics (not required)	Interventions being used. HACCP size of establishments (frame/population?). Monthly Production Volume. Daily Production for sample day. Sample Weight. Shift sample collected. Date. Time since last cleanup.	Interventions being used. Yes, likely available in plant profile. HACCP size of establishments. Yes, available in plant profile. Monthly Production Volume. Yes, available in eADRS database. Daily Production for sample day. Yes, available in eADRS database. Sample Weight. No Shift sample collected. No Date. Yes, Available on sample collection form Time since last cleanup. No

***Lm* - ALLRTE and RTE001**

	Required	Available
Population	The universe of units for which the characteristic of interest is being assessed.	The population of interest for RTE meat and poultry products is the volume of a certain product produced at non-exempt FSIS regulated establishments.
Sampling Frame	A listing of all the units in the defined population. Alternatively, an aggregated listing of enumeration units provided that each population unit is associated with only one enumeration unit in the frame.	The sampling frame(s) is (are) composed of the list of non-exempt federally inspected establishments that produce RTE products.
Collection Frame	This could be the entire sampling frame, or this could be the set of establishments (or other enumeration units) selected for sampling. Define the procedure used to set the frame.	Presently, for the risk-based RTE001 sampling project, field inspectors are instructed to collect the riskiest RTE product samples produced in the establishment at the time of collection. The ALLRTE sampling project is already established as a random sampling project.
Enumeration Unit Selection	Define the procedure used to select enumeration units (establishments) from the collection frame. Random unit choice is preferred. Establishments can be stratified based on a characteristic (e.g. risk, production volume) and then chosen randomly within each stratum.	Establishments are currently chosen for *Lm* sampling based both on random selection (ALLRTE) and risk (RTE001).
Population Unit Selection	Define the procedure used to select population unit(s) from a given enumeration unit. Clustered samples are acceptable, but effect of clustered choice must be addressed. Announced sampling is not preferred. Announced samples may make clustered choice not acceptable.	Current policy specifies that ALLRTE and RTE001 samples are to be collected individually and independently.
Product Type Selection	Define the procedure used to select the product type for sampling for a given product class. 100% judgment based selection is not acceptable.	Under PHIS, there are four basic categories: Acidified/fermented, salt-cured, dried and fully cooked. The first 3 categories can each be divided into unsliced and deli sliced product types, for a total of 6 product types among these 3 categories. Within the category of fully cooked, there are eight product types. Thus, there are a total of 4 product categories and 14 product types within those categories that require sampling for *Lm*.
Collection Date/Time	Day of week and time of day when sample is taken should be randomly chosen	For ALLRTE and RTE001, one sample is collected monthly from a given establishment.
Other Data	Production volume for each establishment is required.	Presently the individual product distributions for such product groups as deli meat, hot dogs, and fermented sausage can be derived from the FSIS form 10,240-1 product volume data for establishments producing post-lethality exposed RTE products. RTE establishments without these data must use model estimates based on HACCP establishment size. However, when PHIS is implemented these data need to be readily available for all RTE establishments.
Other Factors	Determine the probability of selection for each unit of product for each establishment	

Appendix C:
Current *Salmonella* Set Sizes by Product

Product	Completed Set Size	Forms Sent to Plant
Broilers	51	75
Cows/Bulls	58	75
Ground Beef	53	75
Ground Chick	53	75
Ground Turkey	53	75
Market Hog	55	75
Steer/Heifers	82	90
Turkeys	56	75

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