Public Health Risk-Based Inspection System
for
Processing and Slaughter

Appendix D – Data Sources

APPENDIX D – DATA SOURCES

This appendix provides descriptions of data available within the Food Safety and Inspection Service (FSIS) to define the parameters for ranking or categorizing establishments. First the relative risk of species/process as determined by the expert elicitation and the production volume data are discussed. Next, information on the public health significant noncompliance reports (NRs), food safety consumer complaints, food safety recalls, enforcement actions, *Salmonella* verification testing, ready-to-eat (RTE) *Listeria (L.) monocytogenes* alternatives, and pathogen testing programs is presented. Descriptions of those data sources are presented in **Table D-1**. When discussing sampling data, this section addresses how representative, based on the sampling plan and the results of sample collection, the incidence of contamination in samples are to the national prevalence of contamination. Other possible parameters that could be investigated for categorizing establishments are then discussed.

RELATIVE RISK OF SPECIES/PROCESS

FSIS used expert elicitations to develop a risk ranking of FSIS regulated products. In 2005, experts were requested to rank the relative risks posed to public health by various types of processed meat and poultry products, including species type. An additional expert elicitation was conducted in 2007 to address issues raised by stakeholders. The following changes were incorporated into the 2007 expert elicitation: the instrument and instructions were peer reviewed; elicitations from an equal number of individuals from public health, academia, and industry were used; information on sensitive populations was requested; attribution estimates were requested; experts were asked to rate their confidence in their estimates; an upper bound for rankings was established; the experts were asked to only consider bacterial hazards, not viral, chemical, or physical hazards, and thermally-processed, commercially sterile (typically canned) products were rated.

Potential Limitations of the Expert Elicitation Data

Expert elicitation is considered an acceptable method for ranking the hazards inherent to a product in the absence of empirical data. There are, however, limitations to such elicitations, many of which are related to the assumptions used in the elicitation. Some of the assumptions, and subsequent limitations, of the 2007 elicitation and its use are discussed below. Further analyses of the elicitation data are presented in Appendix A of this report, in relation to attribution.

The experts were asked to only consider bacterial hazards, not viral, chemical or physical hazards. The exclusion of those hazards could alter the rankings of the product.

35 **Table D-1. Summary of Data Sources**

Data	*Description*	*Comments*
Production Volume	Measure of the amount of product type produced by an establishment within a certain timeframe (e.g., annual average). Data collected in 3 different ways: • inspector-generated volume data from all processing facilities collected through an extension in the Performance Based Inspection System (PBIS); • volume data collected by inspectors when collecting ground beef samples for *Escherichia coli* O157:H7 (*E. coli* O157:H7) verification testing; and • data on RTE product collected through a survey approved by the Office of Management and Budget (OMB).	Criticized by stakeholders, stating that the FSIS inspection force is not able to precisely collect the information; no analysis to indicate that. Annual production volume collected from industry on Form 10,240-1 might miss seasonal variations.
NRs	Results of thousands of inspection procedures each day to determine whether or not inspected establishments are in compliance with regulatory requirements. Each time inspection program personnel make a noncompliance determination, they complete a report explaining the nature of the regulatory action (an NR) and inform the establishment management. Once issued, an establishment must take action to remedy the situation and should take measures to prevent its recurrence.	Criticized by stakeholders for potential inconsistency in the issuance of NRs nationwide; no analysis to indicate that. Impact of appeals.
Consumer Complaints	Any complaint reported to FSIS that is initiated by a consumer, or on behalf of a consumer, that is related to an FSIS-inspected product. Consumer complaints associated with consumption of a meat, poultry, or egg product involve: • an illness that occurred after eating; • an injury that occurred during eating; • foreign object/material; • an allergic reaction; • under processing of a RTE product; • misbranding, improper labeling; • economic adulteration; or • inferior quality of products.	Designed as a surveillance system, not to assign blame or pinpoint loss of process control. Not every consumer complaint is of public health significance. Passive system could lead to under-reporting. Lacks complete and accurate attribution data or "traceback" information due, in part, to the difficulties that consumers have in tracing illness to food sources. Illnesses could result from circumstances outside control of inspected establishment (post-production temperature abuse, subsequent contamination through mishandling or further processing). There may be a significant lag time (perhaps even several months) between when product is purchased and when a consumer makes a complaint. Could be an "isolated" incident. Reporting may be influenced by factors not directly related to a product's safety (e.g., size and scope of product distribution, behavioral factors, and consumer expectations or perceptions). Bias could be observed after major product recalls.
Food Safety Recalls	Voluntary action by a manufacturer or distributor to protect the public from products that may cause health problems or possible death, sometimes done at the request of FSIS. Classified by FSIS based on the relative health risk:	Does not capture every time there is a food safety system failure in an establishment—the fact that an establishment has not been linked to a recall is not evidence that it has not produced and shipped contaminated product. Once a recall is initiated, information about the recall is tracked in a very timely manner by FSIS, and there may be a

Data	*Description*	*Comments*
	• **Class I** - A Class I recall involves a health hazard situation in which there is a *reasonable* probability that eating the food will cause health problems or death. • **Class II** - A Class II recall involves a potential health hazard situation in which there is a *remote* probability of adverse health consequences from eating the food. • **Class III** - A Class III recall involves a situation in which eating the food will not cause adverse health consequences.	significant lag time (possibly a couple of months) between when product is distributed and when it is determined that a recall is necessary.
Enforcement Actions	Variety of enforcement actions the Agency can take against establishments that fail to sufficiently comply with applicable regulatory requirements. Could be related to either food safety or non-food safety issues, but all enforcement actions probably indicate a need for closer inspection by the Agency. Types of enforcement actions include. Notice of Intent to Enforce (NOIE) Under Deferral; NOIE; Suspension Held in Abeyance; Reinstatement Held in Abeyance; Suspension, Inspection Under Consent; Inspection Under Consent Order; Reinstatement of Suspension; and Complaint to Withdraw Inspection.	Criticized by stakeholders stating that inconsistencies may occur in the issuance of enforcement actions across FSIS regions and personnel; no analysis to indicate that.
Salmonella Verification Testing	Sample sets are collected and analyzed (number of days of sampling varies by product type). Initially, seven product classes were subject to sampling: three ground products (beef, chicken, and turkey) and four carcass classes (young chickens; market hogs; steers/heifers, i.e., younger cattle; and cows/bulls, i.e., older cattle). In 2006, young turkey carcasses were added to the product classes that undergo *Salmonella* testing. Establishments are placed into one of three categories based on the results of the *Salmonella* sets.	Sampling design and guidelines limit the use of the data to determine national prevalence rates of *Salmonella* in FSIS-regulated products, especially because the sampling is random and does not take into account production volume. Current FSIS procedures allow only one product to be tested at a time per establishment. Time needed to complete a S*almonella* set could range from 2 months to more than a year (e.g., in low-volume establishments) Only one product is tested at a time in an establishment, some products in an establishment that produces multiple projects subject to *Salmonella* verification could go untested for several years. Does not take into account post-retail consumer habits (different typical ways of cooking different products). Exotic and minor species, such as lamb, goats, sows/boars, quail, squab, ratites, buffalo, and egg-laying hens, are not currently tested in *Salmonella* sets by FSIS.
L. monocytogenes Alternative for RTE Product	Regulatory requirements for RTE products that have been exposed to the environment after a lethality step (i.e., post-lethality) include requiring establishments producing post-lethality exposed RTE meat and poultry products to adopt one of several options, called alternatives, to reduce the incidence of *L. monocytogenes.* The *L. monocytogenes* alternative categories are as follows: **Alternative 1** - Establishments that apply <u>both</u> a post-lethality treatment to the RTE product to reduce or eliminate microorganisms on product *and* the use of an antimicrobial agent or process	Not all of the establishments regulated under the Interim Final Rule to Control *L. monocytogenes* have submitted Form 10,240-1. Thus, this data element is not captured in the algorithm, and the level of inspection calculated for these plants would not consider how well the establishment controls the risk associated with *L. monocytogenes* in RTE products (probably fewer than 212 establishments). Currently, FSIS does not verify accuracy of the information, including the alternative, submitted by a regulated establishment.

Data	*Description*	*Comments*
	as part of the product formulation. **Alternative 2** - Establishments that apply either: Alternative 2A - A post-lethality treatment to limit the growth of *L. monocytogenes* on the product, *or* Alternative 2B - An antimicrobial agent or process as part of the formulation. **Alternative 3** - Establishments that rely only on testing and sanitation measures.	
Zero Tolerance Pathogen Testing Program		
Microbiological Testing Program for *E. coli* O157:H7 in Raw Ground Beef	Microbiological testing program to detect *E. coli* O157:H7 in raw ground beef. In 2007, added routine and follow-up sampling of raw ground beef components (e.g., beef trim). *E. coli* O157:H7 is a zero tolerance pathogen, therefore, when a sample is found to be positive for *E. coli* O157:H7, the product is deemed adulterated. When a positive sample is from a federally-inspected establishment, inspection program personnel issue an NR, conduct follow-up sampling, and verify that the establishment implements corrective actions as described in their Hazard Analysis and Critical; Control Points (HACCP) plan, prerequisite programs, or sanitation standard operating procedures (SSOPs).	Regulatory program has not been designed to test for statistically significant changes in the national prevalence of *E. coli* O157:H7; changes from year to year and even within a year must be interpreted with caution, especially because the sampling plan prior to 2008 did not take production volume into consideration. In 2006, 11,626 samples of raw ground beef were collected and analyzed from approximately 1,400 federally inspected establishments. As sampling occurs on a random basis, this indicates that most establishments were subject to testing about 8 times during the year. It is unlikely that all ground beef is contaminated at the same percent positive rate. The rate might vary depending on the frequency (and number) of positives in the raw materials (e.g., beef trim), which in turn depends on the "on farm" practices and the hygienic practices used at slaughter and during preparation of the raw materials. As with all FSIS sampling programs, there is 'drop out' of *E. coli* O157:H7 samples (scheduled but not analyzed for a number of reasons, e.g., product scheduled to be sampled at a given establishment is not being made at that point in time, or samples are damaged or lost during shipment to the FSIS laboratory). The FSIS anticipates that not all samples requested will be received and analyzed, so the agency plans for the drop off when determining its plan and schedules extra samples accordingly. A difference between the number of samples planned and analyzed, however, could affect the randomness of the data collection if the drop-off occurred more in one type of establishment or one location.
Ready-to-eat Pathogen Testing Program Results	Regulatory microbiological testing program on RTE meat and poultry products. Certain RTE products are tested for *L. monocytogenes*, *Salmonella* species, and *E. coli* O157:H7 as part of that program.	Need to consider which pathogen test results to use; e.g., for *L. monocytogenes* could be from a variety of sampling projects including ALLRTE, RTE001, RLMPROD, RLMCONT, INTPROD (intensified testing of RTE product), and INTCONT (intensified testing of RTE food contract surfaces). Laboratory procedure that is followed to test RTE*:* under current procedures, FSIS collects one 25-gram sample for analysis, but U.S. Food and Drug Administration (FDA) and some international agencies collect two 25-gram samples for regulatory analysis of RTE products. Question of whether contamination by an organism such as *L. monocytogenes* (and other pathogens such as *E. coli* O157:H7 and *Salmonella*) is uniformly distributed within and among lots of meat and poultry products. Especially problematic for pathogens, such as *L. monocytogenes*, that

Data	*Description*	*Comments*
		are present at very low levels. Data, other than for RLm program, are collected based on an establishment basis, rather than being representative of the volume of RTE products that are produced, which could limit the applicability of the data for determining national prevalence. RTE data are from regulatory testing programs that change from year to year, and possibly even within a year, and therefore any comparisons should be made with caution. A large number of samples have been tested in the RTE testing program, but fortunately few samples have been positive for *Salmonella*, and *L. monocytogenes* and none have been positive for *E. coli* O157:H7.

It was assumed that the product was produced in an FSIS-regulated establishment that operates under SSOPs and a HACCP system, that the product reaches the consumer without further processing, and that the establishment food safety controls are typical. Those assumptions, especially that food safety controls are typical, could result in products which might rank high if food safety control failures were considered, ranking lower.

Raw products for processing were assumed to have come from a slaughter plant, trim producer, grinder, or other firm with average or typical food safety controls. Once purchased, consumer handling of the product is assumed to be typical (which could be safe handling or mishandling). Raw products are assumed to be cooked prior to consumption, and none of the products are irradiated. Once again, the use of the typical establishments and handling of product could downplay the hazards of products that might be of greater concern in the case of a failure of food safety controls.

Unless otherwise stated, RTE products are assumed to be exposed to the environment post-lethality treatment (e.g., the product is sliced, thereby being exposed to the air, after it has undergone a lethality treatment, such as cooking), to not contain an *L. monocytogenes* growth inhibitor, and to not receive any post-lethality treatment to destroy *L. monocytogenes*. Those assumptions for RTE products could result in them ranking higher than they otherwise would.

Expert elicitations are subjective in nature, which could add uncertainty. The 2007 elicitation attempted to semi-quantify that uncertainty by capturing each expert's certainty in their rankings. In addition, the variability across raters within an elicitation, and between the rankings in the 2005 and 2007 elicitation, can also indicate the uncertainty. In general, there was variability in the absolute ratings across experts for some products, although the relative rankings were fairly consistent, both within each elicitation and between the 2005 and 2007 rankings.

Another limitation in the use of the expert elicitation is that it had not yet been interpreted in the context of existing data on food safety hazards. Analyses of it in the context of outbreak data, however, are presented in Appendix A.

PRODUCTION VOLUME

Production volume is a measure of the amount of product type produced by an establishment within a certain timeframe (e.g., annual average). The FSIS has data on production volume from a number of sources, including inspector-generated volume data from all processing facilities collected through an extension in the PBIS, volume data collected by inspectors when collecting ground beef samples for *E. coli* O157:H7 verification testing, and data on RTE product collected through an survey approved by OMB. These three datasets are discussed below.

PBIS Extension Data

In September 2006, FSIS inspection personnel began collecting volume data using an extension of the PBIS database. Data was collected for 19 product classes. The inspectors determined approximately how many pounds of finished product are typically produced and shipped by the establishment in a day across all shifts, and how many days in the last 30 days this product was produced. The inspector then input that information into PBIS by filling out, for each product class (type), a menu of ranges for the pounds produced and/or shipped and days for each product class (type).

Production Volumes Associated with Ground Beef Samples

Inspectors also collect volume data as part of its ground beef sampling program. When an inspector takes a ground beef sample for *E. coli* O157:H7 testing, the inspector is instructed to provide daily ground beef production volume at the establishment in the following ranges:

> 250,000 pounds ground beef,

> 50,000 to 250,000 pounds ground beef,

1,000 to 50,000 pounds ground beef,

< 1,000 pounds ground beef.

RTE Production Volume Data

In October 2003, FSIS issued 9 *Code of Federal Regulations* (CFR) 430, the Interim Final Rule to Control *L. Monocytogenes* in Certain RTE Meat and Poultry Products. The Interim Final Rule set out the regulatory requirements for RTE products that have been exposed to the environment after a lethality step (i.e., post-lethality). As part of the requirements, industry provides volume data for *L. monocytogenes* post-lethality-exposed RTE meat and poultry products. The information is updated annually if there is a significant change in volume of production. In 2007, all facilities were required to complete a new form, updating the volume information. The volume information collected on the form (FSIS Form 10,240-1) is the annual production volume, in pounds, of nine different RTE products.

Potential Limitations of the Data

The production volume data collected by FSIS' inspection force has been criticized by stakeholders, stating that the FSIS inspection force is not able to precisely collect the

information. FSIS is currently exploring methods to collect the data more precisely, and is taking the precision of the data into account when determining how to allocate resources.

The annual production volume collected from industry on Form 10,240-1 might miss seasonal variations.

The different collection methods discussed above use different categories of product type and different timeframes for estimation, making comparisons difficult.

PUBLIC HEALTH SIGNIFICANT NRS

FSIS inspection personnel perform thousands of inspection procedures each day to determine whether or not inspected establishments are in compliance with regulatory requirements. Each time inspection program personnel make a noncompliance determination they complete a report explaining the nature of the regulatory action (an NR) and inform the establishment management. Once issued, an establishment must take action to remedy the situation and should take measures to prevent its recurrence. Some NRs indicate how consistently (or inconsistently) some establishments control food safety risks, whereas others cite non-food safety requirements (e.g., standard of identity, moisture content, etc.). Others document noncompliance with recordkeeping.

When inspection personnel document an NR for a procedure, they cite one or more pertinent regulatory requirements from a list of over 500 in the PBIS. High rates of noncompliance or certain patterns of noncompliance or even certain individual's instances or types of noncompliance are suggestive of an establishment's losing-or actual loss of adequate food safety system process control. While all NRs are documented, FSIS believes that some NRs are more indicative than others of a loss of process control and thus food safety risk. One way the agency is determining what types of NRs may be more predictive of adverse outcomes is by ranking NRs. Ranking of NRs based upon their significance to adverse public health outcomes was performed by nine FSIS subject matter experts using four categories. Each expert had a diverse background of work with related regulatory experience in the meat, poultry, and egg products industries. The four categories and their definitions are presented in **Figure D-1**.

Figure D-1. Definitions of the Four Categories Used for Characterizing How Related an NR is to Public Health

Category 3

Category 3 regulations are provisions of 9 CFR that, if in noncompliance, indicate a definite loss of the food safety system's process control. The loss of process control may not prevent adulterated product from entering commerce. Such conditions include an establishment failing to implement documented features of their HACCP or prerequisite system, or failing to meet explicit regulatory requirements, including corrective action requirements.

Examples: 416.15(a), "Appropriate Corrective Actions" and 417.3(a) "Corrective Action After Deviation from CCP."

Category 2

Category 2 regulations are provisions of 9 CFR that, if in noncompliance, indicate reasonable probability of a loss of the food safety system process control.

Examples: 416.13(a), "Conduct Pre-op Procedures" and 416.14, "Evaluate Effectiveness of SSOP's & Maintain Plan."

Category 1

Category 1 regulations are provisions of 9 CFR that, if in noncompliance, indicate remote probability of a loss of the food safety system process control.

Examples: 416.2 (a), "Establishment Grounds and Facilities" and 416.2 (b)(1), "Sound Construction, Good Repair & Sufficient Size."

Category Zero (0)

Conditions present that do not comply with 9 CFR regulations and that are not classed as category 1, 2 or 3. Conditions considered noncompliant with non-food safety regulatory requirements and that will not cause adverse health consequences. Examples: Product standards of identity in 319.15(a), "Chopped Beef, Ground Beef" and 319.307, "Spaghetti Sauce with Meat."

Potential Limitations of the Data

- One of the issues surrounding the issuance of NRs in the field is inconsistency—the issuance of NRs could vary nationwide. Risk based inspections (RBI) stakeholders (Resolve 2006) have made the criticism that NRs are highly subjective and fundamentally flawed due to the inconsistent application and interpretation of existing requirements.
  - One underlying factor for the inconsistency could be vacancy rates of inspectors in Districts. The rate of NR issuances may be reduced and narrowed due to fewer inspector resources.
  - There could also be an increase in the issuance of a particular NR following the release of a Directive or Notice for a particular regulation associated with an NR due to increased awareness.
- Stakeholders have commented that there could also be potential food safety issues occurring at a plant that may on occasion not be written in an NR because FSIS personnel do not recognize them as a noncompliance. The FSIS conducts ongoing training of its inspection force to limit such events.

- Another potential issue or limitation in the NR data that needs to be examined is the impact of appeals. Due process permits an establishment to file an appeal to an NR. If the appeal is granted, then the NR is rescinded and releases the establishment from the corrective action. However, if an NR is issued and the establishment exhibits a corrective action, the NR is not rescinded unless an appeal is granted. How those appeals should be accounted for when ranking or categorizing establishments should be examined.

CONSUMER COMPLAINTS

FSIS uses consumer complaints to help identify unsafe or inferior quality meat, poultry, and egg products in commerce that may have to be removed from commerce. A consumer complaint is any complaint reported to FSIS that is initiated by a consumer, or on behalf of a consumer, that is related to an FSIS-inspected product. This includes consumer complaints reported to FSIS by a State or local health department or another Federal agency, such as the Food and Nutrition Service (FNS), the Agricultural Marketing Services (AMS), or the FDA. Complaint reports are submitted directly to FSIS by either calling the FSIS 1-800 Meat and Poultry Hotline, FSIS field offices, or the FSIS 24-hour emergency number (1-866-395-9701).

Consumer complaints associated with consumption of a meat, poultry, or egg product involve:

- an illness that occurred after eating;
- an injury that occurred during eating;
- foreign object/material;
- an allergic reaction;
- under processing of an RTE product;
- misbranding, improper labeling;
- economic adulteration; or
- inferior quality of products.

The FSIS Consumer Complaint Monitoring System (CCMS) is an electronic database used to record, triage, coordinate, and track all national consumer complaints about meat or poultry products reported to the agency. It is a passive surveillance system used to facilitate the identification of possible food hazards and the ensuing investigations. With the exceptions of those noted in **Figure D-2**, all consumer complaints reported to FSIS are entered into the CCMS.

After complaints have been entered into the CCMS, FSIS CCMS staff triage the complaints to determine whether the agency should take any additional action in response to the complaint. If not, the case is closed at that point (Note: All consumer complaints are eventually closed). When staff determines that a complaint should be further investigated, they contact the relevant FSIS Office of Field Operations (OFO) District Office and request an investigation. If a complaint is

investigated, OFO District personnel manage the investigation with the CCMS staff providing technical guidance and scientific direction when needed. Product samples may be analyzed by an FSIS laboratory as part of the investigation. The establishment is informed of the results of a consumer complaint investigation, and FSIS documents any responses taken by the establishment in response to the complaint; in some instances, no action by the establishment may be an appropriate response. If the complaint appears to involve a food safety hazard, the CCMS staff will recommend that an OFO Enforcement Investigations and Analysis Officer (EIAO) collect additional information regarding the complaint and evaluate the establishment identified in the complaint. Complaints are categorized in the database by their type as listed above. As further discussed below, not all consumer complaints may have public health significance. For example, a case of mislabeling of a product may not give rise to a public health concern. As detailed below, the majority of complaints received by FSIS are for foreign objects (e.g., extraneous materials, and bone fragments).

Consumer Complaint Frequency

Between 2001, when the CCMS was started, and the end of 2006, there were approximately 5,000 complaints entered into CCMS. In 2006, there were 982 consumer complaints added to the CCMS database. Of these, the majority, 499, (51 percent) were related to foreign object complaints; 149 were related to illness; 19 to economic adulteration; 17 to misbranding; 16 to allergic reaction; 7 to injury; and 81 were classified as other. The breakdown of complaint types for 2004 and 2005 is very similar to those for 2006.

Figure D-2. Consumer Complaints Not Captured in CCMS

Complaints that are not initiated by consumers or by someone on behalf of a consumer, and complaints that do not involve FSIS regulated products, do not meet the FSIS definition of a consumer complaint and are not entered into the CCMS. Examples of complaints that are not captured (entered) by FSIS in the CCMS include:

- Complaints regarding misconduct, waste, fraud, or abuse reported by a whistleblower.
- Complaints involving possible criminal violations of the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), or the EPIA.
- Complaints reported by an industry competitor.
- Complaints regarding food supplied through the USDA's FNS nutrition assistance programs (e.g., National School Lunch Program), unless they involve an FSIS-inspected product.
- Complaints concerning retail-prepared products. These complaints are directed to the appropriate local agency or state agency.
- Complaints that indicate possible product tampering. If criminal conduct is ruled out, OPEER/CID will notify the FSIS CCMS staff, and the complaint will be entered into the CCMS.

Potential Limitations in the Consumer Complaint Data

Consumer complaints potentially serve as indicators of an establishment's ability to maintain an effective food safety system. The reporting of consumer complaints, however, is influenced by an array of factors—both objective and subjective—and, therefore, there are a number of considerations for determining the use of this data within the framework of risk-based inspection. Limitations and uncertainties that may be associated with the use of consumer complaint data in measuring an establishment's risk control, and hence its level of inspection, are discussed below.

An important limitation of FSIS consumer complaint data is related to the use for which FSIS consumer complaint monitoring system was designed. The FSIS consumer complaint monitoring was not designed to assign blame or pinpoint losses of process control; rather it was designed as a surveillance system to alert FSIS and establishment personnel that there have been reports of incidents, and that something may be happening with regards to regulated products that might benefit from evaluation.

As previously discussed, not every consumer complaint is of public health significance. Complaints pertaining to economic adulteration (e.g., product allegedly has too much water weight) or aesthetic quality issues would be examples of complaints that have little value as risk indicators. Therefore, a complaint could really only be considered relevant to establishment rankings or categorization if it attributes to FSIS-inspected product a problem which is of possible consequence to human health. Such reports would include allegations of illness, allergic reactions, or hazardous foreign material (a foreign object is considered hazardous if there is a high likelihood that it could cause significant injury or choking).

Another limitation of the database is the incompleteness of the complaint data relative to the total number of foodborne illnesses in the United States, due to under-reporting of consumer complaints to FSIS. The FSIS consumer monitoring system is passive, therefore, a large number of illnesses might never be captured because consumers do not contact FSIS. Often consumers will complain directly to the company that manufactured a product, especially if the firm has a toll-free consumer complaint hot line, rather than to FSIS. This is directly related to consumer behavior, such as the expectation of receiving compensation from the company for making a complaint. Even more frequently, consumers may fall ill from food consumption, but will not make a complaint or not link their illness to food consumption. In 1999, Centers for Disease Control and Prevention (CDC) estimated that foodborne diseases caused approximately 76 million illnesses in the United States, yet there have been less than 6,000 consumer complaints reported to FSIS over the past 6 years.

FSIS consumer complaint data also lacks complete and accurate attribution data[1] or "traceback" information. This lack of data is due, in part, to the difficulties that consumers have in tracing illness to food sources. Food attribution data is required in order to link illnesses with specific food products.

In addition, illnesses could result from circumstances outside the control of the inspected establishment, such as post-production temperature abuse, subsequent contamination through mishandling, or further processing after the product has left the establishment. Research

[1] *Attribution data has been identified by nearly all RBI stakeholders as a critical need for implementing a successful RBI system.*

suggests that these later factors are more likely to be the root cause of such illnesses than establishment process controls.

Once reported, information on consumer complaints is tracked in a timely manner by FSIS. However, there may be a significant lag time (perhaps even several months) between when product is purchased and when a consumer makes a complaint. A review of CCMS records indicates that where product purchase date is know, there was a 3-to-4 week delay, on average, between purchase and reporting of the complaint to FSIS. Also, if FSIS determines that additional investigation is warranted, this adds time before a final record of details of the incident are added into the database, and subsequently before a determination of the potential public health risk of a complaint would be complete.

Depending on the allegation of a complaint, product-specific factors can be important considerations when determining the significance of a consumer complaint and its relationship to in-plant hazard control. Not all product types are equal in terms of consumer risk, and some product types are associated with hazards that are subject to less establishment control than are other products. For example, a report of illness attributed to an RTE product points more strongly to possible establishment failures than does a report of illness involving a raw product. This is because proper cooking is most critical to ensuring a safe product, and with raw product, this step takes place outside of the establishment.

A consumer complaint can be an "isolated" incident in that there are no other similar, independent reports involving product from the same establishment. The fact that a complaint is isolated cannot be dismissed as a possible indication of a public health related issue, but multiple similar complaints, linked by time, which point to product from the same establishment, can be viewed as greater evidence that a problem which could potentially affect many consumers has arisen from an establishment. Inspector-generated NRs could also be used to establish whether there is evidence of a possible relationship between a complaint and an establishment's food safety system. For example, the significance of a complaint involving allegations of product contamination with metal increases if an inspector has recently cited the identified establishment for metallic debris on a pre-operational food-contact surface. An establishment's NR history, therefore, is an additional consideration when determining which consumer complaints have value in risk-based inspection. Laboratory tests can also confirm an illness and link a complaint to an establishment.

The reporting of consumer complaints may be influenced by a number of factors, many of which are not directly related to a product's safety. These factors include the size and scope of product distribution, behavioral factors, and circumstances that influence the chances that an actual report will be made, for example consumer expectations or perceptions. When these factors affect the reporting of complaints in ways that affect some establishments and product types/brands more so than others, comparisons using consumer complaint data will be biased.

Bias is commonly observed after major product recalls involving pathogen adulteration. Consumers are more likely to attribute illnesses to products after hearing that they have been recalled, simply because of negative perception and heightened concerns. As a result, there will be an increase in complaint reporting for those products. Because of this limitation, caution should always be exercised when consumer complaints are used to draw conclusions about one establishment's food safety system relative to other establishments.

FOOD SAFETY RECALLS

A food recall is a voluntary action by a manufacturer or distributor to protect the public from products that may cause health problems or possible death. A recall is intended to remove food products from commerce when there is reason to believe the products may be adulterated or misbranded.

While recalls are initiated by the manufacturer or distributor, this is sometimes done at the request of FSIS. If a company refuses to recall its products, then FSIS has the legal authority to detain and seize those products in commerce. In almost all cases where FSIS recommends that a company initiate a recall, the company complies.

Recalls are classified by FSIS based on the relative health risk, as follows:

Class I - A Class I recall involves a health hazard situation in which there is a *reasonable* probability that eating the food will cause health problems or death.

Class II - A Class II recall involves a potential health hazard situation in which there is a *remote* probability of adverse health consequences from eating the food.

Class III - A Class III recall involves a situation in which eating the food will not cause adverse health consequences.

To ensure that a recall is effective, FSIS conducts "effectiveness checks" on whether the recalling firm makes all reasonable efforts to notify the consignees of the recalled product that there is a need to remove the product from commerce.

Recall Frequency

In 2006, there were 34 recalls of FSIS-regulated products. Of these, the majority (26) were Class I recalls; 6 were Class II recalls; and 2 were Class 3 recalls. None of these recalls occurred at the same establishment; it is rare for a recall to occur at the same establishment within a 6-month, 1-year, or even longer period.

More recently, in the 6 month period between December 1, 2006, and May 31, 2007, there were 25 recalls. Of these, 20 were Class I; 3 were Class 2; and 2 were Class 3 recalls. None of these recalls occurred at the same establishment.

Potential Limitations of Recall Data

The limitations and uncertainties that may be associated with the use of recall data in measuring an establishment's risk control and, therefore, its level of inspection, are discussed below.

As with consumer complaints, recall data does not capture every time there is a food safety system failure in an establishment. Therefore, the fact that an establishment has **not** been linked to a recall is not evidence that it has not produced and shipped contaminated product.

Once a recall is initiated, information about the recall is tracked in a very timely manner by FSIS, and is readily accessible to analysts who may use the data in the determination of an RCM

score. There may be a significant lag time (possibly a couple of months), however, between when product is distributed and when it is determined that a recall is necessary.

ENFORCEMENT ACTIONS

There are a variety of enforcement actions the Agency can take against establishments that fail to sufficiently comply with applicable regulatory requirements. Those enforcement actions could be related to either food safety or non-food safety issues, but all enforcement actions probably indicate a need for closer inspection by the Agency. Industry and individuals have due diligence to appeal enforcement actions. An extended period of time might be necessary to resolve an enforcement issue. The types of enforcement actions that were proposed in 2006 for use in RBI are as follows: NOIE Under Deferral; NOIE; Suspension Held in Abeyance; Reinstatement Held in Abeyance; Suspension, Inspection Under Consent; Inspection Under Consent Order; Reinstatement of Suspension; and Complaint to Withdraw Inspection. Definitions of those categories are presented in **Figure D-3**.

Potential Limitations in Enforcement Action Data

When using the data to categorize or rank establishments, the following potential limitations and uncertainties in enforcement action data should be examined to see if they exist and whether or how, if they exist, they would impact a ranking or categorization:

- The previously proposed RBI algorithm would not reflect whether there were multiple reasons underlying the enforcement action.

- Concern has been raised by stakeholders in public meetings regarding inconsistencies in the issuance of enforcement actions that may occur across FSIS regions and personnel. The FSIS has a number of controls, including detailed directives and notices, and training to guide enforcement actions, and management controls such as AssuranceNet to monitor field activities and help ensure that its actions are consistent nationwide. There is no data that FSIS is aware of that indicates that this has occurred, but FSIS will analyze its inspection data further to determine if any such inconsistencies occur in different areas of the country or in particular Districts. It also continues to reinforce to its field personnel the importance of issuing enforcement actions in a consistent manner.

Not all enforcement actions are equally related to immediate food safety concerns. Some enforcement actions may result from administrative procedures or be related more to food wholesomeness than food safety. Therefore, if using enforcement actions for risk-based inspection to better protect public health, consideration should be given to ranking them based on how related they are to food safety concerns.

Figure D-3. Definitions of Enforcement Action Categories

Notice of Intent of Enforcement (NOIE) Under Deferral

"Deferral or Abeyance" Stage of Enforcement Stage where the NOIE has been issued and the establishment adequately responded to FSIS. Thus, suspension then temporarily does not go into effect, allowing the establishment to operate and demonstrate the effectiveness of their response.

NOTE

"Enforcement" Stage where the food safety system is not effective and there is a public health food safety concern, and an enforcement action is recommended and issued. This has not resulted in actual shipment of adulterated products. This is issued by the Inspector-In-Charge when it has been established that the establishment has had multiple, recurring noncompliance, or the establishment has failed to implement adequate corrective and preventative measures. The Notice informs the establishment of the nature and scope of the noncompliance and that FSIS intends to withhold the marks of inspection or suspend the assignment of inspectors. The Notice explains the basis and references the documentation for the intended enforcement action, and provides the establishment three (3) business days to contest the basis for the proposed enforcement action or to demonstrate how compliance will be achieved.

Suspension Held in Abeyance

"Deferral or Abeyance" Stage of Enforcement Stage where the establishment is placed under suspension in effect and has adequately responded to agency concerns by corrections are presented to FSIS. The suspension is then temporarily lifted (abeyance) while the establishment demonstrates the effectiveness of their response by implementing and effectively preventing additional problems.

Reinstatement Held in Abeyance

"Deferral or Abeyance" Stage of Enforcement Stage where the establishment is under suspension held in abeyance and FSIS verification results lead to the conclusion that the response is not effective and the suspension is reinstated.

Suspension

"Enforcement" Stage. There are two types of suspensions: suspension of inspection with prior notification and suspension of inspection without prior notification. Giving the suspension with prior notification allows the establishment to respond the Agency's concerns before the suspension goes into effect and provides them due process. The FSIS may temporarily suspend the assignment of inspectors if an establishment fails to prevent preparation and shipment of adulterated products, fails to present a corrective action to bring the establishment's sanitation or process control systems into compliance, or for other reasons. A suspension may shut down all or part of an establishment's operations.

Inspection under Consent Order

The PPIA and the FMIA authorize the Secretary to refuse to provide or withdraw inspection service if the recipient of inspection, the applicant requesting inspection, or anyone responsibly connected with either has been convicted in any Federal or State court of any felony or more than one violation of any law, other than a felony, based on transactions in food. The Acts also authorize the Secretary to withdraw inspection or suspend the assignment of personnel for other reasons, such as for insanitary conditions. In lieu of withdrawing or denying inspection services, both parties can agree to the provisions and conditions of a Stipulation and Consent Decision (Consent), which settles the administrative action.

Reinstatement of Suspension

"Legal" Stage where a complaint to withdraw inspection has been filed by FSIS (i.e., permanently revoke Grant of Inspection, which allows establishment to operate under Federal inspection) and the establishment has appealed the decision and the appeal was denied.

Complaint to Withdraw Inspection

"Legal" Stage where the Agency files a complaint with the USDA Hearing Clerk for withdrawal of inspection (i.e., permanently revoke Grant of Inspection, which allows establishment to operate under Federal inspection). The establishment may request a hearing with an Administrative Law Judge. If the action is based on insanitation, then the establishment will remained closed while proceedings go forward. In cases where there is no direct threat to public health, operations may continue. These actions may be resolved by FSIS and the establishment entering into a consent decision, which allows the establishment to operate under certain conditions. Once an establishment's inspection has been withdrawn, a closed establishment must reapply to receive Federal inspection.

Salmonella **Verification Testing**

As part of its *Pathogen Reduction: Hazard Analysis and Critical Control Point (PR/HACCP)* rule, FSIS set *Salmonella* performance standards that slaughter establishments and establishments that produce raw ground products should meet. In 1998, as part of its regulatory program, FSIS launched its *Salmonella* verification testing program to monitor the effectiveness of its PR/HACCP rule and to assess process control in individual establishments. The program also provides feedback to stimulate industry action to reduce human exposure to *Salmonella* in raw meat and poultry. Initially, seven product classes were subject to sampling: three ground products (beef, chicken, and turkey), and four carcass classes (young chickens; market hogs; steers/heifers, i.e., younger cattle; and cows/bulls, i.e., older cattle). In 2006, young turkey carcasses were added to the product classes that undergo *Salmonella* testing.

In this section, the *Salmonella* standards that are based on the *Salmonella* verification testing are discussed, followed by the sampling plan and sample collection protocol. Available information on *Salmonella* serotyping and subtyping are then discussed, followed by the results of the testing program and available prevalence information. How *Salmonella* results have been used to categorize establishments is then discussed. Limitations of the *Salmonella* verification data and the potential uses of the data in future risk-based inspection and risk-based sampling algorithms are then presented.

Salmonella Standards

As outlined in the FSIS *Progress Report on Salmonella Testing of Raw Meat and Poultry Products, 1998–2006* (FSIS 2006), as part of the *Salmonella* verification testing program, performance standards were set for the prevalence of *Salmonella* on certain raw meat and poultry products. Raw products with established performance standards include the carcasses of cows/bulls (older cattle), steers/heifers (younger cattle), market hogs, broilers, and young turkeys. Processed products measured by performance standards include ground beef, ground chicken, and ground turkey.

The standards were established relative to national estimates of the prevalence of *Salmonella* contamination by product class. Prevalence estimates were derived from nationwide baseline studies of *Salmonella* conducted prior to the implementation of PR/HACCP, or, for the case of young turkey, a turkey sponge baseline study conducted from July 1997 through June 1998. When an establishment operates at the baseline prevalence, it has an 80 percent probability of passing a set. Establishments with lower prevalence have higher probability of passing a set, while establishments with higher prevalence have lower probability of passing a set.

The performance standards and guidance are expressed in terms of the maximum number of *Salmonella*-positive samples per set. The numbers of samples in a sample set and the maximum number of positive samples vary by product. The national prevalence rates, number of samples per set, and the number of positives at which the standard is exceeded are presented in **Table D-2**.

Table D-2. Estimated Nationwide Prevalence of *Salmonella*, the Number of Samples Collected per *Salmonella* Set, and the Number of Positives that Exceed the Standard

Product	Baseline Prevalence (%)	Number of Samples per Set	Maximum Number of Positives to Achieve Standard	Number of Positives to Exceed the Standard
Steers/Heifers	1.0	82	1	2 or more
Cows/Bulls	2.7	58	2	3 or more
Ground Beef	7.5	53	5	6 or more
Market Hogs	8.7	55	6	7 or more
Broilers	20.0	51	12	13 or more
Ground Chicken	44.6	53	26	27 or more
Ground Turkey	49.9	53	29	30 or more
Young Turkeys	19.6	56	13	14 or more

Source: *Federal Register*, February 27, 2006. Volume 71, Number 38, pages: 9772–9777.

The appropriate numbers of samples within a set for a given product are collected from an establishment over successive days, with the plan (or goal) of one sample being collected each day of operation. For example, for a facility processing ground beef, 53 samples will be collected on 53 successive days when the establishment is operating and producing ground beef. Depending on frequency of production, product type, and availability of resources, the time to complete a set ranges from 2 months to over a year. In establishments that produce more than one product subject to *Salmonella* verification testing, only one product is tested at a time.

Sampling Plan and Sample Collection

Each month, FSIS schedules approximately 75 sample sets for *Salmonella* testing across the 8 classes of raw product. Establishments are notified by FSIS prior to testing.

As discussed in the *Salmonella Progress Report* (FSIS 2006), prior to 2006 there were two phases of the FSIS regulatory program for *Salmonella* in raw products: non-targeted and targeted testing. For the non-targeted sets (labeled 'A' sets), each month establishments were randomly selected from the population of eligible establishments, with the goal of scheduling every eligible establishment at least once per year. Follow-up or targeted testing (labeled 'B,' 'C,' and 'D') was scheduled for establishments that failed a *Salmonella* set.

Since 2006, establishments are scheduled for *Salmonella* verification testing using risk-based, not random, criteria. Those criteria are intended to focus FSIS resources on establishments with the most samples positive for *Salmonella*. In addition, at times the establishments with the greatest number of samples with serotypes most frequently associated with human salmonellosis, as defined by the CDC, could also be used to focus resources. The criteria FSIS uses to schedule the sets are presented in **Figure D-4**.

Salmonella results are available from a total of 44,668 samples in 2006. That includes all samples from *Salmonella* sets across the eight products tested in this verification program. The overall percent positive was 4.7 percent, but varied widely across the products; the percent positive ranged from 0.3 percent in steers/heifers to 45.0 percent in ground chicken (see Table D-3).

Table D-3. Results of FSIS *Salmonella* Tests for 2006

Product Class	Number of Tests	Number of Positives	Percentage Positive	Number of Positives in Top 30 Human Serotypes *	Percentage of Positives in 30 Human Serotypes
Ground Chicken	222	72	45.0%	37	51%
Ground Turkey	444	88	20.3%	64	73%
Broilers	10,206	1,141	11.4%	537	47%
Young Turkeys	2,785	197	7.1%	149	76%
Hogs	7,242	261	4.0%	151	58%
Ground Beef	17,849	322	2.0%	172	53%
Cows/Bulls	2,246	19	0.8%	10	53%
Steers/Heifers	3,674	6	0.3%	3	50%
Summary	**44,668**	**2,106**	**4.7%**	**1,123**	**53%**

* Top 30 serotypes of human infection from http://www.cdc.gov/ncidod/dbmd/phlisdata/salmonella.htm (CDC 2005)

Detailed guidelines for collecting raw meat and poultry samples for *Salmonella* testing have been provided to the FSIS inspection force (FSIS 1997, http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/Salmonella_Analysis.pdf). The sample collection method depends upon the product being sampled. Cattle, turkeys, and swine carcasses are sampled by swiping a sterile sponge over specified areas using a template to mark the sampling areas. The sponge is then placed in a sample bag for shipment and analysis. Rinses from chicken carcasses are sampled by placing a whole chicken carcass in a sterile bag with 400 mL of buffered peptone water, shaking, and collecting the peptone water in a sterile screw-cap container. A 25 (g) sample of ground product is collected using a sterile plastic ring template that, when filled, yields the required 25 g sample.

Figure D-4. FSIS Scheduling Criteria for *Salmonella* Sets in Raw Classes of Product*

Each month, FSIS schedules approximately 75 new sample sets for *Salmonella* in raw classes of product. FSIS allocates sampling within classes of raw product according to the following criteria, in descending order (e.g., if criterion 1 does not obligate all available sample sets, then Criterion 2 is fulfilled; when Criteria 2 does not obligate all available sample sets, then Criterion 3 would be fulfilled):

All new plants regardless of product class **

All Category 3 plants regardless of product class. Category 3 plants have a highly variable process control for *Salmonella* reduction. The prevalence of *Salmonella* in these plants is greater than the performance standard or baseline guidance.

All Category 2 plants, depending upon product class. Category 2 plants have variable process control for *Salmonella* reduction. These plants are at 51 percent of the performance standard or baseline guidance, demonstrating intermediate control for this pathogen.

Product class (in descending order, selecting all available plants before moving to the next product class):

Broilers

Young Turkeys

Market Hogs

Ground Poultry (scheduled independent of carcass sampling if combination carcass/grind operation; carcass and ground product sets will not be scheduled concurrently)

Ground Beef (up to 50 percent of available sample sets but no more than 15 per month; scheduled independent of carcass sampling if combination carcass/grind operation; carcass and ground product sets will not be scheduled concurrently)

Cows/Bulls

Steers/Heifers

Within the product class, first priority is given to evidence of *Salmonella* process control on *last* set***

Primary consideration — Above 50 percent of the acceptable number of positives

Secondary consideration — At or below 50 percent of the acceptable number of positives

Within the product class, second priority is given to the level of common human serotype isolate in *last* set (in descending order, grouped by "high, "medium," and "low" level); top 20 serotypes for most recent calendar year reported by CDC).

Within the product class, third priority is given to days since last set (in descending order).

All Category 1 plants. Category 1 plants have consistent process control for *Salmonella* reduction. These plants are at 50 percent or less of the performance standard or baseline guidance, demonstrating the best control for this pathogen.

Within the product class, first priority is given to days since last set (in descending order):
>660 days (i.e., 22 months)

365 to 659 days (12 to 22 months — <12 month not routinely scheduled)

Within the product class, second priority is given to number of common human serotype isolate in *last* set (in descending order, grouped by "high, "medium," and "low" level; top 20 serotypes for most recent calendar year reported by CDC).

* Subject to periodic intraprogram review and adjustment; during natural disasters (e.g., hurricane), Category 2 plants not currently scheduled may be scheduled; all plants eligible that operate sufficient production annually to complete a sample set.

** Includes eligible turkey slaughter plants (carcasses) as of May 2006, and any new plant operating for at least 90 days (to accommodate 9 CFR 304.3).

*** To qualify for Category 1, an establishment must have two consecutive sets at less than or equal to 50 percent of the performance standard or guidance for its product class. An establishment will be placed in Category 2 or Category 3 based on a single set.

***Salmonella* Verification Categories**

As of June 2007, in the eight raw meat and poultry product classes that FSIS monitors, recent *Salmonella* data were available for well over 80percent of meat and poultry operations, including all high-volume establishments. That has allowed FSIS to categorize establishments subject to *Salmonella* verification testing establishments on the basis of their *Salmonella* verification results. As shown in Figure D-4, establishments are categorized into three "*Salmonella* Verification Categories" as follows:

Category I – Achieved *Salmonella* prevalence rates < 50 percent of the performance standard (based on the national estimate baselines for given product) in the two most recent *Salmonella* sets.

Category II – Combinations of results for two most recent sets that do not fit into Category I, but have not failed the most recent *Salmonella* set.

Category III – Failed most recent *Salmonella* set.

The national prevalence rates, number of samples per set, and the number of positives to be categorized as performing at or below 50 percent of the standard, above 50 percent but within the standard, or exceed the standard are presented in **Table D-4**.

The percentages of establishments subject to *Salmonella* verification testing that are in Category 1, 2, and 3 are presented in **Table D-5**. Eighty-one percent (81 percent) of establishments are classified as Category 1, that is, they demonstrate consistent process control across sets, while 16 percent are classified as Category 2 (show variable results without exceeding the standard), and only 3 percent of establishments exceed the *Salmonella* standard (Category 3).

Table D-4. Cut Points of Set Results Defining at or Below Half the *Salmonella* Performance Standard, Above Half the Standard, and Exceeding the Standard by Product Class

Product	Baseline Prevalence (%)	Number of Samples per Set	Number of Positives Relative to Standard		
			≤ 50%	> 50%	Exceeds
Steers/heifers	1.0	82	0	1	2 or more
Cows/bulls	2.7	58	1 or fewer	2	3 or more
Ground Beef	7.5	53	3 or fewer	4-5	6 or more
Market Hogs	8.7	55	3 or fewer	4-6	7 or more
Broilers	20.0	51	6 or fewer	7-12	13 or more
Ground Chicken	44.6	53	13 or fewer	14-26	27 or more
Ground Turkey	49.9	53	15 or fewer	16-29	30 or more
Young Turkeys	19.6	56	7 or fewer	8-13	14 or more

Source: PR/HACCP rule, Section 310.25 (b) 2 (meat), Section 381.94 (b) 2 (poultry)

Table D-5. Summary of Classification of Establishments Subject to *Salmonella* Verification Testing According to *Salmonella* Verification Category Based on 2006 Results

Product Class	Total	Category 1 Establishments		Category 2 Establishments		Category 3 Establishments	
		Number	%	Number	%	Number	%
Ground Chicken	11	6	55	4	36	1	9
Ground Turkey	27	17	63	10	37	0	0
Broilers	187	120	64	54	29	13	7
Young Turkeys	25	20	80	5	20	0	0
Hogs	206	148	72	51	25	7	3
Ground Beef	776	690	89	74	10	12	2
Cows/Bulls	68	57	84	9	13	2	3
Steers/Heifers	65	50	77	13	20	2	3
Summary	**1,365**	**1,108**	**81**	**220**	**16**	**37**	**3**

Salmonella Serotype and Subtype Information

In addition to testing for the presence or absence of *Salmonella* species on samples, the National Veterinary Services Laboratory (NVSL) of the Animal and Plant Health Inspection Service (APHIS) laboratory in Ames, Iowa, determines the serotype of *Salmonella* isolates (e.g., *S. typhimurium*, *S. heidelberg*, *S. kentucky*). The isolates are further subtyped by the Agriculture Research Service's (ARS') Bacterial Epidemiology and Antimicrobial Resistance (BEAR) Unit Laboratory in Athens, GA, for pulsed-field gel electrophoresis (PFGE) typing and determination of antimicrobial resistance.

Results of Testing Program

The FSIS captures the results of its *Salmonella* verification testing program in its databases under code HC01. Aggregate results from the FSIS *Salmonella* verification testing program are presented on the FSIS Web site (http://www.fsis.usda.gov/Science/Microbiology/index.asp), with Quarterly Reports being presented since 2006. The annual results for 2006 are summarized in Table D-3. In 2006, FSIS tested 44,668 raw meat and poultry samples for *Salmonella*, with a total of 2,106 positives (4.7 percent). Of the *Salmonella* isolates, 1,123 (53 percent) were listed by CDC as being in the Top 30 serotypes identified in human salmonellosis.

Regulatory incentives have been proposed to spur progress. One such incentive is posting establishment *Salmonella* results on the FSIS Web site. A year after the incentive was proposed to the chicken slaughter industry, the sector's *Salmonella* performance by establishment improved—the number of establishments in Category 1 increased from 35 percent in July 2006 to 70 percent in July 2007.

Prevalence of *Salmonella* Species

Baseline Studies

As mentioned above, nationwide baseline studies have been conducted to estimate the national prevalence of *Salmonella* in FSIS-regulated products. Prevalence information on *Salmonella* was determined in the following baseline studies: steer and heifer carcasses conducted in 1993; raw ground beef conducted in 1993 and 1994; cows and bull carcasses conducted in 1994; broiler chicken carcasses (young chickens) conducted in 1994 and 1995; market hog carcasses conducted in 1995 and 1996; raw ground turkey conducted in 1995; raw ground chicken conducted in 1995; young turkey carcasses conducted in 1997 and 1998; sponge samples from swine, cattle, young turkeys, and geese conducted in 1997 and 1998; and young chicken (broiler) carcasses conducted in 1999 and 2000. The results from all those baseline studies are available on an FSIS Web site (http://www.fsis.usda.gov/Science/Baseline_Data/index.asp). In addition, FSIS initiated an additional baseline study in young chicken (broiler) carcasses in June 2007; the study plans for that survey are also available on that FSIS Web site.

Salmonella Verification Testing and Prevalence

The *Salmonella* verification test results provide data on the rate of *Salmonella* positives in the samples analyzed across years. Those results, however, must be interpreted cautiously because the sampling protocols were not designed to assess the national prevalence of *Salmonella* in FSIS-regulated products. Neither the random sampling conducted prior to 2006 nor the risk-based sampling conducted after 2006 take into account the production volume. Therefore, the results do not provide a good estimate of the prevalence of *Salmonella* in the nation's supply of those products tested. Furthermore, the changes in the sampling protocol in 2006 complicate comparisons of data across years, making it difficult to compare the data before and after 2006. The data can, however, provide some indication of the changes in the number of establishments in the various *Salmonella* verification categories over time.

Potential Limitations of Data

The data from the *Salmonella* verification testing program provide considerable information on *Salmonella* rates in FSIS-regulated products; however, stakeholders have raised concerns regarding the dataset.

The sampling design and guidelines, although sufficient for the regulatory purpose of the sampling, do limit the use of the data to determine national prevalence rates of *Salmonella* in FSIS-regulated products.

Another feature of the sampling protocol is that current FSIS procedures allow only one product to be tested at a time per establishment. Depending on the frequency of production, the time needed to complete a S*almonella* set could range from 2 months to more than a year. In low volume establishments, it can take years to obtain data for each product produced.

Because only one product is tested at a time in an establishment, some products in an establishment that produces multiple projects subject to *Salmonella* verification could go untested for several years.

The length of time between sets could also be lengthened with the non-random sampling criteria established in 2006. Under those criteria, establishments in Category 1 would be sampled less frequently than others, completing a set on average every 2 years, compared to every year for Category 2, and sooner for Category 3.

Another result of the earlier random sampling design was that all products had equal likelihood of being tested, despite information from baseline studies and indications from regulatory samples that not all products have the same likelihood of testing positive for *Salmonella*.

Both the pre- and post-2006 sampling designs do not take into account the consumption patterns across FSIS-regulated product. A product that is consumed less frequently than another product and, therefore, has less potential for affecting public health (because fewer people will eat it to be exposed to the *Salmonella*) has the same likelihood of being tested as a more heavily consumed product. This, however, does not necessarily limit the usefulness of the dataset for ranking establishments.

The sampling also does not take into account any post-retail consumer habits, such as different typical ways of cooking different products, which could affect the presence and enumeration of *Salmonella*.

Exotic and minor species, such as lamb, goats, sows/boars, quail, squab, ratites, buffalo, and egg laying hens, are not currently tested in *Salmonella* sets by FSIS, and could be another limitation of the dataset.

Currently *Salmonella* is measured as presence or absence, not quantities as to the number of cells present (i.e., enumeration). Enumeration information would provide better information for linking results to human illness. Using presence/absence information to link to public health assumes that a positive sample would cause illness, regardless of subtype.

As mentioned earlier, FSIS informs establishments that *Salmonella* testing is occurring. That, coupled with the electronic notification of each test result about 5 days after sample collection, could influence the activities of an establishment, biasing the results. For example, an establishment might modify its operating parameters (reduce water reuse, change antibacterial chemical usage, slow line speeds, or schedule flocks with favorable *Salmonella* risk profile during the time of day when most specimens are collected) after receiving results in the first few *Salmonella* samples. Although this does result in the plant having better *Salmonella* performance, that improved performance might be temporary, lasting only for the duration of the sampling set.

Use of *Salmonella* Data

The *Salmonella* verification dataset has a large number of samples tested annually across a large number of FSIS products. In addition, *Salmonella* is present in a larger percentage of those samples tested than other pathogens (*E. coli* O157:H7 and *L. monocytogenes*). Although that higher prevalence is not a desired outcome, it does provide greater statistical power for data analysis.

L. MONOCYTOGENES ALTERNATIVE FOR RTE PRODUCT

In October 2003, FSIS issued 9 CFR 430, the Interim Final Rule to Control *L. monocytogenes* in certain RTE meat and poultry products. The Interim Final Rule set out the regulatory requirements for RTE products that have been exposed to the environment after a lethality step (i.e., post-lethality). This includes requiring establishments producing post-lethality exposed RTE meat and poultry products to adopt one of several options, called alternatives, to reduce the incidence of *L. monocytogenes*.

The *L. monocytogenes* alternative categories are as follows:

Alternative 1 - Establishments that apply both a post-lethality treatment to the RTE product to reduce or eliminate microorganisms on product *and* the use of an antimicrobial agent or process as part of the product formulation.

Alternative 2 - Establishments that apply either:

Alternative 2A - A post-lethality treatment to limit the growth of *L. monocytogenes* on the product, *or*

Alternative 2B - An antimicrobial agent or process as part of the formulation.

Alternative 3 - Establishments that rely only on testing and sanitation measures.

As part of this initiative, FSIS-regulated establishments report through an OMB-approved survey (FSIS Form 10,240-1, Production Information on Post-Lethality Exposed Ready-to-Eat Products) which Alternative method they use for controlling *L. monocytogenes*. Once completed, this form is sent to FSIS (faxed, mailed, or emailed using PDF version available on the FSIS Web site). The FSIS began receiving the information in 2004. Industry is required to update the information if significant changes occur.

A revised, direct-input Web-based version of Form 10,240-1 became available in March 2007. The revised version included the addition of a new item, “Plant Size Category”, and the addition of two new product designations: “Frozen Products” and “Paté Products.” In accordance with FSIS Notice 21-07 (3/8/07), FSIS Inspectors-In-Charge (IIC) were instructed to meet with relevant establishments to advise them of the availability of this electronic form, the new designations, and new information required. Establishments are required to complete the new form (either an electronic copy or a paper copy) and provide it to FSIS within 30 days of their meeting with the IIC.

In the form, establishments describe the type of *L. monocytogenes* tests they complete (e.g., food contact, and environmental samples), but not the results of their tests, the pathogen reduction provided by their post-lethality treatment (Alternative 1) or antimicrobial agent/process, or the frequency of testing of food contact surfaces. They also provide estimates of annual production volumes of meat and poultry products they process under 9 CFR 430. These forms are used to populate a database used in the *L. monocytogenes* risk-based sampling program for post-lethality exposed RTE products. This sampling project is discussed in a later section of this report.

Results

As of August 2007, approximately 2,398 active Federal establishments produced RTE products. Of those, 1,948 have been identified as producing post-lethality exposed RTE and have provided FSIS with their *L. monocytogenes* alternative using Form 10,240-1. The actual number of establishments that are subject to the requirements of 9 CFR 430 is likely to be higher than 1,948 since some regulated facilities that produce post-lethality exposed RTE products have not returned the required form. Approximately 50 percent of the 1,948 establishments that produce post-lethality exposed RTE products also produce RTE products that are not subject to 9 CFR 430. Since the issuance of the updated form, to date (August, 2007) approximately 1,650 of the approximately 1,948 regulated facilities have returned a new version of Form 10,240-1.

Potential Limitations in L. monocytogenes *Alternative Data*

One, but probably minor, limitation is that not all of the establishments regulated under the Interim Final Rule to Control *L. monocytogenes* have submitted Form 10,240-1. Thus, this data element is not captured in the algorithm, and the level of inspection calculated for these plants would not consider how well the establishment controls the risk associated with *L. monocytogenes* in RTE products. In 2005, FSIS estimated the number of establishments not submitting Form 10,240-1 to be 212. But as a result of District verification activities and recent FSIS Notice 21-07, many of these facilities did submit forms or submitted updated forms. Therefore, the number of establishments that should submit a Form 10,240-1 but did not is likely to be much smaller than the 212 previously estimated.

Currently, FSIS does not verify the accuracy of the information, including the Alternative, submitted by a regulated establishment via Form 10,240-1. Also, it is left to the establishment to determine when they have had a significant change in operation that warrants submitting a new form, including the possibility of falling into a different Alternative. This uncertainty is decreased because it is probably rare that an establishment incorrectly identifies the Alternative they are using or that the changes in their processes are significant enough to change the level of control from a higher Alternative to a lower level of control, for example from Alternative 1 to Alternative 2.

ZERO TOLERANCE PATHOGEN TESTING PROGRAM

A zero tolerance policy has been established for *E. coli* O157:H7 in non-intact raw beef products and for *Salmonella*, *L. monocytogenes*, and *E. coli* O157:H7 in RTE meat and poultry products. To enforce this policy, pathogen testing within FSIS includes testing raw ground beef and raw ground beef components for *E. coli* O157:H7, and testing RTE products for *Salmonella*, *L. monocytogenes*, and *E. coli* O157:H7. Contamination of those products with those microorganisms is considered adulteration and, therefore, regulatory action is taken if they are present.

This section discusses those zero-tolerance pathogen testing programs, first the testing of raw ground beef products for *E. coli* O157:H7, then the testing in RTE products. The sections include a discussion of the sampling plan and sample collection protocol, the use of the data in risk-based programs, and the limitations of the data.

Microbiological Testing Program for E. coli O157:H7 in Raw Ground Beef

On October 17, 1994, FSIS began a microbiological testing program to detect *E. coli* O157:H7 in raw ground beef. As HACCP was implemented over 1998 to 2000 timeframe, this testing program became an important HACCP verification activity. In 2007, FSIS added routine and follow-up sampling of raw ground beef components (e.g., beef trim). As mentioned previously, *E. coli* O157:H7 is a zero tolerance pathogen, therefore, when a sample is found to be positive for *E. coli* O157:H7, the product is deemed adulterated. Establishments (including retail stores and importers) must ensure proper disposition of adulterated products so that they do not enter commerce. When a positive sample is from a federally-inspected establishment, inspection program personnel issue a noncompliance record, conduct follow-up sampling, and verify that the establishment implements corrective actions as described in their HACCP plan, prerequisite programs or SSOPs.

This section outlines the FSIS sampling program for *E. coli* O157:H7 in raw ground beef and certain raw ground beef components (i.e., beef trim). It includes a description of the sampling plan and sample collection, subtype information, test results, potential limitations of the data, and potential future use of the data.

Sampling Plan and Sample Collection

There are approximately 1,400 federally-inspected establishments producing raw ground beef subject to routine sampling for *E. coli* O157:H7 under 9 CFR 319.15 (a), (b), or (c), as part of the FSIS HACCP verification programs. In recent years, most raw ground beef samples have been collected at the federally-inspected establishments, rather than at retail. Establishments from which raw ground beef samples are taken are chosen at random; no different priority is given to establishments based on production volume or other factors.

Instructions for sampling raw ground beef for *E. coli* O157:H7 are provided in FSIS Directive 10,010.1, Revision 1 and FSIS Directive 10,210.1. Inspection program personnel are to randomly select the day, shift and time within the timeframe requested on the sampling request. Before collecting routine samples of raw ground beef for *E. coli* O157:H7 testing, inspection program personnel notify official establishment management, providing enough time for the establishment to hold all products represented by the sample (this can cover multiple lots over multiple days), but not enough time to alter the production process. Samples should be from that day's production and should be, whenever possible, in their final packages.

The FSIS has always collected two pounds for a sample, however, over time, FSIS changed the amount of product analyzed and adopted more sensitive testing methods to improve its ability to detect *E. coli* O157:H7 in FSIS-regulated product. During October 1997, the amount of product analyzed was increased from 25 g to 325 g (by analyzing five 65 g samples). It was determined that having a larger volume would not affect the ability of the analytical test to detect a positive. However, analyzing the five 65 g samples makes the product analyzed more representative of the lot being tested, increasing the likelihood of identifying a contaminated lot and making the homogeneity of the product less of an issue. Currently, five 65 g subsamples are analyzed (325 g). Any excess from the two-pound sample is reserved at the laboratory. If any of the five subsamples are positive, the sample is declared positive. The results from this routine sampling program in ground beef are captured in the FSIS sampling database under Project Code MT03.

If a positive result is obtained, FSIS inspection program personnel are instructed to collect a follow-up verification sample after the establishment has taken corrective action. The results from this follow-up sampling program are captured in the FSIS sampling database under Project Code MT04.

As an expansion of the *E. coli* O157:H7 sampling program, in 2007, two notices (Notice 17-07 and 18-07) were released which provide for sampling of beef manufacturing trimmings or other raw ground beef or beef patty components used in the production of raw ground beef products. As defined in those notices, "beef manufacturing trimmings" includes trimmings from subprimal cuts such as boneless chuck or other parts of boneless beef that are frequently used as components of raw ground beef. Currently, it does not include other beef components such as head meat, cheek meat, organ meat, and advanced meat recovery (AMR) products, but FSIS plans to expand testing to these products in the future.

FSIS Notice 18-07 outlines the protocol for routine verification sampling of beef manufacturing trimmings intended for use in raw ground beef or beef patty products at the slaughter establishments that produced those trimmings. Testing at suppliers provides approximately five times greater sensitivity for detection of *E. coli* O157:H7, and allows FSIS to identify *E. coli* O157:H7 contamination closer to the source, before it is disseminated to multiple producers and mixed with product from multiple suppliers. The results of this routine testing in beef trim are captured in FSIS' database under Project Code MT50.

Under Notice 17-07, if a ground beef sample from an establishment or retail store tested positive for *E. coli* O157:H7, FSIS performs follow-up sampling at the suppliers whose products went into the lot from which the contaminated sample came—that is, at slaughter establishments that produced and supplied the beef manufacturing trimmings, and/or other establishments that supplied the raw ground beef or beef patty components. For this follow-up sampling, the inspectors at the suppliers are instructed to collect a sample of the component of concern (i.e., the beef manufacturing trimmings or other raw ground beef/raw beef patty components such as beef AMR, cheek meat, or finely textured beef). The results from this sampling program are captured in the FSIS sampling database under Project Code MT52.

The FSIS is designing an intensive follow-up sampling scheme (sampling in response to an *E. coli* O157:H7 positive test result) that will allow FSIS to verify that an establishment is not producing product with a greatly increased positive rate of *E. coli* O157:H7 contamination (relative to the annual rate). At the current rate of *E. coli* O157:H7 positive FSIS samples (0.17 percent in ground beef samples) this could be accomplished by taking 16 samples over a 120-day period. In smaller producers this number could be limited to 8 samples over 120 days to lower the potential economic burden. This scheme is under review and will be implemented as soon as possible.

In addition, in response to outbreaks associated with mechanically tenderized or injected products, FSIS intends to gather information on the production of those products. FSIS plans to identify which establishments produce such products, and will gather information on the volume of production, the controls for *E. coli* O157:H7, *E. coli* O157:H7 testing, sanitation practices, and whether these establishments label product to indicate that it has been mechanically tenderized or injected. Based on the information FSIS collects, FSIS may initiate *E. coli* O157:H7 testing of marinade solutions used in such products.

Also based on information it collects, FSIS may initiate rulemaking to require labeling of mechanically tenderized raw beef products to indicate that the product is not intact and requires thorough cooking.

E. coli O157:H7 Subtype Information

E. coli O157:H7 isolates from ground beef samples are subtyped by the FSIS Eastern Laboratory using PFGE. This provides Deoxyribonucleic acid (DNA) fingerprints of the isolated microorganism. The information is then uploaded into PulseNet, a national network of public health laboratories that uses PFGE patterns to compare the nature and location of strains of *E. coli* O157:H7 isolated from food and isolated from clinical cases (i.e., isolated from ill individuals). PulseNet quickly allows CDC and USDA to match meat and patient *E. coli* O157:H7 isolates, thereby providing evidence potentially linking the food contamination with the clinical case. The FSIS field operations staff works to provide trace-back (suppliers) and trace-forward (commercial distribution of product) information, and collect and test samples from traced establishments for which FSIS has regulatory authority. This process facilitates the rapid recall of contaminated product, reducing the public's exposure to this pathogen. The importance of molecular subtyping was illustrated in 1993, with the outbreak of foodborne illness caused by *E. coli* O157:H7 in the western United States. Scientists in Washington State and at CDC performed DNA fingerprinting and determined that the strain of *E. coli* O157:H7 found in patients had the same pattern as the strain found in hamburger patties served at a large chain of fast food restaurants.

Results of Testing Programs

Results from FSIS field laboratory analysis are used to verify the achievement of pathogen reduction targets. The results are stored in the MARCIS database, and are being migrated into an updated database, M2K. Those databases are automated systems that provide information on FSIS microbiological, chemical, and pathological analyses of domestic and imported meat and poultry products.

Since the testing program was initiated in 1994, more than 90,000 samples of raw ground beef have been tested for *E. coli* O157:H7, with an average of 7,053 samples per year being tested (see **Table D-6**). The number of samples analyzed has increased in the past 3 years, and at the same time, there appears to have been a decrease in the rate of positives found. In the year 2000, 6,375 samples were collected, of which 55 (0.86 percent) were positive. However, in 2006, 11,779 samples were collected, of which only 20 (0.17 percent) were positive. This suggests a decline in the rate of *E. coli* O157:H7 in the samples being tested since the year 2000. A study of the data from 2000 to 2003 showed a statistically significant decline during that timeframe (Naugle et al. 2005). The decrease was attributed to FSIS regulatory actions which resulted in industry actions to reduce *E. coli* O157:H7 in raw ground beef. With the 11,779 samples and a 0.17 positive rate, FSIS would be able to have statistical confidence (95 percent) that it could detect a 55.5 percent change in the percent positive rate. With a sample size of 14,528 samples, FSIS would have statistical confidence (95 percent) that it could detect a 50 percent change in the percent positive rate.

In each of the last 3 years (2004, 2005, and 2006), 0.17 percent of the raw ground beef samples tested were positive for *E. coli* O157:H7 (see Table D-6). Looking specifically at samples from

federally-inspected establishments (see **Table D-7**), the results have also been very consistent since 2004, with a positive rate of 0.18 percent, 0.16 percent, and 0.17 percent in 2004, 2005, and 2006, respectively (see Table D-7). The positive rate for 2007, as of August 19, is 0.21 percent for federally-inspected establishments and 0.20 for all raw ground beef projects (data not shown).

The FSIS goal is to keep the percentage of ground beef positives below 0.17 percent. The Agency, therefore, is closely monitoring the 2007 results, which for the second quarter showed an average of 0.18 percent, indicating the potential for an elevated rate. Because of concerns about that potential increase, FSIS scheduled additional samples in July and August 2007, which will provide more data points for analysis, and improve the Agency's ability to detect an increased rate of positives if it were to occur.

Table D-6. Annual *E. coli* O157:H7 Results for the FSIS Verification Sampling Program of Raw Ground Beef (calendar year 1994 through calendar year 2006)

Calendar Year	Number of Samples Analyzed	Number of Positive Samples	Percentage Positive
1994	891	0	0 %
1995	5,407	3	0.055 %
1996	5,703	4	0.070 %
1997[a]	6,065	4	0.066 %
1998	8,680	14	0.17 %
1999[b]	7,785	32	0.41 %
2000	6,375	55	0.86 %
2001	7,010	59	0.84 %
2002	7,025	55	0.78 %
2003	6,284	20	0.30 %
2004	8,010	14	0.17 %
2005	10,976	19	0.17 %
2006	11,779	20	0.17 %
Total since 2000[c]	**57,459**	**242**	**0.42**

[a] During October 1997, the amount analyzed was increased from a 25 g sample to a 325 g sample to provide increased detection sensitivity.
[b] On September 3, 1999, a new selection and detection method was introduced to further increase test sensitivity.
[c] Data since 2000 can be summed because they were obtained using the same (more sensitive) detection method (see footnotes a and b).

Table D-7. Annual 0157:H7 Results for FSIS' Verification Sampling Program of Raw Ground Beef (calendar year 2004 through calendar year 2006) Broken down by Source of Sample

Source	CY 2004		CY 2005		CY 2006	
	Number of Samples Analyzed	Number of Positive Samples (%)	Number of Samples Analyzed	Number of Positive Samples (%)	Number of Samples Analyzed	Number of Positive Samples (%)
Federal Plants	7,683	14 (0.18 %)	10,866	18 (0.16 %)	11,626	20 (0.17 %)
Retail Stores	311	0 (0 %)	95	0 (0 %)	133	0 (0 %)
Imports	16	0 (0 %)	15	1 (6.7 %)	20	0 (0 %)
Totals	8,010	14	10,976	19	11,779	20 (0.17 %)

Abbreviations: CY, Calendar Year.

Source: FSIS Web site

As discussed earlier, over time, FSIS changed the volume analyzed and adopted more sensitive testing methods to improve its ability to detect *E. coli* O157:H7 in FSIS-regulated product, as part of its goal to continuously improve its sampling programs. With those changes, the number of positives increased from 4 to 14 (or from 0.066 percent to 0.17 percent) between 1997 and 1998 (see Table D-6). On September 3, 1999, a new selection and detection method was introduced to further increase test sensitivity. The number of positives increased from 32 to 55 (from 0.41 percent to 0.86 percent) between 1999 and 2000 (see Table D-6). Both increases were most likely due to improvements in the sensitivity of the sampling protocol and detection method.

Since 2000, the rate of positives has declined—from 0.86 percent in 2000 to 0.17 percent in 2006— while the number of samples tested has increased (see Table D-6). The decline in the rate of positives could be due to industry actions to reduce the levels of *E. coli* O157:H7 during slaughter/dressing procedures and processing (e.g., using antimicrobials on trimmings) operations. Since the initiation of the FSIS testing program, many grinders and suppliers of raw ground beef components have instituted programs to test their ground beef products or raw materials used in ground beef products for *E. coli* O157:H7. Testing may enable industry to identify and subsequently implement more effective interventions that will further reduce the level of *E. coli* O157:H7 in raw ground beef, such as improved pasteurization systems or hot water washing of the carcass, as well as to detect contaminated lots and prevent their entry into commerce.

Preliminary results are available for testing programs on raw ground beef components. As of August 19, 2007, 2 of 310 samples have tested positive for *E. coli* O157:H7 under the routine testing program for raw trim sampling (Project Code MT50 in the FSIS database). As of August 19, none of the 25 follow-up samples have tested positive (Project Code MT52 in the FSIS database).

Prevalence of *E. coli* O157:H7

A baseline survey of 563 samples of raw ground beef was undertaken in 1993 to 1994, and no samples were found positive for *E. coli* O157:H7. However, the sample size analyzed in that study was only 25 g.

A baseline study to determine the national background level of *E. coli* O157:H7 in beef trim was recently completed. A preliminary analysis of this baseline data indicates that approximately 0.66 percent of samples are positive for *E. coli* O157:H7[2]. An assessment was made of the number of samples that would be needed to be tested to determine if the national proportion of *E. coli* O157:H7 positive samples in beef trim is increasing or decreasing from one year to the next. Based on a prevalence of 0.66 percent positive, testing a sample size of 3,000 to 4,000 samples of beef trim per year would allow detection of a 50 percent increase in the national background level of *E. coli* O157:H7 in beef trim.

Potential Limitations of Data

The FSIS *E. coli* O157:H7 testing program provides the agency with considerable information on the pathogen. There are, however, limitations and uncertainties associated with the dataset and with the conclusions that can be drawn on the basis of the data. Some of the limitations and uncertainties are discussed below.

The annual *E. coli* O157:H7 data for ground beef products come from the regulatory testing program. Although some inferences regarding trends in the percent positive rate within the testing program can be made, this regulatory program has not been designed to test for statistically significant changes in the national prevalence of *E. coli* O157:H7. Therefore, changes from year to year and even within a year must be interpreted with caution. However, this is not necessarily a limitation in using *E. coli* O157:H7 as an indication of process control.

In 2006, 11,626 samples of raw ground beef were collected and analyzed from approximately 1,400 federally-inspected establishments. As sampling occurs on a random basis, this indicates that most establishments were subject to testing about 8 times during the year. The percent positive rate of *E. coli* O157:H7 in raw ground beef is low. Since the year 2000, over 57,459 samples have been tested by FSIS, and only 242 were found to be positive (mean percent positive is = 0.42 percent; range 0.17 percent to 0.86 percent (see Table D-6). Having a low percent positive is the desired outcome, however, it does limit the statistical analyses that can be done on the data.

It is unlikely that all ground beef is contaminated at the same percent positive rate. The rate might vary depending on the frequency (and number) of positives in the raw materials (e.g., beef trim), which in turn depends on the "on farm" practices and the hygienic practices used at slaughter and during preparation of the raw materials. Therefore, it is important to test raw materials, and to ideally, if the information is available, to base the frequency of testing on the presence or absence of specific interventions at slaughter or during processing that will reduce the likelihood of contamination.

[2] *Note – Results are preliminary and subject to change.*

As with all FSIS sampling programs, there is 'drop out' of *E. coli* O157:H7 samples. That is, a lower number of samples are analyzed than were scheduled. There are a number of reasons why not all scheduled samples may not be analyzed, including that the product scheduled to be sampled at a given establishment is not being made at that point in time, or samples are damaged or lost during shipment to the FSIS laboratory. During the 2006 calendar year, 72.1 percent of samples scheduled were analyzed. Samples requested from very small facilities are least likely to be tested (large 88.1 percent tested; small 78.5 percent tested; very small 68 percent tested); the main reported reason for the samples not being analyzed was that the product was not being produced at the time so a sample could not collected. The FSIS anticipates that not all samples requested will be received and analyzed, so sampling plans take into account an anticipated 'drop off.' A difference between the number of samples planned and analyzed, however, could affect the randomness of the data collection if the drop-off occurred more in one type of establishment or one location.

Although the randomization of the sampling plan helps decrease biases, it also limits certain interpretations or conclusions that can be drawn from the data. As discussed before, the randomization is not adjusted for production volume, and therefore establishments with large production volumes are not sampled more frequently than those with smaller production volumes. Establishments producing smaller volumes, therefore, are sampled more frequently on a per-volume basis than those producing larger volumes. That results in some limitations in the interpretation of the data (e.g., can not get an accurate picture of the national prevalence rate of *E. coli* O157:H7).

In addition, *E. coli* O157:H7 is likely not randomly distributed within a specific lot, so the possibility exists that a sample could test negative for *E. coli* O157:H7, but some portion of the lot be contaminated. This could be determined by looking at the results of the individual 65 g subsamples to see whether they are all the same or are different. If the contamination is uniform, then if one subsample is positive, all sub-samples should be positive.

Future Use of E. coli O157:H7 Data

Risk Based Inspection

Pathogen data, including the regulatory samples for *E. coli* O157:H7, have been proposed for use in RBI. As seen in the main body of this report, it is proposed to be used as an indication of process control within an establishment.

Risk Based Sampling

Starting in the 2008, FSIS will begin a risk-based sampling program for *E. coli* O157:H7 at establishments producing raw ground beef products and at slaughter establishments producing beef manufacturing trimmings. In the initial phase of the risk-based sampling program, sampling frequency will be based on the average amount of product the establishment produces per day and FSIS *E. coli* O157:H7 test results for the establishment within the past 4 months of FSIS' scheduled sampling. By summer 2008, it is anticipated that the sampling program will also take into account validated interventions and testing programs for *E. coli* O157:H7. The FSIS has designed a sampling program that accounts for volume, but does not make it the sole or primary determinant. Because of this, establishments with no recent FSIS positive *E. coli* O157:H7

results, that have validated interventions and testing programs for the pathogen, will be sampled less frequently than those with recent *E. coli* O157:H7 positive results or those that fail to implement good practices to address the pathogen, regardless of production volume. In addition, seasonal variations might be taken into account; FSIS may collect more samples during April through October (the months when the *E. coli* O157:H7 positive rate is highest) than during November through March.

In order to allocate those samples, FSIS has developed a probabilistic algorithm that will assign a sampling probability to each grinder and each slaughter establishment that produces trim. Using that algorithm, the probability of sampling takes into account the potential for *E. coli* O157:H7 contamination (i.e., the hazard) and volume (i.e., the potential exposure); thus, the Risk = contamination (hazard) x volume (exposure). By design, however, production volume does not drive the equation—positive FSIS results are weighted more heavily in the algorithm than high-production volume. Therefore, a low-volume plant that has had an FSIS positive result in the past four months generally would have a higher chance of being sampled than a high-volume plant that has not had an FSIS positive result in the past 4 months.

As mentioned, the algorithm takes into account past results on *E. coli* O157:H7 tests. FSIS determined the magnitude of the score that should be assigned based on FSIS analysis of *E. coli* O157:H7 test results from 2000 to 2005. For example, the analysis estimated that establishments with a positive sample are five times more likely than other establishments to test positive again within a 120-day period. Therefore, an establishment with a positive FSIS *E. coli* O157:H7 test in the last 120 days will receive a higher score for sample history.

As FSIS gathers more information about production practices that are related to increased or decreased likelihood of positive *E. coli* O157:H7 tests, volume will count even less in the allocation of samples. Establishments will reduce their likelihood of being sampled (that is, they will lower their probability weight in the algorithm) by maintaining production practices that effectively address *E. coli* O157:H7. It is important to note, however, that the algorithm would be designed such that FSIS still tests all eligible plants at a reasonable frequency.

RTE Pathogen Testing Program Results

FSIS has conducted a regulatory microbiological testing program on RTE meat and poultry products since 1983. Certain RTE products are tested for *L. monocytogenes*, *Salmonella* spp., and *E. coli* O157:H7 as part of that program. Because the presence of those pathogens on RTE product is considered adulteration, any product represented by a sample that has tested positive must be reprocessed or destroyed.

The RTE pathogen testing program is described in this section, starting with the sampling plan and sample collection, followed by the results of the RTE testing program and its potential limitations.

Sampling Plan and Sample Collection

For all samples, once inspection program personnel receive a memo for sample collection, they randomly select the day, shift, and time within the sample collection timeframe to pull the sample. They then collect enough intact product so that at least two pounds of product are

submitted to the laboratory for analysis. The inspection program personnel give the establishment management sufficient notification of sampling so that the product represented by the sample may be held and not released into commerce pending the results of FSIS testing. Holding product is at the option of the establishment. How establishments are chosen for sampling by FSIS is described below.

The FSIS sampling of RTE has evolved through the years. This section first provides an overview of the early sampling plans used by FSIS, and then discusses the three sampling projects (RTE001, RLm, and ALLRTE) that are currently active. Finally, the FSIS Intensified RTE Sampling conducted as follow-up sampling is discussed.

From 1990 to 2000, FSIS based its RTE testing program on selected product categories. The products that were analyzed for the various pathogens are presented in **Table D-8**. Establishments to be sampled were randomly selected.

Table D-8. Meat and Poultry RTE Products from FSIS-Regulated Establishments Analyzed for Specific Pathogens from 1990 to 2000

Product	Microbial Test
Cooked beef, roast beef, cooked corned beef	*L. monocytogenes* and *Salmonella*
Sliced ham and luncheon meat - pork only	*L. monocytogenes* and *Salmonella*
Small diameter (up to 1½ inches) cooked comminuted products - meat and/or poultry	*L. monocytogenes* and *Salmonella*
Large diameter (greater than 1½ inches) cooked comminuted products - meat and/or poultry	*L. monocytogenes* and *Salmonella*
Jerky - meat and/or poultry	*L. monocytogenes* and *Salmonella*
Cooked poultry products – uncured	*L. monocytogenes* and *Salmonella*
Meat and/or poultry salads, spreads and pâtés	*L. monocytogenes* and *Salmonella*
Fully cooked meat patties	*E. coli* O157:H7
Dry and semi-dry fermented sausages	*Staphylococcal enterotoxins*, *E. coli* O157:H7, *L. monocytogenes*, and *Salmonella* [a]

[a] *E. coli* O157:H7 analysis was added to this testing project in March 1995. *L. monocytogenes* and *Salmonella* analyses were added in July 1997.

Source: http://www.fsis.usda.gov/Science/Table1_Micro_Testing_RTE_1990-2004/index.asp

After 2000, random sampling of establishments according to the product categories presented in Table D-8 ended, and FSIS began basing the program on HACCP processing categories identified in 9 CFR 417.2 that apply to RTE products. This change in the sampling plan added new products and establishments to the dataset. Samples were randomly scheduled in the establishments where the RTE processes existed. Results were recorded both by the HACCP processes used for scheduling and by 10 product categories as assigned by laboratory personnel when the sample arrives at the laboratory (presented in **Table D-9**). Those 10 product categories were identified based on factors that could be expected to affect the probability that a product could become contaminated during post-lethality exposure or factors that could relate to the effectiveness of the kill step. For example, the categories identified products that were exposed to unique types of post-lethality processing equipment such as peelers or slicers or shredders.

The categories also distinguished whole-muscle cuts from products where the internal tissues were more likely to have been contaminated before the kill step (e.g., a chopped and formed product).

In 2003, Directive 10,240.3 was issued, which further changed FSIS sampling of RTE such that the previous random sampling protocol was no longer followed and a more risk-based approach was taken. That directive defined three categories of RTE products for testing based on risk of *L. monocytogenes*: targeted, low-targeted and non-targeted products. Low-targeted products included products that were less likely to support growth of *L. monocytogenes* because of low pH, low water activity, the addition of antimicrobial agents, or because the product could be expected to remain frozen from production until preparation for consumption. Non-targeted products included regulated products such as lard, mixtures of animal fats, dried soup mixes, and products labeled for further processing in which the product would be expected to receive a lethality treatment. For 2003, most of the samples were collected under the targeted sampling program. All establishments producing targeted or low-targeted products were equally likely to be scheduled for sampling; non-targeted products were not scheduled for sampling.

Table D-9. Product Categories Assigned to Products by Laboratory Personnel in FSIS' Microbiological Testing Program for RTE Meat and Poultry Products [a]

Process Category	Examples (not all inclusive)
Whole sausage-type product, peeled	Hot dogs, frankfurters, knockwurst, and other products cooked in a casing that is removed by a peeling process after the lethality step and before final packaging
Whole sausage type product, unpeeled	Hot dogs, bologna, andouille sausage, pepperoni, salami, and similar products that are shipped in the same casing that exists during the lethality step
Large mass, chopped and formed	Turkey roll, loaves, cooked ham, and other products that have been processed before lethality in a manner where exterior bacteria could be transferred to the internal tissues
Large mass, whole muscle	Cooked roast beef, whole chickens, cooked corned beef, cooked turkey breast, bone in ham, prosciutto, dry cured ham. That is, products with only external bacteria prior to the lethality step
Small mass, chopped and formed	Meatballs, chicken nuggets, patties, breakfast sausage
Small mass, whole muscle	Chicken tenders, whole muscle cutlets, chicken breasts
Salads, pâtés and spreads	Chicken salad, ham salad, liverwurst, *pâté de foi gra*
Sliced, diced, shredded (with or without sauce)	Sliced ham, sliced turkey, diced cooked chicken, beef barbeque, sliced pepperoni, chipped beef
Multi-component products	Dinners, entrees, wraps, pocket sandwiches, egg rolls, pizza
Other	Products that can not be categorized into the other nine categories

[a] Samples are scheduled based on HACCP processing categories identified in 9 CFR 417.2 that apply to RTE products. Results are recorded both by the HACCP process used for scheduling and by these 10 product categories as assigned by laboratory personnel when the sample arrives at the laboratory. The 10 product categories were identified based on factors that could be expected to affect the probability that a product could become contaminated during post-lethality exposure or factors that could relate to the effectiveness of the kill step.

Source: FSIS website (http://www.fsis.usda.gov/Science/Micro_Testing_RTE/index.asp).

In October 2003, FSIS issued Directive 10,240.4. Under this directive, two new sampling projects for 2004 were defined. These projects, which were labeled Ready-to-Eat Risk1

(RTERISK1) and All Ready-to-Eat (ALLRTE), are described below. Under both projects, all RTE establishments were equally likely to be scheduled for sampling each month, however, specific types of products were sampled within the establishment based on risk.

Under the RTERISK 1 project, within which most of the samples were scheduled, from establishments processing RTE products exposed to the environment post-lethality treatment, product selection was based on guidance provided in FSIS Directive 10,240.4, which defined three RTE Alternatives (see *L. monocytogenes* Alternative section for description). Inspection program personnel were to collect only Alternative 3 products (i.e., using only sanitation) if they were available. Directive 10,240.4 also provided a hierarchy within Alternative 3 products as follows: (1) deli meats, (2) hot dogs, (3) deli salads, pâté, meat spreads, and (4) other product. If Alternative 3 products were not available, inspection program personnel would collect an Alternative 2, and an Alternative 1 product only if the establishment produced no Alternative 2 or 3 products. This project was discontinued at the beginning of 2006.

Under project ALLRTE, all RTE-processing establishments were eligible for sampling. Inspection program personnel were instructed to collect, at random, RTE products that fit the previously discussed definitions of targeted or low-targeted products. In that way, the Agency collected random samples across a wide variety of RTE products, but did not expend resources testing the products that have low risk for supporting growth of pathogens.

In 2006, FSIS refined its risk-based approach to sampling RTE products and added taking environmental samples in RTE establishments. It uses a risk-ranking of establishments producing post-lethality exposed RTE meat and poultry product. The risk-ranking is determined using a multivariate equation (algorithm) that is informed by previously developed FSIS peer-reviewed risk assessments and the ongoing results from FSIS tests of RTE meat and poultry products. In this currently used sampling plan, the results of the ranking are used to allocate RTE sampling resources across three different sampling projects with the following priority:

1. Routine *L. monocytogenes* (RLm) risk-based sampling project for establishments in which RTE product is exposed to the environment post-lethality treatment (i.e., with sampling scheduled in the highest-risk establishments), with approximately equal percentage of samples being *L. monocytogenes* Alternative 3 and 2b, up to 5 percent being *L. monocytogenes* Alternative 2a, and the remainder are from Alternative 1. This program includes sampling of food contact surfaces for *L. monocytogenes*, environmental samples for *L. monocytogenes*, and intact product verification testing for *L. monocytogenes*.

2. Routine intact product sampling under RTE001; and then

3. Random sampling under ALLRTE in the remaining RTE establishments.

The sampling for those three sampling projects—RLm, RTE001, and ALLRTE—are discussed below.

RLm

In 2006, as part of the overall FSIS *L. monocytogenes* risk-based verification testing program, FSIS began a new risk-based testing program referred to as the Food Contact, Environmental (Non-Food Contact), and Intact Product Verification Testing Program, which is known as the Routine *L. monocytogenes* Risk-Based sampling program (RLm). Samples collected under this program are limited to establishments subject to 9 CFR Part 430 (i.e., establishments in which RTE products are exposed to the post-lethality environment).

Under this program, testing of food contact and environmental (non-food contact) surfaces for *L. monocytogenes* is conducted concurrent with product testing. The RLm testing program consists of three sampling projects:

- RLMCONT - testing of surfaces that have direct contact with RTE product in the RTE production area;
- RLMENVR - testing of environmental (non-food contact) surfaces in the RTE production areas; and
- RLMPROD - testing of intact product samples collected concurrently with food and environmental contact surface swabs throughout the selected production shift.

RLm sampling is done in conjunction with a comprehensive Food Safety Assessment (FSA). Unlike ALLRTE and RTE001 sampling projects, which are sampled for *Salmonella* and, in some cases, *E. coli* O157:H7, RLm samples are only analyzed for *L. monocytogenes*.

Each month, one establishment per FSIS District (i.e., 15 establishments per month) is selected for RLm testing using FSIS' risk-based algorithm for *L. monocytogenes* sampling among establishments that produce post-lethality exposed products. Those using Alternative 3 control measures will be sampled the most. Samples will be collected at a decreasing frequency in establishments electing to use Alternative 2, Choice 2 (2B); Alternative 2, Choice 1 (2A); and Alternative 1. A Scheduling Memo is sent to Districts to inform them of the establishment selected for RLm sample collection, and the District selects the week the sampling is to occur. EIAOs and Public Health Veterinarians (PHVs) trained in the EIAO methodology are responsible for collecting RLm samples according to FSIS Directive 10,240.5 (March 15, 2006). In conjunction with the sample collection, the EIAOs or PHVs also assess whether the establishment's food safety system complies with 9 CFR Part 430. Once RLm sampling has been conducted in an establishment, it will not be eligible for RLm scheduling again for a 12-month period.

The number and type of samples collected at the establishment by FSIS field personnel varies depending on the process and operation being conducted. In general, one "sampling unit' is collected for each post-lethality exposed RTE line. A standard "sample unit" is defined as 10 food contact surface swabs, 5 environmental swabs, and 3 intact product samples. A maximum of 5 sample units are collected within any selected establishment. This gives a

possible range of 18 to 90 samples per establishment. If the establishment has more than 5 lines, product from the higher risk lines is selected for testing. Products are selected using the hierarchy as described in **Figure D-5**. The average number of samples per establishment taken at an establishment since the beginning of the program in April of 2006 is 8 product samples, 14 environmental samples, and 28 food contract surface samples, giving a total of 50 samples per plant on the average.

The actual sites for food contact and environmental swab sampling are determined by the EIAO/PHV. In accordance with the requirements for a sample unit, more swabs are to be collected from food contact surfaces than the number collected from environmental surfaces. Some food contact surface swabs are collected at the end of pre-operational sanitation activities but before the start of production. However, more food contact surface swabs are to be collected during operations.

Intact samples of three products associated with the same production day, shift and lines represented by the food contact and environmental surface swabs are also randomly collected during the same production day. Product samples taken at an establishment come from only one sampling project during any given timeframe, regardless of who within FSIS is collecting the samples, in the following priority: RLm-related product samples, RTE001, or ALLRTE. If sampling is scheduled to occur at an establishment concurrently under more than one sampling project, FSIS field personnel ensure that different lots of product are sampled for different projects.

Figure D-5. Hierarchy of Risk of Post-lethality Exposed RTE Products.

1. Deli-meats that are sliced in the Federal establishment
2. Deli-meats shipped whole from the Federal establishment (this does not include cook-in-bag products; only those exposed post-lethality)
3. Hot dog products
4. Deli salads, pâtés, and meat spreads
5. Fully cooked type products (other than cooked products in 1 through 4 above)
6. Fermented products
7. Dried products
8. Salt-cured products
9. Products labeled as “Keep Frozen.”

Source: FSIS Directive 10,240.4(2006)

RTE001

In 2004, FSIS initiated a project named RTE001, which was the first HACCP verification project in which RTE establishments were not equally likely to be scheduled for sampling each month, but were risk based. Phase 1 of the FSIS *L. monocytogenes* risk-based verification testing program was implemented in January 2005. In 2006, RTE001 became the primary RTE sampling project in 2006, representing almost 70 percent of regulatory product sampling. Under RTE001, only establishments processing RTE exposed to the environment post-lethality treatment are sampled.

The instructions for implementing RTE001 are in FSIS Directive 10,240.4 (2006). Inspection personnel are to select the highest risk post-lethality exposed RTE product produced at the time of collection according to the hierarchy in Figure D-5.

Under RTE001, 800 to 1,000 establishments are scheduled each month for sampling[3]. Currently, of the more than 800 establishments that are scheduled for sampling each month, sampling is completed for all but about 50. Reasons for not completing sampling under this project vary, but are most often related to an establishment no longer making the RTE product, or a product line being out of service.

ALLRTE

In 2006, the ALLRTE project discussed above was modified. Under the modified ALLRTE project, all FSIS-regulated RTE establishments are considered on an annual basis, except those that were scheduled for sampling under RTE001. FSIS collects one sample of product at a time from the randomly selected individual establishments, and tests for pathogens according to the product as outlined in Table D-8. Eight-five establishments are scheduled each week for sampling under this project. Inspection program personnel were instructed to collect an RTE product that fit the previous definitions of targeted or low-targeted products. In other words, the agency requested random samples across a wide variety of RTE products, with the exception of products that are non-targeted (i.e., have low risk for supporting growth of pathogens like fats and oils, and dried soup mixes). Up to 4,420 product samples per year are collected under this program for microbial analysis.

Follow-up *L. monocytogenes* Sampling—Intensified Verification Testing (IVT)

When a product sample taken under one of the sampling projects outlined above is found to be positive for *L. monocytogenes*, FSIS will conduct follow-up verification testing after the establishment has taken its corrective and preventive actions. The follow-up sampling will be conducted under the IVT projects (Project Code Names INTPROD and INTCONT). Those projects are designed for testing in any operation involving any RTE meat or poultry product, regardless of the establishment's production volume, control procedures, or other risk mitigating factors. IVT could occur because of history of having produced adulterated product (i.e., the preshipment review has been completed), for investigative purposes (e.g., as a result of an outbreak of foodborne disease), or because there is a concern that the establishment may not be properly controlling for pathogens. Multiple samples could be collected through IVT, and include:

- Increased frequency and number of samples taken for product testing (as compared to targeted verification testing), and the collection of environmental samples.

- Increased FSIS record verification checks regarding the design and implementation of the food safety system.

These sampling projects are scheduled by FSIS on a case-by-case basis.

[3] The actual number depends on the number of weeks in the month. There are 200 plants allotted for each week by the laboratories so there can be 800 or 1,000, depending if there are 4 or 5 weeks in the months. The number of weeks is determined by the number of Mondays in the month.

Results of Testing Program

As discussed above, FSIS currently conducts three RTE testing projects: RLm, RTE001 and ALLRTE. The results of each of those three projects are discussed below. Samples collected under the RLm project are only tested for *L. monocytogenes*, and therefore only *L. monocytogenes* results are presented in that section. Under RTE001 and ALLRTE, results for *L. monocytogenes*, and *Salmonella* are presented. Overall results are then presented for *L. monocytogenes*, and *Salmonella*, and *E. coli* O157:H7. *E. coli* O157:H7 results are only presented in the overall section because all samples tested for *E. coli* O157:H7 were negative. The results for the RTE testing program are presented on the FSIS Web site (http://www.fsis.usda.gov/Science/Micro_Testing_RTE/index.asp). Annual results are presented for the calendar years 1990 through 2000. More detailed results have also been published in the Journal of Food Protection, Vol. 64, No. 8, 2001, pages 1188-1193.

RLm

The RLm sampling program began in April 2006. There were 131 establishments sampled under the RLm program from April 2006 through July 2007. Of those establishments, 43 out of total of 6,453 samples had positive cultures, and only one of those was a product sample (RLMPROD). Results to date by sample type over the entire RLm program are shown in **Table D-10**. There were over three times as many environmental culture positives (RLMENVR) as food contact surface positives (RLMCONT).

Table D-10. Total RLm Positive and Negative Culture Results – April 2006 through July 2007

Sample Type	Number of Positive Samples	Number of Negative Samples	Total Number of Samples	Percentage Positive	Percentage Negative
RLMCONT	9	3,624	3,633	0.14	99.86
RLMENVR	33	1,746	1,779	0.51	99.49
RLMPROD	1	1,083	1,084	0.02	99.98
Total	43	6,453	6,496	0.66	99.34
Number of Establishments Tested	43	88	131	32.8	67.18

Abbreviations: RLMCONT, Routine *L. monocytogenes* sampling on food contact surfaces; RLMENVR, Routine *L. monocytogenes* environmental sampling; RLMPROD, Routine *L. monocytogenes* product samples.

RTE001

With respect to *L. monocytogenes*, results for 2005, the first year that the sampling project RTE001 was conducted, indicated a percent positive rate for *L. monocytogenes* for all RTE meat and poultry products tested under RTE001 of 0.72 percent. This represented 51 positive samples out of the 7,089 collected that year. For 2006, results indicated a percent positive rate for *L. monocytogenes* for all RTE meat and poultry products tested of 0.47 percent. This represented 40 positive samples out of the 8,577 collected that year. Given the 8,577 products tested for *L. monocytogenes* under RTE001 in 2006 and the percent positive rate of 0.47 percent, FSIS is 95 percent confident that it could detect a 38.7 percent increase in the positive rate. To detect a 50 percent increase, 5,239 samples would have to be tested.

For *Salmonella*, in 2005 the positive rate for all RTE meat and poultry products tested under RTE001 was 0.04 percent, based on 4 positives out of 7,089 samples. In 2006, the positive rate was 0.02 percent, based on 2 positives out of 8,577 samples. Given the 8,577 products tested for *Salmonella* under RTE001 in 2006 and the percent positive rate of 0.02 percent, FSIS is 95 percent confident that it could detect a 189.9 percent increase in the positive rate. To detect a 50 percent increase, 123,675 samples would have to be tested.

ALLRTE

L. monocytogenes results for 2004, the first year that ALLRTE was conducted, indicated a percent positive rate for *L. monocytogenes* for all RTE meat and poultry products tested of 0.55 percent. This represented 8 positive samples out of the 1,467 collected that year. Results were also recorded across 10 various product categories (e.g., peeled sausage type product).

Results for 2005 for ALLRTE indicated a percent positive rate for *L. monocytogenes* for all RTE meat and poultry products tested of 0.64 percent. This represented 18 positive samples out of the 2,806 collected that year. For *Salmonella* in 2005, 1 sample out of the 2,806 tested positive, for a positive rate of 0.04 percent.

As discussed above, in 2006, the ALLRTE project was modified so that establishments were randomly picked each month for testing from those establishments not scheduled for testing under RTE001. Since many establishments were scheduled every month for an RTE001 sample, they were never available for random selection in the ALLRTE project. Given that the low percentage of positive results for RTE001 (less than 0.5 percent), the ALLRTE results for 2006 were most likely higher than they would have been had all establishments had the chance of being sampled each month (i.e., the addition more establishments would likely increase the total samples or the denominator more than the positives or the enumerator, having the overall effect of decreasing the rate). For *L. monocytogenes*, 18 out of 2,937 samples were positive, for a rate of 0.61 percent. Given the 2,937 products tested for *L. monocytogenes* under ALLRTE in 2006 and the percent positive rate of 0.61 percent, FSIS is 95 percent confident that it could detect a 58.6 percent increase in the positive rate. To detect a 50 percent increase, 4,030 samples would have to be tested.

For 2006, none of the 2,937 samples tested for *Salmonella* under ALLRTE were positive. Given the absence of positive samples, it is not possible to determine how many samples would be needed to determine an increase.

Overall RTE Results

A total of 12,372 RTE products were tested by FSIS for *L. monocytogenes* in 2006 under the sampling projects ALLRTE, RTE001, and RLm (not including the 2,745 product contact surface and environmental samples). The average percentage of positive product samples across all projects was 0.48 percent. Including the 2,745 product contact surface and environmental samples that were analyzed as part of RLm, the total number of *L. monocytogenes* analyses conducted by FSIS for 2006 was 15,117. Given the 12,372 RTE products tested overall for *L. monocytogenes* in 2006 and the percent positive rate of 0.48 percent, FSIS is 95 percent confident that it could detect a 32.3 percent increase in the positive rate. To detect a 50 percent increase, 5,129 samples would have to be tested.

FSIS testing has consistently found very low levels of *Salmonella* in RTE products. The percentage of positive samples has been noticeably lower since 2003. During 2001 to 2002, FSIS found 23 positives in 14,121 samples (0.16 percent positive). From 2003 through 2006, FSIS tested 41,154 samples for *Salmonella* and found 21 positives (0.05 percent positive). The percentage of samples positive for *Salmonella* in CY 2006 was 0.02 percent (2 positives in 11,842 samples), the lowest level since the implementation of HACCP. Given the 11,842 products tested for *Salmonella* in 2006 and the percent positive rate of 0.02 percent, FSIS is 95 percent confident that it could detect a 161.6 percent increase in the positive rate. To detect a 50 percent increase, 123,675 samples would have to be tested.

As detailed above, FSIS has conducted a regulatory microbiological testing program on RTE meat and poultry products since 1983. From 1994 through 2006, 7,683 RTE products (cooked beef patties and dry fermented sausages) were tested for the presence of *E. coli* O157:H7. All RTE samples tested for *E. coli* O157:H7 were negative.

Potential Limitations of RTE Data

The limitations and uncertainties that may be associated with the use of FSIS RTE data in measuring an establishment's risk control and subsequently its level of inspection are discussed below.

The previously proposed algorithm used all pathogen test results that would lead to a regulatory result. For *L. monocytogenes* this included test results from a variety of sampling projects including ALLRTE, RTE001, RLMPROD, RLMCONT, INTPROD (intensified testing of RTE product), and INTCONT (intensified testing of RTE food contract surfaces). It is unclear whether mixing sampling results for random verification testing of any and all RTE products with sample results only for post-lethality exposed RTE products based on risk-based sampling may produce results that are unrepresentative and thus would be misleading in terms of allocating inspection resources.

A possible issue with data quality may exist regarding the laboratory procedure that is followed to test RTE. Under current procedures, FSIS collects one 25-g sample for analysis. However, U.S. FDA and some international agencies collect two 25 g samples for regulatory analysis of RTE products. FSIS is currently evaluating whether changing its procedures would improve the quality of its RTE data and is also evaluating the impact that such a change would have on data analysis efforts.

A related issue to this has to do with whether contamination by an organism such as *L. monocytogenes* (and other pathogens such as *E. coli* O157:H7 and *Salmonella*) is uniformly distributed within and among lots of meat and poultry products. This could affect, for a given lot, the probability that a test will be positive if the lot is positive, and the probability that sampling one lot will find contamination if contamination is not uniform among lots. This becomes especially problematic for pathogens, such as *L. monocytogenes*, that are present at very low levels. This also extends to assumptions made by FSIS in its *L. monocytogenes* Model. The model requires the setting of a probability of detecting 1 colony forming unit (cfu) of *Listeria* species for food contact surface testing and 1 cfu of *L. monocytogenes* for product testing. For the base runs, both probabilities were set at 75 percent (i.e., the model, as a default, assumes a 0.75 probability of detecting a positive if the sample actually is positive). Having better data on

the quantitative sensitivity of the laboratory test, therefore, could decrease the uncertainty in the model.

The data are collected based on an establishment basis, rather than being representative of the volume of RTE products that are produced, which could limit the applicability of the data for determining national prevalence.

In addition, the RTE data are from regulatory testing programs that change from year to year, and possibly even within a year, and therefore any comparisons should be made with caution. These regulatory programs have not been designed to test for statistically significant change from one year to the next.

A large number of samples have been tested in the RTE testing program, but fortunately few samples have been positive for *Salmonella*, and *L. monocytogenes*, and none have been positive for *E. coli* O157:H7. Although from a public health standpoint that is a good outcome, it does limit the ability of this dataset to be used for analysis and comparison to other factors. However, if used independently as a factor that would separate a facility into different categories, this limitation does not has as much of an impact.

OTHER POSSIBLE PARAMETERS

In addition to those parameters that were used in the previously proposed algorithm for RBI in processing facilities, FSIS has considered other data for use in an RBI algorithm. Data on potential variables (e.g., the age and the square footage of production facilities, the number of employees, the HACCP training the facility conducts, and the use of chemical sanitizers that are used in the facility as part of its SSOPs) have been analyzed for FSIS by RTI (RTI 2005). The FSIS does not currently have information on those variables for all facilities.