

# **Improvements for Poultry Slaughter Inspection**

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## **Appendix D – Data Sources**

## APPENDIX D – DATA SOURCES

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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.

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

<i>Data</i>	<i>Description</i>	<i>Comments</i>
Production Volume	<p>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:</p> <ul style="list-style-type: none"> <li>• inspector-generated volume data from all processing facilities collected through an extension in the Performance Based Inspection System (PBIS);</li> <li>• volume data collected by inspectors when collecting ground beef samples for <i>Escherichia coli</i> O157:H7 (<i>E. coli</i> O157:H7) verification testing; and</li> <li>• data on RTE product collected through a survey approved by the Office of Management and Budget (OMB).</li> </ul>	<p>Criticized by stakeholders, stating that the FSIS inspection force is not able to precisely collect the information; no analysis to indicate that.</p> <p>Annual production volume collected from industry on Form 10,240-1 might miss seasonal variations.</p>
NRs	<p>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.</p>	<p>Criticized by stakeholders for potential inconsistency in the issuance of NRs nationwide; no analysis to indicate that.</p> <p>Impact of appeals.</p>
Consumer Complaints	<p>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.</p> <p>Consumer complaints associated with consumption of a meat, poultry, or egg product involve:</p> <ul style="list-style-type: none"> <li>• an illness that occurred after eating;</li> <li>• an injury that occurred during eating;</li> <li>• foreign object/material;</li> <li>• an allergic reaction;</li> <li>• under processing of a RTE product;</li> <li>• misbranding, improper labeling;</li> <li>• economic adulteration; or</li> <li>• inferior quality of products.</li> </ul>	<p>Designed as a surveillance system, not to assign blame or pinpoint loss of process control.</p> <p>Not every consumer complaint is of public health significance.</p> <p>Passive system could lead to under-reporting.</p> <p>Lacks complete and accurate attribution data or “traceback” information due, in part, to the difficulties that consumers have in tracing illness to food sources.</p> <p>Illnesses could result from circumstances outside control of inspected establishment (post-production temperature abuse, subsequent contamination through mishandling or further processing).</p> <p>There may be a significant lag time (perhaps even several months) between when product is purchased and when a consumer makes a complaint.</p> <p>Could be an “isolated” incident.</p> <p>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).</p> <p>Bias could be observed after major product recalls.</p>
Food Safety Recalls	<p>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.</p> <p>Classified by FSIS based on the relative health risk:</p>	<p>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.</p> <p>Once a recall is initiated, information about the recall is tracked in a very timely manner by FSIS, and there may be a</p>

Data	Description	Comments
	<ul style="list-style-type: none"> <li>• <b>Class I</b> - A Class I recall involves a health hazard situation in which there is a <i>reasonable</i> probability that eating the food will cause health problems or death.</li> <li>• <b>Class II</b> - A Class II recall involves a potential health hazard situation in which there is a <i>remote</i> probability of adverse health consequences from eating the food.</li> <li>• <b>Class III</b> - A Class III recall involves a situation in which eating the food will not cause adverse health consequences.</li> </ul>	<p>significant lag time (possibly a couple of months) between when product is distributed and when it is determined that a recall is necessary.</p>
<p>Enforcement Actions</p>	<p>Variety of enforcement actions the Agency can take against establishments that fail to sufficiently comply with applicable regulatory requirements.</p> <p>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.</p> <p>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.</p>	<p>Criticized by stakeholders stating that inconsistencies may occur in the issuance of enforcement actions across FSIS regions and personnel; no analysis to indicate that.</p>
<p><i>Salmonella</i> Verification Testing</p>	<p>Sample sets are collected and analyzed (number of days of sampling varies by product type).</p> <p>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 <i>Salmonella</i> testing.</p> <p>Establishments are placed into one of three categories based on the results of the <i>Salmonella</i> sets.</p>	<p>Sampling design and guidelines limit the use of the data to determine national prevalence rates of <i>Salmonella</i> in FSIS-regulated products, especially because the sampling is random and does not take into account production volume.</p> <p>Current FSIS procedures allow only one product to be tested at a time per establishment. Time needed to complete a <i>Salmonella</i> set could range from 2 months to more than a year (e.g., in low-volume establishments)</p> <p>Only one product is tested at a time in an establishment, some products in an establishment that produces multiple projects subject to <i>Salmonella</i> verification could go untested for several years.</p> <p>Does not take into account post-retail consumer habits (different typical ways of cooking different products).</p> <p>Exotic and minor species, such as lamb, goats, sows/boars, quail, squab, ratites, buffalo, and egg-laying hens, are not currently tested in <i>Salmonella</i> sets by FSIS.</p>
<p><i>L. monocytogenes</i> Alternative for RTE Product</p>	<p>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 <i>L. monocytogenes</i>.</p> <p>The <i>L. monocytogenes</i> alternative categories are as follows:</p> <p><b>Alternative 1</b> - Establishments that apply <u>both</u> a post-lethality treatment to the RTE product to reduce or eliminate microorganisms on product <i>and</i> the use of an antimicrobial agent or process</p>	<p>Not all of the establishments regulated under the Interim Final Rule to Control <i>L. monocytogenes</i> 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 <i>L. monocytogenes</i> in RTE products (probably fewer than 212 establishments).</p> <p>Currently, FSIS does not verify accuracy of the information, including the alternative, submitted by a regulated establishment.</p>

Data	Description	Comments
	<p>as part of the product formulation.</p> <p><b>Alternative 2</b> - Establishments that apply <u>either</u>:</p> <p>Alternative 2A - A post-lethality treatment to limit the growth of <i>L. monocytogenes</i> on the product, <u>or</u></p> <p>Alternative 2B - An antimicrobial agent or process as part of the formulation.</p> <p><b>Alternative 3</b> - Establishments that rely <u>only</u> on testing and sanitation measures.</p>	
<b>Zero Tolerance Pathogen Testing Program</b>		
<p>Microbiological Testing Program for <i>E. coli</i> O157:H7 in Raw Ground Beef</p>	<p>Microbiological testing program to detect <i>E. coli</i> O157:H7 in raw ground beef.</p> <p>In 2007, added routine and follow-up sampling of raw ground beef components (e.g., beef trim).</p> <p><i>E. coli</i> O157:H7 is a zero tolerance pathogen, therefore, when a sample is found to be positive for <i>E. coli</i> O157:H7, the product is deemed adulterated.</p> <p>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).</p>	<p>Regulatory program has not been designed to test for statistically significant changes in the national prevalence of <i>E. coli</i> 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.</p> <p>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.</p> <p>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.</p> <p>As with all FSIS sampling programs, there is ‘drop out’ of <i>E. coli</i> 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.</p>
<p>Ready-to-eat Pathogen Testing Program Results</p>	<p>Regulatory microbiological testing program on RTE meat and poultry products.</p> <p>Certain RTE products are tested for <i>L. monocytogenes</i>, <i>Salmonella</i> species, and <i>E. coli</i> O157:H7 as part of that program.</p>	<p>Need to consider which pathogen test results to use; e.g., for <i>L. monocytogenes</i> 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).</p> <p>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.</p> <p>Question of whether contamination by an organism such as <i>L. monocytogenes</i> (and other pathogens such as <i>E. coli</i> O157:H7 and <i>Salmonella</i>) is uniformly distributed within and among lots of meat and poultry products. Especially problematic for pathogens, such as <i>L. monocytogenes</i>, that</p>

Data	Description	Comments
		<p>are present at very low levels.</p> <p>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.</p> <p>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.</p> <p>A large number of samples have been tested in the RTE testing program, but fortunately few samples have been positive for <i>Salmonella</i>, and <i>L. monocytogenes</i> and none have been positive for <i>E. coli</i> O157:H7.</p>

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

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

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

53 Expert elicitations are subjective in nature, which could add uncertainty. The 2007 elicitation  
 54 attempted to semi-quantify that uncertainty by capturing each expert’s certainty in their rankings.  
 55 In addition, the variability across raters within an elicitation, and between the rankings in the  
 56 2005 and 2007 elicitation, can also indicate the uncertainty. In general, there was variability in  
 57 the absolute ratings across experts for some products, although the relative rankings were fairly  
 58 consistent, both within each elicitation and between the 2005 and 2007 rankings.

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

62 **PRODUCTION VOLUME**

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

69 **PBIS Extension Data**

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

77 **Production Volumes Associated with Ground Beef Samples**

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

- 81 > 250,000 pounds ground beef,
- 82 > 50,000 to 250,000 pounds ground beef,
- 83 1,000 to 50,000 pounds ground beef,
- 84 < 1,000 pounds ground beef.

85 **RTE Production Volume Data**

86 In October 2003, FSIS issued 9 *Code of Federal Regulations* (CFR) 430, the Interim Final Rule  
87 to Control *L. Monocytogenes* in Certain RTE Meat and Poultry Products. The Interim Final Rule  
88 set out the regulatory requirements for RTE products that have been exposed to the environment  
89 after a lethality step (i.e., post-lethality). As part of the requirements, industry provides volume  
90 data for *L. monocytogenes* post-lethality-exposed RTE meat and poultry products. The  
91 information is updated annually if there is a significant change in volume of production. In  
92 2007, all facilities were required to complete a new form, updating the volume information. The  
93 volume information collected on the form (FSIS Form 10,240-1) is the annual production  
94 volume, in pounds, of nine different RTE products.

95 **Potential Limitations of the Data**

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

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

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

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

## 104 **PUBLIC HEALTH SIGNIFICANT NRS**

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

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

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126

**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."

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128 **Potential Limitations of the Data**

- 129
- 130 • One of the issues surrounding the issuance of NRs in the field is inconsistency—the
  - 131 issuance of NRs could vary nationwide. Risk based inspections (RBI) stakeholders
  - 132 (Resolve 2006) have made the criticism that NRs are highly subjective and fundamentally
  - 133 flawed due to the inconsistent application and interpretation of existing requirements.
  - 134
  - 135 – One underlying factor for the inconsistency could be vacancy rates of inspectors in
  - 136 Districts. The rate of NR issuances may be reduced and narrowed due to fewer
  - 137 inspector resources.
  - 138
  - 139 – There could also be an increase in the issuance of a particular NR following the
  - 140 release of a Directive or Notice for a particular regulation associated with an NR due
  - 141 to increased awareness.
  - 142
  - 143 • Stakeholders have commented that there could also be potential food safety issues
  - 144 occurring at a plant that may on occasion not be written in an NR because FSIS personnel
  - 145 do not recognize them as a noncompliance. The FSIS conducts ongoing training of its
  - 146 inspection force to limit such events.

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

## 149   **CONSUMER COMPLAINTS**

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

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

- 159       • an illness that occurred after eating;
- 160       • an injury that occurred during eating;
- 161       • foreign object/material;
- 162       • an allergic reaction;
- 163       • under processing of an RTE product;
- 164       • misbranding, improper labeling;
- 165       • economic adulteration; or
- 166       • inferior quality of products.

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

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

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

### 190 **Consumer Complaint Frequency**

191 Between 2001, when the CCMS was started, and the end of 2006, there were approximately  
192 5,000 complaints entered into CCMS. In 2006, there were 982 consumer complaints added to  
193 the CCMS database. Of these, the majority, 499, (51 percent) were related to foreign object  
194 complaints; 149 were related to illness; 19 to economic adulteration; 17 to misbranding; 16 to  
195 allergic reaction; 7 to injury; and 81 were classified as other. The breakdown of complaint types  
196 for 2004 and 2005 is very similar to those for 2006.

### 197 **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.

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199 **Potential Limitations in the Consumer Complaint Data**

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

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

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

220 Another limitation of the database is the incompleteness of the complaint data relative to the total  
221 number of foodborne illnesses in the United States, due to under-reporting of consumer  
222 complaints to FSIS. The FSIS consumer monitoring system is passive, therefore, a large number  
223 of illnesses might never be captured because consumers do not contact FSIS. Often consumers  
224 will complain directly to the company that manufactured a product, especially if the firm has a  
225 toll-free consumer complaint hot line, rather than to FSIS. This is directly related to consumer  
226 behavior, such as the expectation of receiving compensation from the company for making a  
227 complaint. Even more frequently, consumers may fall ill from food consumption, but will not  
228 make a complaint or not link their illness to food consumption. In 1999, Centers for Disease  
229 Control and Prevention (CDC) estimated that foodborne diseases caused approximately  
230 76 million illnesses in the United States, yet there have been less than 6,000 consumer  
231 complaints reported to FSIS over the past 6 years.

232 FSIS consumer complaint data also lacks complete and accurate attribution data<sup>1</sup> or “traceback”  
233 information. This lack of data is due, in part, to the difficulties that consumers have in tracing  
234 illness to food sources. Food attribution data is required in order to link illnesses with specific  
235 food products.

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

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<sup>1</sup> Attribution data has been identified by nearly all RBI stakeholders as a critical need for implementing a successful RBI system.

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

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

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

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

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

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

## 282 **FOOD SAFETY RECALLS**

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

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

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

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

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

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

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

### 301 **Recall Frequency**

302 In 2006, there were 34 recalls of FSIS-regulated products. Of these, the majority (26) were  
303 Class I recalls; 6 were Class II recalls; and 2 were Class 3 recalls. None of these recalls occurred  
304 at the same establishment; it is rare for a recall to occur at the same establishment within a  
305 6-month, 1-year, or even longer period.

306 More recently, in the 6 month period between December 1, 2006, and May 31, 2007, there were  
307 25 recalls. Of these, 20 were Class I; 3 were Class 2; and 2 were Class 3 recalls. None of these  
308 recalls occurred at the same establishment.

### 309 **Potential Limitations of Recall Data**

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

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

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

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

## 319 **ENFORCEMENT ACTIONS**

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

### 330 **Potential Limitations in Enforcement Action Data**

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

- 334 • The previously proposed RBI algorithm would not reflect whether there were multiple  
335 reasons underlying the enforcement action.
  
- 336 • Concern has been raised by stakeholders in public meetings regarding inconsistencies in  
337 the issuance of enforcement actions that may occur across FSIS regions and personnel.  
338 The FSIS has a number of controls, including detailed directives and notices, and training  
339 to guide enforcement actions, and management controls such as AssuranceNet to monitor  
340 field activities and help ensure that its actions are consistent nationwide. There is no data  
341 that FSIS is aware of that indicates that this has occurred, but FSIS will analyze its  
342 inspection data further to determine if any such inconsistencies occur in different areas of  
343 the country or in particular Districts. It also continues to reinforce to its field personnel  
344 the importance of issuing enforcement actions in a consistent manner.

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

351 **Salmonella Verification Testing**

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

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

369 **Salmonella Standards**

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

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

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

389  
390

**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.

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

398 **Sampling Plan and Sample Collection**

399 Each month, FSIS schedules approximately 75 sample sets for *Salmonella* testing across the  
400 8 classes of raw product. Establishments are notified by FSIS prior to testing.

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

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

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

418

**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%
<b>Summary</b>	<b>44,668</b>	<b>2,106</b>	<b>4.7%</b>	<b>1,123</b>	<b>53%</b>

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

419 Detailed guidelines for collecting raw meat and poultry samples for *Salmonella* testing have been  
 420 provided to the FSIS inspection force (FSIS 1997, [http://www.fsis.usda.gov/OPPDE/rdad/](http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/Salmonella_Analysis.pdf)  
 421 [FSISDirectives/Salmonella\\_Analysis.pdf](http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/Salmonella_Analysis.pdf)). The sample collection method depends upon the  
 422 product being sampled. Cattle, turkeys, and swine carcasses are sampled by swiping a sterile  
 423 sponge over specified areas using a template to mark the sampling areas. The sponge is then  
 424 placed in a sample bag for shipment and analysis. Rinses from chicken carcasses are sampled by  
 425 placing a whole chicken carcass in a sterile bag with 400 mL of buffered peptone water, shaking,  
 426 and collecting the peptone water in a sterile screw-cap container. A 25 (g) sample of ground  
 427 product is collected using a sterile plastic ring template that, when filled, yields the required 25 g  
 428 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.

430 **Salmonella Verification Categories**

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

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

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

442 **Category III** – Failed most recent *Salmonella* set.

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

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

452 **Table D-4. Cut Points of Set Results Defining at or Below Half the *Salmonella***  
 453 **Performance Standard, Above Half the Standard, and Exceeding**  
 454 **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)

455 **Table D-5. Summary of Classification of Establishments Subject to *Salmonella* Verification**  
 456 **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
<b>Summary</b>	<b>1,365</b>	<b>1,108</b>	<b>81</b>	<b>220</b>	<b>16</b>	<b>37</b>	<b>3</b>

457 ***Salmonella* Serotype and Subtype Information**

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

465 **Results of Testing Program**

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

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

478 **Prevalence of *Salmonella* Species**

479 *Baseline Studies*

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

492 ***Salmonella* Verification Testing and Prevalence**

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

503 **Potential Limitations of Data**

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

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

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

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

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

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

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

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

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

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

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

#### 549 **Use of *Salmonella* Data**

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

555 **L. MONOCYTOGENES ALTERNATIVE FOR RTE PRODUCT**

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

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

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

566 **Alternative 2** - Establishments that apply either:

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

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

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

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

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

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

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**592 Results**

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

**602 Potential Limitations in *L. monocytogenes* Alternative Data**

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

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

**620 ZERO TOLERANCE PATHOGEN TESTING PROGRAM**

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

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

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

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

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

648 **Sampling Plan and Sample Collection**

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

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

663 The FSIS has always collected two pounds for a sample, however, over time, FSIS changed the  
664 amount of product analyzed and adopted more sensitive testing methods to improve its ability to  
665 detect *E. coli* O157:H7 in FSIS-regulated product. During October 1997, the amount of product  
666 analyzed was increased from 25 g to 325 g (by analyzing five 65 g samples). It was determined  
667 that having a larger volume would not affect the ability of the analytical test to detect a positive.  
668 However, analyzing the five 65 g samples makes the product analyzed more representative of the  
669 lot being tested, increasing the likelihood of identifying a contaminated lot and making the  
670 homogeneity of the product less of an issue. Currently, five 65 g subsamples are analyzed  
671 (325 g). Any excess from the two-pound sample is reserved at the laboratory. If any of the five  
672 subsamples are positive, the sample is declared positive. The results from this routine sampling  
673 program in ground beef are captured in the FSIS sampling database under Project Code MT03.

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

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

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

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

702 The FSIS is designing an intensive follow-up sampling scheme (sampling in response to an  
703 *E. coli* O157:H7 positive test result) that will allow FSIS to verify that an establishment is not  
704 producing product with a greatly increased positive rate of *E. coli* O157:H7 contamination  
705 (relative to the annual rate). At the current rate of *E. coli* O157:H7 positive FSIS samples  
706 (0.17 percent in ground beef samples) this could be accomplished by taking 16 samples over a  
707 120-day period. In smaller producers this number could be limited to 8 samples over 120 days to  
708 lower the potential economic burden. This scheme is under review and will be implemented as  
709 soon as possible.

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

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

### 720 ***E. coli* O157:H7 Subtype Information**

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

### 737 **Results of Testing Programs**

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

743 Since the testing program was initiated in 1994, more than 90,000 samples of raw ground beef  
744 have been tested for *E. coli* O157:H7, with an average of 7,053 samples per year being tested  
745 (see **Table D-6**). The number of samples analyzed has increased in the past 3 years, and at the  
746 same time, there appears to have been a decrease in the rate of positives found. In the year 2000,  
747 6,375 samples were collected, of which 55 (0.86 percent) were positive. However, in 2006,  
748 11,779 samples were collected, of which only 20 (0.17 percent) were positive. This suggests a  
749 decline in the rate of *E. coli* O157:H7 in the samples being tested since the year 2000. A study  
750 of the data from 2000 to 2003 showed a statistically significant decline during that timeframe  
751 (Naugle et al. 2005). The decrease was attributed to FSIS regulatory actions which resulted in  
752 industry actions to reduce *E. coli* O157:H7 in raw ground beef. With the 11,779 samples and a  
753 0.17 positive rate, FSIS would be able to have statistical confidence (95 percent) that it could  
754 detect a 55.5 percent change in the percent positive rate. With a sample size of 14,528 samples,  
755 FSIS would have statistical confidence (95 percent) that it could detect a 50 percent change in  
756 the percent positive rate.

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

759 federally-inspected establishments (see **Table D-7**), the results have also been very consistent  
 760 since 2004, with a positive rate of 0.18 percent, 0.16 percent, and 0.17 percent in 2004, 2005,  
 761 and 2006, respectively (see Table D-7). The positive rate for 2007, as of August 19, is  
 762 0.21 percent for federally-inspected establishments and 0.20 for all raw ground beef projects  
 763 (data not shown).

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

770 **Table D-6. Annual *E. coli* O157:H7 Results for the FSIS Verification Sampling Program of**  
 771 **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 <sup>a</sup>	6,065	4	0.066 %
1998	8,680	14	0.17 %
1999 <sup>b</sup>	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 %
<b>Total since 2000<sup>c</sup></b>	<b>57,459</b>	<b>242</b>	<b>0.42</b>

<sup>a</sup> During October 1997, the amount analyzed was increased from a 25 g sample to a 325 g sample to provide increased detection sensitivity.

<sup>b</sup> On September 3, 1999, a new selection and detection method was introduced to further increase test sensitivity.

<sup>c</sup> Data since 2000 can be summed because they were obtained using the same (more sensitive) detection method (see footnotes a and b).

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**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

776 As discussed earlier, over time, FSIS changed the volume analyzed and adopted more sensitive  
777 testing methods to improve its ability to detect *E. coli* O157:H7 in FSIS-regulated product, as  
778 part of its goal to continuously improve its sampling programs. With those changes, the number  
779 of positives increased from 4 to 14 (or from 0.066 percent to 0.17 percent) between 1997 and  
780 1998 (see Table D-6). On September 3, 1999, a new selection and detection method was  
781 introduced to further increase test sensitivity. The number of positives increased from 32 to  
782 55 (from 0.41 percent to 0.86 percent) between 1999 and 2000 (see Table D-6). Both increases  
783 were most likely due to improvements in the sensitivity of the sampling protocol and detection  
784 method.

785 Since 2000, the rate of positives has declined—from 0.86 percent in 2000 to 0.17 percent in  
786 2006— while the number of samples tested has increased (see Table D-6). The decline in the  
787 rate of positives could be due to industry actions to reduce the levels of *E. coli* O157:H7 during  
788 slaughter/dressing procedures and processing (e.g., using antimicrobials on trimmings)  
789 operations. Since the initiation of the FSIS testing program, many grinders and suppliers of raw  
790 ground beef components have instituted programs to test their ground beef products or raw  
791 materials used in ground beef products for *E. coli* O157:H7. Testing may enable industry to  
792 identify and subsequently implement more effective interventions that will further reduce the  
793 level of *E. coli* O157:H7 in raw ground beef, such as improved pasteurization systems or hot  
794 water washing of the carcass, as well as to detect contaminated lots and prevent their entry into  
795 commerce.

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

**801 Prevalence of *E. coli* O157:H7**

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

805 A baseline study to determine the national background level of *E. coli* O157:H7 in beef trim was  
806 recently completed. A preliminary analysis of this baseline data indicates that approximately  
807 0.66 percent of samples are positive for *E. coli* O157:H7<sup>2</sup>. An assessment was made of the  
808 number of samples that would be needed to be tested to determine if the national proportion of  
809 *E. coli* O157:H7 positive samples in beef trim is increasing or decreasing from one year to the  
810 next. Based on a prevalence of 0.66 percent positive, testing a sample size of 3,000 to  
811 4,000 samples of beef trim per year would allow detection of a 50 percent increase in the  
812 national background level of *E. coli* O157:H7 in beef trim.

**813 Potential Limitations of Data**

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

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

824 In 2006, 11,626 samples of raw ground beef were collected and analyzed from approximately  
825 1,400 federally-inspected establishments. As sampling occurs on a random basis, this indicates  
826 that most establishments were subject to testing about 8 times during the year. The percent  
827 positive rate of *E. coli* O157:H7 in raw ground beef is low. Since the year 2000, over  
828 57,459 samples have been tested by FSIS, and only 242 were found to be positive (mean percent  
829 positive is = 0.42 percent; range 0.17 percent to 0.86 percent (see Table D-6). Having a low  
830 percent positive is the desired outcome, however, it does limit the statistical analyses that can be  
831 done on the data.

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

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<sup>2</sup> Note – Results are preliminary and subject to change.

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

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

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

#### 865 ***Future Use of E. coli O157:H7 Data***

##### 866 *Risk Based Inspection*

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

##### 870 *Risk Based Sampling*

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

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

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

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

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

### 907 ***RTE Pathogen Testing Program Results***

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

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

### 916 **Sampling Plan and Sample Collection**

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

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

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

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

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

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

<sup>a</sup> *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](http://www.fsis.usda.gov/Science/Table1_Micro_Testing_RTE_1990-2004/index.asp)

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

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

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

960 **Table D-9. Product Categories Assigned to Products by Laboratory Personnel in FSIS’**  
 961 **Microbiological Testing Program for RTE Meat and Poultry Products<sup>a</sup>**

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, <i>pâté de foi gra</i>
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

<sup>a</sup> 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](http://www.fsis.usda.gov/Science/Micro_Testing_RTE/index.asp)).

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

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

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

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

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

- 989 1. Routine *L. monocytogenes* (RLm) risk-based sampling project for establishments in  
990 which RTE product is exposed to the environment post-lethality treatment (i.e., with  
991 sampling scheduled in the highest-risk establishments), with approximately equal  
992 percentage of samples being *L. monocytogenes* Alternative 3 and 2b, up to 5 percent  
993 being *L. monocytogenes* Alternative 2a, and the remainder are from Alternative 1. This  
994 program includes sampling of food contact surfaces for *L. monocytogenes*, environmental  
995 samples for *L. monocytogenes*, and intact product verification testing for  
996 *L. monocytogenes*.
- 997 2. Routine intact product sampling under RTE001; and then
- 998 3. Random sampling under ALLRTE in the remaining RTE establishments.

999 The sampling for those three sampling projects—RLm, RTE001, and ALLRTE—are discussed  
1000 below.

1001 *RLm*

1002 In 2006, as part of the overall FSIS *L. monocytogenes* risk-based verification testing program,  
1003 FSIS began a new risk-based testing program referred to as the Food Contact, Environmental  
1004 (Non-Food Contact), and Intact Product Verification Testing Program, which is known as the  
1005 Routine *L. monocytogenes* Risk-Based sampling program (RLm). Samples collected under this  
1006 program are limited to establishments subject to 9 CFR Part 430 (i.e., establishments in which  
1007 RTE products are exposed to the post-lethality environment).

1008 Under this program, testing of food contact and environmental (non-food contact) surfaces for  
1009 *L. monocytogenes* is conducted concurrent with product testing. The RLm testing program  
1010 consists of three sampling projects:

- 1011 • RLMCONT - testing of surfaces that have direct contact with RTE product in the RTE  
1012 production area;
- 1013 • RLMENVR - testing of environmental (non-food contact) surfaces in the RTE production  
1014 areas; and
- 1015 • RLMPROD - testing of intact product samples collected concurrently with food and  
1016 environmental contact surface swabs throughout the selected production shift.

1017 RLm sampling is done in conjunction with a comprehensive Food Safety Assessment (FSA).  
1018 Unlike ALLRTE and RTE001 sampling projects, which are sampled for *Salmonella* and, in some  
1019 cases, *E. coli* O157:H7, RLm samples are only analyzed for *L. monocytogenes*.

1020 Each month, one establishment per FSIS District (i.e., 15 establishments per month) is selected  
1021 for RLm testing using FSIS’ risk-based algorithm for *L. monocytogenes* sampling among  
1022 establishments that produce post-lethality exposed products. Those using Alternative 3 control  
1023 measures will be sampled the most. Samples will be collected at a decreasing frequency in  
1024 establishments electing to use Alternative 2, Choice 2 (2B); Alternative 2, Choice 1 (2A); and  
1025 Alternative 1. A Scheduling Memo is sent to Districts to inform them of the establishment  
1026 selected for RLm sample collection, and the District selects the week the sampling is to occur.  
1027 EIAOs and Public Health Veterinarians (PHVs) trained in the EIAO methodology are  
1028 responsible for collecting RLm samples according to FSIS Directive 10,240.5 (March 15, 2006).  
1029 In conjunction with the sample collection, the EIAOs or PHVs also assess whether the  
1030 establishment’s food safety system complies with 9 CFR Part 430. Once RLm sampling has  
1031 been conducted in an establishment, it will not be eligible for RLm scheduling again for a  
1032 12-month period.

1033 The number and type of samples collected at the establishment by FSIS field personnel varies  
1034 depending on the process and operation being conducted. In general, one “sampling unit” is  
1035 collected for each post-lethality exposed RTE line. A standard “sample unit” is defined as  
1036 10 food contact surface swabs, 5 environmental swabs, and 3 intact product samples. A  
1037 maximum of 5 sample units are collected within any selected establishment. This gives a

1038 possible range of 18 to 90 samples per establishment. If the establishment has more than 5 lines,  
1039 product from the higher risk lines is selected for testing. Products are selected using the  
1040 hierarchy as described in **Figure D-5**. The average number of samples per establishment taken  
1041 at an establishment since the beginning of the program in April of 2006 is 8 product samples,  
1042 14 environmental samples, and 28 food contact surface samples, giving a total of 50 samples per  
1043 plant on the average.

1044 The actual sites for food contact and environmental swab sampling are determined by the  
1045 EIAO/PHV. In accordance with the requirements for a sample unit, more swabs are to be  
1046 collected from food contact surfaces than the number collected from environmental surfaces.  
1047 Some food contact surface swabs are collected at the end of pre-operational sanitation activities  
1048 but before the start of production. However, more food contact surface swabs are to be collected  
1049 during operations.

1050 Intact samples of three products associated with the same production day, shift and lines  
1051 represented by the food contact and environmental surface swabs are also randomly collected  
1052 during the same production day. Product samples taken at an establishment come from only one  
1053 sampling project during any given timeframe, regardless of who within FSIS is collecting the  
1054 samples, in the following priority: RLM-related product samples, RTE001, or ALLRTE. If  
1055 sampling is scheduled to occur at an establishment concurrently under more than one sampling  
1056 project, FSIS field personnel ensure that different lots of product are sampled for different  
1057 projects.

1058 **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)

1059 *RTE001*

1060 In 2004, FSIS initiated a project named RTE001, which was the first HACCP verification project  
1061 in which RTE establishments were not equally likely to be scheduled for sampling each month,  
1062 but were risk based. Phase 1 of the FSIS *L. monocytogenes* risk-based verification testing  
1063 program was implemented in January 2005. In 2006, RTE001 became the primary RTE  
1064 sampling project in 2006, representing almost 70 percent of regulatory product sampling. Under  
1065 RTE001, only establishments processing RTE exposed to the environment post-lethality  
1066 treatment are sampled.

1067 The instructions for implementing RTE001 are in FSIS Directive 10,240.4 (2006). Inspection  
 1068 personnel are to select the highest risk post-lethality exposed RTE product produced at the time  
 1069 of collection according to the hierarchy in Figure D-5.

1070 Under RTE001, 800 to 1,000 establishments are scheduled each month for sampling<sup>3</sup>. Currently,  
 1071 of the more than 800 establishments that are scheduled for sampling each month, sampling is  
 1072 completed for all but about 50. Reasons for not completing sampling under this project vary, but  
 1073 are most often related to an establishment no longer making the RTE product, or a product line  
 1074 being out of service.

1075 *ALLRTE*

1076 In 2006, the ALLRTE project discussed above was modified. Under the modified ALLRTE  
 1077 project, all FSIS-regulated RTE establishments are considered on an annual basis, except those  
 1078 that were scheduled for sampling under RTE001. FSIS collects one sample of product at a time  
 1079 from the randomly selected individual establishments, and tests for pathogens according to the  
 1080 product as outlined in Table D-8. Eight-five establishments are scheduled each week for  
 1081 sampling under this project. Inspection program personnel were instructed to collect an RTE  
 1082 product that fit the previous definitions of targeted or low-targeted products. In other words, the  
 1083 agency requested random samples across a wide variety of RTE products, with the exception of  
 1084 products that are non-targeted (i.e., have low risk for supporting growth of pathogens like fats  
 1085 and oils, and dried soup mixes). Up to 4,420 product samples per year are collected under this  
 1086 program for microbial analysis.

1087 **Follow-up *L. monocytogenes* Sampling—Intensified Verification Testing (IVT)**

1088 When a product sample taken under one of the sampling projects outlined above is found to be  
 1089 positive for *L. monocytogenes*, FSIS will conduct follow-up verification testing after the  
 1090 establishment has taken its corrective and preventive actions. The follow-up sampling will be  
 1091 conducted under the IVT projects (Project Code Names INTPROD and INTCONT). Those  
 1092 projects are designed for testing in any operation involving any RTE meat or poultry product,  
 1093 regardless of the establishment’s production volume, control procedures, or other risk mitigating  
 1094 factors. IVT could occur because of history of having produced adulterated product (i.e., the  
 1095 preshipment review has been completed), for investigative purposes (e.g., as a result of an  
 1096 outbreak of foodborne disease), or because there is a concern that the establishment may not be  
 1097 properly controlling for pathogens. Multiple samples could be collected through IVT, and  
 1098 include:

- 1099 • Increased frequency and number of samples taken for product testing (as compared to  
 1100 targeted verification testing), and the collection of environmental samples.
- 1101 • Increased FSIS record verification checks regarding the design and implementation of the  
 1102 food safety system.

1103 These sampling projects are scheduled by FSIS on a case-by-case basis.

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<sup>3</sup> 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.

1104 **Results of Testing Program**

1105 As discussed above, FSIS currently conducts three RTE testing projects: RLM, RTE001 and  
 1106 ALLRTE. The results of each of those three projects are discussed below. Samples collected  
 1107 under the RLM project are only tested for *L. monocytogenes*, and therefore only  
 1108 *L. monocytogenes* results are presented in that section. Under RTE001 and ALLRTE, results for  
 1109 *L. monocytogenes*, and *Salmonella* are presented. Overall results are then presented for  
 1110 *L. monocytogenes*, and *Salmonella*, and *E. coli* O157:H7. *E. coli* O157:H7 results are only  
 1111 presented in the overall section because all samples tested for *E. coli* O157:H7 were negative.  
 1112 The results for the RTE testing program are presented on the FSIS Web site  
 1113 ([http://www.fsis.usda.gov/Science/Micro\\_Testing\\_RTE/index.asp](http://www.fsis.usda.gov/Science/Micro_Testing_RTE/index.asp)). Annual results are presented  
 1114 for the calendar years 1990 through 2000. More detailed results have also been published in the  
 1115 Journal of Food Protection, Vol. 64, No. 8, 2001, pages 1188-1193.

1116 *RLM*

1117 The RLM sampling program began in April 2006. There were 131 establishments sampled under  
 1118 the RLM program from April 2006 through July 2007. Of those establishments, 43 out of total  
 1119 of 6,453 samples had positive cultures, and only one of those was a product sample  
 1120 (RLMPROD). Results to date by sample type over the entire RLM program are shown in  
 1121 **Table D-10**. There were over three times as many environmental culture positives (RLMENVR)  
 1122 as food contact surface positives (RLMCONT).

1123 **Table D-10. Total RLM Positive and Negative Culture Results – April 2006 through**  
 1124 **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.

1125 *RTE001*

1126 With respect to *L. monocytogenes*, results for 2005, the first year that the sampling project  
 1127 RTE001 was conducted, indicated a percent positive rate for *L. monocytogenes* for all RTE meat  
 1128 and poultry products tested under RTE001 of 0.72 percent. This represented 51 positive samples  
 1129 out of the 7,089 collected that year. For 2006, results indicated a percent positive rate for  
 1130 *L. monocytogenes* for all RTE meat and poultry products tested of 0.47 percent. This represented  
 1131 40 positive samples out of the 8,577 collected that year. Given the 8,577 products tested for  
 1132 *L. monocytogenes* under RTE001 in 2006 and the percent positive rate of 0.47 percent, FSIS is  
 1133 95 percent confident that it could detect a 38.7 percent increase in the positive rate. To detect a  
 1134 50 percent increase, 5,239 samples would have to be tested.

1135 For *Salmonella*, in 2005 the positive rate for all RTE meat and poultry products tested under  
1136 RTE001 was 0.04 percent, based on 4 positives out of 7,089 samples. In 2006, the positive rate  
1137 was 0.02 percent, based on 2 positives out of 8,577 samples. Given the 8,577 products tested for  
1138 *Salmonella* under RTE001 in 2006 and the percent positive rate of 0.02 percent, FSIS is  
1139 95 percent confident that it could detect a 189.9 percent increase in the positive rate. To detect a  
1140 50 percent increase, 123,675 samples would have to be tested.

#### 1141 *ALLRTE*

1142 *L. monocytogenes* results for 2004, the first year that ALLRTE was conducted, indicated a  
1143 percent positive rate for *L. monocytogenes* for all RTE meat and poultry products tested of 0.55  
1144 percent. This represented 8 positive samples out of the 1,467 collected that year. Results were  
1145 also recorded across 10 various product categories (e.g., peeled sausage type product).

1146 Results for 2005 for ALLRTE indicated a percent positive rate for *L. monocytogenes* for all RTE  
1147 meat and poultry products tested of 0.64 percent. This represented 18 positive samples out of the  
1148 2,806 collected that year. For *Salmonella* in 2005, 1 sample out of the 2,806 tested positive, for  
1149 a positive rate of 0.04 percent.

1150 As discussed above, in 2006, the ALLRTE project was modified so that establishments were  
1151 randomly picked each month for testing from those establishments not scheduled for testing  
1152 under RTE001. Since many establishments were scheduled every month for an RTE001 sample,  
1153 they were never available for random selection in the ALLRTE project. Given that the low  
1154 percentage of positive results for RTE001 (less than 0.5 percent), the ALLRTE results for 2006  
1155 were most likely higher than they would have been had all establishments had the chance of  
1156 being sampled each month (i.e., the addition more establishments would likely increase the total  
1157 samples or the denominator more than the positives or the numerator, having the overall effect  
1158 of decreasing the rate). For *L. monocytogenes*, 18 out of 2,937 samples were positive, for a rate  
1159 of 0.61 percent. Given the 2,937 products tested for *L. monocytogenes* under ALLRTE in 2006  
1160 and the percent positive rate of 0.61 percent, FSIS is 95 percent confident that it could detect a  
1161 58.6 percent increase in the positive rate. To detect a 50 percent increase, 4,030 samples would  
1162 have to be tested.

1163 For 2006, none of the 2,937 samples tested for *Salmonella* under ALLRTE were positive. Given  
1164 the absence of positive samples, it is not possible to determine how many samples would be  
1165 needed to determine an increase.

#### 1166 *Overall RTE Results*

1167 A total of 12,372 RTE products were tested by FSIS for *L. monocytogenes* in 2006 under the  
1168 sampling projects ALLRTE, RTE001, and RLM (not including the 2,745 product contact surface  
1169 and environmental samples). The average percentage of positive product samples across all  
1170 projects was 0.48 percent. Including the 2,745 product contact surface and environmental  
1171 samples that were analyzed as part of RLM, the total number of *L. monocytogenes* analyses  
1172 conducted by FSIS for 2006 was 15,117. Given the 12,372 RTE products tested overall for  
1173 *L. monocytogenes* in 2006 and the percent positive rate of 0.48 percent, FSIS is 95 percent  
1174 confident that it could detect a 32.3 percent increase in the positive rate. To detect a 50 percent  
1175 increase, 5,129 samples would have to be tested.

1176 FSIS testing has consistently found very low levels of *Salmonella* in RTE products. The  
1177 percentage of positive samples has been noticeably lower since 2003. During 2001 to 2002,  
1178 FSIS found 23 positives in 14,121 samples (0.16 percent positive). From 2003 through 2006,  
1179 FSIS tested 41,154 samples for *Salmonella* and found 21 positives (0.05 percent positive). The  
1180 percentage of samples positive for *Salmonella* in CY 2006 was 0.02 percent (2 positives in  
1181 11,842 samples), the lowest level since the implementation of HACCP. Given the 11,842  
1182 products tested for *Salmonella* in 2006 and the percent positive rate of 0.02 percent, FSIS is  
1183 95 percent confident that it could detect a 161.6 percent increase in the positive rate. To detect a  
1184 50 percent increase, 123,675 samples would have to be tested.

1185 As detailed above, FSIS has conducted a regulatory microbiological testing program on RTE  
1186 meat and poultry products since 1983. From 1994 through 2006, 7,683 RTE products (cooked  
1187 beef patties and dry fermented sausages) were tested for the presence of *E. coli* O157:H7. All  
1188 RTE samples tested for *E. coli* O157:H7 were negative.

### 1189 **Potential Limitations of RTE Data**

1190 The limitations and uncertainties that may be associated with the use of FSIS RTE data in  
1191 measuring an establishment's risk control and subsequently its level of inspection are discussed  
1192 below.

1193 The previously proposed algorithm used all pathogen test results that would lead to a regulatory  
1194 result. For *L. monocytogenes* this included test results from a variety of sampling projects  
1195 including ALLRTE, RTE001, RLMPROD, RLMCONT, INTPROD (intensified testing of RTE  
1196 product), and INTCONT (intensified testing of RTE food contact surfaces). It is unclear  
1197 whether mixing sampling results for random verification testing of any and all RTE products  
1198 with sample results only for post-lethality exposed RTE products based on risk-based sampling  
1199 may produce results that are unrepresentative and thus would be misleading in terms of  
1200 allocating inspection resources.

1201 A possible issue with data quality may exist regarding the laboratory procedure that is followed  
1202 to test RTE. Under current procedures, FSIS collects one 25-g sample for analysis. However,  
1203 U.S. FDA and some international agencies collect two 25 g samples for regulatory analysis of  
1204 RTE products. FSIS is currently evaluating whether changing its procedures would improve the  
1205 quality of its RTE data and is also evaluating the impact that such a change would have on data  
1206 analysis efforts.

1207 A related issue to this has to do with whether contamination by an organism such as  
1208 *L. monocytogenes* (and other pathogens such as *E. coli* O157:H7 and *Salmonella*) is uniformly  
1209 distributed within and among lots of meat and poultry products. This could affect, for a given  
1210 lot, the probability that a test will be positive if the lot is positive, and the probability that  
1211 sampling one lot will find contamination if contamination is not uniform among lots. This  
1212 becomes especially problematic for pathogens, such as *L. monocytogenes*, that are present at very  
1213 low levels. This also extends to assumptions made by FSIS in its *L. monocytogenes* Model. The  
1214 model requires the setting of a probability of detecting 1 colony forming unit (cfu) of *Listeria*  
1215 species for food contact surface testing and 1 cfu of *L. monocytogenes* for product testing. For  
1216 the base runs, both probabilities were set at 75 percent (i.e., the model, as a default, assumes a  
1217 0.75 probability of detecting a positive if the sample actually is positive). Having better data on

1218 the quantitative sensitivity of the laboratory test, therefore, could decrease the uncertainty in the  
1219 model.

1220 The data are collected based on an establishment basis, rather than being representative of the  
1221 volume of RTE products that are produced, which could limit the applicability of the data for  
1222 determining national prevalence.

1223 In addition, the RTE data are from regulatory testing programs that change from year to year,  
1224 and possibly even within a year, and therefore any comparisons should be made with caution.  
1225 These regulatory programs have not been designed to test for statistically significant change  
1226 from one year to the next.

1227 A large number of samples have been tested in the RTE testing program, but fortunately few  
1228 samples have been positive for *Salmonella*, and *L. monocytogenes*, and none have been positive  
1229 for *E. coli* O157:H7. Although from a public health standpoint that is a good outcome, it does  
1230 limit the ability of this dataset to be used for analysis and comparison to other factors. However,  
1231 if used independently as a factor that would separate a facility into different categories, this  
1232 limitation does not have as much of an impact.

## 1233 **OTHER POSSIBLE PARAMETERS**

1234 In addition to those parameters that were used in the previously proposed algorithm for RBI in  
1235 processing facilities, FSIS has considered other data for use in an RBI algorithm. Data on  
1236 potential variables (e.g., the age and the square footage of production facilities, the number of  
1237 employees, the HACCP training the facility conducts, and the use of chemical sanitizers that are  
1238 used in the facility as part of its SSOPs) have been analyzed for FSIS by RTI. The FSIS does not  
1239 currently have information on those variables for all facilities.