

Analysis of ALLRTE and RTE001 Sampling Results for *Salmonella* species, Calendar Years 2005 through 2008

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Acronyms and Abbreviations

CDC	Centers for Disease Control and Prevention
DAIG	Data Analysis and Integration Group
EIAO	Enforcement, Investigations, and Analysis Officer
FSA	Food Safety Assessment
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point
IVT	Intensified Verification Testing
<i>Lm</i>	<i>Listeria monocytogenes</i>
LSFS	Laboratory Sample Flow System
OFO	Office of Field Operations
PBIS	Performance-based Inspection System
PHV	Public Health Veterinarian
RTE	Ready-to-eat
USDA	United States Department of Agriculture

EXECUTIVE SUMMARY

In addition to *Listeria monocytogenes* (*Lm*), ready-to-eat (RTE) meat and poultry product samples from the Food Safety and Inspection Service's (FSIS's) ALLRTE and Risk-based RTE001 sampling programs are tested for *Salmonella* spp. The Agency analyzed results of *Salmonella* testing of meat and poultry product samples collected under the ALLRTE and RTE001 sampling programs for calendar years 2005 through 2008. The analyses, which included 11,822 ALLRTE samples collected from 2,556 establishments and 33,276 RTE001 samples collected from 1,989 establishments in calendar years 2005 through 2008, included the following:

- Incidence and categorization of *Salmonella*-positive samples from sampled establishments in the two programs;
- Trends in percentage of positive results for calendar years 2005-2008;
- Types and sources of positive samples;
- Serogroups and serotypes of *Salmonella* isolates from the positive samples; and,
- Descriptive summaries with respect to:
 - establishment HACCP (Hazard Analysis and Critical Control Point) size,
 - establishment production volumes,
 - *Lm* control Alternatives employed by the establishment,
 - geographic location of the establishment, and
 - month (and season) of sample collection.

Results showed low incidences of *Salmonella*-positive samples from the ALLRTE and RTE001 sampling programs relative to the total numbers of samples collected in 2005-2008, with 8 and 14 positive samples, for ALLRTE and RTE001, respectively. Positive product results averaged 0.07% for ALLRTE samples (range, 0-0.13%) and 0.04% for RTE001 samples (range, 0.01-0.08%). Similarly, percentages of establishments with *Salmonella*-positive samples ranged from 0-0.27% for ALLRTE and from 0.07-0.54% for RTE001. Three types of products - head cheese, pork barbecue and sausage products - accounted for over 60% of all *Salmonella*-positive samples. Pork was the predominant source of the positive products, with the remainder being either from chicken or beef. Serogrouping and serotyping of 23 *Salmonella* isolates from the 22 samples yielded 17 distinct serotypes within 8 serogroups.

All but one of the *Salmonella*-positive samples were obtained from establishments with HACCP sizes of Small or Very Small. Results of analysis based on *Lm* control alternatives showed that over half of the positive samples were obtained from establishments employing control Alternative 3 (sanitation only/highest risk). Positive *Salmonella* samples could be found in most geographic regions at all times of the year. However, there were few or no *Salmonella* isolates from establishments in North Central and Southwestern regions (comprised of 15 states). It is recommended that there be an ongoing examination of *Salmonella* data from the ALLRTE and RTE001 sampling programs with respect to applying that information to the prevention of foodborne *Salmonella* outbreaks.

1. INTRODUCTION

FSIS conducts regulatory microbiological testing of ready-to-eat (RTE) meat and poultry products for *Listeria monocytogenes* (*Lm*), *Salmonella* and *Escherichia coli* O157:H7. One such sampling and testing program was ALLRTE (random verification sampling of all RTE meat and poultry products). The ALLRTE sampling program was initiated in January of 2004. All establishments were considered at equal risk under the ALLRTE sampling program. Establishments and products were sampled at random, with the exception of certain products considered to be of low risk, such as lard. These exceptions were eliminated with the issuance of Directive 10,240.4, Revision 2 in 2009.

FSIS regulations mandated the reporting of various production factors by establishments producing meat and poultry products that were exposed to the post-lethality production environment. This served as the basis for another sampling program based on the risk characteristics of the producing establishment and not just on product types. RTE001, a sampling and testing program for RTE products based on these establishment risk factors, was initiated in January 2005. Accordingly, samples collected under the RTE001 program are only from establishments subject to 9 CFR Part 430 (i.e., establishments in which RTE products are exposed to the post-lethality environment [see http://www.access.gpo.gov/nara/cfr/waisidx_08/9cfr430_08.html]). The selection of establishments for sample collection and testing is made each month using a risk-ranking multivariate equation or algorithm. The risk ranking of establishments selected for sampling is made on the basis of controlling *Lm* rather than *Salmonella*.

In both the ALLRTE and RTE001 programs, samples are tested for *Lm*, *Salmonella* and *E. coli* O157:H7.¹ This report is concerned with the collection and testing of the ALLRTE and RTE001 samples with respect to *Salmonella* only. FSIS has reported summarized percent positive *Salmonella* test results for RTE meat and poultry products collected under the ALLRTE and RTE001 sampling programs since their inception (2004/2005) through calendar year 2008. Accordingly, the objectives of this report were to (1) obtain, tabulate and analyze ALLRTE and RTE001 sampling results for *Salmonella*; (2) evaluate the data with respect to program effectiveness; and (3) identify possible trends in the data.

1.1 Background

1.1.1. Information on the Incidence of *Salmonella* in RTE Meat and Poultry Products

Based on the percentages of positive samples, the incidence of *Salmonella* in RTE meat and poultry products is lower than that of *Lm* in RTE products. However, the presence of *Salmonella* in RTE products may imply a more serious processing and public health problem compared to the presence of *Lm*. While *Salmonella* in an establishment may be an environmental contaminant in some circumstances, its presence implies underprocessing or serious deficiencies for sanitary practices.

Salmonella can contaminate RTE products in the following ways:

1. Underprocessing

a. Underprocessing occurs when the cooking process is not adequate to eliminate the pathogens of concern. For heat-treated products, underprocessing may be the result of applying an inadequate time and temperature to the product or the development of bacterial heat resistance before completion of the lethality step.

¹ Only dry and semi-dry fermented sausages and meat patties are tested for *E. coli* O157:H7 as well as for *Lm* and *Salmonella*.

b. For cured and fermented products, inadequate drying, curing or fermentation are causes of underprocessing.

2. Contamination from Raw Materials

a. Raw or partially processed produce (e.g., raw or perhaps blanched), eggs, spices or other ingredients that are introduced to the processed meat or poultry products after the primary lethality event can be a source for *Salmonella*.

b. *Salmonella* from raw meat or poultry products that are processed in the same physical area can contaminate processed products by direct or indirect (e.g., environmental sources or food handlers) contamination routes.

3. Contamination from Food Handlers

a. Given the incidence of human salmonellosis in the U.S. and the potential for asymptomatic human carriers, there is potential for product contamination from establishment employees.

b. The food industry has a high turnover of food handlers. History has shown that personal hygiene and safe food handling training may not be adequate.

4. Contamination from Animal Vectors

a. Animals (e.g., birds, rodents) and insects have been shown to contaminate food products with *Salmonella*.

b. Contamination from within and from outside the establishment can be carried on footwear and clothing into the RTE product environment.

1.1.2. ALLRTE

The ALLRTE sampling program began in January of 2004. ALLRTE was designed to obtain random samples across the full range of RTE products and across all establishments producing a RTE product, regardless of risk. Under the ALLRTE sampling program, establishments are randomly selected for regulatory samples from the total population of establishments producing RTE products. This sampling is conducted by FSIS on all RTE post-lethality and non-post-lethality exposed products. Testing for *Salmonella* is performed concurrently with that for *Lm*. The overall prevalence of *Salmonella* is evaluated from these results. Results of this regulatory testing project are used to verify the effectiveness of food safety systems.

Regulations/directives/notices specific to ALLRTE include the following:

- FSIS Directive 10,240.4 Revision 2 “Verification Procedures for Consumer Safety Inspectors for the *Listeria monocytogenes* (*Lm*) Regulation and *Lm* Sampling Program”, February 3, 2009
- 9 CFR 430.4 “Control of *Listeria monocytogenes* in post-lethality exposed ready-to-eat products” published on June 6, 2003 (68 FR 34207) [includes definitions for RTE Alternatives 1, 2, and 3]
- FSIS Directive 10,210.1, “Unified Sampling Form”, October 14, 1997
- FSIS Directive 10,300.1 “Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces, Environmental Surfaces for *Listeria monocytogenes*”, February 3, 2009.

1.1.2. RTE001

Phase 1 of the FSIS risk-based verification testing program was implemented in January 2005 with the RTE001 sampling project for testing of finished product samples post-lethality exposed RTE meat and poultry products. With RTE001, establishments are selected for sampling based on different risk factors for *Lm*. As with the ALLRTE sampling program, product samples are tested for *Salmonella* as well as for *Lm* (and for certain products, *E. coli* O157:H7).

Regulations/directives/notices specific to RTE001 are as follows:

- 9 CFR 430.4 “Control of *Listeria monocytogenes* in post-lethality exposed ready-to-eat products” published on June 6, 2003 (68 FR 34207) [includes definitions for RTE Alternatives 1, 2, and 3]
- FSIS Directive 10,240.4 Revision 2 “Verification Procedures For Consumer Safety Inspectors for the *Listeria monocytogenes* (*Lm*) Regulation and *Lm* Sampling Programs”, February 3, 2009
- FSIS Directive 10,240.5 Revision 2, “Verification Procedures for Enforcement, Investigations, and Analysis Officers (EIAOs) for the *Listeria monocytogenes* (*Lm*) Regulation and Routine Risk-Based *Listeria monocytogenes* (RLm) Sampling Program”, February 3, 2009
- FSIS Directive 10,300.1 “Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces, Environmental Surfaces for *Listeria monocytogenes*”, February 3, 2009

Further information regarding background/applicable regulations, directives, notices, public meetings and Federal Register notices for both ALLRTE and RTE001 may be found at the FSIS website on the Internet (<http://www.fsis.usda.gov/>).

2. DATA COLLECTION DESIGN AND IMPLEMENTATION

Data routinely generated from the ALLRTE and RTE001 sampling programs were used for all analyses. The data consisted of product test results for samples that were collected and tested for *Salmonella*. These data were extracted from the Data Warehouse (M2K database) via the Laboratory Sample Flow System (LSFS). Supplementary data were obtained using the Performance-based Inspection System (PBIS) reader.

3. DATA ANALYSIS PROCEDURES

FSIS calculated the numbers of positive samples and percentage of positive product samples between January 2005 and December 2008 (four calendar years). The data analyzed were based on sample collection dates (January 1, 2005 through December 31, 2008)¹. These analyses focused on the following:

- incidence and categorization of positive *Salmonella* samples from sampled establishments;
- types and sources of *Salmonella*-positive samples;
- serogroups and serotypes of *Salmonella* isolates from the positive samples;
- descriptive summaries with respect to
 - establishment HACCP size,
 - establishment production volumes,
 - FSIS District,
 - geographic location of the establishment, and
 - season or month of sample collection; and
- trends in percentages of positive results from 2005 through 2008.

Most data analyses were performed through data handling and evaluation techniques using Microsoft Office Excel. Statistical analysis, when required, consisted of logistic regression analysis (SAS LOGISTIC procedures).

¹ FSIS routinely posts summarized annual data for their microbiological testing programs for ready-to-eat (RTE) meat and poultry products (http://www.fsis.usda.gov/Science/Micro_Testing_RTE/index.asp#results08). Prior to calendar year 2008, results that were posted were based on analysis completion date. Beginning in January 2008, results are being posted by sample collection date to include all samples collected within the calendar year. This aligns FSIS' activities in this area with those of other Federal partners. However, as the 2008 results by collection date are not directly comparable with results from previous years, a decision was made to use sample collection date for all data reported and analyzed within the current report. Accordingly, some data, notably the numbers of samples tested, will appear different than those posted online by FSIS.

4. RESULTS AND DISCUSSION

Data collection began in 2004 for the ALLRTE sampling program and in 2005 for the RTE001 sampling program. For comparative purposes, January, 2005 was selected as the start date with respect to *Salmonella* data evaluation for the two sampling programs covered in this report. The Agency has reported summarized *Salmonella* test results for calendar year 2004 at the following Internet location: http://www.fsis.usda.gov/Science/Table13_Micro_Testing_RTE_1990-2004/index.asp.

Some analyses, notably for types of samples and for data trends over time, required the evaluation of combined multi-year data. Previously, FSIS had reported summarized *Salmonella* data through 2007 based on analysis completion date. Beginning in 2008, summarized *Salmonella* data are being reported based on the date of sample collection, in order to better align FSIS data reporting activities with that of other Federal partners. It was noted that because of the change from analysis completion date to sample collection date, the summarized data for calendar year 2008 cannot be directly compared to that from prior years. As noted in Section 3 (Data Analysis Procedures), the 2005-2008 data analyzed for this report were based exclusively on sample collection dates in order to make them directly comparable on an annualized basis. Accordingly, some of the data in the current report, notably the total numbers of samples tested per year, will appear different from those previously posted online by FSIS. The Agency's summarized test results for calendar years 2005-2008 are found at the following Internet locations:

http://www.fsis.usda.gov/Science/Micro_Testing_RTE/index.asp#previous (for 2005-2007) and http://www.fsis.usda.gov/Science/Micro_Testing_RTE/index.asp#results08 (for 2008).

4.1 *Salmonella* Testing Results for the ALLRTE and RTE001 Sampling Programs, January 2005 through December 2008

Table 4.1.1 and Figure 4.1.1 show the results of testing 11,822 samples for *Salmonella* spp. in the ALLRTE sampling program and 33,276 samples for *Salmonella* spp. in the RTE001 sampling program in calendar years 2005-2008 (all based on sample collection date). Overall, 8 (0.07%) of the ALLRTE samples and 14 (0.04%) of the RTE001 samples tested positive for *Salmonella* spp. For comparison, the percentage positive rates for *Lm* in the same samples in both sampling programs (calendar years 2005-2008) were about 0.5%. This underscores the relatively low prevalence of *Salmonella* spp. in RTE meat and poultry samples. Quantitative most-probable number (MPN) determinations of the levels of *Salmonella* were performed for 7 samples (4 ALLRTE, 3 RTE001). All but 1 ALLRTE sample (MPN 0.09 CFU/g) were below detectable levels of 0.03 CFU/g. It should also be noted that all the samples that tested positive for *Salmonella* were negative for *Lm*. This may reflect differences in the sources of contamination for the two pathogens.

Changes in the percentages of *Salmonella*-positive ALLRTE and RTE001 samples between 2005 and 2008 were examined using statistical analysis (SAS LOGISTIC procedures). There were no statistically significant changes in *Salmonella* results for either the ALLRTE sampling program ($P > 0.05$) or the RTE001 sampling program ($P > 0.4$) over time.

The numbers and percentages of establishments that had at least 1 *Salmonella*-positive ALLRTE or RTE001 sample are shown in Table 4.1.2 and Figure 4.1.2. Only 8 of 6,369 (0.13%) ALLRTE establishment sample collection visits (representing 1 or more sample collection from 2,556 RTE establishments), and 13 of 5,447 (0.24%) RTE001 establishment sample collection visits (representing 1 or more sample collection from 1,989 establishments) yielded samples that tested positive for *Salmonella*

over the 2005-2008 sampling period. This also was markedly lower than the percentages of *Lm* in establishments (about 2% and 7% for ALLRTE and RTE001, respectively). One establishment with a *Salmonella*-positive RTE001 sample (head cheese) had a second positive result for the same product type after a second sample was collected approximately 3 months after the first. All other positive samples were from separate establishments. It also is noted that 2 of the 8 ALLRTE positives (25%) were from non-9CFR430 establishments (i.e., establishments that did not have post-lethality exposure of products to the processing environment).

Table 4.1.1. Detection of *Salmonella* spp. in ALLRTE and RTE001 RTE Product Samples, Calendar Years 2005-2008

Year	ALLRTE	Positive Samples		RTE001	Positive Samples	
	Total Tested	No.	%	Total Tested	No.	%
2005	2,813	1	0.04	7,137	4	0.06
2006	2,938	0	0.00	8,546	2	0.02
2007	2,951	3	0.10	8,672	7	0.08
2008	3,120	4	0.13	8,921	1	0.01
Total	11,822	8	0.07	33,276	14	0.04

Figure 4.1.1. Percentage of *Salmonella*-Positive Samples from the ALLRTE and RTE001 Sampling Programs, Calendar Years 2005-2008

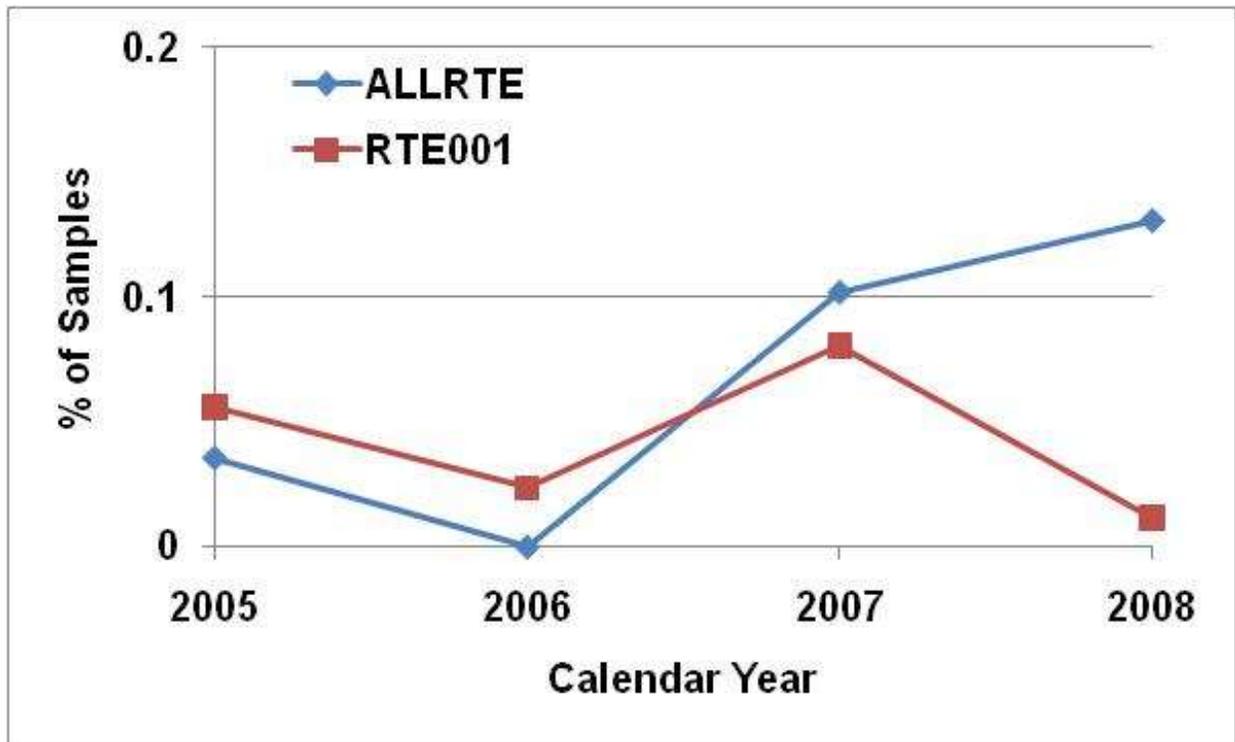


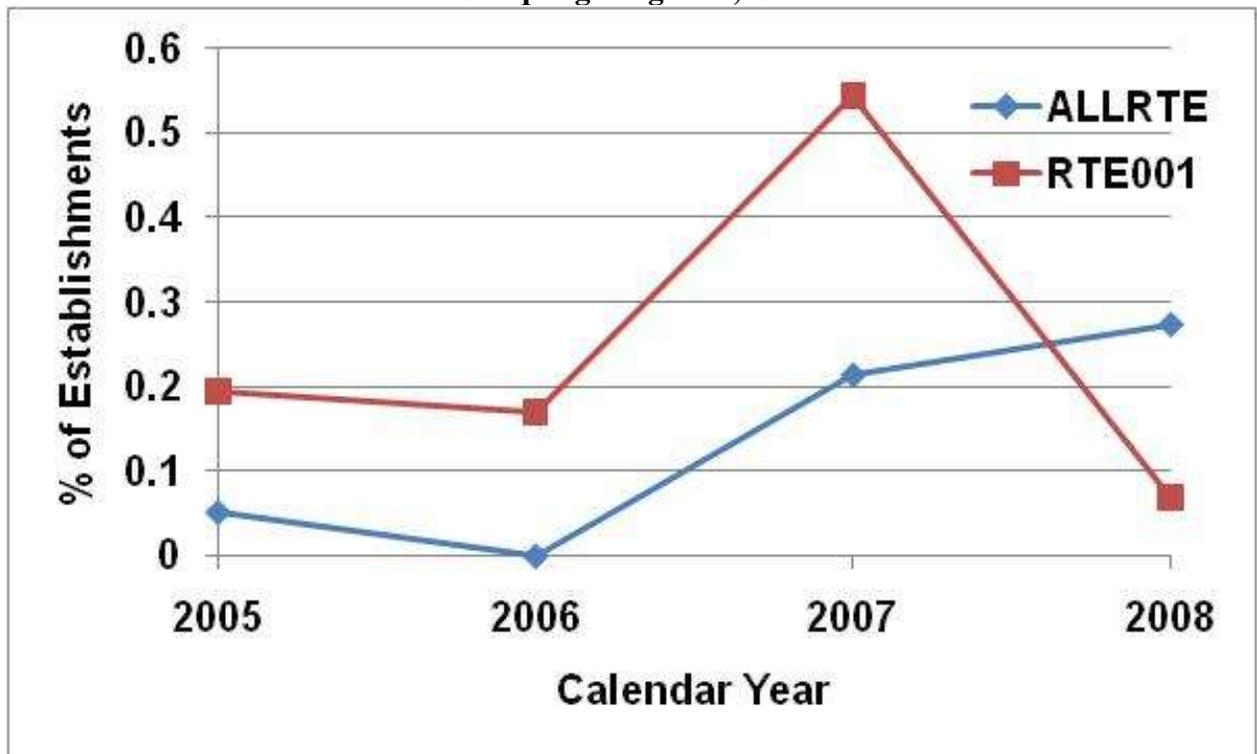
Table 4.1.2. Number and Percentage of Establishments with at Least One *Salmonella*-Positive Sample, 2005-2008

Year	ALLRTE	Establishments with Positive Samples		RTE001	Establishments with Positive Samples	
	# of Establishments Sampled	No.	%	# of Establishments Sampled	No.	%
2005	1,945	1	0.05	1,534	3	0.20
2006	1,532	0	0.00	1,178	2	0.17
2007	1,406	3	0.21	1,286	7	0.54
2008	1,486	4	0.27	1,449	1	0.07
Total	6,369*	8	0.13	5,447**	13	0.24

*Represents the total of one or more sample collection visits to 2,556 RTE establishments in 2005-2008.

**Represents the total of one or more sample collection visits to 1,989 RTE establishments with post-lethality exposure (subject to 9 CFR 430) in 2005-2008.

Figure 4.1.2. Percentage of Establishments with *Salmonella*-Positive Samples in the ALLRTE and RTE001 Sampling Programs, Calendar Years 2005-2008



4.2 Types/Sources of *Salmonella*-Positive Samples from the ALLRTE and RTE001 Sampling Programs, 2005-2008

Because of the relatively small numbers of *Salmonella*-positive samples (8 ALLRTE, 14 RTE001 over 4 years), all positives from the two sampling programs were analyzed together. Table 4.2.1 shows a categorization and incidence of the types of *Salmonella*-positive samples obtained in the two sampling programs. Head cheese (a deli cold cut made up of pieces of meat from the heads of animals; 4 samples) and pork barbecue (4 samples) were common RTE sources of *Salmonella*, accounting for over one-third of the *Salmonella*-positive ALLRTE and RTE001 samples. (It should be noted that two of the four head cheese samples were from the same establishment, but the two samples were collected on two different dates). Sausage products represented another potential source of *Salmonella*, with 6 positive product types (fully-cooked sausage patties, a skinless sausage, sausage rings, smoked sweets, a brand of mild sausage, and a hard salami). Thus, three types of products accounted for 64% (14/22) of all the *Salmonella*-positive RTE product samples over the 4-year sampling period. Pork was the predominant meat source of these products. There also were several chicken products that were positive on an individual basis. The rates of positive product samples relative to the numbers of head cheese, pork barbecue and sausage products sampled between 2005 and 2008 ranged from 0.12-0.63% (Table 4.2.2).

Table 4.2.1. Types of *Salmonella*-Positive Product Samples from the ALLRTE and RTE001 Sampling Programs, Calendar Years 2005-2008

Product Type	Positive Samples	
	No.	%
Head Cheese	4	18.2
Pork Barbecue	4	18.2
Sausage Products (other than patties)	4	18.2
Patties (Sausage and Chicken)	2	9.1
Beef Jerky	1	4.5
Cacciatore (Pork)	1	4.5
Chicken & Cheese Burrito	1	4.5
Chicken Casserole	1	4.5
Breaded Chicken	1	4.5
Smoked Chicken	1	4.5
Hard Salami	1	4.5
Pork Cracklings	1	4.5
Total	22	100

Table 4.2.2. Percent Positive Rates for the Main Types of Food Product Samples, 2005-2008

Food Product Type	Total Collected ^a	Positive Samples	
		No.	%
Head Cheese	790	4	0.51
Pork Barbecue	630	4	0.63
Sausage Products (including patties and salami)	4900	6	0.12

^aApproximate numbers from sample description listings.

4.3 Salmonella Isolate Serogrouping and Serotyping Results

Serogrouping and serotyping were performed on 23 isolates derived from the 22 positive samples from the ALLRTE and RTE001 sampling programs. (The additional isolate was from the same cacciatore sample). As shown in Table 4.3.1, a total of 17 different serotypes within 8 different serogroups were obtained for the 23 isolates. No serotype was obtained more than twice. These results do not suggest any particular serotype being prevalent in *Salmonella* isolates from RTE meat and poultry products.

However, 7 of the 23 isolates (about 30 %) were from serogroup B. Four of these serotypes (6 of the 23 isolates) were present in the Centers for Disease Control and Prevention's (CDC's) ranking of the top 10 *Salmonella* serotypes in 2008: *S. typhimurium* (2 isolates, ranked 2 of 10); *S. heidelberg* (2 isolates, ranked 8 of 10); *S. newport* (1 isolate, ranked 3 of 10); and *S. muenchen* (1 isolate, ranked 7 of 10). The fact that the other 17 isolates were not in the CDC top 10 ranking does not exclude the possibility that any of these isolates could be involved in *Salmonella* infections in humans.

Table 4.3.1. Patterns and Occurrence of *Salmonella* Serogroups and Serotypes Isolated in the ALLRTE and RTE001 Sampling Programs, Calendar Years 2005-2008

Serogroup	Serotype	CDC Rank*	ALLRTE	RTE001	Combined (ALLRTE & RTE001)	% of All Isolates
B	<i>agona</i>		1		1	4.3
B	<i>derby</i>			2	2	8.7
B	<i>heidelberg</i>	8	1	1	2	8.7
B	<i>typhimurium (copenhagen)</i>	2		1	1	4.3
B	<i>typhimurium</i>	2		1	1	4.3
C1	<i>choleraesuis var. kunzendorf</i>			1	1	4.3
C1	<i>infantis</i>			1	1	4.3
C2	<i>livingston</i>		1		1	4.3
C2	<i>muenchen</i>	7		1	1	4.3
C2	<i>newport</i>	3		1	1	4.3
E	<i>anatum</i>			2	2	8.7
E1	<i>3,10:nonmotile</i>			1	1	4.3
E1	<i>london</i>			1	1	4.3
E1	<i>muenster</i>			1	1	4.3
E4	<i>senftenberg</i>		2		2	8.7
Poly-C	<i>gaminara</i>		2		2	8.7
Poly-D	<i>johannesburg</i>		2		2	8.7
Total			9	14	23	100

*Based on the Centers for Disease Control and Prevention's (CDC's) ranking of top 10 *Salmonella* serotypes in 2008 - Foodborne Diseases Active Surveillance Network, United States.

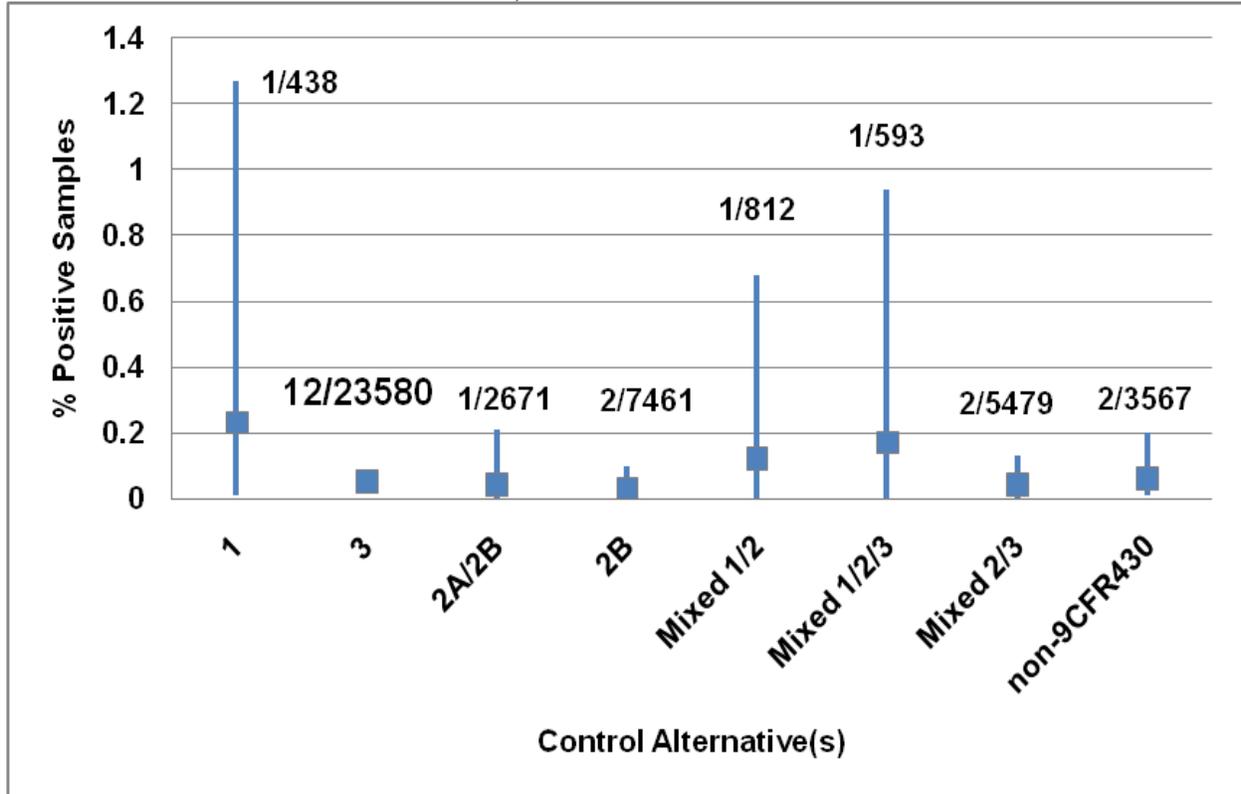
4.4 *Salmonella* Results as a Function of Establishment *Lm* Control Alternatives

Establishments in the RTE001 sampling program use one or more of four possible procedures or control alternatives for eliminating or inhibiting the growth of *Lm* in the particular RTE products produced by each establishment. The four alternative categories are as follows:

- **Alternative 1**, the lowest-risk category, involves using both a post-lethality treatment (which could be a physical treatment or an antimicrobial agent) “that reduces or eliminates microorganisms on the product AND an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*” (FSIS Directive 10,240.4, Revision 1, 3/15/2006).
- **Alternatives 2a (Choice 1) and 2b (Choice 2)**, the next higher-risk categories, provide the option of either a post-lethality treatment that kills or inhibits microorganisms (2a) or an antimicrobial agent or process that specifically inhibits *Lm* (2b).
- **Alternative 3**, the highest-risk category, requires the “use of sanitation procedures only” (FSIS Directive 10,240.4).

These establishments also are referred to as 9 CFR Part 430 establishments, based on the above description in the Code of Federal Regulations. For the ALLRTE sampling program, samples of RTE meat and poultry products can be collected from any RTE establishment - those that are produced under 9 CFR 430 as well as those that are not (non-9 CFR 430 establishments). Figure 4.4.1 and Table 4.4.1 show the percentages of ALLRTE and RTE001 samples that tested positive for *Salmonella* with respect to the four major RTE *Lm* control Alternatives (1, 2a, 2b and 3) for calendar years 2005 through 2008. *Salmonella*-positive samples were found in establishments that employ any of the four types of *Lm* control alternatives (Figure 4.4.1). This may be simply because the *Lm* control alternatives were not designed to control *Salmonella*. That said, over half (about 55%) of the 22 *Salmonella*-positive samples were from establishments that used Alternative 3 (sanitation only). Another 18% of the positive samples were from establishments that used Alternative 2b or a combination of Alternatives 2b and 3 (Table 4.4.1).

Figure 4.4.1. Detection of *Salmonella* as a Function of Establishment *Lm* Control Alternative, Calendar Years 2005-2008



Note: Data presented as percentages (squares) and 95% confidence intervals (error bars). Large error bars indicate greater variability (or lower confidence) in the results.

Table 4.4.1. Detection of *Salmonella* as a Function of Establishment *Lm* Control Alternative, Calendar Years 2005-2008

Alternative	No. of Positive Samples (ALLRTE)	No. of Positive Samples (RTE001)	No. of Positive Samples (Combined)	% of All Positive Samples (Combined)
3	4	8	12	54.5
2B	1	1	2	9.1
Mixed 2/3	0	2	2	9.1
1	1	0	1	4.5
Mixed 1/2	0	1	1	4.5
Mixed 1/2/3	0	1	1	4.5
2A/2B	0	1	1	4.5
Non-9CFR430	2	0	2	9.1
Total	8	14	22	100.0

4.5 Salmonella Results as a Function of Establishment HACCP Size

The percentages of ALLRTE and RTE001 samples positive for *Salmonella* with respect to each establishment's HACCP size of Large, Small, or Very Small for calendar years 2005-2008 are shown in Figure 4.5.1 and Table 4.5.1. All but one of the positive samples were from establishments that were either Small (10) or Very Small (11).

Figure 4.5.1. Detection of Salmonella as a Function of Establishment HACCP Size, Calendar Years 2005-2008

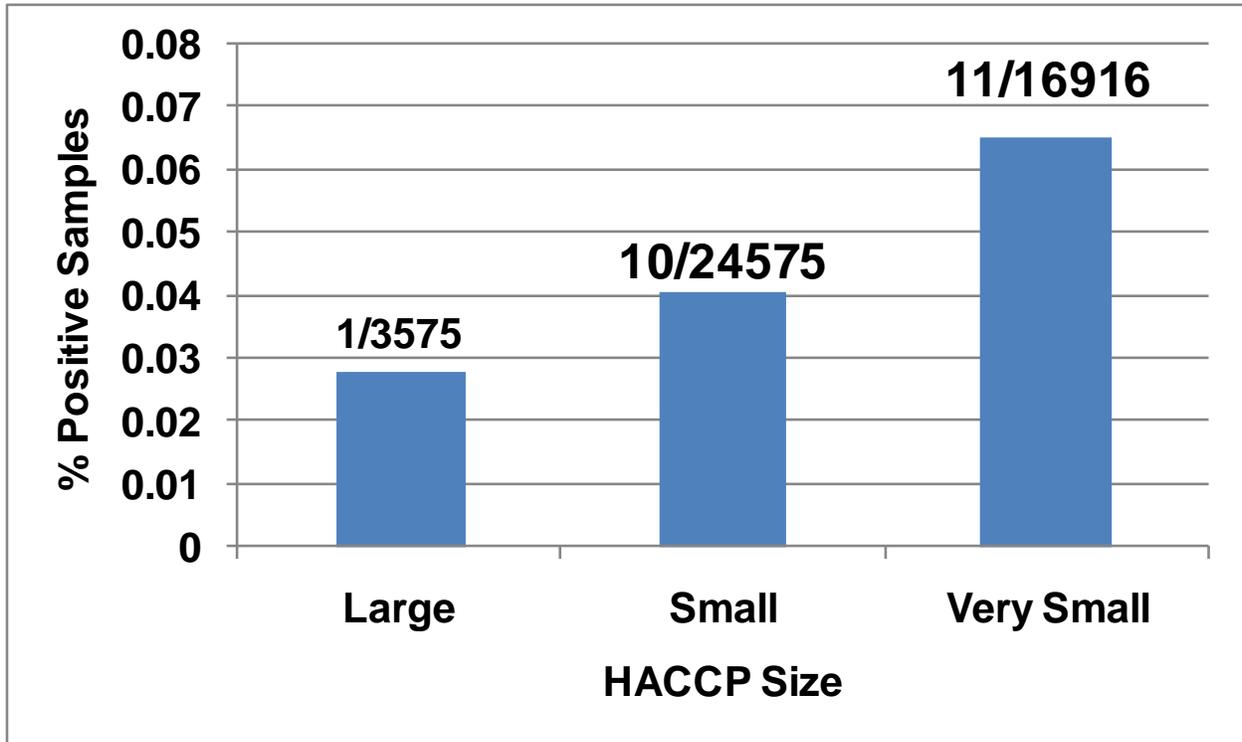


Table 4.5.1. Detection of Salmonella as a Function of Establishment HACCP Size, Calendar Years 2005-2008

HACCP Size	No. of Samples (ALLRTE)	No. of Samples (RTE001)	No. of Samples (Combined)	% of All Positive Samples (Combined)
L	0	1	1	4.5
S	2	8	10	45.5
V	6	5	11	50.0
Total	8	14	22	100.0

4.6. Salmonella Results as a Function of Establishment Production Volumes

Results were analyzed as a function of the annual production volumes of RTE food products. This information, when available, is provided by the producing establishments on FSIS Form 10,240-1. The observations made thus are dependent on the accuracy of the production volumes supplied. The percentages of *Salmonella*-positive ALLRTE and RTE001 with respect to the production volumes for

calendar years 2005 through 2008 are shown in Figure 4.6.1 and Table 4.6.1. The results show that *Salmonella*-positive samples were most commonly found in establishments with production volumes in the range of 10,000-10,000,000 pounds per year.

Figure 4.6.1. Detection of *Salmonella* as a Function of Establishment Annual Production Volumes, Calendar Years 2005-2008

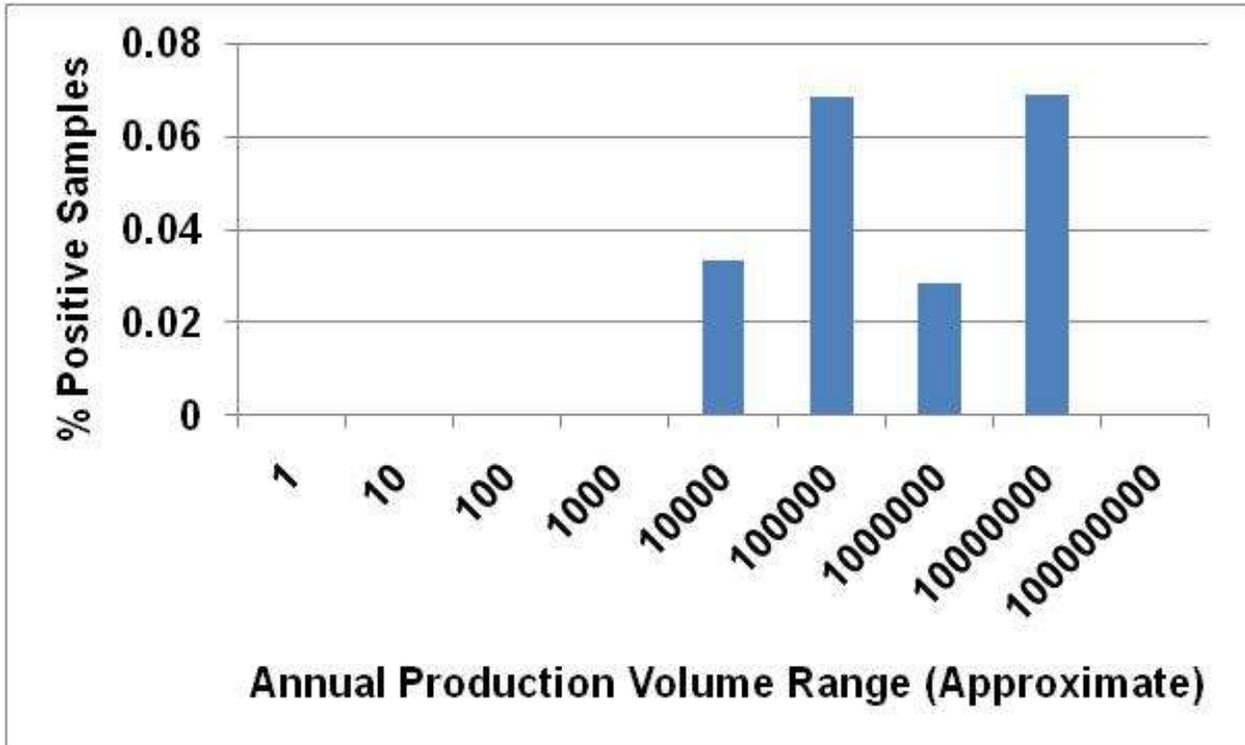


Table 4.6.1. Detection of *Salmonella* as a Function of Establishment Annual Production Volumes, Calendar Years 2005-2008

Establishment Annual Production Volume Range, Pounds*	Total ALLRTE Samples	Positive ALLRTE Samples		Total RTE001 Samples	Positive RTE001 Samples		All Samples	All Positive Samples	
		No.	%		No.	%		No.	%
~10	23	0	0.00	14	0	0.00	37	0	0.00
~100	97	0	0.00	55	0	0.00	152	0	0.00
~1000	1084	0	0.00	1046	0	0.00	2130	0	0.00
~10000	3204	3	0.09	5794	0	0.00	8998	3	0.03
~100000	3102	2	0.06	8669	6	0.07	11771	8	0.07
~1000000	1895	0	0.00	8601	3	0.03	10496	3	0.03
~10000000	952	1	0.11	7780	5	0.06	8732	6	0.07
~100000000	83	0	0.00	1266	0	0.00	1349	0	0.00
#N/A	1382	2	0.14	51	0	0.00	1433	2	0.14
Total	11822	8	0.07	33276	14	0.04	45098	22	0.05

*Approximate, based on information collected on FSIS 10,240-1 forms. #N/A = volumes not available.

4.7 Results by FSIS Geographic Region

To explore possible geographic influences on the detection of *Salmonella*, individual states were classified into the following geographic regions¹:

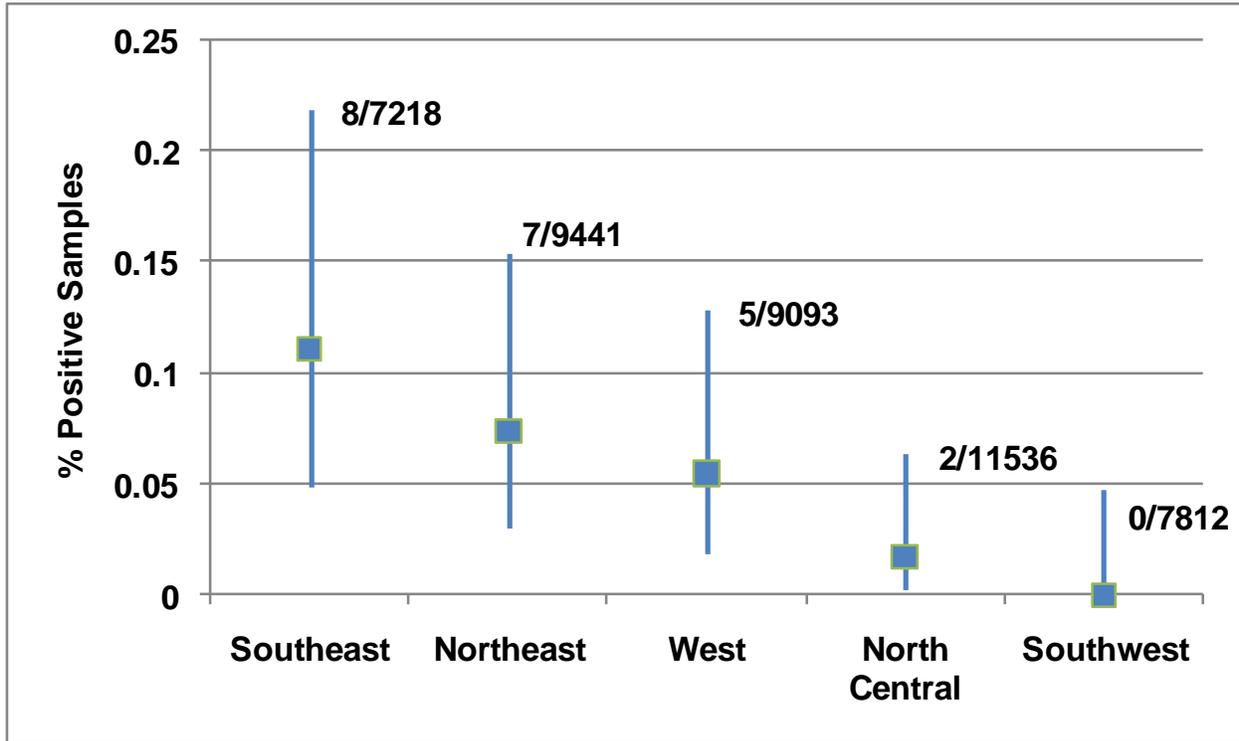
- **Northeast:** Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont and Washington, DC
- **North Central:** Illinois, Indiana, Iowa, Michigan, Minnesota, Ohio and Wisconsin
- **Southeast:** Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, West Virginia, Puerto Rico and the U.S. Virgin Islands
- **Southwest:** Arkansas, Kansas, Louisiana, Missouri, Nebraska, New Mexico, Oklahoma and Texas
- **West:** Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, North Dakota, Nevada, Oregon, South Dakota, Utah, Washington, Wyoming, American Samoa, Guam and the Northern Marianas Islands

The percentages of ALLRTE and RTE001 samples that tested positive for *Salmonella* within these five broad geographic regions for calendar years 2005-2008 are shown in Figure 4.7.1 and Table 4.7.1. *Salmonella* were present in ALLRTE and RTE001 samples from all geographic regions except the Southwest. Also, less than 10% of the positive samples came from the North Central region. The absence or low incidence of *Salmonella*-positive RTE meat and poultry product samples in the Southwest and North Central regions (which are comprised of 15 states) may merely be a function of the relatively low incidence of positive samples nationwide over a 4-year sampling period. On the other hand, there

¹ This classification is taken from the following FSIS manuscript: Naugle et al., Journal of Food Protection 69:2607-2614, 2006.

may be a rational scientific reason(s) for the absence or low incidence of *Salmonella* in product samples from these two geographic regions that may require further investigation. One speculative possibility is that climatological factors (temperature, humidity, precipitation) could be responsible in part for the observed differences.

Figure 4.7.1. Detection of *Salmonella* by FSIS Geographic Region, Calendar Years 2005-2008



Note: Data presented as percentages (squares) and 95% confidence intervals (error bars).

Table 4.7.1. Detection of *Salmonella* by FSIS Geographic Region, Calendar Years 2005-2008

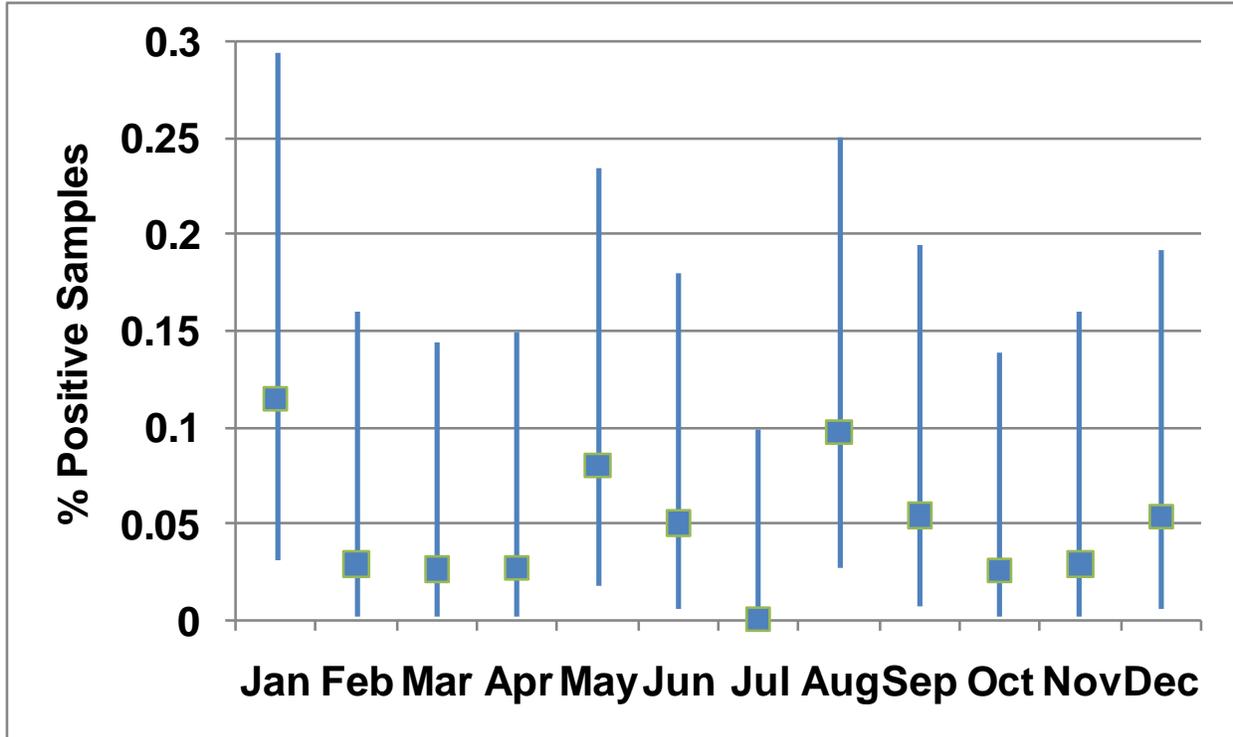
Geographic Region	No. of Positive Samples (ALLRTE)	No. of Positive Samples (RTE001)	No. of Positive Samples (Combined)	% of Positive Samples (Combined)
Northeast	3	5	8	36.4
Southeast	3	4	7	31.8
West	2	3	5	22.7
North Central	0	2	2	9.1
Southwest	0	0	0	0.0
	8	14	22	100.0

4.8 *Salmonella* Results as a Function of Month or Season

To explore possible seasonal influences on the detection of *Salmonella*, positive ALLRTE and RTE001 results were categorized based on month of the year in which positive samples were obtained. The

percentages of samples positive for *Salmonella* by month for calendar years 2005-2008 are shown in Figure 4.8.1. *Salmonella*-positive samples could be isolated from RTE establishments during all seasons or months of the year. These data indicate the lack of a seasonal effect with respect to the detection of *Salmonella* in ALLRTE and RTE001 samples.

Figure 4.8.1. Detection of *Salmonella* Based on Month in Which Samples Were Collected, Calendar Years 2005-2008



Note: Data presented as percentages (squares) and 95% confidence intervals (error bars).

5. SUMMARY AND CONCLUSIONS

FSIS analyzed data with respect to the detection of *Salmonella* in meat and poultry product samples collected under the ALLRTE and RTE001 sampling programs between January, 2005 and December 2008. Overall, 11,822 samples from 6,369 establishment sample collection visits (representing visits to 2,556 individual establishments) and 33,276 samples from 5,447 establishment sample collection visits (representing visits to 1,989 individual establishments) were tested for *Salmonella* in ALLRTE and RTE001, respectively (all based on sample collection date).

Results based on percentages of *Salmonella*-positive samples and percentages of establishments with *Salmonella*-positive results. The incidence of *Salmonella*-positive samples was low relative to the total numbers of samples collected in each year. Yearly percentages of *Salmonella*-positive ALLRTE samples ranged from 0 to 0.27%, while percentages of *Salmonella*-positive RTE001 samples ranged from 0.01% to 0.08%. In comparison, the percentages of *Lm*-positive samples for both the ALLRTE and RTE001 programs over the same 4-year period were about 0.5%. Changes in the percentages of *Salmonella*-positive ALLRTE and RTE001 samples from 2005 to 2008 also were examined using statistical methods. Changes over the 4-year sampling period for both sampling programs were not statistically significant.

The percentages of establishments with *Salmonella*-positive samples collected between 2005 and 2008 ranged from 0 to 0.27% for ALLRTE and from 0.07% to 0.54% for RTE001. These percentages also were low relative to establishments with *Lm*-positive samples, which averaged about 2% for ALLRTE and about 7% for RTE001.

Results based on the type of *Salmonella*-positive sample. Of the 22 samples that were positive for *Salmonella*, 4 head cheese samples, 4 pork barbecue samples and 6 sausage products (including a sausage patty product and a hard salami) were positive, accounting for over 60% of all *Salmonella*-positive ALLRTE and RTE001 samples. The data suggest an increased likelihood of encountering *Salmonella* in head cheese, pork barbecue and various types of sausage products relative to other types of RTE meat and poultry products. The reasons for this are not clear at this time. The other 8 products with positive results were individual isolations, with 4 of these being chicken products. Pork was the predominant source of the positive products (about half of all positives), with smaller numbers of positives among chicken and beef products.

***Salmonella* isolate subtyping and serotyping results.** There were 23 isolates that underwent subtyping and serotyping (two isolates came from the same positive product). This yielded 17 different serotypes within 8 serogroups. About 30% of the isolates were from serogroup B. Four serotypes from about 25% of the isolates were on the CDC ranking of the top 10 *Salmonella* serotypes associated with foodborne diseases in the United States in 2008. However, no serotype was recovered more than twice. These data suggest marked diversity in the serotypes of *Salmonella* isolates recovered from RTE products.

***Salmonella* results based on *Lm* control alternative, HACCP size, geographic region, and month/season.** Results based on *Lm* control alternatives employed by the establishments showed that *Salmonella*-positive samples could be obtained from establishments that employ any of the *Lm* control Alternatives. However, the majority of positive samples were from Alternative 3 (sanitation only/highest risk) and Alternative 2b (antimicrobial treatment/higher-risk) establishments. Results based on establishment HACCP sizes showed that all but 1 of the 22 positive RTE product samples came from either HACCP Small establishments (10 samples) or from HACCP Very Small establishments (11 samples). Evaluation of results by geographic region showed that there were few or no positive

Salmonella samples from 15 North Central or Southwest states. Finally, analysis of results by month/season indicated that *Salmonella*-positive RTE samples are obtained at all times of the year.

In summary, 8 of 11,822 ALLRTE samples (0.07%) and 14 of 33,276 RTE001 samples (0.04%) collected in calendar years 2005 through 2008 have tested positive for *Salmonella*. Head cheese, pork barbecue and sausage products represented over 60% of all positive samples. Pork was the source of about half of all positive products. All but 1 of the 22 positive samples came from establishments that were HACCP sizes of Very Small or Small. Over half of the positive samples came from establishments that employed *Lm* control Alternative 3 (sanitation only). There were some geographic differences in *Salmonella* presence in RTE products. It is recommended that there be an ongoing examination of *Salmonella* data from the ALLRTE and RTE001 sampling programs with respect to applying the information obtained to preventing foodborne *Salmonella* outbreaks. This would include modifications of existing compliance guidelines and other regulatory practices that help protect public health.