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Research Paper

Occurrence of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Product Verification Testing Samples from U.S. Department of Agriculture–Regulated Producing Establishments, 2005 through 2017

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ABSTRACT

Ready-to-eat (RTE) meat and poultry product samples collected between 2005 and 2017 from RTE-producing establishments for the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS) ALLRTE/RTEPROD_RAND (random) and RTE001/RTEPROD_RISK (risk-based) sampling projects were tested for *Listeria monocytogenes* (*Lm*). Data for 45,897 ALLRTE/RTEPROD_RAND samples collected from 3,607 distinct establishments and 112,347 RTE001/RTEPROD_RISK samples collected from 3,283 distinct establishments were analyzed for the presence of *Lm*. These data were also analyzed based upon the percentages of establishments with positive samples, annual production volume, sanitation control alternatives, geographic location, and season or month of sample collection. Results revealed low occurrence of *Lm*-positive samples from the random and risk-based sampling projects, with 152 (0.33%) positive samples for ALLRTE/RTEPROD_RAND and 403 (0.36%) positive samples for RTE001/RTEPROD_RISK. The percentage of positive samples significantly decreased over time, from about 0.7% in 2005 and 2006 to about 0.2% in 2017 ($P < 0.05$). From 2005 to 2017, 3.9% of establishments sampled under the ALLRTE/RTEPROD_RAND sampling project had at least one *Lm*-positive sample. Similarly, 10.0% of establishments sampled under the RTE001/RTEPROD_RISK sampling project had at least one positive sample. Samples positive for *Lm* were found in all geographic regions in all months. Thus, in 13 years of RTE product sampling in FSIS-regulated establishments (2005 through 2017), <0.4% of samples were positive for *Lm* in both risk-based and random sampling projects. The low prevalence of *Lm* in these products suggests that the combination of FSIS policies and industry practices may be effective for controlling *Lm* contamination. Information obtained from these sampling projects is relevant to the ongoing prevention of foodborne *Lm* illnesses from RTE meat and poultry products.

HIGHLIGHTS

- Over 158,000 RTE meat and poultry samples were tested for *Lm* by the FSIS in 2005 to 2017.
- About 0.4% of the samples from both random and risk-based sampling projects were positive for *Lm*.
- The data suggest that FSIS policies and industry practices have helped prevent *Lm* in RTE meat and poultry.

Key words: *Listeria monocytogenes*; Meat; Poultry; Ready to eat

Ready-to-eat (RTE) meat and poultry products can be contaminated by the pathogenic gram-positive bacterium *Listeria monocytogenes* (*Lm*). These meat products may be sources of foodborne illnesses, including reported outbreaks *(1, 4, 10)*. Listeriosis is a foodborne illness that can present as a mild form of gastroenteritis or as severe disease such as meningitis and cerebritis *(4, 5)* and has been associated with high mortality rates of 20 to 30% *(1, 8, 10, 12)*. *Lm* can survive and grow under aerobic and anaerobic conditions and a wide range of temperatures and acid conditions *(1, 5)*. *Lm* can be present in both food and food production environments, such as freezers, warehouses, and other areas of processing facilities and can then contaminate RTE products after postlethality processing.

The U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS) considers *Lm* an adulterant in

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RTE meat and poultry products *(19, 24)*. Accordingly, FSIS collects and tests samples of RTE meat and poultry products for *Lm* before these products are allowed into commerce for consumer consumption. FSIS has been conducting regulatory microbiological testing of RTE product samples from producing establishments for *Lm* since 1990 *(6, 7, 21)*. One such sampling project was ALLRTE (random verification sampling of all RTE meat and poultry products) *(7, 14, 21),* which was initiated in 2004. In this sampling project, RTE establishments were selected at random, and the product collected at each establishment was randomly selected among products being produced, with the exception of products considered to be of low risk such as lard, oil, and margarine. Previous exceptions for certain other RTE products, such as popped pork skins, pork rinds, dried and concentrated soup mixes, and pickled pig's feet, were eliminated in 2010 *(15)*.

Regulations such as those codified in 9 CFR 430 (issued in 2003 and affirmed with minor changes in 2015) mandated the reporting of various production and sanitation control factors (alternatives) by establishments producing meat and poultry products that were exposed to the postlethality production environment *(19, 24)*. This reporting served as the basis for another product sampling project based on the risk characteristics of the producing establishment. RTE001, a sampling project for RTE products based on these establishment risk factors, was initiated in 2005 *(7, 14, 21)*. Accordingly, product samples collected under RTE001 were from only those establishments in which RTE products were exposed to the postlethality environment. The selection of establishments for RTE001 sample collection and testing was made each month using a risk-ranking multivariate algorithm *(13, 14)*. Thus, monthly sample scheduling for both ALLRTE and RTE001 was based on two independent scheduling programs. In August 2013, ALLRTE and RTE001 were superseded by modified random and risk-based sampling projects, RTEPROD_RAND and RTEPROD_RISK, respectively *(18)*. The key change involved creating a combined sample scheduling program to eliminate the possibility that small and very small producing establishments received more than one sampling request (i.e., for both ALLRTE and RTE001) per month. This change had the net effect of both eliminating sampling redundancy in these establishments and permitting sampling in more establishments per month. FSIS has reported summarized percentage of positive *Lm* test results for RTE meat and poultry products collected under the random (ALLRTE/RTEPROD_RAND) and risk-based (RTE001/RTEPROD_RISK) sampling projects since their inception (2004 and 2005) through calendar year 2017 *(6, 21)*. In October 2016, in response to preliminary analyses, FSIS made changes to the percentage of samples allocated to the RTEPROD_RAND and RTEPROD_RISK programs (from a 25 and 75% allocation to a 50 and 50% allocation, respectively) and to the scheduling criteria used to assign RTEPROD_RISK tasks. This study was conducted to provide a detailed analysis of *Lm* results from the ALLRTE/RTEPROD_RAND and RTE001/RTEPROD_RISK sampling projects to identify data trends and determine whether additional changes to the programs are needed.

MATERIALS AND METHODS

Sample scheduling for FSIS-regulated RTE meat and poultry producing establishments. Annually, approximately 2,400 FSIS-regulated establishments producing RTE meat and poultry products were eligible for random sampling under the ALLRTE and RTEPROD_RAND sampling projects. About 2,200 of these establishments produced postlethality-exposed products and thus were sampled under the RTE001 and RTEPROD_RISK sampling projects. Sample scheduling algorithms were used to select establishments for sampling on a monthly basis. The ALLRTE/RTEPROD_RAND sampling algorithm was designed for random selection of all eligible RTE establishments. The RTE001/RTEPROD_RISK algorithm was multivariate, involving several factors such as the RTE sanitation control alternative(s) used by the establishment; establishment product groups or types; annual volume of production for each of the postlethality-exposed product groups; and sample results from current and previous testing for *Lm* in RTE products, food contact surfaces, and nonfood contact environmental surfaces *(13)*. Until 2012, control alternative, product group, and volume data were provided by the producing establishments on an FSIS information form (form 10240-1) in accordance with the original 2003 version of 9 CFR 430.4(d). From 2012 to 2017, these data were obtained from Public Health Information System (PHIS) establishment profiles. Consideration was given to product risk, based on a 2003 risk ranking *(23)*. Fully cooked sliced and unsliced products (e.g., deli meats) and hot dog products were given a higher weighting than other products in the risk-ranking algorithm. Historical sampling results were obtained from FSIS databases (data warehouse). In any given month between January 2005 and July 2013, a given establishment could be scheduled for collection of both an ALLRTE and an RTE001 sample because the two scheduling algorithms were independent. Effective August 2013, ALLRTE and RTE001 were superseded by RTEPROD_RAND and RTEPROD_RISK, respectively. The main difference between the older and newer sampling projects was that a single monthly scheduling algorithm was used to schedule both RTEPROD_RAND and RTEPROD_RISK samples. This change ensured a maximum of one sample per scheduled establishment per month. Until 1 October 2016, the RTEPROD_RAND scheduling algorithm randomly selected approximately 80 establishments per week, and the RTEPROD_RISK risk-ranking algorithm selected approximately 200 establishments were per week. After 1 October 2016, both the RTEPROD_RAND and RTEPROD_RISK scheduling algorithms selected approximately 350 establishments per week (about 175 establishments per project). Also in 2016, FSIS updated the weighting factors used in the RTEPROD_RISK algorithm, such as the weighting factor used for product group. As a result, RTE products identified as posing a greater risk were sampled more frequently each year.

Sample collection and testing. Inspection program personnel used a random number generator to select the day, shift, and time for sample collection. Every RTE product sample collected under the ALLRTE/RTEPROD_RAND and RTE001/RTEPROD_RISK sampling projects consisted of at least 2 lb (0.9 kg) of the finished packaged product. For ALLRTE/RTEPROD_RAND, products were selected at random. For RTE001/RTEPROD_RISK, sample collectors were instructed to select the highest risk postlethality-exposed RTE product produced at the time of collection as per an established risk hierarchy *(14, 18)*. Each sample was shipped cold in an insulated cooler containing refrigeration bricks overnight to one of three FSIS sample testing

TABLE 1. *Detection of* Lm *in ALLRTE/RTEPROD_RAND (random) and RTE001/RTEPROD_RISK (risk-based) RTE product samples, calendar years 2005 through 2017*

	ALLRTE/RTEPROD_RAND				RTE001/RTEPROD_RISK			
Year	No. of samples tested	No. of positive samples	% positive samples	*P* value	No. of samples tested	No. of positive samples	% positive samples	*P* value
2005	2,813	18	0.64	0.004	7,139	51	0.71	<0.0001
2006	2,938	18	0.61	0.007	8,547	41	0.48	0.030
2007	2,951	12	0.41	0.443	8,674	41	0.47	0.038
2008	3,120	14	0.45	0.229	8,921	35	0.39	0.424
2009	2,761	7	0.25	0.468	8,158	35	0.43	0.179
2010	3,152	10	0.32	0.909	8,705	24	0.28	0.254
2011	3,295	8	0.24	0.368	8,885	27	0.30	0.499
2012	3,353	6	0.18	0.114	7,650	26	0.34	0.946
2013	3,261	11	0.34	0.628	8,895	26	0.29	0.383
2014	3,360	13	0.39	0.542	9,769	30	0.31	0.516
2015	3,408	12	0.35	0.803	9,824	32	0.33	0.746
2016	4,588	10	0.22	0.175	9,417	18	0.19	0.008
2017	6,897	13	0.19	0.038	7,763	17	0.22	0.048
Total[a]	45,897	152	0.33		112,347	403	0.36	

[a] Overall sample group (year) *P* values: <0.014 for ALLRTE/RTEPROD_RAND and <0.0001 for RTE001/RTEPROD_RISK.

laboratories. Samples were processed and analyzed for *Lm* in accordance with protocols described in the FSIS *Microbiology Laboratory Guidebook (22)*. Isolates from *Lm*-positive samples were subtyped by pulsed-field gel electrophoresis (PFGE) in accordance with standard protocols *(2)*. PFGE pattern data were supplied by the Outbreaks Section of the Eastern Laboratory Microbiology Branch of FSIS.

Data analysis. Data routinely generated from the ALLRTE/RTEPROD_RAND and RTE001/RTEPROD_RISK sampling projects were used for all analyses. The data consisted of information on producing establishments and sampling and microbiological test results. These data were extracted from the FSIS data warehouse via the Laboratory Sample Flow System, a laboratory information management system. Supplementary data on producing establishments prior to 2012 were obtained from the Performance-based Inspection System. Starting in 2012, supplementary establishment data were obtained from the PHIS *(20)*. FSIS calculated the numbers and percentages of positive product samples for calendar years 2005 through 2017. The data analyzed were based on sample collection dates (1 January 2005 through 31 December 2017). These analyses focused on the occurrence of *Lm*-positive samples from establishments and the product types and commodity sources of these samples. Descriptive summaries were generated with respect to such factors as (i) establishment production volume, (ii) establishment *Lm* control alternative, (iii) geographic location of the establishment, and (iv) season or month of sample collection. Most data analyses were performed through data handling and evaluation techniques with Excel (Microsoft, Redmond, WA). When required, statistical analysis consisted primarily of logistic regression (LOGISTIC procedures, SAS Institute, Cary, NC) for a single variable of interest (e.g., year or geographic location) with the total number of samples and the number of *Lm*-positive samples for each condition of that variable. Comparison of total samples and positive samples by variable of interest generated a table of results, including the *P* values ($\alpha = 0.05$) that determined the statistical significance of the given matrix of variable and data.

RESULTS

Data collection began in 2004 for the ALLRTE sampling project and in 2005 for the RTE001 sampling project. For comparative purposes, January 2005 was selected as the start date with respect to *Lm* data evaluation for the two sampling projects covered in this report. The RTEPROD_RAND and RTEPROD_RISK sampling projects superseded ALLRTE and RTE001, respectively, in 2013. Overall, 152 (0.33%) of 45,897 ALLRTE/RTEPROD_RAND samples and 403 (0.36%) of 112,347 RTE001/RTEPROD_RISK samples tested positive for *Lm* (Table 1). A marked decline in *Lm* in RTE foods was noted from 2005 to 2017 (Table 1 and Fig. 1). Changes in the percentages of *Lm*-positive ALLRTE/RTEPROD_RAND and RTE001/RTEPROD_RISK samples between 2005 and 2017 were evaluated with logistic regression analysis ($\alpha = 0.05$). Significant group (year) effects were found for *Lm* results of both the ALLRTE/RTEPROD_RAND sampling project and the RTE001/RTEPROD_RISK sampling project over time ($P < 0.014$ and $P < 0.0001$, respectively, for overall year effect). With respect to individual years, the percentages of *Lm*-positive ALLRTE/RTEPROD_RAND samples were significantly higher in 2005 and 2006 (0.64 and 0.61%; $P < 0.005$ and $P < 0.007$, respectively) and significantly lower in 2017 (0.19%; $P < 0.04$). Similarly, the percentages of *Lm*-positive RTE001/RTEPROD_RISK samples were significantly higher in 2005 through 2007 (0.71, 0.48, and 0.47%; $P < 0.0001$) and significantly lower in 2016 and 2017 (0.19 and 0.22%; $P < 0.01$ and $P < 0.05$, respectively).

On an establishment basis, the numbers and percentages of establishments that had at least one *Lm*-positive ALLRTE/RTEPROD_RAND or RTE001/RTEPROD_RISK sample are shown in Table 2. In any given year, there were approximately 2,400 RTE establishments subject to sampling. Over the entire 2005 through 2017 sampling period,

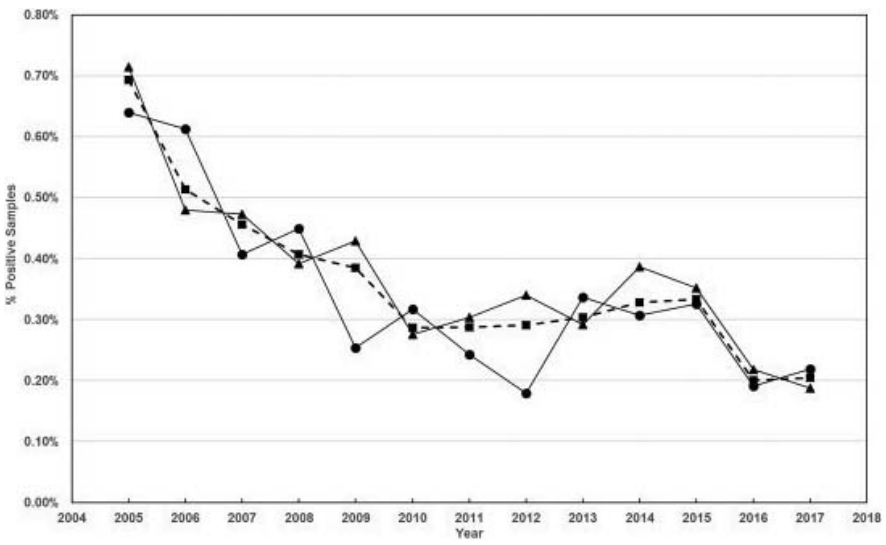

FIGURE 1. *Detection of* Lm *in ALLRTE/RTEPROD_RAND (random) and RTE001/RTEPROD_RISK (risk-based) samples, calendar years 2005 through 2017.* ▲, *ALLRTE/RTEPROD_RAND;* ●, *RTE001/RTEPROD_RISK;* ■, *combined data.*

approximately 800 new establishments were added, and about 400 establishments were no longer subject to RTE sample testing. Subsequently, in 2005 through 2017 a total of 140 (3.9%) of 3,607 distinct ALLRTE/RTEPROD_RAND establishments and 328 (10.0%) of 3,283 distinct RTE001/RTEPROD_RISK establishments yielded *Lm*-positive samples. A total of 433 distinct establishments had one or more *Lm*-positive samples in the combined sampling projects. No group (year) effect was observed for ALLRTE/RTEPROD_RAND establishment data over time ($P < 0.12$). In contrast, a significant group effect was found for RTE001/RTEPROD_RISK establishment data over time ($P < 0.0001$). On an annual basis, the percentages of establishments with one or more *Lm*-positive samples were 0.34 to 1.18% for ALLRTE/RTEPROD_RAND establishments and 0.84 to 3.23% for RTE001/RTEPROD_RISK establishments. RTE001/RTEPROD_RISK establishment percentages were significantly higher in 2005 through 2008 ($P < 0.0001$ for 2005 through 2007, $P < 0.04$ for 2008) and significantly lower in 2016 and 2017 ($P < 0.004$ and $P < 0.016$, respectively).

Isolate subtyping results. PFGE analysis was performed for 541 isolates from the 555 *Lm*-positive RTE product samples obtained from 433 establishments, and 259 PFGE pattern types were obtained (Table 3). The top 25 patterns accounted for 46.5% of the total patterns from all isolates. Seventy of these patterns were isolated multiple times: the top two subtypes were isolated 43 and 28 times, respectively, six subtypes were isolated 10 to 20 times, and 17 subtypes were isolated 4 to 9 times (Table 3). The same PFGE pattern was observed for multiple (two to four)

TABLE 2. *Establishments with at least one* Lm*-positive RTE product sample, 2005 through 2017*

	ALLRTE/RTEPROD_RAND				RTE001/RTEPROD_RISK			
Year	No. of establishments sampled/yr	No. positive	% positive	*P* value	No. of establishments sampled/yr	No. positive	% positive	*P* value
2005	1,941	18	0.93	0.089	1,534	48	3.13	<0.0001
2006	1,530	18	1.18	0.006	1,178	38	3.23	<0.0001
2007	1,403	12	0.86	0.258	1,285	40	3.11	<0.0001
2008	1,485	14	0.94	0.112	1,449	33	2.28	0.035
2009	1,655	7	0.42	0.275	1,850	34	1.84	0.404
2010	1,745	10	0.57	0.777	1,663	21	1.26	0.250
2011	1,899	8	0.42	0.241	1,714	26	1.52	0.773
2012	1,749	6	0.34	0.119	2,204	25	1.13	0.070
2013	1,789	11	0.61	0.958	2,178	23	1.06	0.035
2014	1,847	13	0.70	0.655	2,167	29	1.34	0.313
2015	1,871	12	0.64	0.923	2,156	31	1.44	0.533
2016	2,114	10	0.47	0.358	2,141	18	0.84	0.004
2017	2,227	12	0.54	0.596	1,761	16	0.91	0.016
Total tasks[a]	23,255	151	0.65		23,280	382	1.64	
Total establishments[b]	3,607	140	3.89		3,283	328	10.00	

[a] Cumulative total of one or more sample collection tasks at RTE establishments, 2005 through 2017.
[b] Total of all RTE establishments in which samples were collected, 2005 through 2017. Overall establishment group (year) *P* values: <0.12 for ALLRTE/RTEPROD_RAND and <0.0001 for RTE001/RTEPROD_RISK.

TABLE 3. *PFGE pattern types of* Lm *isolates from ALLRTE/RTEPROD_RAND and RTE001/RTEPROD_RISK product samples, calendar years 2005 through 2017*

PFGE pattern[a]	No. of distinct establishments	Total no. of isolates	% total isolates	Cumulative % of total isolates
1	39	43	7.9	7.9
2	21	28	5.2	13.1
3	17	17	3.1	16.2
4	15	16	3.0	19.2
5	9	11	2.0	21.2
6	9	11	2.0	23.2
7	9	10	1.8	25.1
8	9	10	1.8	26.9
9	7	9	1.7	28.6
10	8	9	1.7	30.3
11	7	9	1.7	31.9
12	7	8	1.5	33.4
13	7	7	1.3	34.7
14	6	7	1.3	36.0
15	4	7	1.3	37.3
16	6	6	1.1	38.4
17	6	6	1.1	39.5
18	5	6	1.1	40.6
19	4	5	0.9	41.5
20	5	5	0.9	42.5
21	5	5	0.9	43.4
22	2	5	0.9	44.3
23	4	4	0.7	45.1
24	3	4	0.7	45.8
25	3	4	0.7	46.5
26–259 (1–3 occurrences)	273	289	53.4	100.0
Total	490[b]	541	100.0	100.0

[a] PFGE pattern types are designated by the CDC and are part of the PulseNet database, which was accessed for this analysis. Actual pattern types are not shown.

[b] Total establishment sample collections in which isolates submitted for PFGE were obtained; 433 distinct establishments had positive samples.

sample isolates from 44 distinct establishments, indicating possible *Lm* harborage in these establishments. This encompassed 18 of the top 25 PFGE patterns, based on a greater number of isolates with a single PFGE pattern than establishments from which that isolate was obtained.

***Lm* results based on RTE product groups.** Each RTE sample is classified as 1 of 11 RTE product groups based on a system established by the FSIS *(18, 20)*. The percentages of RTE product samples positive for *Lm* for each of these product groups are shown in Table 4. The percentages of *Lm*-positive samples from three product groups, salad-spread-pâté products (0.63%, $P < 0.0005$), patty-nugget products (0.51%; $P < 0.05$), and other fully cooked sliced products (0.49%; $P < 0.004$), were significantly higher than those from the other eight product groups. The percentage of *Lm*-positive salt-cured products was 0.55%, but this difference was not significant at $\alpha = 0.05$ possibly because this group contained the smallest number of tested samples.

TABLE 4. *Detection of* Lm *based on RTE product group, calendar years 2005 through 2017*

Product group	No. of samples tested	No. positive	% positive	*P* value
Salad-spread-pâté	5,554	35	0.63	0.0004
Salt cured	2,163	12	0.55	0.095
Patties-nuggets	5,940	30	0.51	0.044
Other fully cooked, sliced	19,851	97	0.49	0.003
Diced, shredded	10,764	44	0.41	0.344
Hot dogs	11,953	47	0.39	0.483
Meat, nonmeat components	25,857	97	0.38	0.619
Other fully cooked, nonsliced	32,701	101	0.31	0.182
Sausages	25,394	63	0.25	0.004
Acidified, fermented	5,972	13	0.22	0.056
Dried	12,095	16	0.13	<0.0001
Total	158,244	555	0.35	

In contrast, the percentages of *Lm*-positive sausage products (0.25%; $P < 0.005$) and dried products (0.13%; $P < 0.0001$) were significantly lower than those of other product groups. The 0.22% *Lm*-positive acidified-fermented products was just above the level of significance ($P < 0.06$).

***Lm* results based on RTE commodity source.** The percentages of RTE product samples positive for *Lm* with respect to the commodity source (chicken, pork, beef, etc.) for each product are shown in Table 5. The highest percentage of *Lm*-positive samples was from chicken-derived products (0.46%), which was just above the level of significance ($P < 0.06$). The percentages of *Lm*-positive samples from all other commodity sources, including products made from a combination of two or more commodity sources (e.g., beef plus pork), were 0.26 to 0.38%. None of these percentages were significantly different at $\alpha = 0.05$.

***Lm* results as a function of establishment annual production volumes.** Results were analyzed as a function of the annual production volumes of RTE food products.

TABLE 5. *Detection of* Lm *based on RTE product source commodity, calendar years 2005 through 2017*[a]

Source commodity	No. of samples tested	No. positive	% positive	*P* value
Chicken	21,367	99	0.46	0.058
Pork	55,334	208	0.38	0.419
Turkey	9,968	36	0.36	0.641
Other poultry	1,200	4	0.33	0.964
Other combinations	26,423	72	0.27	0.344
Beef	36,043	98	0.27	0.320
Other meat	392	1	0.26	0.774
Total	150,727	518	0.34	

[a] For 7,517 tested samples and 37 positive samples, the source commodity was unknown or unlisted.

TABLE 6. *Detection of* Lm *as a function of establishment annual production volumes, calendar years 2005 through 2017*

Annual production vol (lb/yr)[a]	No. of samples tested	No. positive	% positive	*P* value
100	408	1	0.25	0.890
1,000	5,296	6	0.11	0.090
10,000	23,059	68	0.29	0.123
100,000	30,102	125	0.42	0.001
1,000,000	29,709	85	0.29	0.154
10,000,000	17,850	27	0.15	0.122
100,000,000	3,847	6	0.16	0.387
Total	110,271	318	0.29	

[a] Approximate, based on information collected on FSIS form 10240-1 (2005 through 2012) or from PHIS establishment production volume data (2012 through 2017). Classification was made based on the integer of the log-transformed annual production volume. For 47,973 samples tested and 237 positive samples, the annual production volume was unknown, unlisted, or unverifiable.

Samples were classified into one of seven order-of-magnitude volume groups (100, 1,000, etc.) based on the integer of the log-transformed annual production volume. The observations made were dependent on the accuracy of the production volumes supplied, either by the establishments themselves on FSIS form 10240-1 (2005 through 2011) or from PHIS establishment profiles (2012 through 2017). The percentages of *Lm*-positive samples in ALLRTE/RTEPROD_RAND and RTE001/RTEPROD_ RISK with respect to estimated annual production volumes for calendar years 2005 through 2017 are shown in Table 6. *Lm*-positive samples were more commonly found in establishments with production volumes of 10,000 to 1,000,000 lb (4,536 to 453,592 kg) per year (three of the seven volume groups). A significantly higher percentage of *Lm*-positive samples was found for establishments with annual production volumes of approximately 100,000 lb (45,359 kg) per year (0.42%; $P = 0.001$).

Results as a function of establishment *Lm* control alternatives. Establishments whose products have postlethality exposure can be classified into one of three possible control alternatives or procedures for eliminating or inhibiting the growth of *Lm* in these RTE products. These establishments also are referred to as 9 CFR Part 430 establishments based on the information provided for those alternatives described in the regulation *(24)*. Alternative 1, the lowest risk category, involves using both a postlethality 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*" *(24)*. Alternative 2, with potentially higher risk, has two options of either a postlethality treatment that kills or reduces microorganisms (2a, choice 1) or an antimicrobial agent or process that specifically inhibits *Lm* growth (2b, choice 2). Alternative 3, the highest risk alternative, requires the "use of sanitation measures only" *(24)*. The percentages of *Lm*-positive samples in ALLRTE/RTEPROD_RAND and RTE001/RTEPROD_ RISK with respect to control alternative for calendar years 2005 through 2017 are shown in Table 7. Establishments using alternative 3 had a significantly higher percentage of *Lm*-positive samples (0.37%) than establishments using alternatives 1, 2a, or 2b (0.27, 0.21, and 0.26%, respectively; $P < 0.01$).

TABLE 7. *Detection of* Lm *as a function of establishment* Lm *control alternative, calendar years 2005 through 2017*[a]

Control alternative	No. of samples tested	No. positive	% positive	*P* value
1	3,317	9	0.27	0.973
2a	6,583	14	0.21	0.248
2b	41,551	109	0.26	0.741
3	98,926	367	0.37	0.009
Total	150,377	499	0.35	

[a] For 7,867 samples tested and 56 positive samples, either the alternative was unknown or the sample was a product with no postlethality exposure. Almost all of these positive products appeared to be from establishments with postlethality exposure based on product description and establishment profile information.

***Lm* results by FSIS geographic region.** To evaluate geographic effects on the detection of *Lm,* individual states were classified into five geographic regions based on a previously published FSIS classification *(9)*: (i) Northeast (11 states plus the District of Columbia) includes Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and Washington, DC; (ii) North Central (7 states) includes Illinois, Indiana, Iowa, Michigan, Minnesota, Ohio, and Wisconsin; (iii) Southeast (10 states plus two territories) includes Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, West Virginia, Puerto Rico, and the U.S. Virgin Islands; (iv) Southwest (8 states) includes Arkansas, Kansas, Louisiana, Missouri, Nebraska, New Mexico, Oklahoma, and Texas; and (v) West (14 states and three territories) includes 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/RTEPROD_RAND and RTE001/RTEPROD_RISK samples that tested positive for *Lm* within these five broad geographic regions for calendar years 2005 through 2017 are shown in Table 8. *Lm* was present in ALLRTE/RTEPROD_RAND and RTE001/RTEPROD_RISK samples from all geographic regions. The Southeast had the highest percentage of *Lm*-positive samples (0.54%), whereas the North Central and Southwest regions had the lowest percentages (0.26 and 0.28%, respectively). These differences were significant ($P <$

TABLE 8. *Detection of* Lm *by FSIS geographic region, calendar years 2005 through 2017*

Region	No. of samples tested	No. positive	% positive	*P* value
North Central	39,135	103	0.26	0.001
Northeast	32,379	121	0.37	0.393
Southeast	25,537	138	0.54	<0.0001
Southwest	26,888	76	0.28	0.034
West	34,305	117	0.34	0.799
Total	158,244	555	0.35	

0.0001 for Southeast, $P < 0.001$ for North Central, and $P < 0.04$ for Southwest).

***Lm* results as a function of month and season.** To explore possible seasonal effects on the detection of *Lm*, *Lm*-positive ALLRTE/RTEPROD_RAND and RTE001/RTEPROD_RISK results were categorized based on month of the year in which positive samples were obtained. A mean of approximately 1,015 (970 to 1,080) combined RTE product samples were collected and tested in a given month. The percentages of samples positive for *Lm* by month for calendar years 2005 through 2017 are shown in Table 9. *Lm*-positive samples were isolated from RTE establishments during all months. Months with the highest percentage of *Lm*-positive samples were June and August (0.49 and 0.47%, respectively), and these percentages were significantly different from those for the other 10 months ($P < 0.004$ and $P < 0.02$, respectively). The results were also categorized by the season in which positive samples were obtained (Table 10). For spring (April to June) and summer (July to September), percentages of *Lm*-positive samples were almost identical (0.39 and 0.38%, respectively), whereas winter (January to March) had the lowest percentage of *Lm*-positive samples (0.30%). However, these seasonal differences were not significant at $\alpha = 0.05$.

TABLE 9. *Detection of* Lm *by month, calendar years 2005 through 2017*

Month	No. of samples tested	No. positive	% positive	*P* value
Jan.	12,599	36	0.29	0.242
Feb.	12,929	43	0.33	0.822
Mar.	14,023	40	0.29	0.215
Apr.	12,846	40	0.31	0.512
May	12,749	45	0.35	0.852
June	13,996	68	0.49	0.004
July	12,726	47	0.37	0.607
Aug.	13,424	63	0.47	0.011
Sep.	12,792	38	0.30	0.344
Oct.	13,698	56	0.41	0.179
Nov.	12,888	38	0.29	0.320
Dec.	13,574	41	0.30	0.385
Total	158,244	555	0.35	

TABLE 10. *Detection of* Lm *by season, calendar years 2005 through 2017*

Season	No. of samples tested	No. positive	% positive	*P* value
Winter	39,551	119	0.30	<0.06
Spring	39,591	153	0.39	<0.16
Summer	38,942	148	0.38	<0.24
Fall	40,160	135	0.34	<0.61
Total	158,244	555	0.35	

DISCUSSION

Since 1990, FSIS has reported summarized testing results of various RTE meat and poultry products for *Lm* *(21)*. Levine et al. *(6)* analyzed *Lm* data for RTE meat and poultry samples collected and tested by FSIS from 1990 to 1999. In the present report, FSIS data with were analyzed with respect to the detection of *Lm* in RTE meat and poultry product samples collected under the ALLRTE/RTEPROD_RAND and RTE001/RTEPROD_RISK sampling projects between January 2005 and December 2017. Evaluation of the yearly percentages of *Lm*-positive RTE product samples between 1990 and 2017 revealed that overall percentages from all FSIS RTE product sampling projects have decreased from >4.5% in 1990 to about 0.2% in 2017 *(21)*. A substantial decrease (from about 4.5% to about 0.9%) occurred before 2005 owing to a combination of implementation of the pathogen reduction and hazard analysis and critical control points final rule published in 1996, other FSIS policies, and industry actions regarding *Lm* contamination. These combined actions plus the implementation of 9 CFR 430 (the *Listeria* rule) in 2003 resulted in further decreases in the percentages of *Lm*-positive samples over time, with annual percentages in both ALLRTE/RTEPROD_RAND and RTE001/RTEPROD_RISK remaining <0.5% since 2007. However, the overall percentages of establishments that had at least one *Lm*-positive RTE product sample between 2005 and 2017 were 3.89% for ALLRTE/RTEPROD_RAND and 10.0% for RTE001/RTEPROD_RISK. The difference in the two percentages may be related to the nature of risk-based versus random sampling. Other factors also may be involved, such as establishment production volumes and product groups, but these factors were not evaluated further because of the relatively low percentages of *Lm*-positive samples from each sampling project. FSIS performs intensified verification testing and for-cause food safety assessments *(17)* to ensure that positive results from the ALLRTE/RTEPROD_RAND and RTE001/RTEPROD_RISK projects are addressed by the establishment's corrective actions. The intensified verification testing program is a follow-up sampling program for products, food contact surfaces, and environmental surfaces in establishments that had *Lm*-positive sampling results *(17)*.

Of 433 total establishments, 44 had multiple occurrences of the same PFGE pattern type, indicating possible *Lm* harborage (environmental persistence of a given isolate with the same PFGE pattern type) in these establishments.

The PFGE results from the ALLRTE/RTEPROD_RAND and RTE001/RTEPROD_RISK sampling projects are also used in conjunction with data from other FSIS *Lm* sampling programs that test food contact surface samples and nonfood contact environmental samples (plus other RTE product samples) to identify possible harborage situations and/or cross-contamination (i.e., the presence of a specific PFGE pattern type from product, food contact, and/or environmental samples within a given establishment). These other programs include intensified verification testing and food safety assessments plus the RLm sampling program, a routine risk-based testing program for *Lm* in products and on food contact and other environmental surfaces of a given establishment *(16, 17)*. FSIS has systematically reviewed PFGE data across all *Lm* sampling projects to determine whether harborage or cross-contamination may have occurred within a particular establishment and has used this information as a basis to take further regulatory actions. In coordination with the Centers for Disease Control and Prevention PulseNet program, FSIS suspended PFGE for *Lm* and, as of 15 January 2018, started generating *Lm* characterization through whole genome sequencing. Since the transition, FSIS uses whole genome sequencing results to determine potential harborage or cross-contamination and uses this information as the basis for taking further regulatory actions. Because of the time frame of the data set evaluated in the present study, only PFGE data were analyzed. However, future analyses will be based on whole genome sequencing characterization.

Percentages of *Lm*-positive samples based on the 11 RTE product groups evaluated were 0.13 to 0.63% during the 2005 through 2017 time period. In contrast, between 1990 and 1999, the percentages of *Lm*-positive samples from eight product groups were 0.52 to 5.16% *(6)*. Although the RTE product group classification changed over time, some comparison of the 1990 through 1999 and 2005 through 2017 results is warranted. Cumulative percentages of *Lm*-positive salad-spread-pâté product samples decreased from 3.03% in 1990 through 1999 to 0.63% in 2005 through 2017, percentages of *Lm*-positive dried product samples (including jerky products) decreased from 0.52 to 0.13%; percentages of *Lm*-positive fermented product samples (including fermented sausages) decreased from 3.25 to 0.22%; percentages of *Lm*-positive cooked sausage product samples (including both large and small sausages) decreased from 1.31% (large) or 3.56% (small) to 0.25%; percentages of *Lm*-positive other fully cooked not sliced product samples (including the 1990 through 1999 categories of cooked beef and poultry) decreased from 2.12 and 3.09%, respectively, to 0.31%; and the percentages of *Lm*-positive other fully cooked sliced products (including sliced ham and luncheon meats) decreased from 5.16 to 0.49%. No commodity source (e.g., beef, pork, poultry) was prominent among the positive products, although the highest percentage of positive samples (0.46%) was found for chicken products. These results underscore the continued effectiveness of FSIS policies and industry production practices in markedly decreasing the percentages of *Lm*-positive RTE meat and poultry products across various product groups over the past 30 years. As a result of these findings, the FSIS intends to use this analysis to inform changes to its programs, including changing the priority list used by inspectors for selecting a product sample under the RTEPROD_RISK program because, as revealed by the present study, the current priority list based on product groups does not reflect those products most likely to be positive for *Lm*.

Results based on *Lm* control alternatives employed by the establishments revealed that *Lm*-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) establishments, with significantly higher ($P < 0.01$) percentages of positive samples compared with establishments utilizing postlethality treatments and/or antimicrobial agents and processes (alternatives 1, 2a, and 2b). This finding indicates that postlethality treatments and/or antimicrobial agents and processes can be more effective than sanitation alone for controlling *Lm* contamination. For this reason, FSIS is considering having its inspectors prioritize collection of products produced under alternative 3 for the RTEPROD_RISK program. Results based on establishment annual production volumes revealed that *Lm*-positive samples were more likely to be found in establishments with production volumes of 10,000 to 1,000,000 lb (4,536 to 453,592 kg) per year. Although this volume range is broad, the data indicate that *Lm* are less likely to be found in the smallest (<10,000 lb per year) and largest (>1,000,000 lb per year) producing establishments. Evaluation of results by geographic region revealed a significantly higher percentage of *Lm*-positive samples in southeastern states but significantly lower percentages in north-central and western states. However, this analysis does not take into account such factors as regional differences between establishment production volumes, types of products produced, and other confounding variables. Analysis of results by month and season indicated that although *Lm*-positive RTE samples could be obtained at all times of the year, higher percentages of *Lm*-positive samples were obtained in months with warmer weather, e.g., June to August.

In summary, 555 (0.35%) of 158,244 combined ALLRTE/RTEPROD_RAND and RTE001/RTEPROD_RISK RTE product samples from these random and risk-based sampling projects collected in calendar years 2005 through 2017 were positive for *Lm*. Despite the low overall percentage of positive samples, almost 4% of establishments sampled as part of the ALLRTE/RTEPROD_RAND sampling projects and 10% of the establishments sampled as part of the RTE001/RTEPROD_RISK sampling projects had at least one *Lm*-positive product sample over the 13-year time period. During this time, the only outbreak of listeriosis attributed to FSIS-regulated RTE meat and poultry products, which affected 13 individuals, was associated with turkey deli meat and occurred in 2005 *(11)*. However, two outbreaks related to FSIS-regulated RTE pork products occurred in 2018 and affecting a total of eight individuals *(3),* indicating the need for further vigilance in the prevention of *Lm* contamination of RTE products. The information obtained from this analysis is

applicable to ongoing efforts for preventing *Lm* contamination of RTE meat and poultry products. Such efforts have included modifications of existing policies, instructions to field personnel (e.g., directives and notices), compliance guidelines for industry, and other regulatory practices that help protect public health. For example, modifications have been made to the allocation of samples between the RTEPROD_RAND and RTEPROD_RISK programs and to the RTEPROD_RISK sample scheduling algorithm to further improve RTE sample collection and testing. Additional modifications to sample collection protocols are under consideration, such as selecting an RTEPROD_RISK sample based on alternative *Lm* control method rather than product type.

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