United States Department of Agriculture | Food Safety and Inspection Service

The FSIS Microbiological Testing Program for Ready-to-Eat (RTE) Meat and Poultry Products, 1990–2007

INTRODUCTION

FSIS has conducted a regulatory microbiological testing program on Ready-To-Eat (RTE) meat and poultry products since 1983. The data reported here are from product sampling projects covering the years 1990 through 2007. These data do not include the results of follow-up sampling that FSIS conducts in response to a positive result. Products sampled and the microbial hazards for which they are analyzed are those of public health concern. FSIS also analyses samples of RTE egg products for *Salmonella*. The results from those analyses are not included here. All regulatory analyses of RTE products are performed in FSIS laboratories located in Alameda, CA,

St. Louis, MO, and Athens, GA and are reported as of sample analysis completion date. Therefore, all text, tables and graphs are based upon the sample analysis completion date.

Throughout the history of the FSIS microbiological RTE regulatory sampling program, the individual projects have been continuously evolving in response to public health concerns. The data reported here are from these individual sampling projects that have been implemented under the overall RTE program. This testing program has not been designed to test for statistically significant changes from one year to the next. The aggregate data do, however, provide an overall indication of trends.

Through 2004, for all projects, establishments were randomly selected for regulatory samples from different sub-populations or from the total population of establishments producing RTE products. During 2005, FSIS implemented a new project where the establishments are selected for sampling based on different risk factors for *L. monocytogenes*. The new project, designated RTE001, is described below with the 2005 results. RTE001 became the primary sampling project in 2006, representing almost 70 percent of regulatory product sampling. In 2006, FSIS introduced a second project based on risk factors referred to as phase 2 of *L. monocytogenes* risk-based sampling and designated as RLm. RLm includes sampling of products, product contact surfaces and environmental surfaces in conjunction with a comprehensive Food Safety Assessment (FSA). The scheduling of RLm is coordinated through the District Offices. FSIS Directive 10,240.5 (March 15, 2006; PDF Only) provides direction to Enforcement, Investigations, and Analysis Officers (EIAOs) and Public Health Veterinarians (PHVs) trained in the EIAO methodology for collecting samples under the RLm sampling project. RLm samples are analyzed only

for *L. monocytogenes*.

There were no new projects added for CY2007, as FSIS continued the ALLRTE, RTE001, and RLm projects described below for the year when they were introduced. During 2007, there was a modification to the RTE001 project. Following an incident where an unusual proportion of a product using growth inhibitors was found to be *L. monocytogenes* positive, the risk based algorithm was adjusted to ensure that more products using antimicrobials or growth inhibitors were sampled. During April, the algorithm was modified to ensure that 50 percent of the samples each month were scheduled in establishments reporting production of Alternative 2b products, i.e., products with an antimicrobial or growth inhibitor but without any post exposure pasteurization. As originally designed, the algorithm will direct the majority of samples to establishments using sanitation alone to control *L. monocytogenes* in RTE products, i.e., establishments reporting using Alternative 3. There is no way to assess what effect this modification had on the overall CY2007 results for RTE001.

For projects other than RLm, when an establishment is selected for testing, the inspection program personnel are sent a sample request form identifying the sampling project, the microbial hazard(s) for which the sample of product will be analyzed, and the FSIS laboratory to which the sample is to be sent. The form also identifies a window of time within which to collect a sample of product for shipment to an FSIS laboratory. Additional guidance for how to select the product to be sampled is contained in different FSIS Directives. After the product or product category is identified, the sample is randomly selected. All samples (except RLm) are analyzed for *Salmonella* and *L. monocytogenes*. A few specific products containing beef are also analyzed for *Escherichia coli* O157:H7.

Any product represented by a positive sample result must be reprocessed or destroyed. Most establishments voluntarily hold all RTE product represented by a specific regulatory sample pending notification of the FSIS laboratory test results. If all product implicated by a positive laboratory result is not under the establishment's control, then steps must be taken by the producing establishment to remove adulterated product from distribution channels and/or commerce, which may entail a voluntary recall.

With the posting of the CY 2004 RTE microbiological testing program results FSIS revised the nomenclature that had previously been used. Results are now reported as both the number and percentage of analyzed samples that have tested positive for *Salmonella* or *L. monocytogenes*. Previous postings described these results as "prevalence." However, the term "prevalence" seems to imply that results from the regulatory sampling projects are statistical estimates of national product prevalence. To avoid confusion, FSIS will now only use "prevalence" to describe testing results from nationwide baseline studies specifically designed to provide statistically valid baseline estimates of national product prevalence for various microorganisms and for regulatory purposes. Results of regulatory testing projects conducted to verify the effectiveness of food safety systems, and not designed to provide statistically valid baseline estimates of national product prevalence, will be reported as the percent of analyzed samples that tested positive.

The 2007 Results

The results for CY 2007 are presented in Tables 19 and 20. The 10 product categories introduced in CY 2001 and listed in Table 4 were continued for CY 2007,

so all results are organized around those 10 product categories. The results from CY 2007 for *Salmonella* are presented in Table 19. The results for *L. monocytogenes* are presented in Table 20. Table 20 includes the product sampling results from RLm, designated as RLmPROD to indicate it is just the product portion of RLm. A total of 12,665 products were tested for *L. monocytogenes* in CY 2007, excluding all follow-up sampling and sampling of imported products. The percentage of positive product samples across all projects was 0.43%. Table 18 does not include 5,198 product contact surface and environmental samples that were analyzed as part of RLm. The total number of analyses for *L. monocytogenes*, *Salmonella* and *E. coli* O157:H7 in CY 2007 was 30,113, not including follow-up samples and imports. The total of 30,113 analyses increased from 27,505 in CY 2006.

Discussion of Trends

As was mentioned above, FSIS does not view the results of regulatory testing as estimates of national product prevalence. The Agency does, however, consider the RTE regulatory results to be an excellent indicator of the trends in pathogen presence in RTE products over several years. The Agency implemented the ALLRTE project in order to have *L. monocytogenes* results that could be better compared with earlier years (before CY 2004) as the Agency moved to make its RTE projects less random and more risk-based.

Last year, the Agency recognized that changes in how samples were scheduled did limit the ALLRTE results as a trend indicator. The concept behind ALLRTE was to get a random sample across the full range of RTE products and across all establishments producing an RTE product. Because many establishments are scheduled almost every month under RTE001, they are never sampled under ALLRTE. Because of

continuing concerns about ALLRTE as a good trend indicator, the Agency, for this year, included two graphs illustrating the trend in results from regulatory sampling for Lm, one using the ALLRTE results from CY 2004 through CY 2007 and the other using the sum of all product sampling from each year, regardless of whether the sampling was random or based on a risk-based algorithm.

For CY 2007, the ALLRTE project had 11 positive *L. monocytogenes* results in 2,963 samples, a positive rate of 0.37%. That result is shown in Figure 1. Figure 1 illustrates the trend for the percentage of RTE regulatory samples positive for *L. monocytogenes* during the time period from 1990 through 2007, using the ALLRTE project for 2004 through 2007. Figure 2 illustrates the trend for the percentage of RTE regulatory samples positive for *L. monocytogenes* during the time period from 1990 through 2007, using all product sampling from 2004 through 2007. When examining overall trends in regulatory findings, the two graphs show the same thing. That is, there has been a continuing and consistent decline in the percentage of positive samples in the projects where FSIS analyzes RTE meat and poultry products for *L. monocytogenes.* In both cases, CY 2007 has the lowest level of positive *L. monocytogenes* samples to date.

For CY 2007, the RTE001 had 42 positive *L. monocytogenes* results in 8,690 samples, a positive rate of 0.48%, almost the same as the CY 2006 rate of 0.47 %. The last two years can be compared to the 51 positives in 7,089 RTE001 samples (0.72%) for CY 2005. This decrease is very important in terms of consumer exposure to *L. monocytogenes* contamination occurring during the production and packaging of higher risk products. Even with the CY 2007 modification discussed earlier, RTE001 remains a risk-based project that targets the higher risk product categories

of deli meats and hotdogs. This project is now the primary project where inspectors collect a single product on a specific day. This project is complemented by the RLm project.

The 10 product categories, introduced in December of 2000, 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. Over the past several years, these product categories have appeared to provide some differentiation in the results, at least in the area of potential for post-lethality exposure to *L. monocytogenes*. For example, when FSIS reported the CY 2004 data, the Agency noted that the highest percentage of samples positive for *L. monocytogenes* in each year had been in the sliced, diced, and shredded product category where exposure to product contact surfaces would be considered high. From 2001 through 2004, FSIS had analyzed samples from 5,143 sliced, diced, or shredded products and recorded 91 positive results (1.77 percent positive). In CY 2005 and CY 2006 the percentages of positive samples for sliced and diced products were noticeably lower, 0.67 percent and 0.83 percent, respectively. In CY 2007, FSIS analyzed 3,408 samples of sliced and diced products and found positive results in only 0.38 percent, a dramatic change from the 2.59 percent positive of CY2001. For CY 2007, the highest positive rate was for multi-component products at 0.88 percent (12 positives in 1,356 samples). Examples of multi-component products include sandwiches or wraps or dishes such as lasagna and chicken fried rice.

The other category where there have historically been a large number of samples is the product category of unpeeled sausage products. From 2001 through 2005, FSIS

analyzed 9,381 samples of unpeeled sausage products and found 62 positive results (0.66 percent positive). For CY 2006, the percentage of unpeeled sausage samples positive for *L. monocytogenes* was only 0.14 percent, only 4 positives in 2,903 samples. The 2007 results were almost the same with 4 positives in 2,656 samples, or 0.15 percent. The last two years represent a noticeable change for this product category.

As noted above, the 10 product categories were also based on factors that could relate to the effectiveness of the kill step. The *Salmonella* results for RTE products do not indicate any differences related to the effectiveness of lethality. FSIS testing has consistently found very low levels of *Salmonella* in RTE products. While the percentage of samples positive for *Salmonella* in CY 2006 had been the lowest level since the implementation of HACCP (2 positives in 11,842 samples), FSIS found 10 positives in 11,651 samples for CY2007 (0.09 percent), the highest percentage since 2002.

Lastly, all of the results presented here so far are for *Salmonella* and *L. monocytogenes*. For some of the time period the Agency has also tested RTE products for *E. coli* O157:H7 and staphylococcal enterotoxins. From 1994 through 2007, 8,282 RTE products (cooked beef patties and dry fermented sausages) were tested for the presence of *E. coli* O157:H7 (excluding imported products). All RTE samples tested for *E. coli* O157:H7 have been negative. Between 1994 and December 2002, 3,105 RTE products were tested for the presence of staphylococcal enterotoxins. FSIS stopped testing RTE products for staphylococcal enterotoxins in January 2003. All RTE samples tested for staphylococcal enterotoxins were negative.

RESULTS FROM PREVIOUS YEARS

The 1990–2000 Results

The information presented in Table 1 (USDA/FSIS microbiological testing projects for RTE meat and poultry products produced in USDA-inspected establishments in CY 1990-2000) lists the product categories used for scheduling samples collected until the end of 2000. Table 2 (Percent Positive *Salmonella* Tests for RTE meat and poultry products, CY 1999-2000) and Table 3 (Percent Positive *L. monocytogenes* Tests for RTE meat and poultry products, CY 1990-2000) represent 11 years (1990-2000) of results from FSIS testing of RTE meat and poultry products. A more detailed description of these microbiological testing projects and test results for the years 1990 through 1999 has been published in the Journal of Food Protection, Vol. 64, No. 8, 2001, Pages 1188-1193.

The 2001–2002 Results

In December of 2000, FSIS discontinued basing its RTE testing program on selected product categories and instead began basing the program on Hazard Analysis and Critical Control Point (HACCP) processing categories identified in 9 CFR 417.2 that apply to ready-to-eat (RTE) products. This is detailed in FSIS Directive 10,240.2, Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program, which became effective in December 2000. The Performance Based Inspection System (PBIS) identified the establishments that had HACCP plans in the processes like 03G, Fully Cooked/Not Shelf Stable or 03E, Not Heat Treated/Shelf Stable or 03F, Heat Treated/Shelf Stable, or 03I, Product with Secondary Inhibitors/Not Shelf Stable. Thus, samples were scheduled based on the different RTE HACCP Processes utilized in USDA-Inspected establishments. Samples were

randomly scheduled in the establishments where the RTE processes existed.

Results were recorded both by the HACCP Processes used for scheduling and by the 10 product categories listed in Table 4 (USDA/FSIS microbiological HACCP verification testing program for RTE meat and poultry products produced in USDA-inspected establishments). Laboratory personnel assign the Table 4 product categories to the product samples when they arrived 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. For example, the categories identified products that were exposed to unique types of post-lethality processing equipment such as peelers or slicers or shredders. The categories also distinguished whole muscle cuts from products where the internal tissues were more likely to have been contaminated before the kill step, e.g., a chopped and formed product.

The sampling projects implemented in December 2000 added both RTE products and establishments that had not been included in the nine microbiology monitoring projects reported for 1990 through 2000. In addition, FSIS Directive 10,240.2 provided for reduced sampling frequency in establishments that had sampling programs meeting criteria outlined in the Directive. Thus, the results for 2001 and 2002 are not directly comparable to the results published for previous years.

Table 5 (Percent Positive *Salmonella* Tests for RTE meat and poultry products, CY 2001), Table 6 (Percent Positive *L. monocytogenes* Tests for RTE meat and poultry

products, CY 2001), Table 7 (Percent Positive *Salmonella* Tests for RTE meat and poultry products, CY 2002), Table 8 (Percent Positive *L. monocytogenes* Tests for RTE meat and poultry products, CY 2002), Table 9 (Percent Positive *Salmonella* Tests for RTE meat and poultry products, CY 2001-2002-combined results), and Table 10 (Percent Positive *L. monocytogenes* Tests for RTE meat and poultry products, CY 2001-2002-combined results), represent the percentage of positive regulatory samples collected and analyzed under FSIS Directive 10,240.2.

The overall RTE sampling program, under which those products were tested and whose results are displayed in Tables 5 through 10, was outlined in FSIS Directive 10,240.2, which was issued in December 2000, but is no longer available on the FSIS Web site. See current RTE sampling directive: FSIS Directive 10,240.4, Revision 1, March 15, 2006 (PDF Only).

The 2003 Results

FSIS Directive 10,240.3 defined three categories of products; targeted, low-targeted and non-targeted products. Low-targeted products included products that were less likely to support growth of *L. monocytogenes* because of low pH, low water activity, the addition of antimicrobial agents, or because the product could be expected to remain frozen from production until preparation for consumption. Non-targeted products included regulated products such as lard, mixtures of animal fats, popped pork skins, dried soup mixes, and products labeled for further processing in which the product would be expected to receive a lethality treatment.

Most of the RTE sampling for 2003 was conducted under a project designated as Target sampling for the collection of targeted and low-targeted products. Under FSIS

Directive 10,240.3, when inspection program personnel received a form requesting a sample under the Target project, the form included instructions to collect a RTE sample from other than non-targeted products, giving priority to high (e.g., deli meats) and medium risk products (e.g., franks/hotdogs). Each form requested the collector to designate the product as a targeted product or low-targeted product.

Under the Target project, all establishments producing targeted or low-targeted RTE products were equally likely to be scheduled each month. Under FSIS Directive 10,240.3, FSIS did not sample non-targeted products. The reduced sampling frequency, that had been part of FSIS Directive 10,240.2, was discontinued.

The results for CY 2003 are presented in Tables 11 and 12. The 10 product categories listed in Table 4 were continued for CY 2003 so all results are organized around those 10 product categories. The results from CY 2003 for *Salmonella* are presented in Table 11. The results for *L. monocytogenes* are presented in Table 12. The majority of results are for targeted products. For *L. monocytogenes*, the results for targeted and low-targeted products were essentially the same, 0.81 percent positive for targeted products and 0.84 percent positive for low-targeted products. However, there was no expectation that the contamination levels at production would be different, only the potential for growth during the shelf life.

FSIS Directive 10,240.3 is no longer available on the Web site. See the current RTE sampling directive: FSIS Directive 10,240.4, Revision 1, March 15, 2006 (PDF Only).

The 2004 Results

FSIS issued Directive 10,240.4 in October 2003 to implement 9 CFR part 430 that was published on June 6, 2003 (68 FR 34207). Under the new Directive, the Agency defined two new sampling projects for CY 2004. These projects were identified as All Ready-to-Eat (ALLRTE) and Ready-to-Eat Risk1 (RTERISK1). Under the project ALLRTE, inspection program personnel were instructed to collect, at random, a RTE product that fit the previous definitions of targeted or low-targeted products. In other words, the Agency wanted random samples across a wide variety of RTE products, but didn't want to expend resources testing the products that have low risk for supporting growth of pathogens like fats and oils, dried soup mixes, and popped pork skins.

Most of the samples would be scheduled under RTERISK1. Product selection under RTERISK1 would be based on the risk-based guidance provided in FSIS Directive 10,240.4, October 2003. Under both projects, all RTE establishments were equally likely to be scheduled each month. However, once a RTERISK1 sample was scheduled, inspection program personnel were instructed to collect only Alternative 3 products if they were available. (Definitions for RTE Alternatives 1, 2, and 3, can be found in 9 CFR 430.4.) Within Alternative 3, FSIS Directive 10,240.4 provided the hierarchy of (1) deli meats, (2) hotdogs, (3) deli salads, pâté, meat spreads, and (4) other product. Inspection program personnel would collect an Alternative 2 product only when Alternative 3 was not available, and an Alternative 1 product only if the establishment produced no Alternative 2 or 3 products. The intent of this risk based sampling project was to always select the highest risk product. So an establishment that was always producing Alternative 3 deli meats would have their Alternative 3 deli meats sampled every time a RTERISK1 sample was scheduled. For this reason,

there would be an expectation that the percentage of positive samples would be higher in RTERISK1 than under ALLRTE sampling. The 2004 findings did show some difference.

The results for CY 2004 are presented in Tables 13 and 14. The 10 product categories listed in Table 4 were continued for CY 2004 so all results are organized around those 10 product categories. The results from CY 2004 for *Salmonella* are presented in Table 13. The results for *L. monocytogenes* are presented in Table 14.

FSIS Directive 10,240.4, issued October 2, 2003 is no longer available on the Web site. However, the project for ALLRTE is still in place under the current RTE sampling directive: FSIS Directive 10,240.4, Revision 1, March 15, 2006 (PDF Only). The project RTERISK1 was continued through CY 2005, but was discontinued at the beginning of CY 2006.

The 2005 Results

During CY 2005, FSIS continued projects ALLRTE and RTERISK1 that were initiated in CY 2004. FSIS also initiated a new project identified as RTE001. This new project is the first HACCP verification project where RTE establishments are not equally likely to be scheduled each month. Rather, each month an RTE001 sample is requested from a list of establishments with the highest risk ranking for *L. monocytogenes*. This ranking is based on a number of factors including the RTE Alternative(s) used by the establishment, the volume of production for post-lethality exposed products, and the sample results from previous testing for *L. monocytogenes*.

The instructions for implementing RTE001 were first issued as FSIS Notice 61-04,

issued on December 23, 2004, which were later incorporated into FSIS Directive 10,240.4, March 15, 2006 (PDF Only). This Directive instructs sample collectors to select the highest risk post-lethality exposed RTE product produced at the time of collection. Directive 10,240.4 provides a hierarchy of products to sample that has been revised from that described above for RTERISK 1. A key difference is that deli products have been divided into those that are sliced in the inspected establishment and those shipped intact to be sliced at grocery store deli counters and other retail outlets. The hierarchy for RTE001 is:

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. Hotdog Products
4. Deli salads, pâtés, and meat spreads
5. Fully cooked type products (other than cooked products in 1-4 above)
6. Fermented products
7. Dried products
8. Salt-cured products
9. Products labeled as "Keep Frozen".

The results for CY 2005 are presented in Tables 15 and 16. There was a major increase in RTE sampling in CY 2005, where almost 16,000 samples were analyzed

for both *Salmonella* and *L. monocytogenes*. The 10 product categories listed in Table 4 were continued for CY 2005 so all results are organized around those 10 product categories. The results from CY 2005 for *Salmonella* are presented in Table 15. The results for *L. monocytogenes* are presented in Table 16.

The 2006 Results

FSIS initiated three changes during CY 2006. First, the RTERISK1 project was discontinued, although there were still 328 results reported in 2006 from samples that were scheduled at the end of 2005. Second, the ALLRTE project was modified so that establishments were randomly picked each month from the population of establishments that were not scheduled that month for a risk-based sample under project RTE001. With this change more establishments were scheduled each month and the possibility of ever getting two samples representing the same product was further minimized. This change did, however, limit the ALLRTE results as a trend indicator. The concept behind ALLRTE was to get a random sample across the full range of RTE products and across all establishments producing an RTE product. Since many establishments were scheduled every month for an RTE001 sample, they were never available for random selection in the ALLRTE project. Given that the percentage of positive results for RTE001 was less than 0.5 percent for either *Salmonella* or *L. monocytogenes*, the ALLRTE results for CY2006 were most likely higher than they would have been had all establishments had the chance of being sampled each month.

The third change for CY 2006 was the introduction of RLm, the risk-based intensified sampling project where products, product contact surfaces and environmental surfaces are sampled in conjunction with a comprehensive FSA. Establishments are

selected for RLm based on a risk ranking algorithm that is formed by previously developed peer-reviewed risk assessments and the ongoing results from FSIS tests of RTE meat and poultry products. Once an establishment is selected for RLm, the products are selected using the same hierarchy as described above for RTE001. That hierarchy is based on what is usually referred to as the FDA-FSIS risk ranking model summarized at http://www.foodsafety.gov/~dms/lmr2-su.html. Instructions for RLm are contained in FSIS Directive 10,240.5, March 15, 2006 (PDF Only).

The results for CY 2006 are presented in Tables 17 and 18. The 10 product categories listed in Table 4 were continued for CY 2006, so all results are organized around those 10 product categories. The results from CY 2006 for *Salmonella* are presented in Table 17. The results for *L. monocytogenes* are presented in Table 18. Table 18 includes the product sampling results from RLm, designated as RLmPROD to indicate it is just the product portion of RLm. A total of 12,372 products were tested for *L. monocytogenes* in CY 2006, excluding all follow-up sampling and sampling of imported products. The percentage of positive product samples across all projects was 0.48%. Table 18 does not include 2,745 product contact surface and environmental samples that were analyzed as part of RLm. Thus, the number of *L. monocytogenes* analyses remained above 15,000 for the second consecutive year and the total number of analyses for *L. monocytogenes*, *Salmonella* and *E. coli* O157:H7 was 27,505.

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