

Clostridium Perfringens Market Basket Study

Summary

The Food Safety and Inspection Service (FSIS) commissioned a Market Basket Study from May through September 2021 to assess the levels of *Clostridium perfringens* (*C. perfringens*) in federally inspected ready-to-eat (RTE) meat and poultry products sold at retail locations. With the exception of one RTE beef sample found to be positive at 1.08 log₁₀ cfu/g, all samples were below the limit of detection (0.5 log₁₀ cfu/g). The results of this study support the conclusion that guidance currently being used for the cooling of large mass non-intact RTE meat and poultry products is adequate and does not merit revision. Therefore, establishments may continue to use the less stringent cooling procedures identified for these products in the 2021 FSIS Stabilization Guideline for Meat and Poultry Products ([Revised Appendix B](#)). The study was not designed to be a baseline, so FSIS is not planning to make changes to regulatory performance standards based on the results.

Background

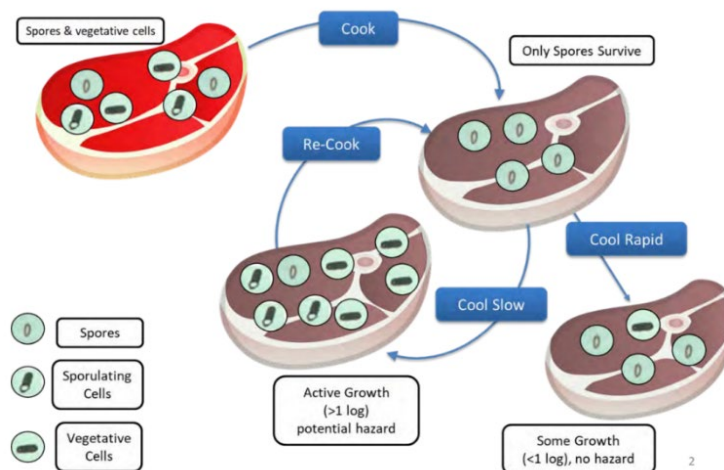
FSIS commissioned the Market Basket Study through the Federal Emergency Response Network (FERN) laboratories in response to comments on the 2017 Appendix B guideline indicating that large mass non-intact products could not be cooled quickly enough to meet recommended cooling options in the 2017 version of Appendix B (e.g., cooling from 120 to 80°F in < 1.5 hours or from 130 to 80°F in < 1.5 hours during the first stage of cooling). These cooling options were designed to meet FSIS' regulatory performance standards of no more than 1 log₁₀ outgrowth of *C. perfringens* in meat and poultry products during cooling (9 CFR 318.17(a)(2), 9 CFR 318.23(c)(1), and 9 CFR 381.150(a)(2)). The performance standards were developed using baseline studies and supported with newer data demonstrating that 3-4 log₁₀ level of *C. perfringens* could occur in raw products ([86 FR 71007](#)). The agency subsequently added a 2 log₁₀ safety margin as recommended by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF)¹. At this level of contamination, if spores germinate and grow greater than 1 log₁₀ during the cooling process (Figure 1) then levels could approach the > 6 log₁₀ level needed to cause illness identified by the Centers for Disease Control and Prevention (CDC). Therefore, by considering the worst-case scenario, FSIS established that allowing up to 1 log₁₀ growth of *C. perfringens* in product is an acceptable level of protection.

FSIS identified a "scientific gap" in the processing of large-mass non-intact RTE products in the 2021 Revised Appendix B. The scientific gap allows establishments to cool these products using the recommendations from the 1999 guideline (i.e., cooling from 120°F to 55°F in ≤ 6 hours without monitoring the time during the first stage of cooling between 120°F to 80° F). While the 2021 Revised Appendix B guideline indicates that these critical operational parameters taken from the 1999 version of the guideline may be used to cool these products, modeling and empirical studies have demonstrated that a 3 log₁₀ growth of *C. perfringens* could occur using the older cooling parameters, exceeding the

¹National Advisory Committee on Microbiological Criteria for Foods. 2010. Parameters for Determining Inoculated Pack/Challenge Study Protocol. J. Food Prot. 73:140-20.

performance standard². However, no known foodborne illness outbreaks have been attributed to consumption of large mass non-intact RTE meat and poultry products produced under FSIS inspection. Therefore, FSIS commissioned the Market Basket Study to determine the potential risk from these products if establishments continue to follow the cooling parameters from the 1999 version of the guideline that are included in the 2021 Revised Appendix B.

Figure 1. *C. perfringens* Spore Formation, Germination, and Growth in Meat and Poultry Products after Heat is Applied



Hypothesis

The Market Basket Study explored the hypothesis that at least 95% of finished RTE products would have no more than 4 log₁₀ cfu/g of *C. perfringens*, supporting the determination that processing these products using the cooling parameters from the 1999 guideline is not a food-safety risk. Although > 6 log₁₀ growth of *C. perfringens* is needed to cause illness, the agency chose 4 log₁₀ for the study as a conservative estimate to include the 2 log₁₀ margin of safety identified by NACMCF.

Study Design

Samples were purchased from RTE beef, poultry and pork shoulder products sold at retail locations in eight states (California, Colorado, Iowa, Michigan, Minnesota, Missouri, Ohio, and Virginia) and analyzed by the FERN laboratories. The number of samples (n=494) was based on the number needed to test the hypothesis with 95% confidence. The FERN laboratories collected products that were available for purchase at the time of the study; therefore, a different number of samples were collected from each of the product types and states. Large mass (> 4 inches in diameter or > 8 lbs.) non-intact products that were formulated without antimicrobial agents (e.g., nitrite, including from a natural source such as celery powder or lactate/diacetate) were purchased. FSIS selected large mass non-intact products for the study because they are the worst-case scenario for *C. perfringens* growth due to their long cooling times and because *C. perfringens* could have been introduced below the product surface during needle tenderization and injection of solutions, making the pathogen more likely to survive during cooling.

²Smith et al. 2018. Inhibition of *Clostridium perfringens* growth during extended cooling of cooked uncured roast turkey and roast beef using a concentrated buffered vinegar product and a buffered vinegar product. Journal of Food Protection. 81(3):461-466.

Products formulated without antimicrobial agents were also selected because antimicrobial agents could prevent *C. perfringens* from growing in the product. Samples were analyzed for *C. perfringens* spores using a modified version of the FSIS Microbiology Laboratory Guidebook (MLG) method used in the original baseline studies ([MLG Chapter 13](#)). The method was modified by adding an additional heating step that would kill the vegetative cells in the sample³. Then, when plated, the colonies would represent any spores in the sample.

Results

In total, 494 products were collected and tested in eight states. Table 1 describes the number of samples collected by state and commodity. One RTE beef sample had a low level of *C. perfringens* at 1.08 log₁₀ cfu/g (12 cfu/g). All other products tested were below the limit of detection (0.5 log₁₀ cfu/g). The one positive result was below the level of public health concern because > 6 log₁₀ of *C. perfringens* is needed for illness to occur.

Table 1. *Clostridium perfringens* Market Basket Study of RTE Meats Collected in Eight States

	Chicken (n)	Turkey (n)	Beef (n)	Pork (n)	Total (n)
California	12	36	2	10	60
Colorado	10	38	10	2	60
Iowa		44	22		66
Michigan	14	36	9 ^a	1	60
Minnesota	19	34	5	8	66
Missouri	23	28	5		56
Ohio	14	32	8	12	66
Virginia	15	31	11	3	60
Total	107	279	72	36	494

Source: Federal Emergency Response Network laboratories

^a Beef sample that was 1.08 log₁₀ cfu/g

Conclusions

The *C. perfringens* Market Basket study was not designed to be a comprehensive baseline and the results cannot be used to support changes to the regulatory performance standards. However, the results suggest that the presence and outgrowth of *C. perfringens* in RTE large mass non-intact meat and poultry products produced under FSIS inspection is controlled using the less stringent cooling parameters from the 1999 guideline included in the scientific gap. This study demonstrates the risk to following the cooling parameters in the scientific gap is minimal. Therefore, establishments may continue to use the less stringent cooling procedures identified for these products in the 2021 Revised Appendix B and FSIS is not planning to make changes to the regulatory performance standards at this time.

³Compendium of Methods for the Microbiological Examination of Foods, Fifth Ed, 2015.