Appendix B: Stabilization Option 2 Rapid Cooling Between 120°F and 80°F

I am using Appendix B: Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization) as my supporting document to meet 9 CFR 417.5(a)(2) for my critical limit (CL) at my critical control point (CCP) for cooling per my HACCP plan. I am using the second cooling option under the Stabilization Guidelines section. This option stipulates that I need to chill my product from 120°F to 55°F in no more than 6 hours. In the last sentence, this cooling option also states, "If product remains between 120°F and 80°F more than one hour, compliance with the performance standard is less certain."

Do I need to collect data to show that my meat/poultry product remains between 120°F and 80°F for no more than one hour?

Does my CL need to be measured (i.e., the one hour between 120°F and 80°F) every time I use this cooling option?

FSIS considers Appendix B to be a guideline. However, if followed precisely, Appendix B is a validated process schedule because the guideline contains processing methods already accepted by the Agency as effective in safely cooling cooked meat and poultry products. Therefore, the answer to the first question is "yes", the collection of this cooling profile data is part of the support for the decision to select and use the second option (9 CFR 417.5(a)(2)). The answer to the second question is "no", the CL of one hour maximum is not required to be measured with every stabilized lot of product once data have been established to show that the conditions are the same and the CL is met. Conditions affecting consistent cooling include size, shape, and weight of product. In addition, stacking/storage in the cooler also can impact the rate of cooling. An overstuffed cooler might not cool at the same rate as a relatively empty cooler.

The reason data initially needs to be collected to support the cooling option chosen is that the establishment has more than one option and therefore needs to have sound decisions in its selection to show compliance. An establishment should understand that the shape of the cooked product's time/temperature cooling profile (or chill rate) could have a significant impact on the amount of growth of Clostridium perfringens, even though the initial and final temperatures and the length of chilling is the same for different chilling profiles. The company may consider picking a time/temperature midpoint (e.g., x time to reach 80°F) to monitor its chilling process to help define the shape of the cooked product's time/temperature cooling profile in order to ensure that excessive growth of C. perfringens does not occur. This is why the first and third cooling options in Appendix B require that the product reach 80°F within a certain time frame, and why it states in the second cooling option "If product remains between 120°F and 80°F more than one hour, compliance with the performance standard is less certain."
FSIS issued this compliance guideline to assist establishments in meeting the stabilization requirements and based the guidance on previously existing FSIS Directives and the product cooling requirements contained in previous regulations that had been revised with the implementation of HACCP (e.g., *Performance Standards for the Production of Certain Meat and Poultry Products*, 95 FR 732 (January 6, 1999).) As stated in the Compliance Guideline, the second cooling option has a significantly smaller margin of safety than the first option cooling guideline.

In this stabilization guideline, it states that it is very important that cooling be continuous through the given time/temperature control point. Excessive dwell time in the range of 120° to 80°F is especially hazardous, as this temperature range is where the most rapid growth of Clostridia occurs. Therefore cooling between these temperature control points should be as rapid as possible. Data has shown that 80°F is the approximate transition between rapid growth and slower growth of many food-borne pathogenic bacteria, including *C. perfringens* and *C. botulinum*. While growth is slower below, 80°F, some growth will occur. At 100°F rapid growth of most food poisoning bacteria occurs, so the product should not dwell around this time for very long. At 120°F, a traditional USDA cooling control point; there is still some rapid germination and growth of *C. perfringens*; but minimal to no growth of *C. botulinum*. The upper growth limit for *C. perfringens* is about ~126°F, which is one reason why the first option is better than the second option.

If the establishment cannot rapidly cool the product in accordance with one of the two cooling options provided for rapid cooling of product, a processing authority or someone knowledgeable in pathogen modeling programs may need to evaluate the data. A laboratory challenge study is always a definitive validation option.