FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments

2014 Compliance Guideline

This guidance document is designed to help very small meat and poultry establishments that manufacture jerky identify:

- The key steps in the jerky process needed to ensure safety; and
- The scientific support available to help develop a safe process and product.

This Compliance Guideline provides **guidance** to assist establishments in meeting FSIS regulations related to jerky processing. The guideline also contains recommendations to help industry produce a safe product based on the scientific information available in the literature. Guidance represents **best practice** recommendations by FSIS, based on the best scientific and practical considerations, and does not represent **requirements** that must be met. Establishments may choose to adopt different procedures than those outlined in the guideline, but they would need to support why those procedures are effective. It is important to note that this guideline represents FSIS's current thinking on this topic and should be considered usable as of the issuance date.

This version of the guidance document, dated August 2014, replaces previous versions of the document which was last updated in July 2012. FSIS updated the guideline based on four comments from three trade associations and one individual. The following are changes made in response to comments:

- Broken link on page 4 (see footnote) has been changed to a link to a report from the New Mexico Department of Health;
- Surface preparation step was added to the step-by-step guide on page 7;
- Definition of shelf-stability and recommended shelf-stability parameters were clarified on page 15;
- Continuously introducing steam option was clarified on page 22;
- Attachment 4, which provides guidance on supporting the continuously introducing steam option, was added.

A more detailed summary of the comments and FSIS' responses can be found in Attachment 1.

In addition to making changes in response to public comments, FSIS also made the following changes in response to questions submitted through askFSIS:

- Clarified on page 8 that the lethality treatment of poultry jerky should achieve at least a 5.0-$\log_{10}$ reduction of *Salmonella* spp.;
- Provided guidance on pages 13 – 14 on how to calibrate a humidity recorder;
- Clarified on page 19 that reference to the cooking time in the humidity options in *Appendix A* refers to the entire cooking time (including come up time), not just the time during which the temperature in *Appendix A* is achieved and maintained (e.g., 145°F for 4 minutes);
- Clarified in the text on page 19 that if an establishment using *Appendix A* as support for the lethality treatment introduces steam or seals the oven, cooking time should never be less than one hour; and
- Clarified the documentation that should be collected to support that humidity is being implemented consistent with *Appendix A* when the sealed oven or continuously introducing steam methods are used on pages 21 and 22.

Although comments will no longer be accepted through regulations.gov on this guidance document, FSIS will update this document as necessary should new information become available.

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Purpose

This guideline is designed to help small and very small meat and poultry establishments that manufacture jerky to identify:

- The key steps in the jerky process needed to ensure safety; and
- The scientific support available to help develop a safe process and product.

This guideline is not intended to set any regulatory requirements. This document replaces previous versions of the guideline last updated in July 2012.

Background

Meat or poultry jerky is a ready-to-eat (RTE), dried product that is considered shelf-stable (i.e., it does not require refrigeration after proper processing). Following a 2003 salmonellosis outbreak from *Salmonella* Kiambu in jerky produced in New Mexico[1], FSIS published the first version of the *Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments*. The Compliance Guideline provided guidance for small and very small meat and poultry establishments on the critical steps for jerky processing and the controls needed at each of these steps to ensure a safe product is produced.

One potential cause of the 2003 *Salmonella* Kiambu outbreak in jerky was the very slow drying process under low humidity conditions (1% Relative Humidity - 82°C dry bulb, 30°C wet bulb), which allowed *Salmonella* organisms to dehydrate during drying and become resistant to heat. Therefore, the first version of the jerky compliance guidelines emphasized the need for high levels of humidity during jerky processing. Since 2003, a number of journal articles have been published that has increased scientific understanding of the critical factors during jerky processing including the role of humidity.

One potential cause of the 2003 *Salmonella* Kiambu in jerky outbreak was the very slow drying process under low humidity conditions

This document updates and replaces the 2007 and 2012 versions of the guideline to reflect the most up-to-date science and understanding of jerky processing. This guideline also addresses concerns identified through Food Safety Assessments (FSAs) and askFSIS questions and responds to public comments received on the 2012 version.

[1] http://aces.nmsu.edu/ces/nmhs/documents/albanese.pdf

Step-by-Step Guide for Jerky Processing

Below is a summary of the eight (8) general processing steps used in jerky production. Although an establishment's process may not include these same steps, **the lethality treatment followed by drying should be used to produce a safe product**. Other steps such as the intervention and post-drying steps may be used by establishments when the lethality and drying steps do not achieve adequate lethality. Further descriptions of the key steps in the jerky process, including the microbial interventions that can be applied to ensure safety, are included in the pages that follow.

- **Step 1 - Strip preparation**: Whole muscle is sliced or ground; ground product is formed into strips (some jerky is formed).

- **Step 2 – Marination**: The strips are marinated in a solution that often contains salt, sugar, and flavoring ingredients.

- **Step 3 – Interventions**: Antimicrobial interventions before, during, and after marinating the strips of raw product may be added to increase the level of pathogen reduction beyond that achieved by heating alone.

- **Step 4 - Surface preparation:** Strips are heated using a low temperature heat step, which makes the surface tacky to aid in smoke adherence and improve product texture.

- **Step 5 – Lethality**: The lethality treatment is defined as the process step or steps used to destroy pathogenic microorganisms on or in a product to make the product safe for human consumption. The lethality treatment is considered to include the time when the product is placed in the heated oven (including surface preparation and color setting) until the product reaches the desired lethality time-temperature combination (also referred to as "the cooking time").

  In order to achieve adequate lethality, it is important that an establishment's actual process adheres to the following critical operational parameters (see Key Definitions on page 8) in the scientific support:
  - Product time-temperature combination
  - Relative humidity

- **Step 6 – Drying:** Drying is the process during which water (moisture) is removed from the product. After the lethality treatment, jerky is dried to meet a water activity level sufficient to prevent the growth of microorganisms, especially toxigenic microorganisms, such as *Staphylococcus aureus*.

- **Step 7 – Post-drying heat step**: A post-drying heat step may be added to increase the level of pathogen reduction beyond that achieved by heating alone.

- **Step 8 – Handling**: Product is often handled after the lethality and drying steps and prior to packaging.

Jerky producers (and all producers of RTE product) are required to control the food safety hazards in their products (9 CFR 417.4(a)) and to document that their Hazard Analysis and Critical Control Point (HACCP) systems work according to 9 CFR 417.5(a). Establishments producing RTE products need to achieve lethality of pathogens (e.g., *Salmonella*) in the product, and stabilize the product to inhibit the growth of spore-forming bacteria (e.g., *C. botulinum* and *C. perfringens*). In addition, jerky producers need to ensure the growth of toxigenic microorganisms, such as *Staphylococcus aureus*, is controlled during the process and prevented during the distribution and storage of the finished product. This guideline provides steps jerky processors can take to ensure that the jerky processes they employ effectively control these hazards. The guideline discusses each step in the jerky process in more detail below with key considerations related to pathogen reduction or control highlighted for each step. Each process is unique, so some processors may not use all 8 steps. Some may perform the steps below in different order, or some may use additional steps.

- **Step 1 - <u>Strip preparation</u>**: Whole muscle is sliced or ground; ground product is formed into strips (some jerky is formed).

It is critical for establishments to use source materials prepared under good manufacturing practices (GMPs) designed to minimize contamination and the presence and growth of pathogens of public health concern, so the initial pathogen load is not higher than what the process is designed to reduce. Establishments that choose to purchase source materials known to be contaminated with pathogens of public health concern, such as *Salmonella* or shiga toxin-producing *Escherichia coli* (*E. coli)* (STEC) organisms such as *E. coli* O157:H7 or *E. coli* O45, should pay special attention to the controls they put in place to ensure cross-contamination between raw and RTE product does not occur.

- **Step 2 – <u>Marination</u>**: The strips are marinated in a solution that often contains salt, sugar, and flavoring ingredients.

Establishments should use non-meat ingredients for marinades and spice mixes that are prepared under GMPs designed to minimize contamination and the presence and growth of pathogens of public health concern, so the initial pathogen load is not higher than what the process is designed to reduce. FSIS recommends that establishments use a new liquid marinade solution or dry spice mix with each production batch to reduce chances of cross-contamination from one batch of production to another. If an establishment does reuse a marinade or spice mix, it should consider and address the potential hazards associated with cross-contamination from one batch of production to another.

- **Step 3 - <u>Interventions</u>**: Antimicrobial interventions before, during, and, after marinating the strips of raw product have been shown to increase the level of pathogen reduction beyond that achieved by heating alone.

Some heating processes may not deliver an adequate lethality and, thus, may require an additional intervention step to ensure product safety. Examples of interventions that may increase the lethality of the process are:

- Preheating the meat or poultry jerky strips in the marinade to a minimum internal temperature of 160°F will provide an immediate reduction of *Salmonella* (Harrison and Harrison, 1996). Heating in marinade may produce unacceptable flavors for some products; however, other liquids such as water could be used. The times and temperatures in *FSIS Appendix A: Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat and Poultry Products* (referred to throughout this document as Appendix A) could be used for preheating in the liquid, although the product internal temperature should be monitored to ensure adequate lethality is achieved).

- Dipping the product in 5% acetic acid for 10 minutes before placing it in the marinade can augment the log reduction effects of drying but not enough to eliminate pathogens (Calicioglu, 2002 & 2003). This intervention may also result in an undesirable flavor.

- Dipping the product in 1:2 or 1:3 mixtures of calcium sulfate (Mionix Safe$_2$O™) and water for 30 seconds or dipping in acidified sodium chlorite (Keeper®) at concentrations between 500 and 1,200 ppm can reduce the level of *Salmonella*, *Listeria monocytogenes (Lm)*, and *E. coli* O157:H7 compared with no pretreatment. These pretreatments were effective in both dehydrators and smokehouse processing (Harrison et al., 2006).

➢ **Step 4 - Surface preparation:** Strips are heated using a low temperature heat step which makes the surface tacky to aid in smoke adherence and improve product texture.

Humidity is often not introduced until the next step, the lethality treatment. The lack of humidity during the initial surface preparation step is generally not a food safety concern because the step is usually too short (30 minutes or less) to dry out the product to such a degree that the heat resistance of *Salmonella* would be increased. This step may include or be followed by a color setting step during which humidity is also not introduced. This color setting step plus the surface preparation step should be 30 minutes or less in total. If an establishment uses a preparation or color setting step that is longer than 30 minutes, it should provide support for why the lack of humidity does not result in the product drying out before the lethality treatment.

➢ **Step 5 - Lethality treatment**: The lethality treatment is defined as the process step or steps used to destroy pathogenic microorganisms on or in a product to make the product safe for human consumption. The lethality treatment is considered to include the time when the product is placed in the heated oven (including surface preparation and color setting) until the point at which the product reaches the desired lethality time-temperature combination (also referred to as the “cooking time”).

In order to achieve adequate lethality, the establishment’s actual process needs to adhere to the following critical operational parameters (see Key Definitions on page 8) in the scientific support:

- Product time-temperature combination
- Relative humidity

In recent years, several jerky products have been found to be adulterated with *Salmonella* or *E. coli* O157:H7. Often the contamination has been linked to inadequate lethality treatment. The lethality treatment of meat jerky should achieve at least a 5.0-$\log_{10}$ reduction of *Salmonella* spp. and at least a 5.0-$\log_{10}$ reduction for shiga toxin-producing *Escherichia coli* (*E. coli)* (STEC) for products containing beef as recommended in the *Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products*. The lethality treatment of poultry jerky should achieve at least a 5.0-$\log_{10}$ reduction of *Salmonella* spp. Although poultry jerky is considered to fall under the performance standard in 9 CFR 381.150 (i.e., a 7.0-$\log_{10}$ reduction of *Salmonella* spp.), the regulation allows for the use of an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product. Research has supported that a 5.0-$\log_{10}$ reduction in *Salmonella* is sufficient for such shelf-stable products. Indeed, the *FSIS Risk Assessment of the Impact of Lethality Standards on Salmonellosis from Ready-to-Eat Meat and Poultry Products* found that there would not be a significant increase in the cases of salmonellosis if jerky and other shelf-stable products achieved a 5.0-$\log_{10}$ vs. 7.0-$\log_{10}$ lethality. In addition to *Salmonella spp*., the lethality treatment of meat and poultry jerky should achieve at least a 3.0-$\log_{10}$ reduction in *Lm*, although a 5.0-$\log_{10}$ reduction or greater is desirable for providing an even greater safety margin for ensuring that *Lm* does not grow to detectable levels during storage. However, establishments are not required to validate that their process achieves reduction in *Lm* (or STEC for products containing beef) if it achieves sufficient reductions in *Salmonella* because *Salmonella* is more heat resistant than other pathogens and is, therefore, considered an indicator of lethality.

Establishments should make sound decisions in the hazard analysis that support that source materials were prepared using GMPs and other process controls as discussed in the previous steps of strip preparation and marination such that a 5.0-$\log_{10}$ reduction in *Salmonella* results in the production of a safe product.

Official establishments choosing to use cooking to achieve lethality before drying may consider a number of different

KEY DEFINITIONS

The **lethality treatment** is defined as the process step or steps used to destroy pathogenic microorganisms on or in a product to make the product safe for human consumption. The lethality treatment is considered to include the time when the thermal processing begins (e.g., the product is placed in the heated oven) until the point at which the product reaches the desired lethality time-temperature combination (also referred to as the "cooking time").

Critical operational parameters are those parameters of an intervention that must be met in order for the intervention to operate effectively and as intended. Such parameters include but are not limited to time, temperature, water activity, concentration, relative humidity, and type of equipment (to the extent that the use of different equipment would result in an inability to achieve the critical parameters of the study).

types of scientific documents to support the time-temperature-humidity combination used in the actual process.

Such types of scientific support documents include:

- Compliance Guidelines (e.g., *Appendix A*)
- Journal articles
- Challenge studies
- In-plant data

Finished product testing would not be considered adequate scientific support for the process used on its own, however, because such testing does not support that at least an adequate reduction of *Salmonella* spp. is achieved by the process.

An in-depth discussion of considerations for each of these types of scientific support documents, along with examples, is discussed in the section titled: **Scientific Support Documents for Jerky Processing**.

Critical Operational Parameters during the Lethality Treatment

Regardless of the scientific support document used, it is important that an establishment's actual process and procedures relate and adhere to the critical operational parameters in the scientific support in order to achieve adequate lethality. There are several critical operational parameters that are important for jerky processing that will be reviewed.

Product time-temperature combination

FSIS has found through FSAs that many establishments use temperatures from support documents to set critical limits for the oven temperature; however, setting the oven temperature to the temperature in the support does not ensure that the product will reach the same internal temperature which is critical to ensure adequate lethality is achieved. The FSAs show that some establishments do not measure or verify that the product has achieved the desired internal lethality temperature until after drying. FSIS does not recommended verifying product temperatures only after drying because the product may have dried out before the lethality temperature was reached, resulting in lower than expected pathogen reduction.

One of the critical operational parameters during the jerky process is the time-temperature combination the product achieves. Most often the temperatures used during the lethality treatment that are reported in scientific support documents, such as the *Appendix A* guidelines, are the temperatures that the product should reach. FSIS has found that establishments will use these same temperatures to set critical limits for the oven temperature. However, setting the oven temperature to the temperature in the support is not appropriate because it does not ensure that the product will reach the same internal temperature, which is critical to ensure adequate lethality is achieved.

For this reason, FSIS recommends that

establishments monitor the internal product temperature. Product internal temperature can be measured by inserting a thermocouple probe into the center of a beef strip. Proper insertion may be difficult because the product is so thin; therefore, FSIS recommends that establishments slice one piece of jerky twice as thick as normal so that the probe can be inserted. If this thicker piece reaches the lethality temperature, the thinner pieces should as well. In addition, to accurately measure the product temperature, the establishment should understand factors that could affect the temperature of the product. These factors include cold spots in the oven, as well as variation in oven temperature during different seasons. Although monitoring product temperature is strongly encouraged, establishments can use the oven or smokehouse temperature in place of the product temperature, provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the product temperature in the scientific support.

In addition to the product temperature, the amount of time the product is held at this temperature is also critical to ensuring that adequate lethality is achieved. It is important for the establishment to understand how the actual temperature of the product was taken, the time it takes the product to reach the target temperature (known as the come-up time or CUT), and the amount of time the product is held at the target temperature compared to the scientific support documentation. If the product is held at the target lethality treatment for less time than what was used in the scientific support, then adequate lethality may not be achieved.

KEY DEFINITIONS

Relative Humidity is defined as the degree of saturation of the air by water (vapor), expressed as a percentage. Relative humidity describes the relation of the existing vapor pressure at a given temperature to the maximum vapor pressure at that temperature. Air at a given temperature can absorb vapor until its saturation (100%). The difference between the dry and wet bulb temperature is the relative humidity at that temperature. The following website http://home.fuse.net/clymer/water/wet.html contains a function for calculating the relative humidity given the wet and dry bulb temperatures.

Relative Humidity

In addition to the product time-temperature combination, the relative humidity (e.g., steam) in the oven is also critical to achieve adequate lethality in jerky. It is important that the establishment maintains humidity according to its scientific support. If relative humidity is not added or maintained by the process, the establishment should maintain scientific support demonstrating that humidity is not a critical operational parameter. Some jerky processors may be concerned that adding humidity will affect the ability to dry the meat or poultry and result in unacceptable product texture; however, the lethality treatment during which relative humidity is applied takes very little time. Adding humidity during the lethality treatment should accelerate subsequent drying and prevent case-hardening, which may actually improve product texture.

Relative humidity around a product during the lethality treatment promotes lethality in two ways:

- First, the humidity reduces surface evaporation and the energy or heat that evaporation removes from the product during heating. If sufficient relative humidity surrounding the product is not maintained during the lethality treatment, undesirable evaporative cooling at the surface will occur, and the product will not reach the desired temperature. Producing products under conditions of high humidity early in the cooking process reduces evaporative cooling allowing products to reach higher product surface temperatures which results in a greater reduction in microorganisms.

- Second, the humidity keeps the product surface (and any pathogens) more moist and prevents unwanted concentration of solutes (e.g., sugar and salt) as a result of drying. Research has demonstrated that bacteria can become more heat resistant as their moisture levels decrease, and increased concentrations of solutes, especially sugars, increase the heat resistance of bacteria. Therefore, the drying of the product surface before the pathogens are destroyed will increase pathogen heat resistance and allow them to survive the heating process. By incorporating humidity to minimize evaporation, the D values (time at a constant temperature necessary to destroy 90% or 1-$\log_{10}$ of the target organism) that are the basis for Appendix A and other scientific support documents remain valid (Goepfert, 1970; Goodfellow and Brown, 1978; Faith, N.G. et al. 1998).

Without sufficient humidity the product surface may dry too quickly, and the bacteria may become more heat resistant.

For these reasons, it is crucial that the processor prevent drying of the product until a lethal time-temperature combination is attained. In order to be most effective, the humidity should be applied during the lethality treatment and before the drying step occurs. Although the lethality treatment includes the time when the product is placed in the heated oven until the product reaches the desired lethality time and temperature combination (the “cooking time”), establishments may not introduce relative humidity into the process until 15 to 30 minutes after the product is placed in the heated oven. The establishment would do so because of the previous step of surface preparation that is needed to set the surface to aid in the adherence of smoke. As discussed earlier, the lack of humidity during this initial step is not a food safety concern because of its short duration.

In addition to applying humidity early in the lethality treatment, FSIS also recommends that establishments treat the lethality and drying steps as separate stages to ensure that lethality is achieved before the product dries out. Therefore, the establishment should measure and verify the desired product temperature has been met before the drying stage. One way for an establishment to know that the product has not dried out before a lethal time-temperature combination is attained is to measure the water activity of the

product after the lethality treatment but before drying and again after drying. Some published articles (for example, Buege et al., 2006a) report the water activity at these points in the process for comparison. Another approach is for the establishment to monitor the wet bulb temperature early in the process because it provides a good indication of product surface temperature, which strongly influences lethality (Buege, 2006a). Further explanation and directions for making a wet bulb thermometer are in Attachment 3. Although this information may be useful, establishments do not need such data to validate the process if they are able to demonstrate that their process can achieve the level of relative humidity in their scientific support.

Some simple and practical measures that can be used to aid in meeting the humidity level utilized in the scientific support documents include:

- Seal the oven: Close the smokehouse doors and oven dampers to provide a closed system and prevent moisture loss.

- Add humidity:
  - Place one or more shallow, wide pans of hot water in the oven to increase the humidity in the system. Conduct a test run to determine whether the water evaporates.
  - Injecting steam or a fine water mist into the oven can also add humidity.

The use of a humidity sensor or the use of wet bulb and dry bulb thermometers (to measure relative humidity) would enable the operator to determine whether adequate humidity is being applied for either measure.

In order to ensure that adequate humidity is attained, the establishment should monitor the humidity throughout the lethality treatment. The process should be monitored using wet and dry bulb thermometers (used to determine relative humidity) or a humidity sensor.

The following website http://home.fuse.net/clymer/water/wet.html contains a function for calculating the relative humidity given the wet and dry bulb temperatures. A basic wet bulb thermometer can be prepared by fitting a wet, moisture-wicking cloth around a dry bulb thermometer. To maintain a wet cloth during the process, submerse an end of the cloth in a water supply. The cloth must remain wet during the entire lethality treatment especially if smoke is applied. The establishment

KEY DEFINITIONS

The **dry bulb** temperature refers to the ambient air temperature. It is called "dry bulb" because the air temperature is indicated by a thermometer not affected by the moisture in the air or evaporative cooling that removes heat and moisture from the surface of the product. The dry bulb temperature is most commonly measured by jerky-makers. Jerky makers commonly measure the dry bulb temperature.

The **wet bulb** temperature is the temperature indicated by a moistened thermometer bulb exposed to the air flow. A wet bulb thermometer measures the extent of cooling that happens as moisture dries from a surface, a process also known as evaporative cooling. The wet bulb temperature is always lower than the dry bulb temperature except when there is 100% relative humidity, when they will be identical. Because evaporative cooling occurs on the surface of thin jerky strips, the wet bulb temperature is a more accurate measure of product surface temperature.

A **sealed oven** is generally defined as one in which the smokehouse doors and smokehouse oven dampers are closed to prevent moisture loss.

should inspect the wet bulb sock prior to thermal processing, and the sock should be changed as necessary depending on its condition. Attachment 3 contains more details for creating a wet bulb thermometer.

The use of a wet bulb thermometer is especially important for production at altitudes between 3,000 to 7,000 feet or areas of low humidity. Processing failures in the manufacture of jerky have occurred in establishments in New Mexico located between these altitudes (Eidson et al, 2000). Establishments located at higher altitudes will generally have a lower atmospheric pressure. This lower pressure leads to lower boiling points and faster evaporation from the product surface, which can lead to undesirable evaporative cooling and drying of the product surface. Furthermore, the relative humidity can be less at the higher altitude because of the lower air pressure (if the temperature at sea level and the high altitude is the same). As a result, at higher altitudes, the amount of moisture added to the smokehouse chamber necessary to achieve a given log reduction of bacteria may need to be increased to account for lower levels of humidity in the ambient (or room) air. Relative humidity in the ambient air will have an effect on the relative humidity in the smokehouse chamber, particularly when humidity is maintained by sealing the oven, because heat in the smokehouses is typically provided by heating ambient air that is passed over electrically-heated or steam-heated coils. For this reason, all establishments should also take into account variability in relative humidity in the ambient air throughout different times of year.

Establishments will need to make adjustments to the amount of humidity added to the smokehouse chamber to account for changes in humidity in the ambient air at high altitudes or during dry months. These adjustments should be made on a case-by-case basis as part of the initial design of the system to ensure that the humidity in the actual process matches the level in the scientific support.

FSIS recommends that establishments monitor relative humidity using wet and dry bulb thermometers or a humidity sensor with every lot or batch of product although FSIS does not require this monitoring frequency. Establishments have flexibility in how they address humidity in their HACCP systems. If relative humidity is addressed as part of a critical control point (CCP), the establishment is required to list the critical limits per 9 CFR 417.2(c)(3) and list and support the monitoring procedures and frequencies chosen for each CCP to ensure compliance with the critical limits per 9 CFR 417.2(c)(4) and 9 CFR 417.5(a)(2). Furthermore, per 9 CFR 417.4(a)(2), establishments are required to calibrate process-monitoring instruments as part of ongoing verification activities and, per 417.5(a)(2), are required to support their verification procedures and frequencies of those procedures. If relative humidity is addressed in a prerequisite program, and the establishment determines that the implementation of that program results in potential hazards being not reasonably likely to occur, then it must have supporting documentation for the decisions made in the hazard analysis per 9 CFR 417.5(a)(1).

NOTE: Accurate recordkeeping documenting the implementation of the critical operational parameters is critical to support the fact that safe products are produced. Inadequate or inaccurate recordkeeping (e.g., data entry error or unclear monitoring records) has contributed to jerky product recalls in the past, particularly when such records were associated with a lack of information regarding the implementation of all of the critical operational parameters for each batch or lot produced.

Often the owner's manual for humidity recorders recommends calibration on an annual basis. Establishments should follow the manual's instructions for calibration. Establishments may calibrate by comparing the temperature readouts from the microprocessor to the temperature and time plotted on the recorder charts to check for accuracy. For this procedure, FSIS recommends that the establishment calibrate the microprocessor controls before use and show that the calibration is accurate. This procedure can be performed "in-house" in a few simple steps:

1. The wet bulb and dry bulb probes can be placed in a bucket of hot water along with a National Institute of Standards and Technology (NIST) reference thermometer. Some establishments use a small propane burner to maintain the water at a constant temperature.
2. The NIST thermometer represents the known temperature standard, and the establishment can compare the wet and dry bulb probe readings on the microprocessor to the NIST device to verify accuracy of the probes.
3. Once the probe readings are verified on the microprocessor as being accurate, the temperature reading on the microprocessor can be compared to the chart recorder temperature. The chart recorder is then adjusted (if needed) to the microprocessor reading.

These procedures for calibrating humidity recorders are provided as guidance to establishments; other procedures may be used, provided the establishment maintains support for the method chosen.

- **Step 6 – <u>Drying</u>**: Drying is the process during which water (moisture) is removed from the product. After the lethality treatment, jerky is dried to meet a water activity level sufficient to prevent the growth of microorganisms, especially toxigenic microorganisms such as *Staphylococcus aureus*.

Jerky is a shelf-stable product. After drying is complete, the establishment should monitor or verify the water activity to demonstrate that the product has attained shelf-stability in accordance with the scientific support. FSIS does not have a standard of identity for jerky in its regulations. However, jerky has historically been dried to an MPR of 0.75:1 or below as described in the *<u>FSIS Food Standards and Labeling Policy Book</u>*. FSIS is aware that some manufacturers rely upon the MPR, rather than water activity, for determining whether their process adequately dries the jerky to produce a shelf-stable product. MPR is an inappropriate indicator of shelf-stability. Water activity (also referred to as a_w), measured by an instrument such as a water activity meter, is the more appropriate indicator to verify jerky is properly dried for food safety. This is because water activity is a better measure of available water (or water that is not bound by other components) for microbial growth than is MPR. Minimizing available water (e.g., achieving a sufficiently low water activity) is necessary to achieve shelf stability, provided measures are taken to address mold growth. Such measures to prevent mold growth may include using short inventory pull dates, low pH, antimycotics, coatings, packaging, or any combination of these measures.

KEY QUESTION

Question: Can a product be labeled as "jerky" if it meets the MPR of 0.75:1 but is not shelf-stable?

Answer: No. In order to label a product "jerky" it must be shelf-stable. Although FSIS does not define jerky as shelf-stable in the regulatory standards of identity (9 CFR part 319), consumers consider and expect jerky to be shelf-stable.

In order to achieve a shelf-stable product, a water activity critical limit of 0.85 or lower should be targeted for products stored in an aerobic or oxygen containing environment such as in ambient air, provided the establishment takes steps to prevent mold growth on the finished product. If the product is vacuum packaged in an oxygen impervious packaging (creating an anaerobic environment where no oxygen is present), then the water activity critical limit can be 0.91 or lower. These limits are based on the growth limits for *Staphylococcus aureus* with and without oxygen present (ICMSF, 1996) and FSIS' definition of shelf-stability (see the Key Definition in the right panel).

According to the International Commission on Microbiological Specifications for Foods (ICMSF), the water activity limit for *Staphylococcus aureus* growth is 0.83 under aerobic conditions and 0.90 under anaerobic conditions. However, as noted in a footnote of that book, this criterion is based on optimal conditions. FSIS recognizes that most jerky type products have other intrinsic factors, such as sodium nitrite, indigenous microflora, and salt concentration, that would also act as barriers to *Staphylococcus aureus* growth. By considering these factors, FSIS recommends an upper limit of 0.85 under aerobic conditions or 0.91 under anaerobic conditions.

Establishments that choose to use these limits as support for the shelf-stability of their product may cite this guideline as scientific support for these limits and are not required to provide additional scientific support. Establishments may be able to support other water activity critical limits, provided scientific support is available to support the decision-making. The establishment needs to achieve the water activity of the finished product identified in its scientific support.

KEY DEFINITIONS

Shelf-stable is the condition achieved when meat and poultry products can be stored under ambient temperature and humidity conditions; if the package integrity is maintained during storage, shipping, and display at retail and in the home; and the product will not spoil or become unsafe throughout the manufacturer's specified shelf-life.

Water activity, also referred to as a_w, is a measure of the concentration of moisture (i.e., water) **and** its availability in a food. The amount of water available in a food depends on the total concentration of all dissolved substances in the product because they bind water. Thus, if ingredients such as salt or sugar are added to food, they compete with the bacteria for available water.

Moisture-protein-ratio (MPR) expresses the percent moisture divided by the percent protein. MPR is commonly used in the U.S. to classify dried sausages and other meat products. Although MPR values indicate the degree of product drying, they are not necessarily indicative of microbial safety or product shelf-stability because they do not take into account availability of the water.

NOTE: Vacuum packaged products with a water activity level > 0.85 and ≤ 0.91 should be kept refrigerated once the package is opened because the product would no longer be considered shelf-stable once it is exposed to oxygen. Lack of shelf-stability once the product is exposed to oxygen is mainly a concern for products that would not be consumed within a single serving as these products are not likely to be vacuum packaged by the consumer between servings. Therefore, unless the establishment has support that the product is likely to be consumed in a single serving, vacuum packaged products with a water activity in the range of > 0.85 and ≤ 0.91 should be labeled with a statement such as "Refrigerate After Opening" (as described in 9 CFR 317.2(k)).

Finally, it should be noted that although the establishment may control the water activity level of a product to achieve shelf-stability, controlling water activity alone would not be sufficient to assure the safety of the product. Drying the product does not necessarily result in an adequate reduction of *Salmonella* organisms because the pathogen can be resistant to drying. For this reason, the establishment should use a validated lethality treatment, as described in Step 5 – Lethality treatment.

KEY QUESTION

Question: Should an establishment use the MPR to determine whether its process produces a shelf-stable product?

Answer: No. Establishments should use water activity to demonstrate that the product has attained the critical limit for shelf-stability.

- **Step 7 – Post-drying heat step**: A post-drying heat step may be added to increase the level of pathogen reduction beyond that achieved by heating alone.

This step may be needed for processes that do not result in an adequate reduction of *Salmonella* through the initial heating process. Adding a post-drying heat step has the potential to reduce *Salmonella* levels by approximately 2-$\log_{10}$'s from the level of reduction achieved during the initial heat step. One example of a post-drying heat step that has been found to reduce *Salmonella* levels by approximately 2-$\log_{10}$'s is to heat the dried product in a 275°F oven for 10 minutes (Harrison et al., 2001).

- **Step 8 – Handling**: Product is often handled after the lethality and drying steps and prior to/during packaging.

Establishments should control their processes to prevent contamination of product with pathogens from handling after the lethality and drying steps. Such controls should

include ensuring that cross-contamination of product is minimized before packaging, and ensuring that the product is packaged in such a way that cross-contamination of product post-packaging is also minimized (e.g., with a good seal to maintain package integrity throughout storage, shipment, and display). Preventing cross-contamination is important even if the product is dried to a water activity such that the product is considered shelf-stable. Pathogens may still be able to survive on the product if it becomes contaminated during handling.

Cross-contamination of product can occur from situations such as the following:

- Using the same equipment (e.g., preparation tables, scales, or packaging equipment) for both raw and cooked products without completely cleaning and sanitizing the equipment between production lots.

- Placing cooked product on the same surface (e.g., cutting table) as raw product without completely cleaning and sanitizing the surface before reuse.

- Using the same utensils or containers (e.g., scoops or buckets) for both raw and cooked product without completely cleaning and sanitizing the surface before reuse.

- Condensation, aerosolization, or dusting of dry ingredients into the processing environment.

- Employee movement between raw and ready-to-eat areas without hand-washing or garment changing.

The establishment is required to maintain sanitation in the RTE area to ensure that food contact surfaces are free of contamination from *Lm* and other pathogens, such as *Salmonella*, in accordance with 9 CFR part 430. The establishment is required to develop and implement Sanitation SOPs (9 CFR 416) to ensure that contamination and adulteration of the product is prevented after the lethality treatment.

Further guidance on post-processing handling and sanitation for ready-to-eat products including jerky is in the *Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and the Compliance Guidelines to Control *Listeria monocytogenes* in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products.

Scientific Support Available for Jerky Processing

Establishments have numerous options for the types of scientific documents that can be used to support that the process achieves adequate lethality. Examples of the scientific support available to help develop a safe jerky process and product are discussed below, along with considerations for each type of support. Product sampling results, based on historical data alone, should not be used as scientific support for a jerky process because they do not provide information on the level of pathogen reduction that is achieved for the process.

Compliance Guidelines

FSIS has issued a number of different compliance guidelines that have application to jerky processing. It is important to note that, while FSIS considers these documents to be guidelines, if followed precisely, they are considered as validated process schedules because the guidelines contain processing methods already accepted by the Agency as effective in safely producing meat and poultry products.

Some considerations for each of these compliance guidelines are outlined on the following pages.

- ***FSIS Appendix A: Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat and Poultry Products***

For meat jerky, use of the **product time-temperature combinations** provided in *Appendix A*, including those temperatures above 158°F in which the time for the desired lethality is instantaneous, should help to ensure the safety of the product. These time-temperature combinations are based on experiments that were done with products without added salt or sugar. Added salt, sugar, or other substances that reduce water activity will increase the heat resistance of bacteria in a product. However, time and experience have shown that the time-temperature combinations in the lethality compliance guidelines have been sufficient to produce safe products even with both salt and sugar added, but the **humidity during heating is a critical factor**.
FSIS has found through FSAs and askFSIS questions that there is confusion regarding the humidity options in *Appendix A* that apply to jerky, when establishments can introduce humidity by continuously introducing steam or sealing the oven, and for how long humidity should be introduced.

The humidity options in *Appendix A* that are applicable to jerky processing are:

- Heating jerky to a minimum internal temperature of 145 °F (62.8 °C) in an oven maintained at any temperature if the relative humidity of the oven is maintained either by continuously introducing steam for 50 percent of the cooking time or by use of a sealed oven for over 50 percent of the cooking time, or if the relative humidity of the oven is maintained at 90 percent or above for at least 25 percent of the total cooking time but in no case less than 1 hour; or

- Heating jerky in an oven maintained at any temperature that will satisfy the internal temperature and time combinations from the chart provided in

Appendix A if the relative humidity of the oven is maintained at 90 percent or above for at least 25 percent of the total cooking time but in no case less than 1 hour. The relative humidity may be achieved by use of steam injection or sealed ovens capable of producing and maintaining the required relative humidity.

In order to introduce humidity by continuously introducing steam or sealing the oven, establishments should:

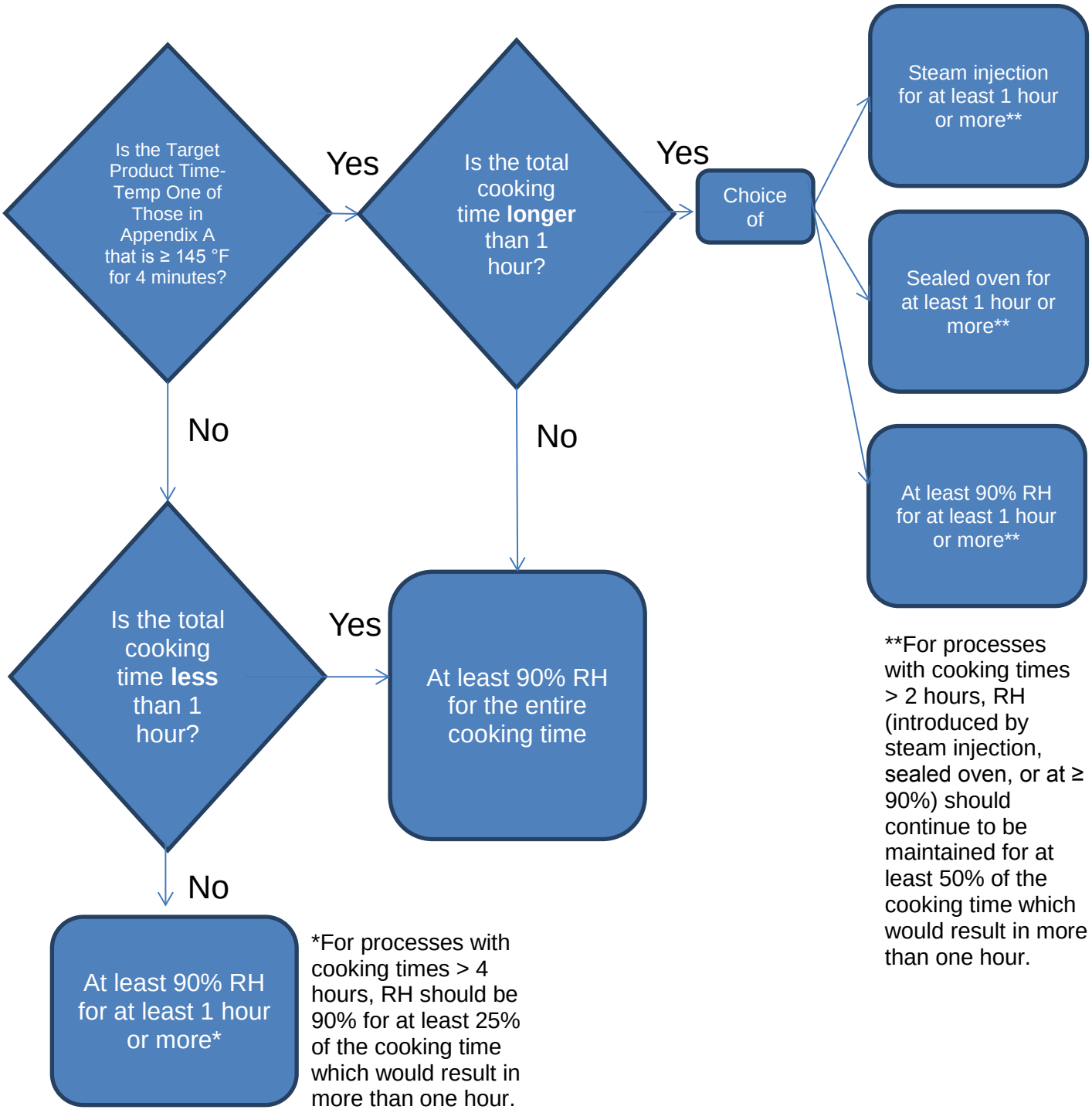
- ☑ Cook the jerky product to an internal temperature-time combination of equal to or greater than 145°F for 4 minutes. It is important to note again that the temperature values in *Appendix A* correspond to product temperatures, not oven temperatures. If an establishment cooks its jerky product to an internal temperature-time combination of less than 145°F for 4 minutes, then the relative humidity should be maintained at 90% or above for at least one hour or 25% of the cooking time (whichever is longer).

AND

- ☑ Cook the jerky product for at least one hour and in some cases longer. Cooking time should never be less than one hour. *Appendix A* states that the relative humidity of the oven should be maintained either by continuously introducing steam for 50 percent of the cooking time or by use of a sealed oven for over 50 percent of the cooking time, but in no case less than one hour. This means that these options should be applied for at least one hour or 50% of the cooking time - whichever is longer. If an establishment can not apply these humidity options for equal to or more than one hour (for example because the lethality treatment takes less than one hour), then the humidity of the oven should be maintained at 90% or above throughout the lethality treatment (not just during the time and temperature combination in *Appendix A)* with the exception of a surface preparation step

Establishments can use the flow chart on the following page to determine the humidity options when using the *Appendix A* guidelines as scientific support for a jerky process. The times listed in the chart do not include any surface preparation or color setting step where humidity is not introduced. So, if a process includes a 30 minute surface preparation or color setting step, the total cooking time would need to be ≥ 90 minutes in order to continuously introduce steam or seal the oven for at least 1 hour (or 50% of the cooking time, whichever is longer) as specified in *Appendix A*.

Flow Chart to Identify Humidity Options when Using the *Appendix A* Guidelines as Scientific Support For a Jerky Process



*For processes with cooking times > 4 hours, RH should be 90% for at least 25% of the cooking time which would result in more than one hour.

**For processes with cooking times > 2 hours, RH (introduced by steam injection, sealed oven, or at ≥ 90%) should continue to be maintained for at least 50% of the cooking time which would result in more than one hour.

Specific guidance for using the sealed oven option to introduce humidity

In order to support that the sealed oven option for introducing humidity is being implemented consistent with the *Appendix A* guidelines, establishments should:

1) **Maintain documentation that supports that the jerky product achieves an internal product time-temperature combination from *Appendix A* of equal to or greater than 145°F for 4 minutes.** Such documentation could include:
   a. Records of internal product temperature and time held at that temperature (if applicable); or
   b. Records of the oven or smokehouse temperature in place of product temperature provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the product temperature in the scientific support*;*

2) **Maintain documentation that supports that the oven dampers are closed for at least one hour or 50% of the cooking time - whichever is longer.** Such documentation could include:
   a. Records from a computerized system that contains the time at which the oven dampers were open and were closed; or
   b. Records of the times at which the oven dampers were open and closed made manually; or
   c. Records demonstrating the relative humidity level in the oven is maintained for at least one hour or 50% of the cooking time - whichever is longer (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement) with correlation data supporting a relationship between the relative humidity level in the oven and the time at which the oven dampers were open and closed (see page 23 for guidance on minimum levels of relative humidity/wet and dry bulb temperatures to achieve);

3) **Maintain documentation that supports that when the oven dampers are closed, humidity is maintained in the ovens.** Such documentation could include:
   a. Records demonstrating the relative humidity level in the ovens is maintained (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement), or
   b. Data gathered during the initial validation period along with ongoing verification which demonstrates that the relative humidity in the oven is maintained while the dampers are closed; and

4) **Have an ongoing procedure for checking that the dampers are properly working along with a maintenance program to periodically monitor that the seals are intact and functional, and that when the oven dampers are closed, a tight seal is obtained.** A tight seal is one in which a significant loss of humidity is prevented. FSIS acknowledges that a small amount of smoke or vapors might be seen escaping the smokehouse even when a tight seal is obtained. Establishments should also consider whether there are other openings, particularly in older smokehouses, such as drain valves or air intake valves, that need to be closed in order to ensure that a seal is obtained. Finally, some older ovens may have a stack or other opening that cannot be closed. For those establishments with older ovens that cannot be completely closed, the sealed oven method should not be used. However, the establishment may choose to close what they are able to and add moisture in the system either by continuously introducing steam or another validated method.

Specific guidance for using the continuously injecting steam option to introduce humidity

In order to support that the continuously introducing steam option for introducing humidity is being implemented consistent with the *Appendix A* guidelines, establishments should:

1) **Maintain documentation that supports that the jerky product achieves an internal product time-temperature combination from *Appendix A* of equal to or greater than 145°F for 4 minutes.** Such documentation could include:
    a. Records of internal product temperature and time held at that temperature (if applicable); or
    b. Records of the oven or smokehouse temperature in place of product temperature provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the product temperature in the scientific support;

2) **Maintain documentation that supports that steam is continuously introduced for at least one hour or 50% of the cooking time - whichever is longer.** Such documentation could include:
    a. Records from a computerized system that contains the time at which the steam is turned on and off; or
    b. Records of the times at which the steam is turned on and off made manually; or
    c. Records demonstrating the relative humidity level in the oven is maintained for at least one hour or 50% of the cooking time - whichever is longer (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement) along with correlation data supporting a relationship between the relative humidity level in the oven and the time steam is turned on or a letter from the manufacturer stating that when the relative humidity is rising it is because of live steam injection (see page 23 for guidance on minimum levels of relative humidity/wet and dry bulb temperatures to achieve);

3) **Maintain documentation that supports that when steam is injected, humidity is maintained in the ovens.** Such documentation could include:
    a. Records demonstrating the relative humidity level in the ovens is maintained (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement), or
    b. Data gathered during the initial validation period along with ongoing verification which demonstrates that the relative humidity in the oven is maintained while steam is being injected.

NOTE: The "continuously introducing steam" option refers to the use of live steam, although it may also apply to establishments that spray water onto hot heating elements, which creates steam that in turn produces humidity in the smokehouse. "Continuous" does not mean that the steam is injected for at least one hour during one stage; rather, steam could be injected during stages or time intervals during the lethality (cooking) treatment as long as the total amount of time the steam is introduced adds up to at least one hour or 50% of the cooking time - whichever is longer. Furthermore, the establishment may turn the steam on and off throughout the cooking time when the target humidity is reached.

Attachment 4 has an example of a temperature chart, with wet and dry bulb temperatures, that an establishment could use to demonstrate it is meeting the option to continuously inject steam on an ongoing basis using monitoring records.

It is important that establishments maintain and monitor the humidity levels in the oven. Establishments using either the sealed oven or continuously introducing steam options for introducing humidity can support that humidity is being introduced consistent with *Appendix A* following the guidance on the previous two pages. Establishments do not need to achieve a specific humidity level in the oven if *Appendix A* is used as the scientific support. However, FSIS recommends that establishments that monitor relative humidity try to achieve a wet bulb temperature of **at least 125-130°F for 1 hour or more** along with a corresponding dry bulb temperature needed to achieve **at least 27-32% relative humidity or more.** FSIS is making this recommendation based on expert opinion and a review of the literature that suggests that the wet bulb temperature should reach at least 125-130°F for an hour or more during the lethality process, and that **at least 27-32% relative humidity** should be present to ensure that adequate lethality is attained. Wet bulb temperature is generally a strong indicator of product surface temperature early in the process. Therefore, maintaining the wet bulb temperature at a high enough level to cause lethality (125-130°F) is recommended (Buege, 2006a; Harper, 2009).

Although establishments using either the sealed oven or continuously introducing steam option for introducing humidity are not required to achieve a specific humidity level, the values provided in this document are listed so that establishments have further guidance concerning minimum levels to achieve as recommended by experts at FSIS. Establishments should be aware that achieving a low wet bulb temperature for a short time (i.e., below 125-130°F for less than one hour) or low relative humidity for a short time (below 27-32% for less than one hour) may indicate that the jerky process may not be achieving sufficient lethality at the product surface which could represent a vulnerability in the establishment's process to control food safety hazards of concern.

NOTE: Achieving a wet bulb temperature of at least 125-130°F and at least 27-32% relative humidity for 1 hour or more is not adequate on its own to support that the process is being implemented consistently with *Appendix A*. Rather, establishments should ensure that all critical operational parameters from *Appendix A* are met (i.e., product time-temperature combination and humidity). Guidance for introducing humidity for the options that require less than 90% relative humidity (continuously introducing steam or sealing the oven) is provided on the previous two pages.

Processes for which Appendix A is not appropriate as scientific support

Finally, although *Appendix A* is commonly used as scientific support for jerky processes, the time-temperature-humidity combinations can not be applied in every scenario. For example, establishments should not use *Appendix A*:

- ☑ **To support a process in which the drying step comes before the cooking step. *Appendix A* was not developed for such processes.**

- ☑ **To support a process that uses a home-style dehydrator. The humidity parameters in *Appendix A* cannot be maintained in a home-style dehydrator. Processes that can achieve an adequate reduction of *Salmonella* and *E. coli* O157:H7 using home-style dehydrators are described in studies by Borowski et al. (2009b), and Harrison et al. (2006).**

- ***FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks***

To support the safe production of meat jerky, establishments can use the time-temperature combinations provided in the *FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks*. Humidity should be considered when using this time-temperature table; therefore, the same options for humidity in *Appendix A* should be used with this guidance. In addition, the same recommendations regarding maintaining and monitoring humidity for *Appendix A* apply for establishments that use the *FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks* for time-temperature combinations.

- ***Time-Temperature Tables For Cooking Ready-To-Eat Poultry Products***

To support the safe production of poultry jerky, establishments can use the minimum internal temperatures listed in *Appendix A* of 160°F for uncured poultry or 155°F for cured and smoked poultry. Establishments should not use the time and temperature combinations provided in *Appendix A* for cooked beef, roast beef, and corned beef for poultry jerky.

NOTE: If highly pathogenic avian influenza (HPAI) virus H5N1 is identified as a hazard reasonably likely to occur, cured and smoked poultry should be cooked to at least 158°F or a time and temperature combination that achieves a 7-$\log_{10}$ reduction of *Salmonella*.

The required reduction of *Salmonella* can also be achieved by using one of the time-temperature combinations listed in the *Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products*. As stated in the *Time-Temperature Tables* guidance document, the tables reflect newer data on the temperatures needed to control *Salmonella* in poultry than the data used in developing *Appendix A*. The Agency has not rescinded the guidance for poultry in Appendix A, but an establishment needs to take into account the data in the *Time-Temperature Tables* regarding increased time at a specific temperature to achieve a given level of reduction of *Salmonella*. An establishment that utilizes *Appendix A* within its process should conduct on-going verification to confirm that the process is being effectively controlled. If an establishment is using *Appendix A*, and the Agency collects an RTE sample that is positive for *Salmonella*, the establishment would be required under 9 CFR 417.3(b), among other things, to support its decision within its hazard analysis.

Regardless of which time-temperature combinations an establishment uses, **humidity during heating is a critical factor**. As with meat jerky, the time-temperature combinations would be sufficient to produce safe products with both salt and sugar additives if the processor uses the humidity parameters applicable to beef as described in *Appendix A*. The same recommendations regarding maintaining and monitoring humidity for *Appendix A* apply for establishments that use the *Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products*.

Journal articles

Journal articles are a primary type of support used for jerky processes. A number of studies have been conducted to determine time-temperature-humidity combinations that result in adequate lethality for jerky. Attachment 2 contains a summary of time-temperature-humidity combinations, along with other critical operational parameters from published studies that have been found to result in adequate lethality.

If an establishment chooses to use a journal article as scientific support, it should ensure that all of the critical operational parameters (i.e., product time-temperature combination and relative humidity) used in the study match those used in the actual process. If one or more of the parameters are not addressed or do not match the level used in the support, then the establishment's process may not achieve the same level of lethality as cited in the journal article. In that case, the establishment should document a justification as to why that parameter does not need to be met or measured, or why it differs from the support. When identifying a journal article, the establishment should consider whether it is using the same:

- Product (e.g., species, type-whole muscle or ground);
- Product formulation;
- Product time-temperature combination;
- Relative humidity at each stage (including, if reported, using the same humidity levels at the beginning and end of each stage);
- Type or pH of marination (if applicable); and
- Smoke (if applicable) as used in the article.

The establishment should also ensure that the composition of the product (% salt, % fat) used in the study is the same as the composition of the actual product being produced. A prudent establishment should have knowledge of the products it produces. Because meeting the critical operational parameters is essential to achieve lethality in the product, the parameters used or measured in the article should be addressed in the process.

Key Considerations for Journal Articles in Attachment 2

Attachment 2 contains a summary of processes, and the critical operational parameters of those processes, that have been found to achieve adequate lethality for jerky in the published literature. The Attachment is provided to help establishments identify alternatives to the *Appendix A* guidelines.

This Attachment is not considered adequate support on its own because it does not provide the details of each study that an establishment needs to determine if the study is representative of the actual process.

For this reason, if an establishment chooses to use one of the articles provided in Attachment 2 for scientific support, the establishment will need to have a full copy of the original article on file.

KEY QUESTION

Question: Can an establishment's process use a different level of a critical operational parameter (for example, a higher concentration of an antimicrobial or a higher processing temperature) than what was used in the scientific support?

Answer: Generally, establishments should use the same critical operational parameters as those in the scientific support. In some circumstances, establishments may be able to support using critical operational parameters (e.g., higher concentrations of antimicrobials or higher thermal processing temperatures) that are different from those in the scientific support. In these cases, establishments should provide justification supporting that the levels chosen are at least as effective as those in the scientific support. This justification is needed because higher levels of a critical operational parameter may not always be equally effective. For example, antimicrobial agents may only be effective within a range of concentration after which point efficacy may decrease. Similarly, higher processing temperatures may result in the surface of the product drying out before adequate lethality is achieved. In addition to ensuring that the levels chosen are at least equally as effective, establishments should ensure the levels are also safe and suitable (*FSIS Directive 7120.1 Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products* and 9 CFR 424.21(c)).

Challenge Studies

In cases where an establishment's process does not match available scientific support documents, such as a Compliance Guideline or published journal article, an establishment may decide to conduct an inoculation challenge study to support that its process achieves adequate lethality (e.g., for meat and poultry jerky at least a 5.0-$\log_{10}$ reduction of *Salmonella* spp.). A challenge study is a study that documents the adequacy of control measures in a process. Obtaining this documentation involves inoculating the target organism (e.g., *Salmonella spp.* or an appropriate surrogate organism such as certain *Pediococcus* strains) into a product to determine the effect of control measures such as cooking and drying to reduce the organism. Challenge studies should be conducted by a microbiologist trained in performing challenge studies in a laboratory to avoid the possible spread of contamination in an establishment. In a challenge study, the number of organisms before and after the application of the control measure is counted to determine the effect of the control measure. The challenge study should be designed to closely match the critical operational parameters (e.g., time, temperature, and relative humidity) in the establishment's actual process.

Challenge studies should be based on a sound statistical design and should also employ positive and negative controls. As recommended by the National Advisory Committee on Microbiological Criteria of Foods (NACMCF), the number of samples to be analyzed initially and at each time interval during processing or storage should be at a minimum two; however, analysis of three or more samples is preferred. Replicates should also be conducted. Replicates should be independent trials using different batches of product and inoculum to account for variations in product, inoculum, and other factors. Generally, the number of samples and replicates should be increased in situations of higher variability or uncertainty. When the number of samples analyzed at each time interval is only two, it is better for the study to be repeated (replicated) more than two times. In studies with three or more samples tested at each time interval, two replicates are usually adequate.

At a minimum, a study for a microbiological food safety hazard should identify:

- The hazard (including the specific strains studied),
- The expected level of hazard reduction or prevention to be achieved,
- The processing steps that will achieve the specified reduction or prevention,
- All critical operational parameters or conditions (e.g., time, temperature, and humidity) necessary to achieve the reduction,
- How these processing steps/parameters can be monitored,
- The critical ingredients (e.g., salt, sugar, and cure), and
- The critical product characteristics (e.g., pH, water activity, and fat content).

In addition, the inoculum level should be at least two logs greater than the log reduction to be demonstrated. FSIS recommends that establishments use *Salmonella* (or an appropriate surrogate of *Salmonella*) as an indicator of lethality because it tends to be more heat resistant than other pathogens (Goodfellow & Brown, 1978; Line et al, 1991). FSIS considers all *Salmonella* serotypes to be pathogens of public health concern.

FSIS does not require establishments to validate that their process achieves reduction in *E. coli* O157:H7 or *Lm* if they achieve sufficient reductions in *Salmonella* because *Salmonella* is an indicator of lethality. Without further scientific support, establishments should not use pathogens other than *Salmonella* as indicators of lethality. For example, establishments should not use reductions in *Lm* to support similar reductions in *Salmonella* without support that *Lm* is at least equally as heat resistant as *Salmonella* under the conditions being studied.

If an establishment chooses to conduct a challenge study in a testing laboratory, the study should use at least five strains of *Salmonella*, including strains associated with human illness and strains isolated from meat and poultry products. Ideally, some of the strains selected should be those with known heat-resistance properties. One good choice, for example, might be *Salmonella enterica* serovar Senftenberg strain 775W, which displays heat resistance properties (Ng et al., 1969). *Salmonella enterica* serovar Senftenberg occurs in the top 10 serotypes seen in FSIS testing for both cow/bull carcass testing and ground beef, as well as in turkeys (carcass and ground) (FSIS testing data, 2012), so it would also be an appropriate choice for what might be seen in these products being tested.

If an establishment chooses to conduct a challenge study in a plant environment, to best represent actual processing conditions for example, then the establishment should choose surrogate organisms that have been found to respond similarly to the pathogens of interest (e.g., *Salmonella*, and if applicable, *E. coli* O157:H7). For example, the University of Wisconsin has conducted research with ground-and-formed jerky and found that two *Pediococcus* strains (*Saga 200* and *Biosource*) have similar heat-resistance to *Salmonella* and can be used in in-plant validation studies (Borowski et al., 2009a). FSIS has identified four surrogate organisms that have been shown to respond similarly to *E. coli* O157:H7 during cooking (the following askFSIS Q&A has more information) for use in in-plant validation studies. For the reasons explained above, establishments also should not use surrogate organisms that have been shown to respond similarly to *E. coli* O157:H7 to support similar reductions in *Salmonella* without support that the organisms are at least as heat resistant as *Salmonella.*

Challenge studies should be equivalent to peer-reviewed scientific literature. All of the critical elements listed above for a study above need to be included to permit evaluation or confirmation of the results. More information on conducting challenge studies is found in the article published by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) in the Journal of Food Protection in 2010.

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Helpful Websites

Dry Bulb, Wet Bulb, and Dew Point Temperature

Compliance Guidelines to Control *Listeria monocytogenes* in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products

Food Safety Regulatory Essentials (FSRE) Processing Procedures: Dried Meats

FSIS Appendix A: Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat and Poultry Products

FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks

Making Your Own Wet Bulb Thermometer

Relative Humidity Calculation Using Dry and Wet Bulb Temperature Measurements

Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products

Time-Temperature Tables For Cooking Ready-To-Eat Poultry Products

Attachment 1: FSIS Response to Comments

The following is a summary of FSIS' response to the comments received during the comment period.

1. Need for guidance

Comment: One commenter questioned the need for the guidance given the limited information publicly available on the causes of past outbreaks in jerky and the importance of humidity in the production of jerky. The commenter also identified a broken link to a reference to one of the past outbreaks in the 2012 version of the guidance.

Response: FSIS initially issued this guidance in 2007 to clarify the importance of introducing humidity to jerky processors given the lack of humidity control identified in past outbreaks. One potential cause of the 2003 *Salmonella* Kiambu outbreak in jerky was the very slow drying process under low humidity conditions (1% RH - 82°C dry bulb, 30°C wet bulb), which allowed *Salmonella* organisms to dehydrate during drying and become resistant to heat. This information was gathered by FSIS during the course of the investigation. Research has demonstrated that bacteria can become more heat resistant as their moisture level decreases, and increased concentrations of solutes, especially sugars, increase the heat resistance of bacteria. Therefore, drying of the product surface before the pathogens are destroyed will increase pathogen heat resistance and allow them to survive the heating process. By incorporating humidity to minimize evaporation, the D values (time at a constant temperature necessary to destroy 90% or 1-$\log_{10}$ of the target organism) that are the basis for *Appendix A* and other scientific support documents remain valid (Goepfert, 1970; Goodfellow and Brown, 1978; Faith, N.G. et al. 1998). For this reason, the low humidity conditions were considered to be a plausible cause of the outbreak. The low humidity conditions were likely related to the location of the processing establishment in Albuquerque, New Mexico, which is at an elevation of greater than 4,000 feet[2]. As described on page 13 of the guidance, the relative humidity in the ambient (or room) air is lower at higher altitudes, which affects the relative humidity in the smokehouse chamber. Prior to the 2003 outbreak, at least six other salmonellosis outbreaks occurred in New Mexico between 1966 and 1995 suggesting the high altitude/low ambient humidity conditions in the state played a role, among other factors (CDC, 1995; Eiden, 2000). Since the 2003 outbreak, FSIS has continued to refine the guidance document based on the most up-to-date science and lessons learned from FSAs.

Finally, the broken link provided in the previous version of the guideline has been replaced with a functioning link to an Epidemiology Presentation from the New Mexico Department of Health (http://aces.nmsu.edu/ces/nmhs/documents/albanese.pdf).

Comment: One commenter questioned why the Jerky Compliance Guidelines focused on small and very small establishments. According to one commenter, small and very small meat processors in the U.S. represent 5 percent of the total meat production volume, but 95 percent of the total meat processing businesses in the U.S.

[2] http://egsc.usgs.gov/isb/pubs/booklets/elvadist/elvadist.html

This commenter suggested that the guidelines not be limited to small and very small establishments but rather should be addressed to the whole industry.

Response: FSIS focused the Jerky Compliance Guidelines on small and very small establishments in support of the Small Business Administration's initiative to provide small and very small establishments with compliance assistance under the Small Business Regulatory Flexibility Act (SBRFA). However, all FSIS regulated meat and poultry establishments may be able to apply the recommendations in this guidance. It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective HACCP systems. Although large establishments can benefit from the guidance that FSIS provides, focusing the guidance on the needs of small and very small establishments provides them with information that may be otherwise unavailable to them because of cost. For example, FSIS included growth limits for *Staphylococcus aureus* published in an ICMSF book chapter. Establishments can reference this guideline for support for the development of critical limits based on these values instead of having to purchase the costly textbook. FSIS also included an inexpensive way for establishment's to make their own wet bulb in Attachment 3 courtesy of University of Wisconsin-Madison Center for Meat Process Validation.

2. Validation

Comment: One commenter recommended FSIS postpone the release of the finalized guidance document until the finalized HACCP systems validation guidance document is released to ensure the documents are cohesive and complete.

Response: This Compliance Guideline articulates how industry can meet FSIS requirements regarding jerky processing as well as FSIS recommendations to help produce a safe product based on the scientific information available in the literature. The primary focus of this guidance document is on the first element of validation: scientific support. This element includes the process of identifying scientific support documents that closely match the establishment's actual process along with identification of the critical operational parameters from the scientific support relevant to the establishment's process. FSIS is currently enforcing this element of the initial validation requirement (9 CFR 417.4(a)(1)). In addition, FSIS does not wish to delay finalizing this document because it reflects the most up-to-date science and understanding of jerky processing and addresses key issues FSIS has identified through FSAs and response to outbreak investigations. FSIS is sharing this information in a timely manner in order to help establishments produce a safe product.

Comment: One commenter expressed concern with the following "Key Question" in the guidance document: "Can an establishment's process use a different level of a critical operational parameter (for example, a higher concentration of an antimicrobial or a higher processing temperature) than what was used in the support document?". The commenter provided an example of shelf-stable jerky that has a water activity of 0.85 or less. In the example, some processors may reduce the water activity lower than 0.85 for quality issues or an extended shelf life. The commenter expressed concern that establishments would have to provide a justification for the lower water activity level chosen.

Response: FSIS has found through FSAs that establishments use levels of critical operational parameters that are different from those in their scientific support without any consideration as to whether this will result in the same efficacy demonstrated in the scientific support. The Agency is recommending that establishments provide a scientific justification as to why the same efficacy would be achieved with a different level of a critical operational parameter. In the example provided by the commenter, an establishment could provide the justification, with reference to applicable scientific support, that pathogen growth decreases as water activity decreases, supporting that if 0.85 is adequate to preclude growth, then a lower water activity would also preclude growth of pathogenic microorganisms. Such a justification would be adequate and could be maintained in the establishment's decision-making documents as scientific support for the process used.

Comment: One commenter indicated that the guidance document is not specific enough in explaining how closely scientific support must match an establishment's process, species, or products. In addition, the commenter stated that inspection program personnel would find noncompliance with the validation regulations simply because the supporting document does not match the establishment's production precisely.

Response: FSIS is not prescriptive in terms of how closely the scientific support should match the actual process. Rather, FSIS recommends that the critical operational parameters used in the scientific support be consistent with those used in the establishment's process and is providing establishments the flexibility to use different levels as long as a scientific justification is provided. FSIS inspection program personnel (IPP) verify establishment validation when performing the Hazard Analysis Verification (HAV) task. Instructions for performing the HAV task are provided in *FSIS Directive 5000.6 Performance of the Hazard Analysis Verification (HAV) Task* and in the HAV section of the Inspection Methods training. FSIS will issue additional instructions to its field personnel for them to verify that establishments meet all validation requirements once the *FSIS HACCP Systems Validation Guidance* is finalized.

Comment: One commenter stated that the type of equipment used in the process should not be considered a critical operational parameter.

Response: FSIS has found through FSAs that establishments use different types of equipment than that used in the scientific support without any consideration as to whether this change will result in the same efficacy demonstrated in the scientific support. The type of equipment, such as a smokehouse, could influence the ability to implement other critical operational parameters such as humidity. FSIS is recommending that establishments consider the type of equipment as a critical operational parameter so that establishments take into account whether changes in equipment affect the implementation of other critical operational parameters. This consideration should be a part of the initial set-up of the system and would not need to be done on an on-going basis unless changes to the equipment are made.

3. Step-by-step guide for jerky processing

Comment: Two commenters stated that Steps 2 (Marination) and 3 (Interventions) in the 2007 and 2012 versions of the guidance are not commonly used steps in the industry.

Response: FSIS recognizes that not all processes may include the same steps listed in the step-by-step guide. FSIS included steps such as intervention in the guidance because some heating processes may not deliver an adequate lethality and, thus, may require an additional intervention step to ensure product safety. To more accurately reflect commonly used processing steps, FSIS has included the surface preparation step (now Step 4) in the guidance, which is a commonly used step in which strips are heated using a low temperature heat step to make the surface tacky, thus aiding in smoke adherence and improving product texture.

Comment: Two commenters stated that steps 5 (drying) and 6 (post-drying heat step) in the 2007 and 2012 versions of the guidance should be combined because they are often performed as single step by processors.

Response: Although the steps may be combined, in a processing schedule, for example, these steps are listed separately for purposes of the guidance document to provide information to establishments on the use of a post-drying heat step for processes that do not result in an adequate reduction of *Salmonella* through the initial heating process. Adding a post-drying heat step has the potential to reduce *Salmonella* levels by approximately 2-$\log_{10}$'s from the level of reduction achieved during initial heat step.

4. Lethality treatment

Comment: One commenter questioned the recommendation that the lethality treatment of meat jerky should achieve at least a 5.0-$\log_{10}$ reduction of *Salmonella* spp. when there is no USDA/FSIS performance standard specifically for this product.

Response: Jerky producers (and all producers of RTE product) are required to control the food safety hazards in their products (9 CFR 417.4(a)) and document that their HACCP systems work according to 9 CFR 417.5(a). For RTE products, this requirement means that, among other controls, the establishment needs to achieve lethality of pathogens (e.g., *Salmonella*) in the product. In the FSIS *Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products*, FSIS recommends that processors achieve a 5-$\log_{10}$ reduction of *Salmonella* in such meat products as jerky to produce a product safe for consumption. This recommendation is based on expected levels of *Salmonella* in raw products. The compliance guideline also provides alternative forms of lethality that establishments may use. Establishments producing a RTE product must provide adequate scientific support that the process for the RTE product will not result in an adulterated product. In addition, FSIS tests ready-to-eat product for *Salmonella* (as well as *Listeria monocytogenes*) to verify that establishments are addressing the pathogen.

5. Highly pathogenic avian influenza

Comment: Two commenters disagreed with the following statement: "If highly pathogenic avian influenza (HPAI) virus H5N1 is identified as a hazard reasonably likely

to occur, cured and smoked poultry should be cooked to at least 158°F or a time and temperature combination that achieves a 7-log reduction of *Salmonella*." The commenters stated that if this statement is included in this guidance document, establishments will now have to reassess all their HACCP plans if inspection personnel interpret it as a requirement.

Response: This statement has appeared in previous versions of the jerky compliance guidance document. The Agency has not required establishments to reassess their HACCP plans for highly pathogenic avian influenza and does not intend to do so at this time. This information has been included as guidance in the event that an establishment identifies HPAI virus H5N1 as a hazard reasonably likely to occur.

6. Humidity

Comment: One commenter disagreed with the following statement: "One way for an establishment to know that the product has not dried out before a lethal time-temperature combination is attained is to measure the water activity of the product after the lethality treatment but before drying." The commenter stated that this is not necessary if the humidity requirements are achieved. The commenter also said the guideline should clearly state that lethality should be achieved prior to drying the product to achieve desired quality and water activity for shelf stability.

Response: FSIS has added the following clarifying information: "Although this information may provide useful information to an establishment, such data are not needed if an establishment is following procedures to achieve the relative humidity in the scientific support."

Comment: One commenter disagreed with statements in the guidance document that establishments should monitor humidity throughout the entire lethality treatment. The commenter stated that establishments could conduct some sort of 90-day validation of their thermal processing schedules to achieve confidence that humidity was properly addressed.

Response: As stated on page 13, FSIS recommends that establishments monitor relative humidity using wet and dry bulb thermometers or a humidity sensor with every lot or batch of product although FSIS does not require this monitoring frequency. It is the responsibility of the establishment to support its monitoring procedures and frequencies. However, inadequate or inaccurate recordkeeping (e.g., data entry error or unclear monitoring records) has contributed to jerky product recalls, particularly when such records were associated with a lack of information regarding the implementation of all of the critical operational parameters for each batch or lot produced.

Comment: One commenter recommended that FSIS remove the following statement related to *Appendix A*: "If an establishment cannot apply these humidity options for equal to or more than one hour, then the humidity of the oven should be maintained at 90% or above throughout the lethality treatment."

Response: The option in *Appendix A* that allows for humidity levels less than 90% is as follows: "Heating roasts of any size to a minimum internal temperature of 145 °F (62.8 °C) in an oven maintained at any temperature if the relative humidity of the

oven is maintained either by continuously introducing steam for 50 percent of the cooking time or by use of a sealed oven for over 50 percent of the cooking time, or if the relative humidity of the oven is maintained at 90 percent or above for at least 25 percent of the total cooking time, but in no case less than 1 hour." The final clause "but in no case less than 1 hour" means that the humidity options of continuously introducing steam or sealing the oven should be applied for at least 1 hour. FSIS recognizes that jerky is a small mass product that often has total cooking times of less than 1 hour. *Appendix A*, and that the additional humidity options were originally designed for large mass products with longer cooking times. In cases where these humidity options can not be applied for at least 1 hour, the establishment should apply at least 90% humidity throughout the cooking time (even if the cooking time is less than 1 hour) in order to use *Appendix A* as scientific support and to ensure product reaches a lethal temperature and does not dry out before lethality is achieved. Establishments have flexibility to use other scientific support if they are unable to meet the critical operational parameters. FSIS clarified this issue in the guidance.

Comment: FSIS received one question through askFSIS inquiring whether reference to the cooking time in the humidity options in *Appendix A* refers to the entire cooking time (including come up time) or just the time during which the temperature in *Appendix A* is achieved and maintained (e.g., 145°F for 4 minutes).

Response: As stated on page 7, the cooking time (also referred to as the lethality treatment) includes the time when the thermal processing begins (e.g., the product is placed in the heated oven) until the time the product reaches the desired lethality time-temperature combination from *Appendix A*. Therefore, if an establishment is applying humidity by continuously introducing steam for 50% of the cooking time, but in no case less than 1 hour, 50% of the cooking time should be calculated based on the total cooking time, not just the time during which the temperature in *Appendix A* is achieved and maintained. If humidity is not applied early in the process, evaporating water will absorb the heat and a lethal temperature will not be achieved.

Comment: One commenter disagreed with the statement: "Establishments using the option to continuously inject steam should also have a procedure or mechanism in place to ensure that steam is being continuously injected…." The commenter indicated that smokehouses do not operate this way, and that if a program is set for 40% relative humidity, the smokehouse may spray water on the heating element to achieve this 40% relative humidity. If the smokehouse reads that the house has, for example, 50% relative humidity, it will stop spraying water on the heating elements and the dampers will fluctuate to achieve the desired 40% relative humidity in the smokehouse.

Response: FSIS recognizes that steam may be turned on and off throughout the cooking time when the target humidity is reached and has included this approach in the guideline. Some of the supporting documentation that can be used to demonstrate that steam is being "continuously introduced" is illustrated in Attachment 4.

7. Ambient vs. smokehouse temperatures

Comment: One commenter requested further explanation of the effects of ambient temperature on the smokehouse or oven temperatures. The commenter also

requested that FSIS acknowledge that smokehouses/ovens cannot be completely sealed.

Response: FSIS has provided additional information on page 12 regarding the role relative humidity in the ambient air plays on the relative humidity in the smokehouse or oven. FSIS has also provided clarification on page 21 that, even when a tight seal is obtained, some loss of humidity is the form of minor smoke or vapors may be seen.

8. Reference to International Commission on Microbiological Specifications in Foods (ICMSF) (1996) Microorganisms in Foods 5

Comment: Two commenters expressed concern that establishments will use the ICMSF book chapter in place of *Appendix A*.

Response: The only reference to the ICMSF book made in this guidance document is provided as support for finished water activity limits in order to support product shelf-stability. It would not be acceptable for an establishment to cite the water activity critical limits or the ICSMF book chapter as support for a lethality or drying process because meeting a specific water activity level does not support that a 5-$\log_{10}$ reduction is achieved. In general, establishments should not use finished product water activity levels alone as support that a product is RTE. The reason is that low water activity alone, without a further heat treatment, would not necessarily result in adequate reduction of *Salmonella* because the pathogen is known to be resistant to drying. This issue has been clarified and addressed in this guidance on page 15.

Comment: One commenter stated that FSIS should not provide specific guidance on water activity values that can be used to support shelf-stability by an establishment within the guidance. The commenter indicated if FSIS provides one specific number in any guidance document, industry or FSIS may consider the guidance a requirement.

Response: FSIS has found through *ask*FSIS questions and FSAs that establishments are not maintaining adequate scientific support that products are shelf-stable. Therefore, water activity values are provided as guidance to provide small and very small establishments with compliance assistance under SBRFA. However, establishments have flexibility in terms of selecting and supporting the critical limits of their process and are not required to use the limits provided. FSIS has made clear that this document is guidance and is not establishing new requirements (see page 2)

Comment: One commenter requested a rationale for the guidance provided on water activity limits to support shelf-stability for products packaged under aerobic and anaerobic conditions because the limits are different than those in the ICMSF book chapter. The commenter also pointed out that the citation for the ICMSF book chapter referenced the wrong page.

Response: The water activity limits of 0.85 under aerobic conditions and 0.91 under anaerobic conditions provided in this document are based on the definition of shelf-stability in the guidance on page 15 and the growth limit of *Staphylococcus aureus* in the ICMSF Book chapter (Page 304 Table B). The definition of shelf-stability in the guidance is stated as the “condition achieved when meat and poultry products can be

stored under ambient temperature and humidity conditions; if the package integrity is maintained during storage, shipping, and display at retail and in the home; and the product will not spoil or become unsafe throughout the manufacturer's specified shelf-life. " Under this definition, no growth of pathogenic organisms occurs. According to the ICMSF book chapter, the limit of growth for *Staphylococcus aureus* is 0.83 under aerobic conditions and 0.90 under anaerobic conditions. However, as noted in the footnote of the book, this criterion is based on optimal conditions. FSIS recognizes that most jerky type products have other intrinsic factors such as sodium nitrite, indigenous microflora, and salt concentration that would also act as barriers to *Staphylococcus aureus* growth. By considering these factors, FSIS has recommended an upper limit of 0.85 under aerobic conditions or 0.91 under anaerobic conditions. This rationale is now provided in the guidance document. The guidance document also now clarifies that these factors may be used to consider a product stable provided the establishment takes steps to prevent mold growth on the finished product. Finally, FSIS revised the reference to include the page number of the specific table containing these values.

Comment: One commenter expressed concern that the ICMSF book chapter used as the reference for the limits of growth of *Staphylococcus aureus* under aerobic and anaerobic conditions does not contain microbiological data supporting the limits.

Response: FSIS considers information found in textbooks and other scientific texts as acceptable scientific support because this type of scientific data goes through a process of evaluation involving qualified individuals within the relevant field. Often textbooks and other scientific texts contain a summary of information based on other peer-reviewed published research, as is the case with the ICMSF book. In the case of the water activity values provided in this guidance, establishments can refer to the guidance and are not required to provide a copy of the ICMSF book chapter or the original research referred to in the book because this guidance document contains the critical operational parameter (water activity).

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Attachment 2: Time, temperature, and humidity combinations reported in the literature for beef jerky that achieve at least a 5-log$_{10}$ reduction in *Salmonella* and *E. coli* O157:H7. Unless noted, finished product water levels were ≤ 0.85.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Oven Temperature (°F)	Time (min)	Humidity (%)	Log$_{10}$ Reduction	
							Salmonella	*E. coli* O157:H7
Buege et al. (2006a) [3]	Whole muscle beef jerky	Yes – pH 5.3	No	Type 1-A* Stage 1 – 145 170	 15 15			
				Stage 2 – Choose either: dry bulb at 170 and wet bulb at 125	at least 60	27	6.5	6.9
				OR dry bulb at 170 and wet bulb at 130†	at least 60	32	6.9	7.1
				OR dry bulb at 170 and wet bulb at 135†	at least 30	37	7.0	7.1
				OR dry bulb at 170 and wet bulb at 140†	at least 10	43	6.9	7.1
				Stage 3- Dry at 170 dry bulb	to targeted doneness			

[3] Buege, D.R., Searls, G., and Ingham, S.C. 2006. Lethality of commercial whole-muscle beef jerky manufacturing processes against *Salmonella* Serovars and *Escherichia coli* O157:H7. Also see the following website for a more detailed, user-friendly critical limit summary document: http://www.meathaccp.wisc.edu/validation/assets/CLSummary_WMJerkyJune2013.pdf.

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Oven Temperature (°F)	Time (min)	Humidity (%)	Log_{10} Reduction	
							Salmonella	***E. coli* O157:H7**
Buege et al. (2006a)	Whole muscle beef jerky	Yes – pH 5.3	No	Type 1-B*[†] Stage 1 – 145	15			
				Then choose either:				
				Stage 2 – dry bulb at 150 THEN dry bulb at 150 and wet bulb at 130; THEN dry bulb at 150	15 60 to targeted doneness	56	6.8	7.0
				OR Stage 2- dry bulb at 190 THEN dry bulb at 190 and wet bulb at 130; THEN dry bulb at 190	15 60 to targeted doneness	19	7.1	7.3
		Yes – pH 5.3	No	Type 2**[†] 145 170	15 to targeted doneness	27-31(start)*** 17-21(end)	6.3	6.0

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Oven Temperature (°F)	Time (min)	Humidity (%)	Log_{10} Reduction	
							Salmonella	***E. coli* O157:H7**
Buege et al. (2006a)	Whole muscle beef jerky	Yes – pH 5.3	No	Type 3**[†] 145 170	90 to targeted doneness	41(start)*** 21(end)	5.5	5.6
		Yes – pH 5.3	No	Type 5** 180	to targeted doneness	29(start)**** 15(end)	5.1	5.6

*Type 1-A and Type 1-B processes with a higher dry bulb temperature in Stage 1, a higher wet bulb temperature or longer time in Stage 2, or a higher dry bulb temperature in Stage 3, as long as other parts of the process are not changed, can also be considered validated because they should have greater lethality.

**Processes reaching higher dry bulb temperatures in either stage can also be considered validated because they would have greater lethality.

***Humidity values are from Table 3 in Buege et al. (2006a).

****Humidity values are from Table 5 in Buege et al. (2006a).

[†]Finished product water activity level was > 0.85 (if an establishment wants to support the product is shelf-stable using 0.85 as a criteria, it should consider further drying the product).

Oven: Pans of water were placed on the lowest rack in the smokehouse, and a low fan speed was used. Humidity (steam or water) was introduced in Type 1-A and 1-B processes. Study did not indicate whether dampers were open or closed.

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Oven Temperature (°F)	Time (min)	Humidity (%)	Log_{10} Reduction	
							Salmonella	***E. coli* O157:H7**
Buege et al. (2006a)	Whole muscle beef jerky	Yes – pH 5.3	No	Type 7**[†]				
				120	60	43***	6.0	5.6
				130	60			
				140	60			
				170	60	15		

**Processes reaching higher dry bulb temperatures in either stage can also be considered validated because they would have greater lethality.
***Humidity values are from Table 3 in Buege et al. (2006a).
[†]Finished product water activity level was > 0.85 (if an establishment wants to support the product is shelf-stable using 0.85 as a criteria, it should consider further drying the product).

Oven: Pans of water were placed on the lowest rack in the smokehouse, and a low fan speed was used. Humidity (steam or water) was introduced in Type 1-A and 1-B processes. Study did not indicate whether dampers were open or closed.

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Oven/Product Temperature (°F)*	Time (hours)	Humidity (%) (Start/End)	Log_{10} Reduction (cfu/strip)	
							Salmonella	*E. coli* O157:H7
Porto-Fett et al. (2008)[4]	Whole muscle beef jerky	Yes – ~pH 5.5	Yes	178	1.5	63.4 21.9	≥7	≥7[†]
	Whole muscle beef jerky	No	Yes	178	1.5	63.4 21.9	≥7	≥7[†]
	Whole muscle beef jerky	Yes – ~pH 5.5	Yes	178.3	2.5	63.8 21.5	≥7	≥7
	Whole muscle beef jerky	No	Yes	178.3	2.5	63.8 21.5	≥7	≥7[†]
	Whole muscle beef jerky	Yes – ~pH 5.5	Yes	178.5	3.5	62.3 19.2	≥7	≥7
		No	Yes	178.5	3.5	62.3 19.2	≥7	≥7

*Oven temperatures are average of continuous readings taken every 30s after CUT.
[†]Finished product water activity level was > 0.85 (if an establishment wants to support the product is shelf-stable using 0.85 as a criteria, it should consider further drying the product).

Oven: Dampers were completely open.

[4] Porto-Fett, A.C.S., Call, J.E., and Luchansky, J.B. 2008. Validation of a commercial process for inactivation of *Escherichia coli* O157:H7, *Salmonella* Typhimurium, and *Listeria monocytogenes* on the surface of whole muscle beef jerky. Journal of Food Protection. 71(5): 918-926.

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Oven Temperature (°F)	Time (min)	Humidity (%)*	Log_{10} Reduction	
							Salmonella	***E. coli* O157:H7**
Harper et al. (2009),[5] Getty et al. (2006)[6]	Chopped and formed beef jerky	No	No (smoke flavor was added)	Stage 0 – Stage 1 – 132	14	32.6	7.1	7.1
				Stage 2 – 132	16	52		
				Stage 3 – 132	14	14.5		
				Stage 4 – 172	16	22		
				Stage 5 – 172	14	22		
				Stage 6 – 172	16	22		
				Stage 7 – 172	14	22		
				Stage 8 – 172	16	22		
				Stage 9 – 172	14	22		
				Stage 10 – 172	16	22		
				Stage 11 – 172	14	22		
				Stage 12 – 172	5 h	22		

*Humidity levels were calculated from actual dry and wet bulb temperatures reported in Getty et al. (2006): http://www.fsis.usda.gov/wps/wcm/connect/35151cb4-1603-4164-b71f-bfea44e487e8/C-12_New_Technology_FY2004_Final_Report.pdf?MOD=AJPERES. Although the report states that humidity remained at less than 10% throughout the entire smokehouse cycle, humidity levels calculated from dry and wet bulb temperatures in the report were higher, as indicated in the table. This was verified through personal communication with the author [April 2011].

Oven: Automated dampers and steam injection.

[5] Harper, N.M., Roberts, M.N., Getty, K.J.K., Boyle, E.A.E., Fung, D.Y.C., Higgins, J.J. 2009. Evaluation of two thermal processing schedules at low relative humidity for elimination of *Escherichia coli* O157:H7 and *Salmonella* Serovars in chopped and formed beef jerky. Journal of Food Protection. 72: 2476-2482.

[6] Getty, K.J.K., Boyle, E.A.E., Roberts, M.N., Lonneker, S.M. 2006. Jerky Validation for Small and Very Small meat and Poultry Businesses: Final Report. Available at: http://www.fsis.usda.gov/wps/wcm/connect/35151cb4-1603-4164-b71f-bfea44e487e8/C-12_New_Technology_FY2004_Final_Report.pdf?MOD=AJPERES. Accessed 17 August 2013.

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Oven Temperature (°F)	Time (min)	Humidity (%)**	Log_{10} Reduction	
							Salmonella	***E. coli* O157:H7**
Borowski et al. (2009a)[7]	Ground-and-formed beef jerky	No*		Type 2-A				
			No	170	30	57	7.4	7.4
			No	130	120	22		
			No	170	90	28		
	Ground-and-formed beef jerky	No*		Type 3-A				
			No	170	30	7	6.1	6.8
			No	170	15	23		
			No	170	130	ND		
	Ground-and-formed beef jerky	No*		Type 4-A				
			No	135	90	67	7.8	8.1
			No	185	150	9		

*A spice rub mix was used. Two types of spice mixes (Colorado and BBQ) were used in the study. Results for one type of spice mix (Colorado) are reported here. Variability in lethality was found due to spice mix type. See Borowski et al. (2009a) for details on the spice mixes used including pH and a_w values and results for products prepared with the BBQ spice mix.
**%RH values are approximate based on an average of the range of actual dry and wet bulb temperatures provided in the article. RH values reported as ND were not determined.

NOTE: All processes reported here used a commercial oven-smokehouse.
Oven: Dampers were open for processes without smoke added.

[7] Borowski, A.G., Ingham, S.C., Ingham, B.H. 2009. Validation of ground-and-formed beef jerky processes using commercial lactic acid bacteria starter cultures as pathogen surrogates. Journal of Food Protection. 72(6): 1234-1247.

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Temperature (°F)	Time (min)	Humidity (%)**	Log_{10} Reduction	
							Salmonella	***E. coli* O157:H7**
Borowski et al. (2009a)	Ground-and-formed beef jerky	No*		Type 2-B				
			Yes	170	30	32	7.2	7.4
			Yes	130	120	ND		
			Yes	170	90	ND		
	Ground-and-formed beef jerky	No*		Type 3-B				
			No	170	30	7	7.3	7.4
			No	170	15	39		
			Yes	170	130	ND		
	Ground-and-formed beef jerky	No*		Type 4-B				
			Yes[8]	135	90	68	7.5	7.5
			Yes[9]	185	150	ND		

**A spice rub mix was used. Two types of spice mixes (Colorado and BBQ) were used in the study. Results for one type of spice mix (Colorado) are reported here. Variability in lethality was found due to spice mix type. See Borowski et al. (2009a) for details on the spice mixes used including pH and a_w values and results for products prepared with the BBQ spice mix.
**%RH values are approximate based on an average of the range of actual dry and wet bulb temperatures provided in the article. RH values reported as ND were not determined.

NOTE: All processes reported here used a commercial oven-smokehouse.
Oven: Dampers were open until smoke was added at which point dampers were closed.

[8] Smoke added after 30 min.
[9] Smoke discontinued after 90 min.

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Oven Temperature (°F)	Time (hours)	Humidity (%)	Log_{10} Reduction	
							Salmonella	***E. coli* O157:H7**
Harrison et al. (2006)[10]	Beef jerky strips	Yes	No	143.6	8-9	33	>6	>6

NOTE: The process reported here used a commercial oven-smokehouse.
Oven: No humidity control. Study did not indicate whether dampers were open or not.

[10] Harrison, M. A., R. K. Singh, J. A. Harrison and N. Singh. 2006. Antimicrobial intervention and process validation in beef jerky processing. Final Report. Available at: http://www.fsis.usda.gov/wps/wcm/connect/8dd0f238-08d7-4ca0-a31a-77fa3ca8acf6/C-17_New_Technology_FY2004_Final_Report.pdf?MOD=AJPERES. Accessed 17 August 2013.

Attachment 3: Making Your Own Wet Bulb Thermometer (Reprinted with permission)

By G. Burnham, S.C. Ingham and B.H. Ingham
University of Wisconsin-Madison Center for Meat Process Validation

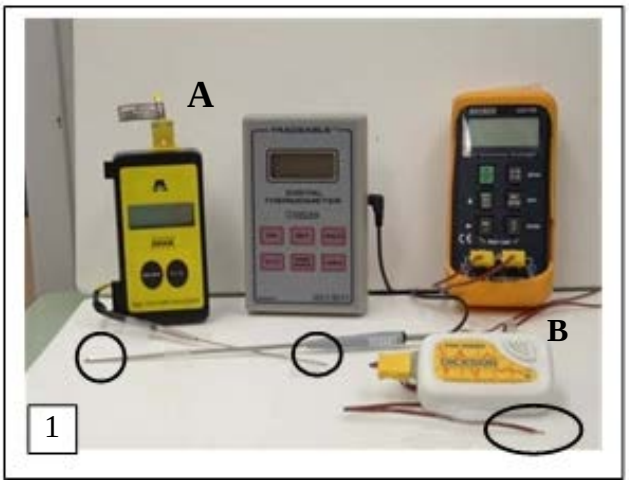
If you are smoking or drying meat, there are several parameters to monitor which will help you control your process: **dry bulb temperature**, **wet bulb temperature**, and **relative humidity**. Research at the University of Wisconsin Center for Meat Process Validation has shown that **monitoring wet bulb temperature is even more important (and much easier!) than monitoring product temperature** during your process. Since wet bulb temperature is critical to process monitoring, this document describes how to easily, and perhaps inexpensively, construct a wet bulb thermometer.

Dry bulb temperature, usually referred to as air temperature, is the smokehouse/oven property that is most commonly measured by jerky-makers. When people refer to the temperature (heat content) of the air, they are normally referring to the dry bulb temperature. It is called "dry bulb" because the air temperature is indicated by a thermometer that is not moistened and will not be affected by evaporative cooling.

Wet bulb temperature is the temperature indicated by a moistened thermometer bulb exposed to air. A wet bulb thermometer measures the extent of cooling that happens as moisture dries from a surface (evaporative cooling). The wet bulb temperature is always lower than the dry bulb temperature except when there is 100% relative humidity. **Because evaporative cooling occurs on the surface of thin jerky strips, the wet bulb temperature is more accurate measurement of product temperature**.

We developed a **wet bulb thermometer (WBT)** which is easy to assemble and economical for a meat processor to use.

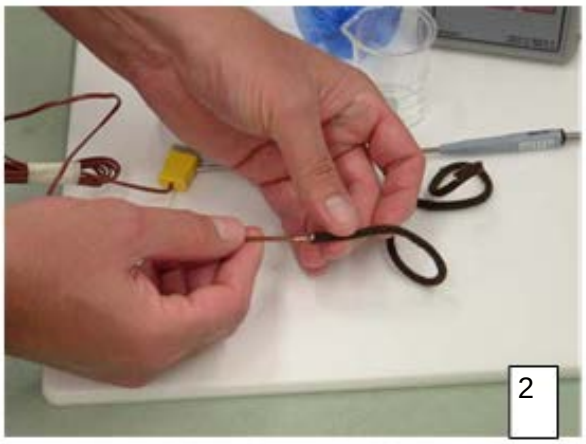
To begin assembling a wet bulb thermometer, you will need to determine what type of **temperature measuring device** you will use. You will need to use a temperature recorder with a “tip reading” probe/wire/stem. Either an **instant read** or a **data-logging temperature measuring device** will work; both are pictured in image 1.



A - 3 styles of ‘instant read’ temperature measuring device
B - a data logger-style of temperature measuring device
In each case, the ‘tip reading’ probe/wire is circled.

Instant read temperature recorders.
(A) An instant read temperature Recorder will offer immediate feedback, with the temperature displayed on the front of the unit. However, data may not be recorded with this type of unit; the processor must record the data periodically. See page 51 for more information on ordering instant-read temperature recorders.

A data logger-style temperature recorder. (B) This type of device keeps track of, or 'logs' temperature over a period of time. An inexpensive data logger usually does not offer immediate readout of data. A processor must connect the data logger to a computer to view the temperature data. A data logger does, however, offer a continuous record of temperature history which can be important for HACCP documentation. See page 51 for information on ordering a standard data logger.

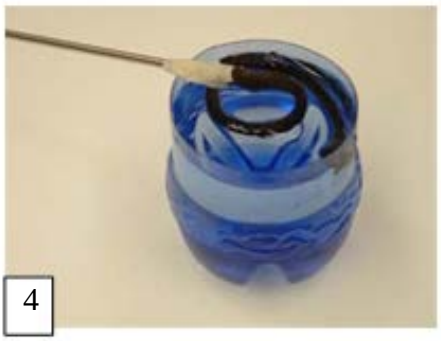

2

Once you have your temperature recorder, you will need to choose material to serve as the **"wick"** to cover the tip probe. Water evaporating from the wick will reduce the temperature recorded, giving an indication of evaporative cooling. The wick should be made from an absorbent material, preferably cotton. It should also be constructed of **two phases**: a loose, absorbent interior, and an exterior that is of an absorbent tighter meshing material. The exterior keeps the inner absorbent material around the sensing portion of the temperature probe and prevents the sensing portion of the recorder from being exposed to direct ambient conditions. You may wish to purchase wicks commercially, such as from an online supplier (http://www.wickstore.com/wetbulbwick.html), or a good substitute is a round cotton bootlace (image 2). See page 51 for more information on supplies for a wet bulb thermometer.

There are several simple steps to setting up a **wet bulb thermometer**.

1. **Gather materials.** You will need a **vessel for holding water** which must either be refilled during processing, or must be sufficiently large to hold enough water (allowing for evaporation) to keep the water level close to the temperature probe. Choosing a vessel with a small diameter opening will reduce evaporation. Once a water vessel has been chosen, simply fill it with water. You will also need a **temperature measuring device** and material to serve as a **wick**. In image 3, the bottom of a soda bottle and a glass beaker are pictured as vessels. Both an instant read and a data logger are shown for measuring temperature and pieces of brown cotton shoelace serve as the wick.


3

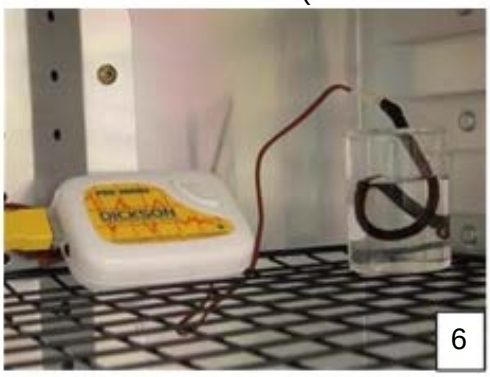

4

2. **Assemble the wet bulb thermometer. Cut** a portion of the wicking material (it should be long enough to reach the bottom of the water vessel and than some). **Connect** the sensing portion of your temperature recorder to the wick by inserting the probe/wire/stem into the center of the wick (image 2). **Secure the end** of the wick to the probe/wire/stem using tape. **Place the wick** in the water-containing vessel. **Make sure** the wick is completely

saturated with water, then position the wick-covered sensing portion of your temperature recorder so that it is completely exposed to ambient conditions, yet as close as possible to the water source (image 4). This will ensure adequate wicking of the water to the sensing portion of the temperature recorder. If exposure to ambient conditions is too great, such as when the wick is too long or the recorder too far from the water surface, the wick may dry out, and evaporative cooling will not be recorded.

3. **Place the wet bulb thermometer inside the chamber.** If you are using an instant reading temperature measuring device to make process adjustments, place the wet bulb thermometer for easy access and readability, such as near a door or window (image 5). If immediate feedback is not a consideration (image 6), place the device where the ambient conditions of your process are least likely to give you optimum conditions - hence a "worst case" reading. Position the wet bulb thermometer in a flow of air (such as in a stream of incoming air), but away from fans which will cause excessive evaporation and drying of the wick.

5



6

4. **Record wet bulb temperature.** Establish a regular schedule of recording or down-loading wet bulb temperature. Check water level in the vessel periodically, and also check the position of the wick. The portion of the wick above the water must remain moist for accurate temperature measurement. The wet bulb temperature can be used to adjust your process conditions, as needed.

Supplies for Making a Wet Bulb Thermometer*

Instant Read Temperature Recorders
Fisher Scientific (800-766-7000)
- Part 15-078-38; price $131.49 plus shipping
- Part 15-077-14; price $111.15 plus shipping

Data Logger-Type Temperature Recorders
Dickson Company (800-323-2448)
- Part SM325 (LCD Display Temperature Data Logger w/ 2 K-thermocouple probes); price $399 plus shipping
- Also order software to download information to computer ($79)

Wick Material
- Round cotton bootlace (pictured in this document) - available at many general stores • Wet-bulb wick ($50-$60 per spool http://www.wickstore.com/wetbulbwick.html)

- Wet-bulb sock: Alkar, part #50040; price $127.00 for bundle of 100 (608-592-4865)

**The items and suppliers listed here are suggestions only, based on price and availability. The mention of particular suppliers is not meant to exclude others from consideration.*

For more information contact:

Steve Ingham, Extension Food Safety Specialist (608) 265-4801, scingham@wisc.edu

May, 2006

The University of Wisconsin-Madison Center for Meat Process Validation provides science-based HACCP support to small meat processors in meeting state and federal mandates for safe food processing and handling. For more information on the Center contact Dr. Steve Ingham, 1605 Linden Drive, UW-Madison, Madison, WI 53706 (608) 265-4801 Email: scingham@wisc.edu

Cooking Program and Recorder Chart Courtesy of: Dr. Jeff J. Sindelar; Meat Science & Muscle Biology Lab, University of Wisconsin-Madison & Robert Hanson; HansonTech, LLC

Attachment 4: Example Time-Temperature Recorder Chart to Support Option to Continuously Inject Steam

The chart on the next page illustrates and supports that steam is being continuously introduced into the smokehouse for at least 50% of the cooking time but in no case for less than one hour per *Appendix A*. The smokehouse schedule is provided for reference below. As can be seen on the recorder chart, during the cooking time (that is the first hour of the process), the wet bulb rises while humidity (in the form of steam) is continuously injected. The process eventually achieves and maintains a wet bulb of 150°F, which at a dry bulb temperature of 170°F equates to a relative humidity of 59%. The process targets an internal product temperature of 145°F for 4 minutes per *Appendix A*.

Cooking program for beef jerky

Stage	Type	Time	Dry Bulb	Wet Bulb	Dampers	Notes
1	Cook	60 min	170°F	150°F	Closed	Humidity continuously injected
2	Dry	120 min	150	---	Closed	
3	Dry	80 min (to a_w)	150	---	Open	

In addition to supporting that steam is being continuously introduced, the chart provides a good illustration of why wet bulb temperature is a better indicator of product internal temperature than dry bulb temperature. As can be seen on the chart, the product internal temperature (shown by the yellow line), follows the wet bulb temperature (shown by the blue line) more closely than the dry bulb temperature (shown by the dark red line) during the lethality treatment. Towards the end of the process, the product internal temperature breaks above the wet bulb temperature and rises towards the dry bulb temperature as a result of diminishing evaporative cooling of the jerky that occurs because the product is drying out (i.e., moisture has been lost) (Buege et al., 2006a).

Cooking Program and Recorder Chart Courtesy of: Dr. Jeff J. Sindelar; Meat Science & Muscle Biology Lab, University of Wisconsin-Madison & Robert Hanson; HansonTech, LLC