Revised Appendices A & B
Update

Jeff J. Sindelar, Ph.D.
University of Wisconsin
Topics for Discussion

• Review & background of Appendices A & B thermal processing and stabilization guidelines

• Revised Appendices A & B documents
  • Changes in revised versions
  • Responses from stakeholders
Review & Background of USDA, FSIS Appendices A & B
Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products --- January 1999

Fate of *Salmonella* Inoculated into Beef for Cooking

S. J. GOODFELLOW* and W. L. BROWN

*American Bacteriological and Chemical Research Corporation*

*P.O. Box 1557, Gainesville, Florida 32602*

*(Received for publication April 17, 1978)*

*Marketing Institute, the National Association of Meat Purveyors and the Greater New York Association of Meat and Poultry Dealers. Appreciation is extended to Dr. J. Bacus and Dr. J. Oblinger for their critical evaluation of this work.*
USDA, FSIS Appendix A
Components

- Lethality (internal)
  - Time/temperature tables

<table>
<thead>
<tr>
<th>Degrees Fahrenheit</th>
<th>Degrees Centigrade</th>
<th>6.5-log₁₀ Lethality</th>
<th>7-log₁₀ Lethality</th>
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<tr>
<td>160</td>
<td>71.1</td>
<td>0 sec.**</td>
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</tr>
</tbody>
</table>
USDA, FSIS Appendix A
Components

- Relative humidity requirement
  - With exceptions (i.e. casing, size)

“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; or…”
USDA, FSIS Appendix A
Components

- Slow come-up time

- “Dwell times of greater than 6 hours in the 50°F to 130°F range should be viewed as especially hazardous, as this temperature range can foster substantial growth of many pathogens of concern”
1. D-value generation
   • 1 gram inoculated meat samples placed in test-tubes immersed in water baths at 125, 135, and 145°F

2. Validation
   • Dialysis tubing technique
   • Temperature collection
   • Beef rounds
   • Water cooked (165°F)
1. IT= 125°F
2. IT= 125°F for 1 hour
3. IT= 125°F for 3 hours
4. IT= 125°F for 5 hours
5. IT= 125°F for 7 hours
6. IT= 130°F
7. IT= 130°F for 10 minutes
8. IT= 130°F for 30 minutes
9. IT= 130°F for 1 hour
10. IT= 130°F for 2 hours
11. IT= 135°F
12. IT= 135°F for 3 minutes
13. IT= 135°F for 6 minutes
14. IT= 135°F for 10 minutes
15. IT= 135°F for 20 minutes
16. IT= 140°F
17. IT= 145°F
3. Surface lethality

- **Dry roasting experiments**
  - Surface inoculated with Salmonella
  - Commercial kitchen oven (Frigidaire) at 200, 225, and 275°F
  - Sampling when *surface* temperature reached 125, 130, and 135°F

- **Mixed steam injected-dry roasting experiments**
  - Single truck batch oven (Vortron)
  - TRT 1: steam injected during first 30 minutes
  - TRT 2: steam injected the last 30 minutes
  - Product temperature collected
  - *Surface* samples collected when *internal* temperature reached 120, 125, 130, and 135°F
Goodfellow & Brown

D-Value Results

- D-value generation
  - Thermal death curves were developed
  - Z-values generated

Figure 1. Thermal death curve of Salmonella in ground meat at 125°F (51.6°C).
Goodfellow & Brown
Validation Results

• Validation (internal)
• 125°F was marginal (survivors after 7 hours)
• 130°F = 7-log reduction if held between 30 and 60 minutes
• 135°F = 7-log reduction if held 3 minutes
• 140°F and 145°F = instantaneous 7-log reduction

• Integrated lethality added margin of safety

TABLE 5. Processing times required for a 7-D kill of Salmonella in cooked beef at various temperatures.

<table>
<thead>
<tr>
<th>Internal Temperature, F</th>
<th>Processing time - Min\textsuperscript{a}</th>
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<tbody>
<tr>
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<td>129</td>
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<td>143</td>
<td>6</td>
</tr>
<tr>
<td>144</td>
<td>5</td>
</tr>
</tbody>
</table>

\textsuperscript{a}D-values employed in calculating processing times were taken from regression line curve provided by the USDA Statistical Division based on submitted data.
Goodfellow & Brown
Surface Lethality Results

- **Dry roasting experiments**
  - Confirmed USDA preliminary data of 175°F roasting was not sufficient
    - Relative humidity (RH) was 0.02%
    - Postulated survival was a result of rapid dehydration creating heat resistance
  - Concluded surface lethality could be achieved if 1) oven and internal finished product temperatures were high enough and 2) product size was large enough
    - Higher roasting and internal temperatures showed increased efficacy
Goodfellow & Brown
Surface Lethality Results

- Mixed steam injected-dry roasting experiments
  - Injection of steam for >30 minutes eliminated Salmonella
    - The point in process wasn’t significantly different
    - Attributed to the “injection of steam”
  - A “very high humidity level” experiment was found to be very effective
    - Level was not measured
USDA, FSIS Appendix B

- Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization) --- January 1999
  - USDA, FSIS has provide guidance for controlling *Clostridium perfringens* since 1985
  - Very low (and sporadic) occurrence of illness from products produced in inspected facilities
  - Very little science and heavy use of baseline data collection and statistical evaluation
  - No more than 1-log growth increase allowed during cooling
How $1\log_{10}$ was established – the approach

- $\geq 6 \log_{10} C. perfringen$ levels are needed to cause illness
- CDC considers viable counts of $5 \log_{10} C. perfringens$ for incriminating a food
- USDA, FSIS Microbiological survey data suggested approximately $4 \log_{10}$/gram is present on meat/poultry
- If cooling results in $1 \log_{10}$ growth, there could be a small percentage of samples with $> 5 \log_{10}$ of $C. perfringens$
- Applying a 1-log theoretical growth (to reach $6 \log_{10}$) established a “no more than $1\log_{10}$ growth” parameter
How $1-\log_{10}$ was established – potential flaws

- Data was collected on raw samples and applied to cooked products
- Baseline studies did not differentiate between vegetative cells and spores
- The microbiological method did not provide confirmation of *C. perfringens*
  - The actual number of *C. perfringens* on the raw samples was not known.
- An overestimation likely occurred resulting in very conservative cooling parameters
Updated Compliance Guidelines for Cooking (Appendix A) and Cooling (Appendix B)

• FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B --- June 2017
Revised Appendix A

• Notable changes
  • “When heating meat or poultry products of any size when the cooking time is less than 1 hour to any internal temperature and time combinations in Appendix A, the Poultry Time-Temperature Tables, and the 5-log table the Relative humidity of the oven is maintained at 90 percent for the entire cooking time.”
  • Relative humidity requirements only applicable to semi-permeable or impermeable casings
Impingement Oven Example
(HansonTech, 2018)

Buffalo wings cooked in an impingement oven
High-temperature impingment process    Relative humidity < 5.0%

HansonTech LLC Jan-2017

Process < 1 hour & <90% RH (5% actual)
Notable changes

- Option 2: $120^\circ F$ to $80^\circ F < 1.0$ hours & $80^\circ F$ to $40^\circ F$ in $< 5.0$ hours
  - Replaced $120^\circ F$ to $55^\circ F < 6.0$ hours
  - Thermodynamically impossibly to achieve for many products thicker than 4.5 inches

- Partially cooked products must be cooled using Option 1 (130°F to 80°F < 1.5 hours & 80°F to 40°F in < 4.0 hours)

- Products containing a minimum of 100 ppm sodium nitrite and 250 ppm ascorbate or erythorbate (regardless of source) can be chilled using the following parameters:
  - 130°F to 80°F < 5.0 hours & 80°F to 40°F in < 10.0 hours
Non-cured Roast Beef Example
(HansonTech, 2018)

Cooling data for non-cured roast beef
HansonTech 09-Nov-2016

<table>
<thead>
<tr>
<th>Cooling Times</th>
<th>130 to 80°F</th>
<th>120 to 80°F</th>
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</thead>
<tbody>
<tr>
<td>Appendix B, new</td>
<td>1.5 hr</td>
<td>1.0 hr</td>
</tr>
<tr>
<td>Actual cooling time</td>
<td>2.58 hr</td>
<td>1.95 hr</td>
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</table>

**Observations:** This product fails both Options 1 and 2. Cooler temperature was 0 to -10°F, which cooled the product as fast as thermodynamically possible. A brand new chiller will not cool it any faster. The new FSIS requirements for Options 1 and 2 are thermodynamically impossible for this product.
Appendices A & B Implementation

- Updated Appendix A & B released June 2017
- Comment period Fall of 2017
- Delay implementation announced March 2018
  - FSIS Notice 17-18
  - New implementation date of March 2019
  - USDA, FSIS agreed to meet with non-industry experts to discuss 2017 versions of Appendix A & B
Responses from Stakeholders
Formation of NAMI Appendices A & B Working Group

- Organized group during Spring 2018

- Composed of
  - Core working group members (academic scientists & consultants)
  - Industry advisory group (food safety & regulatory experts)
  - Association partners

- Purpose:
  - Review the revised version of Appendices A and B along with the issues identified in the industry and help determine possible solutions.
Core Working Group Members

- Jonathan Campbell – Pennsylvania State University
- Jim Dickson – Iowa State University
- Kerri Gehring – Texas A & M University
- Kathy Glass – University of Wisconsin-Madison
- Bob Hanson – HansonTech
- Dana Hanson – North Carolina State University
- Margaret Hardin – IEH Laboratories
- John Henson – California State University-Fresno
- Andy Milkowski – University of Wisconsin-Madison
- Jeff Sindelar – University of Wisconsin-Madison
- Peter Taormina – Etna Consulting Group
- Bruce Tompkin – Retired/Consultant
Industry Advisory Group

- Aaron Asmus – Hormel
- Larry Epling – Case Farms
- Dan Etzler – Cargill
- Alison Griffino – Tyson Foods
- Nancy Gushing – Ok Foods
- Barry Hays – Bar S
- Jeremiah Johnson – Hormel
- Kristin Lindahl – Cargill
- Tina Rendon – Pilgrims
Association Partners

- Jonathan Campbell – Eastern State Meat Packers
- Joe Harris – Southwest Meat Association
- Lisa Picard – National Turkey Federation
- Ashley Peterson – National Chicken Council
- KatieRose McCullough – North American Meat Institute
- Rafael Rivera – US Poultry and Egg
- Kristen Spotz – Grocery Manufacturers Association
- Jessica Watson – National Cattleman’s Beef Association
- Chris Young – American Association of Meat Processors
NAMI Appendices A&B Working Group Activity

- First meeting (conference call) on May 11, 2018
- Several conference calls/emails/correspondences
- Review/discussion of historic and current regulatory and scientific documentation
- Electronic file sharing system established
- Participated in USDA, FSIS / Working Group meeting
  - July 30, 2018
NAMI Foundation for Meat and Poultry Research and Education
“mini grants”

• Three funded (January 31, 2019 final reports due)
  1. Effects of Product Moisture and Process Humidity on Pathogen Lethality during Continuous Cooking of Meat and Poultry Products
  2. Validating growth models for *Clostridium perfringens*, *Clostridium botulinum*, and *Bacillus cereus* during cooling of uncured meat and poultry products
Appendices A and B Industry Scientific Work Group and USDA Meeting

Agenda

July 30 at 1 pm to 4 pm

Purpose: The purpose of this meeting is to provide a brief history of the information on the studies used to write the 1999 versions of Appendices A and B as well as the information used to signal the 2017 update. Additionally, the purpose of the meeting is to share information on current efforts being undertaken by both Industry and USDA regarding Appendices A and B.

Objective: Ensure both FSIS and Industry are effectively sharing information regarding potential changes or suggested changes to the 2017 versions of Appendices A and B and discuss future actions for both the Working Group and FSIS moving forward.

Agenda:

I. Welcome and Introductions — Roberta and Katie Rose
   a. USDA Personnel
   b. Industry Working Group
II. Brief History of Appendix A and B — FSIS Perspective — Meryl Silverman
III. Scientific Gaps Identified by FSIS — Meryl Silverman
IV. Research Gaps and Problematic Areas — Working Group — Discussion Led by Jeff Sindelar
   a. Appendix A
   b. Background on 1999 Appendix B — Working Group — Bruce Tompkin
   c. Appendix B
   d. Bacillus cereus
V. On-Going Efforts — FSIS
VI. On Going Efforts and Overview of Recently Funded Projects to Address Gaps — Working Group
   — Pi’s of Projects and/or NAMI/US Poultry (co-funders)
VII. Next Steps — Working Group and USDA
7/30 Meeting Attendees

- Jonathan Campbell – Pennsylvania State University/Eastern State Meat Packers
- Bob Hanson – Hanson Tech Consulting
- Kathy Glass – University of Wisconsin
- Jeff Sindelar – University of Wisconsin
- Bruce Tompkin – Retired/Consultant
- Andy Milkowski – University of Wisconsin
- Aaron Asmus – Hormel
- Alison Griffino – Tyson
- Barry Hays – Bar S
- Dan Etzler – Cargill
- Kristin Lindahl – Cargill
- Ashley Peterson – National Chicken Council
- Nelson Gaydos – American Association of Meat Processors
- Joe Harris – Southwest Meat Association
- KatieRose McCullough – North American Meat Institute
- Kristen Spotz – Grocery Manufacturers Association
- Lisa Picard – National Turkey Federation
- Roberta Wagner – FSIS
- Bill Shaw – FSIS
- Anna Porto-Fett – ARS
- John Luchansky – ARS
- Denise Eblen – FSIS
- Evelyne Mbandi – FSIS
- Johnathan Huang – FSIS
- Jude Smedra – FSIS
- Kevin Dutch – FSIS
- Kis Robertson – FSIS
- Kristina Barlow – FSIS
- Meryl Silverman – FSIS
- Michael Updike – FSIS
- Rachel Edelstein – FSIS
- Sharon Costley – FSIS
- Susan Hammonds – FSIS
- Tim Mohr – FSIS
- Udit Minocha – FSIS
USDA, FSIS Identified Scientific Gaps & Possible Solutions

• Some products can’t meeting cooling limits in Appendix B
  • **Options 1-4:** As listed in 2017 Stabilization Guideline
  • **Option 5:** Any pH; 130°F to 80°F in 2 h; to 40 °F ≤ 7 h total
  • **Option 6:** Any pH; 126°F to 80°F in 1.75 h; to 55 °F ≤ 6 h total
  • **Option 7:** pH ≤6.0; 126°F to 80°F in 2.25 h; to 55 °F ≤ 6 h total
  • **Option 8:** pH ≤5.8; 126°F to 80°F in 2.75 h; to 55 °F ≤ 6 h total
  • **Option 9:** Partially cooked products CUT ≤ 3 hour + 2% salt + 150 ppm nitrite + erythorbate; to 40 °F ≤ 6.5 h total

• Physiochemical e.g. (pH, salt, etc.) impact on cooling
  • Computer modeling
USDA, FSIS Open Research Gaps

- Support for short-time, high-temperature cooking
  - Validated methods to measure moisture and
  - Validated temperature, time, and moisture parameters.

- Support for lethality treatments for baked goods cooked with raw meat and poultry components where relative humidity in the cooking environment is not desired.

- Support for the conditions that impact when and how natural casings begin maintaining sufficient moisture to ensure product lethality using FSIS time and temperature tables without addressing relative humidity.

- Support for extended come-up and come-down time for partially heat treated smoked products other than bacon (e.g., hams and sausages) and identification of the active constituents in liquid smoke and natural smoke.
Working Group Identified Scientific Gaps & Possible Solutions for Appendix A
Desiccated Salmonella
(HansonTech, 2018)

FSIS Appendix A (2017) — Humidity Options

If $IT > 145^\circ F$ and cooking time $> 60$ minutes, then —

Option 1. Steam injection for 50% of time, or 1 hr

Option 2. Sealed oven capable of maintaining humidity level for 50% of time, or 1 hr

Option 3. Humidity $\geq 90\%$ for 25% of time, or 1 hr

If $IT < 145^\circ F$ and cooking time $> 60$ minutes, then —

Option 4. Maintain humidity $\geq 90\%$ for 25% of time, or 1 hr

If cooking time $< 60$ minutes, then —

Option 5. Maintain humidity $\geq 90\%$ for the entire time
Preventing desiccation

Appendix A: Situations where humidity is not needed

1. Water or steam cook
2. Impermeable bag
3. Direct contact or flame heat
4. Impermeable or semi-permeable casing
5. Beef patties
**The Problem: Heat Tolerance of Desiccated Pathogens** *(HansonTech, 2018)*

**Effect of desiccation on heat tolerance of *Salmonella enterica***

Average numbers of cells that survived exposure to 140, 176, or 212°F for 60 minutes

(adapted from Gruzdev et al, 2011)

<table>
<thead>
<tr>
<th>Temperature (°F)</th>
<th>Non-desiccated</th>
<th>Rehydrated</th>
<th>Desiccated</th>
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<tbody>
<tr>
<td>140</td>
<td>6</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>176</td>
<td>7</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>212</td>
<td></td>
<td></td>
<td>No detectable survivors</td>
</tr>
</tbody>
</table>
Surface Lethality Step (SLS)

Chicken tenders (3% fat) cooked in impingement oven -- Surface Lethality Step
(adapted from Sindelar et al, 2016)

Survivors = 3.4 logs

Surface was dehydrated early in process.

Surface was not re-hydrated in SLS step.
Roasted chicken wings cooked in JSO impingement oven

HansonTech 10-Jan-2018

Option 5: If cooking time is less than 1 hr, RH must be 90% for entire cook

Process: RH = 2% (PsyCalc)
Possible Solutions: Defining the Problem

- Two requirements to assure surface lethality:
  - Heat the surface to a lethal time-temperature combination
  - Surface must be hydrated during the lethal time-temperature period

- How can you tell if the surface is hydrated?
  - During steam cooking, the surface will be hydrated
  - During dry cooking, you can compare the surface temperature to the wet-bulb temperature to tell if the surface is wet or dry
    - If the surface is hydrated, the wet bulb temperature remains at (or higher) than the surface temperature
Smokehouse: Steam Cook Lethality Step (HansonTech, 2018)

Netted hams cooked in forced-air smokehouse
Pre-smoked-nets, 5.1" diameter, football-shape

Steam Cook Lethality Step
- 50 minutes @ 178°F steam
Impingement: Hydrated Surface Lethality Step (HansonTech, 2018)

Roasted chicken wings cooked in JSO impingement oven

HSL time = 3.5 minutes

Hydrated Surface Lethality Time = 3.5 min

HSL option: The surface temperature achieved 158°F before exceeding the wet-bulb temperature.
Alternative Ideas (Proposed)

If IT > 145°F and cooking time > 60 minutes, then —

Option 1. Steam injection for 50% of time, or 1 hr

Option 2. Sealed oven capable of maintaining humidity level for 50% of time, or 1 hr

Option 3. Humidity ≥ 90% for 25% of time, or 1 hr

Steam Cook Lethality Step

Option X. Use steam-cook lethality step where the steam temperature is maintained for the time-temperatures listed in Appendix A.

Hydrated Surface Lethality Step

Option Y. Use a hydrated-surface lethality step where the surface temperature is maintained at the time-temperatures listed in Appendix A without exceeding the wet-bulb temperature.
Working Group Identified Scientific Gaps & Possible Solutions for Appendix B
Compilation of Cooling Times for Large Non-cured Meat and Poultry Products

<table>
<thead>
<tr>
<th>Product</th>
<th>130 to 80°F</th>
<th>Appendix B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dome breast</td>
<td>3.03 h</td>
<td>1.5 h</td>
</tr>
<tr>
<td>Pan breast</td>
<td>2.2 h</td>
<td></td>
</tr>
<tr>
<td>Roast beef</td>
<td>2.25 h</td>
<td></td>
</tr>
<tr>
<td>Roast beef</td>
<td>1.8 h</td>
<td></td>
</tr>
<tr>
<td>Roast beef</td>
<td>2.6 h</td>
<td></td>
</tr>
<tr>
<td>Dome breast</td>
<td>1.9 h</td>
<td></td>
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<tr>
<td>(Marlen)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dome breast</td>
<td>2.9 h</td>
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<td>(Marlen)</td>
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</tr>
<tr>
<td>Whole tom</td>
<td>1.82 h</td>
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Appendix B Talking Points

• The rate of chilling required to meet new guidelines is thermodynamically impossible for large products

• Is limitation for 1-log growth an appropriate and necessary target?

• Will millions of dollars of chiller upgrades advance food safety?

• For many products, upgraded chillers will still not meet the new compliance guidelines

• For small and very small, the cost will be too high, so whole product categories will have to be eliminated
Working Group / USDA, FSIS
Action Steps

- **Follow Up Letters**
  - Association
  - Core Working Group

- **Additional engagement/working meetings (suggested)**
  - Appendix A – Surface lethality and casing
  - Appendix B – Extended cooling of large diameter products, *C. perfringens* baseline, partially heat treated items.
  - *Bacillus cereus*
  - Presentation of research projects – 3 Recently Funded and the Slow Come Up Time Work (ISU/UW)
  - Final presentation of suggestions
Working Group / USDA, FSIS

Action Steps

• *Clostridium perfringens* baseline study
  • Identify appropriate methodology
  • Collect baseline data from industry establishments willing to share

• Continued conference calls (every 2-3 weeks)

• Proposed additional delay of implementation (if needed)
Questions?