

One Team, One Purpose



Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



The Stabilization of Cooked/Heat-Treated Meat and Poultry Products and the Use of Cooling Models

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FSIS performs approximately 190,000 scientific analyses every year.

Public Health Science Employees:

- Assist in investigating national and international outbreaks
- Monitor current and emerging foodborne threats
- Advise leadership on matters of science to improve policies and program







Topics to be Covered – Part 1

- Hazard Analysis
 - Hazard Identification
 - Hazard Evaluation
- HACCP System Design
 - Critical Limit Development
 - Scientific Support
- Corrective Actions
 - Support for Product Safety

Topics to be Covered – Part 2

- Available Cooling Models
- General Comments on Cooling Models
- Product's Time/Temp Profile Shape and Cp Growth
- Using Cooling Models in HACCP Plans/Food Safety System
- Cooling Models and Product Safety: Two Scenarios
- Cp Growth: Final Comments

Hazard Analysis

- Every establishment must conduct a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process (9 CFR 417.2(a));
- Hazard analysis process includes multiple stages:
 - Hazard Evaluation
 - Hazard Identification

Hazard Identification

- Establishment's HACCP team assembles or reviews information about:
 - Raw materials and/or ingredients used in the product,
 - Activities conducted at each step in the process,
 - Equipment used to make the product,
 - Type(s) of packaging and packaging material,
 - Method(s) of storage and distribution, and the
 - Intended use and consumers of the product

Hazard Identification - Stabilization (Cooling)

- Lethality treatment kills vegetative cells, but spores may survive
- During stabilization (cooling), spores may germinate and grow
- Spore-formers of concern in meat and poultry products include:
 - Clostridium botulinum
 - Clostridium perfringens
 - Bacillus cereus
- *C. perfringens* is the target, because the other pathogens grow more slowly

Clostridia Is a Concern in:

- Meat and poultry products including roast beef, gravies, and poultry products cooked in large batches (*C. perfringens* and *C. botulinum*)
- Improperly canned low acid foods (*C. botulinum*)
- Raw honey (*C. botulinum*)
- Fermented, smoked, and salted seafood (*C. botulinum*)

Clostridia

- Gram positive, rod-shaped spore forming bacteria
 - Vegetative cells: active cells that can grow and produce toxin
 - Spore: dormant cells that are resistant to heat and other extreme conditions



Clostridia

- Commonly found in soil and water
- Anaerobic organisms (grow without oxygen)
 Micro-aerotolerant

 Clostridia do not grow well with normal amounts of oxygen present in the atmosphere; however, they do not need a complete lack of oxygen

Hazard Evaluation

- After an establishment has identified one or more hazards in its process it evaluates the hazards to:
 - Assess severity of health consequences if potential hazard is not properly controlled,
 - Determine likelihood of occurrence of potential hazard if not properly controlled, and
 - Using this information, determine if this potential hazard is to be addressed in the HACCP plan

Foodborne Illnesses Associated with C. perfringens

- Estimated mean domestic:
 - Illnesses: 965,958
 - Hospitalizations: 438
 - Deaths: 26
- Illnesses are largely attributed to food served at institutions/events and not FSIS regulated products
- Toxin release as bacteria make spores in the gut leads to diarrhea, abdominal cramps, vomiting, and fever
- Illness onset: 8 to 18 hours
- <u>High</u> Infectious Dose: 10⁶ CFU

Levels of Concern for C. perfringens Illness

- The critical level for human illness is <u>high</u>: 6 logs/gram or higher
- <u>Maximum</u> levels of *C. perfringens* spores usually found in raw meat and poultry are usually 2-3 logs/gram
- Therefore, conditions that allow for 3-log growth or higher may be a public health concern

(ICMSF, 1996 and in-plant data)

Number of foodborne illnesses associated with *C. botulinum*

- Estimated mean domestic:
 - Illnesses: 55
 - Hospitalizations: 42
 - Deaths: 9
- Illnesses primarily attributed to improper canning of low acid canned foods
- Preformed neurotoxin mediated leads to muscle paralysis and suffocation
- Illness onset: 12 to 36 hours
- Infectious dose: As little as 1 ng/kg of body

How do Meat and Poultry Products Become Contaminated?

- Slaughter/dressing.
- Exposure to contamination from the environment during processing (insanitary conditions).
- Ingredients added during formulation (e.g., spices and herbs).

Pathways to Growth

- Most outbreaks are from food served in restaurants, homes for the elderly, or at large gatherings (referred to as the "food service germ")
 - Held at room temperature for too long
 - Often cooled in large batches increasing the cooling rate
- While thermal processing of meat products should be sufficient to destroy vegetative cells, spores may survive cooking and multiply during prolonged cooling or poor hot holding

Control Measures for *C. perfringens* and *C. botulinum* Growth

- Limiting the amount of time products are held at temperatures conducive to growth is the primary means of control that establishments use to ensure spores do not germinate and grow to high levels
 - C. perfringens growth limit: 10°C and 52°C (50°F and 126°F)
 - C. botulinum growth limit: 10°C and 50 °C (50 °F and 122 °F)

HACCP System Design -Establishing Critical Limits

- A food safety hazard that is reasonably likely to occur (RLTO) is one for which a prudent establishment would establish controls (9 CFR 417.2(a))
- Establishments must list the critical control points (CCPs) for each food safety hazard identified and must list the critical limits that must be met at each CCP (9 CFR 417.2(c)(2) and 9 CFR 417.2(c)(3)

Establishing Critical Limits – The Role of FSIS Performance Standards

- Critical limits incorporated into the establishment's HACCP plan must at a minimum assure that any performance standard established by FSIS pertaining to the product it produces is met (9 CFR 417.2(c)(3))
- For certain ready-to-eat (RTE) products, FSIS has established regulatory performance standards because they have a higher public health risk

Stabilization (Cooling) Performance Standard

- For cooked beef, roast beef, cooked corned beef, cooked meat patties
 (318.17(a)(2) and 318.23(c)(1)), partially cooked meat patties, char-marked meat
 patties (318.23(c)(1)), and fully cooked poultry products, partially cooked poultry
 breakfast strips, partially cooked small mass poultry products (318.150(b)), during
 cooling, the critical limit must be designed such that:
 - There can be no multiplication (growth) of toxigenic microorganisms such as *C. botulinum*, and
 - No more than a 1-log₁₀ multiplication (growth) of *C. perfringens* within the finished product

Other Products

- For products that do not fall under the performance standards, the Agency guidance is that the critical limit should be designed so that:
 - There can be no multiplication (growth) of toxigenic microorganisms, such as *C. botulinum*, and
 - No more than a 1-log₁₀ multiplication (growth) of *C. perfringens* within the finished product

HACCP System Design -Pre-requisite Programs

- An establishment may determine that biological hazards are NRLTO at the stabilization (cooling) step due to the implementation of a pre requisite program.
- To support this decision (9 CFR 417.5(a)(1), the pre-requisite program must meet four characteristics:
 - The program is written and describes procedures that the establishment will implement to show the hazard is not reasonably likely to occur.
 - The program describes records that the establishment will keep to demonstrate that the program is being implemented as written.
 - The program describes records the establishment will keep to demonstrate the program effectively prevents the hazard.
 - The program describes actions the establishment will take when it fails to implement the program, or when it finds the program has failed to prevent the hazard.

Scientific Support that can be use to Develop Critical Limits

- FSIS Guidance (Appendix B)
- Journal Articles
- Challenge Studies
- Validated Cooling Models

FSIS Guidance: Appendix B

- Option 1
 - Internal temperature:
 - -130-80 °F ≤ 1.5 hours (optimum growth range)
 - 80 40 °F \leq 5 hours
- Option 2
 - Chilling within 90 minutes of cooking
 - Internal temperature:
 - 120 55 °F \leq 6 hours
 - 120 80 °F \le 1 hr (optimum growth range)
 - Less than 40 °F before shipping
- Option 3
 - FOR NITRITE (i.e., ≥ 100 ppm) CONTAINING PRODUCTS ONLY
 - Internal temperature:
 - 130 80 °F \leq 5 hrs (optimum growth range)
 - 80 45 °F \leq 10 hrs

Additional Heating and Cooling Steps

 When a process has more than one heating and cooling step and the heating step does not achieve complete lethality of all vegetative cells, the cumulative growth of *C. perfringens* cannot be more than 1-log₁₀

Corrective Actions - Cooling Deviations

- In the event of a deviation, the establishment must ensure (9 CFR 417.3(a)):
 - The cause of the deviation is identified and eliminated;
 - The CCP will be under control after the corrective action is taken;
 - Measures to prevent recurrence are established; and
 - No product that is injurious to health enters commerce.

What should establishments consider to ensure product safety?

- That levels of *C. perfringens* and *C. botulinum* that would not be injurious to health
- After a deviation, different factors are considered than those used to design the HACCP system
- Establishments can support releasing product that does not meet the performance standard following a cooling deviation, however, noncompliance with the performance standard may still exist (if applicable)

What support can an establishments use to demonstrate product safety?

- It is up to the establishment to determine disposition and support the safety of their products
- Product <u>on-hold</u> may be salvaged (released as is, recooked, or condemned depending on the results) using:
 - Pathogen modeling programs
 - Past cooling deviations
 - Current cooling deviations
 - Other scientific supporting documentation
 - Sampling

Agency Policy Concerning *C. perfringens* and *C. botulinum* Levels

- Based on modeling and/or sampling:
 - If no more than 1 log growth of *C. perfringens* and no *C. botulinum* growth (mean net growth ≤ 0.30 log), then the process meets the stabilization performance standard or Agency policy and the product can be released.
 - If there is greater than a 1 log growth of *C. perfringens* <u>and > 0.30 log</u>
 <u>increase of *C. botulinum*</u>, then the product should be destroyed

Agency Policy Concerning C. perfringens and C. botulinum Levels

- Based on modeling and/or sampling:
 - If there is more than a 1 log growth of *C. perfringens* and no *C.* <u>botulinum growth</u> (mean net growth ≤ 0.30 log), then product may be either:
 - \circ Recooked or
 - \circ Microbiologically tested (N \geq 10) or
 - o Destroyed
 - Establishments may also be able to support <u>release</u> of product if other supporting documentation is provided

What types of scientific support can be provided?

- Modeling results and/or sampling
- Documentation addressing:
 - Were antimicrobials used in the formulations? Models generally do not take into account the effect of lactate/diacetate and other antimicrobials.
 - Were raw materials produced under good manufacturing practices?
 - Did the plant have operational sanitation issues?
 - Is the product RTE or NRTE?
 - Will the product receive an additional lethality treatment?
 - Is the product post-lethality exposed?
 - What were the packaging materials?
 - Does the establishment have in-plant data showing routine levels of *C. perfringens* in their products is low?
 - Does the product go to institutions?

Why can this type of support be used?

- The performance standard requires ≤ 1 log growth of *C. perfringens* in certain meat and poultry products but critical level for human illness is <u>high</u>: ≥ 6 logs/gram
- So while the establishment may not be in compliance with the standard they may be able to support product safety as they work through all parts of corrective actions
- Product risk depends on raw materials and exposure to contamination from the environment as well as how it is handled after leaving the establishment

Stabilization Policy

- Regulatory requirements and policy related to stabilization will continue to change
- If you have questions regarding cooling deviations or the use of a pathogen modeling program submit them through askFSIS (<u>http://askfsis.custhelp.com</u>)

Key Take Away Points

- *C. perfringens* and *C. botulinum* are hazards of concern in processed meat and poultry products, however, most common pathway for *C. perfringens* illness is at institutions/events
- *C. perfringens* has a high critical level for human illness 6 logs/gram or higher
- Establishments can support releasing product that does not meet the performance standard following a cooling deviation, however, noncompliance with the performance standard may still exist (if applicable)
- Use askFSIS if you need assistance

Evaluating Cooling Deviations Using Predictive Microbial Models

- Valuable tools for establishments evaluating the relative severity of problems caused by process deviations
- It is not possible or appropriate to rely solely upon a predictive microbial model to determine the safety of foods and processing systems unless the model has been validated for the product and process in question

Cooling Models Available

- Cooling Models currently available:
 - ARS PMP 7.0 Cooling Models
 - ARS Predictive Microbiology Information Portal (PMIP)
 - Cooling of cooked uncured beef, pork, and chicken and cooked cured pork
 - UK IFR ComBase *Perfringens* Predictor Model
 - Smith-Schaffner Model version #3

Cooling Models

- Websites with free cooling models:
 - <u>http://ars.usda.gov/Services/docs.htm?docid=6786</u>
 - <u>http://portal.arserrc.gov/</u>
 - <u>http://www.ifr.ac.uk/safety/growthpredictor/</u>
 - <u>http://foodsci.rutgers.edu/schaffner/files.htm</u>

PMP 7.0 C. perfringens in beef broth model

- Consistently under predicts *C. perfringens* growth (1 to 3 log CFU/ml)
- Not validated for cooked, uncured meat and poultry products
- Results may be used in combination with other scientific supporting documentation (for example, in-plant data showing *C. perfringens* in their finished products is low, etc.)



Proteolytic *Clostridium botulinum* in Beef Broth *Clostridium perfringens* in Beef Broth *Clostridium perfringens* – Cooling Cured Beef *Clostridium perfringens* – Cooling Cured Chicken

ARS PMP 7.0 Cooling Model's Requirements

 When entering cooling profile data, you must enter time in hours (e.g., 15 minutes = 0.25 hours)

 Temperature data is to be entered in the appropriate column as either °C or °F (conversions are automatic)

ARS PMP 7.0 Cooling Model's Requirements

- When applying these predictions to foods, a minimum of 5 time-temperature combinations must be measured, with 3 or more above 70° F (21° C)
 - At least 5 time-temperature combinations are needed to sufficiently define the shape of cooked product cooling profile.
 - The shape of cooked product cooling profile impacts on the amount of growth of *C. perfringens* and *C. botulinum*

The PMIP C. perfringens Models

- For the cooling of cooked, uncured beef, pork, and chicken
 - Analysis shows that these three cooling models significantly over predicts the growth of *C. perfringens* that occurs in cooked, uncured meat and poultry products
 - These models are all considered validated for predicting the growth of *C. perfringens* in cooked or heat-treated uncured meat and poultry products

PMIP Cooling Model – Cooked, Uncured Beef



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The other PMP & PMIP Cooling Models

- C. perfringens in cooked, cured beef, pork, and chicken – these models have not been validated and should not be used alone
- *C. botulinum* in beef broth
 - Only cooling model available for *C. botulinum*
 - The model has not been validated
 - The best tool available at this time
 - FSIS does not object to its use

The ComBase Perfringens Predictor Model

- Validated for cooked, cured and uncured meat and poultry products
- Provides a good estimation of the growth of *C.* perfringens in cooked, cured and uncured meat and poultry products

Food Safety and Inspection Service: Office of Public Health Science The ComBase Perfringens Predictor Model

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Note that the cured meat option should only be used provided the	initial concentration of sodium nitrite is 100 ppm or higher and the residual sodium nitrite concentration is 10 ppm or greater
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ComBase *Perfringens* Predictor Model's Requirements

- The time unit is hours, and the temperature unit is degrees centigrade (°C)
- A minimum of 5 and a maximum of 100 points (time versus temperature) records in the cooling profile
- The temperature values must be between 0 and 95°C
- The records must be recorded in chronological order
- The first time-point must be zero
- The final temperature must be less than 15°C.

The Smith-Schaffner Version #3 Model

- Analysis shows that this cooling model provides a reliable estimation of the growth of *C. perfringens* in cooked, uncured meat and poultry products
- Relatively high percentage of accurate and fail-safe predictions (Mohr et al, 2015)
- Considered validated for predicting the growth of C. perfringens in cooked or heat-treated uncured meat and poultry products

Food Safety and Inspection Service: Office of Public Health Science The Smith-Schaffner version #3 Model

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51	24.00	0 3.83	2.55	2.55	0.000	0.20	10.72	2.59	388.4										
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Cooling Profile

 The shape of a cooked product's cooling profile affects the amount of growth of *C. perfringens* and *C. botulinum* even though the beginning product temperature, ending product temperature and the chilling time is the same

Cooling/Growth Chart for Rapid Cooling



Cooling/Growth Chart for Slow Cooling



Cooling/Growth Chart for Very Slow Cooling



A Validated Cooling Model

- A valuable tool to support:
 - the selection of time and temperature critical limits at the cooling CCP, and
 - -corrective actions for a cooling process deviation

Cooling Models

- The cooling/growth model can be used for cooling deviations if:
 - The model is validated for the specific cooked RTE meat/poultry product; or
 - Other credible scientific documentation (e.g., finished product testing for *C. perfringens*) is provided to support modeling results if model is not validated

Cooling Deviation

- <u>Scenario #1:</u>
- The plant has a cooling CCP CL

"product's maximum internal temperature should not remain between 130° F and 80° F for more than 1.5 nor between 80° F and 40° F for more than 5 hours"

 For this cooling deviation, the cooked, uncured perishable product took 2 hours to reach an internal temperature of 80° F and then another 6 hours to reach an internal temperature of 40° F.

- <u>Scenario #1 (cont.):</u>
- The plant plans to use the validated ComBase *Perfringens* Predictor Model and the PMP 7.0 cooling model for *C. botulinum* to estimate the growth of *C. perfringens* and *C. botulinum*, respectively, that occurred in their affected product.
- The plant has documentation on the pH (6.2) and salt concentration (1%) for their affected product.

- <u>Scenario #1 (cont.):</u>
- The company recorded the following time/temp data as the product cooled down:

Time (Hr)	Temp (F)	Time (Hr)	Temp (F)	Time (Hr)	Temp (F)
0.0	130	2.0	80	6.0	50
0.5	110	3.0	71	7.0	45
1.0	95	4.0	63	8.0	40
1.5	85	5.0	56		

- <u>Scenario #1 -</u> Results from ComBase and PMP 7.0 Cooling Models
 - C. perfringens
 - Mean Net Growth = 0.75 log increase
 - C. botulinum
 - Mean Net Growth = 0.00 log increase
 - LCL Net Growth = 0.01 log increase
 - UCL Net Growth = 0.01 log increase

- <u>Scenario #1 Product Disposition</u>
- Product may be released without any further action because:
 - The predicted growth for *C. perfringens* is a 0.75 log increase which meets the Agency performance standard/policy of no more than 1.0 log increase for the pathogen; and
 - The predicted mean net growth for *C. botulinum* is 0.00 log which is not more than a 0.3 mean log increase indicating no multiplication of the pathogen thus meeting the Agency performance standard/policy

Cooling Deviation

- <u>Scenario #2:</u>
- The plant has a cooling CCP CL

"product's maximum internal temperature should not remain between 130° F and 80° F for more than 1.5, nor between 80° F and 40° F for more than 5 hours"

 For this cooling deviation, the cooked, uncured perishable product took approximately 4 hours to reach an internal temperature of 80° F and then another 11 hours to reach an internal temperature of 40° F.

- <u>Scenario #2 (cont.):</u>
- The plant plans to use the validated ComBase *Perfringens* Predictor Model and the PMP 7.0 cooling model for *C. botulinum* to estimate the growth of *C. perfringens* and *C. botulinum*, respectively, that occurred in their affected product.
- The plant has documentation on the pH (6.0) and salt concentration (1.5%) for their affected product.

- Scenario #2 (cont.):
- The company recorded the following time/temp data as the product cooled down:

Time (Hr)	Temp (F)	Time (Hr)	Temp (F)	Time (Hr)	Temp (F)
0.0	129.92	6.0	65.48	12.0	44.24
1.0	110.12	7.0	60.26	13.0	42.44
2.0	97.34	8.0	55.76	14.0	40.82
3.0	87.26	9.0	52.16	15.0	39.56
4.0	78.80	10.0	49.10		
5.0	71.60	11.0	46.58		

- <u>Scenario #2</u>-Results from ComBase and PMP 7.0 Cooling Models
 - C. perfringens
 - Mean Net Growth = 2.10 log increase
 - C. botulinum
 - Mean Net Growth = 0.19 log increase
 - LCL Net Growth = 0.08 log increase
 - UCL Net Growth = 0.29 log increase

Cooling Deviation

• <u>Scenario #2 - Product Disposition</u>

- Product can be recooked because:
 - The predicted growth for *Clostridium perfringens* is a 2.1 log increase which exceeds the Agency performance standard/policy of no more than 1.0 log increase for the pathogen; and
 - The predicted mean net growth for *Clostridium botulinum* is 0.19 log which is not more than a 0.3 mean log increase indicating there was no multiplication of the pathogen thus meeting the Agency performance standard/policy
- Plant may elect to microbiologically test or destroy affected product instead of recooking the product

Intrinsic Factors that can affect the growth of *C. perfringens*

- pH
- Aw
- Nitrite
- Buffered sodium citrate
- Buffered sodium citrate/sodium diacetate
- Lactate/diacetate
- Sodium lactate and sodium acetate

Intrinsic and Extrinsic Factors that can affect the growth of *C. perfringens*

- % Salt (NaCl)
- Sample bag type (oxygen permeability)
- Growth Medium
 - FTG medium versus ground beef
 - Faster growth rates in ground beef



THANK YOU! DO YOU HAVE ANY QUESTIONS?

