The “Catch-All Clause:” Assessing Unfamiliar Processes

dhec

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Using HACCP Thinking to Assess Risk

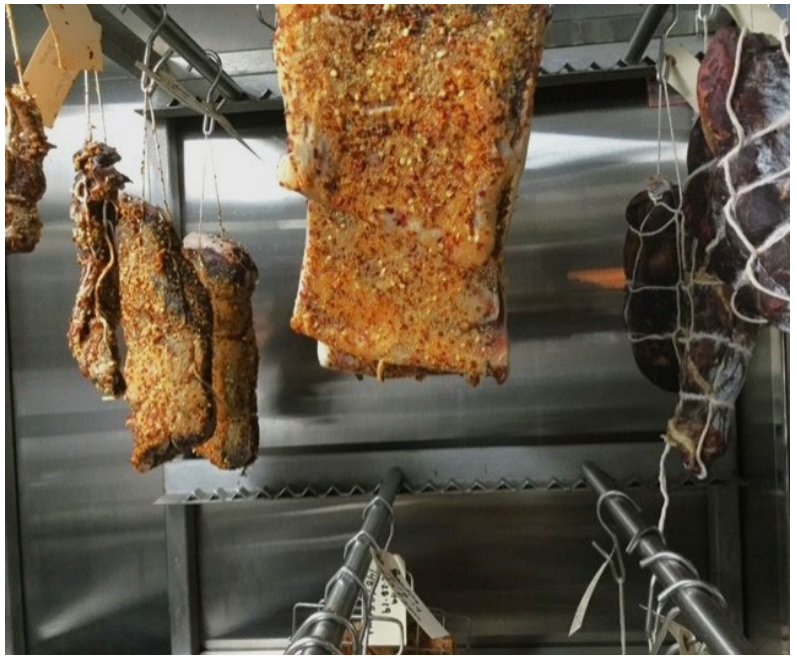
- The requirement of Food Code (2013 and later) 3-502.11(G)
- Assessing a process during inspection
- Assessing risk during process review

Review during inspection

- Assess understanding: open-ended questions
- Consider TCS status
- Temperatures and times during prep?
- Extending TCS shelf life?
- Claiming shelf stability?
- Canning / bottling / ROP?
- Other?

Review during inspection

- Watch basic details!
- Process controls outside Food Code?
- Unusual or atypical equipment?
- Unusual foods / ingredients?
- Other concerns?
- Intended final use of product?



Review during inspection

- Consider resources to assist!
  - Food Code: *Public Health Reasons*
  - Agency regulations, policy, SOP
  - Supervisor; Special Processes staff
  - FDA Retail Food Safety Specialist
  - Food Safety Extension Service
  - Process Authority / Published Research
  - Other jurisdictions
  - Peers, including other jurisdictions

Actions during inspection

- Follow your program policy
  - Process on hold?
  - Discard product?
  - Other immediate guidance?
  - Submit Special Process Application

Regulatory Process Evaluation

Preliminary Steps of HACCP

- Step 2: Describe the product
  - Ingredients
  - Characteristics
  - Packaging & labeling
  - Storage & distribution
- Step 3: Describe intended customer
  - Intended use

Regulatory Process Evaluation

Ingredients and Sources

- Are all ingredients Generally Recognized as Safe?
  - See also 21 CFR Subpart B, Part 182
- Are any ingredients restricted use, such as cure salt?
  - See 9 CFR 424.21
- Are all ingredients from approved sources?

Regulatory Process Evaluation

Food Safety-Related Concerns – Label and Packaging

- What is the expected TCS status?
- Does the product claim to be shelf stable?
- What is the proposed shelf life?
- Does the label contain all required information?
  - Are allergens listed?
- If required – safe handling instructions provided?
- What type packaging is used – variance required?

Regulatory Process Evaluation

Consumer and Distribution

- Demographics of the intended consumers
- Method of distribution
  - In-house use only?
  - Satellite locations or catering?
  - Sold for home use?
  - Both in-house and home use?
  - B2B sales (wholesale)?
- Implications of mode of sale

Regulatory Process Evaluation

Consumer and Distribution

- Implications of mode of sale
  - Labeling requirements
  - Training requirements
  - Records required

Regulatory Process Evaluation

Characterize the food production process

- What processing / packaging methods?

Working definition of food preservation: Formulating, processing and/or packaging a TCS food so that the ready-to-eat product either

- *has shelf life extended beyond 7 days, or*
- *is shelf stable, or*
- *Is both shelf stable and has extended shelf life*

Regulatory Process Evaluation

Characterizing the food production process

- What heat treatment is applied to the TCS food?
  - Cooked at lower temperature than Food Code requires?
  - Cooked for less time than Food Code requires?
- Extended holding in the TDZ?
  - No heat treatment?
- What controls outside Food Code will be used?
- Are those controls backed by accepted science?

Regulatory Process Evaluation

Characterizing the food production process

- Are additives used in accord with federal law?
  - GRAS
  - Restricted uses
  - Limits on amounts
  - Related label claims, including shelf life
- Cultures used to modify pH or other characteristics?
  - Used according to proper guidelines, OEM instructions?
  - No backslopping
- Is equipment used designed for intended use?

Regulatory Process Evaluation

Characterizing the food production process

- What CCPs and CLs?
- Is validation available for each CCP and CL?
  - FDA, USDA
  - Product assessment required? (pH; Aw; challenge study?)
  - Process Letter required?
  - Relevant federal regulations?
- Are comparable processes available to assist review?
- Are written, detailed instructions available?
  - Must address CCPs, CLs

"Lab" session –Example #1

TCS, or non-TCS?

Mango Pineapple Sorbetto

Ingredients: Water, Mango, Pineapple, Cane Sugar, Dextrose, Xanthan Gum

Nutrition Facts

96 servings per container

Serving size	1/2 Cup
Amount Per Serving	
Calories	**90**
	% Daily Value*
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Polyunsaturated Fat 0g	
Monounsaturated Fat 0g	
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 21g	8%
Dietary Fiber 1g	4%
Total Sugars 17g	
Includes 15g Added Sugars	30%
Protein 0g	0%

Not a significant source of vitamin D, calcium, iron, and potassium

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Ingredients: Water, Mango, Pineapple, Cane Sugar, Dextrose, Xanthan Gum

"Lab" session –Example #1

TCS, or non-TCS?

Ingredients: Water, Cane Sugar, Coconut Cream, Dextrose, Cocoa Powder, Chocolate Chip, Maltodextrin, Xanthan Gum

Frozen Scoopable Smoothie

Nutrition Facts

96 servings per container

Serving size	1/2 Cup
Amount Per Serving	
Calories	150
	% Daily Value*
Total Fat 5g	6%
Saturated Fat 2g	10%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 10mg	0%
Total Carbohydrate 12g	4%
Dietary Fiber 0g	0%
Total Sugars 20g	
Includes 16g Added Sugars	32%
Protein 2g	4%

Not a significant source of vitamin D, calcium, iron, and potassium

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Ingredients: Water, Cane Sugar, Coconut Cream, Dextrose, Cocoa Powder, Chocolate Chip, Maltodextrin, Xanthan Gum

"Lab" session –Example #1

TCS, or non-TCS?

Preserved Lemons

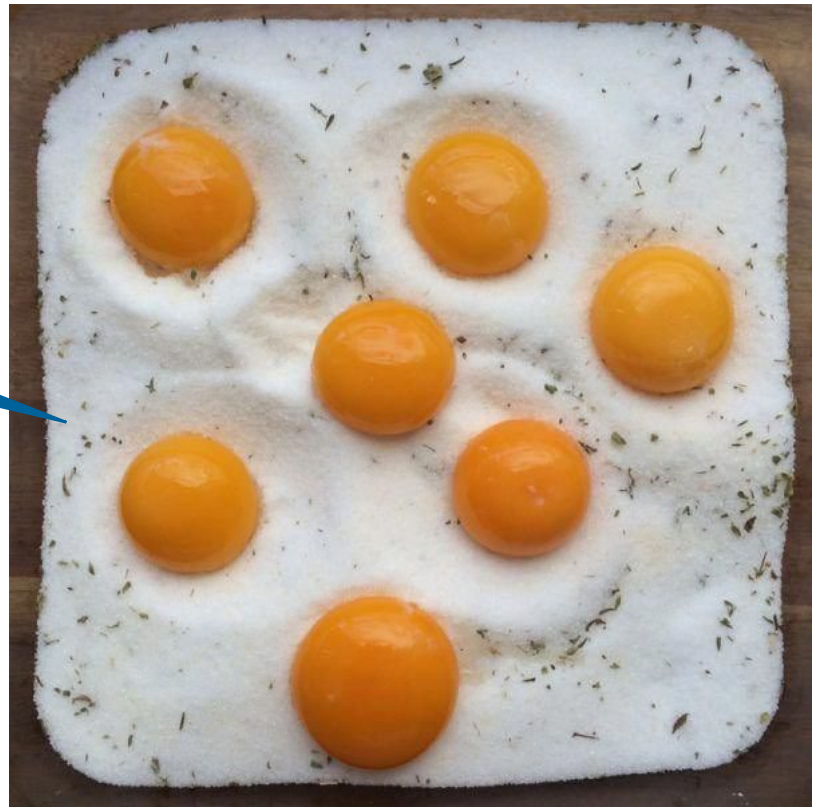
Ingredients: Lemons, Water, Sea Salt

“Lab” session –Example #1

TCS, or non-TCS?

Graved Eggs

Ingredients: Egg yolks, Salt, Seasonings



“Lab” session –Example #1

TCS, or non-TCS?

Freeze-Dried Strawberries

Ingredients:
Strawberries

“Lab” session –Example #1

TCS, or non-TCS?

Freeze-Dried Tomatoes

Ingredients:
Tomatoes

"Lab" session –Example #1

TCS, or non-TCS?

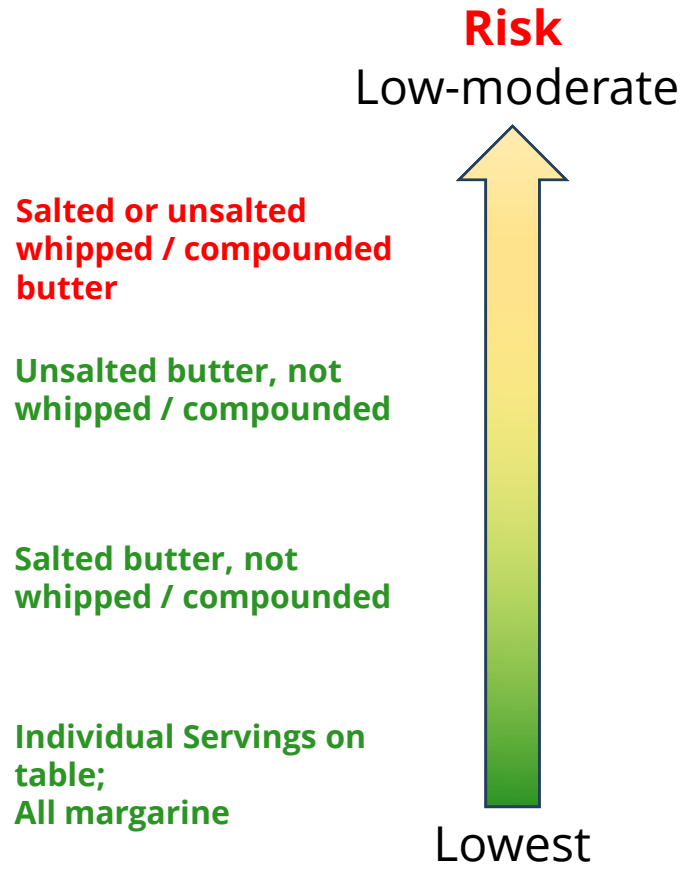
Freeze-Dried Strawberry Yogurt

Ingredients: Sugar, Strawberry, Skim Milk Yogurt, Starch, Natural Flavor, Black Carrot Juice Concentrate.

"Lab" session – Example #2

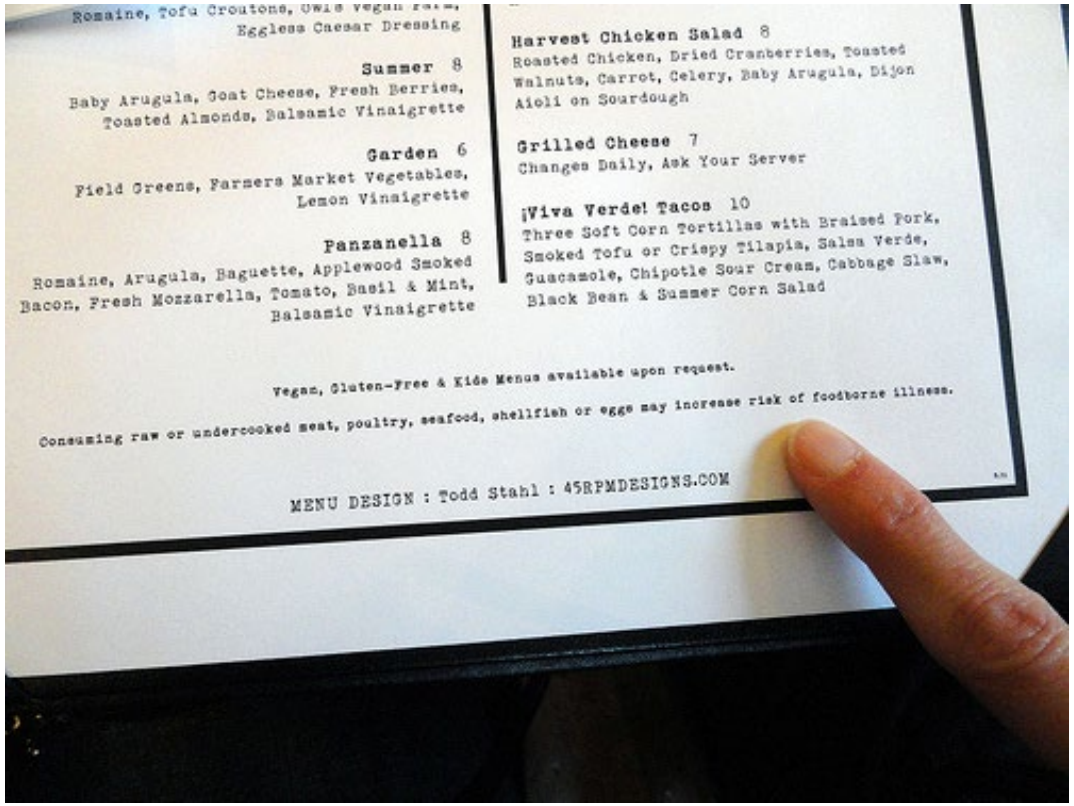
Butter and Margarine

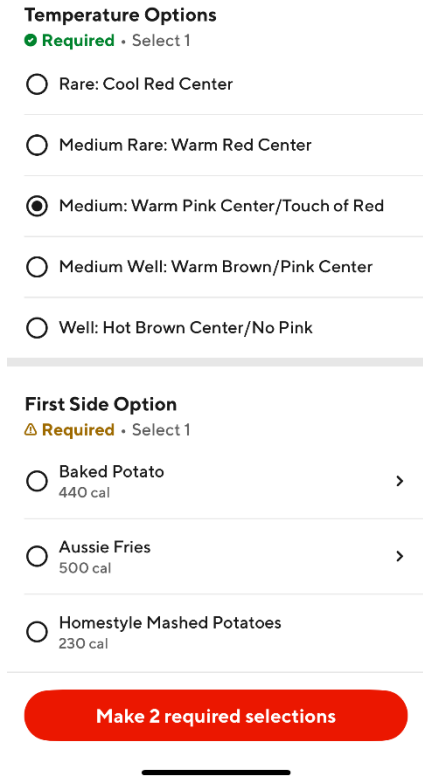
- Tempering for use in baking – extending TPHC
- Historically safe
- Salted or unsalted, butter vs margarine
- Risk considerations
- Recommendations
  - Lowest risk
  - Increased risk
  - Higher risk

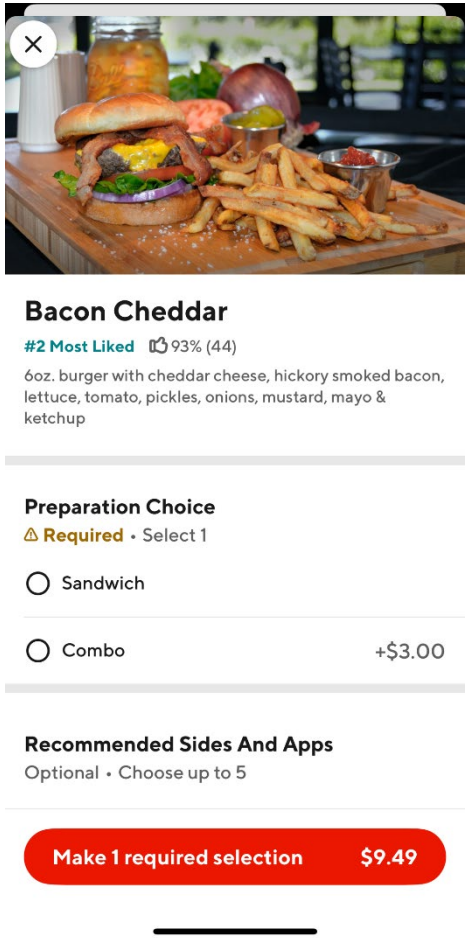


"Lab" session – Example #3

Product labeling: online media







"Lab" session – Example #4

Sous Vide Time and Temperature Options

- Standard temps (meat, poultry), OR
- 3-401.11(B)(1): Whole meat roasts and cured roasts (hams)

cooked to heat all parts to temperature, held for specified time:

Table 3.2			
Temperature Degree F (C)	**Time[1] in Minutes**	**Temperature Degree F (C)**	**Time[1] in Seconds**
130 (54.4)	112	147 (63.9)	134
131 (55.0)	89	149 (65.0)	85
133 (56.1)	56	151 (66.1)	54
135 (57.2)	36	153 (67.2)	34
136 (57.8)	28	155 (68.3)	22
138 (58.9)	18	157 (69.4)	14
140 (60.0)	12	158 (70.0)	0
142 (61.1)	8		
144 (62.2)	5		
145 (62.8)	4		
[1]Holding time may include post-oven heat rise.			

"Lab" session – Example #5

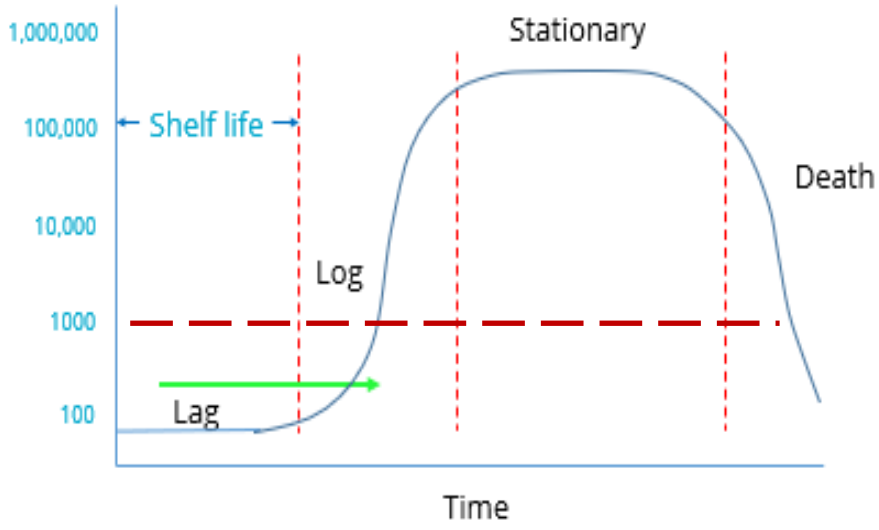
Fermenting Foods

Lactic Acid Bacteria	Alcoholic/Yeast	Acetic Acid Bacteria (biofilm/mother)	Mixed Fermentation
Yogurt, Kimchi, Sauerkraut, Sourdough, Pickles	Bread, Beer, Wine	Vinegar	SCOBY (Symbiotic Culture of Bacteria and Yeast): Kombucha
CHO → lactic acid	CHO/Sugar → alcohol + CO_2	Ethanol → acetic acid	LAB + Yeast: Kefir
Reduces pH/Acidifies	Ethanol production for alcohol		Bread Yeast + LAB: Sourdough bread
2% Salt brine: Texture, inhibit growth of spoilage microorganisms	CO_2 production for bread		Yeast = ethanol + CO_2 (Colony); Bacteria → ethanol → acetic acid (Biofilm)
Optimal growth: 39 to 113 F	Type yeast determines end product		2 weeks + 1-2 weeks for carbonation

"Lab" session – Example #6

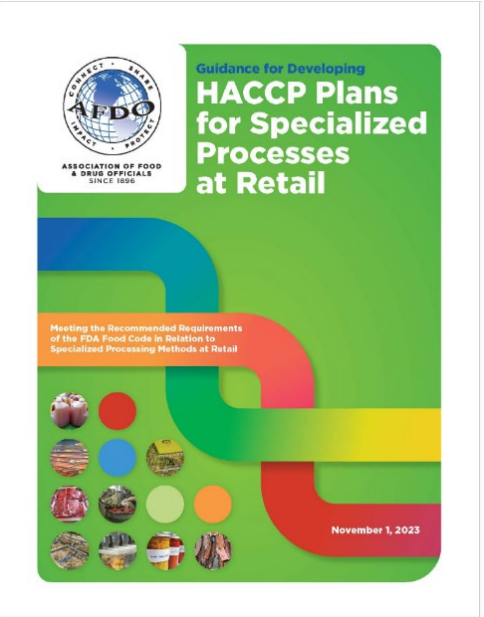
ROP Cook-Chill & Preservatives: Extending Shelf Life

- 7-day shelf life; exceptions
- How preservatives affect allowed shelf life
- Critical details of the request
  - GRAS ingredients
  - Product formulation
  - Challenge study
- Variance and HACCP required; citation?
- Identify correct CCPs



Extending shelf life = extending lag phase

Resources



- Guidance for Developing HACCP Plans for Special Processes at Retail; AFDO 2023
- Evaluation and Definition of Potentially Hazardous Foods – Institute of Food Technologists, December 31, 2001
- "Water Activity Values of Select Food Ingredients and Products" - Shelly J. Schmidt and Anthony J. Fontana: https://onlinelibrary.wiley.com/doi/pdf/10.1002/9780470376454.app5
- "pH Values of Common Foods and Ingredients" – Clemson University Cooperative Extension: https://www.clemson.edu/extension/food/food2market/documents/ph_of_common_foods.pdf
- FDA Job Aid: Time and temperature Control for Safety Foods https://www.fda.gov/files/food/published/Job-Aid--Time-and-Temperature-Control-for-Safety-Foods.pdf
- FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) December, 2021 https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf
- Guidance documents regarding product assessments (3) from the Conference for Food Protection: http://www.foodprotect.org/guides-documents/using-nacmcf-parameters-for-challenge-study-protocols-for-retail-food-operators-and-regulators/

Questions?

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