Identifying and Assessing Special Processes at Retail

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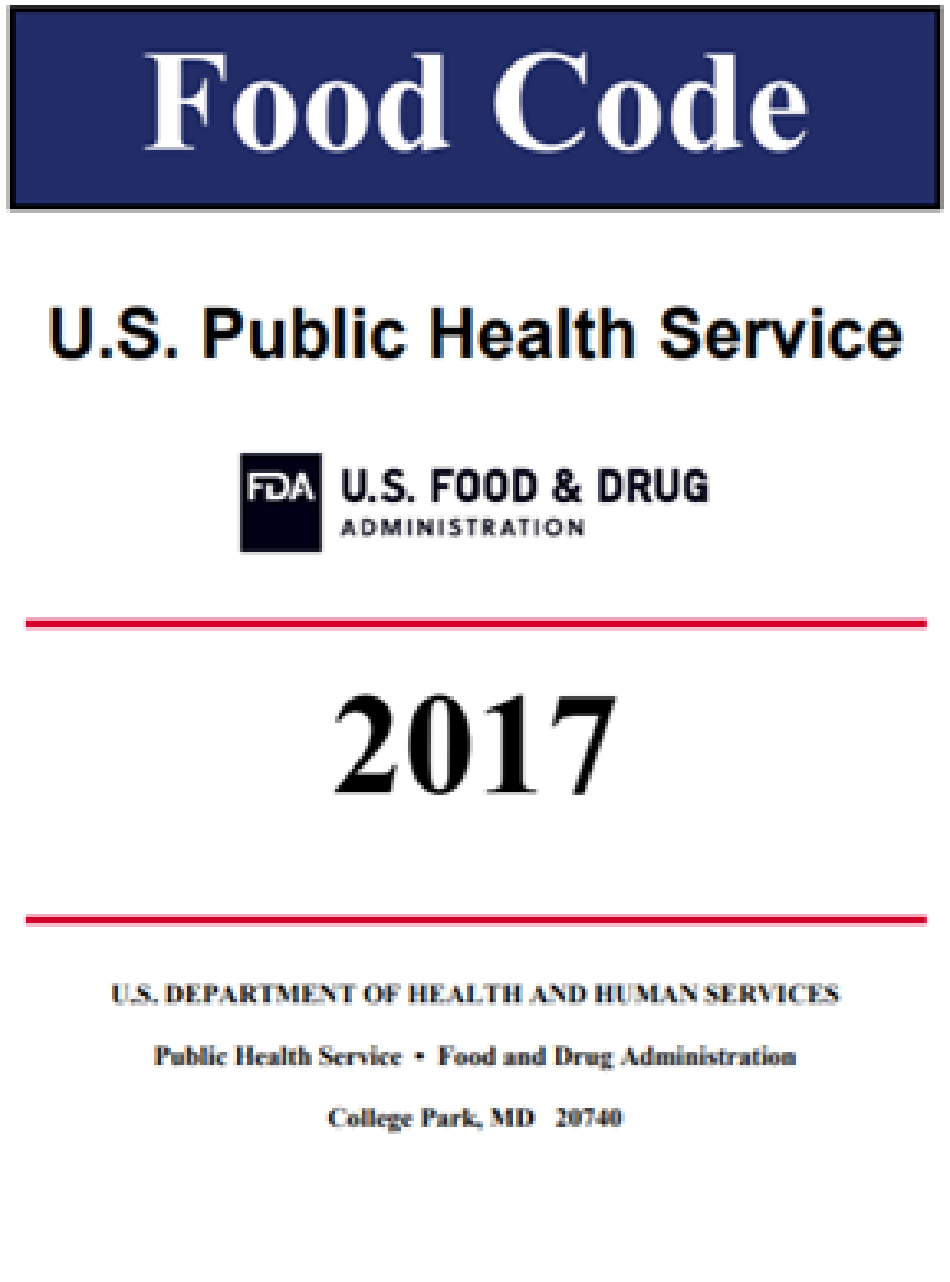
Introduction

- Identify special processes
- Assess the processes
- Make a risk-based determination



What Is a Special Process?

- A process that is not covered by a provision of the Food Code
  - Acidification
  - Dehydration
  - Fermentation
  - Reduced Oxygen Packaging
  - Sous Vide
- The control is above and beyond the temperature of the food product and requires specialized knowledge and equipment to measure and assess

Quiz Time!

- What about roasts?
- Time as a Public Health Control?
- Non-continuous cooking?

Identifying Special Processes

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Additional Ways to Identify Specialized Processes

- Check the menu!
  - Look for items that are or may be acidified, cured, fermented, pickled, or smoked
- Discuss during the pre-operational inspection
  - This is the best opportunity to find out if they're planning to use specialized process
  - It's also much easier to start off equipped with the right information than to halt and re-do a process

When is it Truly a Specialized Process?

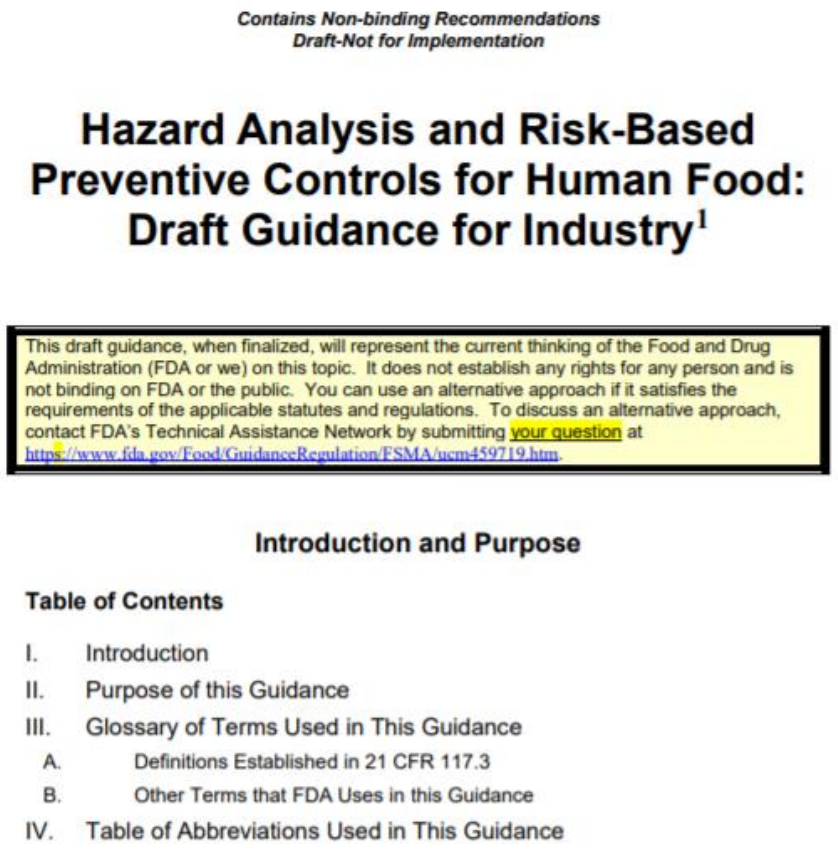
True Specialized Process:

- The process is being used to take a TCS food and make it into a non-TCS food.
- The critical control point(s) in the process must be met or the food item would be unsafe for consumption.
- Example: smoking/curing for preservation

Not a True Specialized Process:

- The food item will remain a TCS food and kept under temperature control after the process.
- There are other kill steps that will take place to control for foodborne pathogens (i.e. cooking).
- Example: smoking/curing for flavor profile

FDA Hazards Guide



Contains Non-binding Recommendations
Draft-Not for Implementation

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm.

Introduction and Purpose

Table of Contents

I. Introduction
II. Purpose of this Guidance
III. Glossary of Terms Used in This Guidance
A. Definitions Established in 21 CFR 117.3
B. Other Terms that FDA Uses in this Guidance
IV. Table of Abbreviations Used in This Guidance

- Non-binding draft guidance (can't be used for enforcement)
- Terrific reference document to research potential hazards (biological, chemical, and physical) for a food product
- Can also be used to review potential "kill step" processes

Appendix 1

Contains Non-binding Recommendations
Draft-Not for Implementation

Tables 1J: Information that you should consider for potential ingredient or other food-related biological hazards for Grains, Beans and Grain Products

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*Shigella* spp.	*S. aureus*	*Giardia lamblia*	*Trichinella spiralis*	Example Products
Grains	1	Raw grains	Shelf-Stable	X					X							Wheat, Rye, Sorghum, Oats, Barley, Triticale, Buckwheat, Corn, Soy, Rice, Teff, Amaranth, Millet, Quinoa
Grains	2	Heat-treated grains	Shelf-Stable							X						Toasted oats, Puffed rice

Table 3-A Limiting Conditions for Pathogen Growth

Pathogen	Min. a_w (using salt)	Min. pH	Max. pH	Max. % Water Phase Salt	Min. Temp.	Max. Temp.	Oxygen Requirement
Bacillus cereus	0.92	4.3	9.3	10	39.2°F 4°C	131°F[1] 55°C	facultative anaerobe[4]
Campylo-bacter jejuni	0.987	4.9	9.5	1.7	86°F 30°C	113°F 45°C	micro-aerophile[2]
Clostridium botulinum, type A, and proteolytic types B and F	0.935	4.6	9	10	50°F 10°C	118.4°F 48°C	anaerobe[3]
Clostridium botulinum, type E, and non-proteolytic types B and F	0.97	5	9	5	37.9°F 3.3°C	113°F 45°C	anaerobe[3]
Clostridium perfringens	0.93	5	9	7	50°F 10°C	125.6°F 52°C	anaerobe[3]

Appendix 3: Bacterial Pathogen Growth and Inactivation

- Easy to reference tables that provide key information on each foodborne pathogen.
- Additional tables provide time/temperature combinations for numerous pathogens
- Listeria-specific guidance table

FORM 2-C PROCESS CONTROLS

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Process Control Step	Hazard(s)	Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records

Validation vs. Verification

Validation is the study/review to make sure that the process an operator wants to use will sufficiently reduce or inhibit pathogens.

Short version: The plan works!

Verification is the review of on-site practices and records to ensure that the validated plan is being used.

Short version: The plan is being followed!

When is Validation Required?

When a process extends beyond the Food Code or an existing document that has already been validated (i.e. Colorado State Extension document for dehydrating tomato slices)

The validation process has two parts:

1. Reviewing the written plan to make sure there are no gaps or inconsistencies
2. Testing the final product to make sure it’s safe to eat.

How is Validation Accomplished?

1. Using an existing process (or recipe) from a validated source (i.e. University Extension)

Must follow the existing process exactly!

2. Write a food process flow diagram and a HACCP Plan.

How do we know that the written HACCP Plan is sufficient?

Questions

1. Who know what a process authority does?

2. Have you received a report from a process authority for one of establishments in your jurisdiction?

What is a Process Authority?

The FDA requires that scheduled processes for preservation including smoking, curing, acidifying, fermenting, brining, and any other method used to eliminate the need for time/temperature control (make shelf stable) must be established by a qualified "Process Authority."

A qualified Process Authority is a person(s) or organization(s) having expert knowledge, acquired through appropriate training and experience, of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions.

The Process Authority must validate the process, safety of the product, and the adequacy of the HACCP plan.

When do you need a Process Authority? If you manufacture a food that is rendered shelf-stable after being subjected to a special process (see above), you need a Process Authority to conduct a process and product review and approve it.

AFDO Food Processing Authorities Directory

www.afdo.org/directories/fpa/

What is Verification?

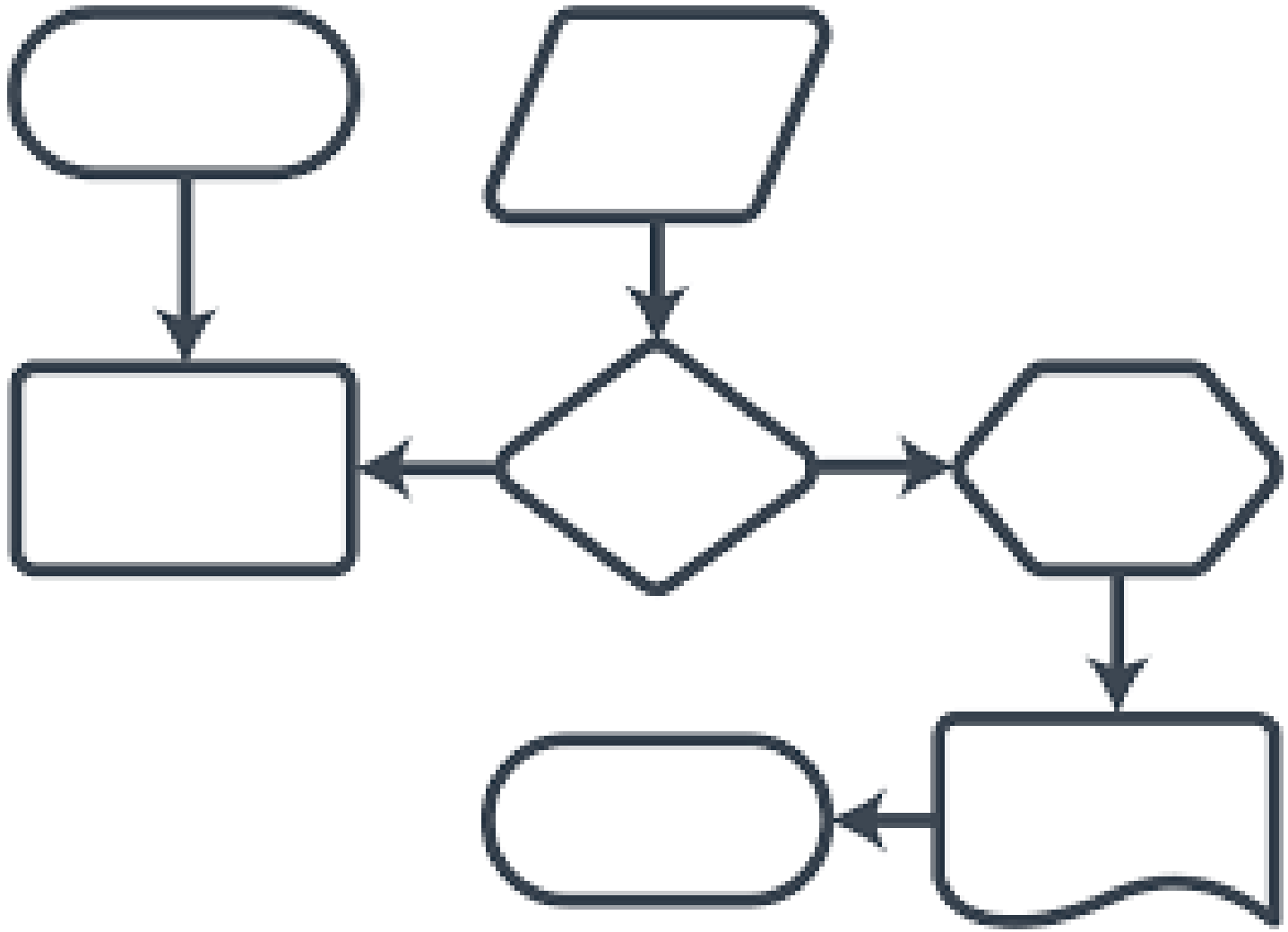
Verification is the act of ensuring that the HACCP system at the establishment is operating according to the plan.

Monitoring is not verification –

Monitoring is CCP specific – is the specific CCP met?

Verification looks at the totality of the HACCP system – does it meet the requirements of the validated plan?

Breaking Down the Process



Acidification: Sushi Rice

Receive dry ingredients
↓
Store dry ingredients
↓
Cook rice
↓
Cool rice to 115°F within 2 hours
↓
Heat vinegar mixture
↓
Cool vinegar mixture to 115°F
↓
Stir vinegar mixture into cooked rice until it absorbs
↓
Hold acidified rice at 115°F

Dehydration: Kale Chips

Receive ingredients

↓

Store ingredients

↓

Wash kale in potable water

↓

Weigh 1.5 pounds of kale

↓

Blanch in boiling water for 4 minutes

↓

Shake kale or pat dry

↓

Place on dehydrator tray, dehydrate for 6-10 hours, until remaining kale weighs 2 ounces

Fermentation: Yogurt

Receive ingredients (milk, yogurt)

↓

Store ingredients

↓

Heat 2 cups milk to 180°F

↓

Cool milk to 110-115 °F

↓

Combine ½ cup milk with 2 Tbsp yogurt

↓

Add yogurt mixture to remaining milk and mix

↓

Fill jars, incubate in yogurt maker for 5-10 hours

↓

Chill in refrigerator, covered (to 41°F)

ROP, Sous Vide, Cook Chill: Beef Stew

Receive ingredients (including raw meat)

↓

Store ingredients

↓

Cut and measure raw ingredients

↓

Prepare/cook stew to 145°F

↓

Fill and vacuum seal stew in ROP bags (≥135°F)

↓

Cool [<70°F w/in 2 hrs. and <41°F w/in 4 hrs.]

↓

Label and store at 41°F for no more than 7 days

↓

Reheat to 165°F and serve

Resources

- NC State University Retail HACCP Validation and Verification class
  - Hands-on class offered by the University of Rhode Island and the RIDOH
  - Contact Nicole Richard: nicolerichard@uri.edu
- Colorado State Extension – guidance documents/recipes for various special processes

NC STATE EXTENSION

Retail HACCP Validation and Verification

THE UNIVERSITY OF RHODE ISLAND COLLEGE OF THE ENVIRONMENT AND LIFE SCIENCES

COLORADO STATE UNIVERSITY EXTENSION

RHODE ISLAND DEPARTMENT OF HEALTH

Questions?

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