HACCP PROGRAM & APPLICATION TO SPECIALIZED FOOD PROCESSING

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OUTLINE:

- HISTORY AND COMMON TERMS.
- WHAT ARE HAZARDS?
- HACCP PRINCIPLES
- FOOD PROCESS CATEGORIES
- SPECIALIZED FOOD PROCESSING
  - MODIFIED OXYGEN PACKAGING (MOP)

DEFINITION

- HAZARD
- ANALYSIS
- CRITICAL
- CONTROL
- POINT

- HACCP, a systematic approach to the identification, evaluation, and control of food safety hazards.
A. HACCP HISTORY

- 1960, Inception: For space program.
- By:
  - NASA
  - Pillsbury Company and,
  - US Army Natick Research and Dev. Labs.
- 1982 – HACCP WITH 3 PRINCIPLES,
  - Hazard analysis, determination of CCP, and monitoring of CCP

HACCP HISTORY

- 1987 – Review by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF)
- 1992 - NACMCF defined 7 widely acceptable principles that explain the HACCP process in detail.
- 1997 - NACMCF adds emphasis to pre-requisite programs.

HACCP APPLICATION HISTORY

- First used for:
  - Low Acid and Canned Foods (LACF)
  - Infant formula
- 1997 - FDA applied for seafood and shellfish wholesale processors and distributors, and
- Pilot program for Retail Application, non-regulatory.
HACCP TERMS

- **HACCP Program**: Is defined as a plan designed to ensure that hazards are prevented, eliminated or reduced to an acceptable level.
- A HACCP Program is a tool in food production that can be used to achieve active managerial control of risk factors.

HACCP PROGRAM APPLICATION

- Specialized food processors at retail are required to have a HACCP Program if:
  - A variance is granted at retail level,
  - Operator is using one of the reduced oxygen packaging (ROP) methods: MAP, RAP or, Sous vide.
  - Using a specialized food processing method such as LACF, or vacuum packaging.

HACCP Roles & Pre-requisites:

- **Roles**: Operator is responsible for developing and implementing the HACCP Plan and, regulator to audit.

- **Pre-requisites**: Operator must have:
  - GMPs, SOF, and SSOPs.
  - Control programs for: Employee health, sanitation and pest control.
B. WHAT IS A HAZARD?

- **HAZARD**: Is a biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

- **HAZARD CATEGORIES**:
  - PHYSICAL
  - CHEMICAL AND
  - BIOLOGICAL

**TYPES OF HAZARDS:**

- **Physical Hazards**:
  - Glass
  - Metal
  - Wood
  - Plastic
  - etc.
  - A HAZARD is not based on filth.

**CHEMICAL HAZARDS**

- **Chemical Hazards**: May be naturally occurring or added during the processing of food.
  - Natural: Histamine, aflatoxin.
  - Man made: pesticides, sanitizers, antibiotics.
  - Allergen: As a food hazard, is a naturally-occurring protein in food or a food ingredient.
ALLERGENS, CHEMICAL HAZARD:

- Allergens as a “Food Hazard” have different response symptoms:
  - **Mild**: Hives, itchy rashes, abdominal pain, vomiting and/or diarrhea.
  - **Severe response**: anaphylactic shock and death.

BIOLOGICAL HAZARD:

- Biological hazards in food
  - Bacterial pathogens are major cause of food borne disease outbreaks.

C. HAACP PRINCIPLES:

- **#1) Hazard Analysis** – Determine the hazard that needs control and, the preventive control measures.
  - You must identify the process to control or reduce the hazard.
HAACCP PROGRAM & APPLICATIONS

HAACCP PRINCIPLE #1

Identification of HAZARDS:
- **Who?** Establishment HACCP Team,
- **What?** Product description,
- **Whom?** Intended consumer,
- **Where?** Food Flow diagram,
- **Which?** Pertinent Hazard, by food flow or process.
- **Why?** Rational for inclusion/ exclusion

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**BIOLOGICAL HAZARD** | **ASSOCIATED FOODS** | **CONTROL MEASURES**  
--- | --- | ---  
*Bacillus cereus* | Meat, poultry, starchy foods, puddings, cooked vegetables | Proper cooking, cooling, cold and hot holding.  
*Campylobacter jejuni* | Poultry, raw milk | Proper cooking, hand washing and prevention of cross- contamination.  
*Clostridium botulinum* | Vacuum packed foods, ROPs, canning, garlic-in-oil, T/T abuse | Thermal processing, Cooling, cold holding, drying and acidification.  

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**BIOLOGICAL HAZARD** | **ASSOCIATED FOODS** | **CONTROL MEASURES**  
--- | --- | ---  
*Clostridium perfringens* | Cooked meats and poultry, meat and poultry casseroles, and gravies | Proper cooking, cooling, hot holding and cold holding.  
*E. Coli O157:H7* | Raw ground beef, raw seed sprouts, raw milk, unpasteurized juices, etc. | Cooking, No bare-hand contact with RTE foods, Pasteurization.  
*Listeria monocytogenes* | Raw meat & poultry, soft cheeses, deli meats, deli salads, pate | Cooking, date marking, cold holding.
### BIOLOGICAL HAZARD

<table>
<thead>
<tr>
<th><strong>ASSOCIATED FOODS</strong></th>
<th><strong>CONTROL MEASURES</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Salmonella spp.</strong></td>
<td>Use of pasteurized milk, juices, eggs for HSP, no BHC with RTE foods, employee sick policy</td>
</tr>
<tr>
<td><strong>Shigella spp.</strong></td>
<td>Cooking, no BHC with RTE foods, and proper hand washing monitoring.</td>
</tr>
<tr>
<td><strong>Staphylococcus aureus</strong></td>
<td>Cooking, cold/hot holding; prevent BHC with RTE foods.</td>
</tr>
<tr>
<td><strong>RTE PHF touched by bare hands</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Staphylococcus aureus</strong></td>
<td></td>
</tr>
</tbody>
</table>

### BIOLOGICAL HAZARD

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<th><strong>ASSOCIATED FOODS</strong></th>
<th><strong>CONTROL MEASURES</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vibrio spp.</strong></td>
<td>Cooking, approved source, pasteurized oysters, cold holding, prevention of cross-contamination.</td>
</tr>
<tr>
<td><strong>Parasites:</strong> Anisakis simplex</td>
<td>Cooking, freezing.</td>
</tr>
<tr>
<td><strong>Taenia spp.</strong></td>
<td>Cooking</td>
</tr>
</tbody>
</table>

### BIOLOGICAL HAZARD

<table>
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<th><strong>ASSOCIATED FOODS</strong></th>
<th><strong>CONTROL MEASURES</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parasites:</strong> Trichinella spiralis</td>
<td>Cooking</td>
</tr>
<tr>
<td><strong>Viruses:</strong> Hepatitis A and E</td>
<td>Approved source, NO BHC with RTF, employee health policies restrict/exclude.</td>
</tr>
<tr>
<td><strong>Rotavirus, Norovirus, Reovirus</strong></td>
<td>NO BHC with RTE foods; employee health policy, hand washing.</td>
</tr>
</tbody>
</table>
### CHEMICAL HAZARD | ASSOCIATED FOODS | CONTROL MEASURES
--- | --- | ---
Scombrotxin (HISTAMINE) | Tuna fish, blue fish, Anchovies, mackerel. Also, cheese | Receiving Temps. Cold holding temps. Buyer specifications.
Ciguatoxin | Fin fish from Hawaii, SE US, tropical areas, Barracuda, mackerel. | Approved source, Origin verified (not from an adverse advisory.
Tetrodoxin | Puffer fish (Fugu or Blowfish) | Prohibited consumption. Ethnic markets*

### CHEMICAL HAZARD | ASSOCIATED FOODS | CONTROL MEASURES
--- | --- | ---
Mycotoxins: Aflotoxin, Pauulin | Corn, corn products, peanuts, & tree nuts. Apple juice | Check condition at receiving. Avoid use of rotten apples.
Toxic mushroom species | Numerous varieties of wild mushrooms | Avoid unapproved source. Do not eat unknown varieties.
Shellfish toxins: PSP PARALYTIC | Molluscan shellfish from NE & NW coastal regions | Ensure Molluscan shellfish are properly tagged and from approved source.

### CHEMICAL HAZARD | ASSOCIATED FOODS | CONTROL MEASURES
--- | --- | ---
Shellfish toxins: DSP (DIARRHEIC) | Molluscan shellfish from Japan, Chile, NZ, Western Europe, & Eastern Canada | Ensure Molluscan shellfish are properly tagged and from approved source.
Shellfish toxins: NSP (NEUROLOGIC) | Molluscan shellfish from Gulf of Mexico | Ensure Molluscan shellfish are properly tagged and from approved source.
Shellfish toxins: ASP (Amnesic) | Molluscan shellfish from NE, viscera of Dungeness, tanner, anchovies, red rock crabs | Ensure Molluscan shellfish are properly tagged and from approved source.

*Prohibited for consumption*
### Chemical Hazard: Naturally Occurring Pyrrolizidine Alkaloids

<table>
<thead>
<tr>
<th>Associated Foods</th>
<th>Control Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avoid plant foods that contain these alkaloids. Loguminosa family</td>
<td>Avoid herbs or foods containing these alkaloids.</td>
</tr>
</tbody>
</table>

### Chemical Hazard: Phytohaemagglutinin

<table>
<thead>
<tr>
<th>Associated Foods</th>
<th>Control Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undercooked or raw kidney beans.</td>
<td>Soak in water at least 5 hours. Discard water. Boil in fresh water.</td>
</tr>
</tbody>
</table>

### Added Chemicals: Environmental Contaminants

<table>
<thead>
<tr>
<th>Associated Foods</th>
<th>Control Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any food may become contaminated</td>
<td>Storage: proper chemical storage. Use only approved chemicals.</td>
</tr>
</tbody>
</table>

### Chemical Hazard: Added Chemicals: Prohibited Substances (21 CFR 189)

<table>
<thead>
<tr>
<th>Associated Foods</th>
<th>Control Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numerous substances are prohibited for human consumption</td>
<td>Do not use chemicals not allowed for use in human foods.</td>
</tr>
</tbody>
</table>

### Chemical Hazard: Mercury: Toxic Element

<table>
<thead>
<tr>
<th>Associated Foods</th>
<th>Control Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish exposed to organic mercury: shark, swordfish, King mackerel.</td>
<td>Pregnant women and children under 5 should not eat these fish.</td>
</tr>
</tbody>
</table>

### Chemical Hazard: Copper: Toxic Element

<table>
<thead>
<tr>
<th>Associated Foods</th>
<th>Control Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>High acid foods and beverages.</td>
<td>Storage: Do not store acid foods in copper utensils; backflow prevention device in vending machines.</td>
</tr>
</tbody>
</table>

### Chemical Hazard: Sulfating Agents

<table>
<thead>
<tr>
<th>Associated Foods</th>
<th>Control Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>DO NOT add to fresh fruits or vegetables.</td>
<td>Sulfating agents added to a product must be declared on the label. DO NOT add to fresh fruits or vegetables.</td>
</tr>
</tbody>
</table>

### Chemical Hazard: Toxic Element: Lead

<table>
<thead>
<tr>
<th>Associated Foods</th>
<th>Control Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not use containers w/ lead or, inks on packaging</td>
<td>Pregnant women and children under 5 should not eat these fish.</td>
</tr>
</tbody>
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HACCP Program and Application to Specialized Food Processing

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HACCP Program and Application to Specialized Food Processing

HACCP Program & Applications

Address through SOPs, for proper
storage, labeling, and use. MSDS sheets

Any foods can become contaminated

Use of rigorous sanitation regime
to prevent cross-contamination
between allergenic and non-allergenic
ingredients.

HAACP PRINCIPLE #2

CCP Determination: A step at which
can be applied and is essential
to prevent, reduce or eliminate a hazard.
(NACMCF, 1997).

Meat casserole:
Hazard: biological => Clostridium perfringens.
CCPs: Cooking, cooling, reheating
and holding steps.
**Decision Tree for a CCP**

1) Preventive Measure Necessary for the identified hazard?
   - NO
   - YES

2) Does it reduce, control or eliminate the hazard?
   - NO
   - YES

3) Contamination with identified hazard: Could it exceed or increase acceptable levels?
   - NO
   - YES

4) Will a subsequent step eliminate or reduce identified hazard, or reduce to an acceptable level?
   - NO
   - YES

**HACCP PRINCIPLE #3**

- **CRITICAL LIMIT**: A maximum and/or minimum value to which a biological, chemical or physical hazard must be controlled at a CCP. To prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.
- A CL is based on science to ensure a hazard is under control. It can be measured and be quantifiable.
- **Meat in meat casserole**: Beef cook to 70°C (158°F)

**HACCP PRINCIPLE #4**

- **Monitoring**: Is a planned controlled sequence of observations or measurements to determine if a CCP is under control; an accurate record for future use in verification.
- It must define who, what, when and where to measure accurately that the hazard was eliminated or reduced.
HACCP PRINCIPLE #5

- **Corrective action**: Is a procedure followed when deviation occurs.
- **Must be applied when**: 
  - Monitoring indicated a critical limit was exceeded, and,
  - If monitoring was not performed (it is unknown if the critical limit was exceeded).

Corrective action should include:
- To bring the process into compliance.
- To ensure no PHF/TTCF products gets to the consumer if determined unsafe.
- If unsafe, determine the disposition of the non-compliant product.

HACCP PRINCIPLE #6

- **Verification**: Is the use of methods, procedures, or tests to determine if the implemented HACCP system is in compliance with the HACCP plan.
- **Validation**: Is the element of verification focused on collecting and evaluating information to determine if the HACCP Plan, if properly implemented, it controls the hazard.
HACCP Principle #7:

- Establish Record Keeping Procedures:
  - Records provide documentation that:
    - Corrective actions are executed when CL are exceeded.
    - Operator exercised reasonable care to prevent a hazard during a FBI investigation.
    - Examples: Equipment calibration records, SSOP records, monitoring, corrective action, verification and validation records.

- Record keeping, is used to:
  - Document compliance with the HACCP Plan,
  - Show trends,
  - Measure accuracy,
  - Evaluate if documentation is complete,
  - Provide historical evidence,
  - Document if hazards are controlled or eliminated.

HACCP Audits vs Inspections:

- Inspections:
  - Observations
  - Record Review
  - Interviews
  - Samples/Exam
  - Measuring
  - Specifications
  - Photos
  - Process Inspection

- HACCP Audits:
  - Verification
  - Review of Records
  - Interviews
  - Observations
  - Systems vs Process Review
  - Plans Validation
C. HACCP PROCESS APPROACH

- Hazard analysis is done by food preparation process common to the retail operation.
- It divides the many food flows into broad categories based on activities.
- Identified hazards are analyzed by placing managerial controls on each grouping.

HACC PROCESS APPROACH

- Grouping is based on how many times food passes the danger zone (41° and 135°):
  - Process 1) No-cook Step
  - Process 2) Same Day Service (cook n serve)
  - Process 3) Complex Food Preparation

GROUPING BY DANGER ZONE “DZ” EXPOSURE

- Process 1) No-cook Step “0” DZ exposures.
- Process 2) Same Day Service 1 DZ exposure.
- Process 3) Complex Food Preparation: Up to “3” DZ exposures /passes through the danger zone.
HACCP – PROCESS 1

- Process 1) **No-cook Step** “0” DZ exposures.

Receive → Store → Prepare → Hold → Serve.

There may be variations or other food flows. But, there is no cook step to destroy pathogens!

HACCP – PROCESS 2

- Process 2) **Same Day Service** “1” DZ exposures.

Receive → Store → Prepare → Cook ↓

Serve←Hold

Variations to order of food flow may exist but only on trip or exposure through the danger zone (DZ).

HACCP – PROCESS 3

- Process 3) **Complex Food Processing:**

Receive → Store → Prepare → Cook → Cool ↓

Serve←Reheat

Variations to order of food flow may exist but there are always two or three trips through DZ.
HACCP – PROCESS variations
The 3 Process approach is not all inclusive.

**Cook and serve:** Common to quick service facilities. Process may include:

Receive → Store → Prepare → **Reheat**

↓

Hold → Serve.

Hazard Analysis to a HACCP Process
Menu item specific HACCP hazard analysis is time consuming, labor intensive and unnecessary. HACCP Food Flow and Process Approach:

- Groups menu items into 3 process categories.
- Group within process by **type of food**.
  - Example: Beef, poultry, pork, vegetables.
- Identifies hazard by **type of food or process**.
- Identifies control measures by grouping.

Hazard Analysis to a HACCP Food Process

- **Example:** **No Cook Step Process**
- Grouping by **type of food**: Deli meats, dairy products (cheese, creams, yogurt), produce.
- **Other**: Raw ready-to-eat foods: sashimi, raw oysters, and salads.
- **Common Food Flow:**
  
  Receive → Store → Prepare → Hold → Serve
Hazard Analysis to a HACCP Food Process: No Cook Step Process

No Cook Step Process

- Food Flow, example:
  - Receive → Store → Prepare → Hold → Serve
  - (NO KILL STEP – Hazard: contamination)

Hazard Analysis to a HACCP Food Process: No Cook Step

- No Cook Step Process / Food Flow

Common Managerial Controls:
- Approved source
- Cold Holding: Control bacterial growth and toxin production.
- Receiving Temperatures: Scombrotoxin

Hazard Analysis to a HACCP Food Process: No Cook Step, cont.

- No Cook Step Process / Food Flow

Common Managerial Controls:
- Date Marking: First in, first out (FIFO)
  - Control of psychrophiles: Listeria monocytogenes
- Freezing: Required for certain species of fish for parasite destruction.
- Cooling: From ambient temperature to prevent spore-forming or toxic-forming bacterial growth.
Hazard Analysis to a HACCP Food Process: 2

Same Day Service - Common food flow:
- Receive → Store → Prepare → Cook → Hold → Serve

- Biological Hazard: Control measures
  - **COOKING** food to the proper temperature,
  - **PROPER HOT HOLDING** for spore-formers.

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Hazard Analysis to a HACCP Food Process: 2

Same Day Service - Common food flow:
- Receive → Store → Prepare → Cook → Hold → Serve
- Type of food: Baked chicken and stuffed meatloaf.
- **Identified biological hazards:**
  - Salmonella spp., and *E. coli* O157:H7
  - Spore formers: *Bacillus cereus* and *Clostridium perfringens*.
- **Control measures by grouping:**
  - Both, **COOKING** to 165°F
  - For spore formers, proper hot holding to 135°F

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Hazard Analysis to a HACCP Food Process

- **Example:** Same Day Service Process
- Grouping by type of food: Poultry (chicken) and ground beef (meatloaf).
- Identifies control measures CL for CCP:
- Common CCP involve time/temperature controls: Cooking, holding, reheating & cooling.
- Prevention of Cross-contamination:
  - Hands or employees as a vehicle of contamination.
  - Equipment and Environmental Controls.
Same Day Service Process by Type of Food

- Poultry: Critical limits:
  - Refrigeration: 5°C (41°F)
  - Cooking: 74°C (165°F) for 15 sec.
  - Hot holding: > 57°C (135°F)
    - or time control.
  - Good personal hygiene:
    - NO BHC with RTE food.
    - Exclude or restrict ill employees.
- Ground beef: Critical limits:
  - Refrigeration: 5°C (41°F)
  - Cooking: 68.3°C (155°F) for 15 sec.
  - Hot holding: > 57°C (135°F)
    - or time control.
  - Good personal hygiene:
    - NO BHC with RTE food.
    - Exclude or restrict ill employees.

Hazard Analysis to a HACCP Complex Food Process

- Receive → Store → Prepare → Cook → Hold → Cool → Reheat → Hot Hold → Serve

- Identified biological hazards: Due to multiple passes through the DZ lead to spore formers.
  - Spore formers: Bacillus cereus and Clostridium perfringens.

Complex Food Process Controls

- Holding temps: Cold and Hot
  - Bacterial Growth and Toxin formation.
- Cooking:
  - Destroy bacteria & parasites.
- Date marking:
  - RTE foods control of psychrophiles.
- Reheating for Hot Holding:
  - Destroy vegetative cells.
- Approved food source:
  - Receiving.
  - Cold holding for marine finfish (ciguatera toxin and scombrotoxin).
D. HACCP APPLICATION:

SPECIALIZED FOOD PROCESSING

FOOD PROCESSING CRITERIA:

- REDUCED OXYGEN PACKAGING:
  - FC Section 3-502.12: HACCP Plan required.
  - FC 3-502.11 & 8-103.11: Operator must obtain a Variance from the Regulatory Authority. Evaluate / Audited annually.
  - Required: Written GMP, SOP, SSOP prior to HACCP Plan approval.

- REDUCED OXYGEN PACKAGING (ROP) is a packaging procedure that results in a reduced oxygen level in a sealed package. To include:
  - Cook-chill
  - Controlled Atmosphere Packaging (CAP),
  - Modified Atmospheric Packaging (MAP),
  - Sous-Vide, specialized ROP for partially cooked ingredients.
**ROP TERMS**

- **Cook-chill:** The use of a plastic bag filled with hot cooked food, air expelled and closed with a metal clip or sealed.
- **Controlled-atmosphere Packaging (CAP):**
  
  "An active system that continuously maintains the desired atmosphere to reduce or scavenge oxygen."

**ROP TERMS**

- **Cook-chill:** The use of a plastic bag filled with hot cooked food, air expelled and closed with a metal clip or sealed.
- **Controlled Atmosphere Packaging (CAP):**
  
  "An active system that continuously maintains the desired atmosphere to bind or scavenge oxygen."

**ROP TERMS**

- **Modified Atmosphere Packaging (MAP):**
  
  "A packaging process of a product in an atmosphere which has one-time modification of gaseous composition to a composition different than air; which has 78.0% Nitrogen, 20.96% oxygen and 0.03% carbon dioxide."
ROP TERMS

Sous vide, specialized process of ROP

"Packaging process of partially cooked food alone or mixed with raw foods that require refrigeration or freezing."

Sous vide is a pasteurization step that reduces bacterial growth BUT NOT sufficient to make food shelf stable.

ROP TERMS

- Vacuum packaging (VP): Reduces the amount of air from a package and hermetically seals the package, to create a near perfect vacuum seal.

- Variation: Vacuum Skin Packaging (VSP)
  Using a flexible plastic barrier that mold to the food being packaged.

ROP - Benefits:

- ROP can:
  - Create an anaerobic environment to prevent growth of aerobic/spoilage bacteria & molds.
  - Prevents degradation or oxidative process in food products.
  - Prevents color deterioration in raw meats caused by oxygen.
  - Prevents product shrinkage by reduced water loss.
ROP – Safety Concerns:

- **ROP** increase safety concerns.
  - 1) Psychrotrophic bacteria: Adequate refrigeration required for ROP.
    - 5°C (41°F) of below to prevent growth.
  - 2) Control Clostridium botulinum and, Listeria monocytogenes.
    - Botulism toxin may survive after thermal pasteurization, sous-vide products (partial cooking).
  - 3) Design of heat Processes for Foods in ROP:
    - Sous-vide process practiced in Europe is designed to achieve a 12-13 D thermal death reduction of Streptococcus faecalis. Most products are blast freeze packaged and kept at < 5°C (41°F).
  - Time/temperature control for safety foods (TCS) packaged with ROP process may increase microbial growth if temperature abused.
  - Process must incorporate safety barriers:
    - pH, Aw, or salt concentrations if no preservatives used.
    - Note: Vacuum packaging of smoked fish prohibited.

Note: Vacuum packaging of smoked fish prohibited.
ROP Temperature concerns:
- Anaerobic conditions after ROP packaging promote:
  - Growth of psychrotrophic microorganisms.
  - Refrigeration $\leq 3^\circ C (38^\circ F)$ to control Listeria monocytogenes.
  - ROP processing must reach a 4D (decimal log reduction) of Listeria monocytogenes.
  - Safety barriers: pH, Aw, and short shelf life,
  - Strict monitoring of cold holding procedures.

ROP Temperature concerns:
- Heat process concerns for foods in ROP:
  - Sous vide and cook-chill operations must be designed to destroy vegetative pathogens during pasteurization.
  - NACMCF recommends that an ROP process demonstrate the ability to inactivate L. monocytogenes to achieve a 4 log reduction (4D).
  - Determination by microbial studies.
  - Special labeling instructions for consumers.

ROP – Safety Barrier Verification:
- Operations for all processed foods held in ROP at retail SHALL have written certification from the product manufacturer.
- Changes to product formulation or processing procedures are to be notified to the Regulatory Authority.
- Safety barrier verification should be updated every 12 months.
ROP – Safety Barrier Verification

Exemptions:
- 9-CFR424, Meat and poultry products cured at a food processing plant regulated by the US Department of Agriculture (USDA).

ROP – Without Multiple Barriers

Recommendations:
- Employee training,
- Refrigeration requirements: Label and date with "Use-by Date" refrigerate at < 5°C (41°F), or 14 days after preparation at retail. Below 3°C (38°F) beyond 14 days.

Recommendations, continuation:
- Labeling statement: Must say: "Important – Must be kept refrigerated at < 5°C (41°F) 41°F" or say "Must be kept frozen" on the principal display panel.
Food Products – Variance Requirement

- Processed fish and smoked fish, may not be packaged in ROP. Only if premises are approved for this activity and approved by regulatory authority and has a scheduled process established.
- Soft cheeses such as ricotta, cottage cheese, cheese spreads and combinations. Process must be approved.

Food Products – Variance Requirement

- Smoked or cured meat and poultry, at retail, must have a HACCP Plan approved by the Regulatory authority.

Food Products – Variance Requirement

- Other food processing that require a HACCP and regulatory Variance are:
  - Fermentation, to reduce pH <4.6.
  - Dehydration to reduce Aw to < 0.85.
- Hazards:
  - Product contamination, employee hygiene
  - Product specific treatments.
REFERENCES: