

Overview of Significant Changes to the 2005 FDA Food Code

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Highlighted Changes Addressed During The Call

- Definition of "Potentially Hazardous Food"
- Date Marking
- Special Requirements for Establishments Serving a HSP
- Time as a Public Health Control
- Allergens
- Employee Health Requirements

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Highlighted Changes Addressed During The Call

- Alternative procedure to no bare hand contact with RTE foods
- Hand washing Procedure
- Demonstration of Knowledge
- Reduced Oxygen Packaging
- Annexes

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Potentially Hazardous Food – Definition

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Potentially Hazardous Food – Why Change?

- The “rapid and progressive growth” not clearly defined
- The slow growth of low infectious dose pathogens not considered
- Water activity of 0.85 may be conservatively low
- pH of 4.6 may not be low enough
- Inconsistent use of the word “hazard”
- Use of hurdle technology

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A PHF (TCS Food) Includes . . .

- A food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation
- Includes:
 - An animal food (a food of animal origin)
 - A food of plant origin that is heat-treated
 - Raw seed sprouts
 - Cut melons
 - Garlic-in-oil mixtures that are not modified to prevent growth
 - A food that is designated as Product Assessment Required (PA) in Interaction Table A or B

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PHF (TCS Food) does not include . . .

- Food that is designated as non-PHF/non-TCS in either Interaction Table A or B
- Unopened containers that are hermetically sealed and “commercially sterile”
- Foods for which laboratory evidence shows that T/T control is not required b/c the food contains intrinsic or extrinsic factors preventing growth:
 - Preservatives, antimicrobials, acidulents, etc.
 - Packaging, modified atmospheric packaging, shelf life and use, etc.

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PHF (TCS Food) does not include . . .

- Air-cooled, hard boiled egg – shell intact
- Shell eggs treated to destroy all salmonellae (pasteurized shell eggs)
- A food that does not support the growth of pathogenic microorganisms even though they may be present
- Some foods that are refrigerated for quality, not safety

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When to Use Interaction Table A

- Table A is used when a homogeneous food is heat-treated and subsequently packaged
- Food must be fully cooked to destroy vegetative cells
- Spore forming pathogens are the only remaining biological hazards of concern
 - Food is packaged to prevent re-contamination
- Higher pH & a_w can be safely tolerated
- No variation in day-to-day preparation

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Interaction Table A

Table A. Interaction of pH and a_w for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged.

a_w Values	pH Values		
	4.6 or less	> 4.6 – 5.6	> 5.6
0.92 or less	Non-PHF/non-TCS**	Non-PHF/non-TCS	Non-PHF/non-TCS
> 0.92 – 0.95	Non-PHF/non-TCS	Non-PHF/non-TCS	PA***
> 0.95	Non-PHF/non-TCS	PA	PA

* PHF means "Potentially Hazardous Food"
 ** TCS means "Time/Temperature Control for Safety Food"
 *** PA means "Product Assessment Required"

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When to Use Interaction Table B

- Table B is used when a homogeneous food is:
 - Not heat-treated, or
 - Is heat-treated but not packaged
- Food that is not heat-treated may contain vegetative cells
- Food that is heat-treated but not packaged may become re-contaminated with vegetative cells
- pH values must go as low as 4.2 because *Staphylococcus aureus* can grow at that level

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Interaction Table B

Table B. Interaction of pH and a_w for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged.

a_w Values	pH Values			
	< 4.2	4.2 – 4.6	> 4.6 – 5.0	> 5.0
< 0.88	Non-PHF/non-TCS**	Non-PHF/non-TCS	Non-PHF/non-TCS	Non-PHF/non-TCS
0.88 – 0.90	Non-PHF/non-TCS	Non-PHF/non-TCS	Non-PHF/non-TCS	PA***
> 0.90 – 0.92	Non-PHF/non-TCS	Non-PHF/non-TCS	PA	PA
> 0.92	Non-PHF/non-TCS	PA	PA	PA

* PHF means "Potentially Hazardous Food"
 ** TCS means "Time/Temperature Control for Safety Food"
 *** PA means "Product Assessment Required"

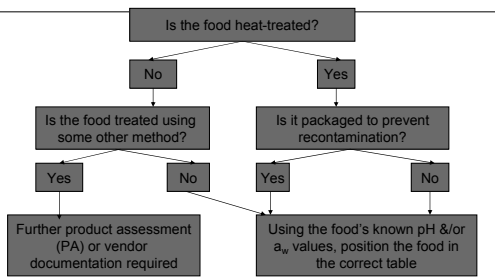
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Future Developments

- Guidance to be issued on how to use the Interaction Tables
- Q and A to be posted
- Conference for Food Protection Issue
 - What is an acceptable challenge study?
 - You may want to use the IFT Report, "Evaluation and Definition of Potentially Hazardous Foods" at www.cfsan.fda.gov/~comm/ift4-toc.html in the interim

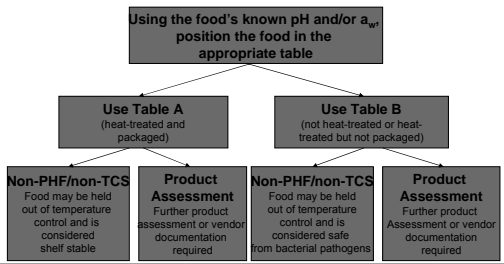
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Use of a_w /pH Interaction Tables - Decision Tree From Food Code Annex 3



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Use of a_w /pH Interaction Tables - Decision Tree From Annex 3 (continued)



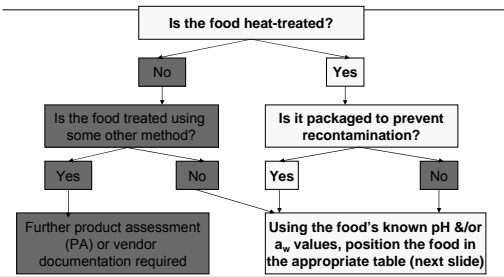
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Application of Interaction Tables - Parmesan Cheese

- **Parmesan Cheese:**
 - $a_w = 0.68 - 0.76$
 - pH = 6.5
 - curd heated to ~ 130°F & cured 2-3 years, then packaged
- Ambient storage desired & no history of related illness
- The food is heat-treated/cured & packaged
- Using this information, Table A is chosen
- Locate the cheese's a_w (0.68 – 0.76) in the correct line and pH (6.5) in the correct column
- They intersect at “Non-PHF/Non-TCS”
 - No time/temperature control is required

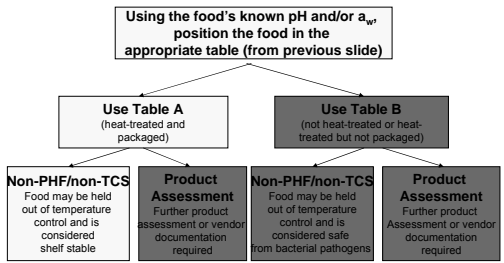
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Application of Interaction Tables - Parmesan Cheese



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Application of Interaction Tables - Parmesan Cheese



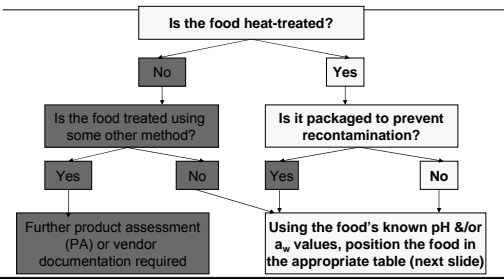
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Application of Interaction Tables - American Process Cheese Slices

- American Process Cheese Slices
 - $a_w = 0.94 - 0.95$
 - pH = 5.5 - 5.8
 - Heat processed and packaged during transportation to retail
- Ambient storage desired for 24 hrs.
- Cheese is heat-treated and unpackaged
- Table B is chosen because it may become recontaminated
- Locate the a_w (0.94 - 0.95) in the correct line and pH (5.5 - 5.8) in the correct column
- They intersect at PA - Product Assessment Required
 - Challenge testing with 4 pathogens at 86°F showed no growth for 24 hrs. and no growth for 210 days when refrigerated

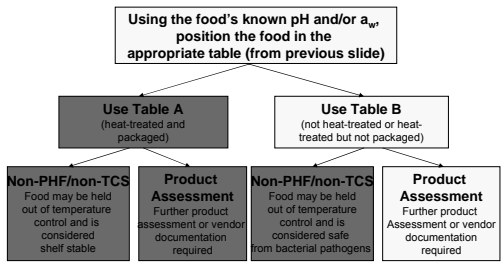
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Application of Interaction Tables - American Process Cheese Slices



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Application of Interaction Tables - American Process Cheese Slices



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Application of Interaction Tables - Industry

- Food considered must be homogeneous (not a combination food)
 - Combination food requires Product Assessment
- May be used to:
 - Formulate recipes to render a food non-PHF (non-TCS) (Requires a variance and HACCP plan)
 - Prove that a certain product is non-PHF (non-TCS) due to its inherent pH and/or a_w

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Laboratory Evidence (Product Assessment)

- When is laboratory evidence likely to be used?
 - Variance application
 - Using performance standards
 - Preservatives added
 - New technologies used
 - pH and a_w Interaction Tables say "PA" – Product Assessment Required
 - Multi-ingredient or combination foods with two or more distinct food components - the interface may have different properties than either of the individual ingredients
 - Operator wants to display food at room temperature when previously refrigerated

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Application of Interaction Tables - Regulators

- May be used to:
 - Assist with process validation when approving variances
 - Assess whether a food requires T/T control for safety when determining policy
- Expectations in the Field
 - Inspectors should conduct business as usual unless a new interpretation from FDA prompts a departmental policy change

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Date Marking

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Date Marking

3-501.11

- Amends date marking based on the results of the Lm Risk Assessment
- Focuses the provision on very high to medium risk foods which are more likely to be vehicles for Lm
- Exempts very low to low risk foods
- Allows use of any approved date marking system

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Relative Risk Ranking and Predicted Median Cases of Listeriosis for the Total United States Population on a per Serving and per Annum Basis

Relative Risk Ranking	Predicted Median Cases of Listeriosis for 23 Food Categories					
	Per Serving Basis ^a			Per Annum Basis ^a		
	Food	Cases		Food	Cases	
1	Deli Meats	7.7x10 ⁻⁸	Very High	Deli Meats	1598.7	
2	Frankfurters, not reheated	6.5x10 ⁻⁸	High Risk	Pasteurized Fluid Milk	90.8	
3	Pâté and Meat Spreads	3.2x10 ⁻⁸		High Fat and Other Dairy Products	56.4	
4	Unpasteurized Fluid Milk	7.1x10 ⁻⁹	Moderate Risk	Frankfurters, not reheated	30.5	
5	Smoked Seafood	6.2x10 ⁻⁹		Soft Unripened Cheese	7.7	
6	Cooked Ready-to-Eat Crustaceans	5.1x10 ⁻⁹		Pâté and Meat Spreads	3.8	
7	High Fat and Other Dairy Products	2.7x10 ⁻⁹	Moderate Risk	Unpasteurized Fluid Milk	3.1	
8	Soft Unripened Cheese	1.8x10 ⁻⁹		Cooked Ready-to-Eat Crustaceans	2.8	
9	Pasteurized Fluid Milk	1.0x10 ⁻⁹		Smoked Seafood	1.3	

Foods For Which Date Marking No Longer Applies

- ***Deli Salads Prepared and Packaged in a Food Processing Plant***
 - Examples: ham salad, chicken salad, egg salad, seafood salad, pasta salad, potato salad, and macaroni salad manufactured according to 21 CFR 110
 - 85% of deli salad sold is prepared in a processing plant
 - Nearly universal practice to add one or more preservatives shown to inhibit the growth of LM (e.g., sorbates, benzoates)

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Foods For Which Date Marking No Longer Applies

- ***Cultured Dairy Products***
 - Yogurt, sour cream, and buttermilk
- ***Hard and Semi-Soft Cheeses***
 - Factors may include organic acids, preservatives, competing microorganisms, pH, water activity, or salt concentration
 - Complete list of exempt cheeses appears in Annex 3

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Foods For Which Date Marking No Longer Applies

- ***Preserved Fish Products***
 - Pickled herring and dried and salted cod
- ***Shelf stable salt-cured products***
 - Prosciutto and Parma (ham)
- ***Shelf stable, dry fermented sausages***
 - Pepperoni and Genoa salami

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3-8
Special Requirements for
Establishments Serving Highly
Susceptible Populations

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3-8

- Added cross-reference to 3-501.19 which prohibits use of time as a public control for raw eggs
- Now prohibits re-service of food to/from persons in quarantine or medical isolation, or protective environment isolation

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Time As a Public
Health Control

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Scientific Basis for Time As A Public Health Control

- Primary hazard in cold food placed out of temperature control is Lm
 - Lag phase of Lm is ~6 hours provided the temp of the food and environment does not exceed 21° C (70° F)
- Primary hazards of concern in hot food placed out of temperature control are *Clostridium perfringens* and *Bacillus cereus*
 - Lag phase of Cp is ~ 4 hours under worse case conditions (i.e. stable temp @ or near 115° F)
 - Lag phase of B. cereus is > 4 hours at optimum temps between 77° F and 86° F

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Time As A Public Health Control

- Any PHF/TCS Food
 - Initial internal temp must be at or below 5° C (41° F) or 57° C (135° F) or greater
 - 4 hour time limit w/ written procedures and record keeping
- Allowance for Cold PHF/TCS Food
 - 6 hour time limit w/ written procedures and record keeping if:
 - Initial internal temp is at or below 5° C (41° F)
 - Internal temperature of food does not exceed 21°C (70°F)
 - Ambient temperature does not exceed 21° C (70° F)

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Allergens

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Allergens

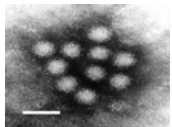
- Changes made to Food Code consistent with Food Allergen Labeling and Consumer Protection Act of 2004
- Added definition for “major food allergens”
 - Includes milk, eggs, fish (including crustaceans), tree nuts, wheat, peanuts, and soybeans
- Added requirement for PIC to be able to describe major food allergens and symptoms - 2-102.11(C)(9)
- Added labeling requirement for allergens in packaged foods

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Employee Health

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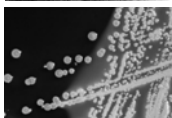
The “BIG FIVE” Pathogens Now Listed in the Food Code



Salmonella Typhi

Hepatitis A Virus

Shigella spp.



Enterohemorrhagic or Shiga toxin-producing

E. coli

Norovirus

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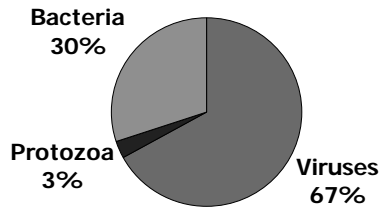
The Problem

- Estimated 76 million foodborne illnesses
- 325,000 hospitalizations annually; hospital stays estimated at more than \$3 billion
- and 5,000 deaths!

Mead et al., *Emerg. Infect. Dis.* 5:607-625

40

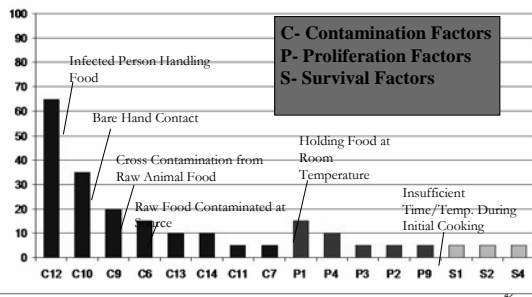
Percentage of Foodborne Illness Attributable to Known Pathogens



Mead et al., 1999

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CDC's EHS NET OUTBREAK/NONOUTBREAK STUDY - Contributing Factors Identified in Outbreaks, EHS-NET, 2002-2003



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All Pathogens Listed In Ch. 2 Have an Extremely Low Infectious Dose

- > Hepatitis A virus ~ 10 or less viral particles
- > Norovirus ~ 10 to 100 viral particles
- > EHEC is as low as 10 bacterial cells
- > *Shigella* spp. can be as low as 10 bacterial cells
- > *S.Typhi* is considered low ~ 1000 bacterial cells

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Potential Contamination Level per Gram of Feces:



- > Hepatitis A (HAV):
10⁸ viral particles
- > Noroviruses (NoV):
10⁷ viral particles
- > Bacterial infections: 10⁶

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Combination of High Levels Shed in the Feces and Low Infectious Dose

- Adds up to create a highly infectious microorganism
- All listed Food Code pathogens are highly infectious fecal-oral route pathogens

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Potential Transmission Level Norovirus

- Shed in the feces at levels up to 10,000,000 viral particles per gram of feces
- One projectile vomiting incident can potentially contaminate the environment with 30,000,000 viral particles
- Infectious dose of NoV is estimated from 10-100 viral particles

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Transmission of Norovirus

- Fecal-Oral Route
- Airborne Inhalation
- Person-to-Person
- Environment-to-Person

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Controlling Norovirus Depends on Preventing the Transmission

- Handwashing & prohibiting bare hand contact with RTE food items is critical
- Removing food workers with active vomiting and/or diarrhea is critical
- Reducing airborne transmission and treat as infectious material
- Cleaning staff should use barriers, such as face masks, gloves, and aprons
- Dispose materials used to clean-up vomiting incident and thoroughly disinfect the area

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Revised Employee Health

- Covered under 3 sections in Chapter 2 of the Food Code.

- 2-201.11 = Responsibility of the Employee & Manager & Reporting Requirements
- 2-201.12 = Exclusion and Restriction guidelines
- 2-201.13 = Removal, Adjustment, or Retention of Exclusions and Restrictions

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New Definition

- **"Conditional Employee"** means a potential food employee to whom a job offer has been made, conditional on responses to subsequent medical questions or examinations designed to identify potential food employees who may be suffering from a disease that can be transmitted through food and done in compliance with Title 1 of the American Disabilities Act of 1990.

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Employee Health

- 2-201.11
 - Identifies responsibilities of the person in charge, conditional employees, food employees, and all employees

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2-201.11 – Reporting Responsibilities

- Food Employee or Conditional Employee to PIC
 - Symptoms
 - Diagnosed illness with Big 5
 - History of exposure
- PIC to Health department
 - Jaundiced employee
 - Diagnosed illness with Big 5

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2-201.11 – Other Responsibilities

- PIC
 - To make sure conditional employee does not become a food employee until criteria are met
 - To exclude or restrict food employees
- Food employee
 - To comply with exclusions and/or restrictions

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Employee Health

- 2-201.12
 - Revises basis for excluding and restricting employees
 - Symptoms only (no Diagnosis)
 - Diagnosis w/ any of the 5 listed pathogens (with or without symptoms)
 - Exposure to any of the 5 listed pathogens

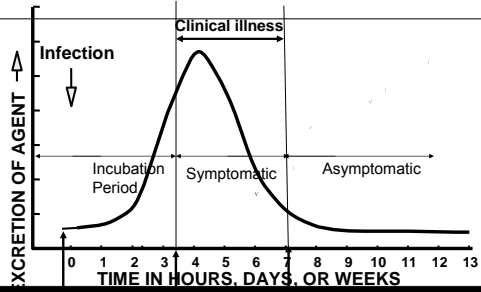
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New Tiered Approach to Employee Health

- Risk
 - How much organism is being excreted?
 - How close is the person to the food?
- The more that is excreted and the closer to food, the greater the risk

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Disease Process Timeline



Exposure Onset of Symptoms End of Symptoms

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Risk-Based Employee Health

- Level I:
 - Active gastrointestinal symptoms or diagnosis with *S. Typhi* or hepatitis A virus
- Level II:
 - Diagnosis and symptom resolution
- Level III:
 - Diagnosis and never developed symptoms
- Level IV:
 - Exposure to listed pathogen

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New Definitions

- **"Exclude"** means to prevent a person from working as an employee in a food establishment or entering a food establishment as an employee.
- **"Restrict"** means to limit the activities of a food employee so that there is no risk of transmitting a disease that is transmissible through food and the food employee does not work with exposed food, clean equipment, utensils, linens; and unwrapped single-service or single-use articles.

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Summary of Food Code Exclusions

- **Active gastrointestinal symptoms:**
 - Jaundice—within 7 days of onset
 - Diarrhea,
 - Vomiting
- **Diagnosis with:**
 - Norovirus + diarrhea and/or vomiting,
 - EHEC + diarrhea and/or vomiting,
 - Shigella spp. + diarrhea and/or vomiting

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Summary of Food Code Exclusions (cont'd)

- **Diagnosis with typhoid fever**
- **Diagnosis with HAV**
 - If within 7 days of jaundice or 14 days of any symptoms
- **Also Exclude in a HSP:**
 - Diagnosis with listed Pathogen and asymptomatic
 - Sore throat with fever

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Summary of Food Code Restrictions

- Infected wound or cut if not protected/covered
- Sore throat with fever if not in a HSP
- Asymptomatic and diagnosed with EHEC, *Shigella*, or Norovirus if not in a HSP
- Exposure to a listed pathogen in a HSP

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2-201.13 – Removal, Adjustment, or Retention of Exclusions and Restrictions

- Rationale for reinstating excluded or restricted employees depends on:
 - Specific pathogen involved
 - Symptomatic vs. diagnosis
 - Resolution of symptoms
 - Type of food facility (HSP vs. general population)

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Implementation Tools

- Annex 3 – Exclusion and Restriction Charts
- Annex 7 – Model Forms
 - Conditional Employee or Food Employee Interview
 - Conditional Employee or Food Employee Reporting Agreement
 - Conditional Employee or Food Employee Medical Referral
- Additional guidance forthcoming

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Alternative Procedure to No Bare Hand Contact

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Alternative Procedure to No Bare Hand Contact

- Added new ¶ (D) to:
 - Provide the criteria that must be met for approval of an alternative procedure to No Bare Hand Contact with ready-to-eat foods, and
 - Require prior approval from regulatory authority
- Added criteria include:
 - a written employee health policy
 - documentation of a training program

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Alternative Procedure to No Bare Hand Contact

- Added criteria include (cont'd):
 - documentation of food employee handwashing compliance
 - documentation that food employees contacting ready-to-eat foods with bare hands utilize two or more control measures
 - documentation that corrective actions are taken
- Annex 7 – Form 1-D – Application for Bare Hand Contact Procedure

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Hand Washing

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2-301.14 - Handwashing

- Amended to update proper sequence for handwashing procedure and avoiding recontamination of the hands, after handwashing.
- Amended handwashing cleaning procedure to be more consistent with the recommended handwashing procedure in CDC's Hygienic Practice Guidelines for Health Care Workers

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Handwashing Procedure

- (1) Rinse hands under clean, running warm water;
- (2) Apply an amount of cleaning compound to hands recommended by the cleaning compound manufacturer;
- (3) Rub hands together vigorously (or by vigorously rubbing the surrogate prosthetic devices for hands or arms) for at least 10 to 15 seconds while:
 - (a) Paying particular attention to removing soil from underneath the fingernails during the cleaning procedure; and
 - (b) Creating friction on the surfaces of the hands and arms, lathered fingers, finger tips and areas between the fingers;

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Handwashing Procedure

- (4) Thoroughly rinse hands, finger tips and arms under clean, running warm water; and
- (5) Immediately follow the cleaning procedure with thorough drying of cleaned hands and arms (or surrogate prosthetic devices).

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Handwashing (Continued)

- 2-301.16
- Amended to clarify term “sanitization” does not apply to hand antiseptics; replaced “hand sanitizer” with “hand antiseptic”

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Demonstration of Knowledge

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Demonstration of Knowledge

- Clarifies that “compliance with this Code” means no critical items – 2-102.11(A)
- Added knowledge of major food allergens – 2-102.11(C)(9)
- Added knowledge of reporting responsibilities 2-102.11(C)(17)

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Demonstration of Knowledge (cont.)

- Notes CFP-recognized accredited agency as certifier of food safety manager programs – 2-102.20

Duties

- Adds to duties that PIC ensures that employees are informed of reporting requirements 2-103.11(M)

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Reduced Oxygen Packaging (ROP)

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Definition of Reduced Oxygen Packaging (ROP)

- Added Cook Chill Packaging
 - Cooked hot food is hot-filled into impermeable bags and sealed
 - Bags are rapidly cooled and refrigerated at temperatures that inhibit psychrotrophic pathogens
- Added Sous Vide Packaging
 - Raw or partially cooked food (seared for color) is hermetically sealed in impermeable bags
 - Food is cooked in the sealed bags
 - Bags are rapidly chilled and refrigerated at temperatures that inhibit psychrotrophic pathogens

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ROP Changes

- In 3-501.12 Reduced Oxygen Packaging, Criteria*
 - Both *Clostridium botulinum* and *Listeria monocytogenes* must be considered
 - Criteria for cook chill and sous vide packaging without a variance added
 - Criteria for packaging certain cheeses under reduced oxygen without a variance added

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ROP Controls in the Food Code

- Primary ROP Barrier is Refrigeration
 - All potentially hazardous food (temperature control for safety food) requires refrigeration
 - Few treatments reliably destroy all pathogenic microorganisms in food except heat sterilization and irradiation
 - Other inhibitory factors (hurdles) used in combination with refrigeration can be equally effective at preventing spoilage and foodborne illness

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ROP Controls in the Food Code

- Secondary barriers or hurdles **with** refrigeration at 41°F (“Hurdle Effect”)
 - pH or acidity ≤ 4.6
 - Water activity (a_w) ≤ 0.85
 - Cured meat or poultry products

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Cook chill or sous vide packaging without a variance

- HACCP plan is developed & implemented and records are held 6 months
- Food is prepared and consumed on the premises (or at a satellite site owned by the establishment)
- No sale of bagged product to another business or directly to the consumer
- All other applicable provisions of the Food Code are followed
- Bagged product is then cooled to 34°F within 48 hrs. and held there for no more than 30 days
- Product temperatures in bags is electronically monitored during transportation and storage
- Bags are labeled with product name and date packaged

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Vacuum packaging cheeses without a variance

- Only cheeses that meet the Standard of Identity for hard cheeses (21 CFR 133.150), semi-soft cheeses (21 CFR 133.187) & pasteurized process cheeses (21 CFR 133.169) may be vacuum packaged in food establishments
- 2 barriers: $\leq 41^\circ\text{F}$ storage and intrinsic factors of cheese
- HACCP plan and labeling requirements
- Sell, use or discard after 30 days

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Annexes

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Highlighted Changes to Annexes

- Various additions to Annex 2
- Various amendments/clarifications made in Annex 3
- Annex 4 and 5 – Major re-writes outlining FDA's current thinking on retail HACCP and RB inspections
- Annex 7 – Updated employee health forms
- Annex 7 – New Inspection Form

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Annex 2 Six New Supporting Documents

- Growing Sprouts in a Retail Food Establishment
- Advisories for Retail Processing with Proper Controls and Variances for Product Safety
- Evaluation and Definition of Potentially Hazardous Foods

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Annex 2

Six New Supporting Documents

- The U.S. Equal Employment Opportunity Commission (EEOC) Guide, *“How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers”*
- Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information
- Recommended Guidelines for Permanent Outdoor Cooking Establishments

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Annex 4

- Completely rewritten and retitled
- *“Management of Food Safety Practices – Achieving Active Managerial Control of Foodborne Illness Risk Factors”*

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Annex 5

- Completely rewritten and retitled
- *“Conducting Risk-based Inspections”*

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