
Re-designation of Food Code Provisions

By the 2008-2010 CFP Criticality
Implementation and Education Committee

Objectives of Criticality Implementation Training

- #1 – Explain the **three new definitions** and the **risk assessment process** used to define the level of risk of Food Code provisions and their relationship to preventing foodborne illness.
- #2 – Provide clear and concise **training** for regulators, operators and trainers in restaurants, retail food stores, institutions and vending with examples and how to communicate this information in an effort to reduce the incidence of foodborne illness and injury

Objectives of Criticality Implementation Training

- #3 – **Increase awareness and understanding of the changes** in compliance and enforcement sections of the Food Code related to the re-designated provisions
- #4 – Give different examples of where and how to **apply the new designations** of Food Code provisions in routine activities to achieve long term behavior change, including in training, active managerial control and inspections

Introduction to Re-Designated Food Code Provisions - History

- The usual inspection/enforcement system in a food establishment emphasizes reactive, rather than preventive measures for food safety
- Additional measures must be taken by operators and regulators to better prevent, eliminate or reduce the occurrence of foodborne illness and injury **before it occurs**
- The re-designated provisions focus attention on the level of risk for foodborne illness or injury for any violation in the Food Code

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The new system of designating the provisions of the Food Code according to the level of risk of causing foodborne illness or injury will help focus attention so operators, regulators and trainers prevent rather than react to a foodborne illness or injury.

History of Changes

- Issues were submitted to CFP since 2000 to remove “critical” and “non-critical” designations of Food Code provisions and replace them
 - “Critical item” was defined as a provision of this Code, that, if in noncompliance, is more likely than other violations to contribute to food contamination, illness, or environmental health hazard.
 - There was misunderstanding about critical items being connected to HACCP
- 11 issues, 3 committees and 1 work group were established to work on the charges
 - In 2004, CFP charged FDA to develop alternative terms

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Members of the Conference for Food Protection have tried since 2000 to remove the terms “critical” and “non-critical” as code provision descriptors. The main reason appeared to be a misunderstanding that “critical” was related to HACCP (as in critical control point or critical limit). The definition of “critical item” was also considered to be a little unclear. More information about the issues that were submitted and the results of the Committees and work groups that considered the issues can be found at CFP’s website, <http://www.foodprotect.org> under Previous Biennial Meetings.

History of Changes

- In 2008, FDA submitted a 3-tiered set of definitions to CFP to rank Food Code provisions by risk
- The definitions were used with a qualitative risk assessment process to rank the Food Code provisions by their risk (high, medium or low risk) of causing foodborne illness or injury
- The re-designated terms were incorporated into the 2009 Food Code

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In 2008, FDA submitted a new 3-tiered set of definitions along with a qualitative risk assessment in response to a charge from CFP in 2004 and 2006. The new designation system for the provisions in the Food Code were based on risk of foodborne illness or injury.

This was a 4 year process where FDA's work group collaborated with the CFP Critical Items Committee, as CFP stakeholders, to develop the process and re-designations.

While there was some disagreement over the name of the designated terms used in the risk assessment, there was good agreement on the process itself. Neither the present committee nor the CFP Executive board were able to come to a full consensus on new terms. Therefore, FDA used the original terms as submitted to the Conference in 2008 to amend the 2009 Food Code.

New Definition of Priority Item

- **“Priority Item”**
 - **“Priority item”** means a provision in this Code whose application contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard.
 - **“Priority item”** includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, handwashing; and
 - **“Priority item”** is an item that is denoted in this Code with a superscript – ^P.

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Note in the “Priority Item” definition:

- These provisions contribute directly to the elimination, prevention or reduction to an acceptable level, hazards (or agents) associated with foodborne illness or injury.
- A test to determine if this is a Priority Item or not is to ask if there is another provision that more directly controls the identified hazards).
- Priority items always have a quantifiable measure (or critical limit) that will indicate control of the hazards.
 - Examples are time/temperature parameters, chemical concentrations, presence/absence, etc.

Priority Item^P

- When a Priority Item in the Food Code is out of compliance, it has the highest risk of causing foodborne illness or injury
- Compliance with a Priority Item eliminates, prevents or reduces to an acceptable level, biological, chemical or physical hazards that **directly** cause foodborne illness or injury (see Annex C – What are common food safety hazards?)
- No other provision more directly controls the hazard
- There is a **quantifiable measure or critical limit** for each Priority Item
- The term Priority Item implies an importance and need for immediate correction.



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Note that a Priority Item directly controls a hazard

•It is designated by a superscript P in the Code.

•Annex C, “What are common food safety hazards?” provides introductory information about hazards that the Food Code provisions are designed to control, either directly or indirectly.

New Definition of Priority Foundation Item

- **“Priority Foundation Item”**
 - **“Priority foundation item”** means a provision in this Code whose application supports, facilitates or enables one or more Priority Items.
 - **“Priority foundation item”** includes an item that requires the purposeful incorporation of specific actions, equipment or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling; and
 - **Priority foundation Item”** is an item that is denoted in this Code with a superscript Pf – ^{Pf}.

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The second defined term is a “Priority Foundation Item”

- A Priority Foundation Item when applied, supports, facilitates or enables a Priority Item
- These provisions are usually actions, equipment or procedures that help or support the control of a hazard by a Priority Item
- A provision is designated by a Pf in the Code.

Priority Foundation Item^{Pf}

- A Priority Foundation Item is usually linked to a Priority Item and supports, enables or helps achieve it
- Active managerial control/industry control systems support the compliance of Priority Items, such as:
 - Conducting personnel training (See Annex A&B)
 - Monitoring and enforcing Priority activities
 - Providing necessary equipment, facilities, etc. to carry out Priority activities
 - Developing & carrying out HACCP plans when necessary
 - Maintaining documents or records as necessary
 - Labeling food for employees or consumers
- The term Priority Foundation links the provision to a Priority Item

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•There is usually a clear link between a Pf and P Item so the Pf Item supports or enables the P Item.

•Using Pf items, industry control systems or active managerial control can support the compliance of P Items.

•Annex A, “How can regulators, operators, and trainers effectively change behavior?” and Annex B, “What are some communication techniques to help convey our messages of food safety?” can assist us achieve more effective training.

•Policies, procedures, documentation, HACCP plans (if required), labeling, equipment, infrastructure, etc. provide a foundation for achieving a Priority Item.

New Definition of Core Item

- **“Core Item”**
 - **“Core item”** means a provision in this Code that is not designated as a Priority Item or a Priority Foundation Item.
 - **“Core item”** includes an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

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A Core Item is usually a general provision that is not directly related to a specific Priority Item but rather to the entire facility.

General sanitation, SSOPs, facility or equipment design and construction, and general maintenance are examples of Core Items.

A Core Item has no specific superscript designation in the Code.

Core Item

- A Core Item is a good retail practice (GRP) which is not intended to control a particular hazard but hazards in general
- A Core Item has no superscript in the Food Code
- Core Items include:
 - General sanitation requirements
 - Sanitation Standard Operating Procedures (SSOPs)
 - Equipment design
 - Design & construction of facilities and structures
 - General maintenance & repair
 - Operational controls

Relationship between Priority Items and Imminent Health Hazards

- **Imminent health hazard:**
 - A significant threat in an entire establishment that may endanger the public health which requires the operation to cease operation if immediate correction is not possible and to notify the RA
 - Priority Items such as smoke or fire damage, flood, extended electrical or water outage, extended lack of hot water, sewage back-up, foodborne outbreaks, misuse of toxic substances, gross insanitary condition, etc.
- **Not all Priority Item violations are imminent health hazards**, only those that affect the operation of the entire establishment or a large part of that operation

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- The Food Code in Section 8-404.11 calls for an Operator to cease operation and report to the Regulatory Authority in case of an imminent health hazard because of an emergency situation.
- An imminent health hazard is a significant threat to public health in the entire establishment and requires the facility to cease operation if immediate correction is not possible.
- The emergency is usually directly related to Priority Items such as”
 - floods,
 - Extensive smoke or fire damage
 - Extended electrical or water outage
 - Extended lack of hot water
 - Sewage backup
 - Foodborne outbreak
 - Misuse of toxic substances (i.e., pesticides)
 - Gross insanitary conditions
- Note that not all Priority Item violations are imminent health hazards, only those that affect the entire establishment operation.
- Note also that often corrective actions can be taken in a short time, i.e., a few hours, to resolve the situation. The situation should be reported to the Regulatory Authority to work out what would be acceptable to continue operating. For example, bottled water could be used for a short time before repairs when a water main breaks or heating water for washing hands and using single-service items could be done when the hot water heater breaks down but can be replaced soon.

Qualitative Risk Assessment Process

- A qualitative risk assessment is used to rank risk of foodborne illness or injury in very complex situations such as a food service/food store or provisions in the Food Code
- A qualitative risk assessment process considers:
 - The likelihood of causing foodborne illness or injury
 - The characteristics of the hazard (virulence and severity)
 - The size and/or number of outbreaks (infectivity or potential for illness or injury)
 - Any contributing factors (contamination, proliferation or survival) identified in previous foodborne outbreaks reported to CDC

What does this change to a risk assessment process mean to me?

- Food Code provisions are prioritized according to their risk of causing foodborne illness or injury (P, Pf or C)
- Using science-based reasoning for the new terms promotes:
 - Internal consistency in the Food Code
 - Objective, not subjective designations
- For further explanation of the ranking process, see:
 - Risk assessment decision making process
 - Public Health Reasons, Annex 3 of the Food Code
 - Published references in the Excel spreadsheet and Annex 2 of the Food Code, available at:
 - <http://fda.gov/Food/FoodSafety/RetailFoodProtection.default.htm>

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- This is a change from critical and non-critical, often difficult to categorize, to a risk-based system that prioritizes enforceable Food Code provisions.
- This is done by ranking the provisions as Priority (P), Priority Foundation (Pf), or Core (C) according to the risk of causing foodborne illness if the provisions are uncontrolled (Out of Compliance)
- The risk assessment process with definitions provides a scientific decision making process for ranking the provisions.
- Annex 2 and 3 of the 2009 Food Code provide additional information about the ranking process.

What does this change to a risk assessment process mean to me?

- It is possible to prioritize operational and regulatory food safety activities according to the level of risk provided by that violation
 - Priority Item – highest risk, direct connection to foodborne illness or injury
 - Priority Foundation Item – supports one or more Priority Items
 - Core Item – lowest risk, general good practices
- There is a recognized critical limit (quantifiable measure) to show compliance with the highest risk priority items

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•Because the provisions have already been ranked according to their level of risk, operators and regulators can use the ranking (P, Pf, or C) to prioritize their food safety activities.

•When a Food Code provision contains a quantifiable measure or critical limit, that usually means it is a P item.

Risk Assessment Process

- The risk assessment process starts by identifying the food safety hazard(s) each provision in the Code will control
- Biological Hazards* include, for example:



- Vegetative bacteria



- Spore-forming bacteria



- Viruses



- Parasites

*** See Annex C for more examples and explanations of hazards in foods**

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- The decision-making process in assigning a risk level to a provision first starts with identifying a food safety hazard(s) that is typically controlled by that provision.
- Biological hazards that may be controlled by a provision include some or all of the following:
 - Vegetative and spore-forming bacteria, viruses and parasites
 - Annex C, “What are common food safety hazards?” contains additional information about the hazards that may be controlled by that provision. The slides can also be used as a stand-alone training course.

Risk Assessment Process

- Chemical hazards* include, for example:



- General chemical contamination (cleaning compounds, sanitizers, allergens, additives)



- Scombroid toxin (*B. proteus* breaks histadine down to histamine in certain temperature-abused fish)
- Ciguatera toxin (natural toxin in reef-fish)

*** See Annex C for more examples and explanations of hazards in foods**

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- Chemical hazards that are controlled by particular Food Code provisions include:
 - Common chemicals used in a food establishment (cleaners, sanitizers, allergens, additives, etc.)
 - Scombrototoxin (histamine) poisoning from certain temperature abused fish.
 - Ciguatera and other phytotoxins that are contained in dinoflagellates and other microscopic plants that are consumed by fish.

Risk Assessment Process

- Physical hazards* include, for example:



Bone



Metal fragments

Bandage

Jewelry



Hair



* See Annex C for more examples and explanations of hazards in foods

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•Physical hazards in food which must be controlled include:

•Non-food items such as bone, metal, glass, bandages, hair and more.

Risk Assessment Process

Initial Evaluation

- After identifying the hazard associated with that provision, determine which of the 3 defined terms (P, Pf or C) most clearly describes this provision, e.g.,
 - Cook poultry to 165°F for 15 sec. (CL) destroys vegetative pathogens (Priority Item)
 - No date marking system used on RTE potentially hazardous/TCS food to limit shelf life and control *Listeria* (Priority foundation Item)
 - Floor in grill area dirty – general sanitation (Core Item)

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- Make an initial determination of the provision designation by considering the hazard, which of the 3 definitions most likely applies and whether there is a quantifiable measure (something measurable).
- If the initial choice is P, ask whether there is another provision that more directly controls the hazard. If so, the provision may not be a P but will probably be a Pf.

Risk Assessment Process

Other Characteristics

- Determine if other characteristics of the hazard increase the risk:
 - Virulence where hazard has severe consequences - HIGH
 - high potential by ill food worker to spread hazard to food or patrons
 - more than one mode of transmissions (ingestion, inhalation, person-to-person)
 - shed at high levels (i.e., norovirus)
 - extremely virulent
 - low infectious dose (i.e., *Listeria monocytogenes*)
 - potential for secondary infection (e.g., Norovirus, *Shigella* spp., *E. coli* O157:H7)
 - extremely toxic chemical or natural toxin (i.e., *Clostridium botulinum*)
 - high incidence of hospitalization and death, (e.g., *Clostridium botulinum*, *Listeria monocytogenes*)
 - chronic sequelae possible (*E. coli* O157:H7, *Salmonella* spp., parasites)

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•Once the initial determination has been made, the consideration of other factors in conjunction with the definitions confirm or change the designation.

•Virulence or severity of the hazard's effect is controlled by the provision under consideration.

•For example, a highly virulent hazard controlled directly by a provision confirmed the provision as a Priority Item.

•The virulence of the controlled hazard can also indicate the priority of attention that provision should receive, that is, the more virulent a pathogen is that is being controlled, the greater attention it should receive.

Risk Assessment Process

Other Characteristics

- Assess characteristics of the hazard:
 - Virulence or severity of hazard - MEDIUM:
 - medium potential for ill food worker to spread hazard to food or patrons
 - medium infectious dose
 - unlikely secondary infection
 - high incidence of hospitalization but few deaths

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•A medium severity for a particular hazard may change the immediacy of corrective action compared to a highly virulent hazard but will not change the fact, for example, that a provision is a Priority Item and directly related to causing foodborne illness.

Risk Assessment Process (cont'd.)

- Assess characteristics of hazard:
 - Virulence or severity of hazard - LOW:
 - low potential for ill food worker to spread hazard to food or patrons
 - low infectious rate
 - unlikely secondary infection (e.g., *Clostridium perfringens*, *Bacillus cereus*)
 - high incidence of illness but low incidence of hospitalization or death
 - mild symptoms
 - short duration

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•A low severity of the hazard associated with that provision does not usually change the designation (P, Pf or C) but may affect the order of response when other violations of the same designation are present.

Risk Assessment Process

Other Characteristics

- Assess size & number of outbreaks based on infectivity of the hazard in the absence of control provided by the Code:
 - **High** – large outbreaks, large number of outbreaks
 - **Medium** – small outbreaks, small number of outbreaks
 - **Low** – individual cases, sporadic cases

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•Infectivity of the hazard does not change the designation, e.g., P, Pf or C. That is based on the definition.

•Infectivity of a biological hazards often has an impact on the number of people involved in an outbreak.

•Norovirus is a good example. This virus is highly infective and often causes large outbreaks, therefore infectivity will be high.

•C. botulinum does not cause large numbers of ill or large numbers of outbreaks but it is highly virulent (the symptoms of botulism are very severe).

Risk Assessment Process

- Identify relevant CDC contributing risk factors including contamination, proliferation or survival
- Revise the initial designation based on additional information
- Provide rationale for the decision and references that explain or support designation

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- The CDC contributing factors can help point out the activities related to contamination, proliferation or survival of particular hazards.
- The number or percentage of a particular contributing factor should not be used to designate or rank provisions because the collated data which CDC summarizes and publishes is incomplete. Nearly half of all outbreaks reported to CDC do not contain identified contributing factors.

What criticality changes were made in the Food Code?

- Three new definitions were added to Chapter 1:
 - Priority Item
 - Priority Foundation Item
 - Core Item
- Section 2-102.11(A) Demonstration (of Knowledge) was changed to say one of the ways the PIC could show compliance with the Code was by having no Priority Item (instead of critical item) violations during the current inspection
- A superscript (^P or ^{Pf}) is used to identify Priority or Priority Foundation Items in Chapters 2-8, Core Items have no superscript
- Five sections in Chapter 8 were amended to change Critical Item and/or Non-Critical Item to Priority Item, Priority Foundation Item and/or Core Item.

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•The 2009 Food Code was amended to remove the terms “critical,” “non-critical” and “swing” items and replace them with the terms “Priority,” “Priority Foundation” and “Core.”

•The new terms P, Pf and C were defined in Chapter 1 of the Code to show how closely linked an individual provisions was to preventing, eliminating or reducing to an acceptable level hazards that cause foodborne illness

•The terms Priority (designated by a superscript P), Priority foundation (designated by a superscript Pf) and Core (no superscript designation) are defined in Chapter 1 and used in Chapter 2 and 8.

•Section titles, statements that work in conjunction with the following provision and italicized language are not designated because they are not enforceable.

Chapter 2 Management and Personnel (2-102.11)

- Paragraph 2-102.11(A) Demonstration (of Knowledge)
 - One of the options open to operators of food establishments to show demonstration of food safety knowledge as it applies to their facility is to have no violations of Priority Items during the current inspection

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- An operator of a food establishment must be able to demonstrate to the regulatory inspector that he/she has knowledge of foodborne disease prevention, application of HACCP principles and requirements of the code in the jurisdiction where the facility is located.
- The operator can demonstrate this knowledge by having no violations of Priority Items during the current inspection according to paragraph (A) in 2-102.11
- The other two options available to the operator or person in charge are:
 - Being a certified food manager based on an accredited test
 - Responding correctly to questions from the inspector about specific areas of knowledge as they relate to that establishment.

Chapter 8 Compliance & Enforcement (8-401.20)

- **Section 8-401.20 Performance- and Risk-Based (inspection frequency)**
 - Prioritize and conduct more frequent inspections based on:
 - Food establishment's history of non-compliance with P & Pf items in the Code or HACCP Plan
 - Numerous or repeat violations of C items
 - This section of Chapter 8 is recommendation only and not enforceable

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- The system used to set the frequency of inspection for food establishments should include consideration of the history of non-compliance with P and Pf Items.
- When an establishment's management control system does not effectively control P and Pf items, the Regulatory Authority should require more frequent regulatory inspections.
- NOTE: this provision is not enforceable (Section 8-401.20 ends in .20 based on the Food Code writing convention).

Chapter 8 Compliance & Enforcement (8-403.10)

- **Section 8-403.10 Documenting Information and Observations (documentation on inspection forms)**
 - Document on an inspection report non-compliance with P and Pf Items and non-conformance with critical limits of a required HACCP Plan
 - This section of Chapter 8 is recommendation only and not enforceable

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•The subparagraphs ((B)(3) and (B)(6) in Section 8-403.10 recommends the inspector document violations on an inspection report observed during an inspection for all P and Pf violations as well as non-conformance with critical limits of any required HACCP Plan (e.g., variances, ROP with or without a variance, packaged juice).

•NOTE: This is a recommendation and not a requirement (Section number ends in .10).

Chapter 8 Compliance & Enforcement (8-405.11)

■ Section 8-405.11 Timely Correction

- Correct P or Pf Items at the time of inspection
- Implement corrective actions for a required HACCP plan provision that is not in compliance with its critical limit (CL)
- The Regulatory Authority may agree to a longer time for correction (usually for Pf Items), not to exceed 10 days, based on the potential hazard and complexity of the corrective action
 - The P Item it supports must be in compliance using some other procedure, method, equipment, etc. for an extended period for compliance

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•Section 8-405.11 requires correction of P and Pf Items at the time of an inspection because of their direct and supporting roles, respectively, in controlling hazards that cause foodborne illness and injury.

•It also requires correction of provisions of a required HACCP plan not in compliance with their critical limits (equivalent to a P Item).

•Paragraph (B) is an exception which allows a Regulatory Authority (inspector) to extend the time for correction of P, Pf or HACCP Plan provisions with a critical limit up to 10 days based on the severity or virulence of the hazard or on the complexity of the corrective action, i.e., extensive repairs are needed, something must be ordered from a supplier.

Chapter 8 Compliance & Enforcement (8-405.20)

- **Section 8-405.20 Verification and Documentation of Correction**
 - Record correction of P and Pf Items or corrected HACCP Plan deviations observed during an inspection on an inspection report
 - After receiving notification that a violation of a P or Pf Item or a HACCP Plan deviation has been corrected, the Regulatory Authority will verify and document correction of the violation
 - This Section of Chapter 8 is recommendation only and not enforceable

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•This section recommends that any P or Pf Item or HACCP Plan deviation that is corrected during the inspection (COS or corrected on-site) should be noted on the inspection report.

•NOTE: This is a recommendation and not required.

Chapter 8 Compliance & Enforcement (8-406.11)

- **Section 8-406.11 Time Frame for Correction**
 - Correct C Items by a date and time agreed to by the Regulatory Authority but no later than 90 days after the inspection
 - The Regulatory Authority may approve a longer compliance schedule:
 - If it is provided in writing
 - If no health hazard exists or will result from the extended compliance schedule

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•Time for correction of Core Items may be extended up to 90 days or longer if the operator or permit holder submits a written plan of correction, i.e., when the facility intends to make the correction when the facility is next remodeled.

Who can use the new terms?

- The new terms allow focusing and prioritizing of tasks, training* and corrective actions for the
 - Inspector
 - Person-in-charge
 - Trainer



* See Annex A – Effective Behavior Change and Annex B – Communication Techniques for training assistance

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- The inspector has a responsibility to conduct food safety inspections to prevent foodborne illness.
- The Person in Charge (PIC) has a responsibility and duty (see Sec. 2-103.11) to explain, train and then monitor employees in certain food safety activities.
- The trainer helps both the inspector and PIC train employees in food safety practices to protect consumers against foodborne illness.
- The new designation terms (P, Pf and C) allow the PIC, inspector and trainer to prioritize and focus on activities that are most directly related to causing and preventing foodborne illness and injury.
- NOTE: Annex A on effective behavior change and Annex B on communication techniques provide additional information to help accomplish these objectives. These annexes are not mandatory.

How can the new terms be used?

- New terms P, Pf and C:
 - Designations help identify issues for “Active Managerial Control”
 - They guide regulatory inspections and enforcement.
 - They aid trainers focus their courses on the most important food safety information for their students



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- These terms give a credible, science-based way to identify the most significant activities requiring incorporation into the:
 - Management’s food safety systems
 - Inspector’s risk-based inspections
 - Trainer’s food safety training

How can regulators, QA & 3rd party inspectors use the new terms?

- Increase frequency of inspections for establishments with history of non-compliance with P Items
- Do risk-based inspections that focus on P Items
- Require immediate correction or initiate correction of all P or Pf violations during inspections
- Use “teachable moments” to explain why P Items are most important
- Develop various options for correction of P Items
 - E.g., different methods for cooling, accomplishing no bare hand contact with RTE food, reheating
- Present inspection findings at exit interview based on level of risk (P Items first, then Pf Items and finally C Items if time permits)
- Assure that P and Pf Items are addressed during plan reviews.

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• Inspections, whether done by a regulatory authority, 3rd part auditor or the manager as he/she does a walk-through, should focus on issues that have the most impact on preventing, eliminating or reducing to an acceptable level, factors that cause foodborne illness or injury.

• The new designation of terms allows them to do that.

Potential Uses - Compliance & Enforcement

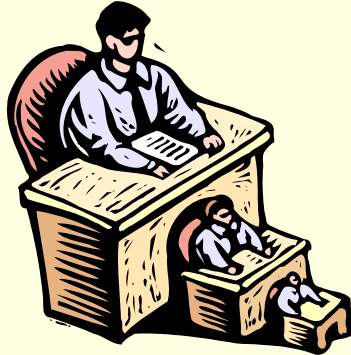
- Develop intervention strategies for long term compliance for “P” items identified in inspection summaries, baseline surveys, foodborne outbreaks, etc.
- Amend state or local Food Code to reflect use of new terms
- Provide longer time for correction of Priority Foundation Items (if the P item it supports is controlled) and Core Items because of lower risk level
- Provide stakeholders with an explanation of the definitions and risk assessment process and their link to preventing foodborne illness and injury

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•Regulatory agencies (or companies) can develop specific long term strategies to change behaviors that contribute to foodborne illness, especially those related to P items.

- Use summary data to identify where attention is needed
- Change codes, policies and procedures to focus attention on new terms
- Require immediate correction of P Items that directly relate to foodborne illness or injury but allow longer periods for correction of Pf Items where there may be other ways to support the item.

How can the food industry use the new terms?



Shift attention to Priority Items in:

- Management systems
- Standard Operating Procedures
- Recipes
- Self inspections
- 3rd Party Audits

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•Operators and managers can review their policies and procedures to determine if all applicable P Items are addressed in:

- Management systems
- SOPs
- Recipes
- Self inspections, walk-throughs and 3rd party audits

How can the food industry use the new terms?



They will help prioritize...

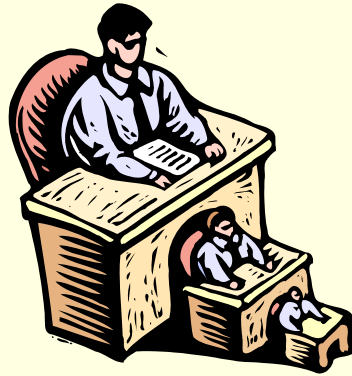
- Corrective actions for “out of compliance” inspection findings
- monitoring, walk throughs
- Training content for employees within food establishments
- Limited resources of time and money

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•The retail food store and food service industries can use the new terms P, Pf and C to help prioritize:

- Corrective actions
- Activities for specific monitoring
- Training content for employees
- Use of limited time and money

How can the food industry use the new terms?



They can build in compliance for Priority Items....

- during Plan Review
- during construction
- during remodeling
- during training

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•Since prevention is always more effective than reacting after the fact, build in compliance for P and Pf Items before violations occur during:

- Plan reviews
- Construction
- Remodeling
- training

How can food safety trainers use the new terms?

- Trainers can explain:
 - The new definitions, 3-tiered re-designation system with examples of each
 - Immediate correction of Priority Items because of direct connection to foodborne illness
 - Priority Foundation Items provide options to correct, manage and control Priority Items
 - Core Items are general good practices
 - How to prepare for accredited Food Protection Manager Certification examinations

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•Trainers for both regulators and industry managers and employees can help their students better understand the new 3 tiered system to designate Food Code provisions by explaining:

- The definitions of P, Pf and C items and giving examples
- Why immediate correction of P Items decreases the risk of foodborne illness and injury the most
- Why C Items or good sanitation practices are general good support for food safety.
- How the new system relates to preparing for and using Food Protection Manager Certification.

What do you think about this? Scenario #1

- **One day, a retail establishment was inspected and several violations were noted.**

- Several holes in drywall of stockroom (pallets hit wall and made a hole)
- Excess fly activity at open trash containers in outside receiving area

When I arrived at the location the following day, I found store personnel repairing and painting the dry storage area. Painting requires ventilation, therefore all receiving doors were propped open. Guess what? The excess fly activity that was once outside was now inside the stockroom and kitchen.

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•This scenario and other that follow will help you understand how to prioritize your response to real life situations in food establishments, based on the three-tiered designation system for Food Code Provisions P, Pf and C.

What do you think about this? Scenario #1

- Do we consider implications and unintended consequences of our activities (opening door for ventilation allows flies to enter)?
- Were the holes in the drywall corrected before more serious violations were corrected (prioritizing risk, time for correction and cost of correction)?
- Were other priority violations (handwashing, time/temperature control, etc.) in compliance when maintenance repairs were made?

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- After identifying the violations and their designation (P, Pf or C), prioritize the corrective response so P Items are corrected first, then Pf Items and finally C Items. This gives the greatest reduction in risk of foodborne illness and injury in the shortest time and also will result in correction of P Items if only some violations are corrected.
- In addition, consider unintended consequences of your corrective actions,
 - Leaving the door open for ventilation allows flies into the establishment
 - Repairmen contaminating food products or making it difficult for employees to wash hands, etc.

What is a risk-based inspection process?

- A risk-based inspection process:
 - Prioritizes inspection activities, corrections and enforcement based on risk of foodborne illness or injury
 - Focuses on factors that contribute more directly to foodborne illness or injury
 - Bases frequency of inspection on establishment type and history of non-compliance
 - Requires more inspection time when more P & Pf Items are present and immediate correction of P and Pf Items
 - Monitors critical limits to determine compliance with P Items

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•A risk-based inspection process is another way to put more focus on factors that are more directly related to the causes of foodborne illness.

•Frequency of inspection and inspection time should be greater for establishments with more Out of Compliance P and Pf Items.

What is a risk-based inspection process?

- Corrective actions are confirmed for P & Pf violations at time of inspection (or later through a written confirmation)
- Explanations of the P & Pf link to foodborne illness or injury are offered to reinforce correct appropriate correction to operators
- Alternate options for correction are used to develop a risk control plan with the operator to achieve long term change (see Annex A for additional advice)

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•To reduce the risk of foodborne illness and injury most effectively, corrective actions are required for P and Pf Items at the time of inspection with explanations and options offered for long term correction.

•A Risk Control Plan in which the inspector and PIC mutually agree to a plan of action that will correct an Out of Compliance Priority Item helps change behavior. Record keeping will encourage employees to document the critical limits or quantifiable measures and continue to do so for a period of time that should result in long terms behavior change (4-6 weeks). The PIC has the responsibility of monitoring (verifying) the behavior and record keeping done by employees and reporting that to the inspector.

What is a risk-based inspection process?

- At the exit interview, an inspector can:
 - Discuss inspection findings with the operator based on the P & Pf risk
 - Confirm understanding of risk and correction with operator
 - Confirm timeline for correction of P & Pf violations

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•Time with the PIC during an exit interview after an inspection can be most effective at decreasing the risk of foodborne illness and injury when the focus of attention is P and Pf Items. This will ensure that everyone's valuable time is spent discussing correction of violations that have the greatest impact on food safety.

Examples of P, Pf and C Violations

- The following examples will provide the:
 - Violation of a P, Pf or C Item
 - Provision in the Food Code that, if Out of Compliance, will result in potential hazards in food that will cause foodborne illness or injury
 - Rationale or explanation of why/how violation of that provision is a P, Pf or C Item.

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•The following examples of P, Pf and C Items on slides #47 – 93 will help explain the new re-designation terms.

Priority Item Examples

Example of Priority Item^P Violation

- **Employee working with symptoms of vomiting**
 - Provision in Food Code: 2-201.11(A)(1)(a) Responsibility of Permit Holder, PIC & Conditional Employees
 - Correction – Employee reports symptoms to PIC and stops working, and
 - Provision in Food Code: 2-201.12(A)(1)
 - Correction – PIC excludes employee from work
 - Rationale – High numbers of pathogens, especially norovirus, contaminate food, clothing, surfaces, air (through aerosols) and cause illness when ingested

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- Vomiting is a typical symptom of foodborne illness.
- Employees should have been informed that they should stop work and report their symptoms to the PIC.
- The PIC should exclude from work the employee exhibiting symptoms of vomiting unless they have a physician's note to say the vomiting is from a non-infectious cause such as pregnancy, etc.
- This is a P Item (as are the other symptoms of foodborne illness – diarrhea, jaundice, sore throat with fever and unprotected lesions with pus on hands and arms because food employees can contaminate food and food contact surfaces. This often results in foodborne illness unless controls such as reporting and exclusion are in place.

Example of Priority Item^P Violation

- **Employee working with uncovered, infected cut on finger**
 - Provision in Food Code: 2-201.11(A) Responsibility of Permit Holder, PIC & Conditional Employees
 - Correction: Employee reports to PIC or covers infected lesion with double, impermeable barriers (i.e., waterproof bandage or finger cot plus a single-use glove worn on top of that)
 - Rationale: Infected lesions with pus, typically contaminated with *Staphylococcus aureus*, can contaminate RTE food unless covered with double, waterproof barrier

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•The rationale for reporting an uncovered, infected lesion on hands or arms is similar to that for vomiting while working (see previous slide) except that the correction is less severe (covering with two layers of impermeable bandages) because the resulting illness from an infected lesion (usually from *Staphylococcus*) is less severe.

Example of Priority Item^P Violation

- **No vigorous hand rubbing during handwashing**
 - Provision of Food Code: 2-301.12(B)(3) Cleaning Procedure
 - Correction: Rub vigorously with soap and water for 10-15 seconds
 - Rationale: Friction from rubbing hands together vigorously helps loosen soil on hands and reduces pathogen levels as they are rinsed off

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•Each part of the handwashing procedure, including vigorous rubbing of hands contributes to the reduction in pathogen load.

Example of Priority Item^P Violation

■ **Home-canned green beans served in a restaurant**

- Provision in Food Code: 3-201.11(B) Compliance with Food Law
- Correction: Discard and do not use home canned foods in a food establishment
- Rationale: Home-canned green beans, a low acid food, are often inadequately processed which allows germination of *C. botulinum* spores and toxin formation

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•Processing of low acid canned foods (LACF) such as green beans requires stringent controls to prevent hazards such as *Clostridium botulinum* from growth and toxin production.

•Most foodborne outbreaks now from *C. botulinum* are related to home-canned foods.

•Note: Many provisions in Chapter 3 Food apply specifically to PHF/TCS food. Before applying a provision to a food or process, first consider whether the food meets the definition of PHF/TCS food.

•Factors that will help you make this determination include:

- Whether the food is raw/heat treated animal food
- Whether the food is heat treated plant food
- Whether the food is raw seed sprouts
- Whether the food is cut melons, cut tomatoes or cut leafy greens
- Whether the food is unmodified (not acidified) garlic-in-oil.

•pH and/or water activity can also show whether the food is or is not PHF/TCS food

•Past epidemiologic history of the food can also give an indication whether it supports the growth of foodborne pathogens.

Example of Priority Item^P Violation

■ **Employee using bare hands to make sandwiches**

- Provision in Food Code: 3-301.11(B) Preventing Contamination from Hands
- Correction: Use utensils or gloves to touch ready-to-eat food, not bare hands
- Rationale: Ill or infected but asymptomatic employees can transfer pathogens from inadequately or unwashed hands to RTE foods such as sandwiches

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- Even if employees report symptoms of foodborne illness and the PIC restricts or excludes as necessary AND handwashing takes place:
 - Asymptomatic employees (infected but not showing symptoms yet, recovering from illness but still shedding pathogens in stool, or in the carrier state where they are infected but not showing any symptoms at all (i.e., Typhoid Mary) may still contaminate food.
 - Employees may not always wash hands thoroughly enough to remove all pathogens present or all supplies such as warm water, soap and towels may not be present to ensure good handwashing
- The last barrier to prevent infected employees from contaminating food is to prohibit bare hand contact with RTE food.

Example of Priority Item^P Violation

- **Chef cooking chicken to 155°F for 15 sec.**
 - Provision in Food Code: 3-401.11(A)(3) Raw Animal Foods
 - Correction: Cook chicken to 165°F for 15 seconds
 - Rationale: Undercooking chicken which may be contaminated with bacteria will allow survival of pathogens

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•Since chicken has a higher pathogen load than other meats, a higher cooking temperature is needed to destroy pathogens present.

Example of Priority Item^P Violation

- **Cooking egg rolls that received a non-continuous (partial) cook to 145°F for 15 sec.**
 - Provision in Food Code: 3-401.14(D) Non-Continuous Cooking of Raw Animal Foods
 - Correction: If cooking process was interrupted and product cooled, it must have a final cook temperature of 165°F for 15 seconds
 - Rationale: The final heating process of 165°F for 15 seconds must overcome any pathogen growth resulting from normal contamination, cooling and cold holding.

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•When a non-continuous cooking process is used (interrupting the cooking process before it reaches the required time/temperature, then cooling the product to 41°F, storing it for a period of time under refrigeration and then completing the final cooking process to 165°F), a higher final cooking temperature is required no matter what the food is to overcome any additional pathogen growth from germinating spores or cross-contamination during cooling and cold holding.

Example of Priority Item^P Violation

- **5 gallons of chili made yesterday afternoon according to the cook now at 57°F in cooler at 9:30 am**
 - Provision in Food Code: 3-501.14(A) Cooling
 - Correction: Discard chili. In future, cool from 135°F to 70°F within 2 hrs., then to 41°F in a total of 6 hrs.
 - Rationale: Spore formers (*C. perfringens*, *B. cereus*) have had sufficient time in optimum temperature range to germinate and form toxins, or produce high levels of bacteria that may not be destroyed by reheating

55

While you are unable to observe the entire cooling process, the cook confirmed that the chili was made in the afternoon of the previous day and at 57°F at 9:30 am the next morning, still hasn't reached the required 41°F within 6 hours total. Even allowing for cooling starting in the late afternoon, the chili has been cooling for more than 15 hours and didn't reach 41°F in less than 6 hrs. This is a P Item violation according to 3-501.14(A)(2).

While cooling large volumes of food in large, deep containers will generally not meet cooling parameters without the assistance of other procedures, (ice bath, stirring, ice paddle, adding ice to food, etc.), this could be considered a "double mark" by some and is discouraged. Corrective methods including experimenting to find the method or combination of methods that are able to meet the requirements with logging times and temperatures for a time to verify that (A Risk Control Plan), should be part of the discussion with the PIC.

Example of Priority Item^P Violation

- **RTE, PHF/TCS food (not exempted) was not date marked or, if date marked, was held for more than 7 days**
 - Provision in Food Code: 3-501.18(A)(1), (A)(2) & (A)(3)
RTE, PHF (TCS Food), Disposition
 - Correction: Discard food, begin using a date marking system and monitor for expiration
 - Rationale: *Listeria monocytogenes* can multiply at refrigeration temperatures, therefore time is the only control. If time is not used, food must be discarded.

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•Developing and using a date marking system (3-501.17) is a Pf Item because it enables the operator to determine a safe shelf life for refrigerated foods that support the growth of *Listeria monocytogenes*.

•Disposal of foods that support growth of *Listeria monocytogenes* (when no date marking system was used or because the storage time exceeded 7 days at 41°F or less) is the actual Priority Item that the date marking system supports or enables.

Example of Priority Item^P Violation

- **Cooked chicken placed in bags, sealed (cook chill/ROP) and held for 30 days at 41°F**
 - Provision in Food Code: 3-502.12(D)(2)(e)(i) Reduced Oxygen Packaging without a Variance, Criteria
 - Correction: Discard food. In future, cook chill processed food must be stored at 34°F, if held for 30 days or submit a validated process (inoculation study) plus variance application and HACCP Plan
 - Rationale: If cooked chicken was re-contaminated or if spore formers were present before ROP packaging, the longer shelf life could allow growth and/or toxin formation

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•The provisions in 3-502.12 are processes that allow certain foods to be processed and packaged using ROP technology without a variance because a validated process was submitted to FDA for approval and inclusion in the FDA Food Code.

•Without any secondary barriers in place besides refrigeration at 41°F (such as $\text{pH} \leq 4.6$, $a_w \leq 0.91$, high levels of competing organisms, curing with nitrite and salt or intrinsic factors in certain cheeses).

•The storage temperature must be decreased to prevent growth of non-proteolytic *C. botulinum* and *Listeria monocytogenes*.

•Since cooked chicken has no secondary barriers, it must be held at 34°F for a shelf life of 30 days or at 38°F for 72 hrs. or a validated process (inoculation study) must be provided according to Section 3-502.11(D).

Example of Priority Item^P Violation

- **Using galvanized metal can to mix and store fruit juice punch**
 - Provision in Food Code: 4-101.15 Galvanized Metal, Use Limitation
 - Correction: Discard. Use glass, plastic or other safe metal (aluminum, stainless steel, etc.)
 - Rationale: Acid fruit punch will leach toxic tin from the galvanized can

58

•The hazard in using galvanized metal in contact with acid fruit juices is that the acid product will leach tin from the container, producing toxic metal poisoning when consumed.

Example of Priority Item^P Violation

- **Hot water dish machine does not achieve 160°F surface temperature on utensils (using temperature sensitive tape or maximum registering thermometer)**
 - Provision in Food Code: 4-703.11(B) Hot Water and Chemical
 - Correction: Re-sanitize if temperature not achieved. Check wash and final rinse water temperatures, method of racking dishes (no masking), clear spray nozzles, etc. and correct as necessary
 - Rationale: Pathogens could survive on the surface of utensils and dishes

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•A surface temperature of 160°F is the control for sanitization that reduces the pathogen load to an acceptable level.

•The requirement for 180°F final rinse water in 4-501.112 (see slide #73) along with other factors such as wash temperature, method of racking dishes, clear spray nozzles, etc. is a Pf Item because it enables the 160°F surface temperature.

Example of Priority Item^P Violation

- **No backflow prevention device on a faucet with hose attached and end in bucket of mop water**
 - Provision of Food Code: 5-203.14(B) Backflow Prevention Device, When Required
 - Correction: Attach a backflow preventer such as an atmospheric vacuum breaker when hose is attached to faucet and no control valve is present
 - Rationale: Mechanical atmospheric vacuum breaker prevents backflow of waste water into water supply

60

•A backflow prevention device directly prevents contamination of the drinking water supply in case of a drop in water pressure.

Example of Priority Item^P Violation

- **Direct connection between building sewer line and drain line of ice machine storage bin and 3-compartment sink**
 - Provision of Food Code: 5-402.11 Backflow Prevention
 - Correction: Provide an air gap on the drain line between the drain/waste line and the ice machine and 3-compartment sink
 - Rationale: Air gap prevents possible backflow of waste water into ice machine and 3-compartment sink

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•An indirect connection on the ice machine drain line will prevent backflow of waste water into ice in the ice machine storage bin.

Example of Priority Item^P Violation

- **Cans of bug spray stored on shelf with bags of chocolate chips**
 - Provision of Food Code: 7-201.11(A) Separation
 - Correction: Separate toxic chemicals from food products
 - Rationale: Dripping of toxic insecticide could cross-contaminate food or food contact surfaces to cause illness, injury or death

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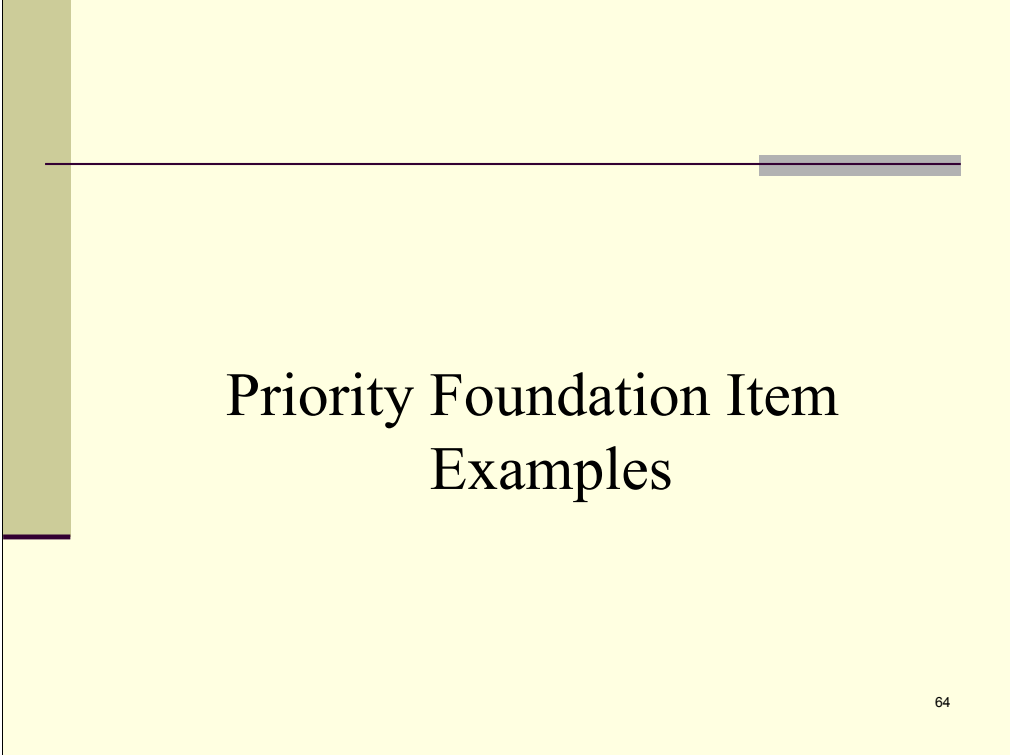
• Improper storage (no separation) of toxic pesticides with food could result in cross-contamination.

Example of Priority Item^P Violation

- **The active chemical ingredient used in a commercially manufactured hard surface sanitizer is not listed in EPA's 40 CFR 180.940.**
 - Provision of Food Code: 7-204.11 Sanitizers, Criteria
 - Correction: Use only EPA registered chemical sanitizers with an EPA Registration number and instructions for use on the sanitizer container's label.
 - Rationale: EPA has not evaluated and approved the sanitizer as safe and effective for use

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•If the manufacturer of the chemical sanitizer has not petitioned and received approval from EPA for safety and efficacy of the chemical sanitizer, it may not effectively sanitize food contact surfaces as advertised.



Priority Foundation Item Examples

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Example of Priority Foundation Item^{Pf} Violation

- **No designated person in charge (PIC)**
 - Provision of Food Code: 2-101.11(A) Assignment
 - Correction: Identify a PIC during all hours of operation
 - Rationale: A PIC facilitates management control systems (monitoring, verification, training, etc.) that ensure Priority Items are in compliance

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•If no one has been specifically identified as the person in charge, times when the regular manager (PIC) is absent from illness or other duties, no one person has the responsibility to make decisions and verify that corrective actions are done and conduct other activities related to active managerial control.

Example of Priority Foundation Item^{Pf} Violation

- **PIC does not monitor employees for necessary handwashing**
 - Provision of Food Code: 2-103.11(D) Person in Charge (Duties)
 - Correction: It is the PIC's duty to monitor employees for handwashing at appropriate times
 - Rationale: There is no management procedure to control (monitor and verify) employee handwashing to prevent fecal contamination of food

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•If the PIC does not monitor handwashing for appropriate time and method used, he/she will not be able to enable this important control for contamination of food and food contact surfaces and will not be able to take corrective action such as explaining and retraining.

Example of Priority Foundation Item^{Pf} Violation

- **Employees are not trained in food safety practices related to their job duties**
 - Provision of Food Code: 2-103.11(L) Person in Charge (Duties)
 - Correction: Communicate and educate employees about food safety in their jobs
 - Rationale: Training facilitates employees' understanding and application of Priority Items as they perform their duties

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•Initial orientation training, refresher training and corrective training at the time inappropriate activities occur enable the PIC to support and enable employees to correctly carry out controls required by Priority Items.

Example of Priority Foundation Item^{Pf} Violation

- **Paper towel dispenser empty at kitchen hand sink**
 - Provision in Food Code: 6-301.12(A) Hand Drying Provision
 - Correction: Monitor and refill as necessary
 - Rationale: Sanitary paper towels enable employees to properly dry their hands after washing and prevent using clothing to dry them

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- Maintaining and refilling supplies for proper handwashing enables employees to wash and dry their hands when necessary.
- Lack of paper towels at one hand sink is not a P Item because an employee who needs to wash and dry their hands could get paper towels from the store room or go to another hand sink for handwashing.
- If they wash hands without using a sanitary hand towel for drying (e.g., they use their clothes or a dirty cloth or don't dry them at all, then this is a P violation (2-301.12)/
- The friction of drying hands with a towel can add another log reduction of pathogens to the handwashing procedure.

Example of Priority Foundation Item^{Pf} Violation

- **Food for self-service sale packaged or re-packaged in-house not labeled with ingredients**
 - Provision in Food Code: 3-602.11(A) Food Labels
 - Correction: Label package with common name of product, ingredient statement, any major food allergens, quantity, place of business and other information as necessary (claims, etc.)
 - Rationale: Proper labeling of ingredients enables consumers to make informed decisions about consumptions of that food

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•Proper ingredient labeling enables consumers to make decisions about consumption because of allergens or other health reasons.

Example of Priority Foundation Item^{Pf} Violation

- **Last date that molluscan shellfish were sold/served was not written on the tag**
 - Provision of Food Code: 3-203.12(B) Shellstock, Maintaining Identification
 - Correction: Train employees of responsibility to put that date on the tag
 - Rationale: Writing this date on the tag facilitates a traceback investigation in case of a shellfish outbreak to prevent other shellfish from that harvest area being consumed

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•Writing the date shellfish were last sold on the tag enables the foodborne illness investigator to bracket the time the shellfish could have been consumed, facilitating tracebacks and stopping shipment for shellfish that may be responsible for an outbreak.

Example of Priority Foundation Item^{Pf} Violation

- **5 gallons of chicken stock in stock pot at 110°F cooling in walk-in cooler for 1 ½ hrs. (put in cooler at 135°F)**
 - Provision of Food Code: 3-501.15(A)(1) to (A)(7) Cooling Methods
 - Correction: Use an appropriate cooling method or combination of methods to cool PHF/TCS food within required criteria (including shallow pans, smaller portions, blast chiller, stirring, ice stick, ice bath, etc.)
 - Rationale: Specific cooling methods that enable rapid cooling would allow product to safely meet cooling parameters

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•Although the chicken stock still has ½ hour to cool to 70°F to meet the first part of the cooling parameters (that is, to cool from 135°F to 70°F within 2 hrs. so this is not a cooling violation yet), your experience and ample research tells you that this method of cooling will not achieve 70°F for this large volume of product within the required time. You should make every effort to take a temperature later before you leave the facility to confirm the violation.

•A Pf Item requires use of specific actions or procedures by industry management to attain control of certain risk factors (P Items). The procedure or method of cooling 5 gallons of PHF in large containers does not adequately meet cooling parameters. The hazard, *Clostridium perfringens*, has a rapid generation time once any spores present have germinated.

•Always check with the PIC or specific individual responsible for moving the containers to be cooled into the walk-in cooler for the times and procedures they normally use so you can understand the process. Work with the PIC to identify methods to meet the cooling parameters.

Example of Priority Foundation Item^{Pf} Violation

- **No date marking system used on RTE, PHF/TCS food (leftovers, opened containers of commercially processed foods) in the facility**
 - Provision of Food Code: 3-501.17(A) RTE, PHF (TCS Food), Date Marking
 - Correction: Date mark RTE, PHF/TCS food (not exempted) held more than 24 hrs. to show when 7 day shelf life has expired
 - Rationale: Use of a date marking system enables PIC to discard or use RTE, PHF/TCS product before high levels of *Listeria* are present

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In this slide, the operator has not developed and implemented a date marking system for RTE, PHF/TCS food held for more than 24 hrs. This system or procedure, 3-501.17, a Pf Item, enables the PIC to identify and discard food that is not served or sold within 7 days. The actual P Item, to prevent a hazard (infective doses of Lm) that could cause foodborne illness, is discarding RTE, PHF/TCS food that has been stored longer than 7 days.

Example of Priority Foundation Item^{Pf} Violation

- **Acidifying sushi rice (to pH 4.1) to hold at room temperature without a variance**
 - Provision of Food Code: 3-502.11(C)(2) Variance Requirement
 - Correction: Variance application with HACCP plan required to show food is non-PHF/non-TCS food
 - Rationale: A variance with HACCP plan and appropriate record keeping enables PIC to verify that acidification and any necessary corrective actions have occurred with rice held at room temperature

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•A variance showing a validated procedure is used and a HACCP Plan that documents and verifies the use of this procedure to acidify rice to pH 4.1 or less enables the PIC to safely hold this product, previously PHF/TCS food, at room temperature.

Example of Priority Foundation Item^{Pf} Violation

- **Hot water temperature gauge shows sanitizing rinse at manifold in the warewashing machine is 170°F**
 - Provision of Food Code: 4-501.112(A)(2) Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures
 - Correction: Check booster heater and water heater are operating at high enough temperature that that the temperature gauge is accurate
 - Rationale: Monitoring temperature at the manifold facilitates trouble-shooting to verify effective sanitization is occurring at the utensil surface

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The temperature gauge for the final rinse in a hot water sanitizing warewashing machine, measuring sanitizing water temperature at the manifold as it sprays out, gives an indication (enables the operator to judge) whether the sanitization process will be effective. Therefore this is a Pf Item. If the gauge shows a temperature less than required (i.e., 160°F instead of 180°F), this is an indication that something is wrong and sanitization at the surface of the utensil will likely not occur. The booster heater may not be operating properly. The water heater may be set too low. (A booster heater can only raise the temperature of water from the hot water heater about 40°F) The temperature gauge may also be inaccurate.

A surface temperature of 160°F or more on the utensil to achieve sanitization is the P Item that this provision supports. Other problems that can contribute to ineffective sanitization include racking dishes so some surfaces are masked from the sanitizing final rinse, clogged spray nozzles, altered spray pattern (nozzles bent), etc.

Example of Priority Foundation Item^{Pf} Violation

- **No thin probe thermometer, thermistor or thermocouple available to check hamburger patty cook temperatures**
 - Provision of Food Code: 4-302.12(B) Food Temperature Measuring Devices
 - Correction: Provide thin probe temperature measuring device
 - Rationale: A thin probe allows verification of the final cook temperature that destroys pathogens

75

•Without the appropriate equipment (thin probe temperature measuring device), it is not possible to accurately measure final cook temperatures of PHF/TCS food. Cooking temperatures is the P Item.

Example of Priority Foundation Item^{Pf} Violation

- **Drinking water from a restaurant's private well is tested every two years**
 - Provision of Food Code: 5-102.13 Sampling
 - Correction: Well water must be tested annually according to state water quality regulations
 - Rationale: Testing well water at a sufficient frequency according to EPA or state standards enables PIC to verify its potability

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•Sampling and testing well water enables the PIC to determine if the water source provides safe drinking water free of pathogens and chemicals. If testing shows that it does not meet the standards, the PIC can treat the water to remove the impurities or use an alternate source of water.

Example of Priority Foundation Item^{Pf} Violation

- **Hot water at handwashing sink is 70°F**
 - Provision in Food Code: 5-202.12(A)
Handwashing Sink, Installation
 - Correction: Adjust water heater, sink mixing valve, etc. to provide 100°F water for handwashing
 - Rationale: Maintaining 100°F water for proper handwashing facilitates optimum temperature for use of soap and more effective removal of food soils and pathogens from hands

77

•Many food greases tend to solidify at lower temperatures, making them more difficult to remove.

•In addition, employees may be less likely to wash hands in cold water because of comfort levels.

Example of Priority Foundation Item^{Pf} Violation

- **No handwashing sink in food preparation and dispensing areas**
 - Provision of Food Code: 5-204.11 Handwashing Sinks
 - Correction: Install convenient handwashing sink in the areas
 - Rationale: Nearby handwashing sinks facilitate handwashing when necessary to remove pathogens and soil from hands

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•Because of the fast-paced environment in food establishments, employees may not leave the immediate area of their work station if there is no nearby hand sink for handwashing.

Example of Priority Foundation Item^{Pf} Violation

- **Evidence of mice with no pest control plan in place**
 - Provision of Food Code: 6-501.111(C) Controlling Pests
 - Correction: Implement a pest control plan such as seal entry holes, place traps, remove harborage, and routinely inspect for water and food sources, as well as presence of pests
 - Rationale: A pest control plan enables PIC to systematically rid establishment of pests which may carry disease –causing organisms to the facility

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•A pest control plan which includes prevention, monitoring and eradication measures enables the PIC to keep the establishment free of pests which can contaminate food and food contact surfaces.

Example of Priority Foundation Item^{Pf} Violation

- **Unlabeled spray container of green liquid**
 - Provision of Food Code: 7-102.11 Common Name
 - Correction: Label working containers of poisonous or toxic chemicals such as cleaners
 - Rationale: Labeling working containers of cleaners prevents mix-ups with food products or the wrong chemical and accidental ingestion of chemicals that can cause illness, injury or death

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•Labeling on containers allows employees to distinguish between foods and chemicals and also between different chemicals which may have different uses and different toxicities.

Example of Priority Foundation Item^{Pf} Violation

- **Safe handling statement not placed on label of fresh meat or poultry packaged in a meat market**
 - Provision of Food Code: 3-201.11(F) Compliance with Food Law
 - Correction: Add the safe handling statement to each consumer sized package of raw meat or poultry
 - Rationale: Information on the Safe Handling Statement enables consumers to safely handle and prepare meat and poultry and avoid foodborne illness

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•This labeling provides information to improve food safety handling of fresh meat and poultry in the home.

Core Item Examples

Example of Core Item Violation

- **Cook not wearing an effective hair restraint**
 - Provision of Food Code: 2-402.11(A)
Effectiveness
 - Correction: Food employees should wear hat, cap, net or other effective hair restraint
 - Rationale: Hair restraints prevent hair from falling into food and keep employees from touching hair and scalp to reduce hands as a vehicle of cross-contamination

83

•A hair restraint prevents loose hair, a direct and indirect vehicle of contamination, from falling into food and may deter employees from touching their hair.

Example of Core Item Violation

- **Cartons of food stored on the floor**

- Provision of Food Code: 3-305.11(A)(3) Food Storage
- Correction: Store food on shelves, pallets, etc. six inches off the floor
- Rationale: Storing food off the floor allows good sanitation practices such as sweeping, mopping, inspection for pests and protecting food containers from splash.

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• Storing food on the floor prevents employees from carrying out good sanitation practices such as cleaning, pest control inspections, etc.

Example of Core Item Violation

- **No drain board on 3-compartment sink for dirty dishes/utensils and air drying dishes & utensils**
 - Provision of Food Code: 4-301.13 Drainboards
 - Correction: Add drain boards or use nearby tables, counters or carts for soiled and clean items
 - Rationale: Proper design with drain boards promotes proper dishwashing procedures and sanitization

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- Drainboards allow separation of dirty and clean dishes and utensils and control the runoff of draining water.
- Lack of a drainboard could promote storage of wet utensils (wet nesting)

Example of Core Item Violation

- **Heavy grease build-up on sides of fryers and grill**
 - Provision of Food Code: 4-601.11(C) Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils
 - Correction: Set up a cleaning schedule to prevent build-up of grease
 - Rationale: Good sanitation practices prevent conditions that contribute to pest problems

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•Heavy grease build up on equipment allows microorganisms to reach high levels in the environment, a potential source for cross-contamination, and also provides an attractant and food source for pests (roaches, mice, etc.)

Example of Core Item Violation

- **Cold water faucet in mop sink leaks**
 - Provision of Food Code: 5-205.15 System Maintained in Good Repair
 - Correction: Repair or replace faucet to prevent leaking
 - Rationale: Leaking faucet provides a water source for pests and erodes fixtures which prevents easy cleaning

87

•In addition to attracting pests and eroding fixtures, dripping faucets increase costs and waste water. If the faucet is turned off at the shut off valve, it also discourages employees from washing hands.

Example of Core Item Violation

- **Garbage dumpster lids open outside**
 - Provision of Food Code: 5-501.113(B) Covering Receptacles
 - Correction: Close lids of dumpsters, grease barrels and garbage cans after each use
 - Rationale: Leaving waste containers uncovered allows flies, rodents and birds access to garbage and creates a nuisance

88

•Uncovered garbage is an attractant which provides food and breeding grounds for pests. They can then easily enter the food establishment to contaminate food and food contact surfaces.

Example of Core Item Violation

- **Broken and missing floor tiles in prep area and toilet room**
 - Provision of Food Code: 6-201.11 Floors, Walls, and Ceilings
 - Correction: Replace broken and missing floor tiles
 - Rationale: Floors in good repair allow easy cleaning and good sanitation practices

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•Broken and missing floor tiles can allow spills and cleaning water to deteriorate subfloors and also prevent easy cleaning and good sanitation practices.

Example of Core Item Violation

- **Missing grease filter in ventilation hood above grill**

- Provision of Food Code: 6-202.12 Heating, Ventilating, Air Conditioning System Vents
- Correction: Replace missing grease filter or close open space with a metal spacer
- Rationale: Closing all openings in hood with grease filters or spacers prevents grease build-up in ductwork, a fire hazard and food source for pests

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- Designing ventilation food systems above cooking appliances so the grease filters close off the entire space ensures that greasy air is filtered before being exhausted decreases the buildup in ductwork
- The PIC should ensure that a full set of grease filters is replaced when they are removed for cleaning.

Example of Core Item Violation

- **Open space (1/3 inch) under back delivery door.**
 - Provision of Food Code: 6-202.15(A)(3) Outer Openings, Protected
 - Correction: Close off space with weather stripping, threshold sill repair, etc.
 - Rationale: Tight fitting doors prevent entry of pests

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•Protecting outer openings (around doors, windows, utility lines that pass through the building walls, etc.) prevents the entry of pests from the environment around the facility.

Example of Core Item Violation

- **No area designated for employees' personal belongings**
 - Provision of Food Code: 6-403.11 Designated Areas
 - Correction: Identify lockers, specific area or room where employees can safely store their coats, shoes, street clothes, purses, etc.
 - Rationale: Street clothes can potentially contaminate food, utensils, single-service articles, etc. if not properly stored

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•If employees do not have a safe and separate area designated for the personal belongings, they will likely keep them nearby their work stations which could potentially contaminate food and food contact surfaces.

Example of Core Item Violation

- **Food employee wearing a watch and decorative ring**
 - Provision of Food Code: 2-303.11 Prohibition
 - Correction: Jewelry, except a plain wedding band, should be removed
 - Rationale: Food debris can accumulate around and under jewelry without notice and is not easily cleaned

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- Jewelry, if not easily cleanable, can act as a reservoir for pathogenic organisms and cross-contaminate food.
- Stones and metal work from decorative jewelry can also fall off and become a physical hazard.

What should you do now? Scenario #2

You (manager or inspector) open the door of a walk-in cooler. You look around and notice:

- Dirty fan guards and dirty shelves
- Broken light covers
- Dirty floors
- Raw chicken (dripping) stored above an uncovered container of salad dressing
- Many leftovers including two 3-gallon stock pots full of refried beans at 40°F on lower shelf – not date marked and not covered

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- This is another scenario to help you identify out of compliance provisions and prioritize or rank them according to their risk of causing foodborne illness.
- Once the priority items in violation are identified, they should be corrected immediately.

What should you do now? Scenario #2

- First, identify & rank the violations according to risk level (P, Pf or C):
 - Priority Items
 - Raw chicken dripping over salad dressing - 3-302.11(A)(1)(b)
 - Disposition of undate marked RTE, PHF/TCS food not date marked - 3-501.18)
 - Priority Foundation Items
 - Refried beans cooled in 3 gallon stock pots - 3-501.15(A)(1-7) (DISCUSS)
 - No date marking system used – 3-501.17(A)
 - Core
 - Dirty fan guards & shelves – 4-601.11(C)
 - Broken light shield – 6-202.11(A)
 - Uncovered food – 3-302.11(A)(4)
- Next, immediately correct P items, then Pf items, then C items as able
- Then, remind or retrain responsible individuals
- Finally, monitor those activities in the future

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The two P Items are RTE salad dressing cross-contaminated with drippings from raw chicken and disposition of many containers of leftover RTE, PHF/TCS food with no date marking.

Immediate correction of the cross-contaminated salad dressing (discard) but disposition of RTE PHF/TCS food with no date marking is more complicated. Section 3-501.18 says undate marked RTE PHF/TCS food must be discarded but there are a number of criteria and exemptions.

- The food must be held more than 24 hrs for required date marking.
- A management system where no food prepared on-site or opened, commercially prepared food is held overnight requires no date marking.
- Some RTE, PHF/TCS foods have natural or added intrinsic factors that inhibit Listeria, the pathogen of concern, so no date marking is required. Examples include:
 - Commercially processed deli salads (generally with a listeriocide added)
 - Hard, semi-soft, or pasteurized process cheese made under a standard of identity.
 - Cultured dairy products (yogurt, sour cream or buttermilk) with live cultures and lowered pH
 - Preserved (pickled or salted) fish products
 - Shelf stable (no refrigeration required), dry fermented sausages (pepperoni or Genoa salami)
 - Shelf stable, salt-cured products (prosciutto or Parma ham)
- When it is confirmed with the PIC that the foods with no date marking are not exempted and should have been date marked, the foods should be discarded if a reasonable way to identify how old they are (daily work orders, etc.) is not available.
- Double marking both 3-501.17 (no date marking system) and 3-501.18 (disposition) is not recommended but inspection remarks written as observations should explain the situation with recommended corrections if that is your policy and the discussion with the PIC should address both development of a system for date marking and disposition.

What should you do now?

Scenario #3

It is 10:30 am. You are inspecting a nursing home kitchen and the first lunch will be served at 11:15.

- You notice the cook taking a tightly covered pan (product 6" deep) out of the reach-in cooler. She goes straight to the steam table and places the pan in it. She reaches down and turns on the steam table. You discover the pan is Spanish rice that was made five days ago according to the tag.
- The cook has no thermometer and the thermostat dial on the steam table is broken.
- You also hear her say to another cook that she started running a fever this morning and her throat was sore.

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•Some of the things you observe are part of a process so you must follow up with questions to verify whether your deductions based on observations are in fact correct. Examples include:

•Whether the cooling method for the Spanish rice was cooling it in 6" deep pans or was it spread in sheet pans for example and then transferred to the deep pan.

•Also check whether the steam table is capable of reheating the Spanish rice to 165°F within 2 hrs when it is not pre-heated and the thermostat is broken.

•Once the Priority Item violations are identified (cooking with a sore throat and fever in a nursing home facility that serves highly susceptible populations and reheating using a method that will not reach the required temperature within the required time period – THIS MUST BE VERIFIED BEFORE IT IS MARKED AS A VIOLATION)

What should you do now?

Scenario #3

- First, identify & rank violations according to risk level (P, Pf or C):
 - Priority Item
 - Cook has not reported fever & sore throat to PIC (exclude for HSP in nursing home, restrict for others) – 2-201.11(A)(1)(d)
 - Reheating Spanish rice (verify final reheated temp. reached 165°F in 2 hrs. or before service) – 3-403.11(A)
 - Priority Foundation Item
 - No thermometer to measure food temps – 4-302.12(A)
 - Spanish rice in 6” pans – 3-501.15(A)(1) (method unlikely to meet cooling parameters, need to verify procedure for cooling)
 - Core Item
 - Broken thermostat in steam table – 4-502.11(C)
- Immediately correct P items, then Pf items, then C items
- Then, remind or retrain responsible individuals
- Finally, monitor those activities in the future

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•The two Priority Items include

- excluding the cook with a sore throat and fever (she/he should report these symptoms to the PIC and the PIC should then in turn exclude the cook from work in a facility that serves HSP or only restrict in a facility that serves a normal population)
- Verifying that the Spanish rice is reheated to 165°F before serving. Since there are only 45 minutes before serving and the steam table was just turned on and may not be in good repair (broken thermostat), reheating criteria may not be met. Make a note to check before serving or point out that the reheating method being used may not meet reheating parameters so another method (microwave oven, steamer, etc.) might be more effective.

•The two Priority Foundation Items are:

- No thermometer to check product temperatures such as refrigeration and reheating
- Apparent method of cooling the Spanish rice (6” deep in containers put into the cooler) is unlikely to meet the cooling parameters. Verify with the PIC or the individual who prepared the rice and put it in the cooler the exact time and method that the rice was cooled. It is possible the rice was prepared and spread in thin layers on sheet pans, put into the cooler and then transferred to a deep container and covered to save storage space in the cooler. You did not observe a P Item violation (cooling) but there may be a Pf cooling methods violation based on their answer.
- If you are unable to stay long enough to verify the effectiveness of either the cooling method or reheating method, you can still make the observation but no mark on the inspection report that methods used were unlikely to comply with Code requirements. Recommendations for meeting the criteria should be discussed with the PIC.

What should you do now?

Scenario #4

You walk into a kitchen. This is what you see.

- The cook is mixing the slaw and dressing with his bare hands
- The back door is propped open so it will not close and there are a lot of flies inside the kitchen
- Several pans on the clean utensil rack are caked with dried food
- Cases of meat labeled “Keep Frozen” are setting on the floor and leaking
- Utensils are being washed in 3-compartment sink and chlorine sanitizer is available but not used
- There is no soap at the handwashing sink

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- The same process of identifying and ranking the violations must be done in this scenario.
- First, identify the Priority Item violations which are most likely to directly result in foodborne illness or injury because they need immediate correction.

What should I do now?

Scenario #4

- First, identify & rank violations according to risk level:
 - Priority Items
 - Mixing slaw with bare hands – 3-301.11(B)
 - No sanitizer used in 3-compartment sink – 4-701.11(C)(1)
 - Priority Foundation Items
 - No soap at handwashing sink – 6-301.11
 - Pans stored with dried food – 4-601.11(A)
 - Meat, labeled “Keep Frozen,” leaking on floor – 3-501.11(A)
 - Many flies, not using some method of fly control – 6-501.111(C)
 - Core Items
 - Cases of meat on floor – 3-305.11(A)(3)
 - Meat, labeled “Keep Frozen,” leaking on floor – 3-501.11
- Immediately correct P items, then Pf items, then C items
- Then, remind or retrain responsible individuals
- Finally, monitor those activities in the future

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•The two P Item violations that have the highest risk of causing foodborne illness are mixing slaw with bare hands (bare hand contact with RTE food) and not using a final sanitizing rinse (hot water or chemical) in the 3 compartment sink utensil washing procedure.

•The Pf Item violations are:

•No soap at hand sink (6-301.11) to assist the handwashing procedure be more effective. They still have the opportunity to go to another hand sink with soap or get soap from supplies for handwashing when it is necessary. If the observation was actually washing hands with no soap, then it would be a P Item violation, 2-301.12(B)(2).

•The procedure for receiving frozen food (“Keep Frozen”) should be to verify it is frozen upon receipt (mark 3-202.11(E), if not, and to place it immediately in the freezer for storage (not leave it out on the floor to thaw after delivery 3-501.11(A)). It is unlikely that the product is intentionally being thawed at room temperature on the floor, therefore 3-501.13(A) is not the correct mark. Ask the PIC what time the delivery was made to the facility.

•No procedure or control measures were being used (pesticide application, fly bait, fly “zapper”, etc.) to control excess flies numbers of flies in the establishment. The corrective action is to not prop the door open (a self-closer is implied in the scenario, check for it) or install a screen door for ventilation (both are design/construction – Core Items). Then they must apply control measures to get rid of the flies. Flies indirectly contribute to spread of foodborne pathogens by walking or vomiting on food or food contact surfaces and transferring pathogens from their bodies.

How to Use the Annexes

- **The Annexes are not requirements!**
- The Annexes are included to support you in your food safety mission:
 - To recognize common food safety hazards
 - To better communicate food safety messages
 - To promote correction and long term behavior change for poor food safety practices

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- The three Annexes attached to these training slides are not requirements of the Food Code.
- Rather, they are provided to help you as you carry out your food safety activities, whether you are a regulator, industry representative or trainer
- One Annex helps you identify common food safety hazards that must be controlled to prevent foodborne illness or injury.
- Another Annex provides some hints to help you communicate better.
- The third Annex helps you make your education and training more effective at changing behavior that results in poor food safety practices.

How to Use the Annexes

- Each individual annex can be extracted and used as a separate training module for that purpose alone (food safety hazard recognition, communication, behavior)
- When a specific food safety problem persists, information in the Annexes may provide assistance in identifying antecedents (contributing factors) to the underlying cause of the problem
- The Annexes provide basic background information which regulators, operators and trainers can find useful for any food safety activity

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Annex A

How can regulators, operators and
trainers effectively change
behavior?

Effective Behavior Change

- Correcting violations without behavior change will result in the same repeated violations
- **Training by itself does not always lead to improved behaviors**
- We must create a culture where everyone knows:
 - Food safety is a **priority**
 - Their personal **responsibility** for food safety
 - Which of their activities, if done incorrectly (Priority Item violations), can result in foodborne illness or injury

A Food Safety Culture

- PICs and Regulators need to have established policies, standards and procedures for food safety
 - the food safety message must be uniform and consistent
 - Priority Items listed in the Food Code can provide that uniformity
- PICs should explain these expectations to employees as it relates to their specific job duties
- PICs and Regulators must hold employees accountable
 - Managers must monitor for expected performance
 - Immediate correction must be done when not in compliance
 - Retraining should be done as necessary
 - Known consequences must be carried out

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Regulatory Inspections

- Uniform, consistent inspections should be made based on P, Pf and C Items in the 2009 Food Code
- Knowledgeable and skilled inspectors can request immediate correction for P Items, explain, demonstrate or provide options to encourage behavior change
 - Developing risk control plans (who, what, when, where, why) for P Items encourages long term correction
- Focus on risk factors (P Items) for foodborne illness demonstrates their importance

A Food Safety Culture

- Managers should serve as good role models, especially for Priority code provisions
 - Otherwise: **“If you don’t do it, I don’t do it.”**
- Managers should provide education and training for all employees – now is the time to explain that food safety and protection of their customers is a high priority
- Managers should reinforce positive behaviors
 - Give positive feedback

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Education and Training

- Certified food safety managers should be knowledgeable and do the following:
 - Provide initial orientation and on-going refresher training related to their job duties
 - Explain why a particular behavior is necessary
 - Explain the food safety reason for requirements – that people can become ill or injured if things go wrong
 - Make it personal – they/their family can get sick, customers can get sick, job/business loss
 - Include personal testimonials, stories, etc.

Education and Training

- The Instructor/Manager should demonstrate the correct way of doing the task from the beginning
- Hands on training works best (coaching)
- Try different approaches and allow individual to choose option they prefer (for better buy-in)

Education and Training

- Management should remove barriers to learning
 - Provide time (on the clock) for training
 - Provide training in appropriate language, using familiar words and examples
 - Provide necessary resources
 - Computer for on-line training
 - Trainer and training materials
 - Supplies, utensils, equipment to carry out the task

Education and Training

- Training should be reinforced
 - Use posters, signs, pamphlets, wallet cards, etc.
 - Provide on-line or face-to-face updates
 - Give reminders during work – “teaching moments”
 - Use novelty to create renewed interest

Incentives Provide Motivation

- Management should consider rewards and the use of positive motivation
 - Recognition – awards, win a contest, media mention, ceremonies
 - Things – tickets, free meal, branded items, etc.
 - Praise – “Good Job!”, certificates
 - Money – prizes, job promotion, cash awards

Incentives Provide Motivation

- Sometimes negative consequences follow poor food safety practices:
 - Re-training
 - Warnings
 - Time-off
 - Loss of job

Annex B

What are some communication techniques to help convey our messages of food safety?

Food Workers as Oral Culture Learners

- Effective communication is necessary to get your message across
- Inspectors and QA staff are usually print culture learners
 - They read for primary information
 - They have linear, analytical thoughts, are task oriented and able to strategize
- Food workers are often oral culture learners
 - Most workers like to give and receive information verbally
 - Workers are less likely to follow rules made by someone they do not know or trust

Oral Culture Learners

- Verbal information, repeated regularly and reinforced with signs, posters, handouts is an effective way to communicate
 - Fewer words and more pictures is better
- Storytelling is an important method of getting information for oral culture communicators
- Many owner/managers think employees should read food safety rules to learn
 - This thinking reveals a lack of understanding of how oral culture communicators learn and process information

Effective Communication

- Communication has to be 2-way to be effective
 - Explain/demonstrate the issue and have it explained/demonstrated back to you
 - Hands on training reinforces explanation
 - Feedback that they are “doing it right” is important
 - Oral culture communicators require interaction to internalize knowledge and change behavior
 - Active listening skills help pinpoint misunderstanding or lack of understanding
 - There is no other way to know if their communication was effective or even heard
 - This promotes joint problem solving

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Communication by Behavior

- Effective communication shapes behavior
- We want to change unsafe food behavior and attitudes that disregard food safety processes
- 80-90% of what we communicate is by non-verbal behavior rather than by what we say
- Doing and correctly practicing the behavior internalizes the information communicated
- It is important for regulators, operators and trainers to consider different methods and their appropriateness to communicate risk and change poor behavior.

Communication by Behavior

- Correct behavior is often not modeled by management
 - **“Do as I say, not as I do”** doesn't work
 - Role models (managers, co-workers, inspectors) are important
- Correct behavior is often not a priority
 - **“If it's not important to you, it's not important to me”**

Use Plain Language

- Use “I,” “you” and “we” and avoid “it”
- Use short sentences, limit subjects to one per sentence
- Use vertical lists with parallel construction
- Avoid technical and legal jargon or “big words”
- Use terms listeners or employees are familiar with
- Make factual statements and avoid subjective statements that imply judgment

Communication

- Pertinence to job duties
 - People learn if they understand the importance of their job behavior
 - Communication is best understood when it is personal
 - Related to assigned job duties
 - Described with vivid, real-life examples
 - Connected to their own family, health and well being

Communication

- General statements may not be considered relevant to the job – be specific
 - Why is something important?
 - What is the right way to do it?
 - Can the right way be demonstrated?
- Provide options/examples that are specific to that job
 - Use easily available equipment, utensils or materials
 - Give employees a choice and ask which one they prefer
 - Ask employees to try it out

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What doesn't work well?

- Presenting all training in written form such as signs, pamphlets, on-line computer training, handout materials
- Using examples that aren't related to their job duties
- Using negative reinforcement (by itself)
- Saying something only once
- Using unfamiliar language or terminology

Annex C

What are common food safety hazards?

Biological, Chemical & Physical Hazards in Food

- **Each provision in the Food Code is intended to prevent, eliminate, reduce to an acceptable level or control hazards that could directly or indirectly contribute to a foodborne illness or injury**
- A hazard is a biological, chemical or physical property or agent that may cause an unacceptable consumer health risk
- A hazard must be identified as the first step in conducting a risk assessment

Biological Hazards

- Biological hazards consist of microbiological pathogens, including:
 - Spore-forming bacteria
 - Vegetative bacteria
 - Viruses
 - Parasites
- Most yeast and molds are spoilage organisms and do not cause illness or injury

New Foodborne Pathogens Identified Since 1977

More than 70 foodborne pathogens are known with the following added to the list since 1977

Campylobacter jejuni
Cryptosporidium parvum
Shiga-toxin producing *E. coli*
Noroviruses
Vibrio vulnificus
Yersinia enterocolitica
Salmonella Typhimurium DT 104
Spongiform encephalopathy prions

Campylobacter fetus ssp. Fetus
Cyclospora cayentanensis
Listeria monocytogenes
Salmonella Enteritidis
Vibrio cholerae 0139
Vibrio parahaemolyticus

Controls for Biological Hazards

- Provisions in the Food Code control biological hazards by eliminating, preventing, and/or reducing to acceptable levels or holding numbers unchanged by:

Cooking, pasteurization	Cooling
Retorting	Refrigeration
pH/acidity	Sanitizers
Water activity	Fermentation
Competing organisms	Irradiation
Bacteriocins, nicin	High pressure
Preservatives	Nitrites, nitrates
Hot holding	

Spore-Forming Bacteria

- *Clostridium botulinum, Clostridium perfringens, Bacillus cereus*
- Spores are able to survive cooking & other adverse conditions
- Spores do not multiply in this form so require no nutrients, water, etc. to survive
- Spores germinate & start to multiply when conditions are right – best control at this stage to prevent growth
- Retort processing (high temp & pressure) is necessary to destroy spores
- Toxins form after germination when the spore is actively growing

Vegetative Bacteria

- The growth phase of spore-forming and non spore-forming bacteria
- Nutrients, water and adequate environmental conditions (pH, a_w , temperature, etc.) are necessary for growth
- May form toxins in food or in the body
- Susceptible to cooking and many other environmental factors on a case-by-case basis
- Controlled by refrigeration although some vegetative bacteria can multiply slowly at refrigeration temperatures (e.g., *Listeria*, non-proteolytic *Clostridium botulinum*)

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Viruses

- Viruses are pathogens which cannot multiply outside of a living cell
- Norovirus, hepatitis A and rotavirus are the most common foodborne viruses
- Infected human beings (not animals) are the usual source
- Preventing contamination (exclude infected workers, handwashing, no hand contact) and thorough cooking control viruses
- Viruses are very heat resistant

Typical Sources of Biological Hazards

- Field and farm crops – soil, birds, other infected animals, failed septic systems, sludge and bio-solids contaminate food products
- Animals – manure, slaughtering process (skin, intestinal tract), service animals, pets and petting zoos contaminate food
- Fish and seafood – marine bacteria, histamine producing bacteria and fish parasites contaminate food

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Some sources of hazards are introduced to the food product while it is being grown, raised, harvested or processed, that is, outside the food establishment and only control or destruction by cooking, for example, is possible, not always prevention.

Typical Sources of Biological Hazards

- Infected workers – fecal material, vomitus, nasal discharge, coughing, sneezing and pus from infected lesions
- Cross-contamination from other sources during transport and storage
- Contaminated equipment, utensils and surfaces
- Water – irrigation, contaminated well water or ice, water main break, backflow or back siphonage

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Some sources of hazards are introduced to the food at the food establishment by food employees or dirty food contact or environmental surfaces. Some provision of the Food Code can prevent, eliminate or reduce to an acceptable level hazards that cause foodborne illness or injury. The degree of risk is dependent on many things:

on the pathogen itself (virulence, severity, etc.)

the level of contamination (pathogen load)

the consuming individual (, immuno-compromised, HSP or not)

Characteristics of Pathogens

- Infectivity – potential or ease of transfer, infectious dose
- Severity – virulence of the pathogen, length & severity of illness, hospitalization or death
- Spore formers/vegetative cells – ability to survive adverse conditions
- Acid resistance – susceptibility to pH
- Heat resistance – ability to survive cooking
- Biofilm formation – ability to form a protective polysaccharide covering resistant to cleaning & sanitizing
- Association with certain foods – SE with eggs, *E. coli* O157:H7 in meat, cider, etc.

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- The characteristics of a pathogen can help determine the risks of causing a foodborne illness and therefore was used to assign risk levels to provisions that are intended to control those pathogens.
- The levels of infectivity, how easily the organism/hazard infects an individual vary according to:
 - Highly infective norovirus can infect through 3 different pathways (ingestion of water or food, contact with mucus membranes such as eyes, or by aerosolization/inhalation)
 - Listeria monocytogenes* has a very low infective dose, tens to hundreds of organisms, and is therefore highly infective.
- Severity describes the effect the hazard has on the individual:
 - Virulence means the hazard/agent is extremely harmful
 - The length, symptoms and severity of the foodborne illness often results in hospitalization and/or death.
 - Less severe illnesses or injuries are shorter, have fewer or less harmful symptoms
- The ability to form spores means the pathogens can survive adverse conditions for long periods of time including normal cooking, dry conditions, lack of oxygen/ROP, etc.
- Acid (low pH) resistance means the pathogens can survive in naturally acid food (fruit and fruit juices) or in acidified foods.
- Heat resistance – some pathogens can adapt to higher temperatures, especially when protected by fats in the food.
- Some organisms including *E. coli* O157:H7, *Salmonella* and *Listeria monocytogenes* can form protective biofilms, a polysaccharide matrix, that protects them in adverse conditions.

Clostridium botulinum

Minimal growth requirement for *C. botulinum*

<u>Property</u>	<u>Group I</u>	<u>Group II</u>
	Proteolytic	Non-Proteolytic
	Type A, B, F	Type B, F, E
Inhibitory pH	4.6	5.0
Inhibitory NaCl	10%	5%
Minimum a _w	0.94	0.97
Temp. optimum	98°F	86°F
Temp. range	50 -118°F	38 -113°F
Toxin production	≥ 50°F	≥ 38°F

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•The minimum growth parameters for *Clostridium botulinum* show why this spore former has to have such stringent controls.

- There are 6 human strains and several different ways to classify *C. botulinum*: by Group, whether it is proteolytic (lyses blood cells) or non-proteolytic and by name of Type.

•The characteristics and sources (part of the world, soil, aquatic, etc.) of the pathogen are used to classify them

- pH or resistance to acid – Group I/Proteolytics are much more resistant to acid environments as they can germinate and produce toxin down to pH 4.6. This is the reason why pH 4.6 was previously considered the lower range of PHF food. Non-proteolytic *C. botulinum* is more sensitive to pH, it can only grow and produce toxin down to pH 5.0.

- Salt concentration – Group I/Proteolytic *C. botulinum* strains are able to grow and produce toxin in a 10% salt solution (very salty) versus 5% for non-proteolytics.

- Water activity – Group I/Proteolytic strains are able to grow and produce toxin at a relatively low water activity of 0.94. Group II/Non-Proteolytic strains' lower limit is 0.97.

- Temperature – Temperature is the parameter most easily controlled with foods and the growth factor for *C. botulinum* that separates the two most easily. Group I/Proteolytic strains have an optimum growth temperature of 98°F and a lower range of 50°F (well controlled by normal refrigeration temperatures.) Group II/Non-Proteolytic strains (generally found in seafood) can multiply and produce toxin at 38°F, below normal refrigeration temperatures, therefore more difficult to control with temperature alone.

Clostridium botulinum

- *C. botulinum* is an obligate anaerobe, spore-former, common in soil & aquatic environments (salt and fresh water)
 - Proteolytic *C. bot* – more pH & salt resistant, more resistant to low a_w , only grows & produces toxin down to 50°F
 - Non-proteolytic *C. bot* – less pH & salt resistant, less able to grow at low a_w , can grow and produce toxin down to 38°F
- Preformed toxin is heat labile (boiling 10 min.)
- Improper canning, retorting and reduced oxygen packaging (ROP) are risks

Clostridium perfringens

- *C. perfringens* is an anaerobic spore-former found in humans, animals, soil and vegetation
- Cooking heat shocks spores
- Generation time can be 8 minutes starting at 122 - 127°F
- Contributing factors for illness include:
 - Slow cooling (allows germination of spores)
 - Inadequate refrigeration (allows growth of cells)
 - Inadequate reheating (allows survival of cells)
- Vegetative cells sporulate (return to spore form) in gut and release toxin
- Large numbers of cells ($\geq 10^5$) are required to cause illness

Bacillus cereus

- *B. cereus* is an aerobic spore-former
- Spores are ubiquitous in the soil & environment
- 2 types of toxins can be formed:
 - Emetic is heat stable, formed in food
 - Diarrheal is heat labile, formed in intestine
- Slow cooling and inadequate refrigeration allow spore germination and growth to high numbers
- Toxin is not produced at temperatures < 50°F
- $10^5 - 10^6$ cells needed to produce toxin

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Salmonella Spp.

- Commensal organism in the lower gut of mammals
- High survival rate in the environment (up to several months)
- More than 2000 species of *Salmonella* are known
- Relatively heat tolerant
- Infected food workers, poor handwashing, hand contact, and cross-contamination are contributing factors to illness
- *Salmonella* is invasive in the gut and causes systemic infections



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• Instead of looking at the clinical aspects of *Salmonella*, let's look at its ecology, how it moves around and interacts with its environment. In other words, why it's so successful as a foodborne pathogen.

• *Salmonella enterica* with over 2000 subtypes is normally a commensal organism in the lower intestine of animals. That means it lives peacefully with other organisms, not doing harm as a parasite might. Obviously several subtypes have gone beyond that.

• *Salmonella* also survives in birds (SE in eggs) and reptiles (reason for the prohibited sale of baby turtles).

• *Salmonella* can survive for many months under the right conditions in the environment.

• *Salmonella* also forms biofilms as a protective mechanism which makes it very difficult to remove from a surface whether it is fresh produce or a cutting board.

• Finally, *Salmonella* is relatively heat resistant.

Escherichia coli O157:H7

- Cattle and other animals are reservoirs
- Survives well in the environment
- Forms biofilms resistant to washing and sanitizing
- pH resistant
- Transmitted mainly through the ingestion of food contaminated with ruminant feces



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• *E. Coli* is also a commensal organism in the lower gut of mammals. All of us in fact, carry *E. coli*. But as with *Salmonella*, some of them exchanged a little genetic material with their bacterial friends and we have Enterotoxigenic *E.coli*, Enterohemorrhagic *E.coli*, or Enteroinvasive *E.coli*.

• Cattle are the primary reservoirs but other animals and humans may be as well.

• It survives well in the environment for weeks or even months under the cool, wet conditions.

• It forms biofilms for protection as does *Salmonella* and *Listeria*.

• It is very pH resistant, surviving in apple cider at pH's as low as 3.3. Many people think that fresh produce, especially fruits are protected by their low pH but this may not always be the case.

• You often see generic *E. coli* used as an indicator organism for fecal contamination. Since an indicator should have a survival rate equal to or slightly higher than the bacteria of interest. *E.coli* may not be a good indicator for *Salmonella*.

Escherichia coli O157:H7

- Inadequate cooking and cross-contamination of RTE food are contributing factors
- Shiga-toxin produced in the gut is absorbed into the blood stream
- Damages small blood vessels
 - Leading to bloody diarrhea, kidney failure and death
 - Causes 90% of diarrhea and associated HUS



Staphylococcus aureus

- People are carriers (skin, nasal passages, infected lesions) as well as dogs, fowl, cows with infected udders
- Non spore-former produces toxin at a_w too low for competing bacteria
 - Growth at $a_w = 0.83$,
 - Toxin production requires $10^6 - 10^7$ CFU/g
 - Toxin produced at $a_w = 0.88$
 - Pre-formed toxin produced in food
- Reheating destroys cells but toxin is heat stable
- Food likely to be contaminated by hand contact with RTE food and infected lesions

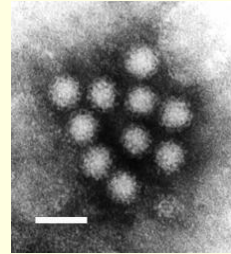
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Listeria monocytogenes (Lm)

- *Listeria* is ubiquitous in the environment
- Lm forms biofilms resistant to washing & sanitizing in high moisture niches
- Lm multiplies slowly at refrigeration temperatures down to 32°F
- Controls include addition of listeriocides to food, short shelf life (datemarking), preventing contamination from the environment, refrigeration, cooking, adequate cleaning & sanitizing
- Fetuses (miscarriages), babies, pregnant women and the elderly are particularly susceptible – high case fatality rate

Norovirus (NOV)

- Human beings are the reservoir for NOV
- Norovirus is reported as the single most common cause of gastroenteritis in the western world
- NOV is transmitted by:
 - Fecal-oral route (through food)
 - Inhalation (breathing vomitus droplets)
 - Person-to-person (touching someone contaminated)
 - Environment to person (touching contaminated surfaces)



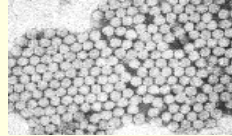
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Norovirus

- NOV infectious dose is 1 particle (a cluster of 200-300 viruses), highly infectious
- $10^9 - 10^{10}$ particles/g feces (the size of the tip of a fingernail)
- NOV is highly resistant to disinfectants
- Projectile vomiting or diarrhea episode
 - Needs to be contained (covered)
 - Then double wash and disinfect surfaces
 - Discard protective clothing and cleaning materials
- Virus survives in environment hours to days

Hepatitis A (HAV)

- HAV is spread from human beings through:
 - Contaminated sewage in wells, seafood harvest areas, recreational waters
 - Fecal-oral route (contaminated food)
 - Person to person
- HAV is shed at 10^8 viral particles /g feces
- Shed in feces midway through incubation period before symptoms appear
- Symptoms can last 6-9 months
- Controls are handwashing, no bare hand contact with RTE foods, exclusion with jaundice, shellfish certification & tag retention for 90 days



Parasites

- ***Anisakis***

- The motile larval stage burrows into the stomach walls
- Infection caused by eating raw or undertreated marine fish

- ***Cryptosporidium parvum***

- Infects 45 different species besides man
- Oocysts (infective stage) often associated with contaminated drinking & recreational water
- Oocysts are highly resistant to disinfection

Parasites

- ***Cyclospora cayentanensis***

- Oocysts are infective
- Often found in contaminated water

- ***Giardia lamblia***

- Reservoir is human beings & wild animals
- Protozoan cysts & trophozoites shed in feces
- Often associated with contaminated water or person-to-person transfer in day cares

Chemical Hazards

- A chemical hazard may be naturally occurring or may be added during processing or preparation
- Normal cleaners, sanitizers and other chemicals used in a facility may be a food hazard
- Scombrototoxin (histamine poisoning)
 - Formed by bacteria that convert histidine to histamine
 - Found in tuna, mackerel, skipjack, bonito, mahi mahi, blue fish and certain cheeses
 - Temperature abuse allows bacterial growth and histamine formation

Chemical Hazards

- Ciguatoxin
 - Found in tropical reef fish (i.e., barracuda, a predator fish)
 - Dinoflagellates and algae that produce the toxin are consumed by fish
 - Causes temperature reversal (hot ↔ cold) and other neurological symptoms, often for years



Chemical Hazards

- Tetrodotoxin
 - Certain fish (e.g., puffer fish, fugu, blow fish) produce toxin in their skin and viscera
 - Tetrodotoxin is heat stable – cooking will not destroy
- Aflatoxin
 - Mycotoxin produced in corn, nuts and other grains
- Patulin
 - Mycotoxin produced in rotten apples
 - Not destroyed by pasteurization or cooking

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Chemical Hazards

- Monitoring shellfish harvest areas for certain phytoplankton prevents shellfish poisoning
- Common shellfish poisoning includes:
 - Paralytic shellfish poisoning (PSP)
 - Molluscan shellfish, lobster and crab concentrate saxitoxin from certain dinoflagellates (“red tide”)
 - From a heat stable toxin
 - Flushed from animal within weeks

Chemical Hazards

- Common shellfish poisoning includes:
 - Diarrhetic shellfish poisoning (DSP)
 - Molluscan shellfish concentrate toxins from certain dinoflagellates
 - Heat stable toxin
 - Neurotoxin shellfish poisoning (NSP)
 - Molluscan shellfish concentrate brinetoxins from algal blooms
 - Toxic to fish, birds and sea mammals too

Chemical Hazards

- Common shellfish poisoning includes:
 - Amnesic shellfish poisoning (ASP)
 - Shellfish, Dungeness crabs and anchovies concentrate domoic acid produced by a diatom
 - Produces short term memory loss
 - Toxic mushroom species – False morels, Little Brown Mushrooms, Jack-O'-Lantern, Green-Spored Lepiota, Deathcap, Death Angel
 - Toxic plant species – Belladonna, bloodroot, buckeyes, castor bean, foxglove, hemlock, holly berries, Lily of the Valley, mandrake, May apple, mistletoe, rhubarb leaves, snakeroot

Physical Hazards

- Illness and injury can result from foreign objects in food including:
 - Glass – from lights, bottles and jars, utensils, gauge covers
 - Wood – from fields, pallets, boxes, buildings
 - Stones, metal fragments – from fields, buildings, machinery, wire
 - Bone – from improper plant processing
 - Plastic – from packaging materials, pallets
 - Personal effects – jewelry, buttons, bandaids, etc.