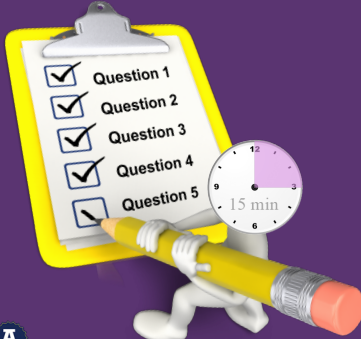


FSMA PCQI Summary Questions

2020-2021

1

SUMMARY



1. There are approximately ____ million foodborne illnesses in the US each year?
2. The FSMA rules are published by the government where ____?
3. A person who completes this workshop is called a ____ (acronym for ____)?
4. To be complaint with FSMA PC a food company must create, document ____ and ____ of a PC food safety system?
5. This version of the course aligns with the ____ who will issue the course certificate?
6. It is possible to send questions directly to the FDA regarding FSMA? T or F?
7. FS risk can be assessed using ____ and ____?

2

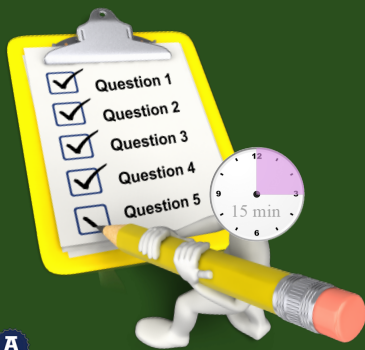
SUMMARY



- Ⓐ Under FSMA PC, a Food Safety plan must be? (a) created, (b) written, (c) submitted, or (d) CCP
- Ⓐ A food safety plan, program, or system are essentially the same thing? T or F?
- Ⓐ The _____ is used to guide the determination of food safety controls in a food safety system?
- Ⓐ It is possible to have a food safety plan that has **no** Preventive Controls? T or F?
- Ⓐ **Every** food safety plan **MUST** have a recall plan? T or F?
- Ⓐ Effective records (monitoring, verifications, corrective actions, and validations) in FSMA PC demonstrates that a food safety system is ____?
- Ⓐ The FS Plan must follow the prescribed format from the FDA? T or F?

3

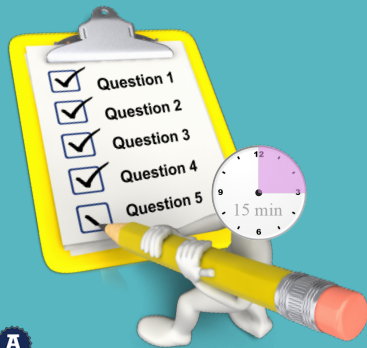
SUMMARY



1. The new GMPs are found in 21 CFR 117 ____?
2. Cross ____ is now distinct from cross contamination? Why?
3. Shall is now replaced by the word ____?
4. oPRPs stands for ____? Where do these come from?
5. Visitor control and food defense programs are examples of? (a) GMPs, (b) oPRPs, or (c) PCs
6. Cleaning walls and ceilings are most likely examples of? (a) GMPs, (b) oPRPs, or (c) PCs
7. Allergen controls are most likely examples of? (a) GMPs, (b) oPRPs, or (c) PCs
8. The majority of supplies and ingredients procurement is an example of (a) GMPs, (b) oPRPs, or (c) PCs

4

SUMMARY

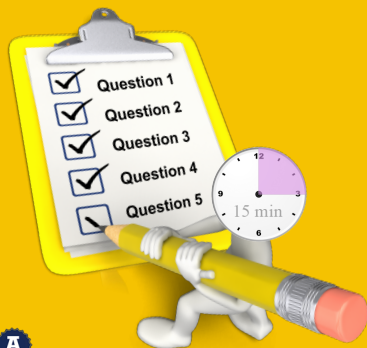


A

- Ⓐ Hazards B ____, C ____ and P ____ stand for?
- Ⓐ Microbes are found ____?
- Ⓐ What are the four groups of microorganisms?
- Ⓐ Which of the four groups...
 - Ⓐ does **NOT** cause FBI?
 - Ⓐ grows in food
 - Ⓐ is associated with people (workers)
 - Ⓐ is associated most with water
 - Ⓐ is associated most with fecal origins
- Ⓐ Which bacteria is responsible for approx. 25% recalls ____ and approx. 19% recalls ____?
- Ⓐ What are the four groups of immunocompromised people?
- Ⓐ Bacteria can cause illness by ____ or _____. One causes symptoms in hours, the other days.
- Ⓐ Which three pathogens form spores?
- Ⓐ What does adulterated mean?

5

SUMMARY

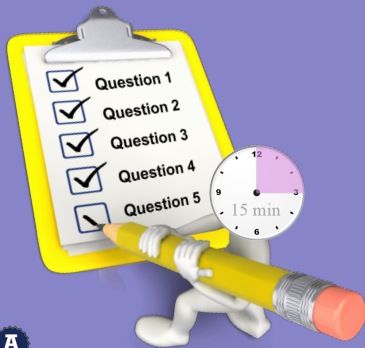


A

- Ⓐ Radiological is classified as a ____ hazard.
- Ⓐ Mycotoxins are classified as a ____ hazard.
- Ⓐ Name some chemical hazards that are found naturally in some foods?
- Ⓐ Name some chemical hazards that are considered intentional in some foods – e.g. ingredients?
- Ⓐ Name some chemical hazards that are unintentionally found in some foods?
- Ⓐ Both ____ and ____ objects are physical hazards.
- Ⓐ Objects from ____ mm to ____ mm are considered choking hazards.
- Ⓐ Purely economic fraud is considered a B, C, P, or not a hazard?
- Ⓐ Can a food be adulterated with chemicals of physical objects? T or F?

6

SUMMARY



A

- Ⓐ Without _____ support a HACCP/PC system will likely fail.
- Ⓐ Support often includes _____, _____, and _____.
- Ⓐ The HACCP/PC team _____, _____, _____ and _____ the food safety plan (system).
- Ⓐ The HACCP/PC team must also ensure staff are _____?
- Ⓐ _____ information is not required by FDA but very helpful?
- Ⓐ _____ information is required and is a foundation to the hazard analysis?
- Ⓐ Information on food items and their _____ are vital for the hazard analysis.
- Ⓐ The last two requirements in preliminary steps is to create and verify a _____.
- Ⓐ A written narrative [is | is not] required by FDA.

7

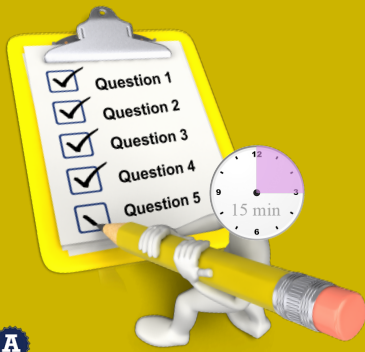
SUMMARY



8

- Ⓐ The PC & HACCP hazard analyses are the same? T or F.
- Ⓐ A _____ hazard is any _____, _____, or _____ item.
- Ⓐ A known hazard has the _____ to be associated with a food or facility? Also called a _____ hazard.
- Ⓐ A _____ hazard has been determined by a knowledgeable person to require a PC?
- Ⓐ The Preventive control goal is to significantly _____ or _____ significant hazards using current science.
- Ⓐ A hazard analysis form can have slight variations?
- Ⓐ Risk-based means evaluating hazard _____ and _____.
- Ⓐ A hazard analysis must include _____, packaging, and _____.
- Ⓐ Hazard analyses can designate controls at three levels _____, _____, and _____.
- Ⓐ A hazard analysis can designate that a specific hazard is controlled at a later step? T or F.

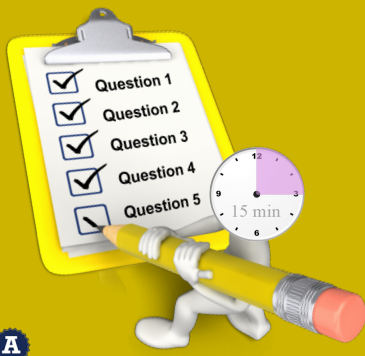
SUMMARY Part 1



- Ⓐ Under FSMA PC, a CCP Summary Chart can be called the _____ Summary Chart?
- Ⓐ Under FSMA PC, critical limits are termed _____ and _____?
- Ⓐ How does *qualitative vs quantitative attributes* affect the question directly above?
- Ⓐ Failure to meet a critical limit is a _____?
- Ⓐ Failure to meet an operational limit is a _____?
- Ⓐ FSMA PC uses the term _____ to indicate trained and competent?
- Ⓐ Monitoring generally requires the questions of _____, _____, _____, and _____?
- Ⓐ What is the role of *drift* in monitoring?
- Ⓐ What are the differences between a *correction* and a *corrective action*?

9

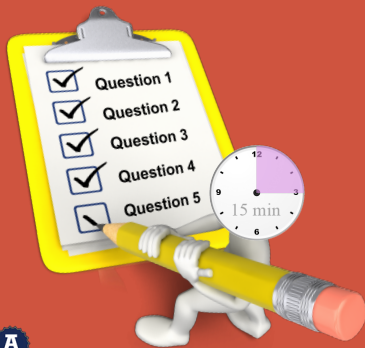
SUMMARY Part 2



- Ⓐ What are safe harbor critical limits?
- Ⓐ What are exceptions? Are records required?
- Ⓐ What must be done when you encounter an unanticipated deviation?
- Ⓐ What are some examples of using technology to make monitoring easier and/or more effective?
- Ⓐ When a staff member fakes data it is sometimes called _____?
- Ⓐ How might a supervisor prevent _____ from the question directly above?
- Ⓐ Corrective actions should be _____ and _____?
- Ⓐ What **MUST** be done after a corrective action is applied?
- Ⓐ What can be done with non-compliant product?

10

SUMMARY

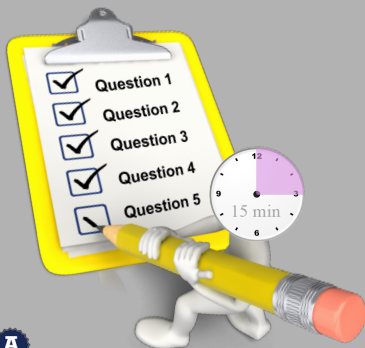


A

- Ⓐ Allergens are the number ___ reason for recalls?
- Ⓐ All **true** allergens are _____?
- Ⓐ If you have \geq ___ allergen, you _____ have an Allergen Preventive Control Program?
- Ⓐ Allergens spreading in the food processing environment is called cross _____?
- Ⓐ If an allergen is declared (on the label) it **(a) does or (b) does not** require allergen PC control?
- Ⓐ There are ___ major US Allergens? Can you name them all?
- Ⓐ All Allergen controls must be in the allergen PC program? **T or F?**
- Ⓐ The USDA allergen controls: _____, _____, and _____ are **optional** elements of an Allergen PC?

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SUMMARY

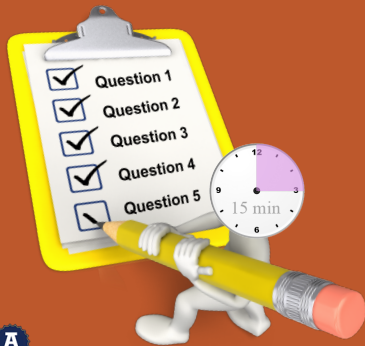


A

- Ⓐ What are the main differences between GMP and PC sanitation? Records?
- Ⓐ Can allergen cleaning be in the Allergen PC?
- Ⓐ The Sanitation PC relies on _____ to help accomplish its objectives?
- Ⓐ Is PC sanitation confined to FCS / Zone 1?
- Ⓐ If a product has a full lethality as its last step (in package) – *is there a significant pathogen hazard requiring a Sanitation PC?*
- Ⓐ If a product is **ready-to-cook**, *is there a significant pathogen hazard requiring a Sanitation PC?*
- Ⓐ *Name some additional food examples that would require a Sanitation PC?*

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SUMMARY

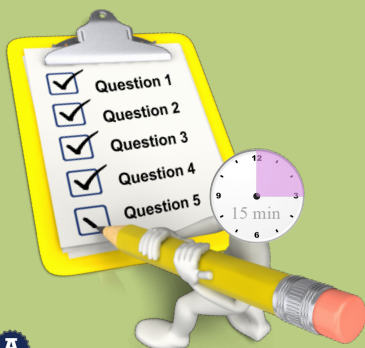


A

- Ⓐ Where is a Supplier PC control determined?
- Ⓐ Is Supplier control required for ALL suppliers?
- Ⓐ A Supplier Control Program typically consists of several _____s.
- Ⓐ What are some supplier criteria?
- Ⓐ What is a LoG?
- Ⓐ What are some purchasing criteria?
- Ⓐ What are some receiving criteria?
- Ⓐ What is a COA?
- Ⓐ How might you verify implementation of above items?
- Ⓐ How might you verify the food safety controls of a Supplier? How often?
- Ⓐ Can anyone audit a supplier for you?

13

SUMMARY



A

- Ⓐ _____ is actually a part of _____.
- Ⓐ Plan components working correctly are _____?
- Ⓐ Are you doing what you say you will do is _____?
- Ⓐ Plan components based on sound science are _____?
- Ⓐ All persons providing verifications must be _____.
- Ⓐ All persons providing process control verifications must be _____.
- Ⓐ Equipment accuracy/calibration is _____?
- Ⓐ Microbial testing is a _____ activity?
- Ⓐ Referencing critical limits in process controls is _____?
- Ⓐ ATP sampling for soils is _____?
- Ⓐ What does overt staff observation achieve?
- Ⓐ What does covert staff observation achieve?
- Ⓐ Can the entire food safety plan be verified?
- Ⓐ **[Can or must]** the entire food safety plan be verified? How often?
- Ⓐ The FDA has provided allergen threshold levels for validation? T or F.

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SUMMARY

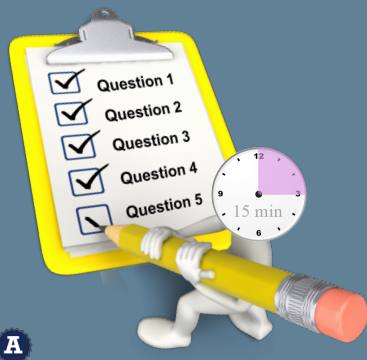


A

- Ⓐ All _____ controls **require** records?
- Ⓐ Records for ___ and ___ are optional.
- Ⓐ Records must be ___ and ___ copies?
- Ⓐ Electronic records [**are | are not**] permitted?
- Ⓐ All records must be _____ and _____ by a responsible person (e.g. supervisor).
- Ⓐ When records are quantitative they must capture _____.
- Ⓐ Equipment accuracy/calibration records are [**required | optional**]?
- Ⓐ Corrections require records? T or F.
- Ⓐ Corrective Actions require records? T or F.
- Ⓐ GMP Staff training requires records? T or F.
- Ⓐ PC Staff training requires records? T or F.
- Ⓐ Audit reports are saved as _____ records?
- Ⓐ Lab data of microbial analyses are saved as _____ records?
- Ⓐ A HACCP/PC team meeting to verify and validate the food safety plan after three years requires records? T or F.
- Ⓐ Supplier _____'s and _____'s are saved as records.

15

SUMMARY



A

- Ⓐ An operator with no preventive control programs [**is or is not**] required to have a recall plan?
- Ⓐ Food pathogens or undeclared allergens is a class _____ recall?
- Ⓐ A mislabeled product has or 6 ounces and it should have been 7 ounces. All other factors are correct. This is a class _____ recall.
- Ⓐ Who determines the need for a market withdrawal?
- Ⓐ What are the three main groups that might need notification during a recall?
- Ⓐ A crisis manager [**is or is not**] required under FSMA for a recall?
- Ⓐ All recalled foods must be discarded after getting them back to the facility. **T or F.**
- Ⓐ What is the effectiveness value for 1000 cases of donuts recalled and receiving 900 cases of returned product?
- Ⓐ Records of a recall event [**are or are not**] required?

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