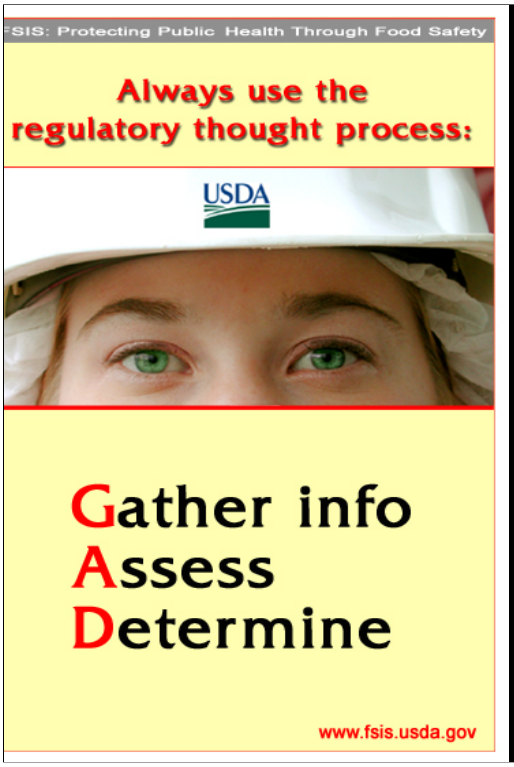


PREREQUISITE PROGRAMS

The World Health Organization defines **prerequisite program** as “practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety”. Prerequisite programs provide a foundation for an effective HACCP system. They are often facility-wide programs rather than process or product specific. They reduce the likelihood of certain hazards.

Learning objectives:

Define prerequisite program.

Describe the relationship between prerequisite programs and the HACCP System.

Distinguish between a prerequisite program and a CCP.

Evaluate if the prerequisite program is effective.

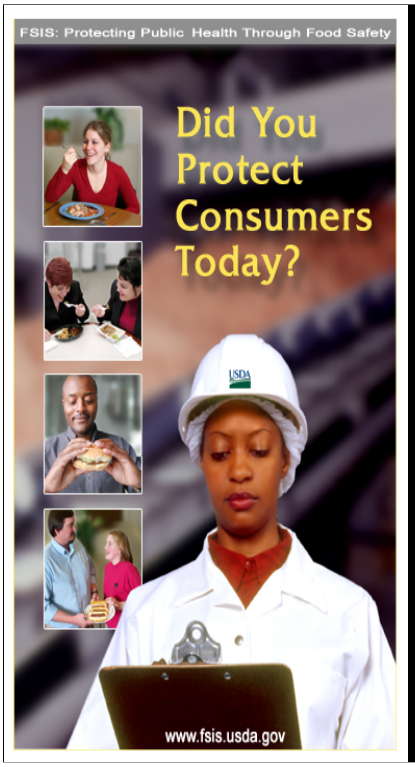
Evaluate that the prerequisite program is being implemented appropriately.

Identify when a failure to meet a prerequisite program is a noncompliance.

Describe how often to review the records of a prerequisite program.

Prerequisite Programs Support the HACCP Plan

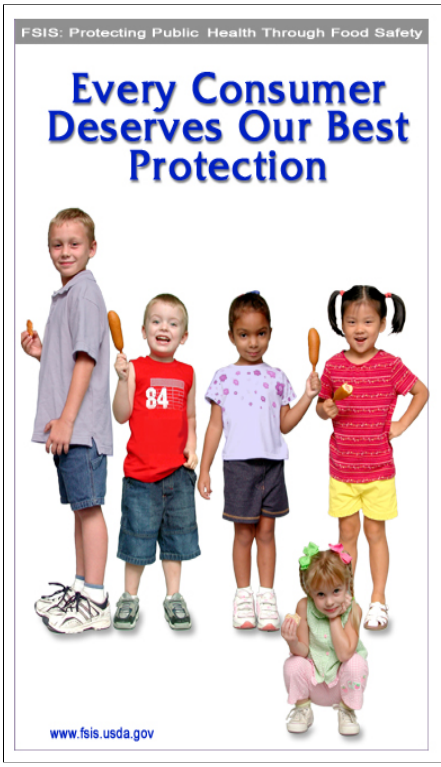
Prerequisite programs deal with the "**good housekeeping**" concerns of the establishment, whereas, HACCP manages specific process hazards. The plant must provide all documentation including the written program, records and results for all prerequisite programs which support their HACCP system. For example, an establishment may conclude that *E. coli O157:H7* is a hazard not reasonably likely to occur in the establishment's processing because the establishment has a prerequisite program with purchase specifications addressing *E. coli O157:H7*. The information regarding this prerequisite program is supporting documentation which must be maintained according to 417.5(a)(1). Without this documentation, FSIS would question the adequacy of the establishment's HACCP system and Hazard Analysis. FSIS expects the supporting documentation concerning prerequisite programs to include the program's procedures and operational controls in writing. In addition, FSIS expects the documentation to include records that document the program is effective and that *E. coli O157:H7* is not reasonably likely to occur. Inspectors are required to review testing and prerequisite program records at least once per week according to Directive 5000.2.



Prerequisite Programs

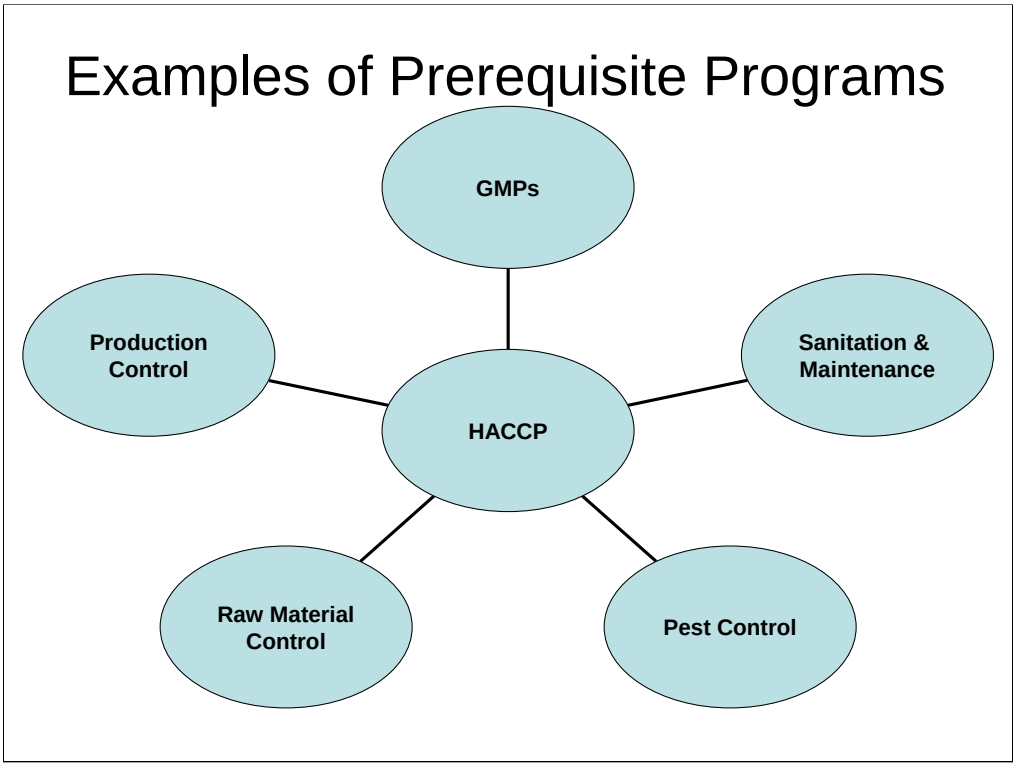
May prevent food safety concerns

Prerequisite programs are outside the HACCP Plan but still within the HACCP System. The inspector **can not** apply the same criteria as they would verifying the regulatory requirements of the HACCP Plan. Inspection program personnel should evaluate prerequisite programs and determine if they continue to support the decision in the hazard analysis. What is the difference between a CCP in the establishment's HACCP plan and a prerequisite program? A CCP is designed to control a food safety hazard that has been determined to be reasonably likely to occur. A prerequisite program may prevent a food safety hazard from occurring.



Establishments must follow their Prerequisite Programs.

Prerequisite programs set the stage for a HACCP system and provide on-going support for the establishment's food safety system. They keep potential hazards from becoming serious enough to adversely impact the safety of foods produced. If an establishment fails to follow their prerequisite program related to the production of E. coli O157:H7 beef products, there is a significant food safety concern.



Here are some examples of prerequisite programs. Not all plants have the same prerequisite programs.

-Pest Control Program

-Good Manufacturing Practices (GMPs)

-Raw Material Control: *E. coli O157:H7*, Receiving product temperature, Residue controls

-Production Control – Foreign Material, Allergens, Chemical

-Sanitation & maintenance

Establishments should revise their prerequisite programs, as necessary, to ensure their effectiveness, and should take appropriate corrective actions when they determine that their prerequisite programs may have failed to prevent contamination and/or adulteration of product. Suppose an establishment addresses *E. coli O157:H7* in their prerequisite program but not in their HACCP Plan. If they produce *E. coli O157H:7* positive product, this occurrence would be considered a "deviation not covered by a specific corrective action" or an "unforeseen hazard according to 417.3 (b). Therefore, the establishment would be required to take the corrective actions, including reassessment according to 417.3 (b). The prerequisite program was not effective in reducing the likely risk in the processing environment.

Prerequisite programs must be implemented and have documentation such as records to verify implementation if referenced in the hazard analysis, HACCP plan, or SSOP. Records associated with monitoring and testing may include instances of less than perfect control without resulting in a threat to food or product safety. However, records generated from these programs must continue to support the decisions made in the establishment's Hazard Analysis. As instructed in FSIS Directive 5000.2, when performing a HACCP 01 procedure, the inspector should review the records, results, and supporting documentation for the plant's HACCP plan. If you are reviewing the results and records on a weekly basis-you may identify trends, missing records, etc., in which the program may no longer support the decisions made in the hazard analysis which would be a noncompliance.

(Note: Remember that the HACCP 01 procedure is a random selection of one of the 5 regulatory requirements, and the instructions above represent a description of verifying the recordkeeping requirements.)

According to SSOP regulations, establishments that include purchase specifications addressing *E. coli O157:H7* will need to evaluate routinely the effectiveness of these purchase specifications in preventing the adulteration of their products. They will need to revise these purchase specifications as necessary to keep them effective according 416.14. Establishments need to maintain records to document the implementation, monitoring and correction of their purchase specifications according to 416.15 and 416.16. Under 416.15, establishments are required to implement corrective actions when they determine that their SSOP may have failed to prevent direct contamination or adulteration of product, however, under 416.15, establishments are not required to reassess their SSOP when they have made that determination.

For example, if the plant's prerequisite program includes purchase specifications for suppliers, and the records of the plant's testing of product that is received from suppliers shows multiple positive results, this would cause the establishment to document their corrective action under 416.15 because the purchase specifications appear to have been ineffective in preventing direct contamination or adulteration of product.

One isolated incidence of failure to meet a prerequisite program is not a non-compliance unless:

-Insanitary conditions are created as a result of the failure (SSOP or Sanitation Performance Standards noncompliance)

-A food safety hazard is created as a result of the failure (unforeseen Hazard, 9 CFR 417.3 (b))

-Example: In its hazard analysis, the establishment determined that *E. coli* O157:H7 is a hazard not reasonably likely to occur due to a prerequisite program that includes purchase specifications that require all suppliers to provide a COA for beef trim. When performing the HACCP 01 procedure and reviewing the records of this prerequisite program, the inspector notices that a COA for the most recent shipment of beef trim is not recorded in the records. What are some questions the inspector should ask to determine if there is noncompliance?

·Has the establishment held the product for this shipment of beef trim pending the receipt of the COA?

·Does the prerequisite program contain procedures for the establishment to follow when a COA is not included with a shipment of beef trim? If so, is there evidence to show that the establishment is following these procedures?

If the answer to either one of these questions is yes, at this time there is no noncompliance.

·Are there other shipments of beef trim that are missing COAs?

·Has the establishment used the shipment of beef trim that is missing the COA in the production of product and shipped it in commerce?

·Is there other evidence that the establishment is failing to follow its prerequisite program to prevent or control for *E. coli* O157:H7?

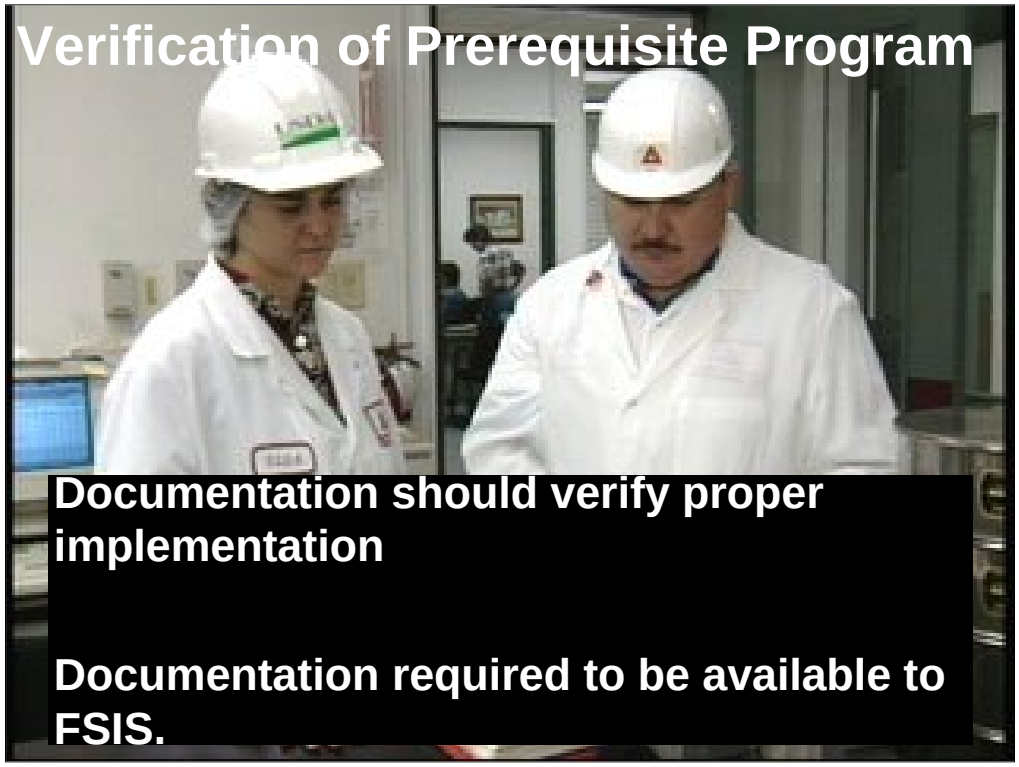
If the answer to any of these questions is yes, there is evidence that the establishment is not following is prerequisite program. This information indicates that a food safety hazard has resulted from this failure to follow the prerequisite program. The inspector should write an NR citing 9 CFR 417.3(b), and the establishment must take the actions related to an instance of an unforeseen hazard.

If the establishment included the prerequisite program requiring suppliers to submit a COA in its SSOP, the inspector would write an NR based on noncompliance with 9 CFR 416.15.

Repeated failures may indicate that prerequisite program does not support the decisions made in the hazard analysis.

-This is a noncompliance with 417.5(a)(1) for failing to have adequate supporting documentation of the decisions made in the hazard analysis.

-Here's an example where the plant included purchase specifications in the SSOP, and the plant's hazard analysis indicates that *E. coli* O157:H7 is a hazard not reasonably likely to occur. The plant's records show that the purchase specifications are not effective, and the plant has not provided corrective action under 416.15. This is an SSOP noncompliance as well as a HCCP noncompliance. The inspector should document both of these noncompliances in the NR.



If Prerequisite programs are used to met the Sanitation Performance Standards, referenced in the Hazard Analysis, HACCP Plan, or SSOP, the records associated with the prerequisite programs are required to be available to FSIS.

The plant's documentation should show that the prerequisite program is being implemented properly.

Verification

Include records associated with prerequisite programs relevant to the ISP procedures being performed.

01

According to FSIS Directive 5000.2, as part of performing HACCP 01 procedures, inspection personnel are to include a review of the records associated with prerequisite programs that are relevant to the HACCP verification procedures being performed.

For example, if the establishment has a prerequisite program for *E. coli* O157:H7 testing, the inspector should at least weekly, review the results of the plant's *E. coli* O157:H7 testing.

Questions to Consider

Purchase Specifications Example

Example: Purchase Specifications

Here are some examples of questions you might ask when verifying an establishment's purchase specifications that are included as part of a prerequisite program in its HACCP plan.

Has the company developed purchase specifications, in writing, and presented them to each supplier?

Does the company maintain records to show incoming product is being monitored to ensure purchase specifications are met?

Does the company have letters from suppliers indicating what they are doing to meet the purchase specifications?

What is the specification that the supplying company is trying to accomplish?

Is the supplier certifying that its process is in control, or each load is free of pathogens, foreign materials, allergens etc.?

How is the receiving establishment ensuring that the suppliers interventions are being accomplished?

Is the receiving establishment notified when the supplier finds they have been ineffective in achieving process control?

At what frequency does the supplying company re-evaluate the effectiveness of their process control?

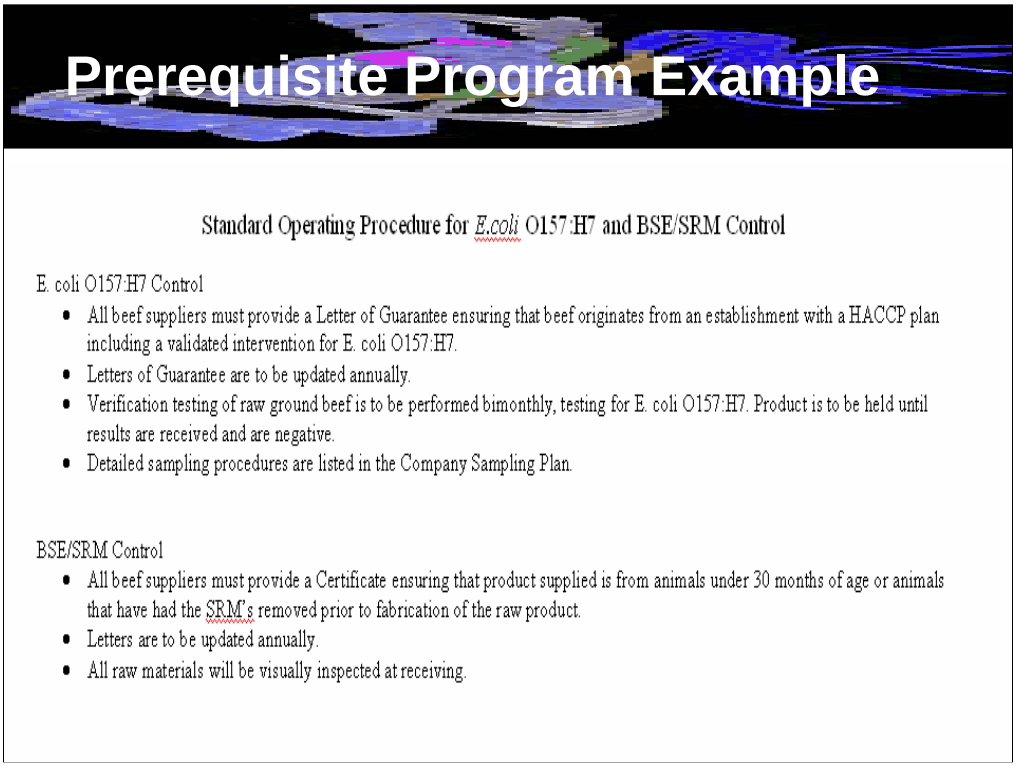
Hazard Analysis Example

HAZARD ANALYSIS – RAW, GROUND – Ground Beef

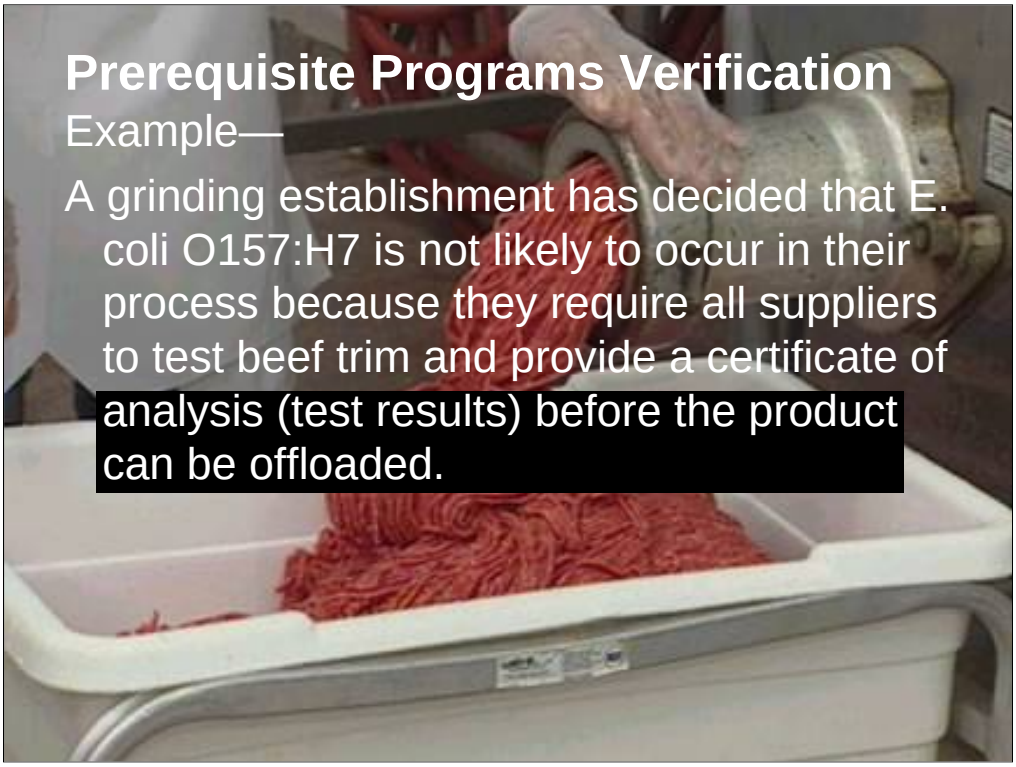
1. Process Step	2. Food Safety Hazard	3. Reasonably likely to occur	4. Basis of Reasonably likely to occur	5. If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?	6. Critical Control Point
1. Receiving – Packaging Materials	Biological – Contamination with meat, other biological material	No	SOP for receiving makes hazards unlikely to occur.		
	Chemical – Non-food grade materials	No	Letter of guarantee for packaging materials makes hazards unlikely to occur.		
	Physical – None	No	SOP for receiving makes hazards unlikely to occur.		
2. Receiving – Raw Meat	Biological- Pathogens: *E. coli* 0157:H7, BSE, and SRMs	No	SOP for E. coli O157:H7, BSE, and SRMs makes hazards unlikely to occur	Letter of guarantee is on file for each supplier of beef trim documenting the application of at least one intervention step against E. coli O157:H7. Certificate from suppliers that product supplied is from animals under 30 months of age or animals that have had the SRM's removed prior to fabrication of the raw product.	
	Chemical – None	No	SOP for receiving makes hazards unlikely to occur.		
	Physical – None	No	SOP for receiving makes hazards unlikely to occur.		

Pre-requisite Program

Here is an example of a how an establishment may reference a prerequisite program in the establishment's Hazard Analysis. This example shows that the establishment determined that *E. coli* O157:H7 is a hazard that is not reasonably likely to occur at the receiving step for receiving raw meat ingredients because the establishment requires suppliers to submit a letter of guarantee documenting the application of at least one intervention step (e.g., an antimicrobial treatment to suppress the growth of *E. coli* O157:H7). The establishment will have a written description of its prerequisite program as supporting documentation for the decision made in the hazard analysis at this receiving step.



Here is an example of a prerequisite program included in an establishment's SSOP. This prerequisite program indicates that all suppliers must provide a letter of guarantee that documents beef is supplied from an establishment with a HACCP plan that includes a validated intervention for *E. coli O157:H7*. The letter must be updated annually. The establishment also tests product for *E. coli O157:H7* and holds products until results are received.



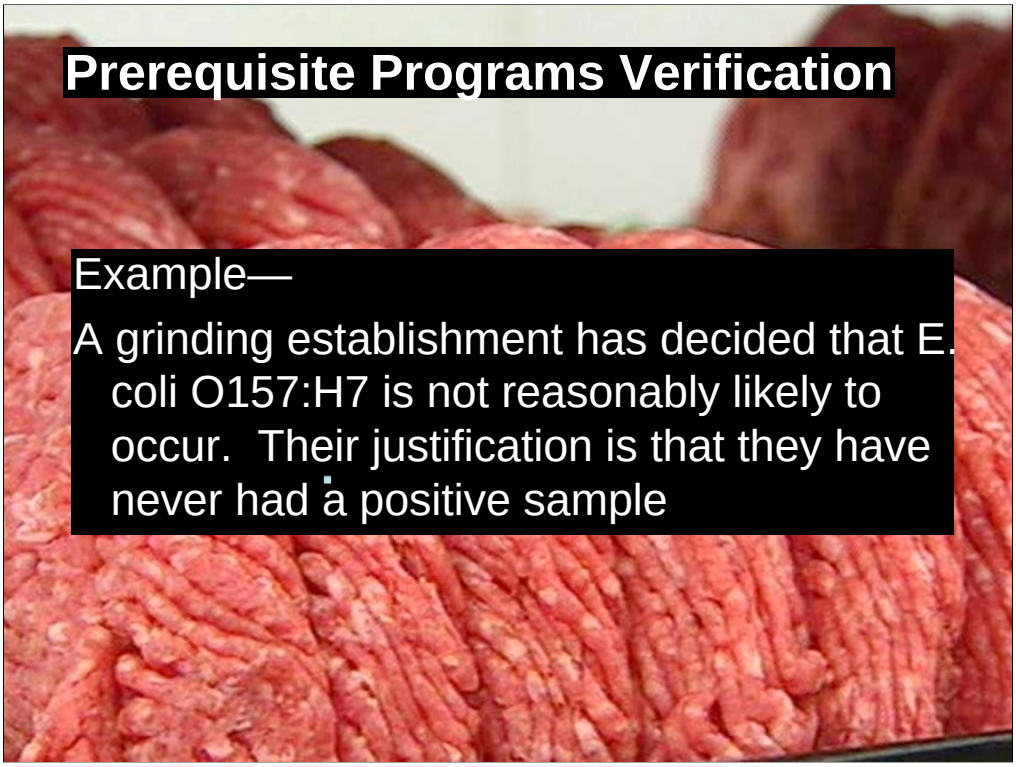
Is this an example of a pre requisite program? Why or why not?

Can the establishment support this decision? Why or why not?

Answer: Yes, this is a type of prerequisite program called a purchase specification. The purchasing plant has specified that they will only accept beef trim if it tests negative for E. coli O157:H7, and they have specified that test results must be available before they will receive the product. They can support the decision that *E. coli O157:H7* is not likely to occur because they have taken steps to prevent it by requiring testing of each load.

What actions would the inspector take if he or she found this while performing the HACCP 01 task?

Answer: If the establishment does have the COA or test results on file for each supplier and shipment, then no further action would be taken. If the establishment did not have any COA or test results, or they were missing a significant number of them, then the inspector needs to consider whether the plant is following this prerequisite program to prevent adulteration with *E. coli* O157:H7. If the inspector can reasonably conclude that this program is not being followed, then he or she will write a NR for recordkeeping and reference 417.5(a)(1). Block 10 of the NR should state that the establishment is not following their prerequisite program for *E. coli O157:H7*, describe their findings, and conclude that since this program has not been effectively implemented, it does not support the decision made in the hazard analysis. The inspector may want to contact a supervisor to discuss this thought process before writing the NR.

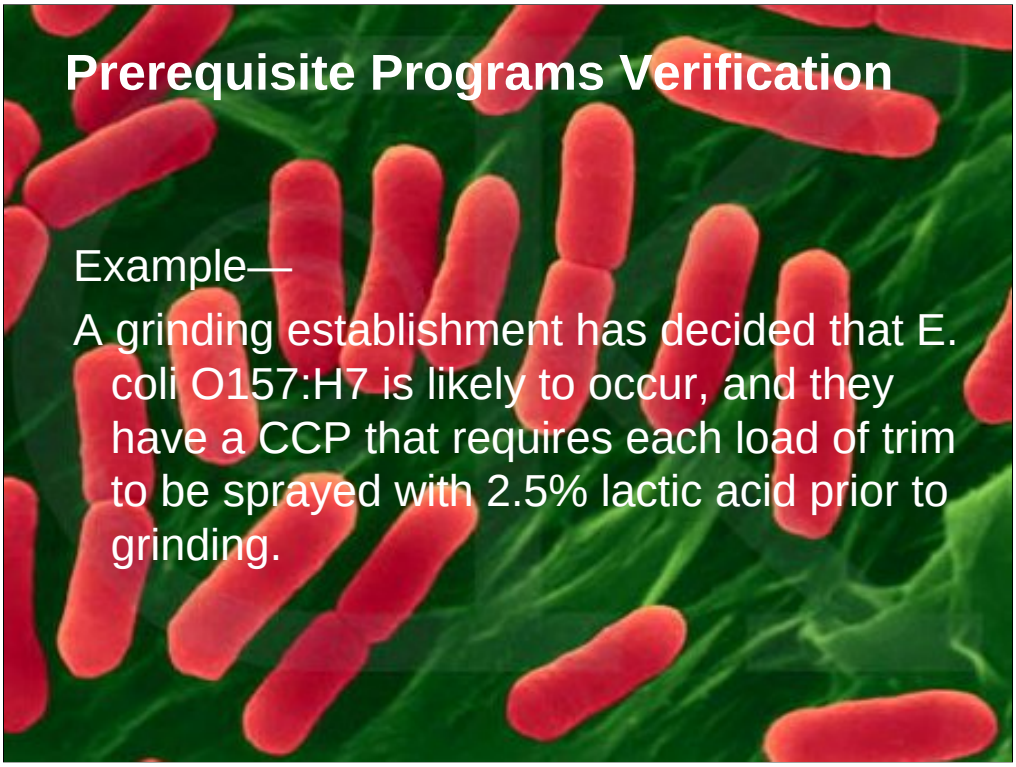


Is this a prerequisite program? Why or why not?

Do you think this decision is adequately supported? Why or why not?

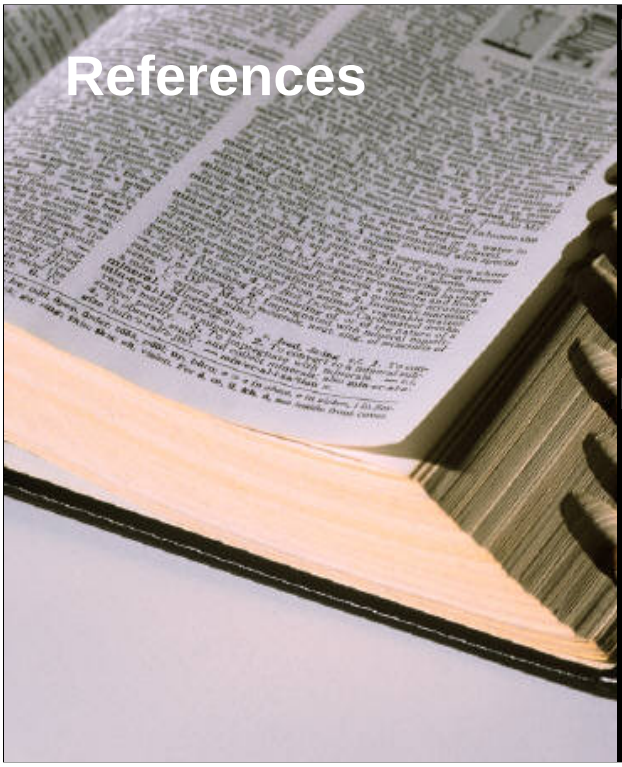
Answer: This is not a prerequisite program. This is a decision made in a hazard analysis. The establishment has supported their decision, but they did not develop a program to support it.

However, this decision is not adequately supported. Just because the establishment has never produced a positive sample does not mean that adulteration from *E. coli O157:H7* will not occur. *E. coli* O157:H7 is a known adulterant of beef. In the absence of any preventive measures, adulteration with *E. coli O157:H7* is likely to occur. If an inspector sees something like this in the hazard analysis while performing a HACCP procedure and they have questions, they should contact their supervisor for additional directions.



Is this an example of a prerequisite program? Why or why not?

Answer: No. This establishment decided that *E. coli O157:H7* is likely to occur, so they developed a CCP with critical limits.



References

- FSIS Directive 5000.1, Rev. 2, Verifying an Establishment's Food Safety System
- FSIS Directive 5000.2, Review of Establishment Data by Inspection Program Personnel