

Reassessment

Annual Reassessment Requirement/Changes in Plant Processes

The regulation that applies to reassessment of the HACCP plan is:

9 CFR 417.4(a)(3)--Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with §417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of §417.2(c) of this part.

The establishment is not required to document reassessments that are conducted as a result of changes in the process, unless the reassessment reveals that modification of the plan is necessary. If reassessment reveals that the HACCP plan no longer meets regulatory requirements, the HACCP plan must be modified immediately, and signed and dated. To demonstrate that the annual reassessment has been performed, the establishment is required to sign and date the HACCP plan.

NOTE: The establishment can reassess its HACCP plan any time during the calendar year to meet the annual reassessment requirement. This requirement does not require the establishment to reassess every 12 months. The CSI should verify the establishment is meeting the annual reassessment requirement somewhere close to the anniversary date of HACCP implementation in the establishment.

You would perform procedure 03A01 to verify the annual reassessment requirement. Use the basic compliance checklist, only the parts which pertain to the annual reassessment.

The thought process you should use when verifying regulatory requirements includes:

- **G**athering information by asking questions;
- **A**ssessing the information; and
- **D**etermining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

When verifying compliance with §417.4(a)(3), the CSI should consider the following questions:

1. Has a reassessment been conducted to meet the annual reassessment requirement?
2. Did the establishment consider any significant developments that have occurred in the plant or that have occurred with respect to the types of products produced by the plant, in its analysis?
3. Has any change occurred that could affect the hazard analysis or HACCP plan?
4. Did the establishment reassess?
5. If the reassessment revealed that the HACCP plan no longer met regulatory requirements, was the HACCP plan modified immediately?

Assess the information

To verify compliance with 417.4(a)(3), you should review:

- Reassessment records, if available.
- HACCP plan.

Verify that the annual reassessment has been performed and that the establishment has considered any significant changes or developments in its slaughter-related processes.

Reassessment Example 1:

On 2-1-2003, you are performing the 03A01 procedure in a turkey slaughter operation. Because it is close to the HACCP plan's anniversary date of implementation, you decide to verify the annual reassessment requirement. You review the HACCP plan and verify that the annual reassessment was last performed and signed off on 1-1-2002. You learned in your HACCP training that the establishment reassessment requirement is based upon the calendar year and not upon a 12-month period. Therefore, you determine that the establishment is in compliance with the annual requirement since reassessment was performed in 2002.

If changes have occurred that could affect the hazard analysis or HACCP plan, you should verify that the plant did perform a reassessment. If the reassessment revealed that the HACCP plan no longer met regulatory requirements, you should verify that the HACCP plan was modified immediately.

Reassessment Example 2:

You are a CSI in a small beef slaughter operation which has just recently begun to slaughter bob veal calves. On 5-10-03, you decide to review the HACCP plan to determine if a reassessment was performed and, if so, were any changes made to the HACCP plan as a result of that reassessment. You find that reassessment was last performed and signed off on 5-1-2003. You also note that, as a result of the reassessment, the HACCP plan was changed by adding a CCP for chemical hazards at receiving. The supporting documentation for adding the CCP states the establishment had begun slaughtering bob veal calves. There were several sources of data in the supporting documentation that showed bob veal calves to be a much greater risk for residue violations. Based on your review, you determine that the establishment is in compliance with the reassessment requirement as a result of process

Determine Compliance

After you have gathered and assessed all available information pertaining to the reassessment requirement, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

Noncompliance with the Reassessment Requirements in 417.4(a)(3)

The following are examples of noncompliance with 417.4(a)(3):

- 1. On 2-2-2003, you are performing the 03A01 procedure and are reviewing the HACCP plan to verify it meets the annual reassessment requirement. The HACCP plan is signed and dated 11-11-2001. You question the HACCP coordinator and determine that the last reassessment was in November of 2001. **The annual reassessment requirement was not met.***
- 2. In November of 2002, a large beef slaughter establishment reassessed its HACCP plan in light of the new data showing E. coli O157:H7 is more prevalent than previously thought. On 12-6-02, you are reviewing the hazard analysis and find that E.coli O157:H7 was judged to be a hazard reasonably likely to occur at dehiding and evisceration. However, in reviewing the HACCP plan you find no CCP to address the hazard. **In this case, reassessment revealed that the HACCP plan no longer met the requirements of 417.2(c) and the plan was not immediately modified.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

Reassessment of the Hazard Analysis

9 CFR 417.4(b)--Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

You will have to rely on your knowledge of the operation and the changes that occur within that operation. You would verify this requirement using the 01 procedure.

The thought process you should use when verifying regulatory requirements includes:

- **G**athering information by asking questions;
- **A**ssessing the information; and
- **D**etermining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

When verifying compliance with §417.4(b), you must answer the following questions:

1. Does the establishment have a process without a HACCP plan because the hazard analysis has revealed there is no food safety hazard likely to occur?
2. Have any changes occurred in the process that could reasonably affect whether a food safety hazard exists?
3. If changes have occurred in the process, has a reassessment been conducted as a result of these changes?

Assess the information

You would review the hazard analysis.

FSIS knows of no process that inherently has no hazards. If you encounter an establishment with no HACCP plan, you should notify the District Office. You

should verify food safety to ensure the process is not producing adulterated product.

Determine Compliance

After you have gathered and assessed all available information pertaining to the reassessment requirement, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

Noncompliance with the Reassessment Requirements in 417.4(b)

1. The establishment has a process with no HACCP plan, changes occurred that could affect whether a food safety hazard exists, and the establishment did not conduct a reassessment of the hazard analysis.
2. Changes occurred that could affect whether a food safety hazard exists, reassessment was conducted, the reassessment revealed that a food safety hazard exists, and no HACCP plan was developed.

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

