

Reassessment

This section covers how to perform your HACCP duties to verify compliance with the reassessment requirements.

The thought process the CSI should use when verifying regulatory requirements should include:

- **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

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 HACCP plan is necessary. If the reassessment reveals that modification of the HACCP plan is necessary, the HACCP plan must be modified immediately, and then signed and dated. The establishment is also required to sign and date the HACCP plan to demonstrate that the annual reassessment was conducted. The CSI should review reassessment records, if available, and the HACCP plan to verify these requirements. When verifying compliance with 9 CFR §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 have occurred with respect to the types of products produced by the plant in its analysis?
3. Has 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 meets regulatory requirements, was the HACCP plan modified immediately?

Assessing the Information

When assessing the information gathered, the CSI should do the following:

- Review the HACCP plan to determine if the establishment signed and dated the HACCP plan to demonstrate it was reassessed annually.
- Evaluate the process to determine if changes have occurred in the establishment that could affect the hazard analysis or HACCP plan. Such changes may include 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.
- Review any reassessment documentation available to determine that if the reassessment revealed that the HACCP plan no longer meets regulatory requirements, the HACCP plan was modified immediately.

Keep in mind that there is no recordkeeping requirement for reassessment other than to meet the annual reassessment requirement **and** as part of the corrective actions. Reassessment does not always result in modification to the HACCP plan.

Determine Compliance

After the CSI has gathered and assessed all available information pertaining to the reassessment requirement, he/she must determine regulatory compliance. If the CSI finds that the establishment has met all these regulatory requirements, there is no noncompliance. If the CSI finds that the establishment has not met all these regulatory requirements, there is noncompliance.

Some examples of noncompliance include the following:

- The annual reassessment was not conducted.
- Reassessment revealed that the HACCP plan no longer meets the requirements of 9 CFR §417.2(c) and the plan was not immediately modified.

Note: “Annually” does not mean that if the establishment initiated the plan on January 25, every year on or very near January 25 it must reassess the plan. What it does mean is that if the plan was initiated in 1999, it should have been reassessed in 2000, 2001, 2002, and sometime in 2003. The actual month and day is immaterial to the meaning of “annually.” This is based on the calendar year. FSIS verifies this regulatory requirement near the anniversary date of the HACCP plan for uniformity associated with the verification of this reassessment requirement.

Reassessment of the Hazard Analysis

The thought process the CSI should use when verifying regulatory requirements should include:

- **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

The CSI must rely on his or her knowledge of the operation and the changes that occur within that operation.

When verifying compliance with §417.4(b), the CSI should answer the following questions:

- 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?
- Have any changes occurred in the process that could reasonably affect whether a food safety hazard exists?
- If changes have occurred in the process, has a reassessment been conducted as a result of these changes?

Assessing the Information

When assessing the information gathered, the CSI should do the following:

- Evaluate the process to determine if changes have occurred that could affect whether there is a food safety hazard reasonably likely to occur. Such changes might be 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.
- Review the hazard analysis to determine if a reassessment has been conducted as a result of any changes that might have occurred. If during the reassessment of the hazard analysis a food safety hazard was

determined to be reasonably likely to occur, verify that the establishment developed a HACCP plan.

Determine Compliance

After the CSI has gathered and assessed all available information pertaining to the reassessment requirement, he/she must determine regulatory compliance. If the CSI finds that the establishment has met all these regulatory requirements, there is no noncompliance. If the CSI finds that the establishment has not met all these regulatory requirements, there is noncompliance.

Some examples of noncompliance include the following:

- 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.
- 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.

The CSI may need to discuss concerns with the establishment and issue a 30-day reassessment letter. The CSI will document any noncompliance.