

## 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. You 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, but only the parts which pertain to the annual reassessment.

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

- gathering information by asking questions;
- assessing the information; and
- determining 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), you 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 the:

- 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 shelf-stable processes.

**Reassessment Example 1:** *On 2-1-2005, you are performing the 03F01 procedure in a jerky 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 on 1-1-2004. 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 2004.*

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 performing the 03F01 procedure in an establishment that makes several kinds of salami. The establishment notifies you that it is planning to begin producing a different type of salami, dry Italian salami. This product will contain non-fat dry milk, and will be dried under controlled conditions that will result in growth of a white mold on the surface. Establishment management shows you a dry room that is being specially adjusted for this product line. You review the flow chart, and note the addition of the mold starter culture and the use of the dedicated dry room. You review the hazard analysis and HACCP plan. You see that a reassessment was conducted recently. You observe that the establishment has considered the potential hazards due to the non-fat dry milk and the white mold. The establishment provides several sources of supporting documentation for the safety of the white mold, and shows you a new procedure in its SSOP to address cross contamination issues due to the use*

*of the non-fat dry milk and mold. Based on your review, you determine that the establishment is in compliance with the reassessment requirement as a result of process changes.*

## **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 the reassessment regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met the reassessment 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 2-2-2005, 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 12-22-2003. You question the HACCP coordinator and determine that the last reassessment was in December of 2003. **The annual reassessment requirement was not met.***
- 2. In March of 2005, a jerky producer reassesses its HACCP plan in light of new information regarding the importance of humidity in elimination of pathogens, contained in the FSIS jerky compliance guidelines. The establishment documents, on 3-1-05, the need for humidity at the cooking CCP, which previously only had time and temperature. The establishment documents the decision to add a critical limit for humidity. You review the hazard analysis and HACCP plan on 4-1-05, and observe that the establishment has not changed the CCP to address the identified need for a humidity critical limit at cooking. **Reassessment revealed that the HACCP plan no longer met the requirements of 417.2(c) and the plan was not immediately modified.***

## **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:

- gathering information by asking questions;
- assessing the information; and
- determining 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 the reassessment regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met the

reassessment regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

#### ► Noncompliance with the Reassessment Requirements

The following is an example of noncompliance with §417.4(b).

*A canning establishment which produces product in metal cans has no HACCP plan because the hazard analysis revealed no chemical or physical hazards likely to occur, and the establishment addresses food safety hazards associated with microbiological contamination by compliance with the canning regulation. You observe that the establishment has added a new production line, to produce baby food in glass jars. **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.***

The following is an example of noncompliance with §417.2(b).

*In March of 05 you review the hazard analysis and flow chart at a popped pork skin operation. You observe that a reassessment was done in January 05, due to a change in type of raw materials received. The reassessment revealed a microbiological hazard reasonably likely to occur, and the establishment determined that a CCP is now needed to control pathogens. You request the HACCP plan and are told that there is a contractor working on it, but the plan has not yet been completed. **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. Note: Since the reassessment was conducted, this is noncompliance with 417.2(b)(1).***

### **30-Day Reassessment Letter**

You should issue a 30-day reassessment letter when you need more information to determine whether the establishment is meeting the requirements of §417.2. The 30-day reassessment letter gives the establishment an opportunity to support the decisions made or to reassess the hazard analysis and HACCP plan and make supportable decisions. Do **not** use a 30-day reassessment letter when there is noncompliance.

You must use good judgment when assessing an establishment's supporting documentation. If you determine that the lack of supporting documentation results in an imminent food safety issue, follow the Rules of Practice. For example, if the establishment has a critical limit for a final  $a_w$  for jerky of 0.89, and it has no support for this critical limit, then the 30-day reassessment letter is **not** appropriate, because in this situation food safety is clearly questionable.

You should discuss your supporting documentation concerns with establishment management, and contact the Technical Service Center if technical guidance is needed.