

## Verifying the Hazard Analysis

You verify that an establishment has performed a hazard analysis during the performance of the 03A01 procedure. Perform this procedure whenever new plants come under inspection or when an existing plant starts producing a product under a new HACCP plan or a significantly revised plan. You can use the Basic Compliance checklist (FSIS Form 5000-1) to assist you in performing 03A01. The questions from the checklist include:

1. Did the establishment conduct a hazard analysis or have one conducted for it?
2. Did the establishment's analysis start by identifying all hazards that may occur?
3. Does the hazard analysis identify preventive measures the establishment can apply to the food safety hazards?
4. Does the hazard analysis include a flow chart that describes (diagrams) the steps of each process and production flow in the establishment?
5. Does the hazard analysis identify the intended use or the consumers of the finished product?
6. Does the result of the establishment's hazard analysis reveal one or more food safety hazards that are reasonably likely to occur?
7. Does the establishment have a written HACCP plan for each of its products?
8. Has the establishment conducted validation activities to determine if a HACCP plan can function as intended?
9. Do the establishment's records include multiple results that verify the monitoring of CCP and conformance with critical limits?
10. Does the establishment have subsequent results that support the adequacy of corrective action in achieving control at a CCP after a deviation from a critical limit has occurred?

When an establishment references a prerequisite program in its hazard analysis as supporting documentation that a food safety hazard is not likely to occur, the CSI should verify that the establishment is:

1. Maintaining the prerequisite program on file,

2. Executing the program as designed, and
3. Maintaining records that evidence that the program is being executed as designed and continues to support decisions made in the hazard analysis (9 CFR 417.5).

**NOTE:** If CSIs have questions regarding the design of the hazard analysis they should contact the DO.

There are no specific regulatory requirements for prerequisite program activities. CSIs should focus on:

1. The overall execution of the program to verify that its execution is as designed,
2. Whether execution problems are such that the use of the program may not be continuing to support the decisions made in the hazard analysis that a hazard is unlikely to occur.

If you have reason to believe that the overall execution of a prerequisite program is not as designed and that the use of the program may not support the decisions made in the hazard analysis you would document noncompliance with 9 CFR 417.5(a)(1) and verify that the establishment:

1. Reassesses its hazard analysis as required in 9 CFR 417.4(b) because the decisions made in the hazard analysis may no longer be supported (9 CFR 417.5(a)(1)), and
2. Provides data supporting the decisions made during this reassessment required in 9 CFR 417.5(a)(1).

When basic noncompliance is identified while conducting 03A01, you must know the appropriate regulatory actions to take.

1. The basic compliance checklist is completed. This document is to be attached to the inspection file copy of the NR.
2. An NR is generated under procedure code 03A01.
3. The establishment is not to be permitted to start the production of products under the noncompliant HACCP plan. If the plant has been producing the products covered under the plan, contact the DO for further instructions. A withholding action should not immediately be taken because the plant has already been producing products. You are expected to take appropriate actions to ensure that no product that may be harmful to the consumer enters commerce, regardless of how long the establishment has been

producing product under the conditions in question. Once you have taken necessary action to ensure product safety, you should contact the District Office.