

Hazard Analysis

The hazard analysis is used to create the list of hazards identified to meet the first principle of HACCP and is used for the basis of the HACCP plan. The hazard analysis and HACCP plan are the building blocks of the HACCP system.

The CSI should use the thought process and methodology described below when verifying the hazard analysis. CSIs will verify compliance by reviewing the flow charts the hazard analysis, the HACCP plan, and HACCP records.

Before reviewing the hazard analysis, the CSI should understand that a food safety hazard is defined in 9 CFR §417.1 as any biological, chemical, or physical property that may cause a food to be unsafe for human consumption. The CSI must review hazard analysis records to determine if the analysis considered those properties that have a real chance of occurring in the food or in the processing of the food, and of causing the food to be unsafe.

The hazard must be one that would be identified by a reasonable consideration of the food, how it was processed, and where safety issues can arise. The fact that it is possible to imagine a hazard (e.g., a meteor may fall onto the plant) does not mean that the hazard analysis must address that hazard. If the CSI has a concern about whether relevant hazards have been considered, he or she may decide to discuss issues with the establishment or may seek guidance through the TSC.

The Basic Compliance Checklist (FSIS Form 5000-1) can be used by the CSI to assist in assessing compliance with Part 417 in a new establishment, with the addition of a new product or new process, or when the CSI becomes aware that a modification has been made to the HACCP plan.

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 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?

Note: Section 417.4(a)(1) provides more details about the requirement for initial validation, "...The establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan."

Validation data for any HACCP plan must include some practical data or information reflecting an establishment's actual experience in implementing the HACCP plan. This is necessary because validation must demonstrate not only that the HACCP plan is theoretically sound, but also that the establishment can implement it and make it work on a day-to-day basis.

9. Do the establishment's records include multiple results that verify the monitoring of CCPs 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?

If noncompliance exists with the hazard analysis, the CSI will document it appropriately. For example, **noncompliance** results if the establishment is not maintaining supporting documentation if the flow chart is missing a step, if the plant failed to consider a step in the hazard analysis, etc.

If noncompliance is determined when the CSI verifies §417.5(a), the CSI uses the recordkeeping trend indicator. The information gained during this verification can impact if the CSI documents the noncompliance and whether other enforcement action is necessary.

If the CSI makes the determination that more information is needed or that questions still remain regarding the hazard analysis the CSI may issue a 30-day reassessment letter.

30-Day Reassessment Letter

The CSI should issue a 30-day reassessment letter when the CSI needs more information to determine whether the establishment is meeting the requirements

of §417.2. The 30 day 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 letter when there is noncompliance.

Examples of when the CSI might write a 30-day reassessment letter are when the establishment has supporting documentation which still raises questions with the CSI:

- That the only CCP is at receiving and is determined to be adequate to control the food safety hazards identified in the hazard analysis throughout the process.
- For monitoring procedures and frequencies.
- For the verification procedures and frequencies in the HACCP plan.
- For the decisions made in the hazard analysis.

The CSI must use good judgment in assessing these situations. If the CSI determines that any of the situations result in imminent food safety issues, follow the Rules of Practice. For example, if the establishment has a critical limit for lethality of an internal product temperature of 140° F with no holding time, and it has no support for this critical limit, then the 30-day reassessment letter is **not** appropriate.

The CSI should discuss his or her concerns with establishment management, and contact the Technical Service Center if technical guidance is needed.