

Determining Inadequacy

To determine the plant's HACCP system adequacy, you must consider more than the HACCP plan. All available evidence and supporting documentation must be taken into account. You should evaluate other systems within the plant (SSOP, in-plant testing programs, etc.). Depending on the problems identified, the establishment may need to reassess the HACCP plan. For example, if an establishment has not identified E. coli O157:H7 as a food safety hazard likely to occur in its process and is testing outside the HACCP plan or SSOP and gets a positive result, a reassessment of its HACCP plan and hazard analysis is required in 9 CFR 417.4(a)(3). The establishment is required to support the decisions made during the reassessment as specified in 417.5(a)(1)&(2).

It is the responsibility of the CSI to verify that the establishment is meeting these requirements. If the establishment did not reassess its HACCP plan and hazard analysis as required by 417.4(a)(3) or does not have supporting documentation required by 417.5(a)(1)&(2), you cannot determine that the HACCP plan is meeting the requirements of 417.2, therefore the HACCP system may be determined to be inadequate as described in 417.6.

To determine if there is an inadequate system you need to answer the following:

1. Does the HACCP plan meet the regulatory requirements of Part 417?

If the establishment is not implementing all or some of its program, it has not met regulatory requirements. For example, if an establishment is not maintaining **any** records associated with its HACCP plan, the establishment is not monitoring critical limits at any CCP, the establishment did not reassess the HACCP plan when required, or the establishment did not modify its HACCP plan when it no longer met the requirements---then the establishment has not met the regulatory requirements. Therefore, you are unable to determine whether or not the establishment is producing adulterated product, and, therefore the HACCP system is inadequate. In these cases, the HACCP system would be considered inadequate because it did not meet the regulatory requirements of Part 417.

If the answer is **no** to question 1, this may be indicative of an **inadequate system**.

2. Was adulterated product produced or shipped?

If the HACCP system did not prevent the production and distribution of adulterated product, it is an inadequate system. If you determine that the establishment failed to meet a critical limit for a CCP and did not take the corrective actions as per Section 417.3 of the Federal regulations, and the establishment has performed its pre-shipment review, the HACCP system is inadequate.

If the answer is **yes** to question 2, this may be indicative of an **inadequate system**.

3. Is there a trend in establishment noncompliance?

You should observe trends in the noncompliance classification indicators marked on NRs when determining whether an establishment's HACCP system is inadequate. If two or more NRs have the same noncompliance classification indicators marked and if

descriptions of noncompliance indicate that similar problems are recurring, there may be a trend indicating the HACCP system is inadequate.

There is no specific number of incidents which determine a trend.

Because there will be a variety of processing environments and HACCP plans, FSIS cannot establish that a specific number of the same or similar incidents of noncompliance necessarily supports an inadequate system. Therefore, you must thoroughly analyze and document noncompliance trends that may support a determination. When reviewing a possible trend in incidents of noncompliance, you must closely review the descriptions of noncompliance contained in Block 10 of the NR form. You should not solely rely on the number of marked noncompliance classification indicators. Only through careful analysis of written descriptions of noncompliance can you determine whether there is a trend indicating that a HACCP system may be inadequate.

If the answer is **yes** to question 3, this may be indicative of an **inadequate system**.

Action to Take If an Inadequate System Exists

If you determine that an **inadequate system** exists, then you must take action.

- You would notify the District Office, which is covered in step 3A in the diagram.
- If you determine that adulterated product has been produced and shipped, you would take an immediate withholding action, according to the Rules of Practice.

The main point to remember is to contact the District Office if you believe an inadequate system exists. We will cover these enforcement actions in more detail in later sections.