

Adequacy of the HACCP System

To determine the plant's HACCP system adequacy, you must look beyond just the actual written HACCP plan. All available evidence and supporting documentation must be taken into account. You should have intimate knowledge of the plant's process capabilities and use this knowledge to assist you in your determination. You should evaluate other systems within the plant (SSOP, in-plant testing programs like environmental testing or end-product testing, etc.).

For example, if an establishment has not identified *L. monocytogenes* 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) and (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) and (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.

Remember at the beginning of the verification methodology you were told not to be afraid to ask very **specific** questions when you are trying to determine food safety. That thought process is something you should continue throughout your verification of the HACCP regulatory requirements. For example, construction that could impact on *L. monocytogenes* should be closely assessed. Ask what preventive measure the plant will take to prevent product contamination. Ask if the plant will do environmental testing during the construction project, and if so, what will the plant do if the results indicate any significant microflora changes during that time. Ask if the plant will implement any additional sanitation procedures during the construction project, and if it will do any testing to determine the effectiveness of these special procedures. Be curious and always look a step beyond what you know to be sure that you understand all aspects of the plant environment and production practices that have an impact on the safety of the products produced.

Documentation, both by the plant and by you, is vital to the success of HACCP. It is difficult to determine system adequacy without documentation. Likewise, if you are trying to initiate an enforcement action based on trends or a series of problems, and you do not have the NRs or other documents, you may not be able to support that enforcement action. To show a trend, you need to have linked NRs.

To properly determine the appropriate enforcement actions, you need to answer three key questions.

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

If the plant is not implementing all or some of its program, it has not met the regulatory requirements. For example, if a plant is not maintaining **any** records associated with its HACCP plan, not monitoring critical limits at any CCP, not reassessing the HACCP plan when required, or not modifying its HACCP plan when it no longer meets the requirements, then the plant has not met the regulatory requirements. You are then unable to make the determination that the plant is not producing adulterated product, and therefore the HACCP system is deemed inadequate. In these cases, the HACCP system is considered inadequate for not meeting the regulatory requirements of Part 417.

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 the plant failed to meet a critical limit at a CCP and did not take corrective actions per §417.3, but the plant had performed its pre-shipment review, then the HACCP system is inadequate.

3. Is there a trend in establishment noncompliance?

You should observe trends when determining whether a plant's HACCP system is inadequate. If multiple NRs have been documented for the same or similar cause, there may be a trend developing. Because there are a variety of processing environments and HACCP plans, FSIS cannot establish that a specific number of the same or similar incidents of noncompliance necessarily support 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 noncompliance descriptions (block 10 on the NR).

Action to Take If an Inadequate System Exists

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

- You notify the District Office.
- If you determine that adulterated (unsafe) 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.