HACCP Plan Reassessment
For Smaller Processing Plants

The third element listed at right likewise has three components: initial validation, ongoing verification and reassessment.

**Initial validation** demonstrates that developed HACCP plans can operate as written at the start-up of the plant’s HACCP program. It is a *shake down* cruise for the HACCP system testing the effectiveness of critical control points (CCPs), critical limits, monitoring and record keeping procedures, and corrective actions as outlined in the HACCP plans. Another aspect of validation is providing evidence that the critical limits employed are scientifically valid to ensure safe food production.

**Ongoing verification** continually tests whether the developed HACCP system is operating satisfactorily and providing reliable documentation. Verification activities often include, but are not limited to: a review of generated records, calibration of instruments used in monitoring CCPs, and direct observations of monitoring procedures to ensure they are being done, as described in the HACCP plans.

**Reassessment** periodically evaluates operation of the total HACCP system. Because changes will occur over time in plant procedures, products, personnel and knowledge of hazards, it is prudent that a processor should occasionally re-evaluate existing HACCP plans and their application to current plant operations. The purpose of this fact sheet is to provide information about the reassessment process.

**Reassessment Defined by Current Regulations**

The 1996 Final Rule, “Pathogen Reduction; Hazard and Critical Control Point (HACCP) System,” describes HACCP reassessment (9 CFR 417.4):

> 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.
Simply stated, reassessment is evaluating how your HACCP program is operating and updating it where necessary. It should examine the entire processing system, and ensure that it adequately identifies and controls food safety hazards. This might include a review of the written HACCP plan, HACCP records, validation of critical limits, and key pre-requisite programs such as Sanitation Standard Operating Procedures (SSOPs) and Good Manufacturing Practices (GMPs).

Reassessment must be performed at least annually (at any time within a given calendar year), but should also be conducted when a product or process has changed, when an unexpected hazard has occurred, to address new regulatory requirements or when it is in the company's best interest to do so. Once developed, a HACCP system is always open to modification for any of the above reasons.

Questions to Consider in Conducting a Reassessment

1. Do current sanitation procedures follow what is written in the SSOP? Is the effectiveness of the SSOP being properly monitored and documented, including corrective actions?
2. Are the procedures described in current HACCP plans being carried out, and are measurements, observations and other information required to be documented by the plant being recorded?
3. If new products have been introduced have they been incorporated into HACCP plans? Are products still listed in HACCP plans which are no longer being produced?
4. Has any new process been added to plant operations? If so, has it been added to the HACCP plans, or will it require development of another plan for a new product category.
5. Has the process flow or procedures used changed for any existing operations? Does the flow chart include steps for rework and returned products?
6. Has different equipment been added? If so, has this affected the hazards which may be present?
7. Have any new ingredients or ingredient suppliers been added? Are there any new hazards associated with these changes? Are up-to-date letters of guarantee available from all suppliers (recommended to be updated annually)?
8. Are critical control points (CCPs) providing the needed control? Are CCPs at the proper step? Should a CCP be moved, added or removed?
9. Are the critical limits consistently being met? If not, why? Are there any trends to indicate problems? Have the critical limits been validated to be scientifically adequate to prevent the identified food safety hazard?
10. Is monitoring being done as described in the HACCP plans? Are there times when monitoring is overlooked (not done when it should be)?
11. Are corrective actions suitably carried out and recorded? Are the four elements of corrective action as described in section 417.3(a) of the regulation being addressed in the corrective action log?
   • cause of the deviation is identified and eliminated
   • CCP is under control after corrective action
   • measures to prevent reoccurrence are established
   • no unsafe product has been distributed
12. Are verification activities being properly carried out? Is the record keeping system working? Are measurements or observations at critical control points being made, recorded and filed? Are direct observations of monitoring procedures being made? Are thermometers and other process-monitoring instruments calibrated regularly, and is this documented? Are measurements related to supporting prerequisite programs being taken and recorded where necessary?
13. What have been the results of any microbiological testing that has been conducted? What do these results tell about plant operations? If your plant has had any unfavorable microbiological results, what has or could be done to address the situation?
14. Are there any new employees in key roles in the plant? Do they understand the operation of the HACCP system?
Documenting a Reassessment

There is some flexibility in how to document that a reassessment has been conducted. At a minimum it is recommended that the responsible HACCP-trained person sign and date the HACCP plans again if no changes are needed. However, many plants prepare a cover sheet that clearly states that reassessment was conducted, and provides a place to list any findings, changes or other information that came out of the reassessment. It is recommended that the names of the persons involved with the reassessment, the programs and documents reviewed, and the changes made (including the reasons for the changes) be documented. The responsible plant official needs to sign and date this cover sheet at the time of annual or other reassessments.

While considerable effort goes into initially establishing a HACCP program and operating it on a daily basis, investing time in a thorough reassessment will keep the plan up-to-date and assure its effectiveness in maintaining the necessary process control to produce safe and wholesome food products.

References

