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● HACCP: Validation vs verification



# Introduction



The risk assessment methodology for Hazard Analysis Critical Control Point, known as HACCP, has been around since 1969 and has become the backbone of food safety standards and regulations globally. The concept of HACCP has continued to expand to include new classifications of food safety hazards to demonstrate preventative food safety controls throughout the food supply chain.

Food businesses that already have a HACCP system can't rely on their past history of compliance to assure continued food safety. Each HACCP plan that makes up a HACCP system needs to be periodically challenged to ensure it remains relevant to the business operations, and that new and emerging food safety hazards are considered and addressed where relevant to the products, processes and regulations in the country of sale.

HACCP plans aren't written once and then forgotten. They evolve through a developing knowledge and understanding of specific product and process food safety hazards, changes to regulations, changes within business operations and the inclusion of new and emerging food safety hazards. This is where the concepts of validation and verification become important to the integrity of the HACCP system. The revised CODEX HACCP requirements provide clarity of these expectations.

The terms validation and verification are often used interchangeably however they are distinctly different. Validation is the process that confirms that the HACCP plan will provide safe food when implemented. This is achieved by obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome<sup>1</sup>. Validation is completed before the HACCP plan is implemented, and as ongoing activity to revalidate the entire HACCP plan; confirming the intended level of control is maintained.

In contrast, monitoring and verification activities confirm that the control measures have worked as intended and this occurs after the validation of the control measures. Monitoring is a real-time measurement, whereas verification is an ongoing activity that is used to assess if the control measures have been implemented and that they are working as intended.



# Validation

CODEX HACCP requires two validation activities to be completed by food businesses; establishment of validated critical limits for each CCP (Principle three) and validation of the HACCP plan.

The critical limits for each control measure or combination of control measures are required to be scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if properly implemented'.

There are two components to this validation; confirmation that the selected critical limits are correct and evidence to demonstrate that the business can consistently achieve these limits.

- Confirmation that the critical limits are correct are known as 'theoretical validation'. This requires a food business to source reliable and scientifically proven information from regulatory requirements, industry codes of practice, published journal articles, suppliers of equipment and raw materials, advice from technical experts or results from inhouse analytical product testing for microbiological and chemical criteria. A critical limit from a regulatory requirement or industry code of practice doesn't require any further validation to confirm it's the correct limit as this work has been done by the regulatory authority or the representative industry body.
- **Food manufacturing example:** The chosen critical limits for a thermal process CCP are 70°C for two minutes as referenced in scientifically validated thermal equivalence data to achieve a five log reduction of *Listeria Monocytogenes* for short shelf-life foods.
- **Food service example:** The chosen critical limit for the storage of potentially hazardous foods is a maximum product temperature of 5°C as referenced in food safety regulatory requirements in the country of manufacture.
- The second part of critical limit validation is a 'process capability' where the food business demonstrates they're able to consistently achieve the critical limit, even when the likely worst-case scenario is applied. The processes used needs to be controlled as an out-of-control process can't be validated given there are too many unknown variables to take into consideration.
- **Food manufacturing example:** Crumb-coated chicken pieces are flash fried and fully cooked in an automated process where a belt carrying the product passes through a continuous oven with critical limits determined for time at temperature. The process variables to consider include: size of the chicken pieces, product temperature prior to the oven, belt speed and the orientation of the products on the belt when they pass through the oven. The worst-case scenario must include the potential for chicken pieces to join together after flash frying, but prior to cooking in the oven, which impacts the ability to achieve time at temperature.



- **Food service example:** Chilled foods are stored in a coolroom with an air temperature set at 3°C to meet the regulatory critical limit for potentially hazardous food to be maintained at less than 5°C. This requires a correlation between the air and product temperature to confirm product temperatures below 5°C, in addition to other variables such as space around products for air circulation to maintain product temperatures, how often the door is opened (resulting in loss of cold air) and the location of hot and cold spots due to the airflow from the refrigeration unit.

# Validation of the HACCP Plan



In addition to the validation of critical limits, CODEX Principle six requires that the HACCP plan is validated before it's implemented to confirm:

- Correct hazards are identified
- Correct CCP control measures have been determined
- Validated critical limits are defined for CCP control measures
- CCP monitoring is capable of identifying when critical limits are not met
- Predetermined corrective actions will prevent the release of unsafe food
- Verification activities confirm compliance to the HACCP plan
- Type of information recorded is sufficient to demonstrate historical proof of compliance to the HACCP plan

A revalidation of the HACCP plan is required following any system or process failure or changes that impact food safety. Examples of events that would prompt a review and potential revalidation include:

- A failure in control measures resulting in a process deviation for which the is of failure is not yet known
- A non-compliance to monitoring or verification activities
- Control of a hazard that is not achieved due to an inadequate or incomplete hazard analysis
- A process change due the introduction of a new control measure, use of new technology or different equipment
- A change to product formulation impacting food safety such as a reduction in sugar or salt, addition or removal of a preservative, change in finished product moisture content or pH

A food business with an existing HACCP system needs to revalidate their HACCP plans to ensure their continued capability for safe food production.

The HACCP team could ask the following questions to challenge and revalidate their HACCP plans for each preliminary step through the principles of HACCP:

**Preliminary step one: HACCP team and scope:**

- Does the current HACCP team have the required technical knowledge and expertise in the application of HACCP? Are all functions in the business that impact food safety represented?
- Does the scope of the HACCP system still cover all of the relevant food products and processes?

**Preliminary step two: Product description**

- Are there changes or a lack of detail in the product descriptions that will impact the hazard assessment?

**Preliminary step three: Intended use and users**

- Is there an alternate use for the products that impacts food safety? For example, flour that is intended to be baked into bread is also added as a topping to bread loaves after baking; the flour used for topping won't receive the full cook like the flour used in the dough.

**Preliminary step four: Construct flow diagram**

- Does the flow diagram for each process include all steps? This should include outsourced processes and the correct sequence of steps as errors in the process flow diagram may impact the hazard assessment.
- Have environmental contamination risks from people, equipment and air movement been considered for the process?

**Preliminary step five: On-site confirmation of flow diagram**

- Has a physical walk-through of each process flow diagram been completed?

**Principle one/step six: Hazards analysis**

- Are there new or emerging hazards, allergens or supply chain impacts to be considered?
- Are the correct hazards identified? Are they specific for each type of hazard?

**Principle two/step seven: Determine critical control points**

- Are the correct CCPs' control measures identified?

**Principle three/step eight: Establish validated critical limits for each CCP**

- Does the theoretical validation reference the correct and current regulations, industry codes of practice, etc.?
- Is the validation data to demonstrate process capability complete and current?

**Principle four/step nine: Establish a monitoring system for each CCP**

- Do the monitoring activities measure all critical limits identified for each CCP?
- Does the monitoring frequency provide sufficient control to prevent the release of unsafe food?

**Principle five/step ten: Establish corrective actions**

- Do the corrective actions provide sufficient instruction for product and process actions to prevent the release of unsafe food?

**Principle six/step eleven: Validation of the HACCP plan and verification of procedures**

- Are the verification activities adequate to provide confidence the HACCP system can provide the intended level of hazard control?
- Are the results of verification activities used to challenge the HACCP plan?

**Principle seven/step twelve: Establish documentation and record keeping**

- Is there sufficient proof of compliance (due diligence) demonstrated through monitoring and corrective records?





# ● Verification procedures



In addition to validation of the HACCP plan, CODEX Principle six also requires verification procedures to confirm that the HACCP system is working effectively. This is assessed by confirming the HACCP plan is being followed and that the control measures are working as intended and are capable of preventing, eliminating or reducing the food safety hazards to an acceptable level.

Verification activities also include observing procedures, such as CCP monitoring to confirm compliance, completing routine internal and external audits of the HACCP system, calibration of equipment used to measure critical limits, sampling and testing of raw materials, work in progress and finished products, environmental monitoring programmes as well as a review of monitoring and corrective action records to determine if the HACCP system is working correctly and as planned.

Although many food safety compliance standards require an annual review of the HACCP system, CODEX requires that the frequency of verification activities is sufficient to confirm that the HACCP system is working effectively, which may be more or less frequent than an annual review.

Significant changes to the raw materials, formulation (recipe), process, packaging or a food safety incident such as a product recall would require the HACCP team to reverify the HACCP system.

The following list of questions, organized according to the HACCP principles, are questions the HACCP team could ask to verify the continued effectiveness of HACCP plans:

**Principle one: Hazards analysis**

- Have the appropriate significant hazards been identified?

**Principle two: Critical control points**

- Have control measures been adequate to control the significant hazards?

**Principle three: Establish validated critical limits for each CCP**

- Have critical limits been adequate to control significant hazards?

**Principle four: Establish a monitoring system for each CCP**

- Have monitoring activities occurred as planned?
- Are the monitoring activities capable of detecting when critical limits are not met?

**Principle five: Establish corrective actions**

- Have corrective actions been appropriate for the deviations that have occurred?

**Principle six: Validation of the HACCP plan and verification of procedures**

- Have verification activities occurred as planned?

**Principle seven: Establish documentation and record keeping**

- Has sufficient retrospective proof of compliance (due diligence) been retained for CCP monitoring and corrective actions?

An increased understanding of food safety hazards, innovations in food packaging and advances in processing technology have provided many options for food safety control measures. Time taken by the HACCP team to validate HACCP plans and verify the HACCP system is time well spent to ensure the preventative food safety risk management remains relevant and effective for the long term.



# ● Why BSI?



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