Envato/seventyfourimages

Process validation of food safety control measures

By Wendy Katiyo (PhD), Food Science Centre, Mérieux NutriSciences SA

Wendy is the Project Leader for Process Validation research at the Food Science Centre at Mérieux NutriSciences South Africa.

Introduction

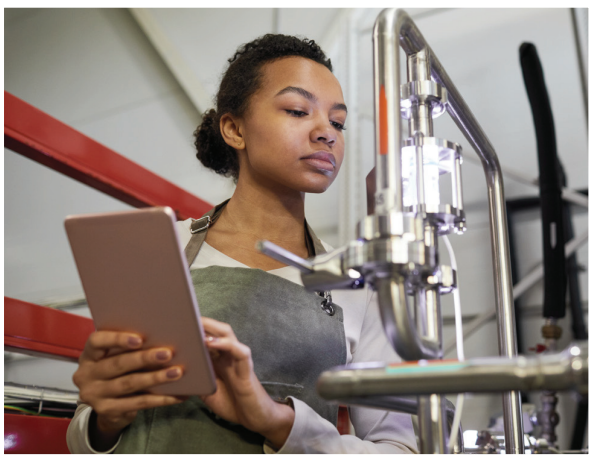
It is accepted practice that we cannot control hazards and achieve food safety by testing or inspecting finished products only. Food safety must be designed and built into the manufacturing process. Each step of the manufacturing process must be controlled to ensure that the finished product meets all safety and quality specifications. The food industry has the responsibility to develop processes that are effective in producing safe and quality food products. Food safety failures cause consumers to lose confidence in a food manufacturing company and its brands. Unfortunately, new challenges to food safety management will continue to emerge, predominantly because of:

- Changes in the environment leading to increased food contamination
- Changes in food production and supply, including food imports and globalisation
- New and emerging pathogenic bacteria, toxins and antibiotic resistance
- Evolving of detection and identification methods of food contaminants
- The growing number of people at high risk for severe food-borne diseases
- Changes in consumer food preferences and habits.

Process validation

Process validation is defined as: obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of effectively controlling the hazard to a specified outcome (*Codex Alimentarius* guidelines for the validation of food safety control measures, CAC/GL 69-2008).

It is a science-based, systematic and preventive approach to food safety management. Through the validation process, one can demonstrate that the selected control measures are sufficient to provide a safe and stable product. Process validation is not a new concept to the food processing industry. The Hazard Analysis and Critical Control Point (HACCP) system mandated the validation of Critical Control Points (CCPs) since the introduction of the seven principles. There is a greater issue in today's food safety management due to the increasing prevalence of food-borne disease outbreaks. Food safety standards require formal validation of CCPs and operational prerequisite programmes. Even though this is a requirement, some food manufacturers may not perform process validation because they may be unaware of how to collect and evaluate the information required to determine whether their control measures are effective against microbial hazards and other contaminants.



Envato/seventyfourimages

Process validation approaches

Validation is specific to the intended product, process and process parameters being evaluated. Examples of processes that need validation include (but are not limited to) thermal and non-thermal preservation techniques, end-product cooking instructions, control of metal fragments and other foreign matter, testing for chemical residues and allergen cleaning. The following approaches to validation may be used individually or in combination, as appropriate:

- Scientifically valid experimental data that demonstrate the adequacy of the control measure
- Reference to scientific or technical literature, previous validation studies or historical knowledge of the performance of the control measure
- Collection of data during operating conditions in the whole food operation
- Mathematical modelling
- Surveys.

Steps to process validation

According to the *Codex Alimentarius* guidelines for the validation of food safety control measures (CAC/GL 69-2008), there are five steps to process validation (Figure 1).

Figure 1: Five steps to process validation of food safety control measures

Step 1
Decide on the approach or combination of approaches

Step 2
Define the processing parameters and target criteria

Step 3
Assemble relevant validation information and conduct the studies where needed

Step 4
Analyse the results

Step 5
Document and review validation

Significance of surrogate microorganisms in process validation

Scientifically valid experiments that demonstrate the adequacy of the control measure against hazards are highly recommended, because the validation study can be conducted using the actual equipment utilised in the manufacturing process and the food matrix. Since the use of pathogenic microorganisms in food processing facilities is unacceptable, surrogate microorganisms are used as substitute test microorganisms for in-plant validation studies. A surrogate microorganism is a non-pathogenic species and strain whose growth parameters and resistance to a particular treatment are similar to that of the pathogen of concern. For example, *Enterococcus faecium* NRRL B-2354 has been reported as a suitable surrogate for *Salmonella* relating to thermal processing of low moisture foods, such as almonds, cocoa beans, flour, corn-soya blends, seasonings, spices and pet food.

When selecting a surrogate, the product, process and target pathogen should be considered. However, there are limited studies available on the identification of surrogates for different food matrices and processes. More research is needed in this area.

Process re-validation

Re-validation means repeating the initial validation effort or any part of it. This approach is essential to maintain the validated status of the food manufacturing process. The scope of re-validation procedures depends on the extent of the changes and the effect upon the food product. Potential reasons for re-validation include:

- The emergence of a new pathogen or higher risk in the product or ingredients
- Process parameter and product formulation changes
- Verification, or monitoring, shows system failure
- Upgrading processing equipment and technologies
- Latest scientific or regulatory information.

Process validation or verification?

There are two objectives to the 6th HACCP principle: (i) to determine if the plan is valid and (ii) to verify that the HACCP system is operating according to plan. There is frequently confusion regarding validation and verification activities. The *Codex Alimentarius* (CXC 1-1969, rev.2020) and ISO 22000:2018 separate these two as distinct but related concepts. It is important to think of verification more as a periodic audit process. Verification activities include:

- Review of the food safety plan and its records
- Review of deviation analyses and product dispositions
- Confirmation that CCPs and other preventive controls are kept under control
- Ensuring that proper change control procedures are in place and are followed.

Conclusion

As food manufacturers, being able to provide scientific and technical evidence that the validation of food processes was employed is a formidable statement that control measures are effective. This means that there is validated capability to achieve the targeted level of safety and/or meet regulatory and customer requirements.

References are available.