Validation and Verification of Food Safety Control Measures

Food manufacturers are responsible for developing and implementing a food safety program that is scientifically effective (validation) in controlling hazards and complies with current food safety programs (verification).

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of food production that the FDA regulates. Validation and verification cover a broad area and can be applied to all segments of manufacturing. Many food safety professionals use validation and verification interchangeably, but each has a different meaning and purpose. This article describes their functions from a kill-step perspective.

VALIDATION. Although most food products undergo a supposed kill step at the point of production (such as baking, roasting, extruding, or frying) these control points lack scientific validation. Validation is a preemptive scientific evaluation that provides documented evidence that a particular process (e.g., cooking, frying, chemical treatment, extrusion, etc.) is capable of consistently delivering a product that meets predetermined specifications. In other words, it’s a collection of scientific proof that a particular process involving chemical, physical, and biological inputs is consistently delivering a desired effect to ensure the destruction of pathogenic microorganisms. This is often expressed as “log reduction.”

Logarithmic reduction reduces the count of pathogenic organisms by a specific exponent, such as reducing the count from 10⁶ (1,000,000) bacterial cells to 10¹ (10 bacterial cells). According to FSMA’s proposed rule, it’s the collection and evaluation of scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control identified hazards.

Validation proof can come from a variety of sources such as peer-reviewed scientific literature, mathematical modeling, or regulatory resources. When such information is not available or sufficient, in-house challenge studies can be used. In most situations, validation is conducted prior to implementing a new method or process. Activities include challenge testing, shelf-life testing, etc. A kill-step validation is the only way to prove that a particular process is consistently delivering the desired lethal effect to ensure the destruction of pathogenic microorganisms.

The major steps involved in validation include: determining the method(s), selecting a surrogate or pathogenic microorganism, identifying worst-case scenarios, executing the validation study by a qualified microbiologist or food safety expert, collecting and analyzing data, and preparing a validation report. The validation report should include the following sections: introduction, contact information, background information, general information about the product, parameters studied, details of equipment (type and make) used, method used, microbial strains used, results, date of the validation study, detailed discussion, significance, etc. Also, the validation report should be written in sufficient detail so that the purpose, significance, and outcome of the study are clearly understood by other food safety experts. Once the process validation is completed, the facility needs to establish verification procedures.

VERIFICATION. This is the activity or activities conducted to ensure that the implemented processes are effectively and consistently carried out. In other words, it is the confirmation that you are doing what you intended or planned to do and that it is effective. According to the FSMA proposed rule, these are activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan. Verification activities can include the food safety plan review; walk-through; document review; testing; internal auditing; confirmation that the CCPs, HACCP plan, and other preventive controls are effective, etc.

The first step in performing verification activities is to determine all of the processes and parameters that need to be verified and identify qualified experts who can perform this task. These experts could be internal employees or external consultants. However, verification should be carried out by someone other than the person responsible for the process monitoring and corrective actions. In most situations, the internal quality assurance team or third-party auditors perform this task to ensure that the method or process follows the specifications and complies with current food safety standards.

Verification activities should include documented evidence to confirm the efficacy of all elements of the food safety system. For example, a science-based environmental monitoring program may be used as a verification activity in some segments of the food industry. The verification activity will confirm the overall performance of the food safety program, identify the need for updating or improving the food safety control measures, provide evidence that corrective actions are effective, and verify that finished products comply with current standards.

SUMMARY. Validation and verification are vital to achieving food safety and are complementary to each other. Food manufacturers are responsible for developing and implementing a food safety program that is scientifically effective (validation) in controlling the hazards and complies with the current food safety programs (verification). Validation and verification processes are considered to be an ongoing component of the food safety system and there is always a scope for continuous improvement.

Whenever necessary, re-validation and re-verification should be conducted to adjust the food safety standards to ensure the food produced is safe. Once validation and verification are completed, it is important to document results and communicate them to the rest of the food safety team to ensure that the objectives of the food safety program are clearly understood by all staff members.

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