

Validation versus Verification: What is the difference?

THE ISSUE:

The Hazard Analysis and Critical Control Point (HACCP) subcommittee of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) revised and added definitions of terms and expanded the explanations for the HACCP principles (NACMCF, 1988). NACMCF defines validation as a component of verification. The United States Department of Agriculture Food Safety and Inspection Service (USDA-FSIS) does not provide a definition of verification or validation in the HACCP Systems regulation (USDA-FSIS, 1996). However, 9 CFR 417.4(a) states, “Every establishment shall **validate** the HACCP plan’s adequacy in controlling the food safety hazards identified during the hazard analysis, and shall **verify** that the plan is being effectively implemented.”

Unfortunately, there appears to be substantial confusion about these terms and how validation activities differ from verification activities. FSIS is currently drafting the final version of a validation guidance document intended to aid small and very small plants in meeting the validation requirements set forth in 9 CFR 417.4. Industry awareness of the Agency’s development of this document has prompted a large number of inquiries into the true meaning and scope of validation versus verification activities.

NACMCF definitions:

1. Verification: those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.
2. Validation: that element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

Objectives:

1. HACCP Validation:
 - a. To establish that implemented process controls are capable of providing control of the identified hazards.
 - b. To provide a measure of the amount of control (when possible).
 - c. To ensure that when the HACCP plan is effectively implemented in-plant, the system will perform as expected.
2. HACCP Verification:
 - a. To determine that an establishment is able to consistently apply their HACCP plan as designed.

Scientific documentation versus in-plant data:

Validation of a HACCP plan requires supporting documentation including (1) scientific documents and (2) data collected from in-plant initial validation studies. Scientific documentation may include expert advice, peer-reviewed journal articles, scientific studies, agency issuances, or other similar documents. In order to satisfy the validation objectives listed above, an establishment will need to collect/conduct in-plant measurements, observations, microbiological test results, or other information demonstrating that the control measures, defined in the HACCP plan, when implemented, will control identified hazards as expected. Supplementing scientific documentation collected in a laboratory setting with in-plant validation studies is necessary to ensure in-plant feasibility, since critical parameters in an establishment under daily operation may not be an exact match to those used in a controlled laboratory setting (i.e. employee variability, line speed, differences in water pressure, environmental temperature, product temperature, etc.).

Example:

An establishment needing to validate a cooling process for large, bone-in hams should obtain scientific justification for cooling times and temperatures needed to prevent outgrowth of target microorganisms associated with cooling such products. Scientific support is typically conducted in a laboratory setting, which may not account for differences in alternative curing ingredient profiles, product throughput, cooler/chiller size, temperature, air flow, etc. Therefore, the establishment should conduct an in-house validation study to obtain data to confirm that the cooling conditions in their process will deliver the same results as those presented in the supporting scientific study.

How validation stands apart from verification:

The focus of validation is to collect and provide scientific basis for decisions made during the development or reassessment of a HACCP system and to provide evidence of hazard control. Verification is used to assess an establishment's ability to consistently implement the HACCP system as it was designed. An additional way to look at the difference between these two terms is relating them to accuracy and precision. A valid HACCP system would be one that is scientifically accurate, or correct — the CCPs have been proven to control the identified hazards. To verify a HACCP system is to make sure it is implemented precisely, or that the steps in the system are repeatable. Therefore, to achieve optimal performance from a HACCP system, it must be both correct (valid) and repeatable (verified).

Examples:

The efficacy of an organic acid against a specific pathogen and non-pathogenic bacteria is proven in a laboratory setting, so it has been validated to be effective under the application parameters used in the laboratory. A beef slaughter establishment identifies the specific pathogen as a hazard and decides to apply the scientifically validated organic acid spray to carcasses; however, the organic acid spray is inconsistently mixed and/or inappropriately applied to the carcasses. The organic acid spray is ineffective and the pathogen is not controlled (validated but not verified).

A different chemical compound is proven to be ineffective against a specific pathogen of concern in a laboratory setting.

A second establishment identifies the same pathogen as a hazard, and decides to use the ineffective chemical compound (not scientifically validated) on carcasses. The establishment verifies that the chemical compound can be applied at consistent concentration, temperature, and carcass coverage as outlined in the laboratory trial. However, the chemical compound is not valid, so the HACCP system is unsuccessful at controlling identified hazards (verified but not validated).

A third establishment, identifies the same pathogen of concern, selects the scientifically validated organic acid spray as an intervention, applies the organic acid at the same concentration and temperature as in the laboratory study, periodically documents full carcass coverage and that the application system delivers the organic acid spray appropriately, and assesses in-plant data following implementation of the spray that demonstrates similar reductions of non-pathogenic surrogate bacteria pre- and post-intervention as those documented in the laboratory study. This HACCP system is successful at controlling the identified hazard (validated and verified).

Both validation and verification must be achieved for the HACCP system to perform with greatest success.

Sources:

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