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Title: Validation of a Food Process

Abstract

Validation is crucial in achieving food safety objectives. Food facilities are required to implement a written food safety plan and document that their preventive controls are working and verified. The U.S. Food and Drug Administration (FDA) defines validation as "obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards." The objective of validation is to demonstrate that the critical limits established for the given control measure are able to deliver the intended hazard control. Hazards can be biological, chemical (including radiological), and physical. Understanding the science to control food safety hazards is needed to construct a successful preventive control program. Food facilities have the flexibility to customize preventive controls in their food safety plan. Significant challenges involve determining key requirements for validation including hazard analysis and risk-based preventive controls. Codex Alimentarius identified three tasks that should be performed prior to a validation study: 1) identify the hazards to be controlled, 2) identify the required food safety outcomes, and 3) identify the measures to be validated. According to FDA, validation is ideally conducted before the food safety plan is implemented, within the first 90 calendar days of production, or within a reasonable timeframe with written justification. Validation proof can come from a variety of sources. Codex Alimnetarius lists five recognized approaches to validate a control measure: 1) reference to scientific, technical literature or previous studies, 2) scientifically valid experimental data, 3) collection of data during the food operation, 4) mathematical modelling, and 5) statistically valid surveys. FDA does not recognize surveys as a method to validate a food safety plan. When such information is not available laboratory or in-plant studies can be performed to prove that a particular process is consistently delivering the desired preventive control. Laboratory studies are generally accepted as alternatives to in-facility validations. When the preventive control measures cannot be simulated in the laboratory, an in-plant study may be conducted in a processing facility. However, the introduction of pathogens into a food plant is not advised. Therefore, a surrogate microorganism may be useful in validating the efficacy of a control measure. An ideal surrogate culture should be a non-pathogenic alternative for the pathogen of concern with similar or more robust survival characteristics under the processing conditions being evaluated. Validation trials should be conducted in "worst-case" manufacturing conditions. When it is possible, temperature mapping and cold spot determination should be conducted prior to inoculated sample trials. It is essential to generate a final report, detailing methods, tests and results. A clear description of the objective, significance, outcome and justification for conclusion drawn should be provided. Validation is specific to intended process, hazard, critical limits, equipment and product being evaluated. Revalidation is needed when critical process parameters are changed. Examples include a significant change in the product, process and raw material, new scientific or regulatory information, system failure, reoccurrences of problems, new consumer handling practices, changes in the distribution system, undetermined root cause of a problem and relocation of equipment. All activities of validation from hazard analysis to data interpretation should be overseen by a qualified individual.