VALIDATING PROCESSES TO MEET FOOD SAFETY OBJECTIVES

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Abstract- The purpose of this paper is to outline the overall approaches that may be used in validating processes to meet food safety objectives. The effective control of any food process begins and ends with validation. Validation involves demonstrating that a process, when operated within specified limits, will consistently produce product meeting predetermined specifications. Validation is performed for a multitude of systems and for a variety of reasons. In the food industry validation is often performed for critical control points (CCP) in HACCP plans for processes and procedures. Additional validation activities may include validating chemical and microbiological test methods, validation of processing equipment, processing procedures, or interventions. A well executed process validation study ensures that the process will consistently achieve a food safety objective (FSO) as designed. The overall objective of process validation is to establish by scientific methods that a process is capable, reliable, and reproducible to control both the process and food safety.

Key Words – Process Control, Process Validation, Critical Control Points, HACCP.

I. INTRODUCTION

The effective control of any food process begins and ends with validation. The purpose of this paper is to provide information that meat and poultry processors can use as a basis for validating their processes to consistently meet their food safety objectives. This paper is based on a more extensive chapter on process validation that has been published [1].

The following sections include discussions of the approach to be taken in validating a production process; factors to be considered when designing validation; how to approach equipment qualification and preliminary data gathering; and examples applying this information to in-plant processes. It must be kept in mind however that process validation is absolutely process and product specific. The specific protocols and design of a validation study for an antimicrobial carcass intervention will not necessarily apply to a continuous oven or a post-pasteurization system however the basic framework and guidelines discussed herein may be applied to most any process.

Validation may be performed for a multitude of systems and for a variety of reasons. In the food industry validation is often performed for processes and procedures including but not limited to the validation of chemical and microbiological test methods, processing equipment, processing procedures, or interventions. The term "validation" is often confused with the term "verification" particularly when applied to a food safety management system such as HACCP. However, these two terms are considerably different in intent and in scope. Validation is defined by the US National Advisory Committee on Microbiological Criteria for Foods (NACMCF) [1] as the element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented will effectively control the hazards. Verification is defined as 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 is that part the verification process involving the up-front work that must be done for a process prior to its introduction into production. This involves demonstrating that a process, when operated within specified limits, will consistently produce product meeting predetermined specifications. Oftentimes these specifications include parameters to meet both food safety objectives (FSOs) for process safety as well as quality parameters.

II. DESIGNING THE VALIDATION PROCESS – INITIAL STEPS

Validation begins with correctly identifying the overall objective of the project and properly designing and planning the project. This is best achieved through a team-based approach which may include representatives from inside the company such as technical service, research and development, quality assurance, engineering, and production, as well as outside experts such as process authorities. Once the team is formed, they can begin to define the objective and scope of the project by asking questions to determine what it is they are trying to achieve. This generally begins with defining the FSO, such as, are all products in a particular batch oven reaching an internal temperature of 160^{o}F, or does a post-pasteurization process consistently result in a 3-log reduction in *Listeria monocytogenes*. The purpose of this exercise is to gain as much knowledge and understanding of the process as possible and necessary to establish what to measure, how to measure, when to measure, and where to measure, in order to capture the current process and product capability and variability. This will also help to ensure that both the equipment and process(es) are designed to consistently achieve the desired end-product specifications and to establish a written plan and protocols for measuring and testing to verify process control. For some processes such as chemical antimicrobial interventions which may be applied to fresh carcasses, cuts, and trimmings, used in product formulation, or applied to ready-to-eat product surfaces, it may also be necessary to determine the appropriate and necessary regulatory approvals before proceeding with a validation study. Oftentimes these approvals include specific requirements and restrictions for use and for labeling.

Before settling on the final design of the study it is often necessary to perform preliminary trials to capture data that will provide an intimate knowledge and a better understanding of the current or planned process and product such as potential variations in product formulation, size, shape and thickness to understand how this will affect process; how the design of the equipment will impact the product under these varying circumstances; and how and where to measure variables such as time, product temperature or pH (product center, external, thickest pieces, etc.). While there are optimum final product specifications and desired characteristics, there may be a certain level of variability to these specifications that is acceptable, within a certain tolerance, for the company and customers. Once the data is gathered and analyzed the process needs to be brought under control to minimize any inherent variability and maximize process and product consistency.

Following the completion of the preliminary objectives and trials, a written master plan should be developed outlining the procedures and tests to be conducted and the data to be collected. The plan should include a sufficient number of replicate process runs necessary to demonstrate the reproducibility of the process, and to account for as much of the process and product variability as possible. It is essential that these parameters be designed to target the worst-case scenario conditions for the product and process. For example, in evaluating the effectiveness of a cook process, this may include accounting for product parameters such as the largest pieces of product, oldest age for the meat and non-meat ingredients, the slowest cooking product formulation and/or the coldest starting temperature for raw ingredients. Identifying and testing the worst-case scenario conditions for the product and the process will provide a high degree of assurance that the process will deliver the desired level of quality and safety for all products produced in that process every time the product is manufactured [1].

The written plan should also document the performance and reliability of the equipment used to monitor and control the process, such as thermometers, pH meters, pressure sensors, flow meters, timers, vacuum, or water activity meters, belt speed controllers and recorders, and processing equipment such as ovens, water tanks, roaster, chillers, retorts, and freezers. The plan will identify how key process variables will be monitored and documented, the finished product and in-process test data to be collected as part of the validation process, and the decision points that define what constitutes acceptable test results. If measurements are taken and samples are pulled for

objective and/or subjective testing such as microbiological, chemical or physical analyses, the laboratory methods used should be published and recognized methods. If there are any questions related to the validity of the methods used, there will be questions about the results, associated data, and about the process they are intended to support.

There are some published guidance documents that can help to guide processors through the validation process. Although many of these documents were originally designed for manufacturers in the medical device and human and animal drug and biological products industry, the guidance and principles contained within these documents are applicable for food manufacturers in preparing for and carrying out process validations for any and all production processes [3, 4]. Whatever guidance a company chooses to follow, they must remember that product safety must be designed and built into the production process as end product testing has little value in verifying control.

While focusing on FSOs and protecting human health is the priority of any food safety management program [5], in the food manufacturing world, parameters to meet food safety must also be balanced with providing a quality product that is acceptable to the consumer. Additional benefits for food processors occur as the process is validated for food safety and the equipment and process become more consistent in delivering a product that meets all the specified food safety standards, the product will also be more consistent in delivering first pass product quality and may also result in reductions in product loss, rework, and the costs and waste associated with these activities. In addition, and based on the results of process validation, procedures for monitoring and controlling the process and associated process parameters are established that will ensure that the specified requirements continue to be met.

III. EQUIPMENT QUALIFICATION AND INITIAL DATA GATHERING

Process validation requires that a process is established that can consistently conform to requirements and this includes understanding, and removing or controlling, as many of the potential sources of variation as possible inherent to the process, the equipment and the product. Therefore, it is crucial to properly identify all the critical equipment features that could affect the process and end-product. This includes both the overall design of the equipment, including preventative maintenance requirements and cleanability, as well as critical in-process parameters that could affect the process and product, such as machine settings and in-process adjustment requirements. For examples, several factors need to be considered during the equipment qualification for thermal processes in order to maximize heat transfer and microbial death. Significant variations can occur depending on the load configuration, the initial temperature of the product, and product load variations. Equipment factors should also be monitored to determine the areas in a thermal process that heat the slowest, oftentimes referred to as “cold spots” in an oven, water cook tank, or across a cook belt.

While it is important to perform rigorous testing to demonstrate the effectiveness and reproducibility of the process under normal operating conditions, it is equally important to consider and account for process variability under less than optimal or “worst-case scenario” situations. The more knowledge and understanding that can be gained about the equipment and the equipment parameters and associated limitations under all processing conditions, the more operations personnel will understand how even the most subtle adjustment may ultimately affect the process and final product [1]. These insights and understanding are vital in controlling the process and assuring product quality and safety.

In order to qualify the equipment, several initial studies may be necessary to qualify equipment with and without product. While validation of the equipment without product will provide information about the operation of the equipment itself, it will not provide the necessary details relative to how that equipment functions when loaded with product, including how products of varying characteristics such as ingredients, size, shape, thickness, temperature,

will affect and be effected by the process. Initial tests of equipment without product, will also fail to demonstrate how the equipment, such as a smokehouse, will perform when it is only partially loaded with product or when filled with multiple and different types of product in the same cook batch that can significantly affect equipment operations and operating parameters such as air flow, humidity, and heat transfer [1]. Proper spacing of product is important is important for all production processes from chilling carcasses to cooking ready-to-eat products, from fermentation to drying, allowing for optimal heat transfer, air flow and/or desiccation.

IV. VALIDATING A PROCESS

During the validation process each step in the process must be carefully controlled, monitored, and recorded. For example, during the validation of a post-pasteurization process, product and equipment temperatures must be monitored before during and after treatment and the spacing of product during the process must be controlled to ensure all sides (surfaces) of the product are treated evenly. If the application process includes (uses) spray nozzles, they should be tested and verified that they are the correct nozzles, they not clogged and that the flow rate, and/or pressure and the spray pattern is correct. The temperature of the steam or hot water as it exits the nozzles and as it hits the product should also be monitored. Product overlap should be avoided so that any cold spots in the product are exposed to the hot water or steam process thereby resulting in more uniform lethality. Temperature measurements should be taken at multiple spots in the process and for all different types of products. Temperature labels or data trace probes may be placed at multiple areas on and around the product to map product exposure and track the temperatures achieved.

V. NEXT STEPS

Appropriate measures should be taken to eliminate controllable causes of variation in order to ensure that the product will consistently meet specifications. Without a well-established process control program, product quality and safety can drift. Therefore, when changes in the process or process deviations occur, the company should review and evaluate the process and perform additional validation or revalidate where appropriate. This may include changes in raw material suppliers, and product formulation, equipment changes and equipment wear and tear. The maximum variability allowed and expected in the process and in the final the product will help define the tolerances for validation. Removing major sources of variability and maintaining control of the process and associated process parameters for every batch, every day and every shift will help maintain a constant state of validation for consistent quality and product safety.

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