Validation Study Guidelines

Walmart Raw Ground Beef | Bison Initiative

Introduction

Suppliers required to submit a study to validate interventions within their process(s) must ensure the study meets our validation study guidelines. Once submitted, the validation will be reviewed internally to determine if it can be approved. Suppliers should note they are ***not*** to ship product from any facility until they have received full approval from their Walmart Food Safety Manager.

Guidance

Any supplier required to submit a study to validate interventions within their process must ensure the study submitted complies with the following guidelines:

1. **Validation Study Format**
   The study must validate the intervention(s) within the facility that will be producing the final product or raw materials (as applicable.) The study must be written in a scientific report format containing the following sections:
   a. **Introduction** – At a minimum, this section should contain the name and establishment number (or other facility identifier) where the validation study was performed along with information about the intervention(s). Where applicable, operating parameters should be provided. For example, if you are using an organic acid spray, the concentration and dwell time should be provided.
   b. **Methodology** – This section should include details regarding where and how sampling occurred within the process, i.e., how many samples were taken at each location, where the samples were collected in relation to the intervention(s), how the samples were collected, how the samples were stored or shipped for testing, and how the samples were analyzed. Units of measurement must be provided (g, mL, or cm^2) as well as a description of how the log reductions were calculated. If a surrogate was used for testing, please also include where the inoculum was sources, how it was prepared, and method of inoculation.
   c. **Raw Data** – All raw microbiological data must be provided. While not required, if you would like to attach the laboratory testing results, please ensure the data is also presented in at least one table within the document.
   d. **Conclusions** – At a minimum, this section should contain a statement indicating if the validation study conducted successfully met the Walmart initiative requirement for the facility.

2. **Additional Information**
    a. **Microbiological Organisms** – Validation studies using Aerobic Plate Count (APC) will not be accepted. All validation studies must utilize counts of bacteria capable of indicating reductions of enteric pathogens, such as Enterobacteriaceae (EB), coliforms, or *Escherichia coli*.
    b. **Low Incoming Microbial Counts** – If a facility's incoming microbial counts are not high enough to demonstrate the required log-reduction, the use of a non-pathogenic, USDA-approved surrogate is recommended. While we do not require the use of a specific surrogate, Walmart recommends sourcing from ATCC for purity and quality reasons. The recommended indicator panel is ATCC MP-26.
    c. **Who Can Conduct Studies** – Validation studies may be conducted by the supplier, the facility, or be outsourced to a third-party. Depending on resources, suppliers may choose to outsource the sampling, testing, and/or the entire process – including the writing of the final validation study report.