Kill-Step Validation for FOOD SAFETY

Most food products undergo a supposed kill step, but there is often a lack of scientific proof. Thus, there is a need for a scientific-validation procedure.

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Kill-step validation is a preemptive scientific evaluation that provides documentary 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 is a collection of evidence that a particular process involving chemical or physical inputs/parameters in a food establishment are consistently delivering a desired effect to ensure the destruction of pathogenic microorganisms often expressed as “log reduction.”

WHY DO WE NEED TO VALIDATE A KILL STEP?

Ensuring food safety is always a complex and daunting task. Although most food products undergo a supposed kill step at the point of production, there is often a lack of scientific proof. This has created an urgent, industry-wide need for developing a scientific-validation procedure that can better ensure product safety.

ADVANTAGES OF VALIDATING A KILL STEP:

• Helps achieve maximum food safety and protect consumers.
• Helps meet the safety standards (e.g., five log reduction of pathogenic E. coli/Salmonella) set by regulatory agencies.
• Helps determine effective treatment.
• Saves food industry millions of dollars by avoiding recalls and other legal penalties due to foodborne illness outbreaks.
• Helps to retain consumer confidence.
• Supports business success.

KILL-STEP VALIDATION — REQUIREMENTS

A successful validation study requires diverse expertise, detailed design, an experienced microbiologist, a statistician,
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a containment facility (e.g., Bio Safety Level (BSL) 2 or 3 laboratories) in case of a pathogen, and a keen eye for sources of process variability.

CONDUCTING KILL-STEP VALIDATION STUDIES

All kill-step validation studies involving microbes should be conducted by a qualified microbiologist. It is very critical to follow established laboratory safety practices and standard operating procedures during the study. A kill-step validation study involving a pathogen (e.g., *E. coli* O157:H7) should be conducted in certified BSL 2 or 3 laboratories depending on the type of pathogen. However, it is important to accurately reproduce the process (similar to industry) in the laboratory to achieve desired specifications (e.g., five log reduction of pathogenic *E. coli/Salmonella*).

An establishment may use an approved surrogate non-pathogenic organism to validate a kill step in its facility. Sufficient care should be taken when using surrogates in plants, as organisms can have adverse sanitary or regulatory implications, should they survive, and may contaminate the plant environment.

It is recommended that all validation experiments be conducted in triplicate. It also would be appropriate to run the three tests on different days using three different batches of ingredients or products in order to account for potential variations between production runs. Enumeration of treated and untreated samples (e.g., samples not exposed to thermal or chemical treatment) should be performed to determine the log reduction.

SELECTION OF A SURROGATE OR A PATHOGENIC BACTERIUM

The first step in a kill-step validation study is to select the right surrogate or bacterial pathogen. If you plan to use a surrogate, choose surrogate bacterium that has characteristics similar to the pathogen of concern. A surrogate of equal or greater resistance compared to the pathogen of concern can be used, provided a scientifically reliable correlation has been established for comparison. It is more practical and convenient to choose a surrogate of equal or greater resistance compared to a pathogen of concern (e.g., *Salmonella*) for validation studies, due to ease of enumeration, and for determining the proper treatment options to achieve food safety. The microbiologist working with you on the project can help identify the appropriate surrogates. If you plan to use a cocktail (two or more pathogenic or surrogate strains together), then antagonistic effects needs to be tested for before using.

WORST-CASE SCENARIO

A kill-step validation experiment should be designed and tested for “worst-case conditions” such as lowest oven temperature, fastest belt speed, lowest zone temperature, coldest spot possible, shortest time exposed, maximum load per batch, lowest concentration (e.g., during chemical inhibition), lowest and highest relative humidity, lowest moisture content, highest fat content, etc.

D VALUE. The time required at a certain temperature to kill 90% of specific bacterial populations or reduce the bacterial load by one log under specified conditions.

Z VALUE. The change in the temperature, in degrees Fahrenheit (F) or Celsius (C), required to reduce the specific bacterial load by a factor of 10 or by one log.

THERMAL DEATH TIME (TDT). The shortest time needed to kill all bacteria or microorganisms in a product at a specific temperature and under defined conditions.
TIME/TEMPERATURE RELATIONSHIP AND MICROBIAL KINETICS

Time and temperature values are critical for achieving desired log kill (e.g., five log reduction). The temperature and time should be recorded throughout the entire run using calibrated thermocouples and should be reviewed for consistency across the runs. The effective use of mathematical modeling is very important in a process validation. Determining microbial kinetics such as D-value, Z-value, and TDT (Thermal Death Time) is very important to knowing the thermal resistance of a bacterium in a particular food product. Microbial kinetics will help determine the shortest as well as proper treatment options. D and Z values will allow adjustment of the time and temperature, thus optimizing the process.

AUDITING A KILL-STEP VALIDATION STUDY

Kill-step validated processes should be audited yearly or as directed by a HACCP reassessment by a qualified microbiologist or an expert to ensure that a particular process is consistently delivering a desired effect. Further, for any major change in the process parameters or ingredients, or for a new pathogen, a process should be validated after a thorough literature review.

A VALIDATION REPORT

Once the validation study is completed, it is important to compile all the data, analyze it, and prepare a validation report which may be requested by stakeholders, clients, or regulatory authorities. The validation report should include sections such as introduction, contact information, background information, general information of the produce, parameters studied, details of equipment (type & make) used, validation methodology, TDT, Z-value, D-value, microbial strains used in this study, results, date of experiment, detailed discussion, significance, etc.

SUMMARY

Despite improvements in production, handling, and distribution of food products in recent years, protecting consumers from foodborne illness still remains a challenge. Therefore, scientific validation of a process that is intended to deliver some degree of lethality is important to achieve food safety. The success of any validation study depends on an effective HACCP plan, solid GMPs, sanitation program, employee hygiene practices, pest control program, and good hygiene post-process handling procedures. It is important to conduct process validation after ensuring these controls are established in a facility. AIB

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Many foodborne illness outbreaks result from lack of food safety knowledge, lack of testing and monitoring, poor hygiene practices, and lack of kill step validation. Concerns about microbial issues in the food industry continue to become more challenging from a scientific and a regulatory standpoint. The Food Safety Modernization Act includes microbiological requirements related to hazard analysis, product testing, water testing, and environmental monitoring.

AIB International provides customized services to help our clients in their commitment to produce the safest food possible in every step of manufacturing. Our microbiological food safety consulting services are tailored to the specific needs of our customers.

To schedule food safety microbiology consultation or training at your facility, contact AIB’s Food Safety Education Department at 800-633-5137 or foodsafetyeducation@aibonline.org.