

Ensuring food safety through validation of control measures

Challenge tests are experimental approaches that provide a solid scientific foundation for making food safety decisions. Incorporating them as validation procedures within the food safety management system helps minimize risks, ensure legal compliance, and protect public health.

The food safety management framework provides food business operators with flexibility regarding the selection and application of control measures (e.g. thermal treatments, high-pressure processing, acidification, drying, or shelf-life).

For this reason, validation becomes highly important, as it is through validation that it is demonstrated that the applied control measures are capable — if correctly implemented — of controlling the relevant microbiological hazards



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Main reference documents:

¹*EUROLm TECHNICAL GUIDANCE DOCUMENT on challenge tests and durability studies for assessing shelf-life of ready-to-eat foods related to *Listeria monocytogenes* (version 4, 2021)*

²*ISO 20976. Microbiology of the food chain — Requirements and guidelines for conducting challenge tests of food and feed products (part 1 and 2)*



Challenge Testing for the Validation of Control Measures in the Food Industry

Activitat de Demostració de transferència de coneixements

Actuació del Pla estratègic de la PAC 2023-2027 cofinançada per:



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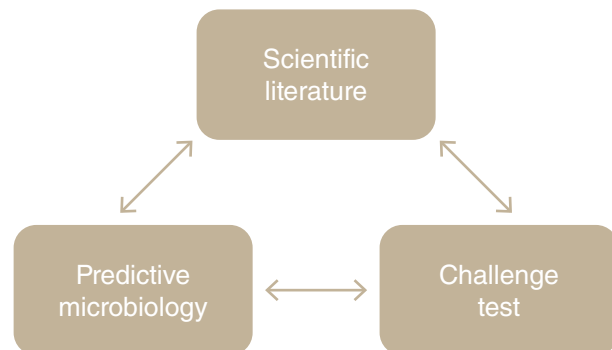
Validation

Obtaining evidence that demonstrates a control measure is capable of controlling a hazard to the extent required according to the reference standard.

For example:

- 1 Demonstrating that a high pressure processing treatment achieves a lethality against *Salmonella* of at least 6 log units.
- 2 Demonstrating that the levels of *Listeria monocytogenes* in a ready-to-eat food will not exceed 100 CFU/g during its shelf life.

Validation procedures



Challenge test

Experimental assay in which a food product is deliberately contaminated with a relevant pathogen in order to study and quantify its behavior under controlled processing or storage conditions.

Applications

Validation of lethality treatments (cooking, high-pressure processing, etc.).

Determining whether a product can support the growth of *Listeria monocytogenes* (categorization according to Regulation (EC) 2073/2005).

Establishing safe shelf-life and documenting compliance with microbiological criteria for ready-to-eat foods.

Assessing the impact of changes in processing, formulation or storage, including packaging.

Key points

Characterize the product and process beforehand (understand variability).

Perform assays in biocontained facilities and properly trained personnel.

Apply an inoculum method representative of real contamination conditions that does not modify the product.

Use qualified surrogate microorganisms (non-pathogenic) for in-plant validations.

Processing conditions, product characteristics (e.g. pH, water activity), and storage temperature during shelf-life must reflect reasonably foreseeable conservative scenarios.

Consider variability and, if necessary, accompanying microbiota or other factors relevant in the food.

Interpret and exploit results considering the scope, applicability, and possible limitations of the study.