

## Challenge Testing of Microbiological Safety of Raw Milk Cheeses: The Challenge Trial Toolkit

New Zealand cheese makers are permitted to produce cheeses from raw milk in cases when they can demonstrate the manufacturing process can reliably deliver products that comply with the appropriate microbiological criteria, and when manufacture is undertaken in accordance with an approved Risk Management Programme.

One method for “validating a process” (i.e. demonstrating that a manufacturing process can, with appropriate controls, deliver food that complies with the microbiological criteria), is to undertake challenge trials. Challenge trials are often considered the “gold standard” for determining the fate of pathogens in food however they can only yield useful information if conducted appropriately. Many factors must be taken into consideration to ensure challenge trials are appropriate to validate a given process.

This report presents detailed information about the conduct of challenge trials to assess the microbiological safety of raw milk cheeses made in New Zealand, along with explanation for those recommended procedures and strategies. Given the complexity of design and interpretation of challenge trials relevant to raw milk cheeses, two example challenge trial protocols are included as an appendix to the report.

The report provides useful guide to industry and researchers wishing to undertake challenge trials for process validation or to support model development. It will also assist risk managers and verifiers to determine whether a challenge trial undertaken to validate a process is rigorous enough to be accepted as evidence for assurance of the safety of the raw milk cheese process and product.

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