

Validation in the dairy manufacturing sector

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validation
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Content

- Overview
- Definitions – validate or verify
- Why validate?
- Validation considerations
- Validation tools
- Examples of validation
- Conclusions



Definitions



CODEX ALIMENTARIUS

- CODEX CAC/GL 69-2008:

Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome

- Types of validation:
 - process validation
 - shelf-life validation
 - allergen cleaning validation

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Avoid confusion



- **Validation** – Obtaining evidence that the control measures managed by the food safety program and pre-requisite programs (PRPs) are capable of being effective

Involves conducting assessments prior to commencing operations

- **Verification** – includes record review, audits of the system, and periodic review to demonstrate compliance with the food safety program

Always verify

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Trust
(but verify)

Why validate?

- Dairy manufacturers need to demonstrate their controls are effective in preventing, eliminating, or reducing food safety hazards and risks
- **Importantly** – regulatory agencies, certification bodies, and customers expect that you have validated your controls



What's in it for the dairy manufacturer?



- The driver for validation should be the manufacturer's commitment to prepare and market a safe dairy food



What is a safe dairy food?

- Your food safety program identifies potential hazards and identifies how you propose controlling them
- Guidance
 - Microbiological limits in the Food Standards Code (Standard 1.6.1, Schedule 27)
e.g. limit for *Salmonella* spp. in powdered infant formula
 - Control point: pasteurisation of raw milk, cleaning and sanitation procedures

Validation considerations



- What are my hazards? How will I manage them?
- Will my product meet the requirements of the Food Standards Code
- Will my process or other controls effectively manage identified hazards? Such as:
 - prevent growth of *Listeria monocytogenes*
 - achieve a specific shelf-life
 - achieve a 5 log reduction in pathogens
 - provide a 12D reduction in *Clostridium botulinum*
 - prevent cross-contamination with allergens



Do I need to validate?



Pasteurisation

- Temperature and time for HTST pasteurisation is well defined
Parameters are specified in the Food Standards Code and technical notes
- Validate – NO
- Verify – YES

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Do I need to validate?



New product formulation

- Yoghurt-based dip – is there a risk that *Clostridium botulinum* may grow during storage?

Product has a pH 4.2 – literature confirms the organism will not grow below pH 4.5

- Validate – NO
- Verify – YES

Do I need to validate?



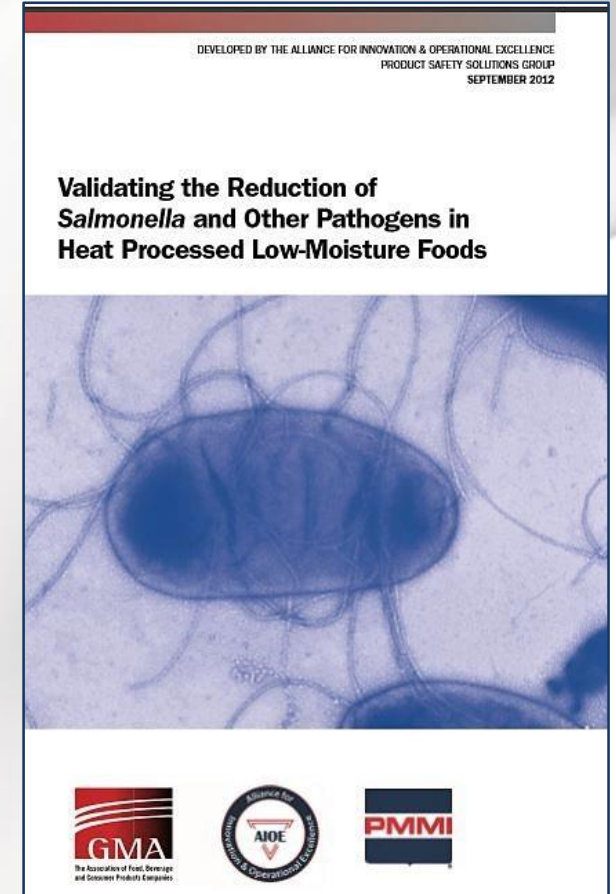
Metal detector

- Installed by manufacturer to detect metal fragments in 100 gram packages of shredded cheese

Factory upgrade means the detector will now be used to screen 1.5 kg blocks of packaged cheddar cheese
- Validate – YES
- Verify – YES

Validation tools

- Historically established and recognized control measures e.g. pasteurisation
- Published guidance documents
 - Developed by industry and/or regulators
 - International standards and Codex publications
 - Scientific literature – peer reviewed journals, ICMSF
- Scientifically valid technical data (in-house)
 - Influenced by experimental design, competence of individuals, and data collection/laboratory capability

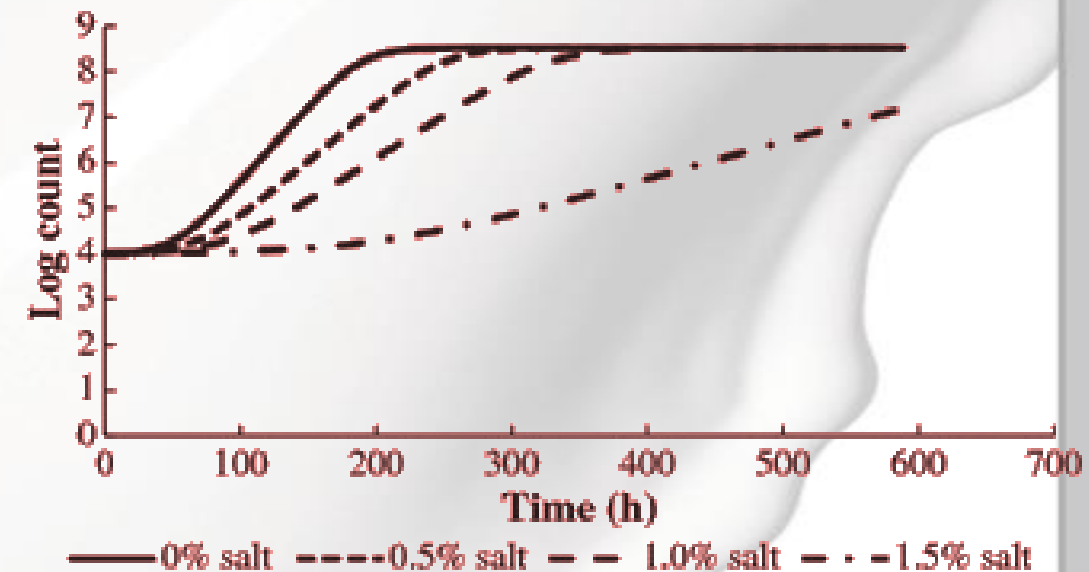


Validation tools

[continued]



- Microbiological modeling – using predictive models, Combase, pathogen modelling program (PMP), etc
 - Models describe growth, survival, or inactivation of organisms in a food
 - Require data: pH, water activity, temperature, redox potential, etc
 - **Caution:** are they valid for the food being evaluated
 - **Caution:** be conservative with the outputs

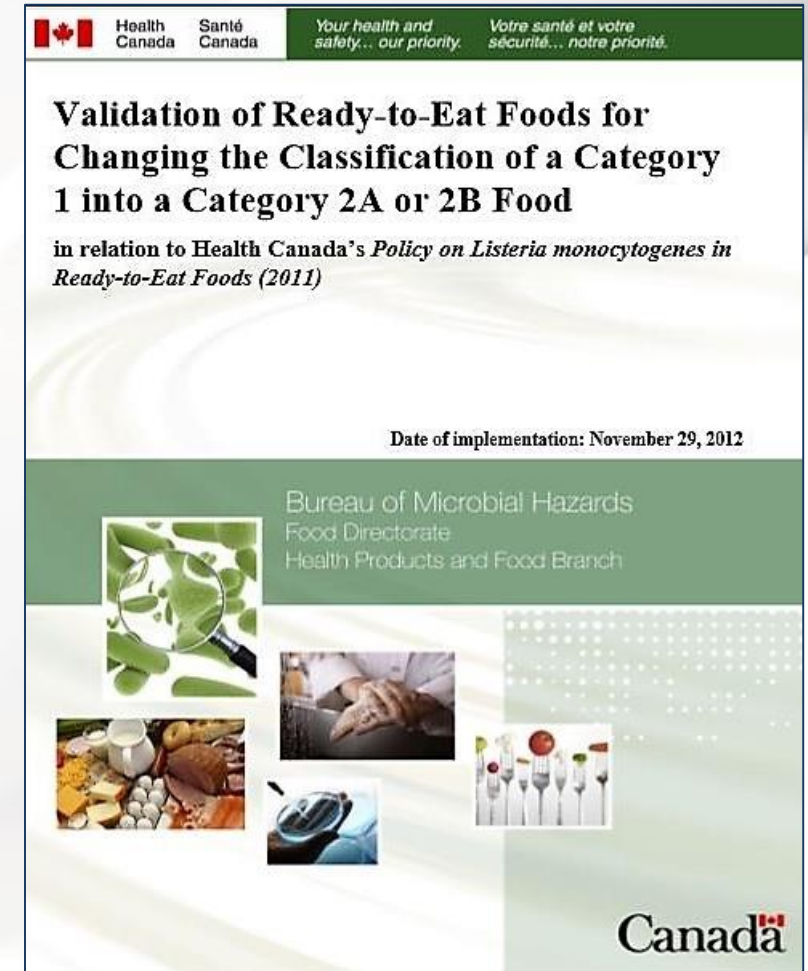


Validation tools

[continued]



- Challenge studies – laboratory trials that generate new experimental data on the growth or survival of pathogenic organisms
 - Important to follow recognised protocols
 - Be conservative
 - Selection of surrogates is critical
 - Goal – e.g. 5 log reduction in pathogens, no net increase in numbers
 - Requires significant resources and is expensive



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Steps in validation of a process



Pre-validation

- Identify the hazards to be controlled and determine the most resistant pathogen (most likely to survive process)
- Identify the outcome required (level of inactivation to achieve acceptable level of hazard)
- Identify the measures that need to be validated (process and product criteria)

Validation

- Decide on the approach
- Define critical limits that need to be met during processing
- Define the specific equipment and operating parameters for the proposed process
- Assemble relevant validation information and conduct studies where needed
- Analyse the results
- Document the validation

Getting started: get advice



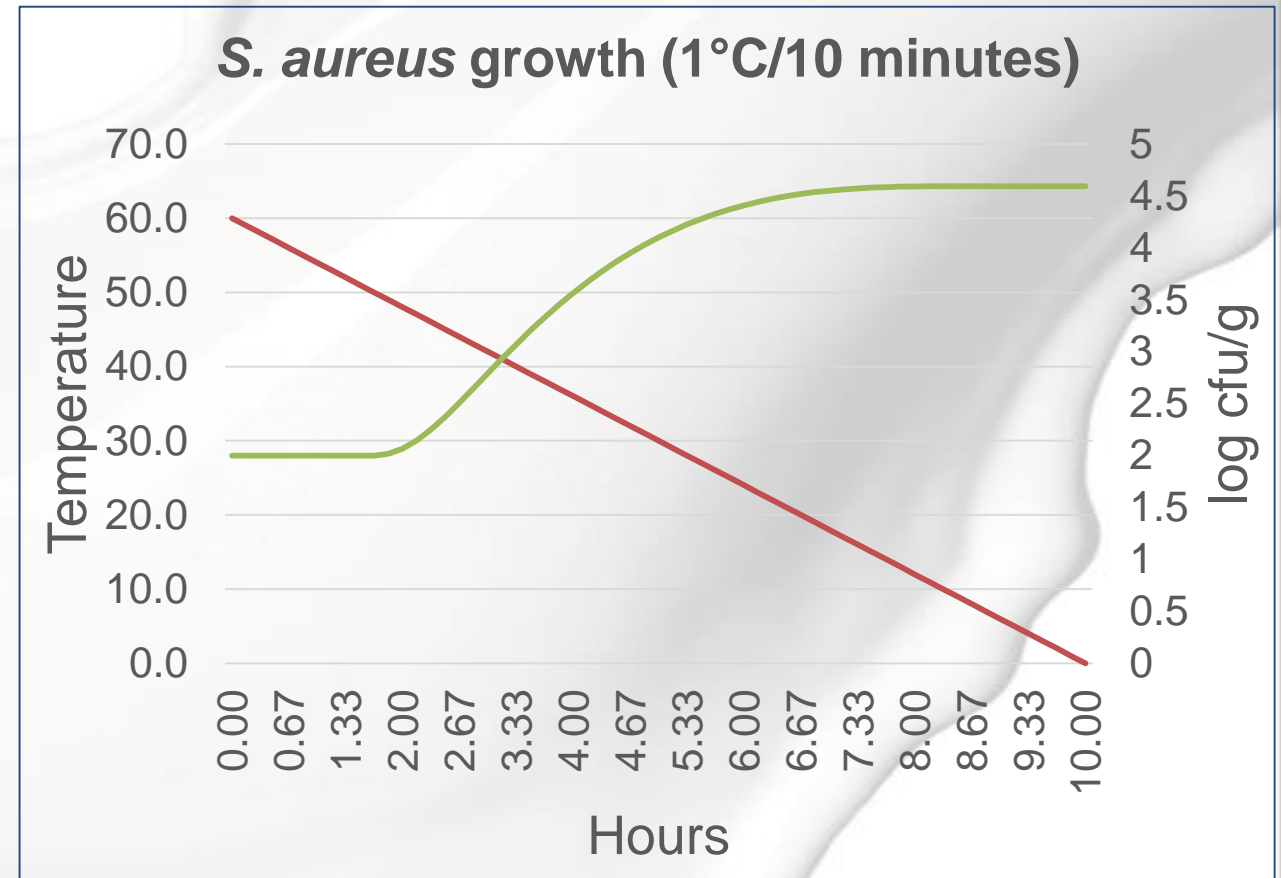
- It is difficult to design the perfect study that validates a process, or challenges the safety of a dairy product:
 - Seek guidance, advice, and suggestions
 - Design is critical – identify study weaknesses/limitations
 - Determine if there are easier ways to do it
 - It may already have been done
- Get good people involved: qualified, experienced, and capable
- Contact your dairy regulator – sit down with the regulator and outline what you are proposing



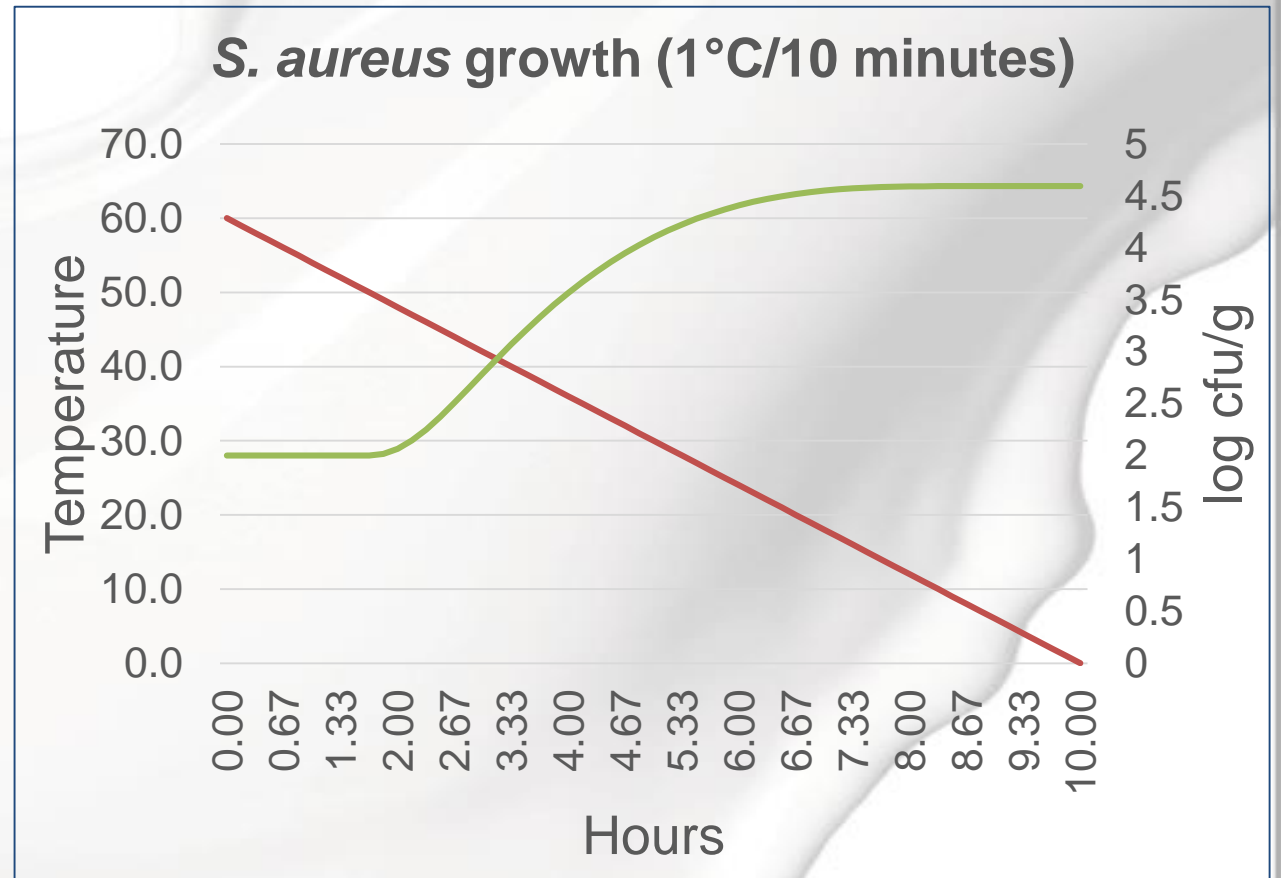
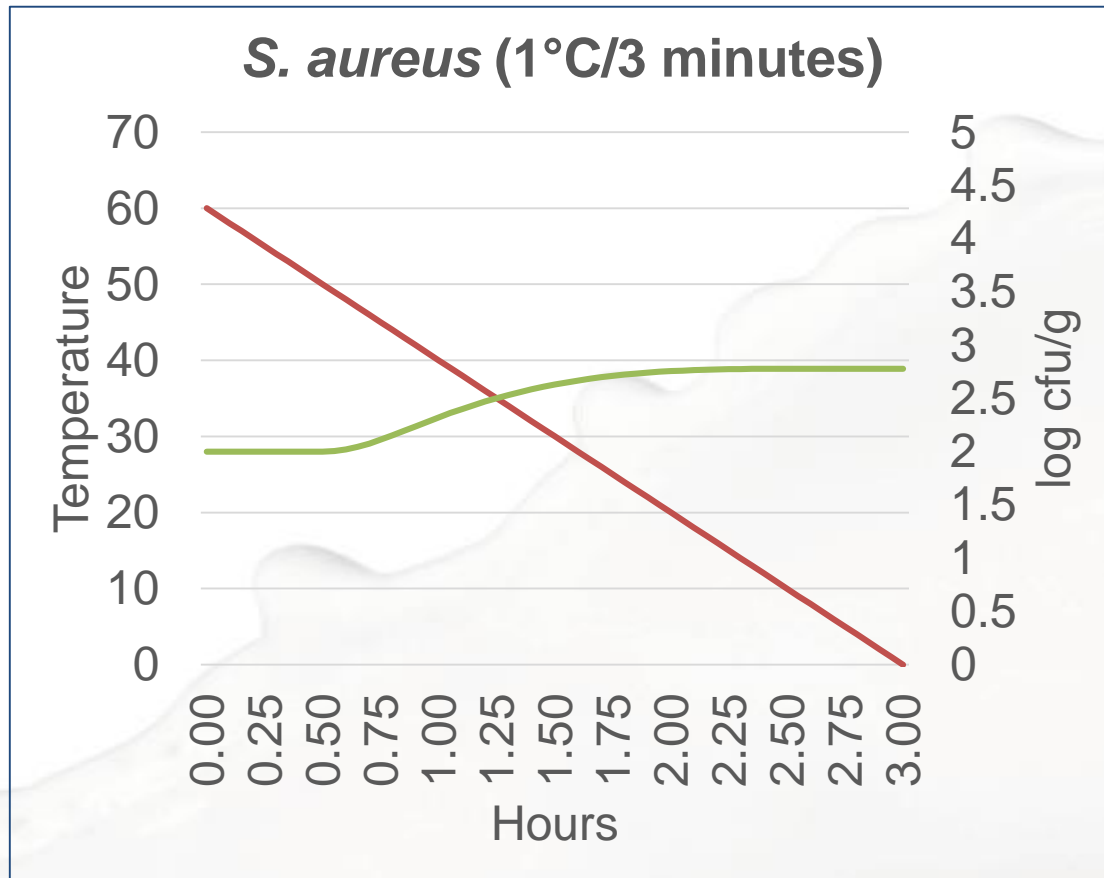
Case study: Cooling ricotta cheese



- Issue: Manufacturers must ensure that refrigerators have the capacity to cool foods promptly
- Hazard: *Staphylococcus aureus*
- Risk: will it grow during cooling
- Approach:
 - Thermocouples placed in cheese during cooling phase
 - Use modelling program to plot temperatures against growth of the organism
 - Initial level 100 cfu/gram



Case study: Cooling ricotta cheese

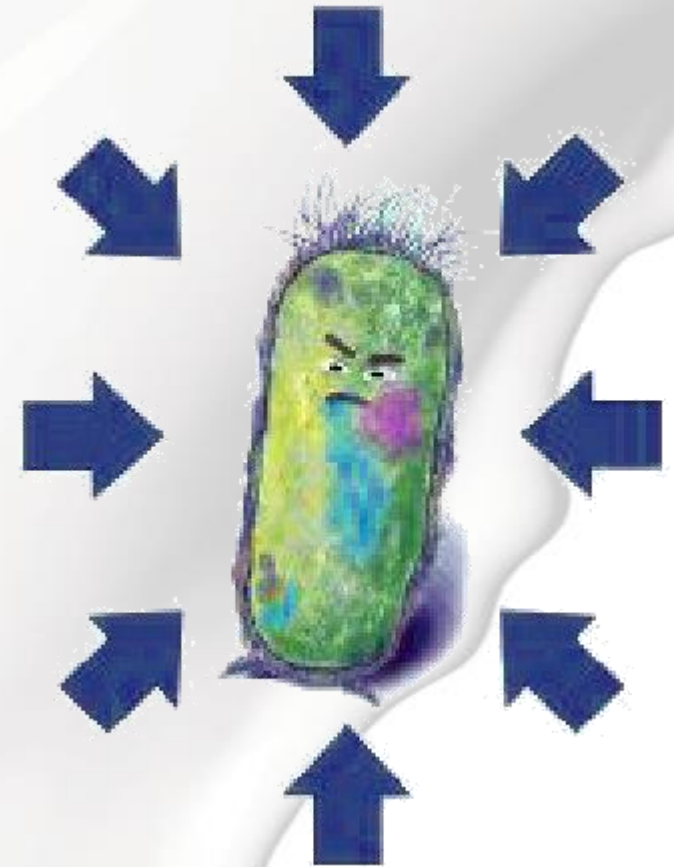


Findings: Prolonged cooling (10 hours) results in excessive growth of *S. aureus*. Need to ensure product reaches >5°C in less than 3 hours

Case study: High pressure processing of milk



- Proposal to use HPP as an alternative to pasteurisation for producing high-quality, long shelf-life, whole milk product
- High pressures reduce bacterial levels
- Is it sufficiently lethal to all potentially harmful bacterial?
- What does the Food Standards Code require?



Food Standards Code – Chapter 4.2.4



15 Processing of milk and dairy products

- (1) Milk must be pasteurised by –
- (a) heating to a temperature of no less than 72°C and retaining at such temperature for no less than 15 seconds; or
 - (b) heating, using any other time and temperature combination of equivalent or greater lethal effect on any pathogenic microorganisms in the milk; or
 - (c) **using any other process that provides an equivalent or greater lethal effect on any pathogenic microorganisms**

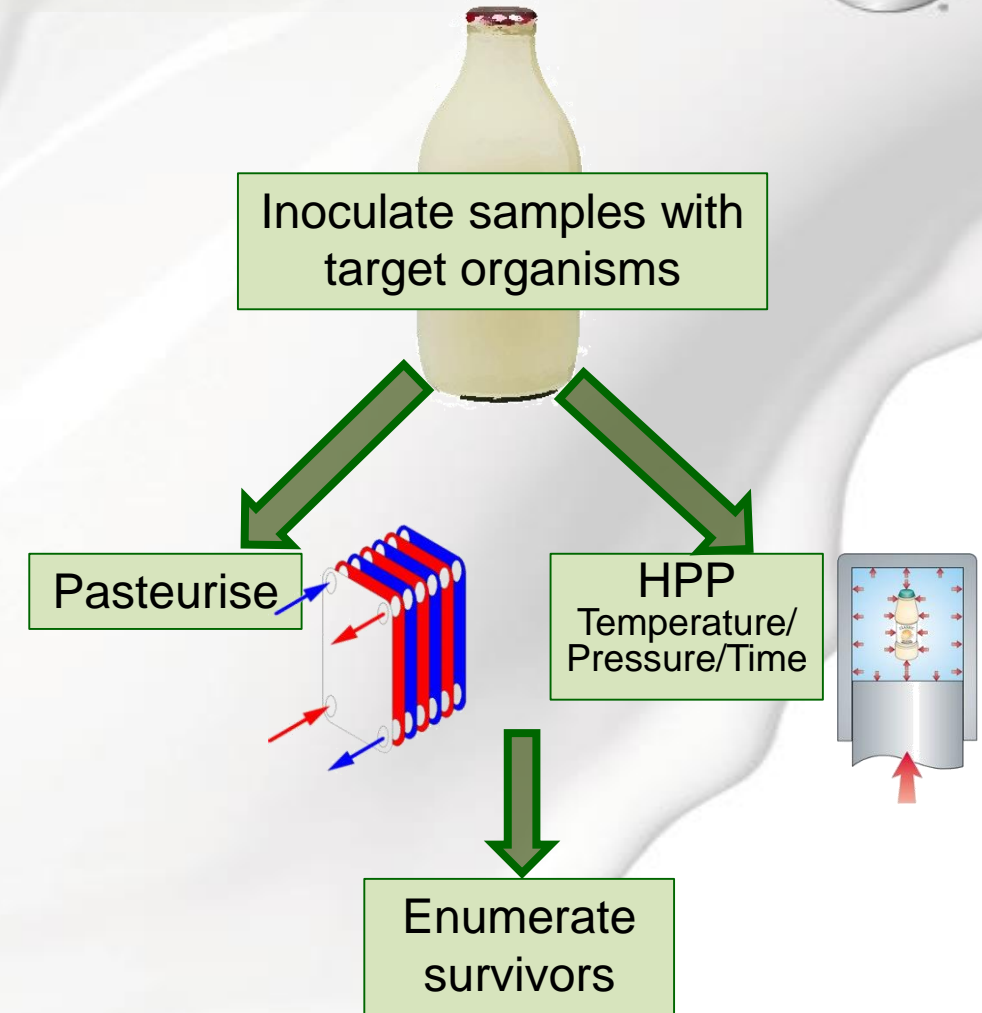


Editorial note:

For paragraph 15 (1) (c), any other process used would need to be **validated by the business** and verified by the Authority

Validating high pressure processing

- Demonstrate equivalence
- Identify target organisms:
 - Pathogenic *Escherichia coli*
 - *Salmonella* spp.
 - *Listeria monocytogenes*
 - *Staphylococcus aureus*
 - Sporeformers
- Add relevant cultures to milk and run lethality trials
- Goal: equivalent or greater lethality



Challenge studies: selection of organisms



- How many strains of each organism?
 - Three or five
 - Characteristics: isolated from the commodity, specific traits, identified outbreaks strains
- How do you inoculate and when?
- How many replicates?
- What lethality – 5 log destruction?
- Intrinsic properties of the food: pH, water activity, redox potential, salt concentration, etc



Allergen cleaning validation



VALIDATION

- Look at the process flow diagram:
 - Check that all equipment is listed
- Describe how it is cleaned
- Identify multiple sampling sites
- Swap to confirm the documented allergen cleaning program at allergen change-over is effective:
 - Effectiveness of CIP or manual cleaning can vary and various factors need to be considered



VERIFICATION

- Inspect difficult to clean parts
- Routinely sample visually clean parts to ensure they don't have residues of allergens

Conclusions

- Validation is an essential part of understanding your food control system and its limitations
- Food regulatory agencies, as well as certification bodies and customers seek certainty – validation provides assurances
- Some hazard control measures may need to be validated when developing your food safety program
- The design, execution, and interpretation of validation studies must be performed correctly
- *Once you have validated a process or practise, what will be your monitoring and verification strategy?*



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