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How to validate in a variable world: Use Data, Lots of Data, Both from Experiments and Literature

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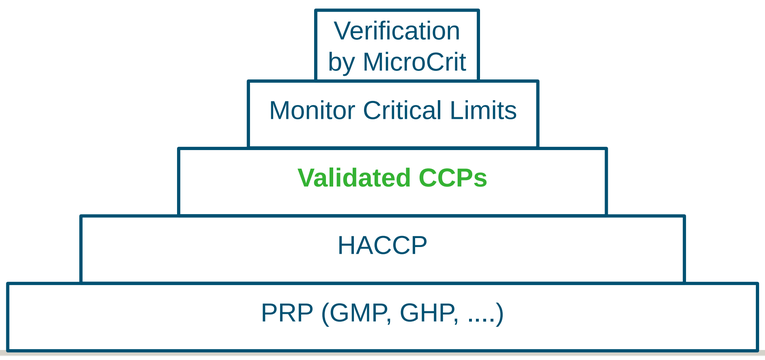
Introduction and Objective

- We want to be absolutely sure when we control food safety !
- But absolute does not exist
- Food products, microorganisms, and humans are biological entities
- Variability is inherent in biology
- Also technical parameters show variability .....

This all together gives complexity ..... and difficult decisions.

Food Safety Management

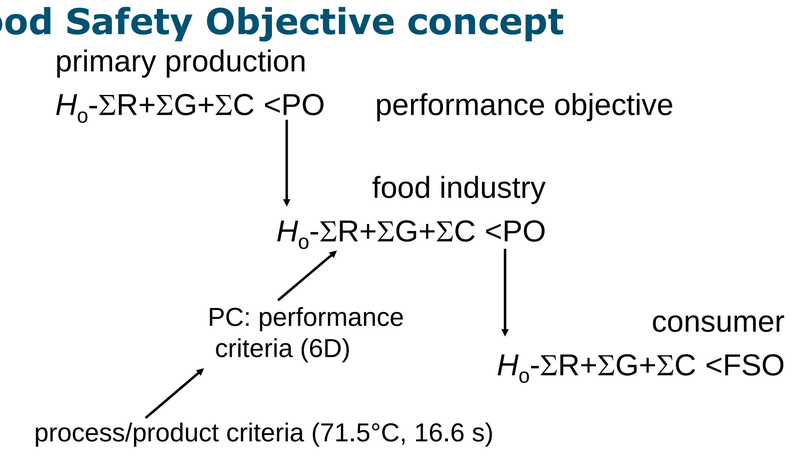
Validation is an important aspect of Food Safety Management:



Definitions

- **Monitoring:** a planned sequence of observations of control parameters to assess whether a control measure is under control: e.g. 72°C, 15 s
- **Verification:** The application of procedures and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended (e.g. using microbiological criteria)
- **Validation:** Obtaining evidence that a control measure, if properly implemented, is capable of controlling the hazard to a specified outcome

The Food Safety Objective concept



The FSO concept forces to quantify and to set performance objectives over the whole chain. It also forces to include the variability of all factors: initial contamination (H_0), growth (G), inactivation (R) and (re)-contamination (C). So many data are needed.

Experimental data on strain variation: HUGE !

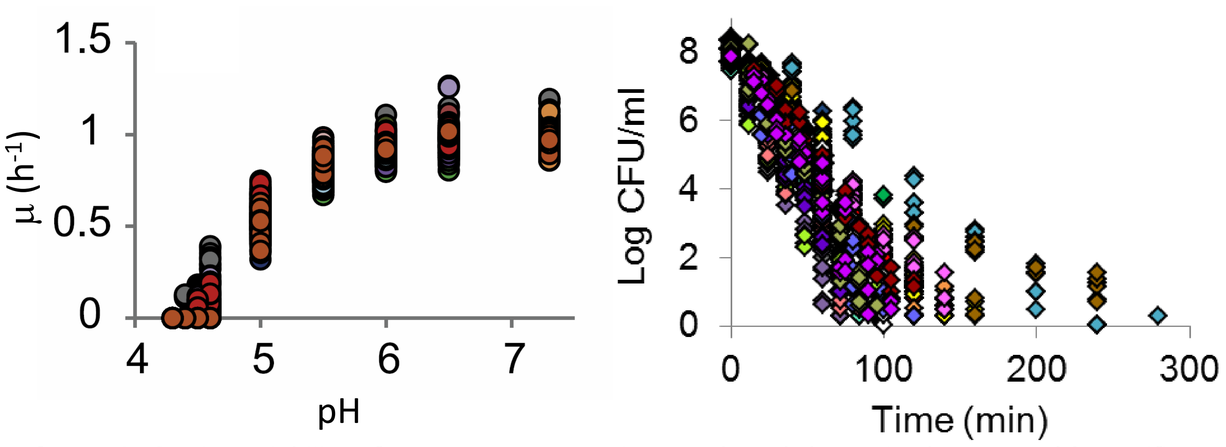


Figure 1. Strain variability of *L. monocytogenes* in growth and thermal robustness. (I) specific growth of 20 strains as function of pH; (II) thermal inactivation of 20 strains at 65°C.

Meta-analysis: MANY DATA !

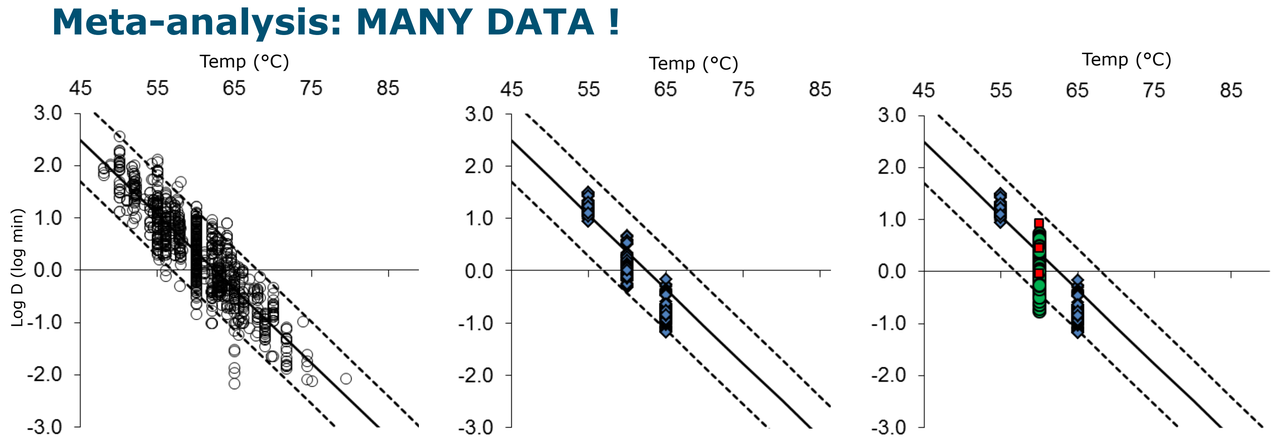


Figure 2. Benchmarking of *D*-values of *L. monocytogenes* (I) data from various food products compiled from literature; (II) variability of 20 strains; (III) strain variability and effect of history (preculturing).

Effect of variability on a chain analysis: NIGHT AND DAY

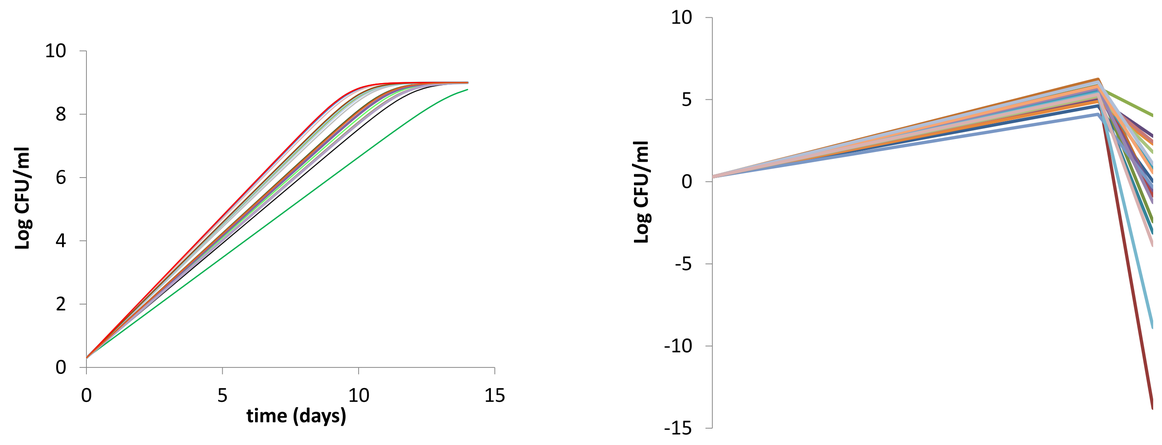


Figure 3. Effect of strain variability of *L. monocytogenes* on (I) growth (7°C, pH 6.6, a_w 0.993); and (II) on growth (7°C, 7 days) followed by an inactivation treatment (65°C, 1 min).

Many Data Sources

Data sources: literature data; databases; experimental data; storage tests; challenge tests; predictive models; safe harbours; basic knowledge; logic ..... and criticism !
The all have their weak and their strong points, the strength lies in the combination of these sources

But then..... Setting limits

What if we use the 95 percentile, or the 99th ?

In a batch with 100.000 product units ?
With 10.000 batches produced per year ?
But to have 5 factors all at their 99th percentile it is just 1 out of 10.000.000.000.....

But only if these 5 are equally important; when one factor is the main determinant, then it is still 1 out of 100 !
What is fail safe ???

Conclusions

- All variabilities are equal but some are more equal than others
- Making discrete decisions in a variable world is not at all easy
- To do so, many data are needed, but also the bird's eye view.

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