Application of QMRA to go beyond safe harbors in thermal processes. Part 2: quantification and examples

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Re-visiting safe harbor processes in the new safety management context

ICMSF's conceptual equation[1]

ALOP/TLR

$$H_0 - \Sigma R + \Sigma I \leq PO \text{ or } FSO$$

Raw material contamination (prevalence & level)

Reduction (inactivation)

Increase (Growth, Recontamination)

Level at step x in the food chain (e.g. after packaging)

Level at point of consumption

Management options
- Control of H_0
- Product formulation
- Aseptic filling/ environmental control
- Injury

Σ = sum of events	PO: Performance Objective	FS0: Food Safety Objective

[1]Microbiological testing in Food Safety Management, ICMSF (2002); Book 7

Ex. 1: 4.4 log reduction of *E. coli* O157:H7 in frozen beef patties (ICMSF, 2002)



- *Hazard identification*: EHEC/cattle
- *Hazard characterization*: moderate to severe disease (HUS)/ deaths, with a relatively low infective dose (<100 cells) => FSO $\leq$ -2.4 ($\leq$ 1cfu/250 g)
- *Exposure assessment*: carcass surface contamination & decontamination, no increase under controlled chilling/fabrication operations => $\Sigma I=0$

  small proportion: high prevalence and concentration (1-10 g^{-1}) => $H_0 = 2$
- **$\Sigma R \geq H_0+\Sigma I-FSO = 2+0+2.4=4.4$**

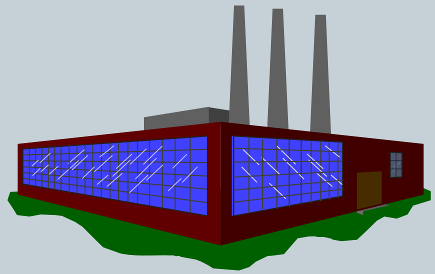
Ex. 2: 5 log reduction of *L. monocytogenes* in shrimp (Walls 2005)

- *Hazard identification*: *L. monocytogenes/* shrimp
- *Hazard characterization*: listeriosis
- *Exposure assessment*:
  mostly < 100 cfu g^{-1} => $H_0 = 2$

  $\Sigma I=0$

  no detectable cells per serving of 100 g => FSO ≤ -2
- **$\Sigma R \geq H_0 + \Sigma I - FSO = 2+0+2=4$**
- Added safety margin of 1 log: **$\Sigma R \geq 5$**
- Further recommendations: Shrimp are sorted by size, and the plant has determined the minimum time at the target temperature for the largest shrimp processed in any batch.

Ex. 3: *Salmonella* in pasteurized frozen foods (Membré et al. 2007)

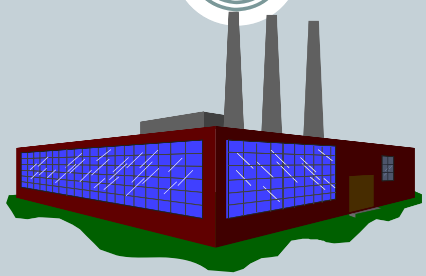


Raw Material → Chilled conditions → Pasteurisation step → Frozen product

No recontamination after HT no re-heating step by consumer

- Safe Harbor: UK ACMSF : **70°C / 2min** gives 6D reductions of *E. coli* 0157:H7, *Salmonella spp*. and *L. monocytogenes*
- Can we safely reduce this heat treatment?

Deterministic method



Raw Material → Chilled conditions

Pasteurisation step → Frozen product

$1\text{x}10^{3.2}$ cfu/g

1,500 cfu/g

$\Sigma R=4.6$

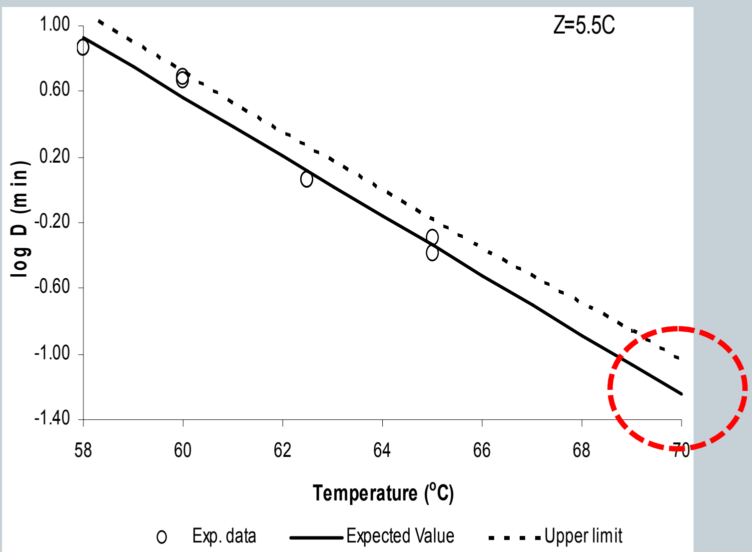
$1\text{x}10^{-1.4}$ cfu/g

0.04 cfu/g

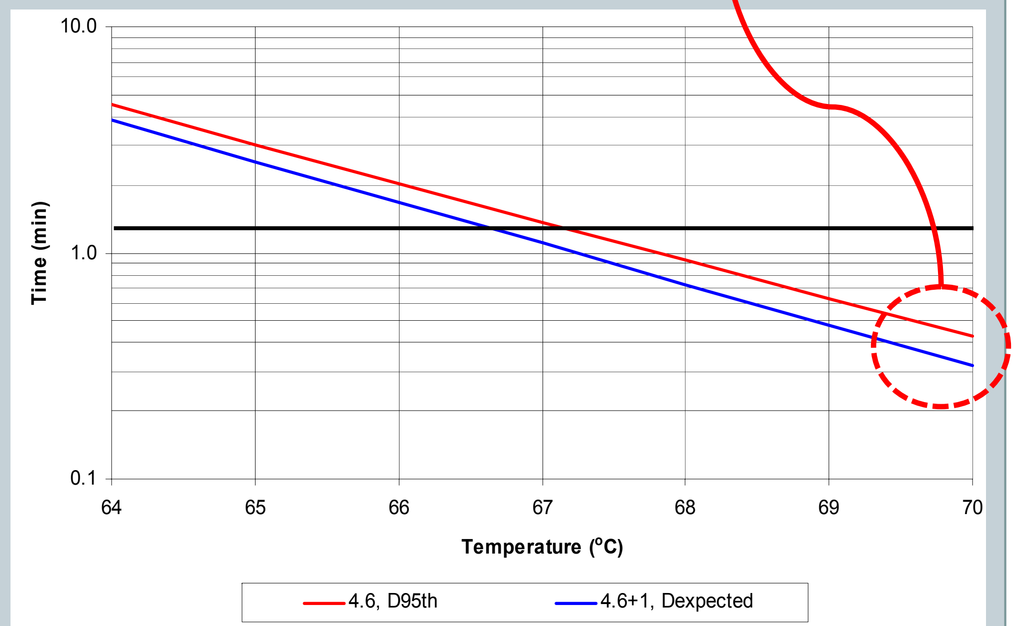
Deterministic method

- $\Sigma R = 4.6 = PC$
- **Heat treatment duration HTT**
  - Option 1: $HTT = PC \cdot D_{95th}$
  - Option 2: $HTT = (PC+1) \cdot D_{expected}$

From 2 min to 0.3 - 0.4 min

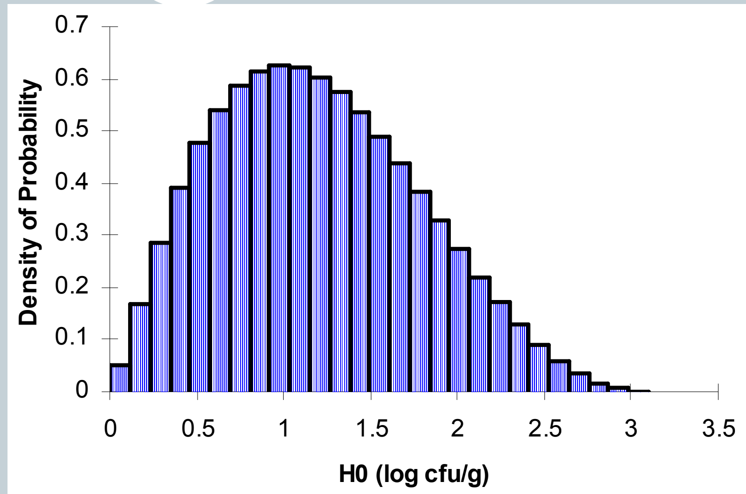


Data from Juneja et al. (2001)

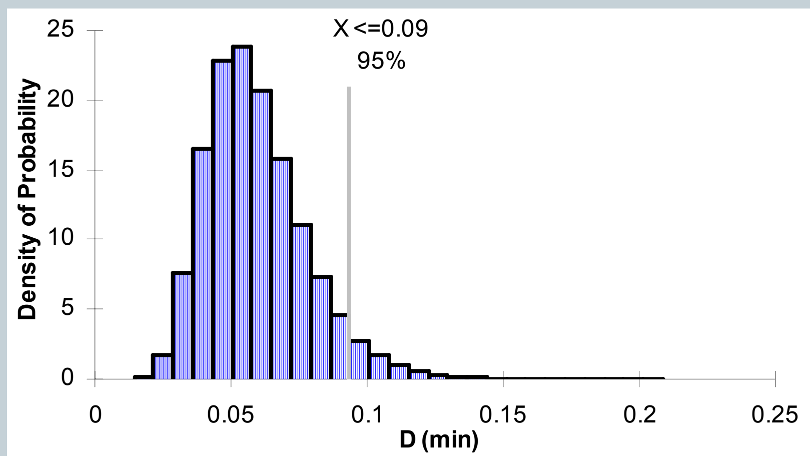


Probabilistic method

- H0: Pert (0,1,3.18)



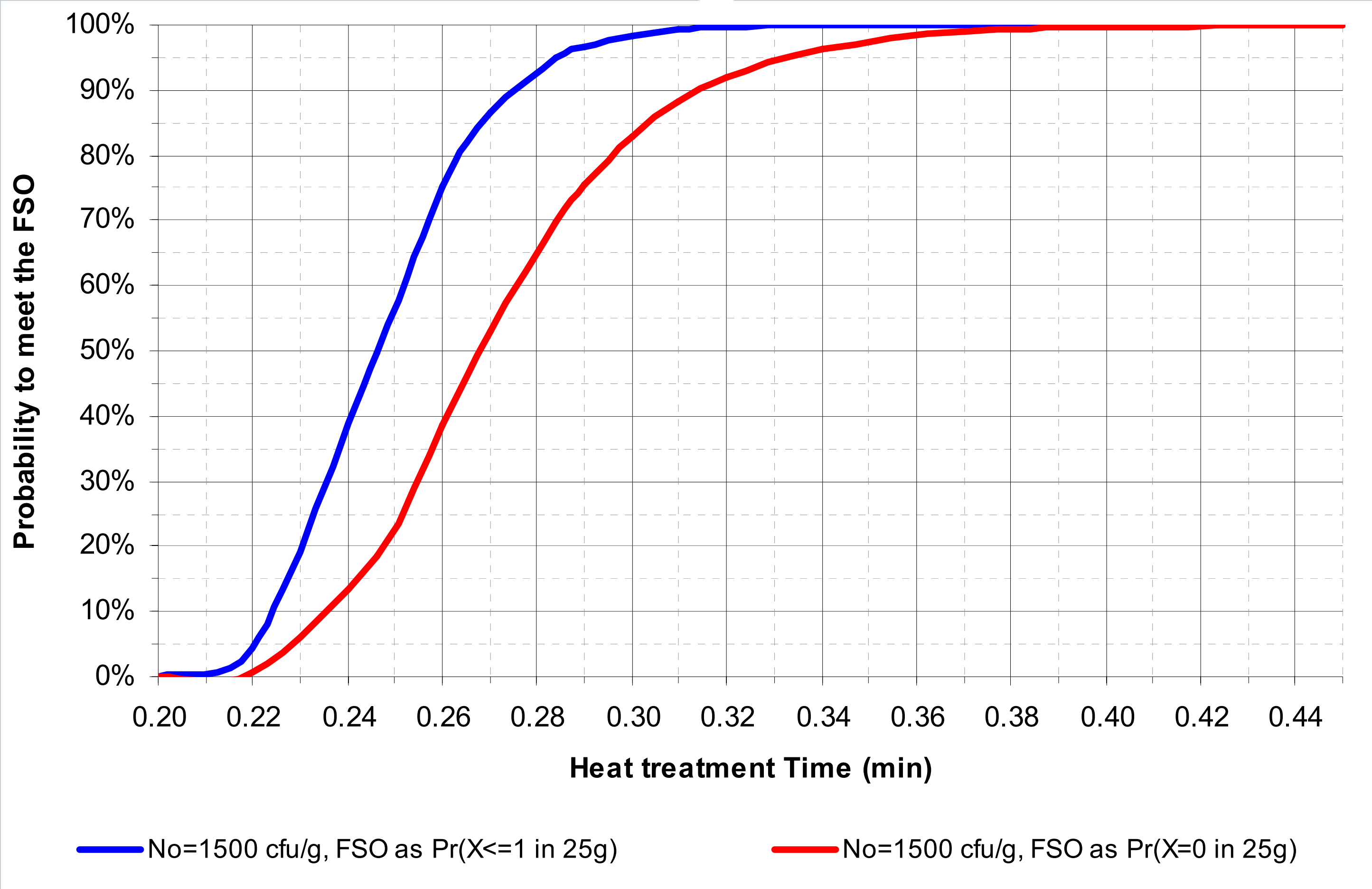
- D-values



Probabilistic method

- $N = N0.10^{-time/D}$
- p = probability for one cell to survive the treatment in 25 g portions = $10^{-time/D}$
- or time = -log(p). D with
  - N ~Binomial(N0,p)
  - p ~Beta(1+N_{target} ,1+N0-N_{target})
- HTT= 95th percentile of (-log(p). D)
- FSO can be either 0 or 1 cell per portion
  - p ~Beta(1+FSO ,1+N0-FSO)
- HTT = 0.30 or 0.26 min

Assessing the probability of meeting the FSO



Quantification of the log reduction obtainable during thermal processing

Micro-organism	**T_{ref} [°C]**	**z [°C] mean (range)**	**Log(D_{ref}) range**	**D_{ref} [min] range**	**Reference**
sporeformer	121.1	10 (7 to 12)	-2 to 0.69	0.01 to 5	Holdsworth, 2004
vegetative cells	70	5 (4 to 7)	-1.52 to 1.04	0.03 to 11	Mossel, 1995

Micro-organism	**T_{ref} [°C]**	**z [°C]**	**Log(D_{ref}) mean (95% prediction interval)**	**D_{ref} mean (95% prediction interval)**	**Reference**
C. botulinum (ABF)	120	10.2	-0.78 (-1.24 to -0.32)	0.17 (0.058 to 0.48)	Van Asselt and Zwietering, 2006
L. monocytogenes	70	7	-1.06 (-1.84 to -0.28)	0.087 (0.014 to 0.52)	Van Asselt and Zwietering, 2006

Guidelines for prediction purposes
Level I - a safe harbor approach

- Assuming the approximation of a realistic time-temperature profile with static intervals
- Basic model approach with general parameter values, e.g., consensus safe harbor of a *D*-value not exceeding 0.25 min at 72°C for *L. monocytogenes* in RTE-foods

$$\log\left(\frac{N}{N_0}\right) = -\frac{t}{D}$$

$$D = D_{ref}\,10^{\left(\frac{T_{ref}-T}{z}\right)}$$

Guidelines for prediction purposes
Level II – an approach based on databases

- Extended database for *L. monocytogenes*
  - All products (940 data): D_{72} = 0.274 min, z= 7°C
  - Dairy products (280 data): D_{72} = 0.104 min, z=6.4°C
  - Milk (226 data): D_{72} = 0.091 min, z=6.2°C
  - Basic model approach
  - More advanced model, e.g., Weibull type model

$$\log\left(\frac{N}{N_0}\right) = -\left(\frac{t}{\delta}\right)^{b}$$

?

$$\delta = \delta_{ref} 10^{\left(\frac{T_{ref}-T}{z}\right)}$$

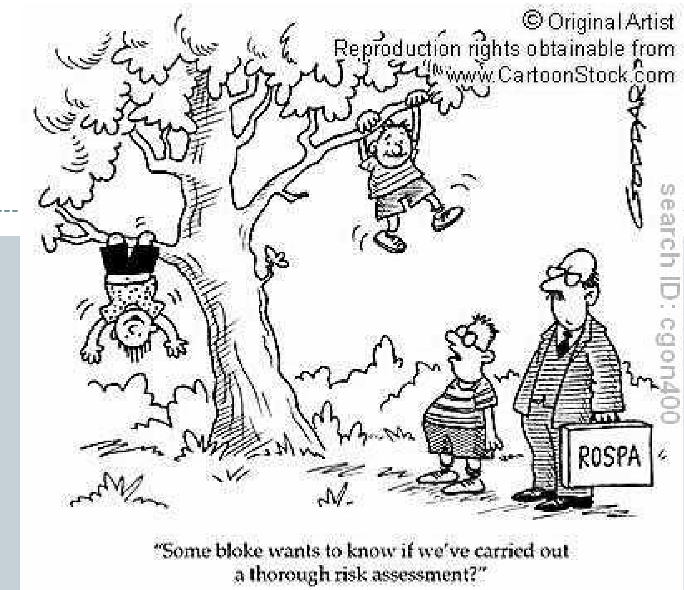
Guidelines for prediction purposes
Level III– an approach based on user-specific data

- User-specific data and/or data from ComBase
- Identification of, e.g., a Weibull type model with GInaFiT
- Estimates of the parameters
  - *b => generally no need for a secondary model*
  - *δ => (extended) Bigelow type model*

Application of these guidelines for prediction purposes

1. Quantification of the ΣR term for a given temperature profile (monitored or calculated)
2. Options to adjust the time duration or temperature to achieve a pre-specified ΣR
3. Optimization of heat processing design

Conclusions



- Risk assessment is an appropriate framework to go beyond safe harbors; by
   1. combining in an accurate way the performance of a certain, specified thermal treatment with performances in other stages of the food production chain;
   2. reducing the uncertainty on predictions, and therefore decreasing the need for being conservative;
   3. calculating accurately the time needed at a specified treatment temperature or the temperature needed for a specified treatment duration using more complicated models to attain a stated performance level.
- Nevertheless, safe harbors to set a heat treatment remain valuable

Thank You for your attention

ILSI Report "RISK ASSESSMENT APPROACHES TO SETTING THERMAL PROCESSES IN FOOD MANUFACTURE" to be published in 2010