Risk assessment approaches to setting thermal processes in food manufacture

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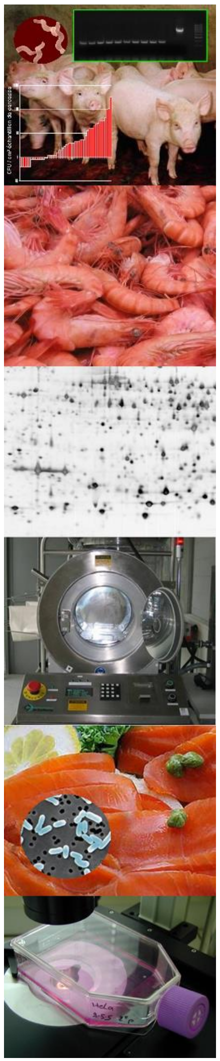
SECALIM

Microbiologists working for food safety



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Overview

- New Food safety management
- ILSI Thermal process activity
- Review of examples
- Conclusion and further reference

New Food Safety Management

New Food Safety Management

- WHO and FAO have called upon countries to apply modern international food safety and quality standards to protect consumer health.
- They are in the forefront of the development of risk-based approaches for the management of public health hazards in food.
- In the context of food safety, an Appropriate Level of Protection (ALOP) is a statement of the degree of public health protection that has to be achieved by the food safety systems implemented within a country.
- For example, an ALOP may be stated for a particular country as incidence of salmonellosis attributable to poultry to be less than 10 cases per 100 000 population.

New Food Safety Management

- Whilst expression of an ALOP in terms relevant to public health, e.g. the reported number of cases per 100 000 population serves to inform the public, the ALOP is not a useful measure in the actual implementation of food controls throughout the food chain.
- Instead, a measurable target for producers, manufacturers and control authorities is required; this is the basis of the Food Safety Objective (FSO) concept.
- An FSO corresponds to the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the ALOP.

New Food Safety Management

- For some food hazards, the FSO is likely to be very low. For instance, for a processor that makes ingredients or foods that require cooking prior to consumption, this level may be very difficult to use as a guideline in the factory.

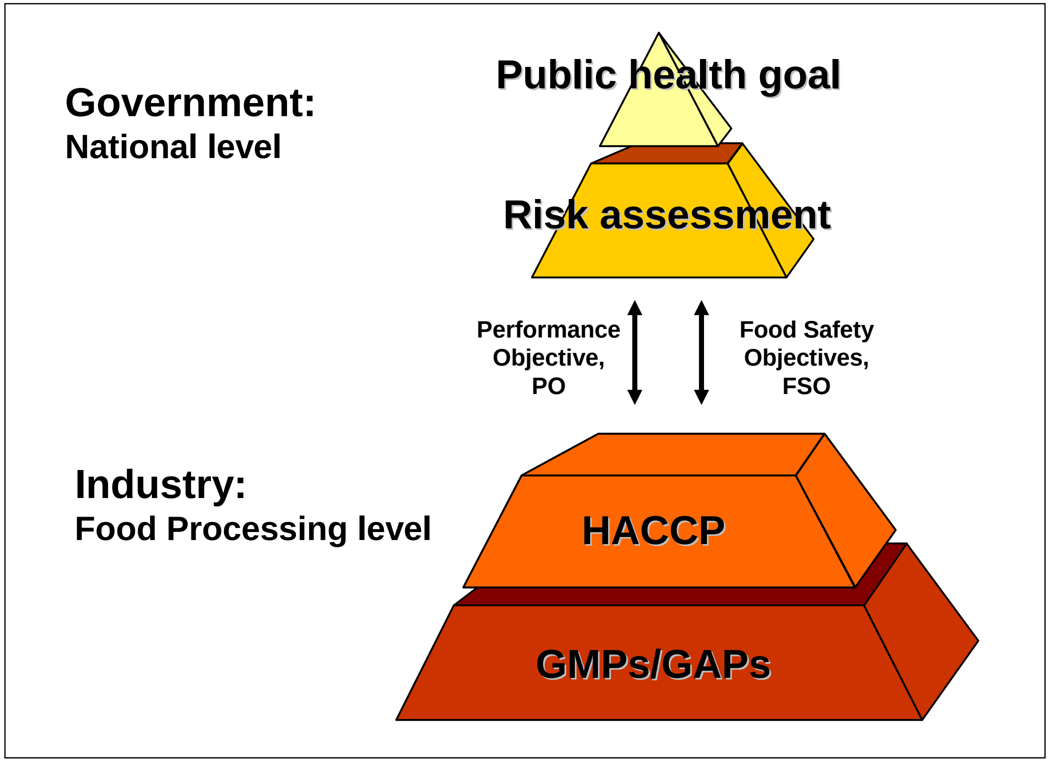
- Therefore, it is often required to set a level that must be met at earlier steps in the food chain. This level is called a performance objective (PO).

- A PO corresponds to a maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable

New Food Safety Management

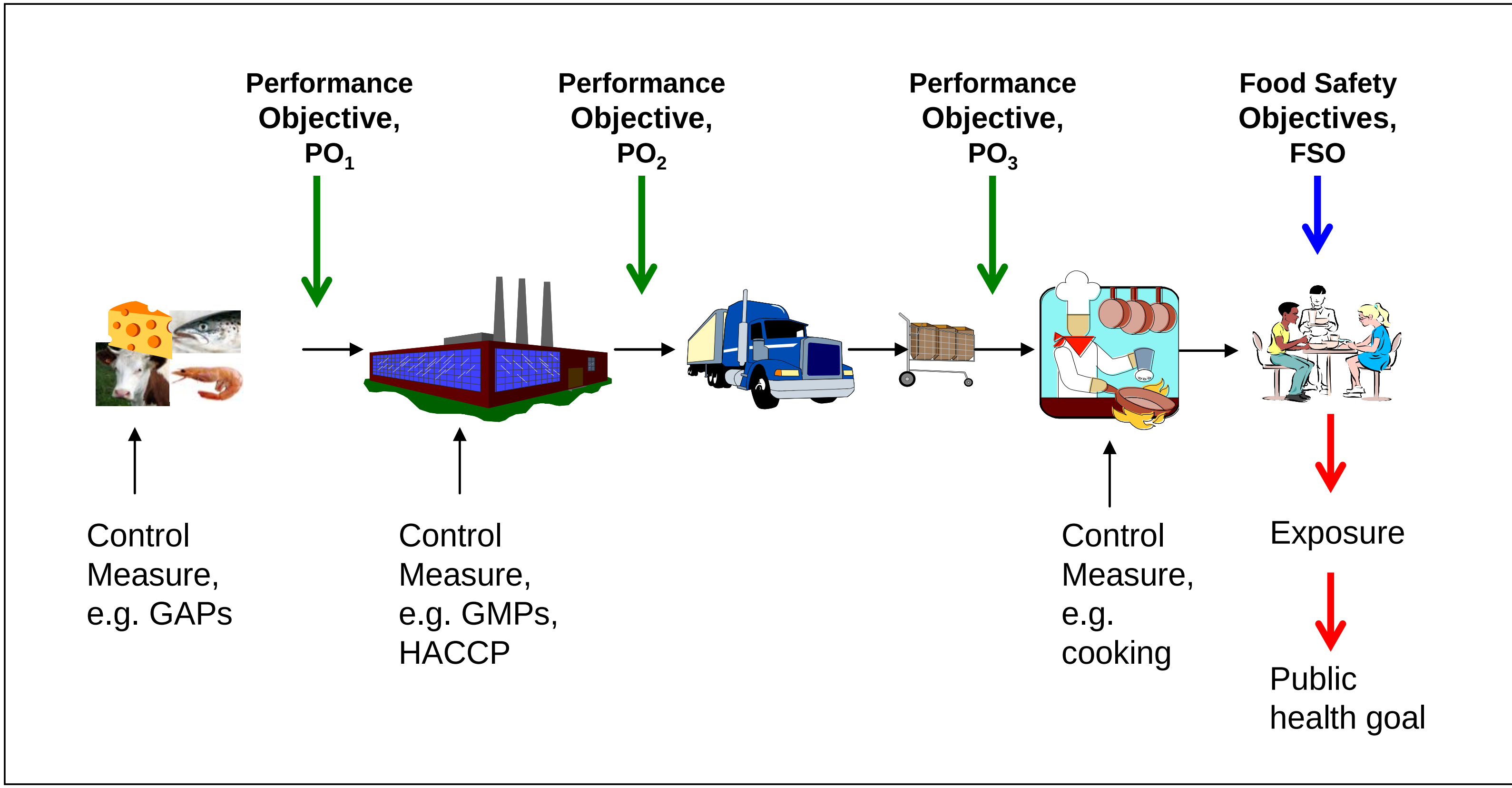
Articulation of food safety management and risk-based approach, set at Government and Industry levels.

Figure adapted from ICMSF, A simplified guide to understanding and using Food Safety Objectives and Performance Objectives [on line] (2005) by Membré, 2010.



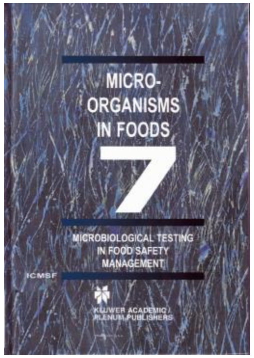
Membré, 2010. Setting of thermal processes in a context of food safety objectives (FSOs) and related concepts. In “Progress on Quantitative Approaches of Thermal Food Processing” (edited by Valdramidis, V.P. & Van Impe, J.F.M.) In the Series “Advances in Food Safety and Food Microbiology” edited by Dr. Anderson De Souza Sant’ana. In progress.

FSO concept



Adapted from ICMSF 2005 by Membré, 2010.

ICMSF's conceptual equation[1]



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

- H_0: Raw material contamination (prevalence & level)
- ΣR: Reduction (inactivation, inhibition)
- ΣI: Increase (Growth, Recontamination)
- PO: Level at step x in the food chain (e.g. after packaging)
- FSO: Level at point of consumption

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

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

FSO concepts

- **Performance Objective (PO):** maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable

- **Performance Criteria (PC):** effect required of one or more control measure(s) working in concert to meet a PO

$$\mathbf{PC = \Sigma R - \Sigma I}$$

- **Process criteria (PrC):** control parameters (eg heat-treatment time, heat-treatment temperature, flow rate, but also product pH and water activity) at a step or combination of steps that can be applied to achieve a PC.   Sometimes called ‘Product criteria’

INTRODUCTION TO THE ILSI THERMAL PROCESSING ACTIVITY

ILSI Thermal Activity (2009)

Dr. Andy Davies - Chair -	H J Heinz	UK
Dr. David Bean	Mars	UK
Mr. François Bourdichon	Groupe Danone	FR
Dr. David Bresnahan	Kraft Foods	US
Prof. Josse De Baerdemaeker	University of Leuven	BE
Prof. Anemie Geeraerd	University of Leuven	BE
Dr. Tim Jackson	Nestlé	CA
Dr. Jeanne-Marie Membré	Unilever	UK
Dr. Bizhan Pourkomailian	McDonald's Europe	UK
Prof. Philip Richardson	Campden BRI	UK
Dr. Mike Stringer	Campden BRI	UK
Prof. Mieke Uyttendaele	University of Ghent	BE
Prof. Marcel Zwietering	Wageningen University	NL
Dr. Pratima Rao Jasti	ILSI Europe	BE

RATIONALE FOR TP EXERCISE

- Desk based exercise to demonstrate how risk based concepts and risk management techniques can be applied to the setting of thermal processes in food manufacture.
- Many operations governed by official or industry standards
- These standards provide a safe harbour for manufacturers without detailed knowledge e.g. level of raw material contamination, variability in process, variability in organism response (D value), fate of product in market place
- With more precise knowledge risk assessment concepts and techniques can assist in designing a safe thermal process
- Additional benefits with respect to product quality, cost and energy use can be realised
- Transparency of risk assessment framework allows for the demonstration of safety to regulators and other stakeholders

EXCELLENT HISTORY

- LARGE VOLUMES BUT FEW COMMERCIAL INCIDENCES – HOWEVER MAJOR IMPACT
  - CANNED MEAT – WRONG DELIVERY OF PROCESS
  - SALMON – POST PROCESS (MOST CASES)
  - HAZELNUT PUREE – WRONG PROCESS
- NOTE DOMESTIC INCIDENTS e.g. Poland, USA

Therefore Current Performance Standards Worked Well

Examples of official or industry standards

- 1897 : Prescott & Underwood
  - Scientific rationale of adulteration of canned food: bacterial spores, amongst them *Clostridium botulinum* (*Bacillus botulinus*)

- Esty & Meyer (1922), Townsend (1938), Stumbo (1965)
  - $F_0$3 botulinum cook (12 Log reduction at 121,1°C = 3 minutes)
  - 12D cook : Probability of survival of 1 cell in 1 can out of 10^{12}

F. Bourdichon, A. Geeraerd, M. H. Zwietering, J.-M. Membré. 2009. Application of QRA to go beyond safe harbors in thermal processes. Part 1: introduction and framework. 6th International conference of Predictive modelling in foods. September 2009, Washington DC, US. http://www.icpmf.org/Extended%20Abstracts%202009%20Final.pdf

Examples of official or industry standards

- Regulatory demand
  - Process to achieve a 5-log reduction of enteric pathogens in juice
  - Process to achieve a > 5-log reduction of *Salmonella* in almonds
  - Process to achieve a 7 log reduction of *Salmonella* in poultry products

- Industry Consensus
  - ACMSF: *C. botulinum* equivalent to 90°C for 10 minutes to address non-proteolytic *C. botulinum* in chilled foods
  - 70°C for 2 minutes for "*Listeria* cook"

Performance standards

- Generally recognized processes that have been established by consensus or by regulation
  - Set when there is limited information about the food system or the initial microbial level prior to processing
  - Set based upon the best understanding of microbial physiology/processing, at the time
  - Safety margin built in to account for process variability
  - Assume thermal processing to be the sole intervention

Benefits of alternatives to current Performance Standards

- Improved quality
  - Enhanced flavour, texture and colour
  - Retention of vitamins, compositional factors and active ingredients
- Improved efficiency
  - Faster throughput
  - Lower energy
- Milder treatments
  - New products
  - Combination treatments

Re-visiting Thermal Process in the new safety management context

Inactivation by thermal process developed is put into the context of other factors contributing to the FSO

Equivalent processes with various target reductions

H0	∑R	∑ I	FSO
2	6	2	-2
2	4	0	-2
0	2	0	-2
-2	0	0	-2

Provides the processor flexibility in management approaches to achieve the same objective

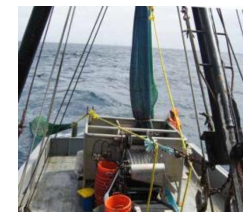
Examples

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 => FSO=-2.4 (< 1cfu/250 g)
- Exposure assessment: carcass surface contamination & decontamination, no increase under controlled chilling/fabrication operations => $\Sigma I=0$

  A very small proportion of lots of ground beef have a relatively high prevalence (5% or higher) and higher concentration of cells (1-10 g^{-1}) => $H_0 = 2$
- Conclusion: $\Sigma R \geq H_0 + \Sigma I - FSO = 2 + 0 + 2.4 = 4.4$

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

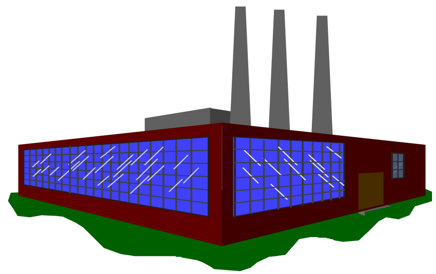


- Hazard identification: *L. monocytogenes/* shrimp
- Exposure assessment: raw shrimp has mostly 100 cfu g^{-1} => $H_0 = 2$

  No opportunity for growth => $\Sigma I=0$
- Hazard characterization: no detectable cells per serving of 100 g

  => FSO=-2
- Conclusion: $\Sigma R \geq H_0 + \Sigma I - FSO = 2 + 0 + 2 = 4$
- Added safety margin (variability due to the season, difference in heat resistance) of 1 log: $\Sigma R \geq 5$

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



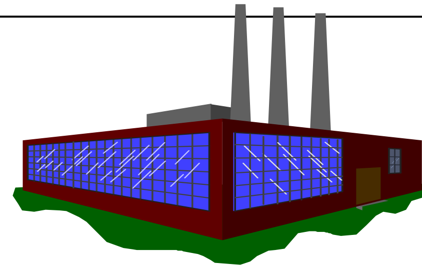
Raw Material → Chilled conditions → Pasteurisation step → Frozen product

- Performance standards: 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?

No recontamination after HT

Meal preparation (warming) not sufficient to inactivate

ΣR



Raw Material → Chilled conditions → Pasteurisation step → Frozen product

$1x10^{3.2}$ cfu/g → **ΣR=4.6** ← $1x10^{-1.4}$ cfu/g

1,500 cfu/g

0.04 cfu/g

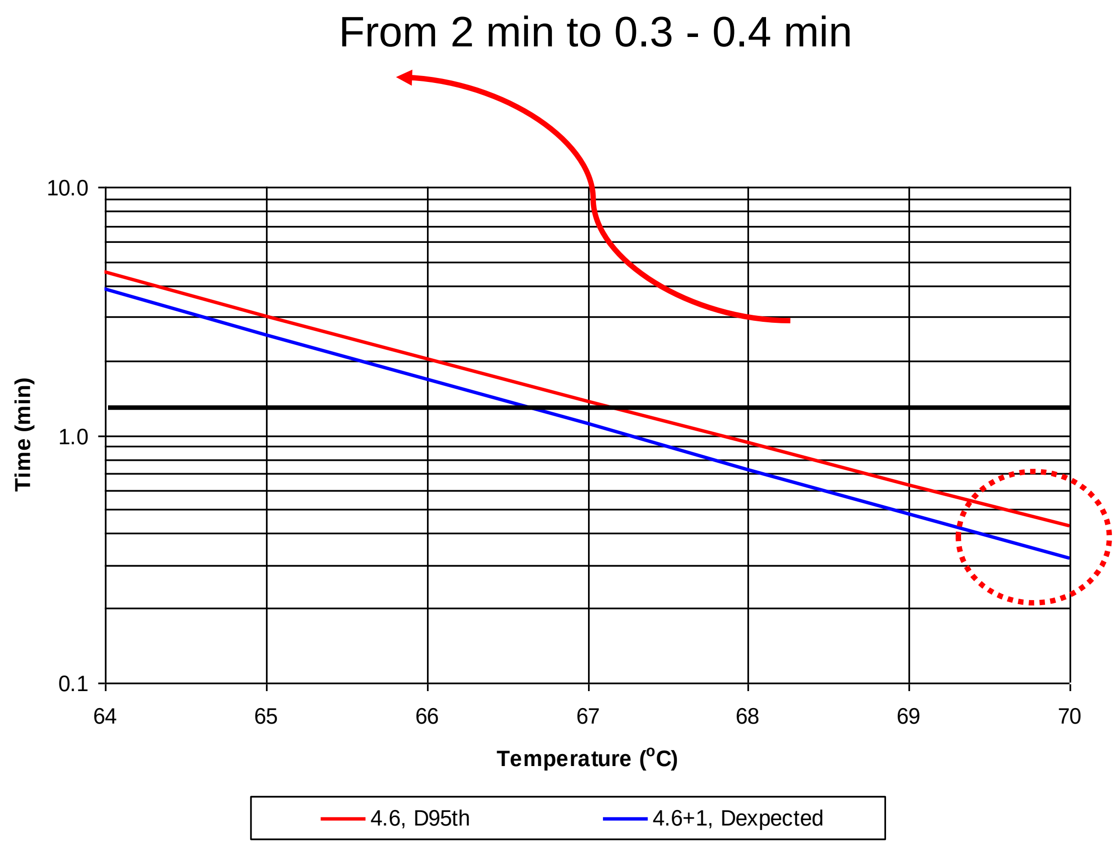
Primary & Secondary Predictive Models

∀ΣR=4.6

- **Heat treatm**
  - **Option 1: HT**
  - **Option 2: HT**

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

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

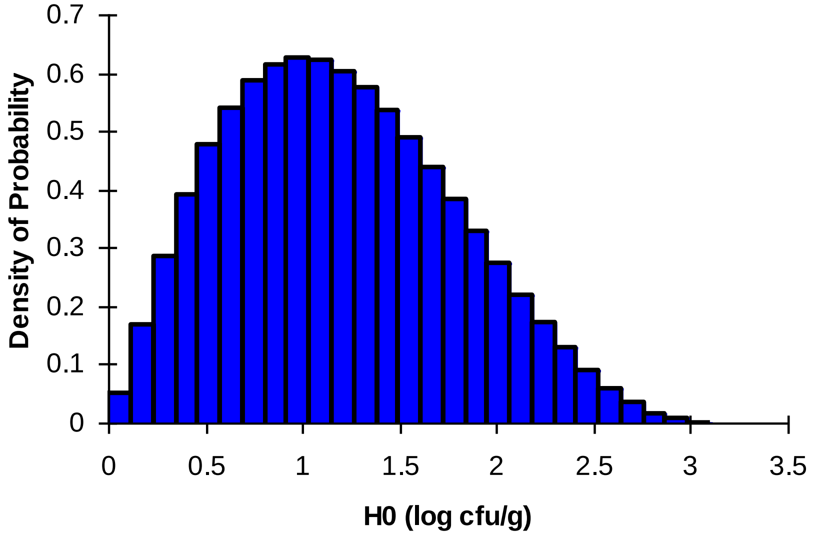


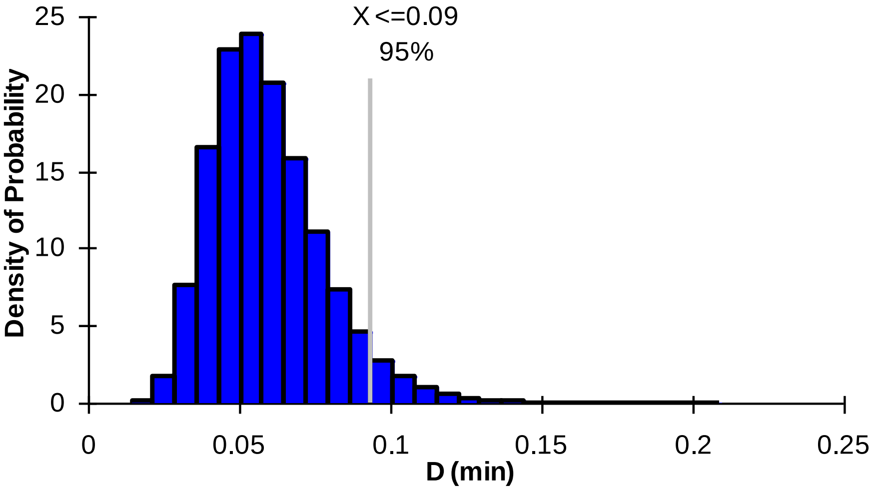
Parameters of the predictive models used in thermal processing setting

Micro-organism	T_{ref} [°C]	z [°C] mean (range)	Log(D_{ref}) range	D_{ref} [min] range	Reference
Spore formers	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

Alternative: Probabilistic approach

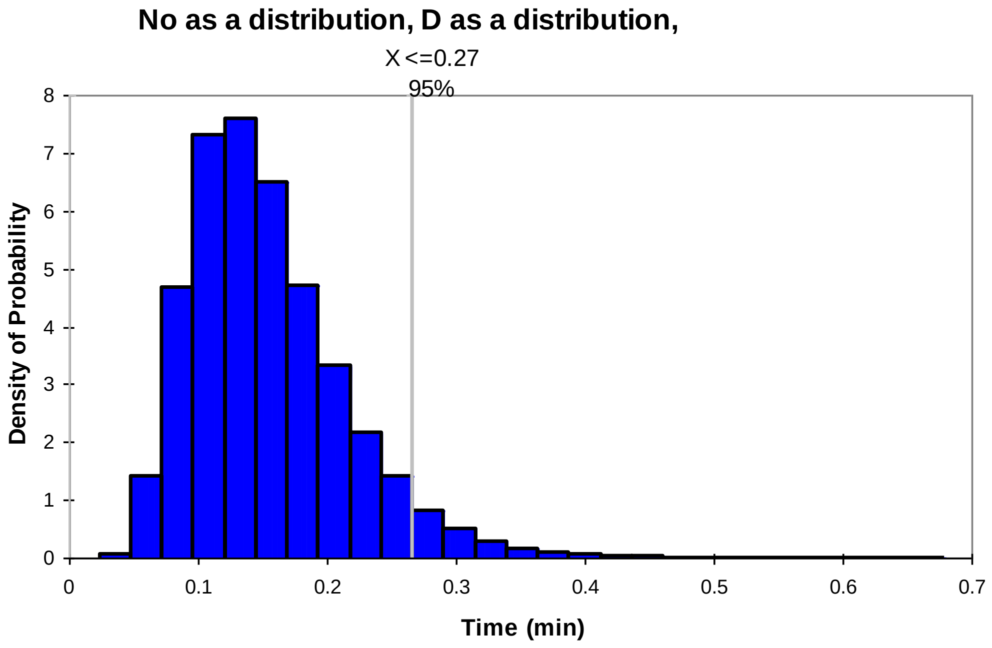




Diversity in raw material sources (seasonal effect, country) and/or in ingredient

Diversity in microbiological species and/or strains

Alternative: Probabilistic approach



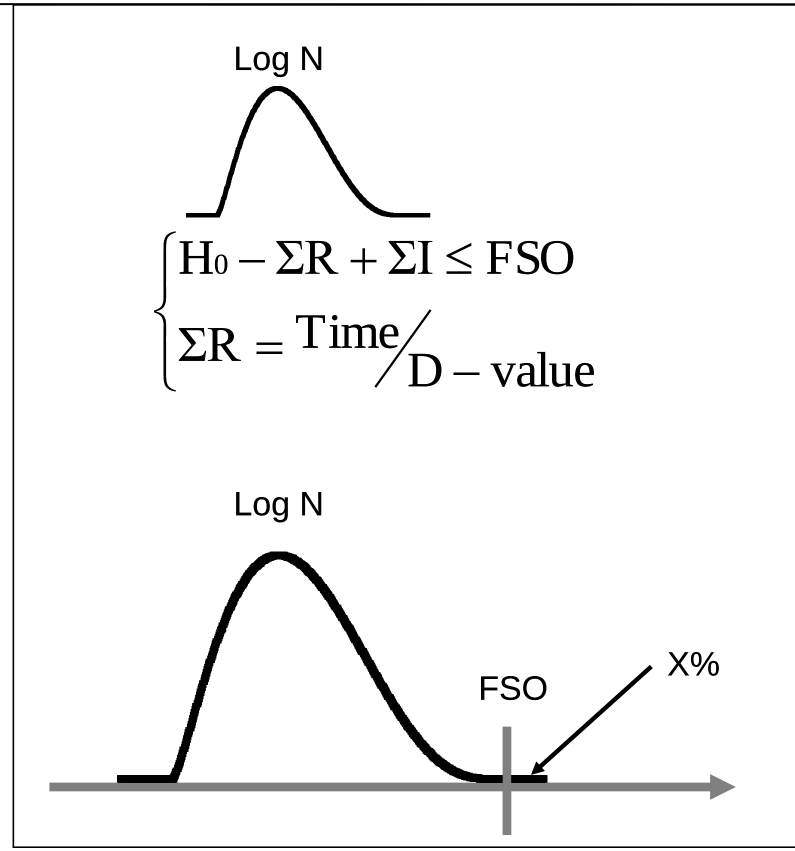
Some limitations in Probabilistic approaches

- The lack of guidance. Currently there are no technical support documents on how to deploy probabilistic techniques and present the results. Guidance for decision-makers who receive the outputs is also lacking

- Resource demanding. Probabilistic techniques require definitively time/computing power and also human resources with modelling expertise, what is generally not available in R&D departments of small and medium enterprises

Probabilistic techniques

Sensitivity analysis (uncertainty analysis, Confidence Interval) required to help interpreting probabilistic outputs



$$\begin{cases} H_0 - \Sigma R + \Sigma I \leq FSO \\ \Sigma R = \text{Time} / D - \text{value} \end{cases}$$

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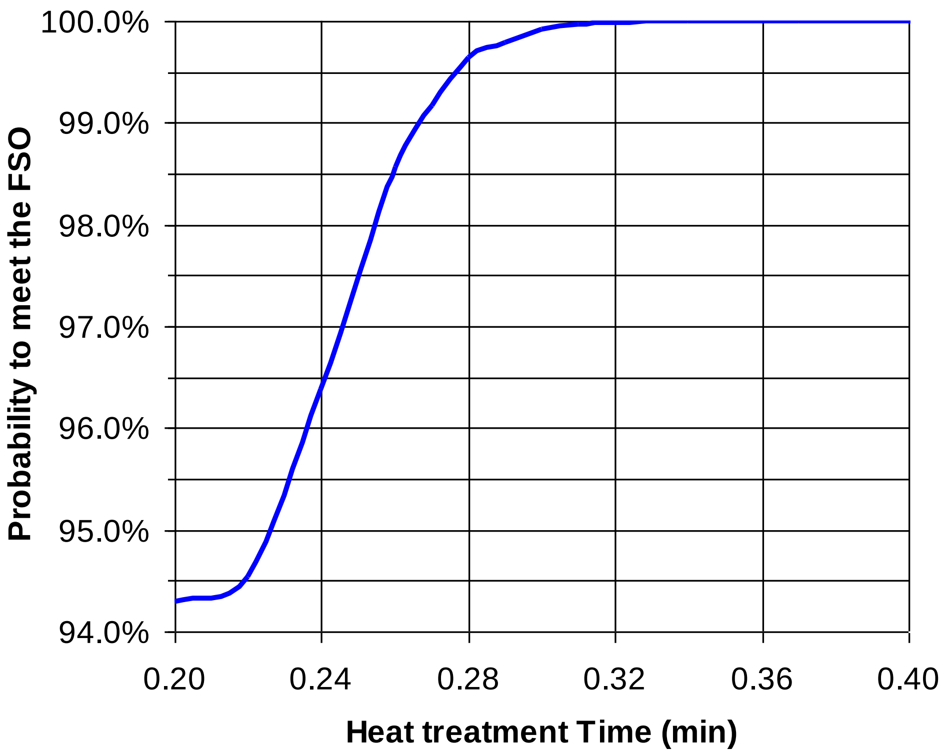
Probabilistic techniques



Calculations based on

$$\text{Poisson}(2.5\times10^{ld}\,p)$$

$$p=10^{(-time/D)}$$

Membré, 2010. Setting of thermal processes in a context of food safety objectives (FSOs) and related concepts. In “Progress on Quantitative Approaches of Thermal Food Processing” (edited by Valdramidis, V.P. & Van Impe, J.F.M.) In progress

Example 3

- REPFEDs
- non proteolytic *Clostridium botulinum*

- Performance standards:
  - PC=6 log, by applying 90°C for 10 min

- Challenge: milder HT by involving other Process and Product Criteria?

Membré J.M., Wemmenhove E., McClure P.J., Exposure assessment model to combine thermal inactivation (log reduction) and thermal injury (heat-treated spore lag time) effects on non-proteolytic *Clostridium botulinum* in Martorell S., Soares C.G., Barnett J. (Eds.), London, 2009.

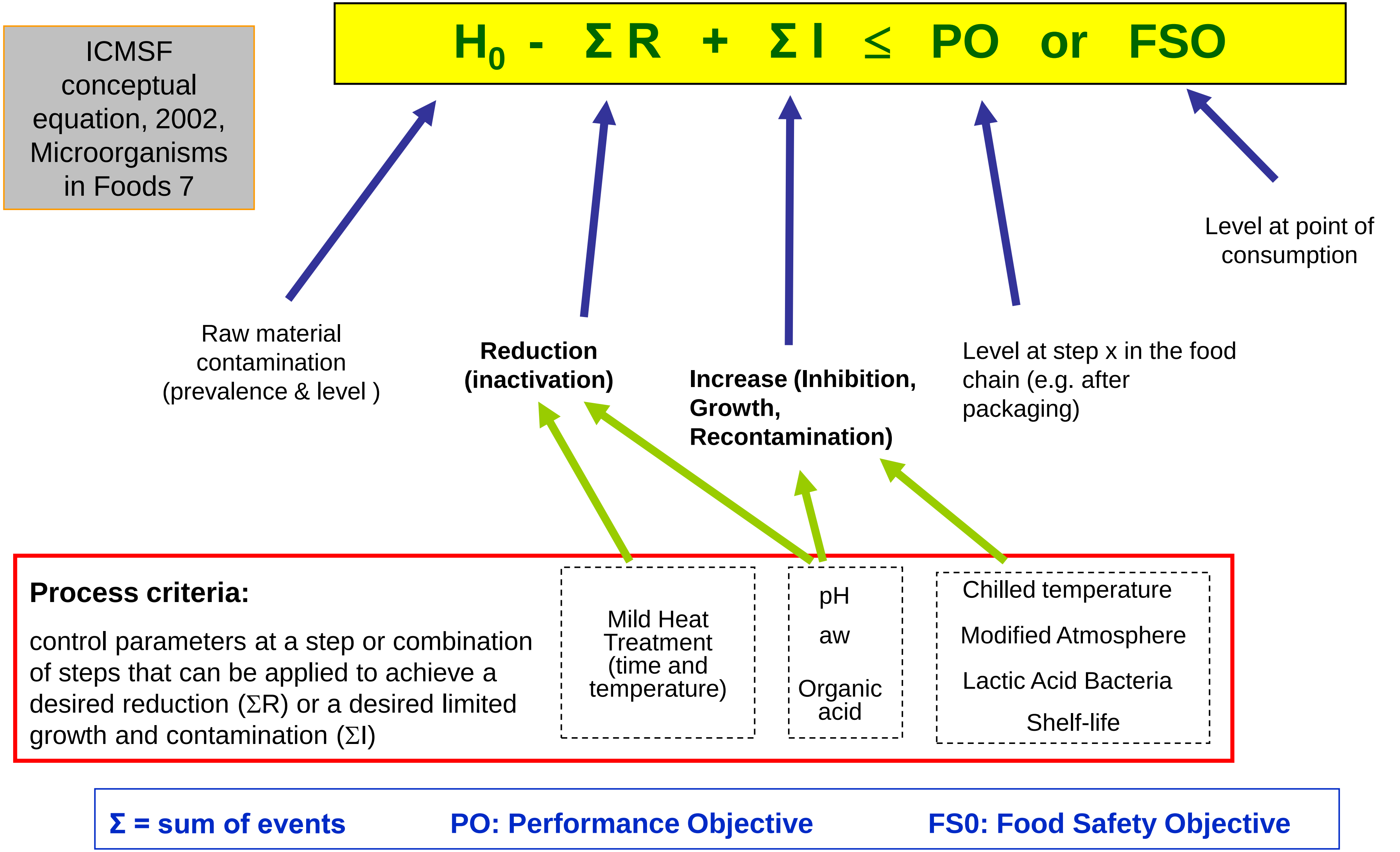
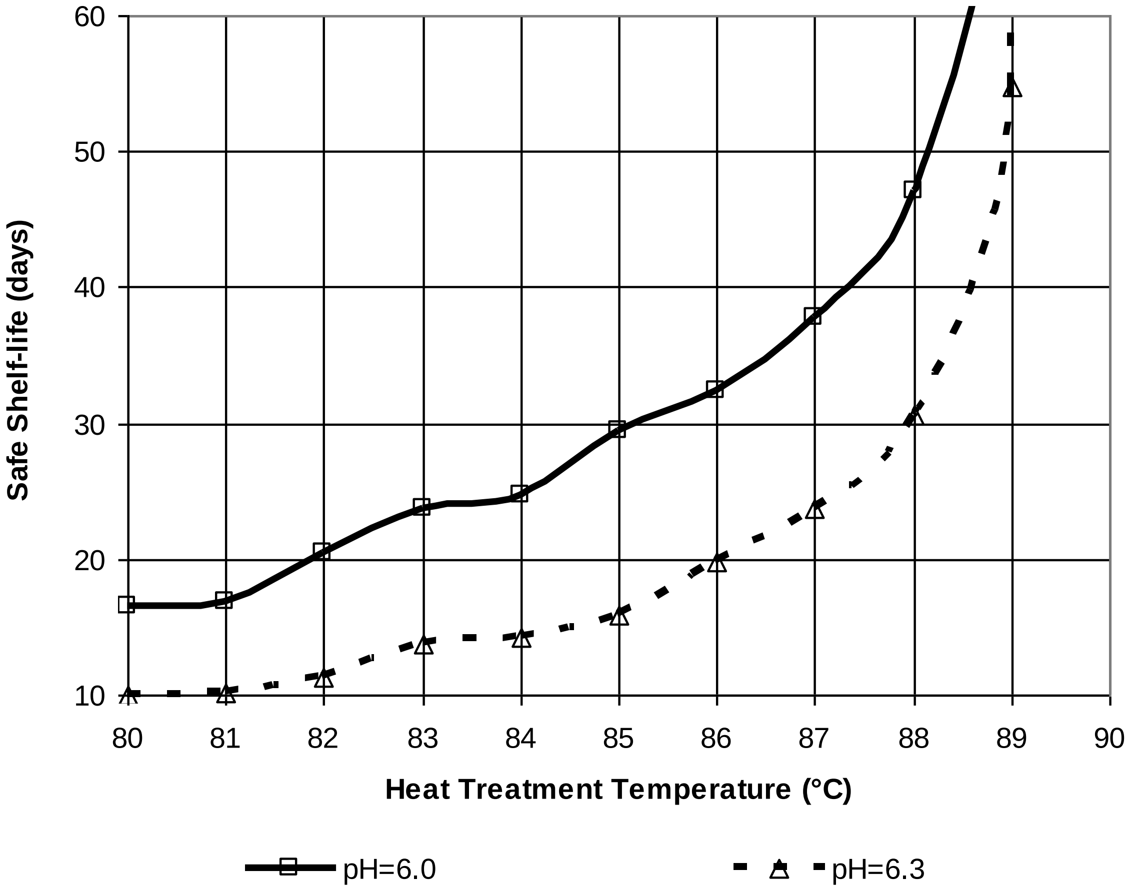


Figure from Membré, 2010, Setting of thermal processes in a context of food safety objectives (FSOs) and related concepts. In “Progress on Quantitative Approaches of Thermal Food Processing” (edited by Valdramidis, V.P. & Van Impe, J.F.M.) In the Series “Advances in Food Safety and Food Microbiology” edited by Dr. Anderson De Souza Sant’ana. In progress.

Example 3



Combination of three Process criteria (shelf life, heat-treatment temperature -applied for 10min- and pH) achieve the Performance Criteria '6 log reduction/inhibition' of non-proteolytic C. botulinum in REPFEDs

From Membré, 2010

Conclusion

- Risk assessment approach is a complex exercises, it requires:
  - a comprehensive food supply-chain analysis
  - data & information + resource
  - education and training
- FSOs are not yet used by regulatory authorities, and consequently not yet applied by food manufacturers
- However, in future, industry & distribution will need to be able to provide evidence that their foods at the moment they are eaten comply with an FSO or a PO.
- Added value of risk-based approach for thermal process setting
  - economic benefit: product quality (milder HT, equivalence of HT) and cost saving
  - newly identified hazard

Further information

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Further information

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J.-M. Membré, F. Bourdichon, A. Geeraerd and M. H. Zwietering. 2009. Application of QRA to go beyond safe harbors in thermal processes. Part 2: quantification and examples. Conference book. 6th International conference of Predictive modelling in foods. September 2009, Washington DC, US. http://www.icpmf.org/Extended%20Abstracts%202009%20Final.pdf

Quantification of microbial inactivation and some implications on commercial processing. ILSI-Europe Workshop. October 2009. IAFP European Symposium of Food Safety, Berlin, Ge.

Further information

http://www.ilsi.org/Europe/Pages/TF_RiskAnalysis.aspx

Thank you for your attention