Tiempo de esterilización (Valor F_o)

Impact of experimental parameter variability on thermal food processing decisions based on microbial safety objectives

Definitions

- **Processor must estimate process time (F_T) inactivating bacterial spores of the pathogen of interest**
  - ***Clostridium botulinum***
    - **Heat-resistant bacterial spore of most severe safety risk**
- **Prediction Model**

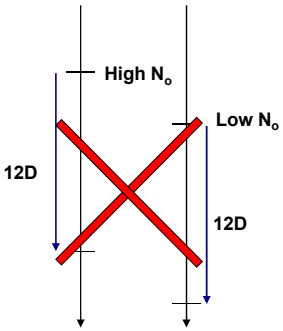
$$F_T = SV \cdot D_T$$

Decimal reduction time

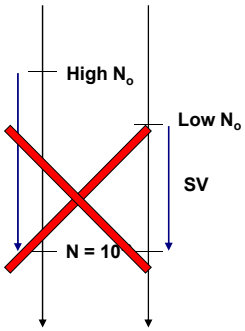
Number of decimal reductions

History of Sterilization Objectives

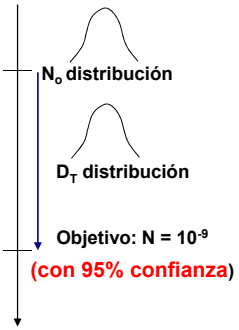
Safety objective: 12D
= Same process



Safety objective: $N = 10^{-9}$
(1 in 1 billion containers)
= Same final load



Tiempo de esterilización (Valor F_o)



$$F_T = SV\,D_T$$

Variabilidad

$$SV = Log\left(\frac{N_o}{N}\right)$$

Valor fijo
Objectivo del proceso
10^{-9} espora/unidad

Tiempo de esterilización (Valor F_o)

Natural prevalence of *C. botulinum* in fresh mushrooms

Sample	Mean N_o log CFU/g
Fresh mushrooms	-1.36 ± 0.87

Decimal reduction time ($D_{110ºC}$), *C. botulinum* in commercially canned mushrooms

Sample	Temp (ºC)	Mean D_T (min)
Commercial canned mushroom	110	0.78 ± 0.17

Data generation:

- **Sample size of each generated dataset must be equal to sample size reported in the literature(1)**
  - **N_o* refers to N_o from simulation (12 values)**
  - **D_T* refers to D_T from simulation (9 values)**

Determination of data acceptability:

- **Metric helps to determine if the distribution of the generated data is approximately equivalent to the distribution of the data reported in the literature**

(1) Chu, 2009

Acceptable error in the minimum

$$metric = \left|\frac{\mu_o - \mu_o^*}{\mu_o}\right| \times f_1 + \left|\frac{a_o - a_o^*}{a_o}\right| \times f_2 + \left|\frac{z_o - z_o^*}{z_o}\right| \times f_3$$

Acceptable error in the mean Acceptable error in the maximum

$f_i =$ **weight factor, a judgment decision**

$$acceptable\ metric = (error_{mean} \times f_1) + (error_{minimum} \times f_2) + (error_{maximum} \times f_3)$$

Statistical consulting group. Summer 2008. Dept of Statistics, OSU

Determination of acceptable error

- **An acceptable error was defined for N_o and D_T values**
  - **Thermal process time error ≤ 0.1 min**

reported $N_o = N_o$
generated $N_o^* = \varepsilon N_o$

reported $D_T = D_T$
generated $D_T^* = \varepsilon D_T$

$$Error = \left|F_T^{reported} - F_T^{generated}\right| \leq 0.1$$

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Evaluate metric for N_o and D_T values:

$$metric = \left|\frac{(\mu_o - \varepsilon\mu_o)}{\mu_o}\right| f_1 + \left|\frac{(a_o - \varepsilon a_o)}{a_o}\right| f_2 + \left|\frac{(z_o - \varepsilon z_o)}{z_o}\right| f_3$$

- Simulation set accepted if the metric value was less than

$$metric = |1-\varepsilon|(f_1 + f_2 + f_3)$$

$$metric_{N_o} \le 393$$

$$metric_{D_{T=110C}} \le 0.45$$

- If rejected, a new set was generated.

This test was a necessary but not a sufficient test as the original experimental dataset was not available to determine its true distribution

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Microbial Inactivation

$$F_T = SV(D_T) = (\log N_o - \log N)\, D_T$$

Objective = 10^{-9}

Experimental values N_o, D_T

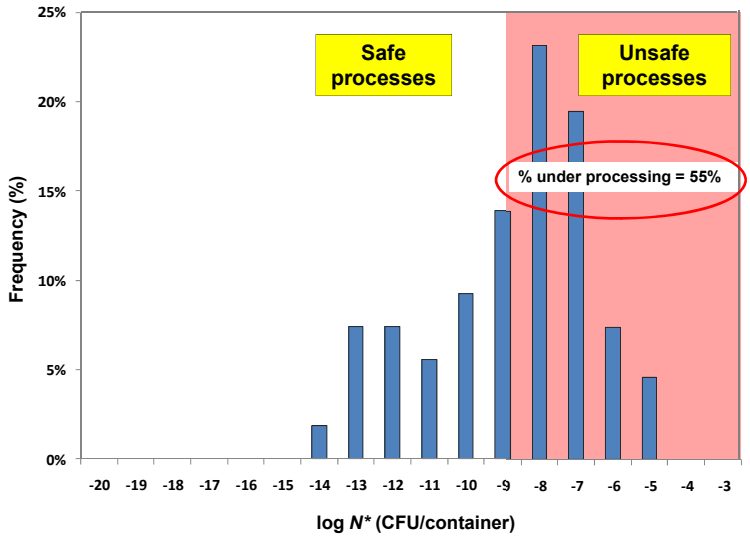
$$\overline{F_T} = \left(\log \overline{N_o} - \log N\right) \overline{D_T}$$

Calculated process based on average values, $\overline{N_o}$, $\overline{D_T}$

$$\log N_j^* = \log N_{o,j}^* - \frac{\overline{F_T}}{D_{T,j}^*}$$

What is the real process safety for data set "j"?

An example of the probability distribution (n = 108) for the estimation *C. botulinum* spore survival (*log N**, CFU/container) based on one accepted N^*_o and $D^*_{110°C}$ dataset

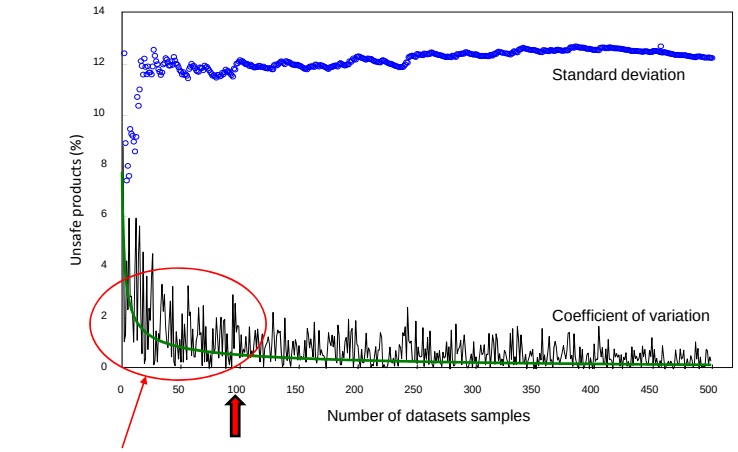


Determination of the recommended number of datasets for the Monte Carlo simulations:

- **Estimate the standard deviation (SD) and coefficient of variation (CV) for the % under processing for 2, 3, 4…, s = 500 datasets**
  - **The recommended sample size S is the one with an acceptable CV value**

Efron & ibshirani ,1986; Almonacid-Merino & Torres, 2009

Determination of the recommended number of Monte Carlo simulations for the estimation of thermal processing time (F_T)



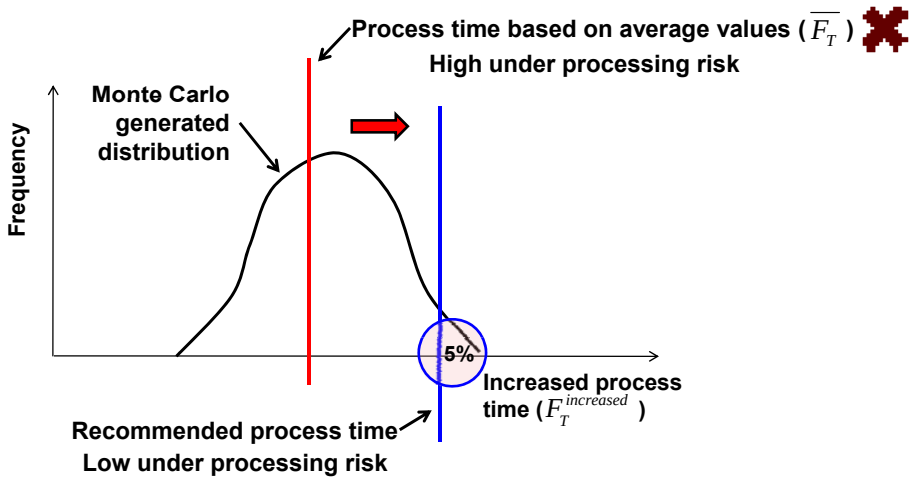
a sample size of 100 was considered sufficient

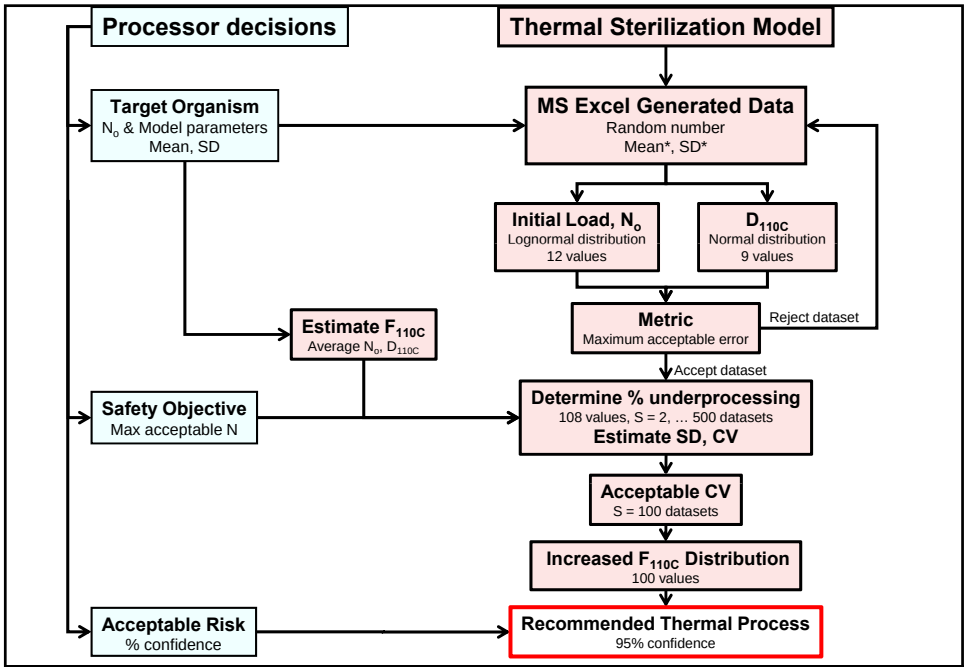
Based on the acceptable 100 datasets:

- Calculate Log N^* (= 12 x 9 = 108 values) for each dataset based on the process time $\overline{F_T}$ calculated using average values ($\overline{N}_o$ & $\overline{D}_T$)
- Use the predictive model to estimate an increased processing time $F_T^{increased}$ for each unique N_o^* & D_T^* combination (n = 100 sets) to achieve $N = 10^{-9}$ spores/container with 95% confidence
- Recommend a process time ($F_T^{recommended}$) larger than 95% of the increased processing time values estimated ($F_T^{increased}$, n = 100)

Definition of a recommended process time

Monte Carlo generated distribution ($F_T^{increased}$, n = 100 values)



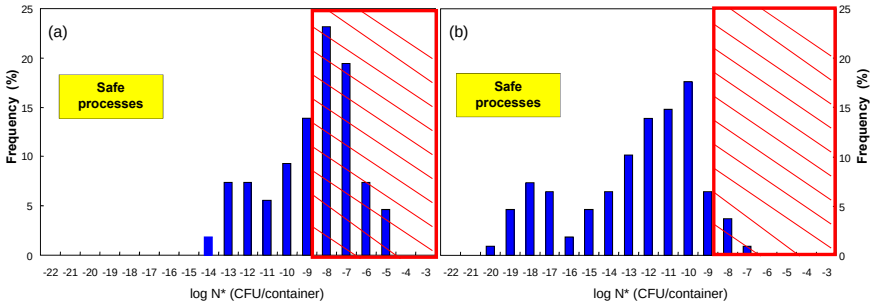


Microbial inactivation

Effect of increasing the processing time to reduce the risk of under processing (an example)

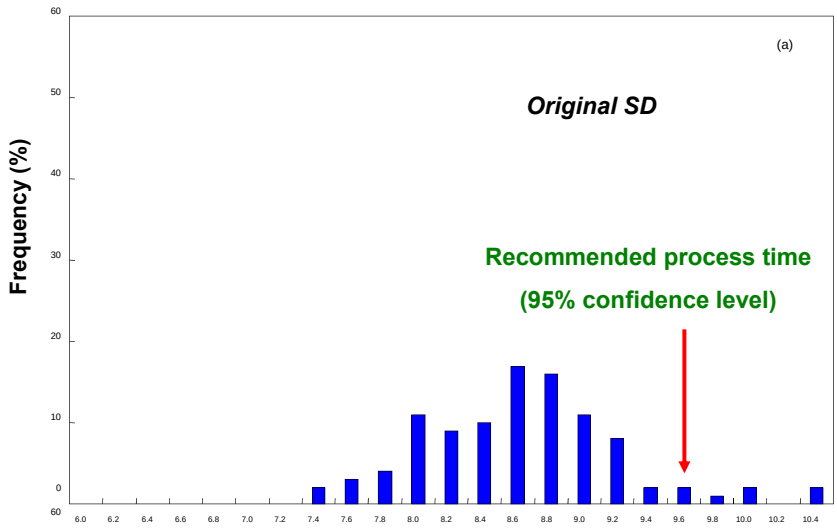
$\overline{F_{110}}$ = 5.96 min

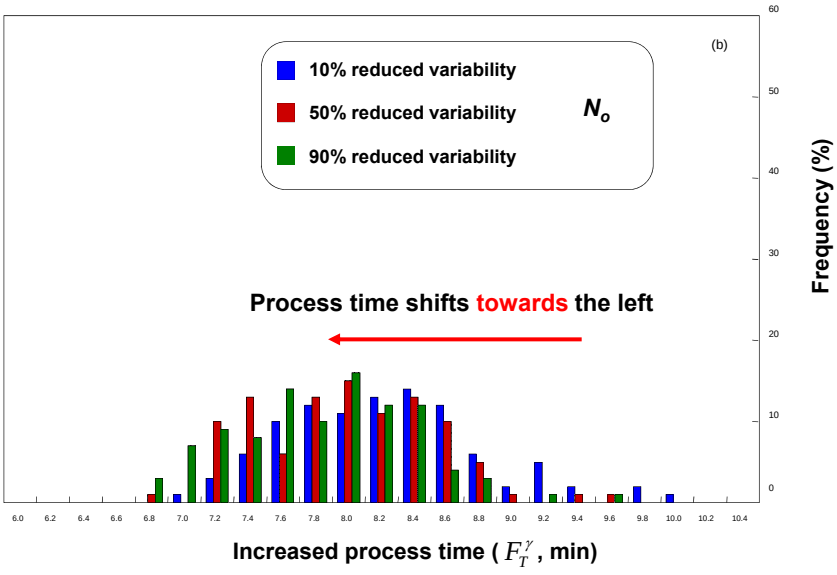
F^{γ}_{110} = 8.89 min

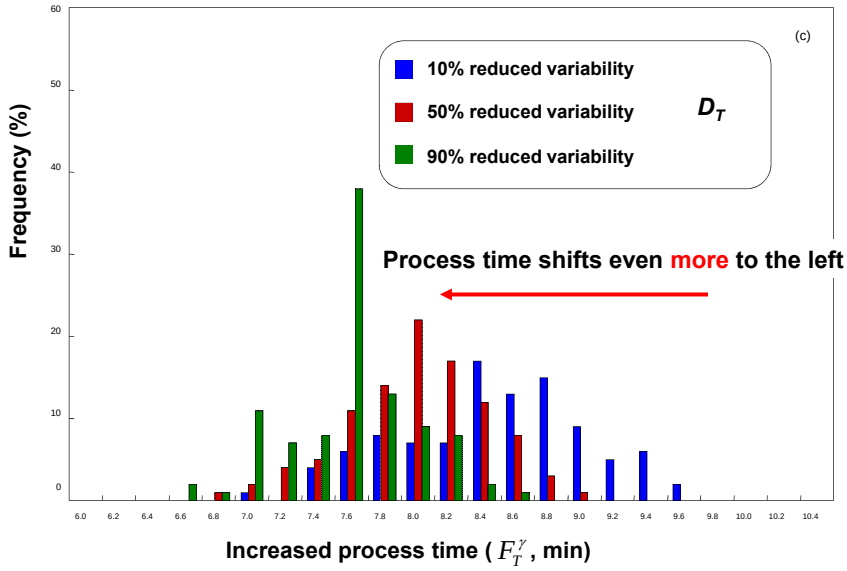


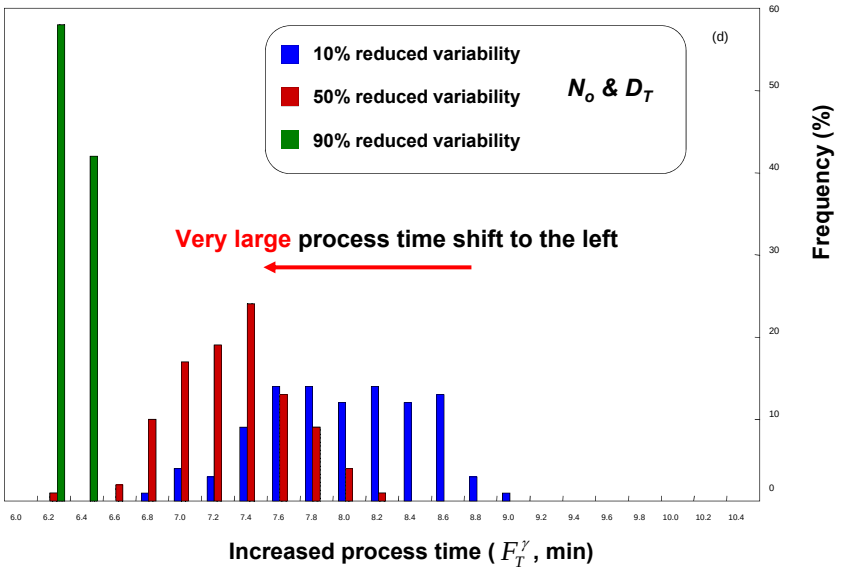
55% under processing

5% under processing




(b)
10% reduced variability
50% reduced variability
90% reduced variability
N_o
Process time shifts towards the left
Frequency (%)
Increased process time (F_T^γ , min)


(c)
10% reduced variability
50% reduced variability
90% reduced variability
D_T
Process time shifts even more to the left
Frequency (%)
Increased process time (F_T^γ , min)



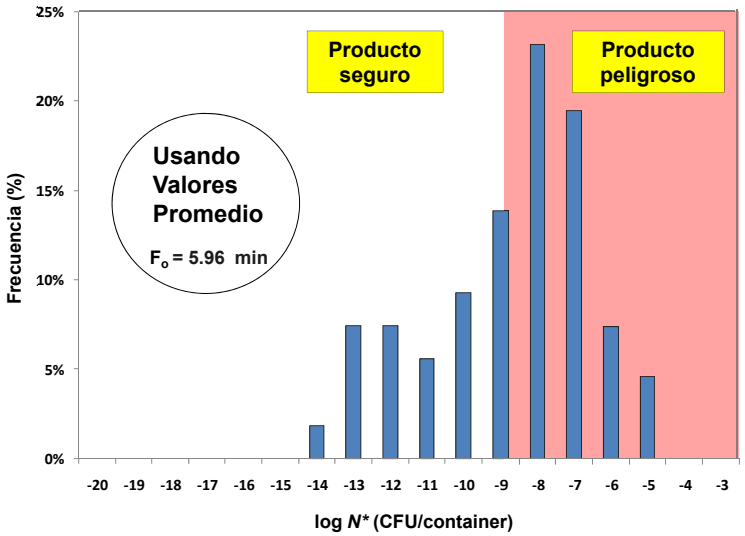
Results:

Effect of the reduction in parameter variability			
Average value based estimation (min) = 5.96 (55% under processing) Monte Carlo based estimation (min) = 9.60 (5% under processing)			
Recommended process time (min), 95% confidence			
SD reduction	10%	50%	90%
N_o	9.2	8.8	8.6
D_T	9.4	8.6	8.2
N_o & D_T	8.6	7.8	6.4 A 3.2 min reduction!

Conclusions

- Monte Carlo-type simulations allowed estimation of thermal processing times achieving a desirable surviving spore load probability with a specified confidence level.
- Monte Carlo-type simulations allowed estimations of the reduction in process time gained by the reduction in the variability of process design parameters.

Tiempo de esterilización (Valor F_o)



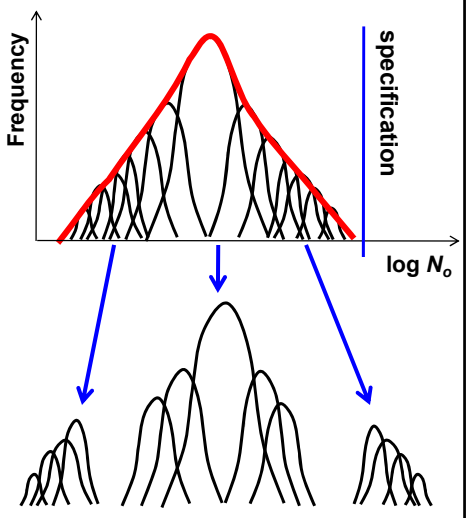
Overall conclusions

- All procedures here presented were implemented on MS Excel spreadsheets and used concepts suitable for inclusion in an FST undergraduate program
- Procedures developed emphasized the importance of minimizing variability, but how can a processor achieve this goal?
- What are the sources of this variability?
  - If the variability source is the measurement itself, you can reduce it by training, improvement of methods and multiple sampling
  - If the source of the variability is the true heterogeneity of the population (i.e., it is irreducible by measurement improvements), one must find the variability source

Reducing true heterogeneity: an example

Thermal processing, initial microbial load, log N_o

- Larger processors need a larger number of suppliers and one can expect microbial load differences among them
- Solution: segregate your suppliers which will reduce variability and reduce processing intensity



¿Preguntas?

Buen Camino!

Have a good Journey!