INTEGRATION OF STATISTICS AND FOOD PROCESS ENGINEERING: ASSESSING THE UNCERTAINTY OF THERMAL PROCESSING AND SHELF-LIFE ESTIMATIONS

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SUMMARY

In response to recent requirements in food regulations, new procedures are now necessary to evaluate the impact of the variability in the parameters of food engineering models used for decisions of safe processing, packaging, storage and distribution conditions. The variability of these parameters generates an uncertainty in the estimations of product safety and quality submitted by food processors to regulatory agencies. Also, consumers and processors want to know the time that products will retain the quality desired and safety expected. This type of problems depends on many factors often described by statistical distributions requiring non-deterministic calculations such as Monte Carlo procedures. A combined predictive microbiology and Monte Carlo procedure were used to determine the shelf-life uncertainty and thus reduce the risk of reaching consumers with unsafe or spoiled products. These benefits are not possible to identify when using conventional estimation methods of shelf-life.

The high probability that thermal processing protocols determined using average values for the parameters in the model are not safe was confirmed. That is why, in the commercial sterilization and pasteurization of foods, it will be required to provide regulatory agencies with determinations of the confidence level that the pathogen risk has been reduced to an acceptable probability level. This can be achieved using the Monte Carlo methodology described in this work. Estimations of the reduction in process time achievable by lowering the statistical variability of process design parameters are also demonstrated. Practical applications of the methodologies here shown are presented including approaches to reduce the variability of input parameters to minimize the uncertainty of thermal processing times. This uncertainty reduction results in more moderate thermal treatments with clear benefits for both processors and consumers.

INTRODUCTION

Monte Carlo procedures can be used to evaluate the uncertainty of food safety and quality estimates associated with the variability in model parameters. This non-deterministic approach will satisfy new international food regulations. In a Monte Carlo procedure (Cassin et al. 1998), model parameters can be described as probability distributions and approximated by random number generators (Fig 1). Calculations are repeated many times yielding each time slightly different outcomes (Schmidheiny 2008) based on the variability of the input data. In conventional calculations, the input parameters have a certain value and the same output values are always obtained. The output from Monte Carlo procedures can be represented as probability distributions or histograms and the conclusion reported as confidence intervals (Wittwer 2004). In this work, two applications are presented in some detail (Chotyakul 2009; Chotyakul et al. 2010a,b), i.e., the assessment of the uncertainty of refrigerated microbial shelf-life and thermal processing estimates.

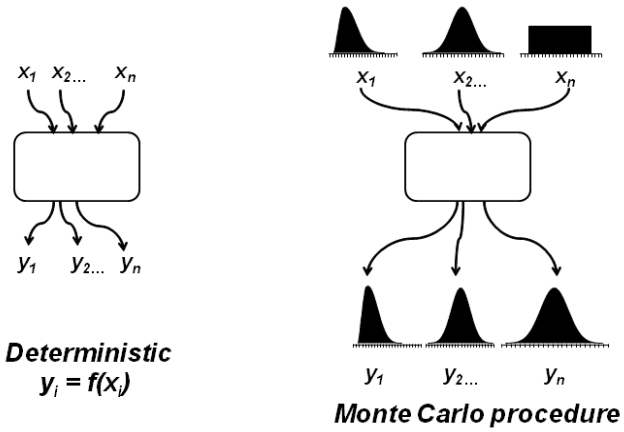

Figure 1. Schematic representation of a Monte Carlo and a conventional calculation procedure

APPLICATION: MICROBIAL SHELF-LIFE ESTIMATES

Shelf-life as affected by storage temperature, water activity, and modified atmosphere packaging was analyzed based on meat spoilage by *Lactobacillus sakei*, a gram-positive anaerobe commonly found in meat and fish products (Martín et al. 2006). Some strains produce exopolysaccharides yielding a slimy appearance (Champomier-Vergès et al. 2001). Longer shelf-life is achieved when carbon dioxide is used (Devlieghere and Debevere 2000; Devlieghere et al. 1998; McMillin 2008). When absorbed by the meat, pH decreases and oxidation is inhibited slowing down deterioration (Aymerich et al. 2006; Jakobsen and Bertelsen 2002). In this work, storage temperature T was assumed fixed (4°C). Water activity (a_w) can be measured with small variability (±0.003, Anonymous 2006) and the value assumed was 0.98 (Rödel 2001). The dissolved carbon dioxide (CO_2) concentration in the meat was the value reported by Jakobsen and Bertelsen (2002; 2004) for chopped pork (2650 ppm). Shelf-life was defined as lag phase (λ), i.e., the time when cell numbers remain relatively constant, plus the exponential growth time t_s needed to reach, at rate μ_{max}, a microbial load N_s from an initial contamination level N_o.

The equations used (Table 1) and the parameter values required (Table 2) generated four cases depending on the factor(s) (T, a_w, CO_2) considered in the shelf-life model. The expressions used for λ and μ_{max} in Table 1 are modifications of the ones proposed by Ratkowsky et al. (1982) with parameter values reported in Table 2. Shelf-life was determined considering only storage temperature T, T and a_w, T and dissolved carbon dioxide CO_2, and T, CO_2 & a_w (Cases 1-4.1).

Table 1. Equations used in the shelf-life models

Case	λ (h)	μ_{max} (h^{-1})
a. Models used with reported standard deviation (SD) (Devlieghere et al. 1999; McKellar and Lu 2004)		
Case 1 (*T*)	$\lambda = \frac{1}{b_1 (T - T_{min})^2}$	$\mu_{max} = b_1 (T - T_{min})^2$
Case 2 (*T*, a_w)	$\lambda = \frac{1}{b_2 (a_w - a_{w\,min})(T - T_{min})^2}$	$\mu_{max} = b_3 (a_w - a_{w\,min})(T - T_{min})^2$
Case 3 (*T*, CO_2)	$\lambda = \frac{1}{b_4 (CO_{2\,max} - CO_2)(T - T_{min})^2}$	$\mu_{max} = b_5 (CO_{2\,max} - CO_2)(T - T_{min})^2$
b. Model used with reported and lowered SD values (Devlieghere et al. 1999)		
Case 4 (T, a_w, CO_2)	$\lambda = \frac{1}{b_4 (a_w - a_{w\,min})(CO_{2\,max} - CO_2)(T - T_{min})^2}$	$\mu_{max} = b_5 (a_w - a_{w\,min})(CO_{2\,max} - CO_2)(T - T_{min})^2$
4.1	Mean and SD for all parameters as reported in the literature	
4.2-4.5	Reported mean and 10, 50, and 90% lower SD for $a_{w\,min}$ (Case 4.2) T_{min} (Case 4.3) (b_4 , b_5) (Case 4.4) and $CO_{2\,max}$ (Case 4.5)	
4.6	Reported mean and 10, 50, and 90% lower SD for all parameters	
4.7	Reported mean and 10, 50, and 90% lower SD for the microbial load	

Table 2. Parameters for the predicted microbiology models
(McKellar and Lu 2004), (Devlieghere et al. 1999), (Martín et al. 2006)

Case	Parameter	λ (h)	Parameter	μ_{max} (h^{-1})
1	b_1	0.0207±0.0008	b_1	0.0207±0.0008
	T_{min}	-2.93±1.27	T_{min}	-2.93±1.27
2	b_2	0.012±0.0012	b_3	0.0141±0.0018
	$a_{w\,min}$	0.9469±0.00087	$a_{w\,min}$	0.9561±0.00107
	T_{min}	-2.31±0.3087	T_{min}	-8.1±1.0714
3	b_4	9.3±1.96E-07	b_5	25±3.57E-07
	$CO_{2\,max}$	1.4±0.26E04	$CO_{2\,max}$	6.1±0.586E03
	T_{min}	-2.38±0.291	T_{min}	-9.0±0.893
4	b_4	9.3±1.96E-07	b_5	25±3.57E-07
	$a_{w\,min}$	0.947±0.00077	$a_{w\,min}$	0.9560±0.00082
	$CO_{2\,max}$	1.4±0.26E04	$CO_{2\,max}$	6.1±0.587E04
	T_{min}	-2.38±0.2908	T_{min}	-9.0±0.8928

Log N_o = 3.40 ± 0.34; T = 4 ºC, a_w = 0.98, CO_2 = 2650 ppm

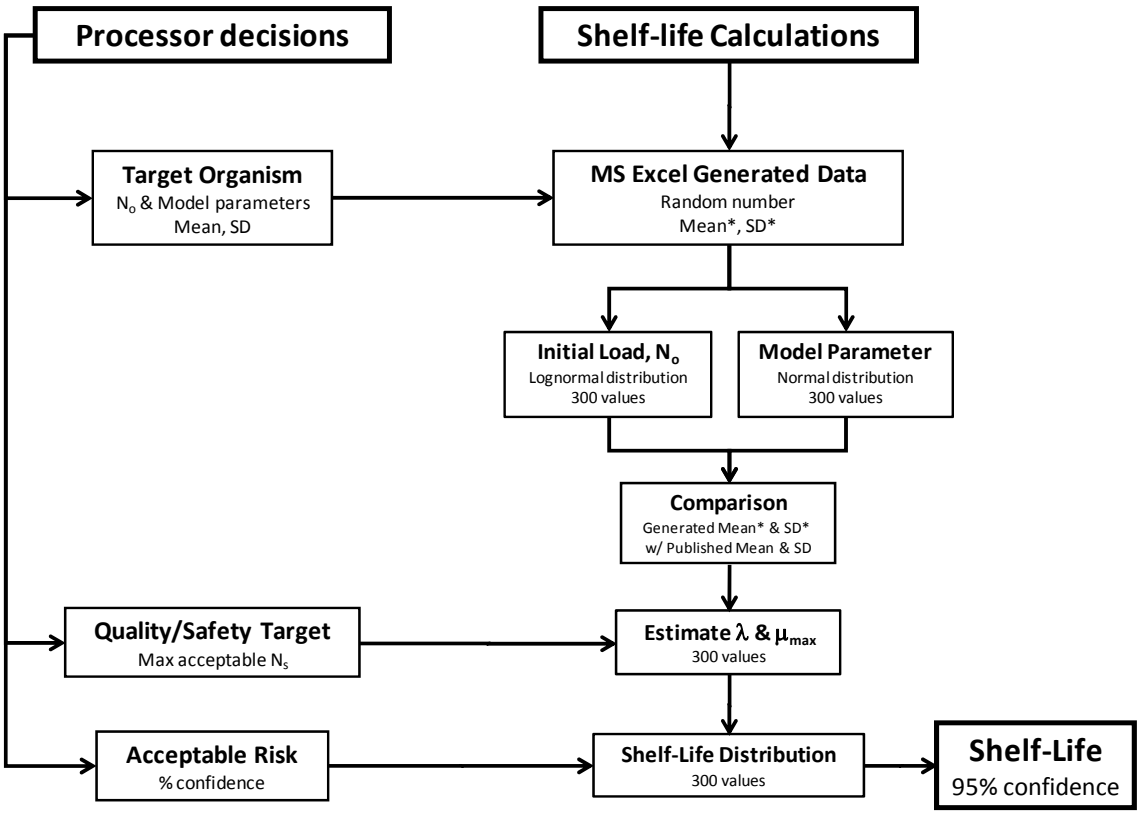

Figure 2. Monte Carlo calculation procedure including information to be provided by the food processor

Figure 2 summarizes all calculation procedures and highlights the key decisions made by the commercial food processor: (1) microorganism(s) causing spoilage and initial microbial load N_o; (2) microbial load level N_s associated with spoilage at the end of shelf-life; and, (3) level of acceptable risk that the shelf-life may be shorter than claimed on the label. The first step in the evaluation of microbial shelf-life is determining the initial microbial load. Lognormal values were used for *L. sakei*, i.e., 3.40±0.34 log CFU/g (Martín et al. 2006) and normal distributions for all other parameters (Table 2). With no repetition, each of the generated initial load and model parameter values were used to obtain 300 values for λ and μ_{max}. The comparison of the reported mean and standard deviation (SD) with the ones calculated for the generated values showed an excellent agreement confirming the distributions assumed (data not reported). Shelf-values were then calculated for each λ and μ_{max} using $log\ N_s = 6$ as the end point (Gram et al. 2002). The 300 values obtained for each parameter were compared with the single value obtained when using only the parameter mean value calculations (from reported references cited in table 2). The probability distribution of the meat shelf-life can also be described in histograms and used to quantify the shelf-life uncertainty as mean and SD (Table 3). The very short shelf-life predicted by the *T*-only model (Case 1, 3.9±1.7 h) confirmed that the meat a_w and/or CO_2 effects cannot be ignored. An expected shift to longer shelf-life by including the effect of a_w and/or CO_2 was confirmed.

The large shelf-life uncertainty observed in the deterministic model was not predictable highlighting the advantages of the Monte Carlo procedure here proposed (Table 3). This large uncertainty explains the reluctance of food processor to provide shelf-life information to consumers. The predicted shelf-life uncertainty was lower when the model considered only one (Case 1) but increased significantly when the model included two (Case 2 and 3) or three factors (Case 4.1). Considering the large shelf-life uncertainty, particularly when considering several preservation factors, the recommendation to a food processor is to use a value equal or less than 95% of the histogram shelf-life values (n = 300 used in this study). Following this strategy, the recommended shelf-life would be 2.5, 100, 3, and 110 h for Cases 1-4.1, respectively (Table 3).

Table 3. Estimates of refrigerated microbial shelf-life for meat (h)

Case	Mean-value calculation	Calculations based on Monte Carlo simulations Mean ± standard deviation / [Shelf life estimate, 95% confidence]		
1	3.6	3.9±1.7 / [2.5]		
2	115.9	119.3±17.4 / [100]		
3	4.1	4.6±1.4 / [3]		
4.1	144.8	160.4±40.3 /[110]		
		% lowering of the SD for the corresponding parameter		
	Parameter	10	50	90
4.2	$a_{w\,min}$	160.4±40.0 / [110]	160.4±40.2 / [110]	160.3±40.0 / [110]
4.3	T_{min}	158.3±38.8 / [110]	158.6±38.9 / [110]	157.6±37.4 / [110]
4.4	b_4, b_5	160.7±39.0 / [110]	157.3±32.4 / [115]	154.6±29.7 / [120]
4.5	$CO_{2\,max}$	159.4±38.3 / [110]	155.4±29.4 / [115]	153.6±27.3 / [120]
4.6	all	157.1±33.6 / [115]	149.2±17.9 / [125]	146.1±10.5/ [130]
		% lowering of the SD for the initial microbial load		
		10	50	90
4.7	Log N_o	158.4±39.0 / [110]	159.1±38.8 / [110]	159.2±38.6 / [115]

The influence of parameter variability on the uncertainty of shelf-life estimates for Case 4.1 (160.4±40.3 h) was studied systematically using the same parameter means but with SD lowered by 10, 50, and 90% (Table 3). Lowering the SD for the parameter $a_{w\,min}$ by 10, 50, and 90% resulted in a negligible uncertainty reduction (160.4±40.0, 160.4±40.2, and 160.3±40.0 h, respectively). Lowering the SD for the parameter T_{min} had a moderate effect and the equivalent values were 158.3±38.8, 158.6±38.9, and 157.6±37.4 h. Lowering the SD for the parameters b_4 and b_5 lowered uncertainty more significantly yielding 160.7±39.0, 157.3±32.4, and 154.6±29.7 h, respectively. A similar effect was observed when lowering the SD for $CO_{2\,max}$ yielding 159.4±38.3, 155.4±29.4, and 153.6±27.3 h, respectively. Lowering simultaneously the SD of all

parameters by 10, 50, and 90% yielded shelf-life of 157.1±33.6, 149.2±17.9, and 146.1±10.5 h, respectively, i.e., a much larger reduction in the estimation uncertainty. Finally, the low uncertainty in the shelf-life estimate for Case 1 (*T* as the only factor) suggested that the larger uncertainty for Cases 2-4.6 was not due to the initial microbial load variability but due to the variability in the model parameters. This was confirmed by examining the effect of lowering the microbial load SD by 10, 50, and 90% yielding only a small change from 110 to 115 h in the recommended shelf-life only when the standard deviation was lowered by 90% (Case 4.7).

In conclusion, Monte Carlo procedures are an effective tool to reduce the risk of offering consumers unsafe or spoiled products and allow the exploration for the cause of the uncertainty sources of shelf-life estimates.

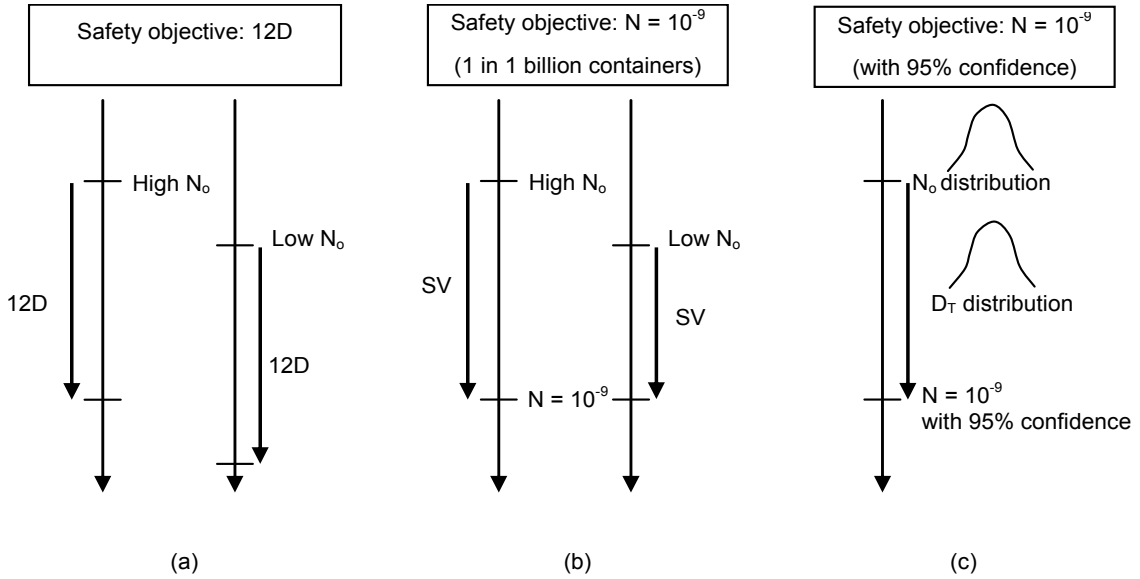

Figure 3. Design of thermal processes. (a) Original objective required the same 12 decimal reduction for all products no matter their initial load; (b) Definition of a process endpoint of 1 spore survival in 1 billion containers encouraged reduction of the initial microbial load; (c) Consideration of the statistical variability in process parameters ensures that food safety is achieved with high statistical confidence.

APPLICATION: UNCERTAINTY OF THERMAL PROCESSING ESTIMATES

Presence of *Clostridium botulinum* spores in low-acid canned foods is a threat to public health and they must be inactivated. The time/temperature combination required to inactivate this and other pathogens must be minimized for product cost and quality reasons (Peck 2006). However, bacterial spores causing spoilage are more heat resistant than those associated with pathogens, and thus calculations are often based on minimizing product spoilage instead of meeting safety risk requirements. In both cases, pathogen or spoilage risk elimination, the calculations begins with the estimation of a processing time at a reference temperature *T* (F_T value) to achieve a desired number of decimal reductions (*SV*) using the decimal reduction time (D_T) required for inactivation of 90% of the target microorganism (Morales-Blancas and Torres

2003a; b; c). Initially, it was required that the minimum process time for low-acid foods be at least sufficient to reduce *C. botulinum* spores by 12 logarithmic cycles (Guldas et al. 2008). This approach did not consider the initial pathogen load (Fig 3a) and thus the *12D* concept evolved into setting the survival probability N (Fig 3b) at 1 in 10^9 containers or less (Toledo 2007). Setting a fixed endpoint encourages a reduction in the initial contamination level (N_o) as it results in a milder process. In addition to cost savings for producers, consumers have benefitted from a higher retention of nutrients and sensory in the final product. More recently (Fig 3c), regulatory agencies have begun to require that the processor considers the variability of the parameters involved in calculations (Stewart et al. 2002) which can be done using a Monte Carlo procedure.

The details of the Monte Carlo procedure to determine the uncertainty of a thermal process highlighting key decisions by the commercial food processor can be obtained from the corresponding authors (Fig 4). In the application example used in this study for a thermal process at 110°C (a temperature chosen based on the availability of published data), the processor must provide (values in parenthesis are the ones used in this study): (1) a thermal process target (*C. botulinum* Type B spores); (2) a safety objective expressed as the probability of finding the target microorganism in the product (1 in 10^9 mushroom cans); and, (3) an acceptable risk level that the actual probability be higher than the specified value (5%).

The calculation process begins with a random number procedure to generate values for N_o and D_T assuming lognormal and normal statistical distributions, respectively. The size of each generated dataset was equal to the number of samples used to determine the reported N_o and D_T

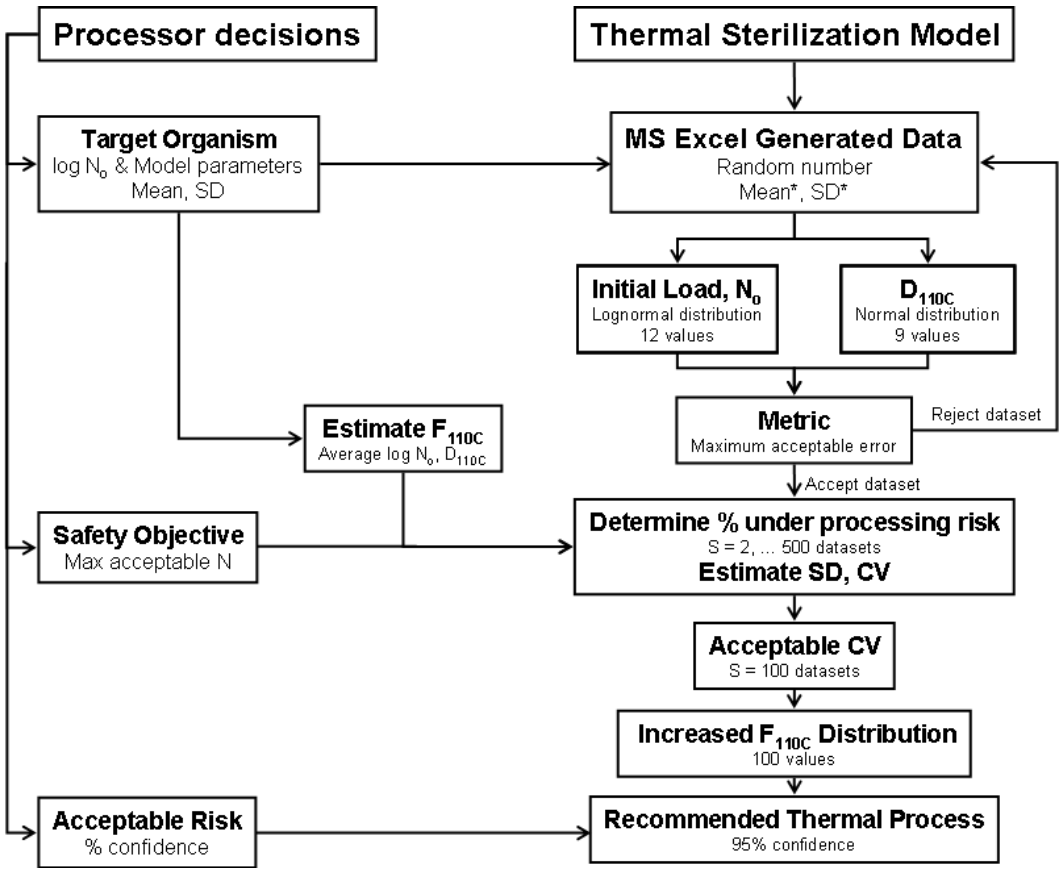

Figure 4. Monte Carlo procedure thermal process including information to be provided by the food processor

values. An important next step, before accepting and using generated data, is to define a metric to identify unacceptable datasets (Chu 2009) based on an acceptable error (in this study, 0.1 min for both D_T and F_T expressions) which can be done as follows:

$$\text{generated } N_o^* = \varepsilon N_o \tag{1}$$

$$F_T^{reported} = SV\,D_T = [\log(\frac{N_o}{N})]D_T = (\log N_o - \log N)D_T \tag{2}$$

$$F_T^{generated} = [\log(\frac{N_o^*}{N})]D_T = \left[\log(\frac{\varepsilon N_o}{N})\right]D_T = (\log\varepsilon + \log N_o - \log N)D_T \tag{3}$$

$$Error = \left|F_T^{reported} - F_T^{generated}\right| \le 0.1 \text{ min} \tag{4}$$

$$Acceptable\ Error = \left|D_T \log\varepsilon\right| \le 0.1 \text{ min} \tag{5}$$

$$\text{generated } D_T^* = \varepsilon D_T \tag{6}$$

$$Acceptable\ Error = \left|D_T - \varepsilon D_T\right| \le 0.1 \tag{7}$$

These acceptable error functions are then used to define a metric determining if the distribution of generated data was similar to the distribution of the data reported in the literature. The metric used based on normalized errors in the mean, minimum and maximum value for N_o and D_T values was defined as follows:

$$metric = \left|\frac{(\mu_o - \mu_o^*)}{\mu_o}\right| f_1 + \left|\frac{(a_o - a_o^*)}{a_o}\right| f_2 + \left|\frac{(z_o - z_o^*)}{z_o}\right| f_3 \tag{8}$$

$$metric = \left|\frac{(\mu_o - \varepsilon\mu_o)}{\mu_o}\right| f_1 + \left|\frac{(a_o - \varepsilon a_o)}{a_o}\right| f_2 + \left|\frac{(z_o - \varepsilon z_o)}{z_o}\right| f_3 \tag{9}$$

$$metric = \left|1 - \varepsilon\right|(f_1 + f_2 + f_3) \tag{10}$$

where (μ_o, a_o, z_o) and (μ^*_o, a^*_o, z^*_o) are the mean, minimum, and maximum values for the reported and generated datasets, respectively, while f_i are subjective importance weight factors. The f_i values used in this study for the mean (1), minimum (0.5), and maximum (2) value gave more importance to the latter. Next, Eq (1) and acceptable errors (ε) for N_o and D_T as determined by Eqs (5 & 7), respectively, were used to determine acceptable metric values.

An initial *C. botulinum* Type B spore load was referred to a typical canned mushroom product size (113.4 g = 4 oz). Based on the spore load information reported by Notermans et al. (1989), the mean and standard deviation values for log N_o used in this study were -1.36 ± 0.87 with minimum -2.83 and maximum 0.08 log spores/container. Using D_T values reported by Odlaug et al. (1978) yielded the following metric inequalities:

$$0 \le metric_{N_o} \le 393.2 \tag{11}$$

$$0 \le metric_{D_{T=110C}} \le 0.45 \quad (12)$$

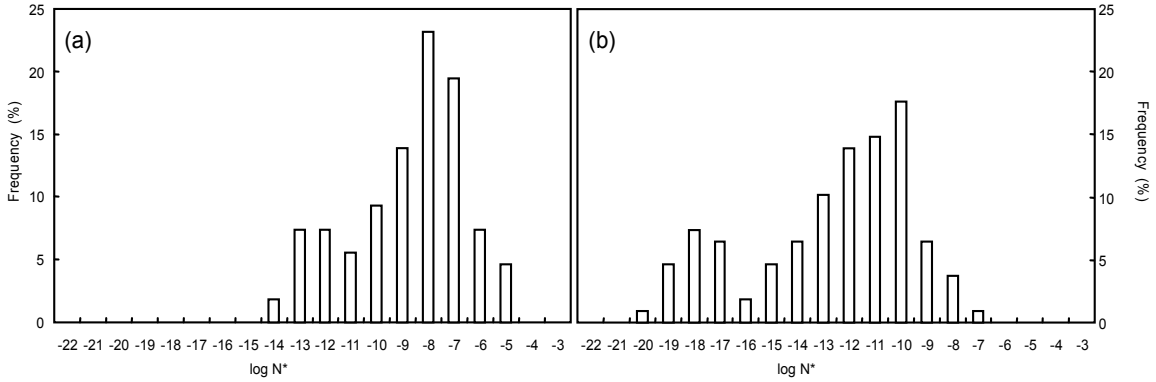

Figure 5. Frequency distribution for *C. botulinum* spore survival (log N*, CFU/container) for one generated N^*_o and D^*_{110C} dataset. (a) Thermal process ($F_{110℃}$ = 5.96 min) based on the reported N_o and $D_{110℃}$ means meeting the process target ($N = 10^{-9}$ spores/container) with 45% confidence; (b) Thermal process time increased ($F_{110℃}$ = 8.89 min) to meet process target ($N = 10^{-9}$ spores/container) with 95% confidence.

These steps were followed to generate N_o^* and D_T^* datasets satisfying the metric. The minimum, mean and maximum number of repetitions needed to find acceptable datasets required to generate 500 approved datasets was 1, 1.98, and 6 for N_o values and 1, 1.3 and 4 for $D_{110℃}$ values, respectively. These low values suggest that the assumption of lognormal and normal distribution for these two parameters respectively, was correct (Pereira 2009). However, the metric test is a necessary but not sufficient test to validate the assumed distribution form for each parameter. Only acceptable generated datasets for N_o^* (12 values each) and D_T^* (9 values each) were used in Monte Carlo simulations. A thermal process calculated using published mean values (Eq.11) and the 500 generated datasets as input parameters were used to generate *log* N^* distributions (9x12 = 108 values) (Eq.12) as in the example shown (Fig 5a).

$$\overline{F_T} = \left(\log \overline{N_o} - \log N\right)\overline{D_T}; \quad \overline{N_o}, \overline{D_T} = reported\ means \quad (11)$$

$$\log N^* = \log N_o^* - \frac{\overline{F_T}}{D_T^*}; \quad N_o^*, D_T^* = generated\ value \quad (12)$$

A Monte Carlo analysis disadvantage is that many simulations are needed to achieve an acceptable accuracy level (Floschet et al. 2003). An underprocessing % value was estimated for each unique combination of the 500 N_o^* and D_T^* datasets to determine a recommended number of generated datasets. The coefficient of variation (*CV*, Eqs 13-14) for s = 2, 3…, S = 500 underprocessing % values (Almonacid-Merino and Torres 2010) decreased rapidly until reaching s = 100 (Fig 6) and was the dataset size used.

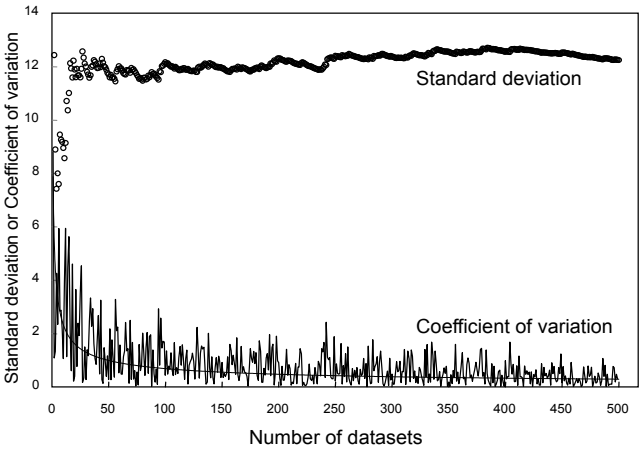

Figure 6. Recommended number of simulations

$$\overline{\mu_S^*} = \sum_{i=1}^{n=S} \frac{x_i^*}{S} \tag{13}$$

$$CV = \left[\sum_{i=1}^{n=S} \frac{\left(x_i^* - \overline{\mu_S^*}\right)^2}{S} \right]^{1/2} \tag{14}$$

Determination of a process time considering parameter variability

During industrial food production, process parameters such as microbial loads are highly variable (Corradini et al. 2001). In addition, the benefits of efforts to lower the variability of the thermal inactivation parameters obtained in laboratory experiments must be assessed. Knowledge of the variability of generated N_o^* and D_T^* values was used to estimate a thermal process time required (F^r) to reach 10^{-9} spores/container with a 95% confidence. The same dataset selected previously as an example was used to demonstrate that increasing thermal processing time from 5.96 min to 8.89 min increased the probability of meeting the spore load target from 45 to 95% (Fig 4). The same process repeated for 100 generated datasets as recommended to obtain reliable results, yielded a frequency distribution of thermal processing times meeting the desired inactivation of bacterial spores. This resulted in 9.6 min as the recommended processing time yielding the desired inactivation level with 95% confidence (Fig 7a, Table 4).

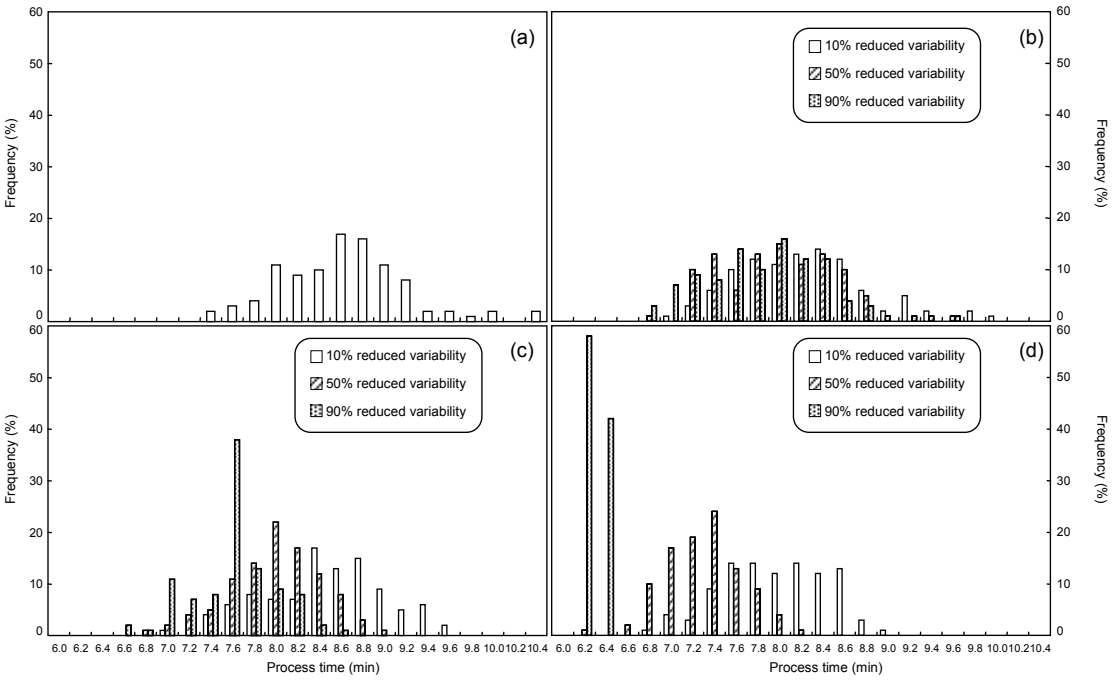

Figure 7. Effect of lowering the standard deviation (SD) of the calculation parameters by 10, 50 and 90% on the frequency distribution of the processing time required to meet with 95% confidence the desired inactivation level, i.e., 10^{-9} spores/container. (a) Based on the original SD for N_o and D_T; (b) Lowering the SD for N_o (c) Lowering the SD for D_T; (d) Lowering the SD for both N_o and D_T.

Benefits of reducing parameter variability in thermal process estimations

Considering parameter variability in food process calculations as required by the new public health regulations will increase the degradation of nutrients and product quality. Processors will have to find means to lower process time as much as possible. An approach explored in this study was to assess the impact of efforts to lower the variability in N_o and D_T values (Table 4).

Lowering the SD of N_o, $D_{110℃}$, and of both simultaneously by 10, 50, and 90% resulted in tighter distributions of thermal process times to reach the desired inactivation level (Fig 7) and thus shorter processing time (Table 4). The recommended thermal process time yielding a safe process with 95% confidence was 9.6 min before lowering variability. The effect of lowering the SD for N_o by 10, 50, and 90% resulted in recommended processes of 9.2, 8.8, and 8.6 min, respectively, while lowering the SD for D_T values the equivalent values would be 9.4, 8.6, and 8.2 min. Lowering the SD for both N_o and D_T yielded a 95% confidence process of 8.6, 7.8, and 6.4 min, respectively. The latter value (6.4 min) is not very different from the value calculated based on reported mean values and resulting in a 55% risk of under processing (5.96 min).

Table 4. Effect of the prevalence of *Clostridium botulinum* (N_o) Type B spores[(1)] and their decimal reduction time[(2)] (D_{110C}) on the thermal processing time for canned mushrooms required to reach the desired inactivation level (10^{-9} spores/container). Calculations based on the recommended number of 100 generated datasets.

(a) Standard deviation reduction (mean ± SD)

Parameter	0%	10%	50%	90%
log N_o	-1.36 ± 0.87[(1)]	-1.36 ± 0.78	-1.36 ± 0.44	-1.36 ± 0.09
D_T	0.78 ± 0.17[(2)]	0.78 ± 0.153	0.78 ± 0.085	0.78 ± 0.017

(b) Process time to produce safe food with > 95% confidence (min)

log N_o		9.2	8.8	8.6
D_T	9.6	9.4	8.6	8.2
Both		8.6	7.8	6.4

(1) Notermans and others (1989); (2) Odlaug and others (1978)

CONCLUSIONS

The estimation procedures presented in this work focused on the uncertainty of shelf-life and thermal process time estimations emphasized the importance of minimizing the variability of the input parameters used. Variability represents either an imperfect knowledge of the parameter value which can be reduced by improved measurements, or the true heterogeneity of the population that is a consequence of the physical system (Akterian et al. 1999; Nauta 2000; 2002). If the sources of the variability are the measurements, it can be lowered by technical training,

improvement of analytical methods, and changes to the experimental design used to obtain them (e.g., additional replications). If the variability source is population heterogeneity, it is irreducible by measurement improvements and thus the source of this heterogeneity must be found.

Knowing and reducing the source of product heterogeneity would have practical applications. For example, large processors work with many suppliers and thus a large heterogeneity in raw materials can be expected. The heterogeneity reflects differences in the production, storage, and transport conditions of raw materials. While those failing to meet the processor specification will be rejected, the remaining raw materials can be segregated into "excellent", "acceptable," and "needs attention" groups. If the specification is the microbial load, products with different contamination levels should be processed differently. In the case of shelf-life, the resulting product could be labeled with different product expiration dates. If the raw materials are thermally processed, this would allow reducing processing time because higher quality supplies will have lower initial microbial load mean (N_o) and all groups will have a lower SD.

In the case of the data on decimal reduction time (D_T), large SD values could result from the aggregation of experimental determinations for other similar products. The recommendation could be to determine this parameter in the specific product to be thermally processed. Since this recommendation would generate costs to the processor, it is important to evaluate the impact on the recommended thermal process time achieved by reducing process uncertainty and variability.

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