Introducing the concept of critical Fo in batch heat processing

Introduzindo o conceito de Fo crítico no processamento térmico em batelada

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Resumo

A determinação do valor de esterilização de alimentos de baixa acidez em autoclaves compreende uma minuciosa avaliação das instalações e utilidades da fábrica, uma validação do equipamento de processo térmico (através de ensaios de distribuição de calor) e, finalmente, ensaios de penetração de calor no produto. A intensidade do processo térmico aplicado ao alimento pode ser expressa pelo valor de Fo (valor de esterilização, em minutos, para uma temperatura de referência de 121,1 °C e índice térmico, z, de 10 °C, para esporos de *Clostridium botulinum*). Com frequência, por questões de segurança, é adotado o valor mais baixo de Fo, obtido nos ensaios de penetração de calor, como indicativo da intensidade mínima do processo aplicado. Este valor mais baixo de Fo deve ser sempre maior que o Fo mínimo recomendado para o alimento em questão. Porém, a utilização do valor de Fo da lata mais fria não explica estatisticamente todas as ocorrências práticas nos processos de tratamento térmicos em alimentos. Procurou-se desenvolver um novo enfoque para determinação do valor do Fo mais baixo, que passa a ser chamado de Fo crítico. O Fo crítico é baseado num modelo estatístico para interpretação dos resultados dos ensaios de penetração de calor em embalagens e depende não só dos valores de Fo obtidos no ponto mais frio da embalagem e no ponto mais frio do equipamento mas também do tamanho do lote de embalagens processado na autoclave, do tempo total de processo na autoclave e do tempo entre CIP (*Cleaning in Plant*) da autoclave. Neste trabalho procura-se explorar os resultados de medidas físicas utilizadas na validação de processos térmicos de alimentos. Para ilustrar a metodologia desenvolvida e introduzir o conceito de Fo crítico no processamento de conservas, foram preparados três exemplos de cálculo.

Palavras-chave: *Fo; processamento térmico; conservas; segurança alimentar.*

Abstract

The determination of the sterilization value for low acid foods in retorts includes a critical evaluation of the factory's facilities and utilities, validation of the heat processing equipment (by heat distribution assays), and finally heat penetration assays with the product. The intensity of the heat process applied to the food can be expressed by the Fo value (sterilization value, in minutes, at a reference temperature of 121.1 °C, and a thermal index, z, of 10 °C, for *Clostridium botulinum* spores). For safety reasons, the lowest value for Fo is frequently adopted, being obtained in heat penetration assays as indicative of the minimum process intensity applied. This lowest Fo value should always be higher than the minimum Fo recommended for the food in question. However, the use of the Fo value for the coldest can fail to statistically explain all the practical occurrences in food heat treatment processes. Thus, as a result of intense experimental work, we aimed to develop a new focus to determine the lowest Fo value, which we renamed the critical Fo. The critical Fo is based on a statistical model for the interpretation of the results of heat penetration assays in packages, and it depends not only on the Fo values found at the coldest point of the package and the coldest point of the equipment, but also on the size of the batch of packages processed in the retort, the total processing time in the retort, and the time between CIPs of the retort. In the present study, we tried to explore the results of physical measurements used in the validation of food heat processes. Three examples of calculations were prepared to illustrate the methodology developed and to introduce the concept of critical Fo for the processing of canned food.

Keywords: *Fo value; heat process; canned foods.*

1 Introduction

The temperature profiles at the critical points of individual packages are rarely the same when submitted to sterilizing heat processes. Even though, the processes are carefully carried out and repeated, differences in the Fo values are attributed to various factors, such as: positioning of the thermocouples on the package; differences in the responses of the thermocouples; calibrations and checking of the sensors; differences in the convection pathways, in special foods in a liquid medium; differences in particle thickness; deformation of flexible packages; presence of air in the packages (mainly in the case of flexible packages); variable headspace in rigid packages; faults in the temperature acquisition equipment during the heat penetration assays; faults in positioning the products on the thermocouples (mainly for specific foods that could

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become loose during the process); decrease or increase in heat transfer due to the privileged position that some packages must assume to carry out the heat penetration assays, oscillation of the counter pressure during cooling (causing damage to the package); differences in size and mass in the packages (as, for example, with tuna fish pieces packaged under vacuum); and non-homogenous initial temperatures of the packages.

In the heat penetration assays, the "coldest points" of the packages are always the target, with the objective of working with the most critical condition of the process. The "worst cases" of transient heat transfer are always studied since the objective of heat penetration assays is to find the lowest values for sterilization. The process engineer should work to exclude all and any possibilities of error that might cause an increase in the variance of the physical measurements of temperature. Thus, all variance found in the measurements would be exclusively attributable to the process of heat transference in the package during batch heat processing.

Despite all such care, variations in the temperature profiles always occur during heat penetration trials, even in adequately constructed and operated steam retorts (BOCK, 1973).

Stumbo (1973) considered a minimum Fo value of 3.00 as the process target. This value, based on the heat resistance of *C. botulinum* spores, would be capable of destroying at least 12 decimal reductions of this microorganism. Stumbo did not consider the size of the batch of packages nor the retort process capacity.

On the other hand, Pflug (1987) defined a concept of "the probability of finding a non-sterilized package" (PUNE) in terms of the calculation of the minimum sterilization value. The author used the results of the initial spore counts of the microorganisms (No), reference temperature (Tr), and thermal index (z), and with these results he developed a calculation method for the sterilization value based on PUNE. Thus PUNE can be expressed as 1/(batch of packages).

Our study premises, (3) were based on Varga et al. (2000a) for simulations of retort processes. According to Varga et al. (2000a), the sterilization value shows gamma distribution (not a normal distribution). A normal distribution presupposes no extreme limits, that is, the random variable, in this case Fo, varies from $-\infty$ to $+\infty$, which is not the case, since Fo is limited by zero to the left. The gamma function is limited to the left, corroborating this observation. For the same level of significance, the value of the ordinate of the gamma probability distribution function would be smaller than that of a normal probability distribution function. Varga et al. (2000a), concluded that the sterilization values for 211 × 304 and 307 × 113 cans (British measurements) were more affected by three factors: initial package temperature, the external heat transfer coefficient, and processing time. The effect of the headspace on Fo was negligible.

2 Materials and methods

2.1 Statistical approach

The whole model developed in the present study was restricted to three premises:

1) Batch processes, that is, non-continuous sterilization;
2) Sampling representative of the process and non-addictive; and
3) The distribution of Fo in the processed packages given by Fo~Gama (α, β).

The three premises were reviewed as from the sampling plan study with continuous random variables according to Cochran (1963) and Varga et al. (2000a).

Premise 1) restricts the procedure to batch-type processing retorts. Premise 2) essentially requires two special points:

1) The arrangement of the sample packages containing the previously processed food must be identical to that used in the industrial process, and the thermocouple must be fixed to the package according to IFTPS (2004b).
2) The packages must be distributed in the retort in the coldest region, as specified by IFTPS (2004a) and (2004c).

Equation (1), according to Winer (1971), describes the gamma probability distribution function.

$$Gama(\alpha, p, x) = \frac{\alpha^{p}.\, e^{-\alpha x}.\, x^{p-1}}{\Gamma(\alpha)} \alpha, p, x > 0 \quad (1)$$

where the parameters are:

$$\alpha = \frac{p}{\mu} = \frac{\mu}{\sigma^2}$$

$$p = \sigma^2.\, \alpha^2 = \frac{\mu^2}{\sigma^2}$$

σ^2 = population variance; and

μ = population mean.

$$\Gamma(\alpha) = \int_0^{+\infty} t^{\alpha-1}.\, e^{t}\, dt$$

The estimators for gamma function parameters are:

$$\hat{a} = \frac{\overline{x}}{s^2}$$

$$\hat{p} = \frac{\overline{x}^2}{s^2}$$

where,

s^2 = sample variance; and

$\overline{x}$ = sample mean.

The chi-squared distribution is a special case of gamma distribution, in which the parameters are α = ½ and p = k/2. The parameter k represents the degrees of freedom of the chi-squared distribution (WINER, 1971). The function of density corresponding to the special case of gamma function is described as follows Equation (2):

$$\chi^2(k) = Gama\left(\frac{1}{2}, \frac{k}{2}\right) k \in Z^+ \quad (2)$$

The expression "sterilization value", symbolized by Fo (Tr = 121.1 °C and z = 10 °C), was used in the present study, but the reader can adjust the equations described to make them adequate to apply to other sterilization values or even to pasteurization.

2.2 Calculation of the critical Fo

The analytical methodology described in this study consisted of calculating the critical Fo using the results of heat penetration assays in packages, the size of the batch of packages processed in each retort, the total processing time in the retort, and the time between CIP treatments of the retort. The value for critical Fo was only calculated after proving the sample variance hypothesis test. The hypothesis test evaluates whether the sample variance belonged to the region of acceptance within the maximum and minimum limits of variance. The critical Fo values were so called, since they were calculated using the maximum variance sampled.

The methodology was divided into 5 steps:

1) Preliminary calculations;

2) Variance hypothesis test;

3) Critical Fo;

4) Calculation of the minimum Fo; and

5) Criteria for decisions.

The calculation of the minimum Fo, based on Stumbo (1973) and Pflug (1987), was not part of the calculations for the critical Fo, but it was important to decide whether the heat process guaranteed food safety. Thus, this procedure was included in the fourth step (the calculation of the minimum Fo).

2.3 Preliminary calculations

The probability of failure or the probability of a contaminated package in a processed batch was calculated using Equation (3).

$$p = \frac{1}{N} \quad (3)$$

where,

N (capital) was the total number of packages processed per batch in the retort (retort load).

Equation (3) calculates the probability of finding a sub-processed package in a processed batch with N packages.

2.4 Variance hypothesis test

Like the mean sterilization value, the sample variance is a function of the sample. For this reason, the result of the variance was evaluated. In this test, the variance value was compared as a function of the Fo value (lower) with the maximum and minimum limits of variance.

The variance hypothesis test is given by

Ho: $\sigma^2 = s^2$, the variances are statistically the same.

H1: $\sigma^2 \neq s^2$, the variances are statistically different.

In the present study, the same test was carried out to evaluate the hypotheses:

Ho: $\sigma^2 = s^2_{(lowest\ Fo)}$, the variances (population, σ^2, and that calculated as a function of the lower Fo value) are statistically the same.

H1: $\sigma^2 \neq s^2_{(lowest\ Fo)}$, the variances are statistically different.

The comparison was made using the confidence interval calculated in Equation (4):

$$P[s^2(lower\ limit) \leq s^2(lowest\ Fo) \leq s^2(upper\ limit)] = 1 - \delta \quad (4)$$

where,

$s^2_{(lower\ limit)}$ = the lower variance limit, according to Equation (13);

$s^2_{(lowest\ Fo)}$ = the variance as a function of the lowest Fo, according to Equation (14);

$s^2_{(upper\ limit)}$ = the upper variance limit, according to Equation (11);

δ = the level of significance, according to Equation (6); and

Equation (4) was rewritten in more detail, as shown in Equation (5).

$$P\left\{\left[(n-1)\cdot s^2 / \chi^2_{sup}\right] \leq s^2_{(lowest\ Fo)} \leq \left[(n-1)\cdot s^2 / \chi^2_{inf}\right]\right\} = 1 - \delta \quad (5)$$

where,

$\chi^2_{sup} = \chi^2_{(\delta/2,n-1)}$ was the upper limit of the chi-squared distribution function;

$\chi^2_{inf} = \chi^2_{(1-\delta/2,n-1)}$ was the lower limit of the chi-squared distribution function;

s^2 = the sample variance, calculated according to Equation (8);

$s^2_{(lowest\ Fo)}$ = the lowest variance observed for Fo, calculated according to Equation (14);

n = the number of samples (packages); and

δ = the level of significance, according to Equation (6).

The level of significance, δ, was dimensioned to express the true functioning of the retort. Equation (6) calculates the probability of failure in the retort processes.

$$\delta = \frac{1}{[(1/\text{process time}) \times \text{number of work days between retort CIP procedures} + 1]} \quad (6)$$

The levels of significance (δ) were calculated considering the following two factors:

1) The process time in the retort (BOCK, 1973), and

2) The number of work days between retort CIP procedures.

3) The process time was the sum of the times to load the baskets; the come up time; the process time; the cooling time (when done in the actual retort); and the time to unload the baskets (including depressurization and drainage if cooling was not done in the actual retort).

With the objective of excluding any possible failure, still within the work time in question, the factor "1" was included, added to the retort processes in Equation (6).

In general, companies adopt a period consisting of 3 shifts, each of eight working hours. This is the reason for the use of a 24–hour workday in Equation (6).

The level of significance, δ, allowed for a resolution for the hypothesis test to be established according to the individual need of each industrial case, without generalizations.

The mean for the Fo heat processing values was calculated according to Equation (7).

$$\bar{F}o = \frac{\sum_{i=1}^{n} Fo_i}{n} \quad (7)$$

where,

Fo_i = the values for heat processing of each of the packages monitored; and

n = (small letter) the number of packages analyzed.

The sample variance, s^2, for the sterilization values measured in the heat processing assays was calculated according to Equation (8):

$$s^2 = \frac{\left[\sum Fo_i^2 - \frac{\left(\sum Fo_i\right)^2}{n}\right]}{(n-1)} \quad (8)$$

The hypothesis Ho (equal variances) can be accepted when the value for $s^2_{(\text{lowest Fo})}$ is limited to the interval of confidence. On the other hand, it is rejected when the value for $s^2_{(\text{lowest Fo})}$ is out of the interval of confidence Equation (9).

$$\beta = \frac{s^2}{Fo} \quad (9)$$

The lowest chi-squared value was calculated according to Equation (10) presented in both the theoretical and practical forms using the implicit function of MS-Excel.

$$\chi^2_{\text{inf}} = \chi^2_{(1-\delta/2,\, n-1)} = \text{"} = \text{INV.QUI}(1-\delta/2; n-1)\text{"} \quad (10)$$

The value for $s^2_{(\text{upper limit})}$ was calculated using Equation (11).

$$s^2_{(\text{upper limit})} = \frac{(n-1)\cdot s^2}{\chi^2_{\text{inf}}} \quad (11)$$

Similarly, the upper chi-squared value was calculated using Equation (12). The upper variance limit was calculated from the lower chi-squared value and the lower limit was calculated from the upper chi-squared values. Similar to what was described in Equation (10), Equation (12) can be presented in its theoretical and practical forms using the implicit function of MS-Excel.

$$\chi^2_{\text{sup}} = \chi^2_{(\delta/2, n-1)} = \text{"} = \text{INV.QUI}(\delta/2; n-1)\text{"} \quad (12)$$

The value for $s^2_{(\text{lower limit})}$ was calculated using Equation (13).

$$s^2_{(\text{lower limit})} = \frac{(n-1)\cdot s^2}{\chi^2_{\text{sup}}} \quad (13)$$

The value for $s^2_{(\text{lowest Fo})}$ was calculated using Equation (14).

$$s^2_{(\text{lowest } Fo)} = F_{0\,lower} \cdot \beta \quad (14)$$

Where the lowest value for Fo was the lowest value of Fo sampled.

2.5 The critical Fo

The value for the critical Fo was calculated according to Equation (15), using the inverse function of the gamma function. The right hand side of Equation (15) is the form of the function when written by MS-Excel®.

$$Fo_{(critical)} = G^{-1}(p, \alpha, \beta)\cdot c \text{ "= INVGAMA(p,}\alpha,\beta)*\text{c"} \quad (15)$$

where:

p = the probability of failure calculated according to Equation (3); and

c = the correction for sample size according to Equation (18).

The estimator for parameter α was calculated according to Equation (16).

$$\alpha = \frac{\bar{F}o^2}{s^2_{(\text{upper limit})}} \quad (16)$$

where,

$\bar{F}o$ = calculated according to Equation (7); and

$s^2_{(\text{upper limit})}$ = calculated according to Equation (11).

The estimator for parameter β was calculated according to Equation (17).

$$\beta = \frac{s^2_{(\text{upper limit})}}{\bar{F}o} \quad (17)$$

where,

$\bar{F}o$ = calculated according to Equation (7); and

$s^2_{(\text{upper limit})}$ = calculated according to Equation (11).

Both Equations (9) and (17) calculated the value of the parameter β, but with numerically different results, dependent on each step of the calculation.

The sample size correction for small samples was calculated according to Equation (18), where n is the number of packages monitored by thermocouples:

$$c = \sqrt{\frac{(N-n)}{(N-1)}} \quad (18)$$

Sample size correction is recommended when the sample is significantly larger if compared to the batch of packages processed in the Cochran retort (1963).

2.6 Calculation of the minimum Fo

The sterilization value necessary or required to garantee a determined food was calculated based on Stumbo (1973) and Pflug (1987).

Equation (19) was applied to calculate the initial contamination inside each package (VANDERZANT; SPLITTSTOESSER, 1992).

$$C_o = N_o.CC \quad (19)$$

where,

C_o = the initial food contamination level (CFU.g^{-1}) colony forming units/g;

N_o = total initial microbiological count in the food (CFU.g^{-1}) of the process target microorganism; and

CC = the package capacity (g).

The final concentration, C_F was considered to be a function of two variables: the probability of failure, p, and the package capacity, CC. Thus, in Equation (20), the final concentration was expressed in CFU and the contamination volume corrected as a function of product mass.

$$C_F = \frac{p}{CC} \quad (20)$$

p = is the probability of finding a contaminated package in the batch processed, according to Equation (3).

When processing low acid foods with a high risk of initial contamination, the value for p can be divided by ten in Equation (3), in other words, expressing 0.1 sub-processed packages in N processed packages. In this way, the minimum Fo required increases and the process guarantees the complete safety of the processed batch.

Equation (21) was applied to calculate the number of decimal reductions required to guarantee only one contaminated package per processed batch.

$$\gamma = \log(C_o) - \log(C_F) \quad (21)$$

where,

C_o = the initial food contamination level, calculated according to Equation (19).

Finally, Equation (22) was used to calculate the minimum sterilization value required.

$$F_{o(\text{minimum})} = \gamma \cdot D_{Tr} \quad (22)$$

where,

γ = the number of decimal reductions calculated according to Equation (21), non-dimensional; and

D_{Tr} = the time required for the target microbial population to be reduced 10 times (minutes). D_{Tr} should be chosen under the same conditions as the food in question (pH, salt, sugar, fat, curing agents, and sodium nitrite concentrations, and Aw). The value for D_{Tr} is always associated with the reference temperature, Tr. In the present study, *C. botulinum* spores were used as the process microbiological target and their value for $D_{121.1°C}$ equal to 0.21 minutes (STUMBO, 1973).

2.7 Criteria for decisions

In the preliminary calculations, the levels of significance (α) were calculated considering the number of packages processed per retort (or batch) and the correction factor c according to Equations (3) and (18).

The variance hypothesis test was carried out according to Equations (6) to (14). The hypothesis Ho (equal variances) was accepted when the value for $s^2_{(\text{lowest Fo})}$ (Equation 14) was limited to the interval of confidence (Equations 4 and 5). On the other hand, the Ho hypothesis was rejected when the value for $s^2_{(\text{lowest Fo})}$ was outside the interval of confidence. In such a case, the following corrective measures are suggested:

1) Increase the number of samples;
2) Exclude doubtful results as a function, for example, of the loss of vacuum or significant difference in vacuum in some packages before and after the process;
3) Maintain the initial package temperatures homogenous;
4) Check the fixture of the thermocouples on the packages containing product and the distribution of the packages in the basket;
5) In the case of flexible packages, check the counter pressure and the fixing of the thermocouples;
6) Check for failure in the readings of the thermocouples;

7) Check for leaky packages (check the mass before and after the assays); and

8) In the cases where the null hypothesis (Ho) was rejected, the critical Fo was calculated according to Equations (15) and (17). The minimum Fo was calculated in order to compare it with the critical Fo, according to Equations (19) to (22). The results obtained for the values of the critical Fo for each of the processes were judiciously analyzed.

2.8 Heat processes selected

Three examples were chosen for the calculations using real data. The first was a vegetable mix (potato, carrot, runner beans, corn, and peas) in brine in 270 g cans, with no headspace and processed in a vertical steam retort. The second product consisted of 350 g portions of lasagna in plastic trays, and the third of 35 g portions of bolognaise sauce in flexible pouches. The last two products were processed in a retort with a hot water spray and air counter pressure. In the three cases, the heat penetration assays were carried out after a judicious evaluation of the heat processing installations, heat distribution assays and selection of the cold points of the retorts according to IFTPS (2004a).

In the three cases, an initial contamination, No, of 10^6 CFU.g^{-1} was considered, which is a very high initial contamination for a recently filled product. However, this was applied due to the characteristics of the industrial processes in food conserve factories, involving, amongst other factors, process safety and cooking of the product.

The readings of the heat processing temperatures (thermal history) were carried out using a device consisting of 16 cables with needle-type thermocouples with T type, data acquisition apparatus, and the model TM 9616 *E-Val*™ Ver 2.00 ELLAB A/S *Krondalvej* 9, *DK-2610 Roedovre* software (Denmark) connected to a PC compatible computer. The whole system was grounded and previously calibrated with a reliable standard. The thermocouples used with packages containing foods with convective heat exchange characteristics were installed at 1/3 of their internal height. The thermocouples used with packages containing foods with conductive heat exchange characteristics (trays) were installed in the geometric center.

Finally the calculation of the critical Fo values was introduced using the data published by Varga et al. (2000b). In the original publication, Vargas et al. (2000b) did not specify the retort capacity nor the time between CIP treatments (probably because they were using a test equipment on a pilot plant scale), and thus, in the present study, the values N = 200 and time between CIP treatments of 7 days were arbitrarily adopted.

3 Results and discussion

3.1 Vegetable mix example

Table 1 shows the results for the heat penetration assays in cans (211 × 304, British measurements) containing the vegetable mix. The first column (i) shows the numbers of the packages monitored, and the second column the respective Fo values (minute). The third column shows the steps of the calculation procedure, the fourth column shows the names of all the calculation variables, the fifth column shows the numerical results, the sixth column shows the units of each of the results and finally, in the seventh column, the equations used.

In the first step (preliminary calculations), it was shown that the processing capacity of the retort was for 1944 cans per batch. Eight test cans were used (n = 8) in the heat penetration assay. The values for p and c were calculated. The second step was the variance hypothesis test. Each batch was done in 1.2 hours. The time between CIP treatments was 7 days, that is, the retort worked 7 days without interruption for maintenance nor conference. The technicians checked the retort sensors and valves once a week. The level of significance for the variance hypothesis test was 0.71%. The following parameters were calculated: δ, $\bar{F}o$, Fo (lowest), s^2, X^2_{lower}, X^2_{upper}, s^2 (lower limit), s^2 (lowest Fo) and s^2 (upper limit). The hypothesis test resulted in the non-rejection of the Ho hypothesis, that is, the population variance could be the variance for the lowest Fo established. The non-rejection of the Ho hypothesis allowed for the calculation of the critical Fo using the variance at the upper limit since there was statistical correspondence for this. In the third step, the critical Fo value was calculated, and was found to be 19.46 minutes. Step 4 shows the calculations for the minimum Fo required for the process. The value found was 2.972 minutes, considering an initial count of 10^6 CFU.g^{-1} of food. Thus the critical Fo was greater than the required minimal Fo and the process time guaranteed the safety of the food.

3.2 Example of lasagna on a tray

Table 2 shows the results for the heat penetration assays with 350 g portions of lasagna in trays. Similar to Table 1, the packages monitored in the heat penetration assays are numbered in the first column (i), and their respective Fo values (min) shown in the second column. The steps of the calculation procedure are shown in the third column, and the names of each of the variables in the calculation are shown in the fourth column. The numerical results are shown in the fifth column and the units for each of the results in the sixth column. Finally, the equations used are shown in the seventh column.

In the first step (preliminary calculations) the processing capacity of the retort was 4800 per batch. Fourteen cans (n = 14) were used in the heat penetration assay and the values for p and c calculated. The second step was the variance hypothesis step. Each batch took 2:00 hours and the time between CIPs was 7 days, that is, the retort functioned for 7 days without interruptions for maintenance or conference. The technicians checked the retort sensors and valves once a week. The level of significance in the variance hypothesis test was 1.18%. The values for δ, $\bar{F}o$, Fo (lowest), s^2, X^2_{lower}, X^2_{upper}, s^2 (lower limit), s^2 (Fo (minimum)),

and s^2 (upper limit) were calculated. The hypothesis test resulted in the non-rejection of the Ho hypothesis, that is, the population variance can be the variance for the lowest Fo established. The non-rejection of the Ho hypothesis allowed for the calculation of the critical Fo using the variance of the upper limit, since there was adequate statistical correspondence for this. In the third and last steps, the critical Fo was calculated and was found to have a value of 3.89 minutes. Step 4 shows the calculations and results for the value of the required minimum Fo, in this case found to be 3.102, considering an initial count of 10^6 CFU.g^{-1} food. Thus, since the critical Fo was greater than the required Fo, it was concluded that the heat process guaranteed the safety of the food process.

3.3 Example of bolognaise sauce

Table 3 shows the results for the heat penetration assays in 350 g portions of bolognaise sauce in pouches. Similar to Tables 1 and 2, the packages monitored in the heat penetration assays are shown in the first column (i), and their respective Fo values (minute) are shown in the second column. The steps of the calculation procedure are shown in the third column, and the names of each one of the variables in the calculation are shown in the fourth column. The numerical results are shown in the fifth column and the units for each of the results in the sixth column. Finally, the equations used are shown in the seventh column.

In the preliminary calculations, the processing capacity of the retort was for 3360 pouches per batch. Fourteen pouches (n = 14) were used in the heat penetration assay and the values for p and c calculated. The second step was the variance hypothesis step. Each batch took 2:00 hours and the time between CIPs was 7 days, that is, the retort functioned for 7 days without interruptions for maintenance or conference. The instrumentation technicians checked the retort sensors and valves once a week. The level of significance in the variance hypothesis test was 1.18%. The values for δ, $\bar{F}o$, Fo (lowest), s^2, X^2_{lower}, X^2_{upper}, s^2 (lower limit), s^2 (Fo (lowest)) and s^2 (upper limit) were calculated. The hypothesis test resulted in the rejection of the Ho hypothesis, that is, the population variance could

Table 1. Data & results for the calculation of the critical Fo for the canned vegetable mix.

i	Fo_i	Step	Calculation procedure			
1	26.63	1)	Preliminary calculations			
2	26.64		N	1944	Package	
3	26.66		n	8	Package	
4	27.04		p	0.000514	(–)	Equation (3)
5	27.81		c	0.998197	(–)	Equation (18)
6	27.99	2)	Variance hypothesis test			
7	28.34		Process time	1.2	(h)	
8	29.26		Time between CIPs	7	(days)	
			δ	0.71%	(–)	Equation (6)
			$\bar{F}o$	27.55	minute	Equation (7)
			Fo (lowest)	26.63	minute	Minimum (Fo)
			s^2	0.93	$minute^2$	Equation (8)
			$\beta = s^2/\bar{F}o$	0.034	minute	Equation (9)
			X^2lowest	0.89	(–)	Equation (10)
			X^2highest	21.16	(–)	Equation (12)
			s^2 (lower limit)	0.31	$minute^2$	Equation (13)
			s^2 (Fo(lowest))	0.90	$minute^2$	Equation (14)
			s^2 (upper limit)	7.37	$minute^2$	Equation (11)
			Result	Accept Ho		
		3)	Calculation of critical Fo			
			$\alpha = \bar{F}o^2/s^2$(upper)	102.951	(–)	Equation (16)
			$\beta = s^2$(upper)$/\bar{F}o$	0.268	minute	Equation (17)
			Fo (critical)	19.46	minute	Equation (15)
		4)	D_{Tr}	0.21	minute	Reference
			No	1.00×10^6	CFU.g^{-1}	–
			CC	270	G	–
			Co	2.70×10^8	CFU	Equation (19)
			C_F	1.91×10^{-6}	CFU	Equation (20)
			γ	14.15	(–)	Equation (21)
			Fo (required)	2.972	minute	Equation (22)

Table 2. Data & results of the calculation for the lasagna in trays

i	Fo_i	Step	Calculation procedure			
1	7.97	1)	Preliminary calculations			
2	8.48		N	4800	Package	
3	9.00		n	14	Package	
4	9.01		p	0.000208333	(–)	Equation (3)
5	9.04		c	0.998644633	(–)	Equation (18)
6	9.20	2)	Variance hypothesis test			
7	9.29		Process time	2	(h)	
8	9.79		Time between CIPs	7	(days)	
9	10.22		δ	1.18%	(–)	Equation (6)
10	10.31		$\overline{Fo}$	9.81	minute	Equation (7)
11	10.48		Fo (lowest)	7.97	minute	Minimum (Fo)
12	11.46		s^2	1.35	$minute^2$	Equation (8)
13	11.54		$\beta = s^2/\overline{Fo}$	0.137	minute	Equation (9)
14	11.61		X^2lower	3.68	(–)	Equation (10)
			X^2upper	29.33	(–)	Equation (11)
			s^2 (Lower limit)	0.60	$minute^2$	Equation (13)
			s^2 (Fo(lowest))	1.09	$minute^2$	Equation (14)
			s^2 (Upper limit)	4.76	$minute^2$	Equation (11)
			Result	Accepted Ho		
		3)	Calculation of critical Fo			
			$\alpha = \overline{Fo}^2/s^2$(upper)	(–)		Equation (16)
			$\beta = s^2$(upper)$/\overline{Fo}$	minute		Equation (17)
			Critical Fo	minute		Equation (15)
		4)	D_{Tr}	minute		Reference
			No	$CFU.g^{-1}$		–
			CC	G		–
			Co	CFU		Equation (19)
			C_F			Equation (20)
			γ			Equation (21)
			Fo (required)			Equation (22)

not be the variance for the lowest Fo established. There was no statistical correspondence for the critical Fo, however, with the objective of illustrating the results, the critical Fo was calculated (step 4 of Table 3) and the required minimum Fo.

This unfavorable result occurred as a function of the high sample variation of the results. The high variance of the results was the factor causing rejection of the Ho. In this case, alterations in the operational procedures of the company were indicated for greater homogeneity of heat transfer in the package. As an emergency solution, a 10 minute increase in the process time was suggested together internal pressure.

3.4 Examples Varga et al. (2000b)

The data described in Table 4 are the experimental results presented by Varga et al. (2000b) for Retort A and B. The values for N (number of cans per retort batch) and TCIP (time between CIPs) are arbitrary since the authors have not published them. The intermediary results of the calculations of the critical Fo values were not written in the present article, but, based on this previous article, the values found for the critical Fo were 2.685 minutes for heating phase and 20.462 minutes for the total process (Retort A); and 0.207 minutes for heating phase and 2.293 minutes for the total process (Retort B). Then, the measured Fo value should be equal or greater than these values.

It is well known that products like corn and pea can be contaminated with spores of the deteriorative microorganism *Bacillus stearothermophilus*, a non-pathogenic, sporulated thermophile that causes flat sour spoilage, which can result in the loss of a batch if the conditions are adequate for its growth. The solution employed by the industries should be cooling (T < 40 °C) the batch before applying the secondary packaging and, preferably, applying a Fo adequate to reach 10^{-6} contaminated packages in the batch (PFLUG, 1990). In this case, the heat resistance value of the spores is $D_{121.1\,°C}$ = 3.2 minutes (STUMBO, 1973), and applying this parameter in the calculation of the minimum Fo required for thermophiles, considering a No of 10^2 $CFUg^{-1}$, the minimum Fo would be reached in 25.6 minutes (8 × 3.2 minutes). This value

Table 3. Data & results for the calculations for the bolognaise sauce in pouches.

i	Fo_i	Step	Calculation procedure			
1	3.56	1)	Preliminary calculation			
2	4.99		N	3360	Package	
3	5.26		n	14	Package	
4	5.54		p	0.000298	(–)	Equation (3)
5	5.81		c	0.998063	(–)	Equation (18)
6	9.41	2)	Variance hypothesis test			
7	9.63		Process time	2	(h)	
8	9.94		Time between CIPs	7	(days)	
9	10.44		δ	1.18%	(–)	Equation (6)
10	11.99		$\bar{F}o$	9.64	minute	Equation (7)
11	12.53		Fo (lowest)	3.56	minute	Minimum (Fo)
12	12.65		s^2	18.22	$minute^2$	Equation (8)
13	14.82		$\beta = s^2/\bar{F}o$	1.890	Min	Equation (9)
14	18.42		X^2lower	3.68	(–)	Equation (10)
			X^2upper	29.33	(–)	Equation (12)
			s^2 (lower limit)	8.08	$minute^2$	Equation (13)
			s^2 (Fo(lowest))	6.72	$minute^2$	Equation (14)
			s^2 (Upper limit)	64.31	$minute^2$	Equation (11)
			Result	Reject Ho		
		3)	Calculation of the critical Fo (just for illustration)			
			$\alpha = \bar{F}o^2/s^2$(upper)	1.446	(–)	Equation (16)
			$\beta = s^2$(upper)$/\bar{F}o$	6.669	minute	Equation (17)
			Critical Fo	0.029	minute	Equation (15)
		4)	D_{Tr}	0.21	minute	Reference
			No	1.00×10^6	$CFU.g^{-1}$	–
			CC	350	G	–
			Co	3.50×10^8	CFU	Equation (19)
			C_F	8.50×10^{-7}	CFU	Equation (20)
			γ	14.61	(–)	Equation (21)
			Fo (required)	3.069	minute	Equation (22)

Table 4. Experimental values for the Fo (minute) of cans in retort A and B.

	Retort A		Retort B	
	Fo (heating)	Fo (total)	Fo (heating)	Fo (total)
N	20	20	30	30
$\bar{F}o$	6.5	26.8	0.37	3.67
S	1.2	1.8	0.04	0.11
Minimum Fo	4.4	22.8	0.23	3.52
N	200	200	200	200
Process time (hour)	2.33	2.33	0.8	0.8
TCIP	7	7	7	7
Fo (critical)	2.685	20.462	0.007	2.293

should be greater then the critical Fo if an approach with respect to the probability of product contamination by thermophilic microorganisms is also carried out based on the same concepts discussed earlier.

4 Conclusions

1) The use of the greatest probable variance s^2 (upper) in the calculation of the critical Fo provided a safer result. The methodology applied in four steps, among which two were eliminatory, allowed for the determination of the critical Fo with safety;

2) The judicious calculation of the critical Fo allows for the orientation of data collection during the heat penetration assays;

3) The results for the critical Fo allowed for the heat treatment processes to be reprogrammed to guarantee food safety; and

4) In this study, the level of significance was interpreted as the probability of failure. It was used in the calculation of the critical package and also in the calculation of the probability of failure in the retort process.

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