Simplified Procedure for Estimating the Effect of a Change in Heating Rate on Sterilization Value[1]

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(Received for publication February 12, 1982)

ABSTRACT

A general relationship between a relative change in the temperature response parameter, f, and the sterilization value delivered in a thermal process has been developed. The relationship is based on numerical differentiation of Ball's formula method and employs a dimensionless elasticity term to express the relative change in sterilization value due to a relative change in heating rate. The funtion presented can be used for g's of up to 30°F and for changes of 3 to 20% in the value of the temperature response parameter.

During the decade of the 1970s, both government and industry worked to bring food and pharmaceutical product sterilization processes under increasingly more close control. As a result of these efforts a question that was regularly raised was the effect of the amount of normal variation of the product and process parameters on the delivered F_o-values. This is not a new problem. Hicks (3) addressed the variation in the canning process F_o-value. He concluded that uncertainty, both in the heating rate values obtained from heat penetration measurements and the microbiological data, contributed significantly to overall F_o uncertainty.

Lenz and Lund (4), in discussing the accuracy of sterilization processes, indicated that the variability of both sterilization process system parameters, such as heating medium temperature, initial product temperature, cooling medium temperature, container size and geometry and process time, was small, and that these parameters can be controlled within rather narrow limits. However, variability in the heating rate and variability in the number and resistance of the microorganisms in the product have a major effect on the sterilization process F_o-value and warranted

further study. Powers et al. (5) used the general method to assess biological variability in heat penetration data, and Herndon (2) demonstrated discrepancies between inoculated pack studies and calculated F_o's related to variability in heating curves.

It has always been possible to determine the effect of f on F_o by recalculating the process, but this is a relatively tedious analysis. What is needed is a simple means of assessing the effect of a change in f on the delivered sterilization values, F_o. For example, we need to be able to ascertain the effect on the delivered F_o-value of a given process of an increase in the heating rate temperature response parameter, f, of 10%, from 40 to 44 min.

This problem has been in front of us for many years, but it was only through fortuitous insight that we came upon a way to obtain a nearly direct measure of the sterilization value brought about by a percentage change in the f-value.

It was reasoned that the change in F_o, as a function of a change in heating rate, could be expressed using an elasticity approach, such as used in economics or in material science, with Ball's formula method.

DEVELOPMENT OF THE ELASTICITY FUNCTION

The relationship between f and g is given by

$$\log (g) = -tB/f + \log [j(T_1 - T_o)] \qquad (1)$$

where tB is process time,

g is the difference between the retort and product temperature $(T_1 - T)$ at the slowest heating zone at steam-off,

T_1 is heating medium temperature

T_o is initial product temperature, and

f is temperature response parameter.

Ball and Olson (1) present tables of a function, $\emptyset(g)$, which gives the values of fh/U vs. g for a given z and cooling temperature driving force (T1 - T2).

$$f/U = \emptyset(g); T_1 - T_2, z \text{ constants} \qquad (2)$$

where T_2 is the cooling medium temperature,

z is the microbial temperature coefficient, and

U is the equivalent sterilization value at heating medium temperature.

It is obvious that the value of $\partial\emptyset/\partial f$ and of $\partial(\emptyset^{-1})/\partial f$ is, for a given value

of T_1 - T_2, z, and g (T_1 - T_o), a function of g only (Equation 3).

$$\partial(\varnothing^{-1})/\partial f = \psi(g); \ T_1\text{-}T_2, \ z, \ j(T_1\text{-}T_o) \text{ constants} \qquad (3)$$

Equation 3 states that for given values of (T_1 - T_2), z, and j (T_1 - T_o), a change in the f-value will result in a change in U value that is dependent only on the magnitude of g of the sterilization process.

Since the effect of a relative change in f on the relative change in U, or the elasticity of U, with respect to f, is more useful than the ratio of changes itself, the value of $\eta = \left(\dfrac{\partial U}{U}\right)\left(\dfrac{\partial f}{f}\right)$ is of interest. Clearly, this function is also dependent on g alone under the above conditions. In practice, since we are dealing with finite changes in f, Δ f, the value of η' $\eta' = \left(\dfrac{\Delta U}{U}\right)\left(\dfrac{\Delta f}{f}\right)$ is to be evaluated.

The elasticities were evaluated by numerical differentiation of the frequently-used Ball table for z = 18, T_1 - T_2 = 180°F, using a Cyber 172 computer. The elasticities were computed between g's of 0.01°F to 30°F, for (T_1 - T_o) = 300°F, and for Δf/f of 0.03 to 0.2. The latter are the practical limits of accuracy expected in the measurement of f.

EXAMPLE USE OF RELATIVE ERROR GRAPH

The following design parameters were used for the sterilization of a meat product in a No. 2 (307 × 409) container.

T_o = 100°F,
T_1 = 250°F,
T_2 = 70°F,
f_h = 50 min,
j_h = 2,
Design F_o: 9 min
To convert F_o into U we use U = F_o/L where L = $10^{\frac{T_1-250}{18}}$

In the case at hand, since T_1 = 250, L = 1 and U = F_o = 9 min.

Therefore, using the tables of Ball and Olson (1) and Equation 1, tB = 84.90 min and the value of g is 6.01°F. What would be the sterilization value of this process if the f(h)-value was 10% larger (Δf/f = 0.1)?

SOLUTION

For a g of 6.01°F, the value of η' is 3.3 from Fig. 1. From the definition of η' we get $\Delta U/U = \eta \ \Delta f/f$. Therefore, $\Delta U/U = 3.3 \times 0.1 = 0.33$ and $\Delta U = 0.33 \times 9 = 2.97$. The sterilization value of the process for the fh of 55 min will then be U - ΔU = 9-2.97 = 6.03 min.

A direct calculation of the U value, from the Ball and Olson tables using f_h = 55 min, gives a g of 8.04°F and a U value of 5.97 min.

RESULTS AND DISCUSSION

For large values of g the value of η' is affected by the magnitude of the relative error (Δ f/f) in the temperature response parameter itself. This phenomenon occurs because a change in the f-value (keeping the process time, tB, constant) causes the value of g to change; this change is more pronounced when the assumed g is large (i.e., for smaller values of tB/f). In the theoretical derivation it was earlier shown that $\partial U/\partial f = f(g)$ only. Since in practice, changes in f are finite and simultaneously cause changes in g, n may differ from η'. This is what happens at large values of g.

The problem was solved by the construction of several lines in Fig. 1 for various relative changes in the value of f (i.e. 3, 10, and 20% change) for those g-values (>0.5°F) where the appreciable difference exists between the assumed g (based on f) and that calculated after the change (based on f + Δ f).

When Fig. 1 is used to predict the magnitude of error, for practical purposes, the solid line, which was constructed based on a 10% error in f for g's greater than 0.5°F, can be used for the range of 3-20% error over the whole range of g's given.
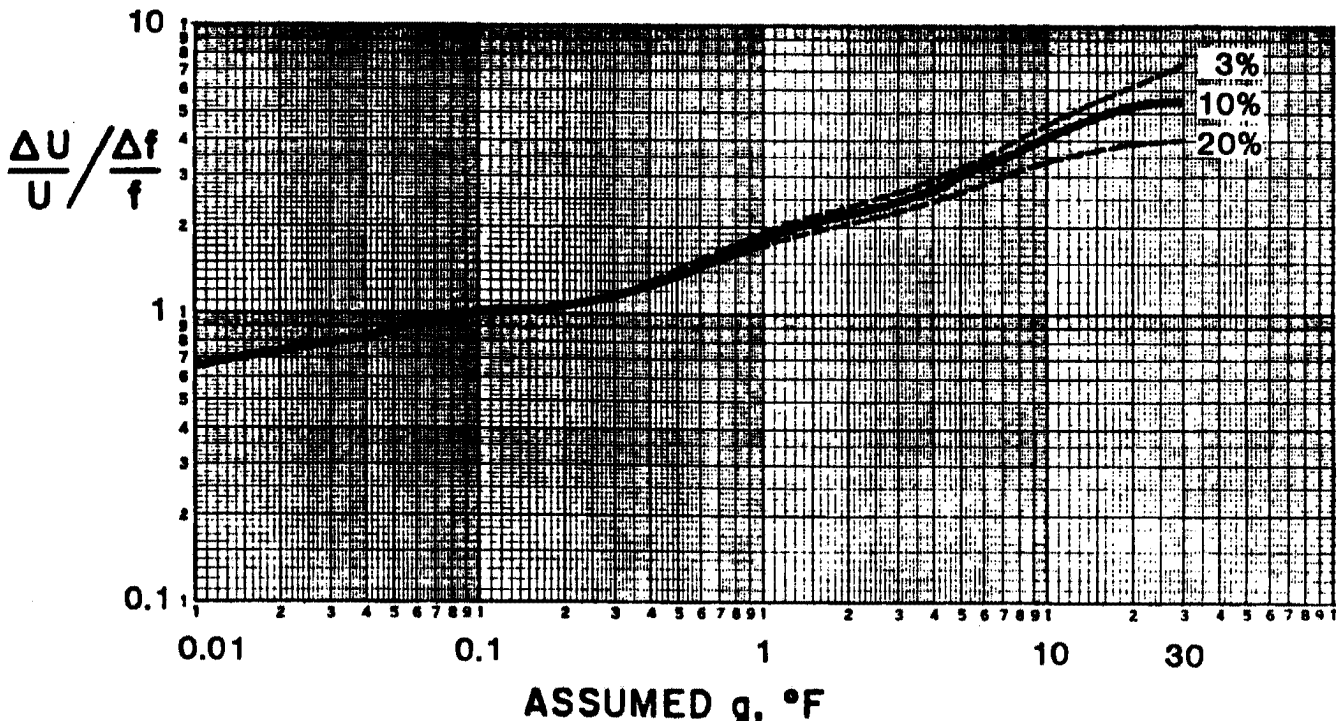

Figure 1. *Elasticity, sterilization value with respect to temperature response parameter as a function of the g value for values of $\Delta f/f$ of 3 to 20%, z = 18°F, m + g = 180°F, and j(T_1 - T_o) = 300°F.*

Figure 1 is based on data of Ball and Olson (*1*) where the heating to cooling medium temperature difference is 180°F. For temperature difference values larger than 180°F, the cooling rate will increase and thus the cooling contribution to process lethality will decrease. This will, in turn, increase the sensitivity of the sterilization value to changes in heating rates and elasticity will increase. Similar considerations suggest that when the value of this temperature difference is less than 180°F, a decrease in the elasticity will occur. The temperature difference of 180°F was selected, as suggested by Stumbo (*6*), who reported that the U value can be adjusted for temperature differ-other than 180°F; a 10°F change in the temperature difference will change U by 1%. Furthermore, the effect of cooling rates becomes important only for large values of g. However, for those processes that are designed with a large g, the degree of accuracy of the formula method, itself, may introduce significant errors into the value of U (*3*).These considerations make Fig. 1 applicable over a range of heating-cooling temperature differences.

The chart, which was constructed to provide a quick estimate of the effect of a small change in the temperature response parameters, f, on the sterilization value of a process, can also be used to assess the effect of a change in the thermal diffusivity (α) of a conduction heating product on the sterilization value, F_o. Assuming that there is no error in the measurement of the container dimensions, this can be done using the relationship

$$\partial U / \partial f = \partial U / \partial(1/\alpha). \qquad (4)$$

For a Newtonian heating product, if no error is assumed in values of product volume, surface area, density and heat capacitance, the change in sterilization value can similarly be directly related to the overall heat transfer coefficient, h, using

$$\partial U / \partial f = \partial U / \partial(1/h). \qquad (5)$$

CONCLUSIONS

1. A graph has been developed that can be used to assess the effect of a change in the heating rate, f, on the sterilization value, F_o, of a thermal process. For error analysis in a typical sterilization process and for commonly-encountered relative changes in f, the solid line in Fig. 1 is sufficiently accurate for practical use.

2. The relationship of the change in U or F_o with the causative change in f is not constant for all values of g but increases as g increases. Equal relative errors in f will have totally different effects on the sterilization value delivered, depending on the g value of the process. For equal accuracy in U or F_o the f-value error must be smaller when g is large.

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