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Use of Linear Models for Thermal Processing of Acidified Foods

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ABSTRACT

Acidified vegetable products with a pH above 3.3 must be heat processed to assure the destruction of *Escherichia coli* O157:H7, *Salmonella enterica*, *Listeria monocytogenes*, and other pathogenic bacteria that might be present in the product. Recently, the Food and Drug Administration has required that linear models for heat process data be used with electronic process filing forms. Existing recommendations for heat processing acidified vegetables are based on non-linear (Weibull and exponential decay) models. We report here the parameters for a linear model that meets or exceeds the established heat processing conditions needed to assure safety.

INTRODUCTION

Acid and acidified foods are partially defined in the Code of Federal Regulations as foods having a final equilibrium pH at or below 4.6 (21 CFR part 114), with a water activity of 0.85 or greater. Fermented and refrigerated products are excluded from this regulation. The pH 4.6 value was based on data show-

ing that spores of *Clostridium botulinum* will not germinate and produce neurotoxin at or below pH 4.6 (6). Acid foods include, among other things, fermented vegetables such as cucumber pickles or sauerkraut, which naturally have a pH below 4.6. Acidified foods achieve pH 4.6 or lower by the addition of an acidulent (typically acetic acid) or acid food ingredients. Acidified foods include most fresh pack cucumber pickle and pepper products.

Fermented cucumber pickles are primarily sold to customers who purchase hamburger dill pickle slices on a wholesale basis. Fermented pickles are excluded from regulation in 21 CFR part 114 because a variety of antimicrobial metabolites (such as organic aids, peroxides, antimicrobial peptides) that eliminate vegetative pathogens are produced during fermentation (5). The retail market, however, is dominated by acidified shelf stable pickled vegetables (fresh pack products), including cucumber pickles, peppers and other vegetables. Acetic acid is commonly used as the primary acidulent in these products. The pH of acidified cucumber pickles is typically between 3.4 and 4.1. At this pH, the survival of acid resistant bacterial pathogens (Escherichia coli O157:H7, Salmonella enterica, and Listeria monocytogenes) that may be present on fresh vegetables is a concern. While these pathogens do not grow in acidified vegetables, they may survive long enough to cause disease (2).

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TABLE I. D values from TDT data				
Temp (°C)	R ²	D value ^a		
50	0.96	17.65 (0.91)		
52	0.94	12.58 (0.68)		
54	0.86	7.34 (0.70)		
56	0.90	4.31 (0.45)		
58	0.98	1.37 (0.034)		
60	0.97	0.58 (0.023)		

^aOne log reduction time (min.); standard error for each value is shown in parentheses.

TABLE 2. Z and F Values		
Model ^a	Z value (°F)	F ₁₆₀ ^b
Exp. Decay (5SE)	19.50	1.20
Exp. Decay	15.70	0.34
Five D Model	11.98	0.08
One D Model	11.98	0.02

^aModels as described in the text: Exp. Decay (5SE), exponential decay model with five times the standard error added; Exp. Decay, exponential decay model; Five D Model, linear model based on a five log reduction; One D Model, linear model based on a one log reduction.

^bF₁₆₀:Time in minutes (F value) needed to achieve the predicted reduction in cell numbers at a reference temperature of 160°F.

The infectious dose for *E. coli* O157:H7 may be as low as one to ten cells. For this reason, acidified vegetables must be processed to assure a five log reduction in acid resistant pathogenic bacteria.

The details of the processes that are needed to assure safety of acidified vegetables are included in process filings, which manufacturers file with the Food and Drug Administration (FDA). There are two kinds of processes that have been shown to assure a five log reduction in acid resistant pathogens. The acid present in some products may be sufficient to assure a five log reduction in numbers of acid resistant pathogens. For this reason, products with acetic acid as the primary acidulent and a pH below 3.3 do not require a heat process, but do require a temperature dependent holding time to assure safety (3). E. coli O157:H7 has been found to be the most acid resistant pathogen of concern for these products (3). To achieve a five log reduction at 77°F (25°C), a holding time of 48 hours is needed. However, at 50°F (10°C), a holding time of six days is required for a five log reduction. Interestingly, L. monocytogenes, a psychrotrophic organism, which can grow at refrigeration temperatures at neutral pH, does not survive as well as E. coli O157:H7 under similar cold and acidic conditions (3).

For products with a pH above 3.3, heat processes needed to assure a five log reduction in vegetative bacterial pathogens in acidified vegetable products have been published (4). The processing conditions were determined using a Weibull model, because, in some cases, non-linear kinetics were observed for the thermal destruction of the *E. coli* O157:H7, *Salmonella*, and *Listeria* strains used in the study. For required process filing forms, FDA has recently requested that a linear model be used for the thermal destruction of vegetative pathogens. The use of linear model parameters (Z and Fvalues, reference temperature, and a least sterilizing value) allows a comparison of processes for both low acid canned food processes and acidified foods.

There are some differences, however, between the methods for processing low acid canned foods and acidified pickled vegetable products. In heat processed acidified foods, spores are not inactivated. Pathogenic spore outgrowth is prevented by maintaining the pH at or below 4.6. The objective in heat processing acidified foods is to eliminate vegetative cells of microbial pathogens and spoilage microorganisms capable of surviving in the product. A five log reduction in E. coli O157:H7 cell numbers is sufficient for assuring safety of acidified foods, similar to the juice HACCP regulations (21 CFR part 120). Another difference between low acid canned foods and acidified foods is that most acidified foods are heat processed in multi-stage pasteurizers that have several different temperatures, unlike a sealed retort with a fixed temperature. Most processors remove jars from pasteurizer segments and manually determine the internal temperature to confirm that the appropriate center temperature for a given process has been achieved. The time-temperature conditions needed for a five log reduction in bacterial pathogens occur within an internal segment of the pasteurizer, after the containers have been pre-heated.

To meet published safe processing conditions (4) and allow electronic filing of acidified food processes, a new linear model is needed. We describe a linear model that meets or exceeds the published times and temperatures required for achieving a five log reduction of *E. coli* O157:H7 and other vegetative pathogens that may be present in acidified vegetable products.

MATERIALS AND METHODS

Modeling of microbial heat kill data was based on the F-value method

FIGURE I. D values for existing TDT data. Temperatures for each data set are shown on the graph in °C. Data for three replicates at the indicated times for 50°C (122°F, octagons), 52°C (126°F, triangles), 54°C (129°F, squares), 56°C (133°F, circles), 58°F (136°F, diamonds), and 60°C (140°F, inverted triangles) are shown. Regression lines for each data set are shown next to the corresponding temperature number.



FIGURE 2. Processing times based on three different models. The triangles represent the \log_{10} of the D values determined for the linear model as described in the text. The squares represent the published Weibull five log reduction data with five times the standard error added. The regression lines are as follows: dotted line, from the one log reduction values (triangles); solid black line, five log reduction times; dashed black line, exponential decay model with five times the standard error added.



(1), and the D and Z values were determined by two approaches. The first approach was to develop a linear model based on the published five log reduction times that were originally determined by a non-linear (Weibull) model (4). A log-linear transformation of the published five log reduction times (generated by use of the Weibull model) was plotted against temperature. Linear regression was then carried out to determine a Z value from the slope of the regression line. In the second approach, the existing thermal death time (TDT) raw data (4) was re-examined using a linear model instead of a Weibull model. Linear regression of log10 surviving cells vs. time, and \log_{10} D values vs. temperature, to determine D and Z values (respectively), was carried out. All regression calculations were performed with SigmaPlot software (Version 10.0, Systat Software, Inc, Chicago IL). For both methods, 160°F was chosen as a reference temperature.

RESULTS

The D values for a temperature range of 50°C (122°F) to 60°C (140°F) were generated by use of a linear model with the existing TDT data (Fig. 1). Based on these D values (Table 1), a Z value of 11.98°F was determined for E. coli O157:H7. For a reference temperature of 160°F, a processing time of 0.016 min. was determined for the linear model (Fig. 2). The five log reduction line from these data has the same slope and Z value, but the processing time at the reference temperature of 160°F was 0.08 min (Table 2). The R² value for the log-linear regression to determine the Z value was 0.96 (Fig.2).

Previously, Breidt et al. (4) used a Weibull model and a exponential decay function to predict five log reduction times. The predicted values from an exponential decay model were used to determine safe processing times for temperatures between 160°F and 180°F (4). Recommendations for safe processing times for industry included the addition of five times the standard error to the predicted processing times. From these data, a linear model was used to fit the predicted values from the exponential decay model by taking the log₁₀ of the predicted

Temp (°F)	Time (min.)	Temp (°F)	Time (min.)
140	12.7	161	1.1
141	11.3	162	0.9
142	10.1	163	0.8
143	8.9	164	0.7
144	7.9	165	0.7
145	7.1	166	0.6
146	6.3	167	0.5
147	5.6	168	0.5
148	4.9	169	0.4
149	4.4	170	0.4
150	3.9	171	0.3
151	3.5	172	0.3
152	3.1	173	0.3
153	2.7	174	0.2
154	2.4	175	0.2
155	2.2	176	0.2
156	1.9	177	0.2
157	1.7	178	0.1
158	1.5	179	0.1
159	1.4	180	0.1
160	1.2	181	0.1

TABLE 3. Recommended heat processing time/temperature combinations for a 5-log reductionin bacterial pathogens for acidified products with a pH of 4.1 or below

curve (Fig. 2). The Z values determined for each model are shown in Table 2. The recommended time-temperature processing conditions from the log-linear transform of the exponential decay data are shown in Table 3. The Z value for these data was 19.5°F with an F value of 1.2 min. at a reference temperature of 160°F.

DISCUSSION

Recently, FDA has returned process filings because of a lack of a Z, F and least sterilizing value as well as a reference temperature on the filing forms. Linear kinetic parameters were desired for comparison with other thermal processes for a wide variety of food products. The original data used to generate the published five log reduction times for *Salmonella, Listeria*, and *E. coli* O157:H7 included non-linear heat killing curves. Fitting the non-linear curves with a linear model resulted in significant under-processing, compared to the published five log reduction times.

An alternate approach, using a linear approximation of the existing five log reduction values generated from a non-linear (Weibull) model, resulted in a model that would assure safety, based on the published data. This model has an F value of 1.2 min., a Z value of 19.5°F, and a reference temperature of 160°F (Table 2). These conservative processing time-temperature conditions (Table 3) are well below the times and temperatures used for many commercial processes for shelf stable acidified foods. For example, a processing temperature of 165°F (74°C) for 15 min. was recommended by Monroe et al. (7) for fresh-pack dill pickles for microbial stability and quality factors, including the inactivation of softening enzymes. Typical industry practices therefore have a large margin of safety. The linear model described here predicts the minimum times and temperatures needed for safety, in terms of the destruction of E. coli O157:H7, Salmonella, and Listeria, and can be used with either FDA electronic or paper filing forms.

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