Clostridium botulinum Control

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Abstract

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Clostridium botulinum has been actively studied for more than 100 years. For the last 50 years, there has been a relatively good understanding of the problem. The volume of literature is large, but relatively diverse.

In this booklet, I have assembled two reports that, in general, cover the present knowledge of *Clostridium* control. The complete manuscripts of the two reports follow in reverse order, the newest manuscript is first and the other last.

The purpose of the first manuscript, Controlling *Clostridium botulinum* in Heat-Preserved Food, is to explain, in easy to understand outline form, the basic principles of controlling *Clostridium botulinum* in heat-preserved food.

The second manuscript, Science, Practice and Human Errors in Controlling *Clostridium botulinum* in Heat-Preserved Food in Hermetic Containers, is an extensive report that covers the following topics:

Controlling *Clostridium botulinum* in Heat-Preserved Food
The Role of Human Error on the Incidence of Botulism.
A Brief History of *C. botulinum* Control
Laboratory Study of Microorganisms.
CDC Data on Home-Processed Food Botulism Outbreaks Suggest
Relatively Constant Rate of Human Error.
Probability that a Surviving Spore Will Result in a Botulism Incident.
Outcomes as a Function of Processing Conditions
Discussion of the Outcomes of LACF Processes with F_0-Values (a) in the Normal Area and (b) in the *C. botulinum* Hazard Area, Data Shown in Table 7.
Post-Processing Observation of Food Containers.
Discussion of a Study fof Recovered Post-Processing Swelled Containers.
Estimating Process Outcomes for Resistant, Mesophilic, Sporeforming Microorganisms.
Estimating the Probability of Process Failure
Discussion of Process Failure
Errors that May Occur in the Process Design Area
Errors that May Occur in the Process Delivery Area
Conclusions Regarding Controlling the *C. botulinum* Hazard

Controlling *Clostridium botulinum* in Heat-Preserved Food

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The purpose of this report is to explain, in easy to understand outline form, the basic principles of ***controlling Clostridium botulinum in heat-preserved food.***

Quite simply, there are three major aspects to *Clostridium botulinum* control: (1) facts regarding the *Clostridium botulinum* organism and its spores*;* (2) how to control the *Clostridium botulinum* hazard; and (3) estimating the probability of process failure.

1. Truths Regarding the *Clostridium botulinum* Problem

Clostridium botulinum spores are not our problem; we are the problem in not being willing to accept and solve our human errors.

a. Errors in delivering the thermal process are the overwhelming cause of botulism food-poisoning incidents. This fact was recognized by those who prepared the 1971, FDA Commercial Food Processing Regulations; the regulations included procedures for finding and correcting commercial processing errors when they occur. We need to recognize and accept that human errors are always occurring and that they regularly occur in the processing of low-acid canned foods.

b. Acceptance of the idea that microbial survival is a function of the number of microorganisms present and the resistance of the specific culture. The factors involved are best described by the equation,

$$F_{121.1^{\circ}C} = D_{121.1\ C}\ (\log N_0 - \log N_F).$$

c. Acceptance of the probability nature of microbial survival that was stimulated by the NASA Viking Project.

d. The ability of any bacterial-spore species to survive a heat process is not a constant value but is variable; it is determined by the species and how the spores were grown, how tested, and the post-heating environment. Bacterial spores **do not** have constant *D*-values!

e. In preserving low-acid canned foods (LACFs), we have three microbial groups, regarding heat resistance: *C. botulinum* ($D_{121.1°C}$-value of less than 0.2 min); Resistant, mesophilic, spore-forming microorganisms ($D_{121.1°C}$-value of the order of 1 min); and thermophilic, spore-forming microorganisms ($D_{121.1°C}$-value of 3 to 6 min).

2. Controlling the *Clostridium botulinum* Hazard

a. The delivery of the thermal process to cans of food is the weak link in the chain of operations in preventing botulism. **Human operators** who fail to use the posted or a correct thermal process or are careless in the delivery of the thermal process are the primary cause of botulism problems. Botulism incidents such as the Bon Vivant or Castleberry Foods not only cause human suffering but have a very high economic cost. A lack of quality control in the retort room caused both of these companies to suffer great financial loss.

b. When a food manufacturer follows the GMP food regulations, the probability of a failure in the design and validation of the thermal process is so small as to be negligible compared to the probability of delivery failure. The probability of a process delivery failure is also small when the operator follows the FDA regulations regarding the use of accurate instrumentation and the conscientious gathering and reviewing of processing records.

c. Controlling *C. botulinum* in both commercially and home-processed food is a management and quality-control problem: In commercial processing, the FDA mandates there must be a series of measurements and QC checks to develop confidence that the probability of the designed process **not being delivered** to the retort load of product is of the order of one in one million (1.0×10^{-6}). In restaurant and home processing, we have to rely on the operator to carry out the processing specifications correctly. It is suggested that a data record for the process be kept to reduce the probability of an error.

d. The studies of Esty and Meyer (1922) regarding the resistance of laboratory-grown *C. botulinum* spores, tested using conditions designed to determine maximum survival times, are the basic data of the maximum F_T- and D_T-values available today. The probability of any laboratory-grown *C. botulinum* spores surviving an F_0-value of 2.45 minutes is extremely small. It is realistic to use this value as the starting point in designing commercial LACF processes because (1) it offers a large factor of safety and (2) it has almost no effect on the design F_0 which must also take care of the resistant mesophiles that are usually at least five times as resistant as *C. botulinum* spores.

5. Circumstantial evidence indicates that Appert's (1810) water-bath process or the home-canning water-bath processes, of 180 or 210 minutes in use from 1900 to 1930, were able to control *C. botulinum* spores. Consequently, a thermal-process F_0 of the order of 1.0 minute must be able to control *C. botulinum* spores on products with natural contamination.

6. Significant spoilage by mesophilic spores in product that supports their growth is a sign of an inadequate process and should warrant immediate process analysis.

7. Cans of food that contain botulinum toxin **will have** received a small F_0-value.

3. Estimating the Probability of Process Failure

How do we arrive at an overall probability of an LACF botulism incident when we have a situation where there are several vastly-different probability levels among processing conditions?

A first step toward making a statistical analysis is to define the experimental unit. We are going to use a different experimental unit in the process-design area than in the process delivery area. For process design, we will use **the individual container;** however, in the process-delivery area, we will make our probability judgments on the basis of **the processing unit.** What is the processing unit? A processing unit is one or more containers that have the same general microbial load and receive the same thermal process. Each processing unit is a separate consideration and is an independent probability from all other processes. It is the batch, lot, retort (autoclave) load, or the single product, single-day production, of the restaurant or home canner. When there is a problem, it is a specific retort (autoclave) load problem, or in the restaurant or home-preservation area, it is the batch of a specific product production.

Process design probability judgments should be made on the basis of the total number of individual containers to which the process design is applicable.

3.1 Errors that May Occur in the Process Design Area

- The calculated process is incorrect for processing conditions.
- Error in the heat-penetration data: wrong product, product ingredient change, change in viscosity, change in particle conditions.
- Wrong process parameters used in the process calculation: i.e., *z*-value, temperatures both initial and cooling.
- Error in the calculated scheduled process; is estimated to be of the order of one error in 10^6 processes designed.
- Inadequate process validation (no validation carried out).
- Failure to validate or inadequate validation is estimated to be of the order of one non-validated process in 10^4 processes designed.

3.2 Errors that May Occur in the Process Delivery Area

- Process Failure: manufacturing errors that affect delivery of the scheduled process.
- Product: change in formulation; f_h different from value used in calculation; change in viscosity of the product; change in particle size.
- Equipment: change in headspace or fill weight.
- The probability of a manufacturing error is estimated to be of the order of one delivery error in 40 to 100 batches.
- People failures: operator failure; operator failed to follow written procedures - wrong temperature, time, or both; errors in review of records.
- Record failure: errors in critical values in processing records; for example, retort temperature, process time, pressure, process records, etc.
- Review failure: Failure to review records by the production supervisor, and quality-control department and another member of management.
- Failure to act: Failure of QC department to take corrective action on an adverse processing-record report.
- The probability of an undetected delivery error is estimated to be of the order of one in 1.0×10^6 (after 3 reviews). The equation for this calculation is: $P = P(1) \times P(2) \times P(3) = P(0.01) \times P(0.01) \times P(0.01) = 1.0 \times 10^{-6}$

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Science, Practice and Human Errors in Controlling *Clostridium botulinum* in Heat-Preserved Food in Hermetic Containers

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Abstract

The incidence of botulism in canned food in the last century is reviewed along with the background science; a few conclusions are reached on the basis of an analysis of published data.

There are two primary aspects to botulism control: the design of an adequate process and the delivery of the adequate process to cans of food. We conclude that botulism incidents in canned food are primarily the result of human failure in the delivery of the designed or specified process to cans of food that, in turn, results in the survival, outgrowth, and toxin production of *C. botulinum* spores. It is possible but very rare to have botulism result from post processing contamination.

The probability that the designed process will be inadequate to control *C. botulinum* is very small, probably less than 1.0×10^{-6}, on the basis of cans of food, whereas the failure of the operator of the processing equipment to deliver the specified process to cans of food may be of the order of one in 40 to one in 100, on the basis of processing units (retort loads). In the commercial food-canning industry, failure to deliver the process will probably be of the order of 1.0×10^{-4} to 1.0×10^{-6} when FDA regulations are followed. Botulism incidents have occurred in food canning plants that have not followed the FDA regulations.

It is recommended that our efforts in *C. botulinum* control be concentrated on reducing human errors in the delivery of the specified process to cans of food.

Table 1: Number (%) of Foodborne Botulism Outbreaks By Place of Food Processing, 1950-1996.* (Note: The food incidence numbers in this table represent only 15% of total botulism incidents.)

Process Location	1950-1959 No. (%)	1960-1969 No. (%)	1970-1979 No. (%)	1980-1989 No. (%)	1990-1996 No. (%)	Total No. (%)
Home Processed	51 (49.0)	44 (56.4)	85 (66.9)	69 (87.3)	40 (71.4)	289 (65.1)
Commercially Processed	2 (1.9)	10 (12.8)	9 (7.1)	6 (7.6)	4 (7.1)	31 (7.0)
Unknown	51 (49.0)	24 (30.8)	33 (26.0)	4 (5.1)	12 (21.4)	124 (27.9)
Total	104	78	127	79	56	444

*Handbook for Epidemiologists, Clinicians, and Laboratory Workers, CDC (1998).

1.0 Introduction

In this report, we will review the history and several important aspects of the microbiology of *Clostridium botulinum* spores and the thermal processes to control *C. botulinum* spores.

There are many enigmas in the processing of low-acid canned foods; the *C. botulinum* Public-Health problem is one of the most difficult to understand. In working to understand this problem, I have often felt as if I am one of the blind men trying to identify the elephant. This year, after several epiphanies, I feel I have a new and better perspective of the elephant.

There are five facts that are critical to a practical understanding of the *C. botulinum* Public-Health problem. These basic principles have been known for more than 50 years but, since most require a change in our historical thinking, often they are not included in the treatment of the botulism problem.

(1) Errors in delivering the thermal process are the overwhelming cause of botulism food-poisoning incidents. This fact was recognized by those who prepared the 1971, FDA Commercial Food Processing Regulations; the regulations included procedures for finding and correcting commercial processing errors when they occur. We need to recognize and accept that human errors are always occurring and that they regularly occur in the processing of low-acid canned foods.

(2) Acceptance of the idea that microbial survival is a function of the number of microorganisms present and the resistance of the specific culture: The factors involved are best described by the equation,

$$F_{121.1^\circ C} = D_{121.1\,C}(\log N_0 - \log N_F). \qquad (1)$$

(3) Acceptance of the probability nature of microbial survival that was stimulated by the NASA Viking Project.

(4) The ability of any bacterial-spore species to survive a heat process is not a constant value but is variable; it is determined by the species and how the spores were grown, how tested, and the post-heating environment.

(5) In preserving LACFs, we have three microbial groups, heat resistance-wise:
(a) *C. botulinum* ($D_{121.1^\circ C}$-value of less than 0.2 min);
(b) resistant, mesophilic, spore-forming microorganisms ($D_{121.1^\circ C}$-value of the order of 1 min); and
(c) thermophilic, spore-forming microorganisms ($D_{121.1^\circ C}$-value of 3 to 6 min).

Table 2: U.S. Commercially-Canned Foods Contaminated with Botulinum Toxin, 1971-2009[a].

ID	Date	Product	Type of Toxin	No. of Clinical Cases
1	June, 1971	Vichyssoise	A	2
2	August, 1971	Chicken Vegetable Soup	A, B	0
3	May, 1973	Peppers	B	7
4	July, 1973	Marinated Mushrooms	B	1
5	April, 1974	Tuna	C	0
6	November, 1974	Beef Stew	A	2
7	August, 1978	Salmon (United Kingdom)[b]	E	4
8	February, 1982	Salmon (Belgium)[b]	E	2
9	July, 2007	Hot Dog Chili Sauce*	A	8

[a]Original table from Lynt et al. (1975), Updated by Schaffner (1982), Pflug, (2009) . [b]Canned in Alaska.

2.0 Controlling *Clostridium botulinum* in Heat-Preserved Food

2.1 Foodborne Botulism in the Twentieth Century (1900-1998)

It is said that hindsight is 20/20; if we look back, what is the LACF industry *C. botulinum* hazard data for the last 50 years telling us?

The Center for Disease Control and Prevention (CDC) divides the botulism Public Health hazard into three areas: Some type of food, 25%; Infant, 72%; and Wound, 3%. They further divide food botulism outbreaks into home processed, commercially processed, and unknown. In Table 1 is shown the number and percentage of foodborne botulism outbreaks by place of food processing in the time period 1950-1996 (CDC, 1998). Regarding the commercial processing of food, since the new FDA regulations have been in place, the numbers of incidents per decade have decreased from 9 (1970-1979) to 6 (1980-1989).

In Table 2 are listed botulism incidents from commercially-canned food from 1971 to 2009 (the data from 1971-82 are from Schaffner (1982); we completed the table using data from CDC. The individual outbreaks in Table 2 are discussed further below.

1. Bon Vivant, Vichyssoise (1971)

   A Westchester County, NY banker died after eating chilled vichyssoise. The canned-food product was produced by Bon Vivant Food Company of Newark, NJ.

   It was difficult to pinpoint the cause because of inadequate records. The company had two retorts, one that operated at 240°F and a second newer unit that operated at 250°F. It was speculated that the process time that was to be used for a 250°F retort process was used as the process time for a 240°F process which would result in the delivery of a very low F_0-value, hence product spoilage.

2. Campbell Soup Company, Chicken Vegetable Soup (1971)

   Published data are not available to me. It was rumored, at the time, that a product which normally heated by convection and therefore had a convection-type process, suddenly changed physical characteristics and heated by conduction; consequentially, the convection process was grossly inadequate.

3, 4. In 1973, there were two incidents of improperly-acidified vegetables, peppers, and mushrooms.

5. In 1974, a clinical incident from tuna was avoided through the discovery of faulty cans.

6. Improperly-processed beef stew resulted in two cases of botulism and one death.

Blake et al. (1977) reported two of three persons who ate lunch together became ill with symptoms characteristic of botulism. One died before botulism was suspected and before specimens could be collected for laboratory testing, but a serum specimen from the other patient, who survived, yielded botulin toxin, Type A. The three persons had shared commercially-canned beef stew. The empty stew can was recovered from the garbage, and washings from the can yielded *C. botulinum*, Type A, and its toxin. An FDA and USDA inspection of the food-processing plant indicated a number of processing deficiencies that could have resulted in inadequate retort processes. Can handling in the retort area that could allow unretorted cans to accidentally escape retorting was reported as one of the unacceptable practices.

7, 8. Alaska Salmon, 1979 and 1982[b]

Clinical cases of botulism E occurred in Europe (United Kingdom and Belgium) from salmon packed in Alaska (USA). Both of these incidents were caused by post-processing contamination (leakage) of faulty cans and not by under-processing.

9. Castleberry's Food Company, Hot Dog Chili Sauce[*]

[*] Castleberry Foods' botulism Case, July, 2007: The following information is from a *USA Today* report by Julie Schmit who quoted from an FDA report obtained from a U.S. Congressional Committee. They stated that the containers with toxic product had been processed in either or both of two Malo™ retorts that had been operated improperly; the retorts had non-calibrated thermometers, a leaky water valve, and non-operating safety controls.

Cans of food product (in a conical-shaped space), touched by the leaking-in water (estimate, 5 gpm), will result in a complex heating pattern in that at the top of the retort, in the center of the incoming water, cans may not be exposed to steam, therefore will receive a near-zero F_0-value while cans that are only splashed by the water may receive a near-normal process.

In addition to the effect at the top of the retort, the water flowing in through the leaking valve may be enough to overwhelm the condensate-removal system (control and alert alarm not operational), so cans at the bottom of the retort may be sitting in water, the result being that these cans received a reduced F_0-value.

2.2 The Role of Human Error on the Incidence of Botulism

We believe that it is the **human operators** who either fails to use an adequate heat process for the specific cans of product or are careless in the delivery of the thermal process, that are the primary cause of foodborne-botulism problems.

Human error plays a role in all our daily-life problems: In the USA, between the automobile, the human driver, and the road, we are able to kill an average of more than 100 persons every day. Why do we tolerate, accept this daily slaughter? We accept it because we permit human beings to drive cars and all human beings make errors. We make errors in all the activities we engage in including canning food.

In estimating the *C. botulinum* hazard, we need to include human errors in the equation. Lynn Fraser (2000), who worked on a Human Errors Study Project, parsed errors into three categories: skill-based slips and lapses; rule-based mistakes; and knowledge-based mistakes. Process-delivery errors in the food-canning plant, that may lead to under-processing a retort load of product, may be in any of these three categories. The frequency at which errors in routine operations are made is variable; I estimate that it may be from a high of one error in 30 operations (3.3%) to a very low number in well-operated systems.

In Table 3 are listed the ten most frequently-reported canning-plant deviations from the Good Manufacturing Practices (GMP) regulations. Numbers 4, 8, and 9 are equipment problems; all the rest are failures or errors of people either in management or on the processing floor.

People are always going to make errors; our challenge is to have a system that safeguards the food-canning operation so the probability of an error in a vital activity, i.e., delivering the correct process to a retort load of LACF product, is low, of the order of one error in one million retort loads. We can approach this level of confidence by having records of each critical process variable and reviewing each record at three levels.

Table 3: FDA's List of the Ten Most Frequently-Reported Deviations from the 27 Low-Acid Canned Foods Good-Manufacturing-Practice Regulations.[a]

1. Records inadequate
2. Registration and process filing forms incomplete
3. Process deviations not handled properly
4. Faulty temperature-recording devices
5. Scheduled process adequacy not verified
6. Improper venting
7. Initial temperature not controlled
8. Retorts inadequate
9. Reference thermometers not in compliance
10. Critical factors not controlled

[a] From Schaffner's (1982) "Government's Role in Preventing Foodborne Botulism."

In the FDA-LACF regulations, to keep the effect of human error in canning plants to an acceptably low level, a written, printed, or graphical record of critical data in the food-process delivery system are to be collected: retort temperature, come-up time, hold time, pressure plus data on the product in the retort; container size, fill weight, and headspace. The gathered data are to be reviewed. If the retort operator reviews these data and misses only one process failure in 100 records and the process records are further reviewed two more times, by the supervisor and the quality- control manager (each missing only one failure in 100 records), missed process errors and failures will be one in a million. [The overall probability of missing a "processing error" is the product of the independent inspections, $P = P(1) \times P(2) \times P(3) = P(0.01) \times P(0.01) \times P(0.01) = 1.0 \times 10^{-6}$.]

It is probable that the relativly high instance of botulism in the home canning area is due to human error in the delivery of the thermal processes to the cans of food. For any of many reasons, when not closely supervised, human beings often fail to accurately follow directions. In the restaurant, at camp, or in a domestic setting, the records and reviews mandated by the FDA-LACF regulations do not exist.

2.3 A Brief History of *C. botulinum* Control

In this discussion of botulism and thermal processing, I will use Perkins' (1964) review, "Prevention of Botulism by Thermal Processing," as a primary reference. Perkins' (1964) report is a valuable historical document and a good place to start; however, it was written before the five items listed in the introduction were well understood and, in general, were used. The discussion of the laboratory study of microorganisms below is another important part of this area.

We trace the origin of the canning industry to Appert. Appert's (1810) process for 1-liter bottles of food was a 2.5-hour (150-min) process in a boiling-water bath. If Appert's 1-liter bottles were the diameter of conventional wine bottles, which are approximately the diameter of a commercial 303 glass jar or a one-pint home canning jar, we can use these dimensions to calculate the approximate F_0- or $F_{212.0°F}$-values. Calculated values are shown in Table 4, heat-penetration data are from Townsend et al. (1949).

When the infant commercial-canning industry moved first from a boiling-water bath to salt-water baths and then to the steam retort or autoclave to shorten process times, processing experts became a fixture of the canning industry. Processing experts were individuals who had "secret knowledge" as to how to heat process cans of food. The use of processing experts with their "secret knowledge" continued until about 1900. Unfortunately, a program of secrecy seems to still exist in the canning industry, today. The commercial-canning industry has considered all aspects of canning, including thermal processing, as a "trade secrets" area. The secretive nature of the industry has delayed the spread of processing knowledge and solving problems.

Perkins (1964) discusses the inconsistencies in our processing world. He points out that Dickson (1917) found that several of his laboratory-grown suspensions survived for 2 hours in boiling water. He also pointed out that Prescott and Underwood (1896) observed that some cans, inoculated with unknown microorganisms, spoiled after an 8-hour process in boiling water (estimated F_0-value of the order of 4.0 minutes). Today, we accept that microbial resistance varies widely in spore crops of the same species and that survival time is a function of both the resistance and number of microorganisms in the inoculum (Equation 1). Both Dickson (1917) and Prescott and Underwood (1896) used what must be considered to be laboratory-grown spores (they certainly were not natural-product microflora).

Making a ball-park evaluation of the data above (we do not know the actual conditions in terms of numbers of microorganisms and test details), Dickson's (1917) spores' survival for 2 hours in boiling water is not incompatible with published *C. botulinum* $D_{121.1°C}$-values (Pflug and Odlaug, 1978). Prescott and Underwood (1896) found that there was spore survival after 8 hours in boiling water; this resistance is compatible with today's resistance levels for resistant mesophiles that have $D_{121.1°C}$-values of 0.5 to 1.0 minute. At first glance, these assorted data may look incompatible but considering the general knowledge at the time all this work was done, they all sort of fit today's resistance values.

There are many ways to approach the *C. botulinum* problem. Esty and Meyer (1922), Townsend et al. (1938), Stumbo (1973), and others have concentrated on developing maximum *C. botulinum* heat-resistance values.

Laboratory Study of Microorganisms. About 1900, a couple generations after Pasteur, work started to be done on the bacteriology of canned-food spoilage. One of the first steps was to identify the causative organisms and then study their heat resistance.

We cannot take a quantity of soil or unprocessed product into the laboratory and directly measure the heat resistance of the microorganisms in the sample. The basic reason we cannot do this is that our field samples will contain many species of microorganisms, and for each species there will be a range of resistance levels (it will be heterogeneous regarding its microbiological population). We can only estimate D_T-values when we have a single species, a homogeneous culture, and the microorgamisms in the culture have an approximate straight-line semi-logarithmic survivor curve. The result of these unique conditions is that all of the microorganisms used in laboratory studies are laboratory-grown microorganisms.

The general procedure in collecting spores from the environment is to sample the raw food product, grow colonies from the isolate on a Petri plate, select an isolated colony and transfer microorganisms from that colony into a tube of growth media. This is repeated dozens of times. The potential test microorganism is identified, screened and after much effort, some are selected as test microorganisms. These test microorganisms are then used to produce spore cultures.

The heat resistance (D_T-value) of a bacterial-spore crop is affected by both the spore-growing and the spore-testing conditions. Growing conditions include the spore-crop growth medium and all the environmental conditions including the growing system, temperature, relative humidity, and growing time. Testing conditions include the vehicle in which the spores are suspended, testing method, recovery method, and post-heat treatment outgrowth medium. As with much of the biological world, the heat resistance (D_T-value) is a function of both the genetics of the spore and the growth and testing environments.

In the food-industry spore-research area, the general pattern has been to use procedures that will produce spore crops with high heat resistance. The laboratory director under whom I did my spore-growing apprenticeship was continually working to find the medium and environmental conditions that would produce the most resistant spores. In the laboratory, we started with heat-resistant isolates and used a suspending medium and a recovery medium that would give us maximum D_T-values along with near straight-line survivor curves. These were the techniques developed and used by people from the Continental Can Company, American Can Company, and the National Food Processors Association, in the 1910-1950s, where there was continual work to find the medium and environmental conditions that would produce the most resistant spores. This is essentially the approach of Esty and Meyer (1922).

One of the major problems of science is assurance of the relevance of the scientific laboratory experiments with the actual real-world conditions. The scientist should, as part of any project, make an accurate scientific assessment of the applicability of the generated data to the actual real-world conditions, rather than being allowed to proceed with an unproven assumption of relevance. The scientist should be expected to establish (prove or defend) the relevance rather than expect the reader or user of the data to have to prove or disprove the applicability of the generated data. Relevance is a universal problem, not just in canning technology.

Table 4: Calculated F_0- and $F_{212.0°F}$-Values for Convection- and Conduction-Heating Product in 303 Glass Jars, for Heating Times of 2.5, 3.0, and 3.5 Hours, in Boiling Water (at Sea Level).

	Convection Heating, 1% Bentonite*		Conduction Heating, 5% Bentonite*	
	f_h = 11.4. j_h = 1.21. IT = 131.0°F. CUT = 9 min.		f_h = 50 min. j_h = 1.23. IT = 140.0°F. CUT = 4.5 min.	
Process Time, Hours	F_0-Value, † min	$F_{212.0°F}$-Value,† min	F_0-Value, † min	$F_{212.0°F}$-Value,† min
2.5	1.05	135.4	0.68	88.1
3.0	1.28	165.4	0.91	118.0
3.5	1.52	195.4	1.14	147.0

*Heating data from Townsend et al. (1949). †F_T-value calculated by Method of Ball (1923) in Pflug 2008.

*The data in Table 4 are for 303 glass jars containing 1% and 5% bentonite, heating data from Townsend et al. (1949). The F_0- and $F_{212.0°F}$-values in Table 4 were calculated for the conditions used by Townsend et al. (1949) and include water cooling. The containers were heated and cooled so that the water temperature cooled from T_1 to 100.0°F in about 5 minutes. When air cooling is used, the *F*-value should be larger.

The size of the No. 303 jars were given as 303 x 411 (3.1875 x 4.6875), capacity 17 fl. oz., and are comparable to pint home-canning jars that are oval in cross section of the order of 3.1 inches x 3.3 inches x 5.2 inches tall.

Stumbo et al. (1975) states that raw food products, especially vegetables, contain a resistant mesophilic, non-pathogenic microbial population that has a $D_{121.1°C}$ ($D_{250.0°F}$)-value of 1.0 to 1.5 minutes. The resistant nonpathogenic, mesophilic spore-forming microorganisms play a role in the botulism hazard picture.

Stumbo et al. (1975) state that "mesophilic spore-forming microorganisms are more than five times as resistant as *C. botulinum* spores." Consequently, when there is a process delivery failure (the delivered F_0-value is less than the process design F_0-value), the resistant nonpathogenic, mesophilic spore-forming microorganisms will be first on the job, spoiling the food. "The numbers of spores of mesophilic bacteria more resistant than those of *C. botulinum* seldom will be greater than one spore per gram of food." "The approximate maximum heat resistance of these more resistant mesophilic spores will have $D_{250°F}$-values in the order of 1.00 - 1.50 min. (Stumbo, 1948; Stumbo et al., 1945; Stumbo et al., 1950; Secrist and Stumbo, 1956)."

"The *z*-values of these more-resistant mesophilic spores are generally in the range of 16°F to 20°F (Stumbo et al., 1950; Secrist and Stumbo, 1956). Because we are concerned with economic spoilage rather than consumer safety, it seems appropriate to assume a *z*-value of 18.0°F in designing processes to accomplish commercial sterility."

It seems to have been the practice over the years to solve all LACF problems by increasing the design F_0-value of the process. When we human beings are confronted with a problem, there is often a tendency to blame that part of the system that we understand least. Applying this behavior pattern to LACFs, we blame the problem on the design of the process and attempt to solve the problem by increasing the F_0-value when the problem is in the process delivery area. In a general way, design and delivery are mutually exclusive. The wrong design cannot be changed in the delivery and no matter how large the F_0-value used in the design calculation, the process will fail if an inadequate process is delivered to the product.

Table 5: Botulism Attributed to Home-Processed Food.
(Data fromTable 3 from Handbook for Epidemiologists, Clinicians, and Laboratory Workers. CDC (1974 and 1998 Issue)]

A	**B**	**C**	D	E	**F**	**G**	H	I
1900 thru 1909	1910 thru 1919	1920 thru 1929	1930 thru 1939	1940 thru 1949	1950 thru 1959	1960 thru 1969	1970 thru 1979	1980 thru 1989
2	**48**	**77**	135	120	**51**	**44**	**85**	**69**
	WATER BATH				PRESSURE COOKER			

Average Number of Outbreaks per Decade, 78.6, per Year, 7.9.
Range of Number of Outbreaks per Year, 4.4 to 13.5.

2.4 CDC Data on Home-Processed Food Botulism Outbreaks Suggest Relatively Constant Rate of Human Error

How do we arrive at the F_0-value necessary to control *Clostridium botulinum* in low-acid canned foods (LACFs)? What is the practical process to control *C. botulinum* in LACFs? We know that "Olympic, sprinter-type" spores have a $D_{121.1°C}$-value of 0.2 minute when heated in phosphate buffer and subcultured in rich nutrient media (Esty and Meyer, 1922), but what are the heat-resistance characteristics of the "garden variety, jogger-type" microorganism that sporulated in nature's garden?

I stated in the introduction that after many years of "groping in the dark," I felt that I was beginning to "see the light." I express this "new-found light" in a "*C. botulinum* Hazard Philosophy."

1. Errors in delivering the thermal process are the overwhelming cause of botulism problems (Drs. Wodicka and Schaffner of the FDA were convinced of this in 1971, hence the FDA-LACF regulations include requirements that the processor have in place a system for identifying process deviations, processing errors, and treating all process deviations before they cause problems.)
2. There are two levels of resistance that we need to be aware of and consider in *C. botulinum* control: the heat-resistance, D_T-value, of laboratory-grown spores and the heat-resistance, D_T-value, of *C. botulinum* spores in nature.
3. We are at the state we are in, regarding botulism, not because any of the physicians or scientists who worked on this problem made errors, but because wrong assumptions were made regarding the shape of the elephant to be identified. Some of the places we went astray were: there was failure to recognize the effect of growing spores in the laboratory vs. spores grown in nature, and the effect of numbers of microorganisms on survival times was not known. In addition, we all operated on the basis that, since we scientists do not make errors, those who operate retorts or water baths also do not make errors.

Studies in the 1920s, suggested water-bath processing was not able to kill *C. botulinum* spores. By 1945, most home-processing bulletins were recommending the use of the pressure cooker for processing LACFs. We are going to revisit this recommendation.

We present, in Table 5, botulism outbreaks attributed to home-processed food, 1900-1996, data taken from the CDC (1974) and CDC (1998) reports on foodborne botulism outbreaks. These data suggest that there was/is no difference in home-canning botulism outbreaks where pressure cookers are used compared with atmospheric water baths. There does not appear to have been any major change in the botulism incidence with the change from water bath to pressure cooker processing; the rate of botulism incidence is relatively constant.

If there is a significant hazard in consuming LACF processed in a water bath, there should have been a significant decrease in the incidence of botulism as home processors adopted the pressure cooker. Since the number of botulism outbreaks did not decrease with the change in processing method, but may have increased, these data suggest that there is some other, relatively constant factor that is producing botulism incidents regardless of whether water- bath or pressure-cooker processing methods are used in a noncommercial setting. We suggest that it is the regular, gross failure of a tiny fraction of human operators to deliver the required process for the specific system that is responsible for the 4 to 13 botulism outbreaks per year from 1910 through 1989.

(We did not include in our comparisons, the data in Table 5 for Decade A, incomplete records, and Decades D & E because this could be considered a transition period regarding processing method but also a stress period; it is my opinion that the number of botulism outbreaks is a function of the volume of home processing; home processing increases in times of economic stress, 1930 to 1939, and during W.W.II, 1940 to 1949.)

We have come to recognize in the past 50 years that human beings regularly and repeatedly error in all activities. We see this regularly in the use of the automobile; we are aware of it in the commercial-canning area, so we should expect it to regularly occur in the noncommercial processing of food. The role of human failure was recognized by those writing the FDA-LACF regulations in 1971. They prescribed, in the regulations, methods to minimize the effect of human error.

2.5 Probability that a Surviving Spore Will Result in a Botulism Incident

In Table 6, we show that it is probable that if *C. botulinum* spore survival is 1.0×10^{-6}, the botulinum-hazard level may be of the order of 1.0×10^{-8} to 1.0×10^{-10}.

When a spore survives in a can of food, there will not be a problem if the spore fails to outgrow or the spore outgrows but does not produce toxins. If a spore outgrows and either (a) produces gas so as to swell the can or (b) since *C. botulinum* has survived, a heat resistant mesophiles also will have survived and when they outgrow, produce gas which swells the can, the can will be thrown out and destroyed.

We believe that the probability of a viable *C. botulinum* spore, surviving the heat process, should be of the order of one in a million (1.0×10^{-6}) to one in a billion (1.0×10^{-9}). The probability of there being a botulism incident is different from the probability of a *C. botulinum* spore surviving, since for there to be an incident the surviving spore must germinate, outgrow, produce toxin, and the food product containing the toxin must be consumed.

Table 6: Probability that a Surviving Spore Will Result in a Botulism Incident.

Conditions Leading to a Botulism Incident	Additional Considerations that Reduce the Probability of a Botulism Food-Poisoning Incident (Probability of Occurrence)
(1) A viable *C. botulinum* spore must survive in a can of food.	1.0×10^{-6} to 1.0×10^{-9}
(2) The spore must germinate, replicate, and produce toxin.	Spore may have been injured, so it may fail to germinate, replicate, and produce toxin; the food product may be a poor growth medium for *C. botulinum* (estimate of the overall probability of surviving spores producing toxin - - 1.0×10^{-1} to 1.0×10^{-2}).
(3) The toxicogenic product must be consumed.	*C. botulinum* or some other more resistant organism may produce gas, swelling the can causing it to be discarded, or they may spoil or putrefy the food so it is discarded, or the food may be heated before being consumed, inactivating the toxin (estimate of the probability of a toxic product being consumed - - 1.0×10^{-1} to 1.0×10^{-2}).

3.0 Outcomes as a Function of Processing Conditions

There is a basic principle in the thermal processing area that is key to developing an understanding of the outcome of processing that is often not given the prominence it deserves: Based on the general philosophy that microorganisms die logarithmically (only with an infinite process will all microorganisms be killed), for all real processes, in a universe of millions of containers of product subjected to a properly designed and delivered sterilization process, **there will always be a finite probability of a container with a surviving microorganism;** most often manifesting itself as a swelled container.

Each post-processing swelled container is a figurative canary-in-the-coal mine and therefore warrants careful examination to ascertain the cause. It is usually not easy to identify the true cause which may fall in either of the following categories: (1) probability occurrence of a microbial survivor as the normal outcome of a properly designed and delivered thermal process, (2) an inadequate process delivered to containers of product, and (3) container failure that allowed microorganisms to enter the container. Pflug et al. (1981) studied post-processing swelled containers, their report is discussed below.

We believe that a discussion and interpretation of the possible outcomes of thermal processes will bring additional understanding to this often confusing area. There are three parts to this analysis: (1) Discussion of Table 7, calculation of outcomes of processes with F_0 s from 0.2 to 8 min. at five D_T-values; (2) a review and discussion of the results of an experimental project that studied post-processing outcomes (Pflug et al. 1981); and (3) estimating process outcomes for resistant, mesophilic, sporeforming microorganisms, Table 8.

3.1 Discussion of the Outcomes of LACF Processes with F_0-Values (a) in the Normal Area and (b) in the *C. botulinum* Hazard Area, Data Shown in Table 7

In Table 7 are shown the estimated number of units with surviving spores per one million units of processed product for 15 F_0-values from 0.2 to 8.0 minutes, for $D_{121.1°C}$-values from 0.08 to 0.7 minute for an N_0-value of 1,000 spores per test unit. Values were calculated using the semilogarithmic survivor-curve equation below:

$$F_{121.1°C} = D_{121.1°C} (\log N_0 - \log N_F). \qquad (1)$$

Columns A, B, and C are process-outcome data for $D_{121.1°C}$-values of 0.08, 0.10, and 0.20 minute, applicable to *C. botulinum*. The *C. botulinum* spore $D_{121.1\,C}$-value of 0.20 minute is the value reported for *C. botulinum* spores grown and evaluated under ideal laboratory conditions (Esty and Meyer, 1922; Stumbo, 1973). I believe that the $D_{121.1°C}$-value of 0.08 minute, Column A, is most representative of the heat resistance of *C. botulinum* spores grown in nature.

Table 7: Estimated Number of Units* with Surviving Spores per One Million Units as a Function of Delivered F_0-Values for an N_0 of 1.0 x 10^3 and Three $D_{121.1\,C}$-Values for *C. botulinum* and Two $D_{121.1\,C}$-Values of the Resistant, Nonpathogenic, Mesophilic Microorganisms.

	A	B	C	D	E
F(0)	D=0.08 min	D=0.10 min	D=0.2 min	D=0.5 min	D=0.7 min
	N(0)=1.0E3	N(0)=1.0E3	N(0)=1.0E3	N(0)=1.0E3	N(0)=1.0E3
Min	No. spores	No. spores	No. spores	No. spores	No. spores
	per 10^6	per 10^6	per 10^6	per 10^6	per 10^6
8.00	< 1	< 1	< 1	< 1	<1
6.00	< 1	< 1	< 1	< 1	3
5.00	< 1	< 1	< 1	< 1	72
4.00	< 1	< 1	< 1	10	1,931
3.00	< 1	< 1	< 1	1,000	51,795
2.45	< 1	< 1	< 1	12,589	316,228
2.00	< 1	< 1	< 1	100,000	1,000,000.
1.75	< 1	< 1	2	316,228	1,000,000.
1.50	< 1	< 1	32	1,000,000.	1,000,000.
1.25	< 1	< 1	562	1,000,000.	1,000,000.
1.00	< 1	< 1	10,000	1,000,000.	1,000,000.
0.80	< 1	10	100,000	1,000,000.	1,000,000.
0.60	32	1,000.	1,000,000.	1,000,000.	1,000,000.
0.40	10,000	100,000.	1,000,000.	1,000,000.	1,000,000.
0.20	1,000,000.	1,000,000.	1,000,000.	1,000,000.	1,000,000.

***** Assuming one spore per unit.

Examination of the processing outcomes in Column A, $D_{121.1°C}$-value of 0.08 minute, shows at a glance that to have more than one positive unit per one million units the F_0-value must be less than 0.80 minute. These data suggest that a botulism hazard occurs at a very low F_0-value. We must have a very small delivered F_0-value to have a significant number of *C. botulinum* positive containers with surviving *C. botulinum* spores.

Columns D and E of Table 7 are process outcomes for $D_{121.1°C}$-values of 0.5 and 0.7 minute, which represent average processing conditions required for resistant mesophilic spores. For the processing conditions represented in Table 7, Column D, $D_{121.1°C}$-value of 0.5 minute, an F_0-value of 3.0 minutes will have more than 0.1% of cans (10^3 in 10^6) with spore growth (assuming one surviving spore produces one spoiled can); at an F_0-value of 2.0 minutes, 10% of the containers will contain surviving spores.

Letting our eyes move down the rows of outcomes for each F_0-value in Table 7, starting with an F_0-value of 8.00 minutes and using the data in Column D, $D_{121.1°C}$-value of 0.5 minute as a reference, we observe large numbers of containers with surviving, resistant mesophilic spores many F_0-value minutes before we have more than one container per million containers for the *C. botulinum* $D_{121.1°C}$-values in Columns A, B, or C. These data suggest that, to have a *C. botulinum* positive can, we must have a low delivered F_0-value and that the probability is very small that a *C. botulinum* spore will be in a can alone, without a resistant, mesophilic spore present.

3.2 Post-Processing Observation of Food Containers

The production of safe, wholesome, and quality low-acid canned foods (LACFs) requires: (1) a properly-designed and validated process for the food product and (2) assurance that the designed process is delivered to the containers of food. Because of the exponential nature of microbial death, post-processing observation of the product is a third area that is very important in microbiological control.

Microorganisms subjected to a lethal stress decrease in numbers exponentially (in theory we never kill the last one). Consequently, we should expect to find a few swelled cans in the warehouse and/or at the supermarket. Management should make an organized effort to recover these containers and make this information part of the record of the manufactured lot. Data obtained from a study of recovered, post-processing, swelled containers can provide the management with valuable information on the F_0-value delivered to the product. Table 8 or similar presentations will aid in analyzing recovered, post-processing, swelled-can data.

3.2.1 Discussion of a Study from the Literature of Recovered Post-Processing Swelled Containers

To illustrate the value of recovering post-processing swelled containers and analyzing these data, I will use the results of a study reported by Pflug et al. (1981) where, over a 17-month period, swelled cans were collected from outlets of two supermarket food chains in Minnesota. The collected cans and their contents were examined using physical and microbiological tests. Microbiological results were reported by Davidson et al. (1981) and the leakage potential by Davidson and Pflug (1981); their results are discussed in the following five paragraphs.

Number of Cans Examined. Sales volume data for each outlet were obtained from the supermarket management. Incidence rates were calculated. The incidence rates ranged from 21 to 784 swelled cans per one million units sold; it varied with the type of food. Of the 1,104 swelled cans collected, 314 (28.4%) were found to have major container defects which were assumed to have permitted microorganisms to move into the container, grow, and produce gas that caused the swelled condition. The number of cans examined microbiologically was the difference between total swelled cans and cans with major defects, 790 (1,104 - 314).

Microbiological Analyses. Microbiological analyses were performed on the product in the 790 cans; microorganisms were recovered from 47% of the 790 containers tested. Calculations suggested that another approximately 47% of the swelled cans were the result of microbial contamination, although no microorganisms were recovered; 6% of the swells appeared to have been physically induced (non-microbiological). Food type appeared to influence the recovery of microorganisms. Types and incidence of organisms recovered were: 91.6% typical leaker-spoilage microorganisms, 0.5% thermophiles, and 7.9% pure cultures of resistant, mesophilic spore-forming (RMS) microorganisms traditionally associated with under-processing.

There were 24 cans of food that contained pure cultures of mesophilic, anaerobic sporeforming microorganisms. Toxin testing of these pure cultures was carried out by the Minnesota State Department of Health (MSDH) using the traditional mouse test. None of the anaerobic cultures were toxicogenic. Two of the pure cultures of mesophilic anaerobes were identified by the MSDH as *Clostridium bifermentans*; they had been isolated from peas and shrimp.

Table 8: Estimated Number of Units* with Surviving Spores per One Million Units as a Function of Delivered F_0-Values, for Five $D_{121.1°C}$-Values of Resistant, Mesophilic Microorganisms, and for a Specific N_0-Value from 1.0 to 1.0 x 10^4, for each D_T-Value

	A	B	C	D	E
F(0)	D=0.3 min	D=0.5 min	D=0.7 min	D=1.0 min	D=1.5 min
	N(0)=1.0E4	N(0)=1.0E3	N(0)=100	N(0)=10	N(0)=1.0
Min	No. spores	No. spores	No. spores	No. spores	No. spores
	per 10^6	per 10^6	per 10^6	per 10^6	per 10^6
8.00	<1	<1	<1	<1	5
6.00	<1	<1	<1	10	100
5.00	<1	<1	7	100	464
4.00	<1	10	193	1,000	2,154
3.00	1	1,000	5,179	10,000	10,000
2.45	68	12,589	31,623	35,481	23,263
2.00	2,154	100,000	138,950	100,000	46,416
1.75	14,678	316,228	316,228	177,828	68,129
1.50	100,000	1,000,000	719,686	316,228	100,000
1.25	681,292	1,000,000	1,000,000	562,341	146,780
1.00	1,000,000	1,000,000	1,000,000	1,000,000	215,443

***** Assuming one spore per unit.

Discussion

We will discuss the results of the post-processing swelled-can study using the data in Table 7. The outcomes listed in Tables 7 and 8 give us an indication of the numbers of cans with surviving microorgasnisms that we can expect to occur for a range of product microbial-load conditions and process F_0-values. Microbial survival in processed cans of food occurs on a probability basis (Pflug et al., 1981).

The incidence of containers with pure cultures of resistant, mesophilic spore-forming (RMS) microorganisms traditionally associated with under-processing was 79% of the 790 containers tested for a total of 62.4 cans. On the basis that there were 5,000,000 containers in the study, the RMS incidence was 12.5 cans per million cans. The data in Columns D and E, Table 7, suggest a mean delivered process F_0-value of about 4.00 to 6.00 minutes.

None of the swelled cans were positive for botulinum toxin. This should be expected when the range of F_0-values is 4 to 6 minutes, Columns A, B, and C in Table 7.

3.3 Estimating Process Outcomes for Resistant, Mesophilic, Sporeforming Microorganisms

Table 8 was developed to give a picture of the microbial-survival probability landscape with emphasis on resistant, mesophilic, sporeforming microorganisms. The processing outcomes are calculated as the numbers of surviving bacterial spores per one million units of processed product, tabulated for F_0-values from 1.00 to 8.00 minutes for $D_{121.1°C}$-values of 0.3, 0.5, 0.7, 1.0, and 1.5 minutes; and N_0 values of 1.0 x 10^4, 1.0 x 10^3, 100, 10, and 1.0. In preparing Table 8, we varied the initial number (N_0-values) from Columns A to E, high values were used with low D_T-values and low N_0 values were used with the highest D_T-values. Values were calculated using Equation 1.

We believe there are important insights that can be obtained by studying Table 8. The data in Table 8 present a picture of microbial survival as a function of $D_{121.1°C}$-values for F_0-values from 1.00 to 8.00 minutes. We can see at a glance the effect of the contaminating spore $D_{121.1°C}$-value and the sensitivity of processing outcomes to the delivered F_0-value.

4.0 Estimating the Probability of Process Failure

How do we arrive at an overall probability of an LACF botulism incident when we have a situation where there are several vastly-different probability levels among processing conditions?

A first step toward making a statistical analysis is to define the experimental unit. We are going to use a different experimental unit in the process-design area than in the process delivery area. For process design, we will use **the individual container;** however, in the process-delivery area, we will make our probability judgments on the basis of **the processing unit.**

Process design probability judgments should be made on the basis of the total number of individual containers to which the process design is applicable.

In the process-delivery area, probability judgments should be made on the basis of the processing unit. What is the processing unit? A processing unit is one or more containers that have the same general microbial load and receive the same thermal process. Each processing unit is a separate consideration and is an independent probability from all other processes. It is the batch, lot, retort (autoclave) load, or the single product, single-day production, of the restaurant or home canner. When there is a problem, it is a specific retort (autoclave) load problem, or in the restaurant or home-preservation area, it is the batch of a specific product production.

4.1 Discussion of Process Failure

4.1.1 Errors that May Occur in the Process Design Area

1. Calculated process incorrect for processing conditions.
    - 1.1 Error in the heat-penetration data: wrong product, product ingredient change, change in viscosity, change in particle conditions.
    - 1.2 Wrong process parameters used in the process calculation: i.e., *z*-value, temperatures, initial and cooling.
    - 1.3 Error in the calculated scheduled process; is estimated to be of the order of one error in 10^6 processes designed.
2. Inadequate process validation (no validation carried out).
    - 2.1 Failure to validate or inadequate validation is estimated to be of the order of one non-validated process in 10^4 processes designed.

4.1.2 Errors that May Occur in the Process Delivery Area

1. Process Failure: Manufacturing errors that affect the delivery of the scheduled process.
    - 1.1 Product
        - 1.1.1 Change in formulation; f_h different from value used in calculation; change in viscosity of the product; change in particle size.
        - 1.1.2 Equipment
            - 1.1.2.1 Change in headspace, fill weight.
    - 1.2. The probability of a manufacturing error is estimated to be of the order of one delivery error in 40 to 100 batches.
2. People failures: People errors that affect the delivery of the scheduled process.
    - 2.1 Operator failure. Operator failed to follow written procedures - wrong temperature, time, or both; errors in review of records.
    - 2.2 Record failure. Errors in critical values in processing records; for example, retort temperature, process time, pressure, process records, etc.
    - 2.3 Review failure. Failure to review records by the production supervisor and Quality-Control Department.
    - 2.4 Failure to act. Failure of QC Department to follow up on an adverse processing-record report.
3. The probability of an undetected delivery error is estimated to be of the order of one in 1.0×10^6 (after 3 reviews).

5.0 Conclusions Regarding Controlling the *C. botulinum* Hazard

1. The delivery of the thermal process to cans of food is the weak link in the chain of operations in preventing botulism. **Human operators** who fail to use the posted or a correct thermal process or are careless in the delivery of the thermal process are the primary cause of botulism problems. Botulism incidents such as the Bon Vivant or Castleberry Foods not only cause human suffering but have a very high economic cost. A lack of quality control in the retort room caused both of these companies to suffer great financial loss.

2. When a food manufacturer follows the GMP food regulations, the probability of a failure in the design and validation of the thermal process is so small as to be negligible compared to the probability of delivery failure. The probability of a process delivery failure is also small when the operator follows the FDA regulations regarding the use of accurate instrumentation and the conscientious gathering and reviewing of processing records.

3. Controlling *C. botulinum* in both commercially and home-processed food is a management and quality-control problem:

   In commercial processing, the FDA mandates there must be a series of measurements and QC checks to develop confidence that the probability of the designed process **not being delivered** to the retort load of product is of the order of one in one million (1.0×10^{-6}).

   In restaurant and home processing, we have to rely on the operator to carry out the processing specifications correctly. It is suggested that a data record for the process be kept to reduce the probability of an error.

4. The studies of Esty and Meyer (1922) regarding the resistance of laboratory-grown *C. botulinum* spores, tested using conditions designed to determine maximum survival times, are the basic data of the maximum F_T- and D_T-values available today. The probability of any laboratory-grown *C. botulinum* spores surviving an F_0-value of 2.45 minutes is extremely small. It is realistic to use this value as the starting point in designing commercial LACF processes because (a) it offers a large factor of safety and (b) it has almost no effect on the design F_0 which must take care of the resistant mesophiles that are usually at least five times as resistant as *C. botulinum* spores.

5. Circumstantial evidence indicates that Appert's (1810) water-bath process or the home-canning water-bath processes, of 180 or 210 minutes in use from 1900 to 1930, were able to control *C. botulinum* spores. Consequently, a thermal-process F_0 of the order of 1.0 minute must be able to control *C. botulinum* spores on products with natural contamination.

6 Significant spoilage by mesophilic spores in product that supports their growth is a sign of an inadequate process and should warrant immediate process analysis.

7. Cans of food that contain botulinum toxin **will have** received a small F_0-value.

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