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Controlling *Clostridium Botulinum* in Heat-Preserved Food

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Abstract

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.**
There are three major parts to the story:
(1) Truths regarding the *Clostridium botulinum* problem,
(2) Controlling the *Clostridium botulinum* hazard; and
(3) Estimating the probability of process failure.
The later includes errors that may occur in the process design area and errors that may occur in the process delivery area.

In the report, "Science, Practice and Human Errors in Controlling *Clostridium botulinum* in Heat-Preserved Food in Hermetic Containers," by Pflug, Irving J., Journal of Food Protection, 73(5):993-1002 (2010), the important story of *Clostridium botulinum* has been told in detail, but the important results have been hidden by the author's syntax. In this manuscript, "Controlling *Clostridium botulinum* in Heat-Preserved Food," we hope to make available the details of *Clostridium botulinum* control.

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.

Keywords : *Clostridium botulinum* hazard; food-poisoning, Process Delivery Failure; Heat Preserved food.

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, ${}^{F}121.1° C = {}^{D}121.1 C^{(\log N0 - \log NF)}$.
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_T-values!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 Good Manufacturing Practices (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 quality control (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.
(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.
(3) 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.
(4) Significant spoilage by mesophilic spores in product that supports their growth is a sign of an inadequate process and should warrant immediate process analysis.
(5) 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 a low-acid canned food (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 has 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; fh 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, the quality-control department plus 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 x 106 (after 3 reviews). The equation for this calculation is: P = P(1) x P(2) x P(3) = P(0.01) x P(0.01) x P(0.01) = 1.0 x 10-6

Conclusion

- There are several straight forward ways we can control the Clostridium botulinum hazard in heat-preserved food.
- The primary causes of botulism food-poisoning incidents result from human errors.

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