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100 Barr Harbor Dr., West Conshohocken, PA 19428
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Standard Guide for Use in the Establishment of Thermal Processes for Foods Packaged in Flexible Containers[1]

This standard is issued under the fixed designation F 1168; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide contains guidelines and recommended procedures for use in the establishment of thermal processes necessary to produce commercially sterile foods packaged in hermetically sealed flexible containers. It applies to foods packaged in flexible containers that are sterilized by the application of heat from fluid heating media, particularly steam, air, water, their combinations, and their mixtures.

1.2 Specifically, this guide describes procedures for determining environmental conditions in the retort during thermal processing of foods in flexible containers and for determining heating and cooling characteristics of such products during processing. Procedures are described by which these data are used in the determination or evaluation, or both, of safe thermal processes for food packaged in flexible containers.

1.3 *Limitations*—This guide does not cover the theoretical and practical considerations that justify thermal processing as a means of rendering a packaged food product commercially sterile, nor does this guide describe methods by which thermal processes are verified or confirmed by biological methods, such as by inoculated pack and count reduction techniques.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

1.5 The sections in this guide appear in the following sequence:

[1] This guide is under the jurisdiction of ASTM Committee F-2 on Flexible Barrier Materials and is the direct responsibility of Subcommittee F02.30 on Test Methods.

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2. Terminology

2.1 *Definitions of Terms Specific to This Standard:*

2.1.1 *ballast container*—a filled and sealed flexible retortable container enclosing a fixed volume of nonbiological material that is approximately equal to a food-filled container of the same size and shape in terms of the rate and extent to which it will absorb thermal energy by convection and conduction.

2.1.2 *come-up time*—time required following the introduction of heating media into the retort to raise the temperature at the reference thermometer location in the retort to the process temperature.

2.1.3 *cook time*—time span during which the retort is maintained at or above the specified processing temperature (that is, time span between end of come-up and beginning of cooling, sometimes referred to as the operator's process time).

2.1.4 *cooling time*—time required following the introduction of cooling water into the retort to lower the product internal temperature to a specified value (commonly 40 to 45°C).

2.1.5 *critical factors*—physical and chemical factors that influence the thermal response of a product to thermal processing or the inhibition or inactivation of microorganisms, or combination thereof, of public health significance, and which pertain to the flexible container, the enclosed substances (including gases), the retort, and environmental conditions within and around the container from the time of product filling to the end of thermal processing.

2.1.6 *operator's process time*—time between the end of come-up and steam off.

2.1.7 *temperature stability*—the degree to which temperature remains constant at a particular location.

2.1.8 *temperature uniformity*—the degree to which temperatures are equal throughout a particular volume.

2.2 *Symbols:*

2.2.1 F_M—the F_o value for a hypothetical product that uniformly exhibits temperatures that are synchronously identical to that of the internal retort environment at the designated retort location during the designated process cycle, and under the designated process conditions.

2.2.2 F_o—the equivalent time in minutes at 121.1°C for product at the slowest heating point within the container under the designated process conditions to achieve the same level of destruction of bacterial spores or vegetative cells of a particular

organism and z value as by the existence of that reference temperature at that point for that time (centerpoint lethality).

2.2.3 F_s—the equivalent time in minutes at 121.1°C for all points within the container under the designated process conditions to achieve the same level of destruction of bacterial spores or vegetative cells of a particular organism and z value as by the existence of that temperature for that time (integrated lethality).

2.2.4 z—number of Celsius degrees required for the thermal destruction to traverse one log cycle.

3. Summary of Guide

3.1 A food product is prepared and sealed within a flexible container. Information pertaining to its formulation and conditions prior to thermal processing treatment is recorded. The packaged product is subjected to a program of temperature, pressure, and other relevant conditions within a retort, comprising a come-up phase, a cook phase, and a cooling phase. Temperature measurements of the food product at its slowest heating location are made, along with measurements describing processing conditions, at regular time intervals. These data are used to obtain heating and cooling rates for the specific product-retort system, and are used in determining the processing time necessary to achieve the specified lethality (for example, F_o) for the product.

3.2 The procedures involve the following aspects:

3.2.1 Selection, assembly, and testing of the temperature measurement system,

3.2.2 Evaluation and testing of the retort system,

3.2.3 Measurement of (*1*) heating and cooling medium temperatures during processing, and (*2*) the stability and distribution of these temperatures in the retort during each phase of processing,

3.2.4 Identification of data requirements and measurement and reporting of critical factors,

3.2.5 Selection of the number of containers to be tested, the number of replicate tests, and the simulation conditions,

3.2.6 Fitting and placement of the temperature sensing element in the product,

3.2.7 Process lethality and process time determinations,

3.2.8 Verification of the process, and

3.2.9 Reporting of results and scheduled process.

4. Significance and Use

4.1 Food products processed in flexible containers carry with them the same hazard potential as any other thermally processed food product packaged in a hermetically sealed container and subjected to a thermal sterilization process. Stringent process development and control procedures must be employed and maintained to avoid a significant risk to human health from resulting products. The use of this guide in developing these procedures should help to ensure that foods packaged in flexible retort containers will be commercially sterile.

4.2 The intention of this guide is to provide standardized, reproducible, and reliable procedures leading to the establishment of safe thermal processes for foods in flexible containers. Application of this guide should not be made except by specialists competent in the commercial thermal processing of foods and having access to all necessary facilities for making thermal process determinations.

PROCEDURES

5. Temperature Measurement

5.1 *Introduction*:

5.1.1 Temperature measurement within the flexible container can be made difficult by its thin profile and flexibility, and from the potential for irregularity of its thickness. The shorter process times that can be expected for products packaged in thin profile containers (thickness ≤ width) demand a high accuracy and precision of the temperature measuring system, since product internal temperatures change quickly, and because data must be acquired at a rapid rate.

5.1.2 Factors that can produce errors or may affect temperature measurements are:

5.1.2.1 The interaction of heat transfer media with temperature sensing devices,

5.1.2.2 Heat conduction along a temperature sensor or its support device,

5.1.2.3 Sudden or rapid changes in temperature or pressure conditions, or both, and

5.1.2.4 Stray voltages that exist between the contents of the container and its environment.

5.1.3 The acquisition of accurate time-temperature data describing the heating and cooling temperatures attained in the retort, as well as the stability and uniformity of temperature conditions in the product zone of the retort is essential for a meaningful process validation. Measurements of the temperature of the heating media are subject to many of the same precautions that apply to product temperature measurements, and these may be further affected by container racking arrangements and specific factors related to the retort design.

5.2 *Thermometry Systems*:

5.2.1 *Thermocouples*:

5.2.1.1 Thermocouples are used extensively for heat penetration studies and retort temperature distribution tests because they are simply constructed, rugged, and inexpensive. However, care must be exercised when using thermocouples to ensure that measurements result strictly from the temperature of the thermocouple junction and not from stray electrical currents, poorly constructed circuitry, or poorly designed or constructed instrumentation. Copper-constantan (Type T) thermocouple wire insulated with TFE-fluorocarbon is recommended for use in the temperature range of interest in thermal processing. This wire has the advantage of being resistant to heat and corrosion in moist environments. It is recommended that stranded thermocouple lead wire which is 22 gage or larger be used to minimize cold working effects. The effects of shunt leakage between two lead wires or connections is minimized by using a larger wire size.

5.2.1.2 Conditions inside the retort or inside the filled container necessitate special requirements and precautions in the use of thermocouples. The following are considered to be particularly important:

(*a*) Keep connections for thermocouple lead wires to a minimum, using plug and jack connectors designed for this purpose. Ideally, thermocouple connections should *not* be