

PRINCIPLES OF THERMAL PROCESSING

The “canning” of foods has been practiced for almost 200 years, but the science supporting the canning process has been understood for only about half of that time. In this section we will discuss the theory and science that forms the basis for the development and application of thermal processes to low-acid and acidified foods packaged in hermetically sealed containers. This section will identify and review some of the major factors affecting thermal processing of canned food products.

The objectives of this section are for you to be able to:

1. define commercial sterility;
2. identify who can establish a thermal process;
3. identify the components in establishing a thermal process;
4. identify factors that impact the thermal process; and
5. recognize a process deviation.

The Scheduled Process

As mentioned in the Introduction Section, “canned” products are treated with heat to make them commercially sterile. The condition of commercial sterility (or shelf-stability as it is characterized in the FSIS Canning Regulations -9 CFR 318.300 and 9 CFR 381.300) is recognized as follows:

Commercial Sterility – The condition achieved by application of heat, sufficient alone or in combination with other ingredients and/or treatments, to render the product free of microorganism capable of growing in the product at nonrefrigerated condition (over 50°F or 10°C) at which the product is intended to be held during distribution and storage.

A condition of commercial sterility will result in products that are safe to eat because the pathogens of concern are destroyed or inactivated. The product will remain shelf-stable as long as the container is intact because any spoilage organism that favors the environmental conditions within the container (i.e., anaerobic) and normal storage temperatures (i.e., mesophilic bacteria) are also

destroyed with the thermal process. The current FSIS Canning Regulations (9 CFR 318.300 and 9 CFR 381.300) refer to this condition as shelf-stability, but in this course we will refer to “canned” products as being commercially sterile to avoid confusion with the dry and semi-dry meat and poultry products that are also shelf-stable.

The application of heat to make a product commercially sterile is conducted in a controlled manner; this has been traditionally called the scheduled process or process schedule. The FSIS Canning Regulations (9 CFR 318.300 and 9 CFR 381.300) require that scheduled processes be established by a processing authority. A **processing authority** is a person or organization having expert knowledge of thermal processing requirements for foods packed in hermetically sealed containers and having adequate facilities to make these process determinations.

The scheduled process, as designed by a processing authority, if properly executed, will produce a commercially sterile product. The scheduled process, includes thermal processing parameters such as initial temperature of the product, the process temperature and the process time, plus any other critical factors that may affect the attainment of commercial sterility. Critical factors may include any characteristic, condition or aspect of a product, including formulation, container, preparation procedures, or processing system that affect the scheduled process. We will discuss critical factors again later in this section.

Processing authorities use their knowledge of food microbiology (specifically, thermobacteriology), heating characteristics of food, and processing systems as the basis for process schedule establishment. Contrary to other cooked meat and poultry products, the cook process for commercially sterile products is controlled by monitoring the process parameters (such as process temperature and time) rather than monitoring a temperature of the product. Temperature and time are easily controlled and monitored to ensure delivery of a proper thermal process.

For low-acid canned foods (those with a pH greater than 4.6), the thermal process focuses on the destruction of the spores of certain sporeforming bacteria. (These have been discussed in the previous section). The target pathogen for low-acid canned foods is *Clostridium botulinum* (specifically the spores of the organism.) Failure to destroy these spores, followed by germination and growth, can lead to the production of the deadly botulinum toxin, an extremely potent neurotoxin. Low-acid canned food processes that assure

the destruction of *C. botulinum* spores are adequate to protect human health; however, as noted previously, a more substantial process, or a commercial sterility process, is required to destroy spores of other microorganisms that could germinate and grow under normal storage and handling conditions and cause economic spoilage. The target for commercial sterility is typically *C. sporogenes*, an organism very similar to *C. botulinum* but with a higher heat resistance.

Thermal processes for acidified foods are targeted toward vegetative cells of microorganisms and are generally significantly milder than those applied to low-acid foods. This is primarily because spores of microorganisms such as *C. botulinum* will not germinate due to the acid nature in the product. Keeping the spores from germinating will prevent the growth of the vegetative cells of *C. botulinum* and subsequent toxin production. In distinguishing between acidified and low-acid foods, the standard used is a pH of 4.6 (greater than 4.6 is low-acid and less than or equal to 4.6 is acid or acidified). Typical thermal processes for acidified foods will maintain the commercial sterility of a product as long as good sanitation and GMPs are followed. Lack of pH control for an acidified food can lead to problems if the pH is high enough to allow surviving spores of *C. botulinum* to germinate and produce toxin.

Determining the scheduled process with the proper temperature and process time needed to produce commercially sterile products has been the subject of years and years of study in the canning industry. Sound process determinations depend upon good knowledge of the :

1. nature of the product and how it heats;
2. container in which the product is packed;
3. details of the thermal processing procedures used; and
4. characteristics of the target microorganisms such as growth, survival, and thermal resistance.

These four factors are related to the thermal resistance of the microorganisms and the heating characteristics of the product. Utilizing all this information, the processing authority will establish a thermal process that will specify the amount of time at a specific temperature necessary to ensure the destruction of *C. botulinum* and spoilage organisms that may be present.

Establishing a Thermal Process

As mentioned previously, the processing authority will base the establishment of a thermal process for a particular food product on two separate factors: 1) the thermal (also known as heat) resistance of the microorganism of choice in that food and 2) the heating characteristics of the product. In simplified terms, the processing authority needs to know 1) how much heat and for how long is necessary to destroy microorganisms in the food product and 2) how fast does the product heat (in the case of conventional canning) or how does the product flow (in the case of aseptic processing). The combination of these two factors is used to establish the thermal process.

The establishment of the thermal process will also depend upon the method of processing: conventional canning or aseptic processing. As noted in the Introduction section, in conventional canning, the product is filled into the container, the container is hermetically sealed, and the container and product are thermally processed at a specified time and temperature to achieve commercial sterility. For aseptic processing, packages or packaging material and the food product are sterilized in separate systems. Product sterilization involves heating a pumpable product to a sterilizing temperature and holding it at that temperature for sufficient time to sterilize the product. The packaging materials are sterilized with heat, chemicals, radiation or a combination. The sterile package is then filled with sterile product, closed and hermetically sealed in a sterile chamber.

Once a process has been established for a particular food, it is specific for that particular set of parameters regarding formulation, preparation, thermal processing system, container, etc. Since a seemingly insignificant change in any of these parameters could result in under-processing, it is important that processes not be altered without consultation with a processing authority.

Thermal Resistance of Microorganisms

The thermal resistance of microorganisms (vegetative cells or spores) is dependent upon a number of factors: 1) the growth characteristics of the microorganisms, 2) the nature of the food in which the microorganisms are heated, and 3) the kind of food in which the heated microorganisms are allowed to grow. Because of the variability of any biological entity, thermobacteriology is a highly complex science, and variations in any of these factors can affect the heat resistance of microorganisms.

► Thermal Death Time (TDT) Tests

The amount of heat required to destroy microorganisms in a product can be determined through thermal death time (TDT) tests. TDT tests are conducted by thermobacteriologists in a laboratory. Very few food processing establishments have the facilities to conduct TDT tests on-site. The instrumentation and equipment used for TDT tests include TDT retorts, tubes, and/or cans; three-neck flask, oil baths, sealed plastic pouches, and/or capillary tubes. The equipment and instrumentation used will depend on the type of product being tested – whether it is low-acid, acidified, thick puree, solid or a liquid.

TDT tests involve heating a known amount of microorganisms in a buffer solution or food at several temperatures and for several time intervals at each temperature. The results from the TDT tests are used to calculate D- and z-values. These values are used to define the heat resistance of the microorganisms of concern.

► Determination of D- and z-values

In conducting TDT tests, the thermal characteristics (D- and z-values) of the microorganisms will be determined. The D-value is defined as the time at a particular temperature required to reduce a known number of microorganisms by 90% or to result in a 1-log reduction. This is also termed the decimal reduction time because exposure for this length of time decreases the population by 90%, thus shifting the decimal point in the number of microorganisms remaining one place to the left. For example, if you had 100,000 spores and if exposing them to a temperature of 240°F for 3 minutes reduced the count to 10,000 spores, the $D_{240^{\circ}\text{F}}$ would be 3 minutes.

The D-value decreases as the temperature increases, since it takes less time to destroy the microorganisms at the higher temperature. By determining the D-values at various temperatures, a z-value can be determined from the slope of the line that results from plotting the log of D-values versus temperature. The z-value, indicative of the change in the death rate based on temperature, is the number of degrees between a 10-fold change (1 log cycle) in an organism's resistance. As an example, suppose that $z = 18^{\circ}\text{F}$ and the $D_{232^{\circ}\text{F}} = 3$ minutes. The $D_{250^{\circ}\text{F}}$ would be 0.3 minutes. (Because $232^{\circ}\text{F} + 18^{\circ}\text{F} = 250^{\circ}\text{F}$ and $3 \text{ minutes} / 10 = 0.3 \text{ minutes}$.) Both D- and z-values are indirectly used to establish thermal

processes.

► “Minimum Health” and Commercial Sterility Processes

Traditionally, a 12D process for spores of *C. botulinum* has been used to assure public health protection for low-acid canned foods. This has been based on historical data indicating that a heavy load of *C. botulinum* spores in a canned food product would be 10^{12} spores; therefore, a 12D reduction would provide a one-in-a-billion chance that a spore would survive in a canned food. For all practical purposes the 12D process is very conservative, as it is highly unlikely that spore loads of *C. botulinum* would approach these levels, especially in meat and poultry products. (Remember, *Clostridium botulinum* is rare in meats, and when present is there in very low numbers - 0.1 spore to 7 spores per kg meat.) A typical D-value for *C. botulinum* spore destruction in many foods is ~0.2 minutes at 250°F; therefore, a 12D destruction would be ~2.4 (=12 x 0.2) minutes at 250°F. (A value of 3 minutes is sometimes used to incorporate a margin of safety.) However in some products, the components of a food (or ingredients in a formulated food) can have adverse or beneficial effects on the thermal destruction of spores and will impact the D-values. For example, if 3 minutes at 250°F is needed to ensure public health at pH of 6.0, 2.0 minutes may be sufficient if the food is acidified to pH 5.3. (See discussion of F_0 values on the next page.) Processing authorities refer to the times and temperatures needed to inactivate *C. botulinum* as “minimum health” processes because this is what is necessary for public health protection.

In order to attain commercial sterility, a thermal process more strenuous than that required for public health protection must be provided. Commercial sterility means the condition achieved in a product by the application of heat to render the product free of microorganisms capable of reproducing in the food at normal non-refrigerated conditions of storage and distribution. A commercial sterility process will destroy other spores in addition those of *C. botulinum*. These spores, if not destroyed, have the potential to grow under normal storage and handling conditions and cause economic spoilage, even though they pose no public health risk. A 5D destruction of *C. sporogenes* spores (such as PA3679) is the target for commercial sterility. This 5D process for *C. sporogenes* spores is more lethal than a 12D process for *C. botulinum* spores due to the fact that spores of *C. sporogenes* are more heat resistant than spores of *C. botulinum*.

In order to compare thermal processes calculated for different temperatures, a

standard F_0 value is assigned for each product. This F_0 value is the time in minutes (at a reference temperature of 250°F and with a $z = 18^\circ\text{F}$) to provide the appropriate spore destruction (minimum health protection or commercial sterility).

As previously noted, using D- and z-values, this reference value at 250°F can be converted to other temperatures. Due to a variety of factors (e.g., influence of the food on the destruction of spores) different foods will have different F_0 values.

For example, if an F_0 of 6 minutes is needed to ensure commercial sterility at pH of 6.0, an F_0 of 4 minutes may be sufficient if the food is acidified to pH 5.3. In cured meat products containing 150 ppm nitrite and 3-4% brine (% NaCl X 100/ % NaCl + % water), an F_0 of 0.3–1.5 minutes may be sufficient to render the product commercially sterile.

F_0 values are already established for many food products. However, there are times, such as for novel formulas of food products, when TDT work may be needed to determine D- and z-values and appropriate F_0 values for spores of *C. botulinum* and *C. sporogenes* for a specific product. In the absence of TDT data on a specific formulation, a processing authority will apply a conservative F_0 that is known to result in a safe product.

Product Heating Data Determinations

Processing authorities determine product heating characteristics through the use of heat penetration tests. The rate at which a product heats can be measured using devices to monitor the rate of change in temperature of the food as it is being heated within the container (heat penetration studies). These determinations are made with a temperature sensor or thermocouple located in the product at the slowest heating region of the container. The slowest heating region will depend on the type of product, container size, processing method and the heat transfer mechanism. Typical heat transfer mechanisms in canned foods are convection (heat current flowing within the container as experienced in canned broths), conduction (molecule to molecule as experienced in corned beef hash), and combinations (for example, convection then conduction due to thickening of the product as maybe experienced in formulated products such as chicken and dumplings). The number of containers per run and the number of runs necessary to ensure the data are adequate depends on the variability of the product and the processing system. When either demonstrates significant variability, additional containers/runs may be required to ensure confidence in the process.

The need to simulate the worst case scenario likely to occur when producing product cannot be overstated, because the thermal process is controlled by monitoring and controlling the process parameters rather than with the actual temperature of the product. The processing authority will review variables in product preparation such as changing a starch or protein in the formulation, filling procedures, rehydration procedures, etc., to determine the impact on the heating rate of the product. More viscous product, higher fill weights, or improperly rehydrated product can all affect the heating rate of the product. If the heat penetration tests do not account for this effect or if the establishment can not control for these variations, the result could be under-processed product.

The heating characteristics of the product aseptically processed are also important. For aseptic processing, the heated product flows at a constant rate through tubing of a specified length; it is the flow characteristics of the product that determine whether certain particles in the fluid stream move through the tubing faster than others. The speed of the fastest moving particles (which remain at the elevated temperature for the shortest time) and the temperature of the flowing product determine the heat (lethality) attained by the product.

Process Schedule Calculations

For conventionally canned products, the process authority will calculate a process using the product heating data and the thermal resistance data for the significant spoilage organisms or organisms of public health consequence expected to be present in the product. These mathematical procedures combine the F_0 value that provides commercial sterility with the factors that define the product heating rate. There are several acceptable methods for calculating thermal processes. Some of the more common methods are the General Method, the Ball Formula Method, and the NumeriCAL™ Method.

For aseptically processed products, the process authority will calculate a process using the flow characteristics of the product and the thermal resistance data for the significant spoilage organisms or organisms of public health consequence expected to be present in the product. The resulting process schedule will indicate a specific sterilization time or residence time at a specific temperature. The residence time is directly related to the rate of flow of the fastest moving particle/fluid stream through the system.

Although the method of characterizing the product heating rate is different for

conventionally canned and aseptically processed products, the F_0 value for a particular food is the same in either processing method.

ACIDIFIED FOODS

Products that are high acid (have a low pH) or are acidified to a pH of 4.6 or less do not require a high temperature process. The foods may be processed at the temperature of boiling water – 212°F (100°C) – or lower. The thermal process is designed to destroy vegetative cells and some spores of low heat resistance. The product's low pH (4.6 or less) will prevent the remaining spores from growing out.

To produce products with a pH of 4.6 or less, acidification must be properly carried out. Here are some methods to obtain properly acidified foods.

1. **Blanch the food ingredients in an acidified aqueous solution.** To acidify large food particulates, the particulates could be blanched in a hot acid bath. The ability to obtain a properly acidified product is dependent upon blanch time and temperature, as well as the type of and concentration of acid.
2. **Immerse the blanched foods in an acid solution.** That is, blanch the product in the normal steam or water blancher. Then, dip it into an acid solution, remove it from the acid solution and place it into containers. Proper acidification depends upon how well the product is blanched, the concentration of the acid and the contact time.
3. **Direct batch acidification.** This is normally the best way to acidify fluid material. Ingredients are mixed in a kettle, and acid is added directly to the batch. (An elevated temperature may improve the rate of acid penetration into solid particles.) The pH of the batch is checked before the material is sent from the batch kettle to the filler.
4. **Add acid foods to low-acid foods in controlled portions.** Essentially, this is how a formulated product such as pasta sauce is made. Components in the sauce, such as meat or onions, are low-acid foods, while the tomato sauce is an acid food. The acid food is mixed with the low-acid food to get an acidified food product. The formulation, including the proportion of tomato sauce to low-acid components, is critical to obtain uniform and accurate control of pH of the finished product.
5. **Directly add a predetermined amount of acid to individual containers**

during production. This involves addition of acid pellets, known volumes of acid solution, or some other means for direct acidification of each container. This is probably the most inaccurate and least consistent method of acidification, because acid addition to a given container may be overlooked. Although this is a permissible way to acidify, it is not recommended and it is not used for meat and poultry products.

Processes for acidified foods may involve a hot-fill-hold process or the conventional canning process. Hot-fill-hold processing involves filling the product hot, sealing the container, then holding filled containers for a period of time at or above a certain temperature before cooling. Acidified products may also be processed in a pasteurizer, atmospheric cooker or retort for a given period of time to destroy the target microorganisms. The processing authority will calculate a process using pH, fill temperature, and the thermal resistance data for the significant spoilage organisms.

INOCULATED TEST PACK

It is possible and sometimes desirable (e.g., with new products or new processing systems) to confirm the calculated process by means of inoculated test packs. In this procedure, the test product is prepared under commercial plant operating conditions. Appropriate test microorganisms of known heat resistance are added to the product. (It is undesirable to use *C. botulinum* spores in processing plants processing low-acid canned foods due to the risk associated with the potential toxin production.) The product is inoculated with a known number of microorganisms and is then subjected to various processing times at one or a number of different processing temperatures. The product is then incubated at an appropriate temperature for growth of the test organism. Product that received a process inadequate to destroy the added microorganisms will show evidence of spoilage. A satisfactory process is demonstrated by the absence of spoilage. Substantial agreement between calculated processes and those determined by inoculated packs furnishes the strongest possible assurance of the adequacy and safety of a particular process.

Occasionally, due to peculiarities of the thermal processing systems or the product, reliable heating data cannot be obtained. Under these circumstances, consideration may be given to using an inoculated pack alone to establish a safe thermal process. 

Process Deviations

A deviation in processing (or a process deviation) occurs whenever an actual thermal process is less than the scheduled process (or process schedule) or when any critical factor does not comply with the requirements for that factor as specified in the process schedule. Common causes of process deviations for traditional canning operations include failure to meet initial temperature, process time, or retort temperature requirements or failure to meet any other specified critical factor. For aseptic processing and packaging systems, deviations can result from improper hold tube temperature, flow rate, or package sterilization; breach of the aseptic zone; etc. According to FSIS regulations (9 CFR 318.308 and 381.308) deviations involving meat and poultry products may be handled in accordance with a HACCP plan for canned product that addresses hazards associated with microbial contamination or alternative documented procedures that will ensure that only safe and stable product is shipped in commerce. Otherwise, deviations must be handled in accord with procedures specified in paragraph (d) of the regulations.

Product involved in deviations identified during processing may be immediately reprocessed using the full scheduled process, may be given an appropriate alternate process established in accordance with FSIS regulations, or may be held for later evaluation by a processing authority to determine its safety and stability. It should be kept in mind that, in some cases, the original process may change the heating characteristics of the processed product (e.g., thickening due to starch). For this reason it is a good idea to consult with the processing authority to assure that the reprocess is adequate for the product and conditions of use.

Upon completion of the evaluation of the process deviation, the establishment maintains a complete description of the deviation along with all necessary supporting documentation; a copy of the evaluation report; and a description of any product disposition actions, either taken or proposed. Product handled in accordance with paragraph (d) of the regulations shall not be shipped from the establishment until the inspection personnel have reviewed all of the information submitted and the product disposition actions.

If an alternate process schedule is used that is not on file with the inspector or if an alternate process schedule is immediately calculated and used, the product shall be set aside for further evaluation as noted above.

Product involved in process deviations that are identified through review of processing and production records shall be held and the deviations evaluated by a processing authority in accord with the requirements noted above. If product involved in a deviation is destroyed, destruction shall be conducted in accordance with FSIS regulations.

FSIS regulations also require the maintenance of a process deviation file. The establishment shall maintain full records regarding the handling of each deviation, regardless of the seriousness of the deviation. Such records shall include, at a minimum, the appropriate processing and production records, a full description of the corrective actions taken, the evaluation procedures and results, and the disposition of the affected product. Such records shall be maintained in a separate file or in a log that contains the appropriate information. The file or log shall be retained for no less than one year at the establishment, and for an additional 2 years at a suitable location. The file or log shall be made available to inspection personnel upon request. 

Workshop: Process Letter Review

Note: This is a simplified example prepared for instructional purposes only.

Review the following process letter and answer the questions.

1/24/2005

Dr. John Smith
Food Safety Manager
Uncle Sam's Canned Goods Company
1234 E. Canning Plant Rd
Somewhere, ST 12345-1234

Dear John,

Based on the heat penetration data that you provided to us, we would recommend the following thermal processes for your **Chili No Beans** in 300X407 metal cans.

Processing Conditions

Product:	Chili No Beans
Processing System:	Water Immersion with Container Rotation
Container Size:	300x407 metal cans
Least Sterilizing Value (F_o)	5.3
Critical Factors:	
Fill weight of fully soaked beans:	10.0 ounces
Container orientation:	Vertical
RPM:	18-20
Headspace (inches):	10/16
Product:	Preparation method and Formulation
Minimum come up time (minutes):	13

Process Time in Minutes

Initial Temp. (°F)	Process Time (minutes at Retort Temperature (°F))		
	250	251	252
90	40	39	38
100	39	38	37
110	38	37	36
120	38	37	36

These processes are designed to produce a commercially sterile product provided that all processing and packaging operations are completed satisfactorily. Please give us a call if you have any further questions.

Sincerely yours,

Kelly White
Senior Scientist, TPA, Inc.

Questions:

1. What are the critical parameters that will need to be controlled by Uncle Sam's Canned Goods Company when processing this product?
2. There are several errors on the process letter. Please identify the errors or information that needs to be clarified.

3. What would be the impact if the headspace requirement was not met?

4. What would be the impact if the beans were not soaked?

5. What process time would Uncle Sam's Canned Goods Company use if the product initial temperature was 115°F and the retort was operated at 252°F?

Uncle Sam's Canned Goods Company has set the following as the operating process for this product:

Minimum IT = 100°F
Minimum Retort Temperature = 252°F
Minimum Process Time = 40 minutes

6. Would the operating process result in a higher or lower F_0 than the scheduled process? Why would the firm use an operating process rather than a schedule process?

7. Which of the following situations is a processing deviation?

IT = 90°F RT = 250°F Process Time = 40 minutes	IT = 100°F RT = 251°F Process Time = 42 minutes	IT = 112°F RT = 249°F Process Time = 42 minutes
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