How to Submit a Commercial Food Product for Process Review

Guide E-325

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What is a process review of a commercial food product?

A *process review* of a commercial food product is a complete evaluation of how a food product is made, including all the steps of preparation, ingredients, and packaging. These procedures must be followed for each batch processed.

Commercial canning of food has evolved from the closed kettle system developed by A.K. Shriver in 1874—the first retort system, similar to a pressure cooker—to today's aseptic processing method, in which food is sterilized and then packaged under sterile conditions. Boiling-water baths have been used for centuries, but they don't provide adequate heating to prevent microbial spoilage or control *Clostridium botulinum* in low-acid food. Because canned foods should be safe to eat without further cooking by the final consumer, it is critical that these foods be processed with the highest food safety standards to control toxins from *Clostridium botulinum* and other potential health risks.

When is a process review of a commercial food product necessary?

A process review is required to assure the U.S. Food and Drug Administration (FDA) that a *commercially sterile* food product sold will not harm the final consumer.

Low-acid and acidified foods that are shelf-stable and sold without refrigeration must be evaluated by a *process* (or processing) *authority*. As defined in the Code of Federal Regulations (21 C.F.R. § 113.83), a **processing authority** is a person who has "expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and [has] adequate facilities for making such determinations."

Regardless of the method used to can foods, the processor must ensure that the finished product is a safe food product. It is the processor's responsibility to determine the status of their products under the regulations in 21 C.F.R. §§ 113–114. Processors should first request the assistance of a process authority. A process authority is available at New Mexico State University and at other state universities. In the case of novel products, the processor may need to contact the FDA directly about the status of their product.

Additionally, there are other state and federal food safety regulations that must be addressed by acidified food processors. Processors may be required to have specific certified training in Hazard Analysis and Critical Control Plan (HACCP) and Food Safety Modernization Act (FSMA; 21 C.F.R. § 117), also known as Preventive Controls For Human Food Training and Certification. These are food safety systems that are tools to ensure a safe food supply. These terms are further defined in the *Definitions* section below.

How does a process authority evaluate a commercial food product?

A process authority evaluates the thermal process for food and must have expert knowledge of thermal processes, hermetically sealed containers, and food microbiology, and have facilities to determine a safe process or *process schedule* for each product. A process schedule is designed by a process authority to deliver a "commercially sterile" (FDA) or "shelf-stable" (USDA) food product. The process schedule describes acidification, preservatives, packaging, and the application of heat or cooking used to eliminate microorganisms in the product handled under non-refrigerated conditions. The microbial quality of the final food product is determined by collecting a sample and performing bacterial counts such as an aerobic plate count and *E. coli*, coliforms, yeast, and mold counts. The stability (change in water activity or acidity) of the food once canned is another measure of product safety.

The cooking step in making a food product is called a *thermal process*; it is established by understanding the food microbiology and processing method for the specific food that is packaged. Food spoilage microorganisms are present throughout the environment, packaging containers, and ingredients. Additionally, pathogenic

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bacteria such as *Salmonella* and *E. coli* O157:H7 can survive in jarred acidic food. Thermal processes above 160°F will kill the active microorganisms present in food, and the hermetically sealed container prevents re-contamination.

The thermal process is determined by:

- Food product ingredients and shape and piece size
- Container dimensions
- Time and temperature
- Growth and survival of thermal-resistant microorganisms

There are two factors used to evaluate the safety of a thermal process: the heat resistance of microorganisms (or the heat needed to destroy the microorganisms in the food) and the heating rates of specific foods. Thermal processes are specific to food formulation, preparation, container, and thermal method used. The thermal resistance of the microorganisms depends on the growth characteristics of the microorganisms and on the nature of the food; that is, the acidity of the food or if it is whole, chopped, or puréed. A dense food such as meat will heat more slowly than, say, asparagus. Similarly, a mashed vegetable will heat more slowly than whole vegetables in a brine or broth. Food product heating data are collected by placing a temperature sensor in the product at the slowest-heating (coldest) region. Heating rate for the retort process depends on the type of product and the container size and shape. Once the thermal process is determined, the schedule process can be submitted to the Food and Drug Administration, which regulates this type of food product.

How are foods made to be commercially sterile?

Commercially sterile products can be made by several different methods. The most common processes used are retorting—processing at high heat and pressure—and acidification of low-acid foods, which also includes aseptic processing. Each process has specific instrumentation and steps that must be followed to produce a safe product. The following information is a brief introduction to each process.

Retort Processing

Low-acid foods such as meat or vegetables must be thermally processed in a retort. Retort operating procedures are designed to provide uniform temperature distribution under pressure using a heating media (usually steam) throughout the retort. Processing canned food under pressure allows the temperature to rise to 250°F, which will destroy the spores of *Clostridium botulinum*.

A retort thermal process is very complex and requires special instruments to verify the safety of the thermal process. Therefore, most small food processors use an acidified method followed by pasteurization, known as *hot fill and hold*.

Hot Fill Processing

The hot fill and hold process can be used to process foods that are acid or acidified. All ingredients are thermally processed in an open steam kettle, heat exchanger, or other thermal process to a temperature of at least 180°F, then transferred to clean containers, sealed, and held at temperature for a pre-determined time. Reaching a temperature of 180°F is critical to push out any air remaining within the container; as it cools, a vacuum is formed, resulting in a hermetically sealed container. Acidified food can also be thermally processed in a retort to pasteurize the canned food.

Acidification

Acid or acidified foods must have an acidity of less than 4.6 pH at equilibrium (the point at which pH will no longer change). This acidity level will control *Clostridium botulinum*, which is the microorganism of concern for canned food. The acidity equilibrium point may be reached immediately, or it may take several days after processing for it to be reached. The product must be stored under refrigeration until the equilibrium point is reached. This dynamic depends on the ingredients and type of acid used. Regardless of the thermal method, the thermal treatment must be adequate to control spoilage organisms and other potential pathogenic microorganisms of concern.

Aseptic Processing and Packaging

In an aseptic system, the product and package are sterilized in separate systems and then combined in a sterile environment for filling and sealing. The terms aseptic, sterile, and commercially sterile are used interchangeably but imply that the product is clear of microorganisms. Aseptic systems must be capable of sterilizing the equipment used to produce sterile product and sterile packages. Additionally, the environment area of production and filling must be kept sterile. All systems must be monitored and recorded to ensure proper handling of the finished product.

Food that is processed through an aseptic system must be fluid so that a pump can transport the product, and the pump must have a controllable flow rate so that all food particles receive an adequate thermal process. Once the container is filled and sealed, the product is a hermetic, shelf-stable product that can be shipped and stored like any other canned food product. The main advantage of this system is the variety of packaging containers that can be used.

How do I submit a commercial food product for process review to a process authority?

Make a final test batch packaged in final packaging (not prototype) following commercial food processing procedures. Collect information such as weight and acidity of each ingredient and processing steps. Fill out the form used by the process authority as completely as possible with the following information (see example in Table 1):

- The final product name and packaging and distribution method (how does it get to market?).
- The recipe with ingredients listed by weight (not cups or teaspoons) and acidity or pH; novel ingredients may require information from the manufacturer.
- Acidifier, such as vinegar or lemon juice, and preservative (if used).
- Changes in product weight during processing.
- Process controls such as time, temperature, pH, and water activity.
- Processing steps used to make product.
- Consumer preparation used before eating.

Additionally, two samples of the final commercial product should be sent to a laboratory for evaluation of microbial counts, pH, and water activity. A report should be sent to the process authority to assist with evaluation of the food product.

What does the process review tell me about my product?

The process review letter issued to the processor should contain information on the product classification and which FDA form to submit, regulations that apply to the product, and recommended processing steps. The letter may also contain information interpreting microbial and chemical test results.

Note on critical factor monitoring

Regardless of the processing method used to produce hermetically sealed product, there are critical factors that must be monitored for each batch of product made. In most cases acidity, thermal process, and water activity are critical factors to ensure food safety. These factors must be measured using a device or instrument that is accurate and that can be calibrated or verified when used. Additionally, these factors must be monitored for each batch processed. A critical factor such as acidity must be measured with a pH meter that has been calibrated with buffers of pH 4 and 7, temperature is measured with a calibrated thermometer, and, if necessary, water activity is measured with a water activity meter. These instruments are available through various suppliers that can be found on the internet.

Checklist for a process review of a commercial food

1. Contact food processing expert, process authority (NMSU Extension Food Technology).
2. Contact appropriate regulatory agency (U.S. FDA, State Department of Health).
3. Apply for city, state, and federal permits (as needed).
4. Process test batch of final product.
5. Record information from test batch on forms (Table 1).
6. Submit samples to laboratory for evaluation of microbial counts, pH, and water activity.
7. Submit information to process authority.
8. Receive process review letter (copy and store).
9. Fill out FDA forms for acid and acidified foods.
10. Submit paperwork to FDA either in paper format or electronically; also submit similar paperwork to local regulatory agency.
11. Submit final product label (21 C.F.R. §§ 101.1–101.9) to local regulatory agency.
12. Product is now legal for market.

Table 1. Example of Completed Food Tech Nutrition and Process Review Sheet		
Date submitted:		
Product name	**Zow's Favorite Chow Chow**	
Product type and package serving size	**Ready-to-eat food, 6-oz glass jar**	
Distribution method, temperature, and consumer use	**Shelf-stable room temperature; use directly**	
Shelf life (years or days)	**2 years**	
Ingredient	Amount (gal or lb)	pH (average of 3)
98% lean beef broth, canned	**1.0 gallon (8.6 lb)**	**5.6**
Carrots, frozen, drained	**10 lb**	**4.8**
Sweet potato, mashed, canned	**10 lb**	**5.6**
Green peas, frozen, drained	**10 lb**	**5.6**
Oatmeal, rolled	**50 lb**	**6.6**
Flaxseed meal	**10 lb**	**6.6**
Pecans, crushed	**10 lb**	**6.6**
Apples, dried	**10 lb**	**4.8**
Acidifier		
Citric acid powder	**1 lb**	**3.0**
Preservative		
None		
Weight before processing	Weight after processing	% change
119.60 lb	**110 lb**	**-8%**
Process control	Temp: **180°F** Final pH: **4.2** Aw: **0.85** Time: **20 minutes**	
Processing steps	**Chop dried fruit and pecans in food processor**	
	Chop carrots, peas, and sweet potato in food processor	
	Place in steam kettle with beef broth; cook until soft (about 30 minutes)	
	Add oatmeal and flaxseed meal, then mix	
	Add citric acid and mix	
	Cook to 180°F and hold for 20 minutes	
	Collect 20-g sample; cool, then test pH	
	Fill jars, clean edge, and apply cap	
	Cool	
	Code date and label	
	Box to storage	
Consumer preparation	**None; open package and serve; heat if desired**	

Definitions

Acid foods: Foods, including fermented foods, that have a natural pH of 4.6 or below. Natural pH means the pH before processing. However, if during processing the pH rises above 4.6 (through washing, lye peeling, etc.) and an acid or acid food is added to reduce the pH to 4.6 or below, that product would be considered an acidified food.

Acidified foods: Low-acid foods to which acid(s) or acid food(s) are added and which have a water activity (aw) greater than 0.85 and a finished equilibrium pH of 4.6 or below.

***Clostridium botulinum*:** A spore-forming bacteria that is capable of forming botulin toxin under anaerobic (oxygen-free) conditions. The toxin is extremely deadly even in small doses. The toxin is destroyed by heat; therefore, it is recommended to bring home-canned foods to a rolling boil before consumption.

Code of Federal Regulations title 21 part 113 (21 C.F.R. § 113): Thermally Processed Low-Acid Foods Packaged In Hermetically Sealed Containers

Code of Federal Regulations title 21 part 114 (21 C.F.R. § 114): Acidified Foods

Code of Federal Regulations title 21 part 117 (21 C.F.R. § 117): Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

Commercially sterile product: Food in a hermetically sealed package that will not allow any viable microorganisms to grow and in which microorganisms cannot be detected by usual bacterial culturing methods.

Equilibrium pH: The condition achieved when the solid and liquid parts of the product have the same pH. When an acid such as lemon juice is added to whole peppers, equilibrium might not be reached for several hours or several days. The product may need to be refrigerated until a pH of 4.6 is reached. The pH can be determined immediately after processing by blending the entire contents of the finished product container and taking the pH or blending the solid particles and acid brine in the proportion present in the finished product and taking the pH.

Exempt foods: These foods may be called pickles or pickled food. In addition, the following are excluded from regulation under 21 C.F.R. § 114: carbonated beverages, jams, jellies, preserves, acid foods that contain small amounts of low-acid food(s) and have a finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food (this includes such foods as standardized and non-standardized food dressings and condiment sauces), and foods that are **stored, distributed, and retailed under refrigeration.** Jams, jellies, and preserves covered by the standard of identity (21 C.F.R. § 150) are exempt foods if the water activity is 0.85 or less and the pH is 4.6 or less.

FDA forms 2541: Forms used to register food processing facility and low-acid or acidified foods. For filing instructions, see http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/AcidifiedLACF/ucm309376.htm

The following forms are required:

Form FDA 2541d: Food Process Filing for Low-Acid Retorted Method

Form FDA 2541e: Food Process Filing for Acidified Method

Form FDA 2541f: Food Process Filing for Water Activity/Formulation Control Method

Form FDA 2541g: Food Process Filing for Low-Acid Aseptic Systems

Fermented foods: Low-acid foods subjected to the action of certain microorganisms that produce acid during their growth and reduce the pH of the food to 4.6 or below. They may be partially desalted, processed, or preserved in the original salt brine, in new salt brine, or in a vinegar solution with other ingredients. Foods partially fermented require the addition of acid to reduce the pH to 4.6 or less.

Food Safety Modernization Act (FSMA) Preventive Controls for Human Food rule: Requires commercial food processing facilities to "establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. The rule sets requirements for a written food safety plan that includes:

- **Hazard analysis:** The first step is hazard identification, which must consider known or reasonably foreseeable biological, chemical, and physical hazards. These hazards could be present because they occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain (if they affect the safety of the food).

- **Preventive controls:** These measures are required to ensure that hazards requiring a preventive control will be minimized or prevented. They include process, food allergen, and sanitation controls, as well as supply-chain controls and a recall plan.

- **Oversight and management of preventive controls.** The final rule provides flexibility in the steps needed to ensure that preventive controls are effective and to correct problems that may arise.

  – **Monitoring:** These procedures are designed to provide assurance that preventive controls are consistently performed. Monitoring is conducted as appropriate to the preventive control. For example, monitoring of a heat process to kill pathogens would include actual temperature values and be more frequent than monitoring preventive maintenance activities used to minimize metal hazards, which could be a simple record of the date on which the activity took place.

  – **Corrective actions and corrections:** Corrections are steps taken to timely identify and correct a minor, isolated problem that occurs during food production. Corrective actions include actions to identify a problem with preventive control implementation, to reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent it from entering commerce. Corrective actions must be documented with records.

  – **Verification:** These activities are required to ensure that preventive controls are consistently implemented and effective. They include validating with scientific evidence that a preventive control is capable of effectively controlling an identified hazard; calibration (or accuracy checks) of process monitoring and verification instruments such as thermometers, and reviewing records to verify that monitoring and corrective actions (if necessary) are being conducted." (Food and Drug Administration, 2016)

Hazard Analysis Critical Control Point (HACCP): A management tool that utilizes risk analysis to address food safety concerns using specific evaluation of biological, chemical, and physical hazards from raw material production, procurement, and handling, to manufacturing, distribution, and consumption of the finished product.

Hermetic seal: A package that is under anaerobic conditions, that is, lacking the oxygen necessary for the growth of organisms that contaminate food.

Lot: The product produced during a period indicated by a specific code.

Low-acid foods: Food, other than alcoholic beverages, having a finished equilibrium pH greater than 4.6 and a water activity (aw) greater than 0.85 are considered low-acid foods. Tomatoes and tomato products having a finished equilibrium pH less than 4.6 are not classified as low-acid foods.

Pathogenic microorganisms: Also called pathogens; can cause disease or illness.

Scheduled process: A process used to manufacture a food that will not permit the growth of microorganisms that have public health significance. It includes control of pH and other critical factors equivalent to the process established by a competent processing authority. The process that is filed on FDA Form (see "FDA forms 2541" entry in *Definitions* section) is considered to be the scheduled process. The critical factors necessary to achieve and maintain a safe product are listed on the process filing form. They shall be controlled, and records of the results of tests or determinations kept.

Water activity (aw): A measure of the free moisture in a product, which is a measure of relative humidity within the product that can be used by microorganisms to grow. Any food that always has water activity of 0.85 or less is excluded from coverage under 21 C.F.R. §§ 113–114.

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