



## THE CANNERY PRE-LICENSING INSPECTION



Acidified foods and low-acid canned foods (LACF) that may support the growth of *Clostridium botulinum* must be packed under a valid Cannery License. You can learn more about *C. botulinum* by reviewing “What is Foodborne Botulism” and “Significance & History of the Cannery Inspection Program”. You can learn how to have your product evaluated to see if it will support the growth of *C. botulinum* by reviewing the following documents: “Steps for Submission or Re-submission of pH Samples (Acidified Foods)”; “How to Complete the Request for pH Control Form”; “Steps for Submission of Low-Acid Canned Food (LACF) Products”; and “How to Complete the Request for Official Sterilization Process Form”.

A pre-licensing inspection is required in order to obtain the Cannery License, and periodic unannounced inspections are required as a condition of continued licensure. Additionally, the Cannery Inspection Program is a fee-for-service program that requires batch release of all acidified food and/or LACF products prior to distribution.

All canneries are required to comply with the following state and federal laws and regulations:

California Health and Safety Code (H&SC) Section 112650 et. seq.  
Title 17, California Code of Regulations, Section 12400 et. seq.  
Title 21, Code of Federal Regulations (CFR) Part 101  
Title 21, CFR, Part 110  
Title 21, CFR Part 108 – Emergency Permit Control for LACF and AF canners  
Title 21, CFR Part 113 – for LACF products  
Title 21, CFR Part 114 – for acidified food products

Also, if the acidified food or LACF contains fish or fishery products, the canner will be required to meet the federal Hazard Analysis Critical Control Point (HACCP) regulations specified in Title 21, CFR Part 123.

It is the canner’s responsibility to operate in compliance with the applicable laws and regulations. Canners are expected to read and understand the laws/regulations prior to scheduling the cannery inspection.

### **THE PRE-LICENSING INSPECTION WILL INCLUDE EVALUATION OF THE FOLLOWING:**

**General suitability of the facility:** facility construction and design + product flow through the facility.

**Equipment and Food Contact Surfaces:** suitability of food contact materials, cleanliness, storage, protection from potential sources of contamination; instrument calibration and testing procedures (e.g., calibration of pH meters, pH buffer solutions, etc.)

**Pest Exclusion:** methods of excluding pests from the facility; pest control activities

**Plant and Grounds:** cleanliness of the area surrounding the facility.

**Facility sanitation:** cleaning and sanitation practices and procedures.

**Storage and distribution practices:** storage of ingredients, in-process materials and finished goods; distribution methods.

**Food labels:** general requirements (i.e., statement of identity, designation of ingredients, responsible firm information, net weight information); declaration of allergens; food safety warnings (if appropriate).

**Employee health and food-handling practices:** exclusion of ill employees from contact with food/food contact surfaces; hand-washing; appropriate clothing; hair/beard restraint; etc.

**Production process controls:** ingredients; formulation; manufacturing methods and controls (e.g., acidification, hot filling temperatures); equipment specifications and operations (container closure, can seam teardown, retorts); etc.

**Records:** Canners are required to maintain a production record for each day's operation. The production record must identify each product manufactured that day, and contain all critical factors specified on the S letter(s) for the product(s) manufactured.

Each production record will be numbered and initialed by FDB personnel, in numerical sequence starting with number 1 on July 1<sup>st</sup> of each year. FDB personnel will number and initial the production records during the pre-licensing inspection and/or during batch releases.

All production records must be accessible and maintained for at least three (3) years from the date of pack.

Below is an example of a production record for an acidified food:

Packer: Mickey's Gourmet, 12345 Main Street, Anytown, CA 99999										
Product: Spicy Salsa								Date of Pack: 1/15/2015		
Batch #	Container Size	# of Containers	Code (Complete)	Cook Start Time	Cook Start Temp	Cook End Time	Cook End Temp	Fill Temp °F	Canner pH	Inspector pH
1	12 oz.	144	MS011515A					180	3.57	
2	12 oz.	288	MS011515B					180	3.62	
3	12 oz.	147	MS011515C					180	3.59	

Note: FDB personnel will fill out the "Inspector's pH" when the batch release is conducted.

**Conformance to the scheduled process (S letter) issued by FDB:** The canner must maintain copies of all S-letters, "Request for pH Control" forms, and "Request for Official Sterilization Process" forms on file, for review by FDB personnel upon request.

Each batch of product manufactured must comply with the process that was established in the S-letter for that product.

**Lot coding:** A facility-specific container lot coding system must be in place. The product container coding system must address the requirements specified in regulation, such as, any combination of letters or numbers to identify (a) the facility (or company) where the product was packed; (b) the year of pack; (c) a distinct product code; (d) the date of pack; and (e) a batch or cook code. (Please note: unless there is a distinct batch manufactured, the batch number should be changed every 2 hours). The canner must be able to provide a detailed lot code breakdown description to FDB personnel upon request.

Two potential examples for: Mickey's Gourmet Spicy Salsa, packed on January 15, 2015

**MS011515A** where M = Mickey's Gourmet (manufacturer)  
S = Spicy Salsa (product)  
011515 = month (01), date (15), year (15)  
A = first batch or cook

**MS1554** where M = Mickey's Gourmet (manufacturer)  
S = Spicy Salsa (product)  
15 = Julian date (January 15 is the 15th day of the year)  
5 = 2015 (year)  
4 = fourth batch or cook

**Better Process Control School:** All acidified and LACF products must be produced at a licensed cannery under the supervision of at least one person who has passed the prescribed course of instruction and training requirements specified in 21, CFR, 113.10 and/or 21, CFR, 114.10. The canner must be able to provide FDB personnel with documentation to show which employee(s) have completed the required training. Cannerys can contact the University Extension, University of California, Davis for class registration information.

**Federal Food Canning Establishment (FCE):** All canners trading in interstate commerce must be registered as a FCE with the United States Food and Drug Administration (FDA). Cannerys are also responsible for registering all of their acidified food and/or LACF products with FDA. For FDA registration information, contact the FDA at (202) 205-5282, or visit their website. You can also obtain information by writing to FDA at: LACF Registration Coordinator (HFS-618), USFDA, Center for Food Safety & Applied Nutrition, 200 C Street, SW, Washington, DC 20204.

At the conclusion of the inspection, FDB will inform the canner of all violations and/or deficiencies identified. Please note that significant violations or deficiencies will result in the Cannery License being withheld until FDB verifies that appropriate corrective action has been implemented.

Please refer to "Cannery Release Inspection and Retort Operator Exam" for information about on-going cannery operating requirements, including information about cannery billing and batch releases.