



GENERAL REQUIREMENTS FOR pH CONTROL ACIDIFIED FOODS (AF)

Since the 1920s, the California Department of Public Health has been charged with regulating low-acid foods packed in hermetically sealed containers (e.g., cans, jars) that are marketed as shelf-stable products. The State regulations define "acidified foods products packed in hermetically sealed containers", or AF, as those shelf-stable low-acid foods that have their pH reduced to 4.6 or lower by the addition of acids. If your products meet this definition, then they must be packed under pH control, with the Food and Drug Branch (FDB) releasing the products in accordance with the Cannery Inspection Laws and Regulations.

To determine whether a low-acid food meets the above definition, FDB consults with the State contract laboratory, University of California Laboratory for Research in Food Preservation (UCLRFP), for an evaluation and safety assessment of the botulism risk of specific products. New products, such as vegetables in oil, sauces, salsas, and specialty foods that contain low-acid foods/ingredients must be submitted to the Laboratory for evaluation. Please review the [Guideline for pH Sample Submission \(pdf\)](#) and complete the UCLRFP [Request for pH Control \(pdf\)](#) form for submission (keep a copy for your file).

The UCLRFP's evaluation of an AF product is based upon the combination of foods/ ingredients prior to addition of the acidulant, and not the pH of the final product. Other critical factors assessed are: product formulation (recipe); water activity (a_w); acid content of added ingredients; acid content (equilibrium pH) of the final product; preparation procedures; filling temperatures; and production process controls. The FDB's Botulism Control and Cannery Inspection Program, based on the UCLRFP recommendation, will make a determination as to whether the product will be inspected under the program. If the product must be packed under pH control, then the processor must comply with FDB's inspection and release procedures for AF products. All pH control AF products must comply with production process controls in: [Cannery Regulations, Title 17 of the California Code of Regulations \(pdf\)](#) and [Title 21 of the Code of Federal Regulations \(CFR\) Part 114](#). In addition, all pH control AF products must be produced under supervision of a person who has attended an FDA approved 'Better Process Control School' as specified in [21 CFR 114.10](#). Contact the University Extension, University of California, Davis (1-800-752-0881) for registration information.

Any person (or a food processor) manufacturing a pH control low-acid food, must first possess a valid Cannery License issued by FDB. A cannery license can be obtained by:

- a. submitting a fully completed Cannery License Application and applicable fee; and
- b. successfully completing a Cannery License Inspection conducted by FDB.

The following items will be reviewed during a new Cannery License Inspection:

1. General suitability of facility (construction, design, etc)
2. Facility sanitation
3. Storage and distribution processes
4. Food labels and labeling Product formulation (original recipe evaluated by UCLRFP)
5. Employees qualifications
6. Workers safe food handling practices

7. Production process controls
 - a. ingredients
 - b. manufacturing methods and controls (e.g., acidification, hot filling temperatures).
 - c. equipment specifications and operations (container closure, can seams, retorts, etc.)
 - d. instrument calibration and testing procedures (e.g., pH meters, buffer solutions)
 - e. equilibrium pH for each batch of product produced
 - f. production records

Production records are an important requirement for all licensed canneries. Each production record must have the following:

- The name of the canner
- Date of pack
- The product
- The person(s) responsible for processing
- the total number of containers packed
- A distinct code for each product, on each container. The code can consist of any combination of numbers or letters, which the following information must be identified: -- the plant (or company) where product is processed
 - the year of pack
 - a distinct product code
 - the date of pack
 - batch or cook code. (Please note: it is recommended that, unless there is a distinct batch manufactured, the batch number be changed every 2 hours.)

For example: Micky's Gourmet Spicy Salsa, packed on October 28, 1998

Code: MS102898A where M = Micky's Gourmet (manufacturer)
 S = Spicy Salsa (product)
 102898 = Month, Date and Year
 A = Batch or Cook (A = first batch)

or

MS30185 where 301 = Julian Date of Year
 (October 28 is 301 day of the year)
 8 = 1998
 5 = Batch Number

or

MSJBHRCA where J = October
 BH = 28
 RC = 98
 A = Batch A (or Cook A)

The following items are reviewed during a routine inspection:

- Production records for each batch. *Each production record is numbered and initialed by an FDB Investigator in numerical sequence starting from number 1 on July 1 through June 30 of the following year.*
- pH test results at the completion of production by the processor (AKA the canner's pH). *All pH analyses must be conducted on a properly calibrated pH meter.* pH test results at the time of state inspection (the FDB Investigator's pH).
- The number of containers produced per code per day, and a cumulative total of containers packed in a production quarter/season, or year.
- When pH control products meet the all cannery inspection requirements, the FDB Investigator will then release the production batch, by stamping and signing the approved records. *The production record must be accessible and maintained for at least three (3) years from the date of pack.*

Example – A production record for each day's operation with critical factors recorded:

PACKER: MICKY'S GOURMET, 12345 MAIN STREET, SACRAMENTO, CA 95814

PRODUCT: SPICY SALSA DATE OF PACK: 10/11/04

PRODUCTION SUPERVISOR: _____

<i>Batch No.</i>	<i>Container Size</i>	<i>No. of Containers</i>	<i>Code (Complete)</i>	<i>Fill Temp. °F</i>	<i>Canner's pH</i>	<i>Inspector's pH</i>
1	12 oz.	144	MS101104A	180°	3.57	3.52
2	12 oz.	288	MS101104B	180°	3.62	3.51
3	12 oz.	147	MS101104C	180°	3.59	3.52

PLEASE NOTE:

To facilitate scheduling an inspection, FDB must be notified at least 48 hours in advance of any production that will occur.

After each inspection, it is the responsibility of the canner to submit a sample of each production batch, as determined by the FDB Investigator, to the UC Laboratory for final analysis.

For canners of seafood products, all processing operations must also be in compliance with the recently promulgated [Seafood HACCP regulations \(Title 21 CFR Part 123\)](#). All California licensed canners trading in interstate commerce must be registered as a Food Canning Establishment (FCE) with the [U.S. Food and Drug Administration \(FDA\)](#). The canners are also responsible for registering all of their acidified products and low acid canned foods (LACF) with the FDA. For FDA registration information, contact the FDA at (202) 205-5282 or write to:

LACF Registration Coordinator (HFS-618)
U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
200 C Street, SW
Washington, DC 20204

For questions concerning pH control foods or thermally processed low-acid canned foods, please contact the FDB office nearest you.

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For pH Control Sample Submission contact:

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