



WHAT DOES MY OFFICIAL PROCESS LETTER (S-LETTER) MEAN?



Acidified foods and low-acid canned foods (LACF) that may support the growth of *Clostridium botulinum* must be packed under a valid Cannery License issued by the California Department of Public Health, Food and Drug Branch (FDB). The first step in determining whether a Cannery License will be required is to have the acidified and/or LACF product evaluated by the University of California Laboratory for Research in Food Preservation (UCLRFP).

UCLRFP operates under a contract with FDB to provide scientific and technical expertise related to *C. botulinum* control. Upon conclusion of UCLRFP's evaluation, FDB will issue the canner an Official Process Letter (also called an S-Letter). Since there are several variations of S-Letter that can be issued, depending on the specific product evaluated, this document explains the steps the manufacturer needs to take in order to operate in compliance with California law.

IF THE S-LETTER SAYS THE PRODUCT IS:

An "**acidified food**" means that the product was determined to be an acidified food that could support the growth of *C. botulinum* in the absence of proper processing controls. The product **must** be manufactured under a valid Cannery License. Refer to Procedure for Obtaining a Cannery License.

A "**low-acid canned food**" means that the pH of your product was >4.6 and the product must be processed according to the LACF regulations found in Title 21, Code of Federal Regulations, Part 113. Submit a "Request for Official Sterilization Process" form, or have a licensed canner submit the form on your behalf if the canner will co-pack the product for you. Refer to "Steps for Submission of Low-Acid Canned Food (LACF) Products" and "How To Complete the Request for Official Sterilization Process Form" for additional information. UCLRFP will re-evaluate the product as a LACF, and FDB will issue a new S-letter. The product must be manufactured under a valid Cannery License. Refer to Procedure for Obtaining a Cannery License.

"**Not under pH control due to low water activity**" is an indication that pathogenic (disease-causing) microorganisms are not able **grow** in the product. However, recent scientific research shows that if certain pathogens are present, even though they may not grow in the product, they can **survive** and cause consumer illness. For this reason, you need to manufacture the product under strict Good Manufacturing Practices, including process controls; and use of high quality ingredients. You should also periodically monitor the water activity in the product by sending samples to a reputable food laboratory, reviewing the analytical reports, and maintaining the records in your files. Note: although a Cannery License is not required for this product, **the product must be manufactured, packed and held (stored/warehoused) under a valid Processed Food Registration (PFR).**

“Not under pH control because it is a refrigerated food” are foods that must be conspicuously labeled “Perishable Keep Refrigerated” and held under 45°F throughout storage, transportation and display are exempt from the Cannery License requirement. However, **these products must be manufactured, packed and held (stored/warehoused) under a valid Processed Food Registration (PFR).**

“Not under pH control because it is a fermented food” are fermented foods that are exempt from the Cannery License. However, **these products must be manufactured, packed and held (stored/warehoused) under a valid Processed Food Registration (PFR).**

“This is a Cold-Filled Acidified Food” is an acidified food that was not subjected to a thermal processing step to destroy disease causing microorganisms and spoilage organisms. A challenge study must be conducted to determine the hold time to destroy vegetative pathogenic (disease causing) microorganisms. If you have valid challenge study documentation, please submit it to the UCLRFP for review. If you do not have documentation from a valid challenge study, the UCLRFP may be able to conduct the challenge study; please contact UCLRFP for details.

POTENTIAL OPTIONS FOR REMOVING ACIDIFIED FOODS FROM THE CANNERY LICENSE REQUIREMENT

Frequently, FDB and UCLRFP receive inquiries from companies whose acidified food product requires pH control, but the company does not want to operate under a Cannery License. Note, even if the product is successfully removed from the Cannery License requirement, the product will still need to be packed under a valid Processed Food Registration (PFR). Here are some potential options to consider:

- Store, transport and display the product under 45°F and conspicuously label the product “Perishable Keep Refrigerated”. This will remove the product from the Cannery License requirement. However, a valid PFR will be required.
- Retain the services of a qualified food safety consultant to assist you in re-formulating the product. Re-submit the re-formulated product to UCLRFP for evaluation. Refer to “Steps for Submission or Re-submission of pH Samples (Acidified Foods)”. Be sure to read the section about re-submission of samples, which describes the fee for re-submission as well as some specific instructions about how to identify the sample. Once UCLRFP completes the re-evaluation, FDB will issue a new S-letter notifying you of the outcome of the evaluation, which may or may not change the product’s status, depending on the type of changes that were submitted for evaluation. If the product no longer requires a Cannery License, a valid PFR will still be required.
- Have the product co-packed by a licensed canner. That way, you do not have to obtain your own Cannery License. Please note: the licensed canner (co-packer) will need to re-submit the Request for pH Control form under their name, and a new S-letter will be issued for the product.

Important note: UCLRFP does not operate as a consulting laboratory. Do **not** contact UCLRFP to ask for information about how to remove your product from the Cannery License requirement. There are many ways to find food safety consultants: via the Internet, the phone book, industry associations, and on the University of California, Davis website.

FDB recommends that when hiring a food safety consultant, you should be a good consumer - make sure the consultant has experience with your product, and ask for references. FDB is not able to recommend or identify specific food safety consultants because that is a conflict of interest with our regulatory responsibilities.