**21 CFR 113: Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers**

**Background:** 21 CFR 113 was established due to the high risk of food safety issues related to low-acid foods (pH>4.6) packaged in hermetically sealed containers, such as cans or pouches. These foods are referred to Low Acid Canned Foods (LACF), which meet the following criteria:

* pH>4.6
* water activity>0.85
* shelf-stable (non-refrigerated or frozen)
* canned (or other oxygen-free environment)

This criteria creates an environment where *Clostridium botulinum*, a deadly bacteria, can grow. Therefor, the FDA requires certain steps must be met when making these food products.

**Affected foods (non exhaustive list):** Any LACF, such as canned vegetables, soup broth pouches, and canned tuna.

**Requirements:**

* **Regulatory:** There are a variety of regulatory requirements related to 21 CFR 113- one important one is that a *process authority* must verify the safety of your process.
* **Training:** The primary operator of an establishment making must take an FDA-approved course, such as “The Better Process Control School”, which covers how to safely make LACF.

**Additional resources\*:**

* [21 CFR 113 Regulation](https://www.ecfr.gov/cgi-bin/text-idx?SID=e4faef677f5062cb6511c7b1cc452376&mc=true&tpl=/ecfrbrowse/Title21/21cfr113_main_02.tpl)
* [FDA Acidified & Low-Acid Canned Foods Guidance Documents & Regulatory Information](https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/acidified-low-acid-canned-foods-guidance-documents-regulatory-information)
* [Acidified and Low-Acid Food Regulatory Requirements- Penn State](https://extension.psu.edu/acidified-and-low-acid-food-regulatory-requirements)
* [Facility Registration and Initial Regulatory Compliance Activities for Acidified Food and Low-Acid Canned Food Process in Florida- University of Florida](https://edis.ifas.ufl.edu/fs318) (not specific to the state of Florida)
* [Low Acid Foods Packaged in Hermetically Sealed Containers: What You Need to Know](https://www.fdareader.com/blog/2018/12/25/low-acid-foods-packaged-in-hermetically-sealed-containers)
* [How to Submit a Commercial Food Product for Process Review- New Mexico State University](https://aces.nmsu.edu/pubs/_e/E325/welcome.html) (information on filing and process authorities)

\*Note- many of these resources also related to acidified foods, which are different from low acid canned foods. Acidified foods fall under CFR 114- more information can be found [here](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=fcf52c6d383f1802c3210257d7dee987&mc=true&r=PART&n=pt21.2.114)