

Starting an Acidified/Low-Acid Canned Food Business Checklist

The information in this document is current as of the date of publication. It is important to check for changes or updates to applicable laws and regulations, as they are subject to change. This document is intended to be a guide only and may not be all-inclusive. The Minnesota Department of Agriculture (MDA) will determine your specific licensing requirements after reviewing all details about your new food business.

Where Do I Start?

You must first determine the type of food product you will be producing.

Acid foods have a natural pH of less than 4.6.

Acidified foods (AF) have a natural pH of greater than 4.6, to which ingredients such as vinegar or an acid are added to bring the pH below 4.6 to prevent microbial growth when stored at ambient temperatures.

Low-Acid Canned Foods (LACF) are foods (commonly vegetables) with a natural pH of greater than 4.6, that are thermally processed to prevent microbial growth and are stored in hermetically sealed containers.

Reference the [LACF/AF – Precursor Questions and Flow \(PDF\)](#) to aid in your determination.

A finished product would not be considered an acidified food if:

- The product is stored and distributed at refrigerated temperatures (less than 41°F), or
- The final Water Activity (Aw) is below 0.85.

Obtaining a Food License

See [Starting a Wholesale Food Business Checklist \(PDF\)](#) for additional information on general licensing requirements for your facility.

*Contact your local manufactured food inspector for a final licensing inspection at least two weeks prior to needing your license to allow time for scheduling.

You may use the following checklist as a guide to help you get started.

Table 1: Starting an Acidified /Low-Acid Canned Food Business Checklist

Task	Resources	Timeframe	Completed
Contact your MDA Manufactured Foods Inspector for licensing requirements	Find Your Wholesale/Manufactured Food Inspector Tool	Prior to starting food business	<input type="checkbox"/>
Have all potentially acidified and/or low-acid canned food products and production processes evaluated/validated by a Process Authority (PA).	Food Processing Authorities Directory – Association of Food and Drug Officials *The PA is not required to reside in same state as manufacturer.	Prior to producing each new product	<input type="checkbox"/>
Attend/Complete Better Process Control School, training in the principles of acidified foods, or other approved training.	Courses are available on-line and in-person at several universities and other locations throughout the US. A list of current/upcoming courses can be found by searching for “Better Process Control Schools List” or “Acidified Foods Training on the internet.	Prior to producing any acidified/low-acid canned food	<input type="checkbox"/>
Register with the FDA under the Bioterrorism Act registration requirements.	Bioterrorism Act registration information Registration of Food Facilities and Other Submissions	Prior to startup, fall of even numbered years	<input type="checkbox"/>
File for a Food Canning Establishment (FCE) Number using Form FDA 2541.	Instructions for Electronic Submission of Form FDA 2541 (Food Canning Establishment Registration) (PDF)	Within 10 days of startup	<input type="checkbox"/>
File scheduled processes for each variety, size, and container type of acidified and/or low-acid canned food produced. For LACF products: <i>FDA Form 2541 d</i> Food Process Filing for Low-Acid Retorted Method For Acidified products: <i>FDA Form 2541 e</i> Food Process Filing for Acidified Method	Guidance for Industry: Submitting Forms for Food Canning Establishment Registration and Food Process Filing to FDA in Electronic or Paper Format Establishment Registration and Process Filing for Acidified and Low-Acid Canned Foods (LACF): Electronic Submissions Establishment Registration & Process Filing for Acidified and Low-Acid Canned Foods (LACF): Paper Submissions	Within 60 days of registration, and prior to packaging a new product	<input type="checkbox"/>
Develop a process code/lot code.	21 CFR 114.80 (b) (acidified) 21 CFR 113.60 (c) (low-acid)	Prior to sale of product	<input type="checkbox"/>

Task	Resources	Timeframe	Completed
Develop a plan for process deviations.	Reprocess using an alternate process which has been established by a Process Authority, or Process as a Low-Acid Canned Food (LACF) according to 21 CFR 113, or Set aside for evaluation by a Process Authority.	Prior to first production/ Ongoing	<input type="checkbox"/>
Develop recall procedures.	21 CFR 117.139 (Acidified foods) 21 CFR 108.25(e) 21 CFR 108.35(f)	Prior to sale of product	<input type="checkbox"/>
Develop finished product labeling.	21 CFR 101	Prior to sale of product	<input type="checkbox"/>
Maintain required processing records.	21 CFR 114.100 (acidified) 21 CFR 113.100 (low-acid) 21 CFR 117 Subpart F	Required for each batch/all product produced	<input type="checkbox"/>
Provide and maintain required process monitoring equipment.	21 CFR 113.40 (low-acid) 21 CFR 117.40 (f) (acidified) 21 CFR 117.165 (acidified)	Ongoing	<input type="checkbox"/>
Comply with all applicable regulations: <ul style="list-style-type: none"> • 21 CFR Part 101 <i>Food Labeling</i> • 21 CFR Part 108 <i>Emergency Permit Control</i> • 21 CFR Part 113 <i>Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers</i> • 21 CFR Part 114 <i>Acidified Foods</i> • 21 CFR Part 117 <i>Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food</i> 	21 CFR Part 101 -- Food Labeling 21 CFR Part 108 -- Emergency Permit Control 21 CFR Part 113 -- Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers 21 CFR Part 114 -- Acidified Foods 21 CFR Part 117 -- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food	Ongoing	<input type="checkbox"/>

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