

The Step by Step Guide to the Licensed Processing of Acidified Foods

The intent of this handout is to provide the basic requirements and guidance for processors wishing to enter the business of processing acidified foods. This 'Step by Step Guide' contains tools to get started, complete with links for sample forms, and important contact information to help you along the way to becoming a licensed processor of acidified foods in Oregon. Failure to adhere to these requirements may lead to the foods being deemed adulterated and subject to a state or federal recall.

WHAT ARE ACIDIFIED FOODS?

Acidified foods means low-acid foods to which acid(s) or acid food(s) are added; these foods include, but are not limited to, beans, cucumbers, cabbage, artichokes, eggs, cauliflower, puddings, peppers, tropical fruits, and fish; singly or in any combination. Acidified foods have a water activity (A_w) greater than 0.85 and have a finished equilibrium pH of 4.6 or lower. These foods may be called, or may purport to be, "pickles" or "pickled." The following foods are not considered acidified: carbonated beverages, jams, jellies, preserves, acid foods (including such foods as standardized and non-standardized food dressings and condiment sauces) that contain small amounts of low-acid food(s) and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food(s), and foods that are stored, distributed, and retailed under refrigeration See 21 CFR 114.3(b)

STEP 1: SCHEDULE A CONSULTATION VISIT WITH THE OREGON DEPARTMENT OF AGRICULTURE

Contact the Food Safety Program at 503-986-4720. Your facility must be inspected and approved prior to making of the acidified foods. The consultation visit will include an evaluation of the food preparation area to ensure that it meets all applicable health, food safety, construction and sanitation requirements per OAR Division 25, and if applicable the Code of Federal Regulations:

The following link provides access to Oregon Administrative Rules Division 25:

<https://oda.fyi/OARdivision25>

You will also need to provide a detailed description of the process and an ingredient list in avoirdupois measurements. Part of the approval of the location may require the processor to test the source water and ensure it is deemed potable. These test results must be provided to the Food Safety Program.

STEP 2: EVALUATE YOUR PRODUCT

Make a batch of your product and evaluate the product against the flow chart that accompanies this guide. Critical factors such as: pH, water activity, brix, and refrigeration are used to determine food safety parameters and are required to assess whether or not the product is acidified. Once the product has been deemed "likely" acidified, proceed through the remainder of this guidance.

STEP 3: HAVE YOUR PRODUCT TESTED AT A CERTIFIED LABORATORY

Common tests for determining whether or not a food is acidified are pH, water activity (Aw), and brix (soluble solids as compared to pure sucrose). If test results indicate the food is “likely” acidified, continue with the following steps.

STEP 4: SUBMIT THE RECIPE AND FINISHED PRODUCT TO A PROCESS AUTHORITY FOR REVIEW AND APPROVAL

If the food is deemed acidified, you will need the assistance of a recognized *Process Authority* (a person with expert knowledge in the acidification and processing of acidified foods) to approve the safety of your recipe and develop a scheduled process to submit to the FDA (see Step 10).

STEP 5: ATTEND A FDA APPROVED “BETTER PROCESS CONTROL” SCHOOL FOR ACIDIFIED FOODS

You must attend and pass an approved FDA Better Process Control School class for Acidified Foods before engaging in the commercial production of acidified foods. This is a requirement of both the Food and Drug Administration (FDA) and the Oregon Department of Agriculture (ODA) per 21 CFR 114.10. You will need to provide a copy of your successful completion of the Better Process Control School Class to the ODA.

Two suggested courses are:

Oregon State University Food Science

<http://oregonstate.edu/foodsci/fst-extension-schedule>

Washington State University Food Science:

<http://www.foodprocessing.wsu.edu/bpcs/>

STEP 6: PROVIDE THE TOOLS AND DEVELOP PRODUCTION RECORDS SHOWING ADHERENCE TO THE SCHEDULED PROCESS

You will need special equipment to accurately measure pH levels, weights, security closures, and temperatures. Below are items to consider obtaining:

- A pH meter
- pH buffers & cleaning solutions
- Sanitizer & test strips
- A tape measure or ruler
- A thermometer
- A scale
- A clock or timer

You will also need to develop a recall plan, logs for monitoring critical control points (i.e. temperatures, pH, cook times, batch numbers), logs for recording pH meter and thermometer calibrations, a deviation log, container closure log, and a method for recording distribution to the first point of sale for all products sold.

STEP 7: CREATE A LABEL FOR YOUR PRODUCTS

All acidified foods products must at a minimum be labeled with the name and address of the producer, a common or usual name of the product, list of ingredients, and net weight.

See the ODA Food Safety labeling handout as a guide to developing your label. This is available on the ODA website: <https://oda.direct/LabelingGuidance>

STEP 8: Coding

Create a coding scheme as required in 21 CFR 114.80(b) and identify a means to ensure the code is on every label or jar.

STEP 9: REGISTER YOUR FACILITY WITH THE FDA

You must register your facility with FDA before you start processing any acidified foods recipes. See 21 CFR 108.25(c)(1)

FDA Establishment Registration: All commercial processors of acidified foods must submit FDA Form 2541 to register their processing plant (or domestic kitchen) with the FDA. This may be performed on the FDA website at: <https://oda.fyi/FDAEstablishmentRegistration>

The FDA will assign you a Food Canning Establishment (FCE) number. The FCE number identifies your facility and must also be used when you submit acidified foods filings with the FDA. *(Allow approximately 2 - 3 weeks for your number to be sent to you.)*

STEP 10: SUBMIT ACIDIFIED FOODS FILINGS TO THE FDA

You must register your acidified process with FDA before you start processing any acidified foods recipes. See 21 CFR 108.25(c)(2). When you receive the Process Authority letter of approval and the scheduled process for your recipe, complete FDA Form 2541E found online at <https://oda.fyi/FDAForm2541E> or by contacting the LACF Registration Coordinator at 240-402-2411. Use the critical factors and other process information described in the letter provided by the process authority to assist in completing the form. No fee is required for filing.

FDA Guidance and instructions for submitting Forms 2541 and 2541E either online or by paper format can be found at <https://oda.fyi/FDAFormGuidance>

If you do not have access to the FDA internet website, you may contact the FDA:

By email at LACF@fda.hhs.gov

By telephone at 240-402-2411

By mail at the following address:

Food and Drug Administration
LACF Registration Coordinator (HFS-303)
Center for Food Safety and Applied Nutrition
5001 Campus Drive
College Park, Maryland 20740-3835

STEP 11: REQUEST AN ODA FINAL ON-SITE PROCESS REVIEW AND LICENSING INSPECTION

Call the ODA Food Safety Program to arrange an approval inspection. At this time you will demonstrate completion of all the aforementioned requirements. The ODA

will request copies of your Scheduled Process, FDA Form 2541E, product labels, batch sheets used to record critical factors set-forth by the process authority, and any other information requested by the ODA. You will be required to demonstrate your knowledge and ability to meet the sanitation and process requirements for the production of acidified foods. This includes proficient use of your pH meter (21 CFR 114.90).

STEP 12: MAINTAIN ACCURATE RECORDS!

Keep all your records (licenses, certifications, process authority reviews, FDA forms, etc.) together in one place, preferably in a binder. Requirements for retaining records are identified in 21 CFR 114.100. You may receive a visit from FDA or ODA inspectors at any time during the year to observe your process, inspect your facility, and review processing records.

You are required to:

- Complete a 'Processing Log' each time you process a recipe for sale.
- Submit a FDA Form 2541E to the FDA for each new acidified food(s) recipe
- Keep your records up to date and available for inspection
- Upon request, provide copies of all required forms and reports

You may need to register your firm with the FDA in regards to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002:

<https://oda.fyi/FDAFacilityRegistration>

Food Safety Modernization Act (FSMA): Acidified Foods are not specifically exempt from any provisions of 21 CFR 117 and must comply with all applicable sections.

Oregon Department of Agriculture staff is available to advise and guide you through all the steps listed above. If you plan to make these products under the Farm Direct rules, specific rules apply and these can be found at:

<https://oda.direct/FarmDirectRules>

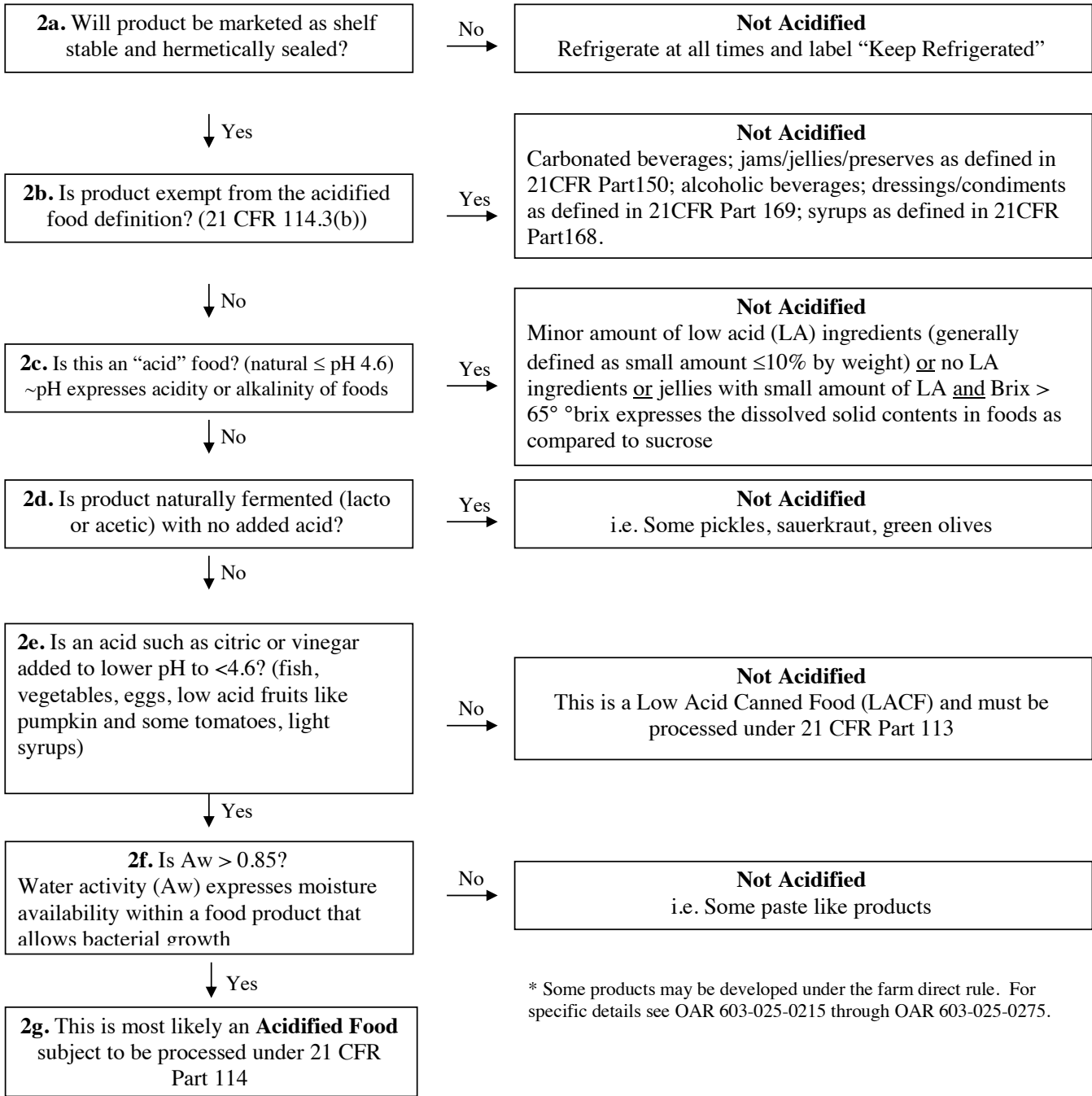
For more information contact the Oregon Dept. of Agriculture, Food Safety Program: (503) 986-4720, 635 Capitol St. NE, Salem, Oregon 97301-2532.

<https://oda.direct/FoodSafetyInformation>

Is it an Acidified Food?

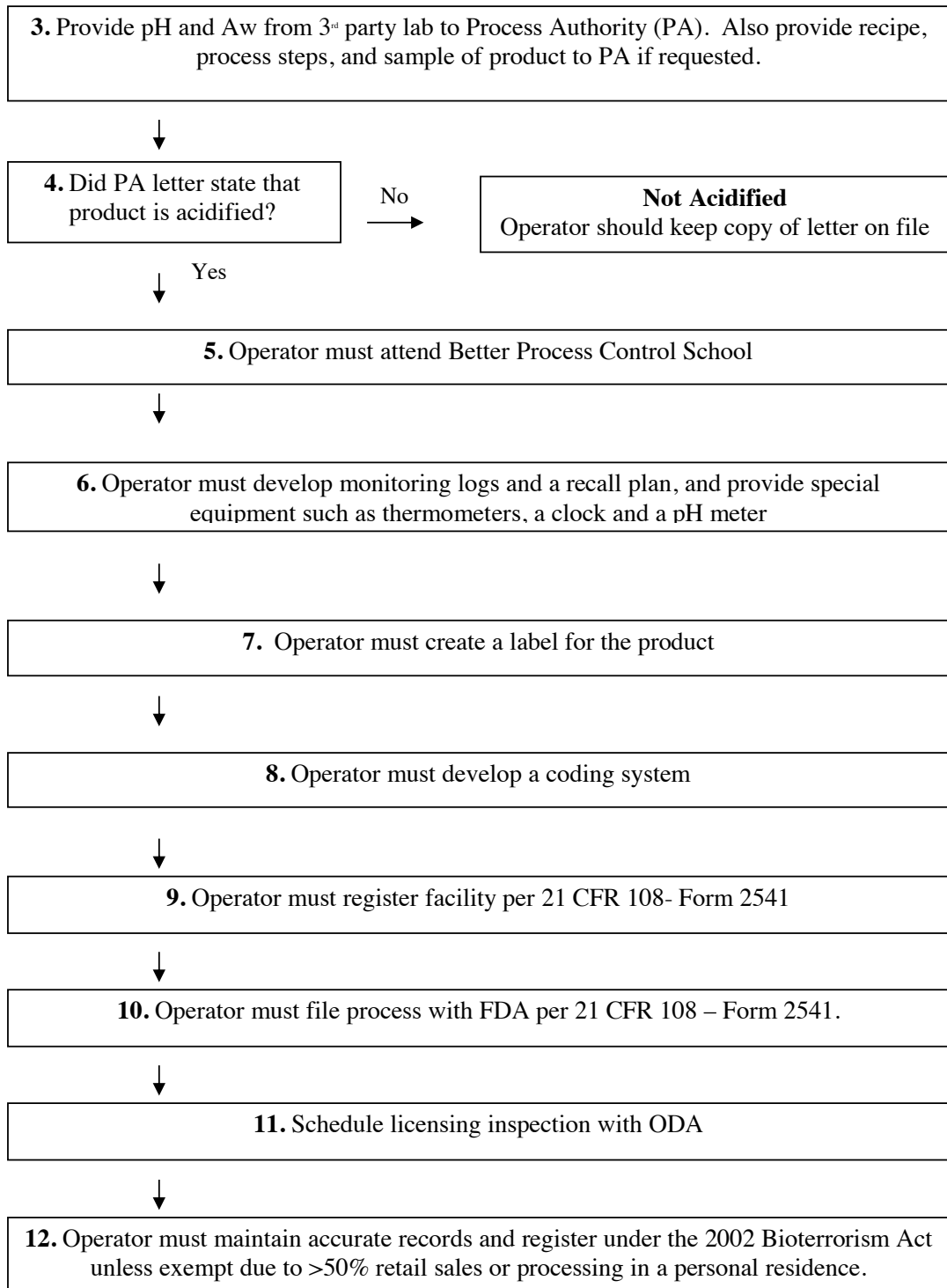


1. Schedule a consultation visit to review facility and product*



* Some products may be developed under the farm direct rule. For specific details see OAR 603-025-0215 through OAR 603-025-0275.

Acidified Foods Next Steps



Draft: Acidified Foods Flow Chart 04-27/18 sk/jb/kw