

I Want to Sell Food in a Retail Market...Now what?

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During the infancy of a new business it is important to understand what regulatory requirements must be met and what the financial implications are in meeting those regulations. The following steps are needed to legally sell your food product in a retail market and their associated costs (**in BOLD**). Keep in mind that these steps do not include costs associated with your facility meeting current Good Manufacturing Practices (cGMP's) and the adherence to those practices during the production of your product. You may find a copy of cGMP's at: <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=cefdff5373327b34dfa6f87642959825&rgn=div5&view=text&node=21:2.0.1.1.10&idno=21>

1. If you are considering making food products in your home begin at:
<http://www.ncagr.gov/fooddrug/food/homebiz.htm>

2. Request product testing at:
http://ncsu.edu/foodscience/extension_program/sample_submit_form.htm

You may be asked to submit a sample to be tested to define the food per FDA regulations. A testing results letter will be returned to you via e-mail.

This testing costs \$100. If your product is considered acidified and you are not considering co-packing please continue to Step 3. If your food is defined as acid or exempt skip to step 12. To learn more about these definitions go to:

http://www.ncsu.edu/foodscience/extension_program/documents/acidified_formulating_dressings.pdf

To learn more about co-packing visit:

http://www.ncsu.edu/foodscience/extension_program/documents/entrepreneurs_copackers.pdf

If you are co-packing you may stop here as they will handle the remaining steps. You may find a list of co-packers at:

http://www.ncsu.edu/foodscience/extension_program/services_supplies.html

3. If your product is acidified you will be required by federal law to pass a better process control school "pickle school." The school is intended for and directed at the level of operating supervisors of conventionally canned processing and packaging systems in food processing establishments. It will qualify individuals to be commercial operators of plants producing conventionally foods canned to meet the requirements of the umbrella Good Manufacturing Practice (GMP), the specific GMP for acidified foods (21 CFR Part 114). By definition, an "operating supervisor" is a person who is in the plant at the time product is processed and packaged. The operating supervisor is responsible for the use of adequate pH and time and temperature processes as well as closure integrity inspections for rendering the product safe, and for proper record keeping and control programs which will detect deviations from safe operating procedures. The operating supervisor may be the same person. However, *each operation during each hour of plant operation must be under the supervision of a person who has been certified as having satisfactorily completed the approved course of instruction. The school is 3-days long and costs \$450 (cost includes materials, thermometer, lunches and certification).* The certification is good for a lifetime.
4. If you are producing product using a water bath you may be asked to process it using a hot fill method that will be provided by NC State after product and process submission (Step 2). If you cannot process your product without a water bath it may also be necessary to validate your procedures

and process in order for NC State to provide you with a process authority letter. A process authority letter is required for you to file your process with the FDA at <https://www.access.fda.gov/oa/> as required by law. The water bath validation is done in person at the processing facility while each product is being made. **In- State rates are \$500 per day, \$300 ½ day or \$75/hr. Out of State rates are \$1,000 per day.**

5. You will need to register your facility as a Canned Food Processing facility with the FDA Form 2541. The form can be found at: <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM076778.pdf> You must print the form, fill it out and then mail it to:

Food and Drug Administration
LACF Registration Coordinator (HFS-303)
Center for Food Safety & Applied Nutrition
5100 Paint Branch Parkway
College Park, Maryland 20740-3835
It will be mailed back to you with an FCE #
6. You will need to send an e-mail to brenda.pinkney@fda.hhs.gov and request that your FCE number be linked to your on-line registration (after you complete Step 12).
7. Register your facility on-line as a Low Acid Canned Food Facility, also at: <https://www.access.fda.gov/oa/signUpSelect.jsp>
8. You must file your process for each product in each container size with the FDA at: <https://www.access.fda.gov/oa/signUpSelect.jsp> with the process authority letter we provided to you. If you choose we can file your process for you. **The cost is \$100 (optional).**
9. If your testing letter indicates you must monitor and record temperature to produce a safe product you may need to purchase a non-glass thermometer that can be calibrated or a digital thermometer. **Cost is approximately \$10.** If you are taking the Better Process Control School “pickle school” mentioned in step 3 one will be provided to you.
10. If your testing letter indicates you must monitor and record pH to produce a safe product you must purchase a pH meter that can be calibrated. **Cost varies widely but we recommend you spend approximately \$200.** Some places to purchase them can be found at: http://www.ncsu.edu/foodscience/extension_program/services_supplies.html
11. Once processing you will be required to perform a closure evaluation and keep a record of it. One of the assessments for proper closure is determination of vacuum which can be checked with a gauge. **The cost for the vacuum gauge is approximately \$110 (optional)** and among other places it can be found at: <http://www.dixiecanner.com/1140.htm#m135a>
12. You will need to create and account register your facility to comply with the Bioterrorism act at: <https://www.access.fda.gov/oa/signUpSelect.jsp>
13. If you choose, you may also have a nutritional facts panel made for your product. This is optional for most small processors however many grocery stores require it for sale in their establishments. **The cost is \$100.** To request this service go to: http://ncsu.edu/foodscience/extension_program/sample_submit_form.htm

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