Federal and State Regulations on Selling Fermented Foods



Introduction¹

Fermented foods are lowacids foods (typically fruits and vegetables) subjected to the action of acid-producing microorganisms to reduce the pH of the food to 4.6 or below. Examples of fermented foods are sauerkraut, some pickles, kimchi, and kombucha. The concern about fermented foods is Clostridium botulinum. Clostridium botulinum is a microorganism that produces a fatal toxin in anaerobic environments with a pH above 4.6. The toxin causes botulism, a serious paralytic illness that can be fatal and is considered a medical emergency. As you may notice, the differences between state regulations are rather large. Take time to ensure you are following the correct laws. Be sure to also look at additional resources for more information.

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Standards of Identity/Definitions

Sauerkraut²—The product of characteristic acid flavor, obtained by the full fermentation, chiefly lactic, of properly prepared and shredded cabbage in the presence of not less than 2 percent nor more than 3 percent of salt. It contains, upon completion of the fermentation, not less than 1.5 percent of acid, expressed as lactic acid. Sauerkraut which has been rebrined in the process of canning or repacking, contains not less than 1 percent of acid, expressed as lactic acid.

Kombucha³—While there is variation among kombucha products, the term "kombucha" generally refers to a fermented beverage produced from a mixture of steeped tea and sugar, combined with a culture of yeast strains and bacteria. The combination of sugar and yeast triggers fermentation, which may produce a kombucha with an alcohol content of 0.5% or more alcohol by volume. When this happens, the kombucha is regulated as an alcoholic beverage under federal law and TTB regulations.

Kimchi⁴—Kimchi is a Korean spicy fermented combination of pickled vegetables. The vegetables most commonly used in its preparation are celery, cabbage, Chinese turnip, and cucumber. The vegetables are sliced, seasoned, and fermented in brine in large earthenware jars. During fermentation, which takes approximately one month depending on weather conditions, the kimchi jars are stored totally or partially underground in cellars or sheds built expressly for this purpose.

Fermented foods⁵ are low-acids foods (typically fruits and vegetables) subjected to the action of acid-producing microorganisms to reduce the pH of the food to 4.6 or below. Examples of fermented foods are sauerkraut, some pickles, kimchi, and kombucha.

The information in this document pertains to specific types of manufacturers. Manufacturers that sell their product directly to consumers through farmers' markets, roadside stands, or other similar venues should direct their attention to the "For Manufacturers Selling Directly to Consumers" portion of this document. Manufacturers that do not sell directly to consumers (those that sell to restaurants, grocery stores, or other manufacturers) should view the "For Manufacturers Not Selling Directly to Consumers" portion of this document, directly below.

For Manufacturers Not Selling Directly to Consumers Federal⁶

All fermented foods producers are required to follow current Good Manufacturing Practices [21 CFR Part 117, Subpart B, and 21 CFR 117.4 (Qualifications of individuals who manufacture, process, pack, or hold food.)]. Most fermented foods producers are required to comply with Hazard Analysis and Risk-based Preventive Controls [21 CFR Part 117, Subpart C]. Businesses which average sales in human food of less than \$1,000,000 annually (adjusted for inflation) during the 3 year period before that current year sales and the market value of any food produced that was held without sale are considered "very small". Fermented foods are exempt from the hazard analysis and preventive controls requirements components in 21 CFR Part 117, Subparts C and G (and are subject to modified requirements in 21 CFR 117.201), but are required to follow current Good Manufacturing Practices. Current Good Manufacturing Practices are practices that minimize the chance of chemical (including allergens), microbial, and physical contamination of foods. Personnel must be trained in food safety as it relates to their job duties. The plant, grounds, equipment, utensils, and processing lines must be kept in good sanitary condition. The fermentation process must be adequate to create a safe fermented product.

Fermented foods with acid added are considered acidified foods under 21 CFR Part 114. Operators must have a supervisor who has attended an FDA recognized training course specifically designed for canning acidified foods. The most widely available approved course is the Better Process Control School. Anyone working on the processing and packaging side of an acidified foods operation must be under supervision by the trained individual during all operating hours.



The food safety plan required by 21 CFR Part 117, Subpart C must include a written hazard analysis. This hazard analysis identifies reasonably foreseeable hazards and whether any of those hazards require preventive controls, or must justify why a hazard does not require a preventive control. If a preventive control is identified, written documentation of monitoring procedures, verification procedures, corrective actions, a recall plan, and validation information for identified process preventive control are required for each process control.^{7,8,9}



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Recipes

Kimchi http:// foodsmartcolorado.colostate.edu/recipes/ preservation/understandingand-making-kimchi/

Sauerkraut

https://extension.psu.edu/ lets-preserve-sauerkraut

Kombucha

http:// foodsmartcolorado.colostate.edu/recipes/ preservation/understandingand-making-kombucha/

Pickles

https://ohioline.osu.edu/ factsheet/HYG-5342

For Manufacturers Selling Directly to Consumers

Illinois10

Fermented foods - Naturally acidic fruits, acidified or fermented fruits and vegetables, and acidified or fermented cut leafy greens are all allowed to be sold under cottage food law. Canned, chilled or frozen sauerkraut and kimchi are allowed. Due to the nature of these foods, a USDA-tested recipe and pH testing are strongly encouraged. Kombucha must be made in a commercial kitchen. **General Guidance–** Labeling and Signage requirements must be met. The name and residence of the person preparing and selling products as a cottage food operation must be registered with the county health department of a unit of local government where the cottage food operation resides. A fee may be charged for registration. The person preparing and selling products as a cottage food operation needs <u>Certified Food Protection Manager (CFPM)</u> <u>certification</u>.

Indiana¹¹

Fermented vegetables- vegetables placed in a brine (saltwater) solution in which bacteria produce lactic acid to acidify the product and do not require refrigeration may be sold by a Home-Based Vendor. Note: Vegetables that require the addition of any acid (e.g., vinegar) are NOT considered fermented.

General Guidance-All Home Based Vendors foods must have the following statement printed at a minimum type size of 10 points on product labels: "This product is home produced and processed and the production area has not been inspected by the State Department of Health." The product must include a detailed label.

lowa¹²

Fermented Products– Home canned fruits and vegetables as well as foods prepared using a specialized process are not allowed to be sold at a farmers' market unless they are produced in a licensed kitchen.

Kansas¹³

Fermented Food- Naturally fermented canned foods– sauerkraut, kimchi, and kombucha- require a license to be sold.

Michigan¹⁴

Fermented food – No beverages, including fruit/vegetable juices and kombucha tea, are allowed to be made in a home kitchen. Canned fruits and vegetables or pickled products like corn relish, pickles, or sauerkraut are not allowed to be made in a home kitchen.

Minnesota^{15,16}

Fermented food– Fermented fruit, vegetables, pickles, sauerkraut, and kimchi that have an equilibrium pH value of 4.6 or lower and heat treated to kill vegetative cells are allowed. Fermented products needing refrigeration and kombucha are not allowed to be home-processed and sold.

General Guidance- Cottage food producers must do the following:

- 1. Register with the MDA before selling exempt food regardless of the amount of food sold.
- 2. Take an approved food safety course once every three years while actively selling cottage food.
- 3. Register with the MDA each year food is sold under the Cottage Food Exemption.
- 4. Prepare and sell only NON-potentially hazardous food (such as baked goods, certain jams and jellies) and/or home canned pickles, vegetables, or fruits with a pH of 4.6 or lower.
- 5. Label food with your name and address, the date produced, and the ingredients, including potential allergens.
- 6. Display a sign that says "These products are homemade and not subject to state inspection." If you are selling on the Internet, post this statement on your webpage.
- 7. Deliver food directly to the ultimate consumer. The person who makes the food must be the same person who sells and delivers the food.
- 8. Sell from a private home, at farmer's markets, community events, or on the Internet.
- 9. Check with your local city, county, or township regarding business licensing or sales prohibitions due to zoning requirements.
- 10. Sell less than \$18,000 in a calendar year. If you sell between \$5,000 and \$18,000 per year, a \$50 fee applies to your registration.

Missouri¹⁷

Fermented foods—Sauerkraut, kimchi and kombucha tea are fermented foods and must be made in an inspected facility.

Nebraska¹⁸

Fermented food—fermented foods may not be sold at farmers' markets without a permit.



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North Dakota^{19,20}

The ND Cottage Foods Act allows for the sale of uninspected, homemade cottage food products to an informed, end consumer for at-home consumption. The following items are allowed if acidified and the equilibrium pH is less than 4.6 verified using a calibrated pH meter: Pickles, sauerkraut, and kimchi. Guidance does not mention kombucha.

General Guidance- Labeling and Handling Instructions guidelines must be met.

Ohio²¹

Fermented food– All fermented foods, including kombucha and kimchi, must be manufactured in an inspected facility.

South Dakota^{22,23}

Fermented food – Fermented foods may be sold at a farmers' market, roadside stand, or similar venue. Fermented foods must have an equilibrium pH value below 4.6 and meet standards that destroy bacteria, yeast, and molds to a required level. All fermented foods must have official verification from a third-party processing authority in writing. All products must be labeled properly.

Wisconsin^{24,25}

A person is not required to obtain a license to sell retail food products that the person prepares and cans at home in Wisconsin if all of the following apply:

- The food products are pickles or other processed vegetables or fruits with an equilibrium pH of 4.6 or lower
- The person sells the food products at a community or social event or a farmers' market in Wisconsin
- The person receives less than \$5,000 per year from the sale of the food products
- The person displays a sign at the place of sale stating: "These canned goods are homemade and not subject to state inspection"
- Each container of food product that is sold is labeled with the name and address of the person who prepared and canned the food product, the date on which the food product was canned, the statement "This product was made in a private home not subject to state licensing or inspection.", and a list of ingredients in descending order of prominence. If any ingredient originates from milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, or soybeans, the list of ingredients shall include the common name of the ingredient.







Resources

¹https://nchfp.uga.edu/how/can6a_ferment.html ² https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074636.htm ³ https://www.ttb.gov/kombucha ⁴ https://www.britannica.com/topic/kimchi ⁵ https://www.britannica.com/technology/vegetable-processing/Fermentation-and-pickling ⁶ https://www.ecfr.gov/cgi-bin/text-idx? SID=c7ab64fd267b222cdeb875f6ab2ccd98&mc=true&node=pt21.2.117&rgn=div5 ⁷ https://www.ecfr.gov/cgi-bin/text-idx?SID=5adb4042d1b92be50b44b5e3653cd3c8&node=pt21.2.114&rgn=div5 ⁸ http://ucfoodsafety.ucdavis.edu/Better Process Control Schools/ ⁹ https://foodsafety.ncsu.edu/acidified-foods-manufacturing-school/ ¹⁰ http://web.extension.illinois.edu/cottage/ ¹¹ https://ag.purdue.edu/foodsci/pages/in-hea-1309-info.aspx ¹² https://dia.iowa.gov/sites/default/files/documents/2016/10/homebasedfoodoperations.pdf ¹³ https://www.bookstore.ksre.ksu.edu/pubs/MF3138.pdf ¹⁴ http://www.michigan.gov/mdard/0,4610,7-125-50772 45851-240577--,00.html ¹⁵ https://www.mda.state.mn.us/food-feed/cottage-food-law-guidance ¹⁶ https://www.mfma.org/CFL ¹⁷ http://health.mo.gov/safety/foodsafety/pdf/FarmersMarketsBrochure.pdf ¹⁸ http://www.nda.nebraska.gov/publications/foods/food safety farmers markets craft shows.pdf ¹⁹ https://www.health.nd.gov/regulation-licensure/food-and-lodging/cottage-food ²⁰ https://www.health.nd.gov/sites/www/files/documents/Files/HR/FL/Cottage%20Foods/Summary%20of% 20Cottage%20Foods%20 Final%20Document%2021220.pdf ²¹ https://agri.ohio.gov/wps/portal/gov/oda/divisions/food-safety/resources/cottage-food ²² https://doh.sd.gov/food/farmers-markets.aspx? ²³ https://extension.sdstate.edu/food/farmers-market ²⁴ https://datcp.wi.gov/Pages/Licenses Permits/FoodLicenses.aspx

²⁵ docs.legis.wisconsin.gov/statutes/statutes/97.pdf

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