CURRENT GUIDANCE: MANUFACTURE AND SALE OF KOMBUCHA

Kombucha is a fermented beverage made from brewed tea and sugar that is gaining popularity throughout New York and the US. It can be found in health food stores, retail food stores, and farmers’ markets. Kombucha teas are considered food and therefore subject to regulation by the Department of Agriculture & Markets (Department). Most kombucha is intended to be sold in unpasteurized form, with refrigeration as the control to prevent further fermentation, and maintain a level of less than 0.5% alcohol by volume. Kombucha produced with a level greater than 0.5% alcohol by volume may also be subject to state regulation by the New York State Liquor Authority (SLA). For more information please contact SLA at: https://www.sla.ny.gov/

Hazards of kombucha include: Biological (pathogen, mold, or wild culture growth), Chemical (potential for acidosis, or alcohol development), Physical (unstable food, possible container integrity). Department requirements for producing kombucha for **wholesale distribution** are as follows:

- Adherence to a process review conducted by a recognized process authority, or
  - Peer reviewed scientific journal article
- A current Article 20-C Food processing establishment license.
- Compliance with 1NYCRR Parts 260 or 261 – Current good manufacturing practices (cGMP's).
- Compliance with 1NYCRR Part 259.1 – Packaging and labeling of food (including “Keep Refrigerated” statement for unpasteurized kombucha).

Department requirements for producing kombucha at **retail** are as follows:

- Adherence to a variance as required under 1NYCRR Part 271.9 – Retail food store sanitation regulations, compliance and enforcement.
- A current Article 20-C Food Processing Establishment license
- Compliance with 1NYCRR Part 271 - Retail food store sanitation regulations.
- Compliance with 1NYCRR Part 259.1 – Packaging and labeling of food (including “Keep Refrigerated” statement for unpasteurized kombucha).

**Transportation, storage, and display requirements:**

Unpasteurized Kombucha contains live cultures and can continue to ferment and raise alcohol content over time, especially if transported, stored or displayed without refrigeration. Unpasteurized kombucha must be refrigerated at or below 41°F at all times. Improperly refrigerated unpasteurized kombucha may be subject to Department Food Seizure.
The Department may collect samples of kombucha routinely, or at any time there is information indicating unpasteurized kombucha may have been transported, stored, or sold in a manner in which continued fermentation may have occurred. Kombucha found by laboratory analysis to contain greater than 0.5% alcohol by volume, and not produced under SLA license, may be subject to the Department of Agriculture and Markets, food seizure authority.

Available References:

1. Listing of Department Recognized Process Authorities
   https://www.agriculture.ny.gov/FS/industry/04circs/Kombucha_Nummer.pdf
3. 1NYCRR Part 261 – Human Foods: Current good manufacturing practice:
   http://www.agriculture.ny.gov/FS/industry/04circs/goodmanufpracticesCIR933.pdf
4. 1NYCRR Part 271 - Retail food store sanitation regulations:
   http://www.agriculture.ny.gov/FS/industry/04circs/rulesandregsretailCIR962.pdf
5. New York State Food Labeling Guide:
6. 1 NYCRR Part 260- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food:
   https://govt.westlaw.com/nycrr/Document/159ca9aa5527911e78de8feddd4b9ac3d?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default) and https://www.ecfr.gov/cgi-bin/text-idx?SID=1c6f404eb2f5e5db8e809140ccab87d&mc=true&node=pt21.2.117&rgn=div5
Naturally, kombucha recipes will vary. The general process includes infusing tea leaves (4-5 g/L) into freshly boiled water. Sugar (sucrose) is added at 50-150 g/L (5% to 15%). The tea is allowed to brew for approximately 10 minutes and the tea leaves are removed. The tea is cooled to room temperature and approximately 100 ml/L (10%) of fresh-fermented kombucha containing the microbial mat from a previous batch is added to the sweetened tea. The product is then covered with a clean porous cloth (i.e. cheese cloth) and incubated at room temperature for about 7-10 days. When the fermentation is allowed to continue beyond 10 days, acidity may rise to levels potentially harmful to consumers (equivalent to drinking undiluted vinegar).

Use only clean, sanitary equipment and utensils. Follow written standard sanitation operating procedures (SSOPs).

**Process Flow**

1. Use hot (> 165°F) water to steep tea (this kills vegetative pathogens if present). Add Sugar. Steep for approximately 10 minutes and remove tea leaves.
2. Cool tea and add culture (SCOBY). Use a commercially purchased culture on first use. Subsequent inoculation can be made from previous batches. Reuse only culture from kombucha that shows no signs of mold or unusual contamination.
3. Cover and ferment product at room temperature for 7-10 days.
4. Test to ensure the pH of the of the product is below 4.2 but greater than or equal to 2.5. Kombucha with a pH of below 2.5 or that tastes especially acidic should not be offered to consumers. A corrective action would be to dilute the high acidity with fresh brewed tea until pH $\geq 2.5$, but never higher than pH 4.2.
5. Discard all kombucha that is showing signs of mold contamination. Do not reuse for inoculum.
6. Bottle product and label “Keep Refrigerated” and a consumer warning stating: “Consumption of no more than 4 oz. per day is recommended” (see CDC references) and “product should not be consumed by immunocompromised individuals”. Furthermore, the label should include a statement that minor amounts of alcohol may be present.
7. Statements concerning health claims may not be included in product labeling or marketing.
Alternate Process Option 1: Product may be pasteurized at 180°F for 30 seconds upright and an additional 30 seconds inverted. Pasteurized kombucha with a pH of \( \leq 4.2 \) is considered shelf stable.

Alternate Process Option 2: Product may include the addition of 0.1% sodium benzoate and 0.1% potassium sorbate to kombucha with a pH of \( \leq 4.2 \). Product must still be held under refrigeration.

SOPs

SOPs are written, step-by-step instructions to accomplish a food safety objective. SOP’s should include:

1. A detailed plan for cleaning and sanitizing equipment.

2. A detailed process instruction sheet to tell employees how to make kombucha using the food safety measures outlined in this report. The SOP must describe how employees will measure and record on a pH log.

3. Detailed instructions (an SOP) on how to calibrate the pH meter.

Supporting Reference: Brian Nummer, Associate Professor, Nutrition, Dietetics and Food Sciences, Utah State University, 8700 Old Main Hill, Logan, UT 84322. E-mail: brian.nummer@usu.edu.
<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>Hazards Created, Eliminated, or Reduced</th>
<th>Preventative Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Boil water.</td>
<td>Potable water should be free of hazards.</td>
<td>Boiling water will kill vegetative pathogens.</td>
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<tr>
<td>2</td>
<td>Add tea and sugar and steep 10 minutes.</td>
<td>Biological: sporeformers may be heat shocked and germinate.</td>
<td><em>Clostridium perfringens</em> and <em>Bacillus cereus</em> do not grow well or at all at pH (\leq 5). <em>Clostridium botulinum</em> can grow down to pH 4.7. The addition of an active fermentation culture will outcompete sporeformers to prevent growth.</td>
</tr>
<tr>
<td>3</td>
<td>Remove tea leaves and cool.</td>
<td>Biological: cross contamination.</td>
<td>Use clean and sanitized utensils. Keep container covered with clean and sanitized porous cloth (e.g., cheese cloth). The pH of (\leq 5) will prevent <em>C. perfringens</em> outgrowth. Therefore cooling parameters need not be monitored.</td>
</tr>
<tr>
<td>4</td>
<td>Add 10% inoculum.</td>
<td>Biological: mold or wild culture cross contamination.</td>
<td>Use a commercially purchased culture on first use. Reuse only culture from kombucha that shows no signs of mold or unusual contamination. The pH of the reused culture should be (\leq 4.2) to minimize the potential for acid resistant pathogens.</td>
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<tr>
<td>5</td>
<td>Ferment at room temperature 7–10 days.</td>
<td>Biological: pathogen, mold, or wild culture growth. Chemical: acetic acid can leach metal.</td>
<td>Ferment aerobically (in the presence of air) to ensure acetic acid production to pH (\leq 4.2). The typical endpoint is pH 2.5. Ferment in a safe, nonmetallic food-grade container.</td>
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<td>6</td>
<td>Refrigerate covered.</td>
<td>Biological: overfermentation may increase acetic acid to hazardous levels. As fermentation slows, mold growth potential increases.</td>
<td>Refrigeration at pH (\leq 4.2) would not be required for food safety, but it should be used for quality and to prevent spoilage from molds. Refrigerated kombucha should be covered, preferably with a tight fitting lid. This way a small amount of carbon dioxide will build up and minimize mold growth.</td>
</tr>
<tr>
<td>7</td>
<td>Filter or remove culture mass.</td>
<td>Biological: cross contamination.</td>
<td>Use clean and sanitized utensils.</td>
</tr>
<tr>
<td>8A</td>
<td>Option 1: consume on premises.</td>
<td>Chemical: a potential for acidosis or acid ingestion exists. If mold is present mycotoxins could form.</td>
<td>The pH end point should be (\geq 2.5). Overfermentation can increase acetic acid to hazardous levels. Consumers should be notified that no more than 4 oz. per day is recommended and that they should not be immunocompromised.</td>
</tr>
<tr>
<td>8B</td>
<td>Option 2: package for retail sale.</td>
<td>Biological: spoilage with mold or yeasts. Over fermentation producing excessive acetic acid.</td>
<td>Option 1: Pasteurize—hot fill at 180°F into clean containers. Cap and invert 15 seconds. Cool. Option 2: Fill packaging at any temperature and store refrigerated with a shelf life that precludes mold development, excessive acetic acid, or excessive carbon dioxide buildup. Option 3: Same as option 2, but add 0.1% sodium benzoate and 0.1% potassium sorbate to prevent mold growth. Consumers should be notified that no more than 4 oz. per day is recommended and that they should not be immunocompromised. They also should be made aware that small amounts of alcohol may be present. Labeling claims are outside the scope of this article, but health claims would not be recommended (e.g., &quot;cures health problems&quot;).</td>
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<tr>
<td>8B</td>
<td>Option 2: labeling.</td>
<td>Chemical: a potential for acidosis or acid ingestion exists.</td>
<td>Labeling claims are outside the scope of this article, but health claims would not be recommended (e.g., &quot;cures health problems&quot;).</td>
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