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Kombucha brewing under the US FDA model Food Code:

Risk analysis and processing guidance

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Retail-foodservice food safety consortium / Utah State University Cooperative Extension

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Abstract

Kombucha is a fermented beverage made from brewed tea and sugar. The taste is slightly sweet and acidic and it may have residual carbon dioxide. Kombucha is consumed in many countries as a health beverage and it is gaining in popularity in the US. Consequently, many retailers and foodservice operators are seeking to brew this beverage on-site. As a fermented beverage, kombucha would be categorized in the US FDA model food code as a specialized process and would require a variance with submission of a food safety plan. This document was created to assist both operators and regulators in preparing or reviewing a kombucha food safety plan.

Introduction

Kombucha is a fermented beverage made from brewed tea and sugar. The taste is slightly sweet and acidic and it may have residual carbon dioxide. Kombucha is consumed in many countries as a health beverage. It is believed to have prophylactic and therapeutic benefits toward a wide variety of ailments (Greenwalt et al 2000).

The kombucha process resembles a vinegar fermentation. Like vinegar, kombucha is a yeast fermentation of sugar to alcohol followed by a bacterial fermentation of alcohol to acetic acid. The symbiotic culture forms a pellicle or biofilm on the surface of the brew often called a

mushroom or SCOBY (symbiotic culture of bacteria and yeast). The yeasts in the mixture metabolize sucrose into glucose and fructose, then into ethanol and carbon dioxide (Mayser et al 1995). Ethanol is then oxidized by the bacteria (in the presence of air) to acetaldehyde, then to acetic acid (Mayser et al 1995). Typically, the alcohol and acetic acid content of kombucha is less than 1% respectively, but each can rise to 3% during a long ferment (~30 days; Mayser et al 1995). The acetic acid bacteria also utilize glucose to produce gluconic acid to approximately 2%. Fructose is used to a lesser extent and some remains after the fermentation. Some glucose will remain unmetabolized, and together with the remaining fructose, provide sweetness.

As a fermented beverage, kombucha would be categorized in the US FDA model food code as a specialized process. A retail or foodservice operator would need to request a variance from their regulatory authority as defined in the Food Code section 3-502.11 (US FDA 2009). This section also requires that the operator submit a food safety plan to the regulatory authority for approval before commencing operations. Below is a HACCP based risk analysis of the process to help both operators and regulators maintain safe production of Kombucha.

Process flow

Naturally, Kombucha recipes will vary. The general process has been described by Greenwalt et al (2000) and includes infusing tea leaves (~4-5 g/L) into freshly boiled water. Sugar (sucrose) is added at 50 to 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. It is then covered with a clean porous cloth (e.g. cheese cloth) and incubated at room temperature for about 7 to 10 days. If the fermentation is allowed to continue

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beyond 10 days, acidity ***may*** rise to levels potentially harmful to consumers (equivalent to drinking undiluted vinegar).

Kombucha hazards analysis

Biological Hazards

Most boiling water with black or green tea infusions start at a pH of ≤ 5. Once fermentation starts that pH is reduced in approximately 7 days to a finishing pH of ≤ 2.5. Fermentations such as wort to beer have a similar pH reduction during fermentation, although beer will finish closer to pH 4. Since the initial infusion uses boiling water we consult Table A of section 1-201.10(B) (US FDA 2009) to determine if this is a potentially hazardous food (PHF). The tea infusion would not be a PHF if the pH were ≤ 4.6. However, since the tea is heated but not packaged, it may be subject to contamination after cooling. Therefore, we must also consult Table B of section 1-201.10(B)(US FDA 2009) that requires a pH ≤ 4.2 to be a non-PHF. Since kombucha starts at a potentially hazardous pH (~5) and finishes below 4.2 this process would require food safety monitoring to ensure safety. This is also confirmed in the Food Code under section 3-502.11 (US FDA 2009) where it requires a food safety plan for any process that uses acidification to make a PHF into a non-PHF.

Chemical hazards

The US FDA has evaluated the practices of several commercial producers of the kombucha and found no pathogenic organisms or other hygiene violations (CDC 1996). Kombucha consumption has proven to be harmful in only a few documented instances (Srinivasan et al 1997). The possibility of toxic effects when Kombucha is consumed in large quantities became a concern after two incidents in the United States in 1995. One individual died from perforations

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of the intestinal tract and severe acidosis. It was ***speculated*** that because they had recently increased their consumption threefold to 12 oz, that Kombucha was the cause. The surviving victim mentioned that they increased the length of the fermentation time from 7 days to 14 days, and they could hardly manage swallowing the very acidic tea but did anyway. It was later determined that the individuals had severe preexisting conditions that made them susceptible to acidosis. These two cases of illness were investigated to determine if Kombucha played a role in the development of metabolic acidosis or other toxic effects. It was concluded that Kombucha is not harmful at about 4 oz per day, however there are potential risks associated with excessive consumption or consumption by an individual with preexisting health problems (CDC 1996).

Alcohol is certainly debatable as a hazard, but is not debatable as an impetus for taxes. Recently Severson (2010) reported some commercial producers of kombucha were forced to recall unpasteurized versions from grocery store shelves when the alcohol content exceeded 0.5%. Some brands continued to ferment and may produce up to 3% alcohol in the bottle. This happens because yeast continues to ferment sugars producing alcohol and carbon dioxide. And, in a closed container the build-up of carbon dioxide inhibits the conversion of alcohol to acetic acid.

Kombucha hazards analysis			
Step	**Description**	**Hazards created, eliminated, or reduced**	**Preventative measures**
1	Boil water	Potable water should be free of hazards	Boiling water will kill vegetative pathogens
2	Add tea and	Biological: Sporeformers	*Clostridium perfringens* and *Bacillus*

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	steep 10 min.	may be heat shocked and germinate	*cereus* do not grow well or at all at pH ≤5. *Clostridium botulinum* can grow down to pH 4.7. The addition of an active fermentation culture will outcompete sporeformers to prevent growth.
3	Remove tea leaves and cool	Biological: Cross contamination	Use clean and sanitized utensils. Keep container covered with clean and sanitized porous cloth (e.g cheese cloth). The pH of ≤5 will prevent *C. perfringens* outgrowth. Therefore cooling parameters need not be monitored.
4	Add 10% inoculum	Biological: Mold or wild culture cross contamination	Use a commercially purchased culture on first use. Re-use only culture from kombucha that shows no signs of mold or unusual contamination. The pH of the reused culture should be ≤4.2 to minimize the potential for acid resistant pathogens.
5	Ferment at room temperature 7-10 days	Biological: Pathogen, mold or wild culture growth. Chemical: acetic	Ferment aerobically (in the presence of air) to ensure acetic acid production to pH ≤4.2. The typical end point is pH

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		acid can leech metal.	2.5. Ferment in a safe non-metallic food grade container.
6	Refrigerate covered	Biological: Over fermentation may increase acetic acid to hazardous levels. As fermentation slows, mold growth potential increases.	Refrigeration at pH ≤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.
7	Filter or remove culture mass	Biological: Cross contamination	Use clean and sanitized utensils.
8A	Option 1: Consume on premises	Chemical: There is a potential for acididosis or acid ingestion. If mold is present mycotoxins could form.	The pH end point should be ≥2.5. Over fermentation 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.
8B	Option 2: Package for retail sale	Biological: Spoilage with mold or yeasts. Over fermentation producing excessive acetic acid.	Option 1: Pasteurize -Hot fill at 180°F into clean containers. Cap and invert 15 seconds. Cool. Option 2: Fill packaging at any

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			temperature and store refrigerated with a shelf life that precludes mold development, excessive acetic acid, or excessive carbon dioxide build-up. Option 3: Same as option 2, but add 0.1% sodium benzoate to prevent mold growth.
	Option 2 : labeling	Chemical: There is a potential for acididosis or acid ingestion.	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. "cures health problems").

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Controlling food safety

Critical control points, critical limits, monitoring, corrective actions, and recordkeeping

Of all of the steps above, only one is ***critical*** to prevent the potential for acid resistant pathogens, step 5. In this step the fermentation proceeds from pH ~5 to ≤ 4.2. Therefore the critical limit is

pH ≤ 4.2. The pH should be monitored using a calibrated digital pH meter for ease and accuracy (versus paper). The main corrective action if the pH >4.3 would be to continue fermentation and re-measure. If the pH does not reach pH ≤ 4.2 in 7 days the culture is most likely contaminated or the fermentation temperature is too cold. In this case discard is recommended. Start a new batch with a newly purchased commercial culture. A record of the pH of Kombucha should be kept to verify that the safe pH level has been reached. An example would be to create a simple table. For each batch, mark the start date (manufacture date) and starting pH, then mark each successive pH measurement until pH ≤ 4.2. You may optionally continue to measure pH since the operational target is 2.5. Operators will also need to keep a calibration log. If the pH goes below 2.5 the operator can add fresh brewed tea return it to pH ≥2.5.

Kombucha pH Log							
No.	Start Date / pH	Date/pH	Date/ pH	Date/ pH	Date/ pH	Date/ pH	Date/ pH
1							
2							
etc							

A pH measurement guide including calibration instructions can be found here.

pH calibration Log					
Date / pH / *	Date / pH / *	Date / pH / *	Date / pH / *	Date / pH / *	Date / pH / *
Record date of calibration, calibration pH, and *initials of calibrator. Indicate manufactures					

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suggested calibration interval (usually daily).

Good manufacturing practices

Controls and preventative measures that don't meet the threshold of critical, but none-the-less are needed to ensure safety are contained in good manufacturing practices and standard operating procedures. These controls are found in the hazards analysis table under preventative measures. Using these preventative measures is recommended.

1. Use hot (≥165°F) water to steep tea (kills vegetative pathogens if present)
2. Use only clean and sanitary equipment and utensils
3. Use a commercially purchased culture on first use. Re-use only culture from kombucha that shows no signs of mold or unusual contamination.
4. Kombucha with a pH of below 2.5 or 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 ≥ 2.5, but never higher than pH 4.2.
5. Discard all kombucha that is showing signs of mold contamination. Do not re-use for inoculum.
6. Consumer warnings: Consumers ***should*** be notified that no more than 4 oz per day is recommended (see CDC references) and that they should not be immunocompromised. Furthermore, they should be made aware that minor amounts of alcohol may be present.
7. Health claims: kombucha is ***suggested*** to offer health benefits. Operators are discouraged from marketing or labeling health claims such as drinking will "cure" some ailment.

Standard operating procedures

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Standard operating procedures are written step-by-step instructions to accomplish a food safety objective. The following are recommended.

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

Retail sale of kombucha (packaging)

Retail sale of kombucha is a little beyond the scope of this document. However, described below are some minimum concerns to this specialized process.

Many commercial processors bottle kombucha. The main food safety hazard is acid resistant pathogens. Bottling kombucha at a pH ≤ 4.2 will ensure no pathogen growth. Another hazard is bottling an actively fermenting kombucha beverage. Carbon dioxide will build-up inside the container causing pressure. As the pressure exceeds the ability of the container to hold it, leakage or breakage occurs. Bottles can explode forming projectile hazards. The last concern is shelf life where spoilage from mold can occur or alcohol can build up $\geq 0.5\%$. Typically, as a little carbon dioxide builds up, acetic acid production will cease. So an excess acid hazard is unusual.

Fermented beverages (foods) are exempt from acidified foods canning regulations. Therefore they do not need any filings or notifications to the FDA. Likewise, any refrigerated beverage (food) is also exempt from these same regulations.

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Option 1: The best method is to pasteurize kombucha for bottling. Pasteurization will kill the culture preventing carbon dioxide or alcohol build-up in bottles. A simple recommendation is to heat kombucha to 180°F and bottle immediately. After 30 seconds invert bottle and hold for another 30 seconds. Allow bottles to cool. Pasteurized and bottled kombucha with a pH ≤ 4.2 is shelf stable (room temperature).

Option 2: This method relies on refrigeration and antifungal preservatives to minimize hazards and spoilage. Add 0.1% sodium benzoate **and** 0.1% potassium sorbate to kombucha with a pH ≤ 4.2. Bottle kombucha at any temperature. Keep refrigerated until use. Benzoate and sorbate will prevent mold growth and minimize yeast growth. Minimal to no growth of acetic acid bacteria will occur in bottles without significant oxygen. A refrigerated shelf life will need to be determined based on eventual yeast growth with carbon dioxide and alcohol production. If this proves difficult the operator may want to find a commercial kombucha culture with yeasts that do not grow well at refrigeration temperature.

Option 3: This method relies on refrigeration alone to minimize hazards and spoilage. Bottle kombucha at any temperature. Keep refrigerated until use. A refrigerated shelf life will need to be determined based on eventual yeast growth with carbon dioxide and alcohol production. If this proves difficult the operator may want to find a commercial kombucha culture with yeasts that do not grow well at refrigeration temperature.

Operators seeking to package kombucha for retail sale must also address labeling. Labeling issues are not covered here and operators are encouraged to inquire with their regulator or their state's department of agriculture. Generally, regulators who oversee grocery (retail) have information on requirements for retail labels.

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Questions and answers

Can I make diet or low sugar kombucha? Answer: No. The sugar is required as part of the fermentation process. Without sugar no alcohol is produced and without alcohol no acetic acid can be produced.

I make kombucha using tea ***and*** other ingredients (e.g. fruit). Can I still use this guideline? *Answer: Yes, provided the added ingredient does not raise the starting pH over that of the original tea (~pH 5). It might still be safe to brew using higher starting pH levels, but the operator would need to consult a processing authority.*

Can I use this document as my HACCP Plan? *Answer: This document contains some of the information needed for a HACCP plan, just not in the typical table format. If the Regulatory Authority will accept it, it is sufficient. Copies of the recipe(s), a pH log, pH calibration log, and SOPs would need to be added to complete the food safety plan. If the kombucha is bottled, information on safe bottling and labels must also be included.*

How strict is the recommendation from the CDC about limiting consumption of kombucha to 4oz per day? *Answer: The CDC recommendations are exactly that – recommendations. They are in response to two older and ill persons who became ill. One died. The analysis suggested they drank 12 oz per day of very acidic kombucha. So, the recommendations are to not over-ferment kombucha and limit servings.*

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