Kombucha- Wonder Tea, Drug, or Alcoholic Beverage?

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Overview

• What is Kombucha?
• How is it made?
• What are the hazards associated with Kombucha?
• What are the regulatory requirements?
• Discuss Florida’s Kombucha Surveillance Sampling Project.
What is Kombucha?

- Kombucha is a beverage made from the fermentation of tea and sugar by bacteria and yeast.
What is Kombucha?

• The beverage originated in China, where it was touted for its detoxifying and energizing properties in as early as 220 BC.
• The culture used to ferment the tea was brought to Japan in 414 by Dr. Kombu to treat the Emperor’s digestive troubles.
• Kombucha later spread to Russia, and throughout Europe (Defresne and Farnworth, 1999).
How is Kombucha Made?

- Kombucha starts as a mixture of brewed tea and sugar (sweet tea.) A culture of yeast and bacteria is added to this mixture. The yeast in the culture ferments the sugar into alcohol, which is in turn fermented by the bacteria and yeast to produce acetic acid. In this way, it is very similar to a vinegar fermentation.
How is Kombucha Made?

• The culture may be referred to as a SCOBY - *Symbiotic Culture of Bacteria and Yeast*. SCOBY may refer to the culture itself, OR to the biofilm ("glob" or "mushroom") which forms on the surface of the fermentation vessel. The culture/SCOBY is generally propagated between batches - with the SCOBY of one batch being used to inoculate the next.
How is Kombucha Made?

• Once the culture is added, the fermentation vessel is covered with a porous cloth (e.g.; cheese cloth) and incubated for 7 - 10 days; after which the liquid is collected and bottled as the finished product - *Kombucha*. 
How is Kombucha Made?

• This is a general process flow - each manufacturer is going to have different starting concentrations of tea and sugar, different incubation periods, and methods of collecting the finished product.
What is a SCOBY?
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What is a SCOBY?

• Some of the major yeast and bacteria found in the SCOBY include:

<table>
<thead>
<tr>
<th>Organism</th>
<th>Fermentation Product</th>
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<tbody>
<tr>
<td><em>Saccharomyces spp.</em></td>
<td>ethanol</td>
</tr>
<tr>
<td><em>Brettanomyces spp.</em></td>
<td>ethanol, acetic acid</td>
</tr>
<tr>
<td><em>Acetobacter spp.</em></td>
<td>acetic acid</td>
</tr>
</tbody>
</table>
How is Kombucha made?

• Fermentation is similar to vinegar production.
• Yeast ferment sugars to ethanol.
• Bacteria/yeast ferment ethanol to acetic acid via oxidation (this process requires oxygen).
Potential hazards

• Fermentation is a delicate balance.
• Under-fermentation = high alcohol content resulting in an alcoholic beverage (as high as 3% alcohol by volume, or abv).
• Over-fermentation= high acid content (pH as low as 1.8) potentially resulting in intestinal damage due to acute acidosis.
Potential hazards

• Potential for SCOBY to change over time by picking up wild yeasts, or bacteria from the environment, including potentially harmful organisms such as *Aspergillus*.

• Although pH is typically low, some molds can still grow causing spoilage.
How is fermentation controlled?

- Validated process using same recipe each time (less fermentables = less alcohol & acetic acid).
- Fermentation can be stopped by pasteurization, or inhibited by use of preservatives (sodium benzoate, potassium sorbate).
Kombucha related illnesses

• 1995 CDC report of two illnesses in Iowa, one resulting in death.
• 48 year old woman admitted to hospital, suffered cardiac arrest, also had severe metabolic acidosis.
• 59 year old woman died from acute metabolic disorder. Blood samples indicated severe acidosis.
Kombucha related illnesses

• Both patients consumed between 4-12 oz. of Kombucha daily.
• Both patients obtained SCOBY from same source.
• CDC investigation suspected Kombucha as likely contributor to illnesses due to the acidity of the beverage, and pre-existing health conditions of the patients (CDC, 1995).
2010 market withdrawal

• In 2010 a Consumer Protection Inspector in Maine noticed leaking bottles of Kombucha on the shelves at a supermarket.

• Samples of different brands of Kombucha were taken and submitted to a Maine Laboratory for alcohol analysis.

• Samples contained up to 2.5% alcohol.
2010 market withdrawal

- The Federal Alcohol Tax and Trade Bureau (TTB) was notified.
- The supermarket chain removed the product from shelves nationwide.
- Production practices were supposedly corrected, and product is back on shelves.
Alcoholic beverages

• TTB has jurisdiction over alcoholic beverages under the Federal Alcohol Administration Act, 27 USC 201.

• The term “alcoholic beverage” includes any beverage in liquid form which contains not less than one-half of one percent of alcohol by volume and is intended for human consumption- 27 USC 214(1).
Alcoholic beverages

- Alcoholic beverages are also foods subject to the FD&C Act.
- Memorandum of Understanding between FDA and TTB to delineate enforcement authority over alcoholic beverages (referenced in 3.2.8.1 of the FDA Investigations Operations Manual).
- FDA has authority over some alcoholic beverages containing less than 7% alcohol.
Other regulatory requirements

• Kombucha is a fermented product (usually refrigerated), therefore it is not subject to acidified food regulation (21 CFR 108.25, 21 CFR 114).

• If produced at retail, Kombucha would be classified as a specialized process subject to the variance and HACCP plan requirements in 3-502.11 of the FDA Food Code (Nummer, 2013).
Other regulatory requirements

• If health claims are made, the products may be considered drugs and subject to FDA Center for Drug Evaluation and Research approval.

• Products may also be marketed as dietary supplements making them subject to 21 CFR 111.
FDACS study

• So far have analyzed 42 samples from small and large food establishments across the state for alcohol, pH, and micro.
• 27 out of 42 samples (64%) were above 0.5% alcohol (up to 2.7% alcohol).
• 0 samples were positive for pathogens
• pH ranged from 3.0-4.0.
FDACS study

- Products collected for sampling were not labeled as alcoholic beverages.
- Samples collected from retail shelves, and also from tap (Kombucha is also served on tap in some establishments).
FDACS study

• So now what?
• Contacted Florida Division of Alcoholic Beverages and Tobacco (AB&T, state regulatory authority over alcoholic beverages).
• AB&T ensures proper licensing and taxation, no public health oversight.
FDACS study

• Still working with AB&T on Kombucha.
• Gave AB&T our sample results, and they are working with food establishments to ensure compliance with alcoholic beverage laws.
• AB&T working with TTB on interstate products.
FDACS response

• Kombucha processors must ensure that alcohol content does not exceed .5% throughout the life of the product, or they must comply with alcoholic beverage laws

• This can be achieved by following a scientifically validated process (process authority, or peer reviewed research such as Nummer, 2013)
Moving forward

• Continue to work with processors-
  1. Must have controls in place to ensure that abv < .5%, or must be in compliance with alcoholic beverage laws.
  2. Must have controls in place to ensure pH is ≥ 2.5 and ≤ 4.2.
• Must have approved process alternative (variance) and HACCP plan if made for retail sale.
References


