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COLD BREW COFFEE REGULATIONS

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New York State Department of Agriculture & Markets
Background

• No standard of identity for cold brew coffee
• “Cold brew” implies ambient temperature water for steeping
• Steeping typically last between 12-24 hours
• The cold brew coffee market grew 580% from 2011-16
Background

• Cold brew coffee often has no “kill step” for pathogen control in the process.

• After the beans have been roasted, they are subject to environmental contamination until sealed in the final container.

• Research into associated hazards has been limited to industry funded challenge studies thus far, most of which are proprietary.
Background

• Cornell University’s challenge study found *Listeria monocytogenes* bacteria surviving for up to three weeks after inoculation into refrigerated cold brew coffee.

• *Escherichia coli* and *Salmonella species* had 5-log reductions after two weeks.
Based on the results of Cornell’s study:

*L. Mono.* was considered by Cornell to be the primary pathogen of concern, or “Target Organism,” for cold brew coffee.
Background

• For an Oregon State University challenge study:
  – viable cells of *L. mono.* were found 14 days after inoculation.
  – *Salmonella spp.* survived seven days.
  – *E. coli.* lasted ten days.
Background

• A major cold brew coffee recall has been conducted recently by Death Wish Coffee in New York (FDA, Death Wish Coffee Co. Announces Recall of Nitro Cold Brew Cans From Retailers, Online Sales (February 07, 2018))

Background

ROASTED WHOLE COFFEE BEANS

GRINDER

STEEPING 18 HOURS AT AMBIENT TEMPERATURE W/MUNICIPAL WATER

SETTLING TANK

Product chilled beyond this point

FILTER

1:1 DILUTION W/ POTABLE WATER

BOTTLING UNDER N2

COLD STORAGE
Background

Retail cold brew operations, ambient...
Background
Background

wholesale + retail cold brew coffee, ROP, nitrogen infused, milk added
Problem Statement

Regulatory strategies employed by food safety agencies to ensure food safety of cold brew coffee processors in the United States are unknown.
Research Questions

1. What hazards have food regulatory agencies determined to be of concern in cold brew coffee and how did they determine the hazards?

2. What regulatory policies are in place for cold brew coffee and how are they enforced?

3. Are there any food regulatory agency plans for potential changes to policies/ regulation of cold brew coffee?
Methodology

- Research consisted of a Survey Monkey e-mailed to food regulatory agencies (See survey questions on next slide)
- Multiple answers were able to be submitted to each question
- Results were compiled into graphs
- Comments tagged to questions by respondents were compiled into lists
- Qualitative results were analyzed for similarities and trends and conclusions drawn from quantitative and qualitative data
Study Population

• Participants were selected from state, county, municipal, territorial, and tribal food regulatory agencies throughout the United States.

• Over 1200 regulators were sent the Survey Monkey. 167 responses were received.
### Results

<table>
<thead>
<tr>
<th>Percentage of Respondents</th>
<th>Indicated Their Agency Had</th>
</tr>
</thead>
<tbody>
<tr>
<td>88%</td>
<td>retail jurisdiction</td>
</tr>
<tr>
<td>24%</td>
<td>wholesale jurisdiction</td>
</tr>
<tr>
<td>8%</td>
<td>no jurisdiction</td>
</tr>
<tr>
<td>2%</td>
<td>“other” jurisdiction</td>
</tr>
</tbody>
</table>
## Results

<table>
<thead>
<tr>
<th>Percentage of Respondents</th>
<th>Indicated Their Agency Regulates</th>
</tr>
</thead>
<tbody>
<tr>
<td>62%</td>
<td>according to the FDA Food Code</td>
</tr>
<tr>
<td>16%</td>
<td>according to CFR 117</td>
</tr>
<tr>
<td>18%</td>
<td>qualified facilities</td>
</tr>
<tr>
<td>41%</td>
<td>“other” (including regulations based off CFR 117 and the Food Code, unique state and local regulations, etc.)</td>
</tr>
</tbody>
</table>
Results

• **74%** of agencies had not determined whether there are any potential hazards associated with cold brew coffee production

• For the **26%** stating their agency had determined potential hazards, 100% of the supplemental responses did not specifically identify all three significant hazards of *L. mono.*, *Clostridium botulinum*, and mycotoxins
Results

• Two respondents listed the hazard of *L. mono*., with one listing only *L. mono*.

• Eight respondents listed the hazard of *C. bot.*., with seven listing *C. bot.* alone.

• Two respondents listed the hazard of mycotoxins, with one listing mycotoxins alone. Another respondent cited mold alone, without other hazards.
Results

94% of respondents indicated their agency has **no plans for potential changes to policies/regulations** related to cold brew coffee.

94% of respondents indicated the cold brew coffee industry **has not brought up any questions or concerns regarding potential hazards** associated with cold brew coffee.
Conclusions

• The results indicate that food regulatory agencies have a broad understanding that there are potential significant hazards in cold brew coffee production, without clear specifics as to what the potential significant hazards are and the basis for evaluating those as hazards.
Conclusions

• The FDA Food Code identifies cold brew coffee as a low-acid food requiring a variance for ambient steeping

• Without a complete hazard analysis, regulators may have insufficient information upon which to evaluate a variance request

• The food regulatory system must continue to transition towards a hazard analysis, systems-based approach, to be effective in controlling hazards
Conclusions (continued)

• Research exists that demonstrates the need for control of *L. mono.*, *C. bot.*, and mycotoxins in cold brew coffee, yet it is not listed as a specialized process in the FDA Food Code.

• Few regulatory agencies are looking into potential necessary changes to regulatory approach and industry has not been active in reaching out to food regulators.
Recommendations

1. Cold brew coffee should be identified as a specialized process in the FDA Food Code.

2. Further publicly available challenge studies are needed.

3. Food regulatory agencies should develop specific policies towards their inspections of cold brew coffee.

4. FDA guidance documents on cold brew coffee could help to standardize regulation and production throughout the United States.

5. The food regulatory system should continue to be developed towards a hazard analysis, systems-based approach.
Acknowledgements

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Questions?

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Background

• Cold brew coffee is a low acid food under the FDA Food Code, requiring a variance for ambient steeping and reduced-oxygen-packaging. This variance may include a HACCP plan and/or process review from a process authority. A process authority is someone with knowledge, experience, and adequate facilities (equipment and resources) to make determinations about the safety of a food process and formulation.

• Wholesale manufacturers of cold brew coffee will often require a preventive controls food safety plan. A process review can serve as a key part of a food safety plan, as part of the firm’s validated process preventive controls.

• Firm’s with a qualified facility exemption (exempt from preventive controls) will either have to attest to having controlling the hazards in their product or being in compliance with applicable state, local, tribal, etc. non-federal laws - which may mean a process review.
Background

• The approximate infective dose of *L. mono.* is estimated to be 10 to 100 million colony forming units (CFU) in healthy hosts, and only 0.1 to 10 million CFU in individuals at high risk of infection. 20 cells of *L. mono.* are sufficient to cause a miscarriage.
Additional Resources, CFSAN Letter

- CFSAN Cold Brew Letter to Florida Department of Agriculture, d122319
Additional Resources

OSU Challenge Study

Survival of Non-sporing Foodborne Pathogens in Cold Brewed Coffee

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Abstract

Inconceivable popular among coffee consumers is a product known as "Cold Brew" that is made by water extraction of ground coffee at temperatures of 6 to 12 °C. Although some studies have investigated the microbial stability of "Cold Brew" across extended storage times at ambient temperatures, few studies have investigated the microbial stability of "Cold Brew" at cold temperatures. The objective of this study was to investigate the microbial stability of "Cold Brew" at various refrigeration temperatures.

Introduction

Coffee beverages such as Cold Brew coffee products are produced by percolating coffee using water at ambient temperatures. This method of extraction is believed to create beverages that are low in acidity and do not require the addition of preservatives to extend shelf life. This process has been shown to impart a distinct flavor profile to the beverage, which is highly desirable to consumers. The microbial stability of these beverages is critical to their shelf life and consumer acceptability. The microbial content of "Cold Brew" beverages at ambient temperatures has been investigated extensively; however, the microbial stability of these beverages at cold temperatures has not been extensively studied.

Materials and Methods

Cold Brew coffee was produced at a regional coffee roaster. The roasted coffee beans were ground using a commercial grinder. The coffee was then combined with water at a ratio of 1:20 and allowed to infuse for 16 hours at ambient temperatures. The resulting "Cold Brew" beverage was then divided into bottles using aseptic packaging techniques. Bottles were then stored at various refrigeration temperatures (4°C, 6°C, 8°C, and 12°C) for a period of 3 weeks. At the end of the storage period, the microbial content of the "Cold Brew" beverage was evaluated using conventional culture methods and molecular techniques.

Results

The microbial content of the "Cold Brew" beverage was evaluated using conventional culture methods and molecular techniques. The microbial content of the beverage was found to be low at all refrigeration temperatures tested. The results of these experiments are presented in Table 1.

Conclusions

Our studies have demonstrated the potential of "Cold Brew" beverages to be a viable alternative to traditionally brewed coffee. The microbial content of the beverage was found to be low at all refrigeration temperatures tested, indicating that the beverage is stable at these temperatures. The results of this study are significant for the coffee industry as they provide evidence for the potential of "Cold Brew" beverages to be a viable alternative to traditionally brewed coffee.
(a) Food processing and production information shall be entered on forms, approved by the commissioner, which shall include the product processed, the code number, the size of the container, the approximate number of containers per coding interval and other appropriate processing data required by the commissioner.

................. A Process Review!
Additional Resources, Cornell’s Validated Process Review Options

1) Steep coffee at or below 41°F for up to 24 hours, then refrigerate product = refrigerated shelf life of 3 to 5 days. (This process used by small scale producers)

2) Steep coffee at or below 41°F for up to 24 hours, flash pasteurize at or above 165°F for 15 seconds, then refrigerate product = refrigerated shelf life of 90 days. (This process used by small scale producers)

3) Steep coffee at or below 41°F for up to 24 hours, filter through clean sanitized filtration housings. Final filtration is at most 0.50 micron nominal, then refrigerate product = refrigerated shelf life of 90 days. (This process used by small to medium scale producers. Cost becomes a limiting factor)

4) Steep coffee at or below 41°F for up to 24 hours, filter through clean sanitized filtration housings. Final filtration is at most 0.50 micron nominal, fill containers using aseptic (sterile) processing = shelf stable product. (This process used by medium to large scale producers. Cost is out of reach for small and some medium size processors) (We would not validate this here)

5) Steep coffee at or below 41°F for up to 24 hours, fill into clean individual containers, retort containers at above 250°F at above 24hg of pressure = shelf stable product (This process used only by large scale producers. Cost is out of reach for small and medium size processors). (We would not validate this here)
Additional Resources, FDA acrylimide

- https://www.fda.gov/food/chemicals/acrylamide
Background
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wholesale + retail cold brew coffee, ROP, nitrogen infused, milk added