ifpti
Fellowship in
Food Protection

*Funding for this statement, publication, press release, etc. was made possible, in part, by the Food and Drug Administration through grant 5U18FD005964-04; views expressed in written materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.

IFPTI Fellowship Cohort VIII: Research Presentation

JOSHUA LOPEZ

FOOD INSPECTOR REGION 3, ZONE 15

New York State Department of Agriculture and Markets

Division of Food Safety and Inspection

COLD BREW COFFEE REGULATIONS

Joshua Lopez, Food Inspector 1
IFPTI 2019-2020 Fellow
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.

Background

Based on the results of Cornell's study:

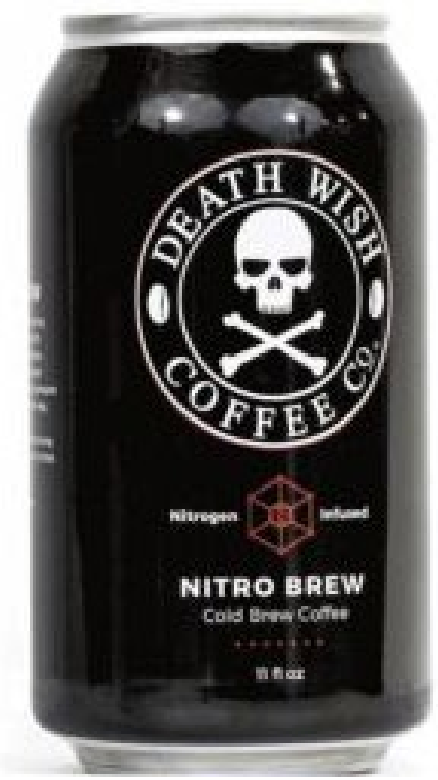
L. Mono. was considered by Cornell to be the primary pathogen of concern, or "Target Organism," for cold brew coffee.

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.

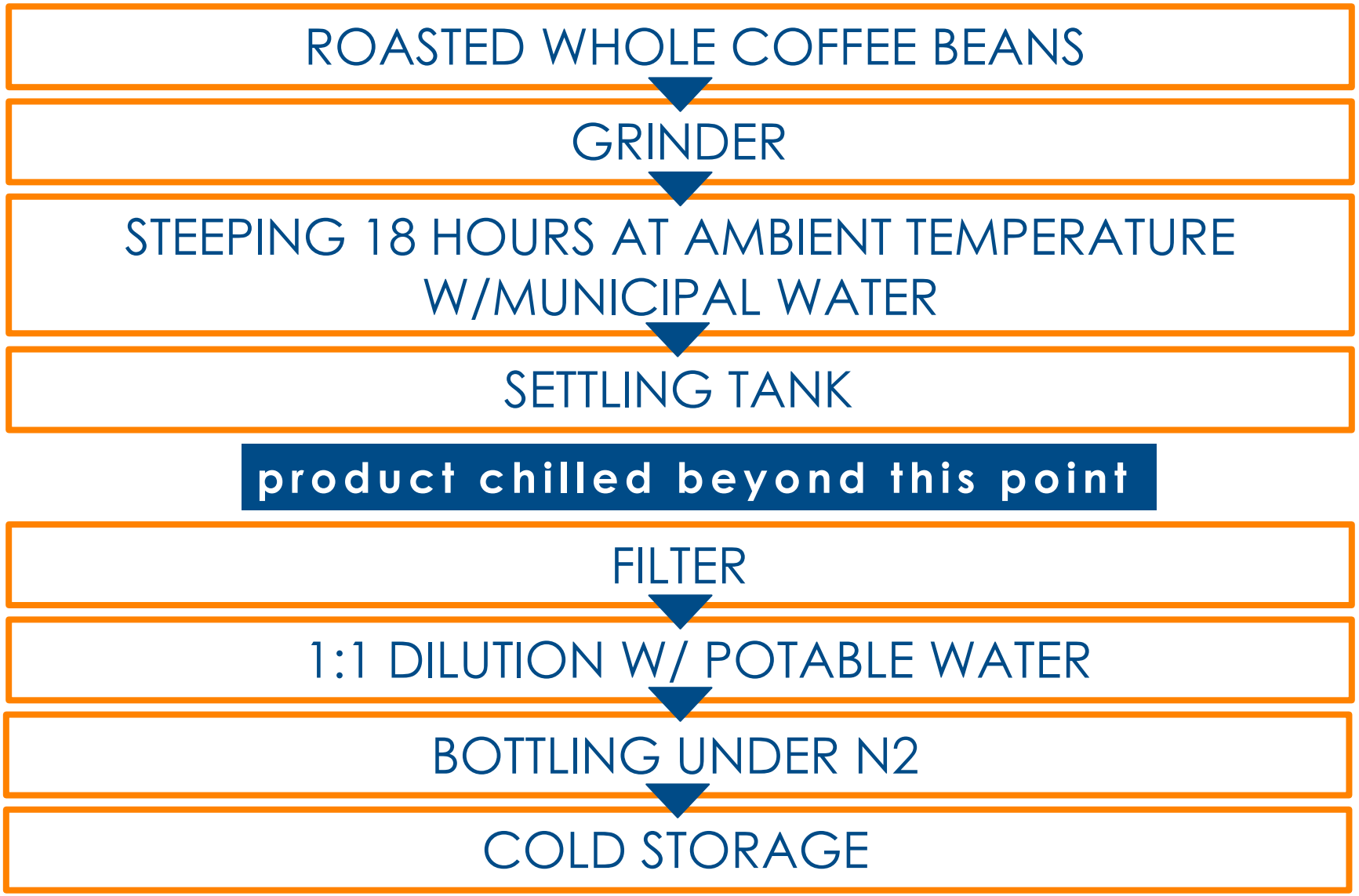
Background

- 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)



retrieved from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/death-wish-coffee-co-announces-recall-nitro-cold-brew-cans-retailers-online-sales

Background



Background

Retail cold brew operations, ambient…

Background

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

Percentage of Respondents	Indicated Their Agency Had
88%	retail jurisdiction
24%	wholesale jurisdiction
8%	no jurisdiction
2%	"other" jurisdiction

Results

Percentage of Respondents	Indicated Their Agency Regulates
62%	according to the FDA Food Code
16%	according to CFR 117
18%	qualified facilities
41%	"other" (including regulations based off CFR 117 and the Food Code, unique state and local regulations, etc.)

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

Thank you to:

- All who completed the survey.
- Bruno Xavier and Ann Charles-Vegdahl of Cornell University.
- All the IFPTI staff for guidance and support in developing this project, including Mentors Dan Gump, Kathy Fedder, Joe Corby, and Doug Saunders.
- IFPTI fellows of Cohort VIII.
- AFDO Program Director Patrick Kennelly for help providing a list of food regulatory agencies.
- IFPTI's Chris Weiss for Survey Monkey technical assistance.
- NYS AGM for allowing me the time and support to complete this project.
- FDA and AGM for training and resources.
- My wife for taking care of our daughter while I was away and my daughter for noticing I was missing for weeks at a time.

Questions?

JOSHUA LOPEZ
FOOD INSPECTOR REGION 3, ZONE 15
New York State Department of Agriculture and Markets
Division of Food Safety and Inspection
55 Hanson Place Brooklyn, NY 11217
(718) 722-2876 joshua.lopez@agriculture.ny.gov
http://www.agriculture.ny.gov

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-spore Forming Foodborne Pathogens In Cold Brewed Coffee

Oregon State University OSU
Mark A. Daeschel[1], Nathan Armbrust[2] and Christine Vieru[1]
Department of Food Science and Technology[1]
Corvallis, OR USA Stumptown Coffee[2], Portland OR USA
Mark.Daeschel@oregonstate.edu

Abstract

Increasingly popular among coffee consumers is a product known as "Cold Brew" that is made by water extraction of ground coffee at ambient temperature for 16-24 hours; then filtered, bottled, and kept under refrigeration to the point of retail sale. The product does not receive any thermal processing and has a pH of about 5.0. Thus, it is a low acid food whose preservation is dependent upon refrigeration and any inherent antimicrobial characteristics. Processors avoid pasteurization, acidification, or preservatives for quality concerns. The objective of this study is to document the survival/growth of foodborne pathogens intentionally introduced into "Cold Brew" products held at commercial refrigeration temperatures. Fresh cold brewed coffee in sealed bottles was obtained from a regional coffee roaster. Populations (~ 1x10^5 CFU/ml) of (3 strains each of *E. coli O15:H7*, *Salmonella* species and *Listeria monocytogenes*) were introduced individually into cold brew (pH 5.0) and into controls (0.1 M potassium phosphate buffer, pH 5.0) and held at 4° C / 21 days. Enumeration was at 2 day intervals. Growth was not observed in either the coffee or controls with any of the strains (n=3). Viable cells were not recovered (n=3) after (7 days-*Salmonella*), (11 days-*E. coli*), and (14 days– *L. monocytogenes*). During the same time intervals, populations in the buffer controls experienced only a 1-1.5 log reduction (the range n=3). We observed "Cold Brew" does not favor the survival or growth of non-spore forming bacterial pathogens; likely due to a lack of nutrients and or the presence of antimicrobial factors from the coffee. Other investigation is being conducted to assess if *Clostridium botulinum* poses a safety threat to this low-acid product.

Introduction

Commercial processors of Cold brewed coffee products are hesitant to use pasteurization, acidification or the addition of preservatives to extend shelf life or to insure safety. Anecdotally, it is believed that such treatments significantly diminishes the delicate flavor and aroma characteristics of "Cold Brew". Questions have arisen regarding the microbial stability of the finished product as the only extrinsic hurdle is that of constant refrigeration. The ground coffee extraction procedure at ambient temperature may also be a process point where microbial stability may be in doubt. To our knowledge no studies have addressed these particular points of the "cold brew" process in regard to the intrinsic microbial populations and their behavior. Furthermore, there apparently have not been any challenge studies conducted with food borne pathogens to assess their growth, survival or persistence in this type of product. The objective of this study is to document the survival of foodborne pathogens intentionally introduced into "Cold Brew" products held at ambient and refrigeration temperatures.

Methodology

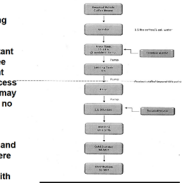
Cold brewed coffee was obtained from a regional coffee roaster. Refrigerated product was received in 11 oz bottles sealed with crown caps. Manufacture date was 7days from receipt. The manufacturing process for this specific product is portrayed in the flow diagram in the next column. The following pathogens were used to inoculate (1x10 5 /ml) coffees to be held at ambient and refrigeration studies. Controls consisted of pH adjusted (5.0) 0.1M phosphate buffer

666 Salmonella hartford
667 Salmonella enterica typhimurium
668 Salmonella enterica stanley
702 Salmonella ubandaka

628 Listeria innocua ATCC 33090
632 Listeria monocytogenes ATCC 19115
633 Listeria monocytogenes 675-3

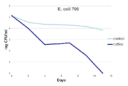
669 E. coli O157:H7 ATCC 43894
700 E. coli O157:H7 ATCC 43895
701 E.coli O157:H7 F-4546

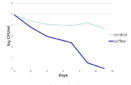
Cold Brew Coffee Flowchart

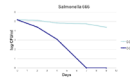


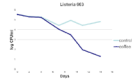
Results

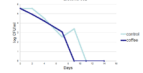
Refrigerated (4 C) Studies











Conclusions

Our studies have consisted of challenge studies that introduce into "Cold Brew" strains of *E.coli O15:H7*, *Salmonella* species and *Listeria monocytogenes* which are implicated in the majority of food-borne outbreaks. Populations of microorganisms were introduced aseptically into bottles of fresh cold brew and held at refrigerator temperature and at room temperatures for periods up to 3 weeks. No growth of any microorganisms was observed during this period but rather they died off during that time. The numbers of microorganisms initially was on the order of 100,000 per ml of brew which is far in excess of what levels of contamination would be in a food processing facility. Our conclusion is that "Cold Brew" does not favor the survival or growth of vegetative bacterial pathogens most likely due to a lack of microbial nutrients and or the presence of antimicrobial factors originating from the coffee.

Background

1 CRR-NY 276.2 276.2 Records.

(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

Background

Background

Background

Background

Background

Background

Background

Background

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