Non-alcohol Beer:
A Review and Key Considerations

Introduction
Sales of low and non-alcohol beer are growing in the United States. In response to the growing demand for these types of products, many craft brewers are adding, or considering adding, non-alcohol beers to their brand portfolio. Brewing non-alcohol beers is fundamentally different from producing traditional beers which typically contain inherent barriers that ensure consumer safety and shelf stability. Besides the need to ensure that a non-alcohol beer does not present a threat to consumer safety, production of these products usually occurs within a different regulatory framework than traditional beer. This document will provide a brief overview of the different considerations craft brewers must address when producing a non-alcohol beer including production methods, preservation techniques, quality verification, good manufacturing practices, and regulatory considerations.

Production Methods
The principal methods used to produce non-alcohol beer are to *prevent* alcohol from being formed or to *remove* alcohol after fermentation. It's important to note that if alcohol is concentrated during the production process (such as to remove from a product), a separate manufacturing license or distillers permit may be required.

No Fermentation
This process is a result of producing wort without the addition of yeast to stimulate fermentation. This results in a sweeter product that requires microbial stabilization.

Limited or Arrested Fermentation
Non-alcohol beers may be produced by arresting fermentation prematurely or with yeast strains that are not capable of completing fermentation. In this type of process, wort is generally designed to be less fermentable than in a typical beer recipe. In arrested fermentation, fermentation is stopped before high levels of alcohol can be produced; this is typically temperature controlled since lowering the fermentation temperature will reduce yeast activity. Because active yeast remains, it is important for this product to be further stabilized through pasteurization or sterile filtration.

Non-alcohol beers may also be produced using special yeast strains. Some of these yeast strains are unable to ferment sugars such as maltose. Many yeast developers are continuing to research these strains and their fermentation positive effects like ester formation.

Dealcoholization
Dealcoholization refers to the process of removing alcohol from a fermented product and there are several ways to accomplish this. Methods used to make non-alcohol beer through dealcoholization include boiling, vacuum distillation, membrane filtration, and reverse osmosis.

Boiling: Due to the difference in boiling temperatures between water and ethanol, beer can be heated to evaporate ethanol from the liquid while retaining the water portion. An important consideration of this method is that it does affect product flavor in part by driving off other volatile aroma compounds in addition to ethanol.

Vacuum distillation: Vacuum distillation is a similar process to boiling beer to remove alcohol but is conducted under vacuum. The vacuum reduces the temperature required to boil off ethanol from 78.4°C to 34°C. This method reduces the impact of temperature on the final product when compared to boiling.

Membrane filtration: Membrane filtration involves a specific filter to physically separate compounds such as alcohol by using a pressure differential between the two sides of the filter. Typically, this

separation occurs with the use of cross flow filtration where the flow of the liquid travels across the membrane rather than through the membrane.

Reverse osmosis: This technique is the most common type of membrane filtration used to produce non-alcohol beers. As the beer passes across the membrane, small molecules like water and ethanol are removed from the beer. Water is added back to the final product to account for the loss of water that occurred during the process.

Regardless of the method of production, the inherent food safety benefits offered by traditional beer are absent in non-alcohol beer and other methods for microbial stabilization should be considered.

Preservation Techniques

The most important goal of stabilizing a non-alcohol beverage is to eliminate all pathogenic and spoilage microbes and ensure a "commercially sterile" product. Compared to "traditional" beer, non-alcohol beer is lacking one of the most important hurdles to bacterial growth: ethanol. In this regard, non-alcohol beer is considered more vulnerable to spoilage by food borne pathogens and microorganisms that affect quality. Further compromising microbial stability, non-alcohol beer may also lack additional hurdles due to low hop bittering compounds, high concentrations of fermentable sugars, and/or elevated pH.

Food Safety and pH

It is critical to control the pH of non-alcohol beer. Verify and maintain a pH of 4.6 or lower to help prevent microbial contamination of non-alcohol beer. If needed, pH may be adjusted by some method such as acidification with food grade acid to prevent potential issues from the food borne pathogen *Clostridium botulinum*.

Preservation methods range from thermal treatment (pasteurization) to sterile filtration, and the use of chemical preservatives.

Pasteurization: Tunnel pasteurization is the most robust form of pasteurization since it occurs when liquid is contained in the final package. Flash pasteurization, which occurs before packaging product, should only be employed if filling equipment is housed in a clean room. Pasteurization Units (PU's) ranging from around 10 to higher than 100 have been reported as being employed for non-alcohol beers. With extremely high PU levels it is important to consider the potential food safety concern of package overpressurization and understand the pressure ratings of the chosen package type.

Sterile Filtration: Filtration can be used to render a stable non-alcohol beer. As with flash pasteurization, a clean room is recommended for filling equipment.

Preservatives: Chemical preservatives such as sorbates and benzoates as well as natural preservatives may be used to render a microbially stable non-alcohol beer. Make sure to follow usage guidance such as provided by the Food and Drug Administration (FDA) Generally Recognized as Safe (GRAS) list. Irrespective of which stabilization method is chosen, it is imperative to validate its efficacy with internal studies and by working with a process authority.

Food Safety Verification

Shelf stable foods, like beer, are intended to be safe to eat or drink without a kill step (i.e., cooking step) by the consumer, so it is critical that they are processed to sufficient standards. To ensure safety and stability, the FDA requires most food producers to obtain approval from a "Process Authority", often referred to as a process review, whereby a document called a "Scheduled Process" is developed. This document includes the product formulation, processing methods, procedures, and critical factors necessary to ensure consumer safety and commercial sterility. Existing references for production techniques can also be utilized to assist in the development and verification of food safe processes, if available.

Process Authority

According to the Code of Federal Regulations (21 C.F.R. § 113.83), a processing authority is a person with "expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and adequate facilities for making such determinations." This person or institution provides validation of the safety and stability of a food or beverage product and provides a scheduled process to deliver a "commercially sterile" (FDA) or "shelf-stable" (USDA) food product. Processing authorities can be found at most state universities as well as through private institutions. The Association of Food and Drug Officials (AFDO) makes it easy to locate a food processing authority near you.

It is best practice to obtain a process review for the manufacturing process of non-alcohol and low-alcohol beverages. While the FDA does not require a process review for beer, it is not uncommon for a food regulator to request verification of the safety of a food manufacturing process. In this situation, it is essential to have a standard process and proper production records readily available. A process review not only provides a form of business insurance, but also ensures that consumers will be able to enjoy their non-alcohol beer safely.

Good Manufacturing Practices and Risk Management

Good Manufacturing Practices (GMPs) are the set of standards used to determine if a manufacturer is maintaining practices set by federal, state and county regulations. GMPs include establishing strong quality management systems, obtaining appropriate quality raw materials, establishing standard operating procedures, detecting and investigating product quality deviations, maintaining reliable laboratory tests, meeting sanitary and processing requirements, and packaging and labeling according to approved standards. GMPs are the foundation for any brewery's quality assurance program. All breweries that qualify as a food manufacturing facility under the Food and Drug Administration (FDA) regulations (most breweries with some exceptions) must comply with subparts A, B, D, E & F of 21 C.F.R. §117; including current GMPs (cGMPs) and record keeping requirements.

Traditional brewing processes yield a set of inherent properties that promote microbiological food safety. As brewers innovate with new production techniques and create new categories and flavor profiles, some of these inherent safety controls may be reduced, changed, or even removed. Producers of non-alcohol offerings, including non-alcohol beer, must comply with all aspects of 21 C.F.R. §117 including Hazard Analysis and Risk-Based Preventive Controls (HARPC) and Supply Chain Program requirements. (Exemptions are available for Very Small Businesses and Qualified Facilities. Refer to the Brewers Association FDA Registration & Food Safety Modernization Act (FSMA) Compliance Flow Chart).

Regardless of regulatory requirements, it is recommended that a specialized process be developed for the manufacture of any non-alcohol products. Recommendations include:

- Consider employing a Process Authority to develop and verify your process.
- Refer to the FDA's Hazard Analysis and Risk-Based Preventive Controls for Human Food.
- Brewers Association Food Safety Planning for Craft Brewers contains helpful guidance for developing a food safety plan at your facility.
- Consider your packaging type carefully and whether you can control distribution to maintain the safety and stability of your product. In most cases assume you cannot control the environment once it reaches the end user.

Packaging Format

While non-alcohol beer can be rendered microbiologically stable for service in bottles and cans, draught beer presents a problematic form of service. Even if a keg of beer is sterile on delivery, the act of connecting the keg to a coupler for bar service can expose the beer to contaminant organisms already present in the draught system. Until substantial further study is conducted regarding the safety of low/non-alcohol beer served on draught, packaging and service of these styles should be restricted to small-pack forms.

It is important to remember that if a brewery knowingly or unknowingly creates a food safety hazard, the FDA has the authority to remove any exemptions that may apply to that brewery and require compliance with every aspect of 21 C.F.R. §117.

Regulatory Considerations

Regulations for the manufacturing of non-alcohol beer vary depending on the production methods and brewery location, however there are certain federal requirements that all facilities must comply with. Read below for a summary of the regulatory requirements (current at the time this resource was published, August 2022).

Federal Requirements

- All breweries and non-alcohol beverage production facilities must register with the Food and Drug Administration (FDA). For more information on specific FSMA requirements for your facility refer to the Brewers Association FSMA Compliance Flow Chart .
- A Brewer's Notice from the TTB is required for any facility brewing malt beverages.
- A Distilled Spirits Permit from the TTB may be required if the process includes removing and distilling the alcohol out of the beer.

Permits

State regulations vary. Examples of types of permits that may be required to produce, bottle, and wholesale non-alcohol beer include Food Manufacturing License, Processed Foods Registration/Permit, and Non-alcohol Beverage License. These types of permits or licenses may be issued by different departments in each state including but not limited to Department of Public Health, Department of Agriculture, and Department of Consumer Protection. For facilities producing beer above 0.5% ABV, these permits would be additional to the state brewery permit and/or distillery permit (see above).

Class and Type Designations

- Acceptable terms for products <0.5% ABV include Malt Beverage, Cereal Beverage, and Near Beer.
- The following terms may not be used in labeling or advertising of non-alcohol beer: Beer, Ale, Stout, Porter, Lager, and any others defined in the Beverage Alcohol Manual (BAM) as having >0.5% ABV.
- Class and Type designates are defined in Chapter 4 of the TTB BAM.

Formulas

Formula submission and approval is required for the following types of products:

- Non-alcohol beers containing non-traditional ingredients not listed in TTB Ruling 2015-1 Attachment 1
- Processes that include filtration or any other process or treatment that substantially changes color, flavor, or character
- Separation into different components
- Reverse osmosis of the product itself

Sample submission is also required for 0.0% ABV formulas and may be requested for any other formula submission. Formula submission requirement details can be found in TTB Guidance 2016-1a.

Labeling

- Labeling requirements include appropriate Class and Type (see limitations above).
- The Health Warning is not required for non-alcohol beer, but the label must include the phrase 'Nontaxable under section 5051 I.R.C.'.
- If the term 'non-alcoholic' is used on the label the phrase 'Contains less than 0.5% alc/vol' must be 'in direct conjunction' with it.

Non-alcohol Beer Label Examples

Unacceptable vs. Acceptable

1. **Non-taxable under section 5051 I.R.C.** is missing from the label
2. **Contains less than 0.5% alcohol by volume** must appear in conjunction with **Non-alcoholic**. If product is **Alcohol-Free**, then the language **contains 0.0% alcohol by volume** must appear in conjunction.
3. The label **Beer** is not allowed as the class designation. The full list of **unacceptable terms** are found in the Beverage Alcohol Manual (BAM).

1. Non-taxable under section 5051 I.R.C. is present on the label.
2. **Contains less that 0.5% alcohol by volume** appears directly in conjunction with **Non-alcoholic**.
3. Terms **malt beverage**, **cereal beverage**, and **near beer** are acceptable class designations under 27 CFR 7.24(d). **Brew** is an acceptable descriptor however is not a valid class designation.

Sample labels provided by Tax and Trade Bureau (TTB), United States Department of the Treasury.

- The alcohol content, 0.0% alc/vol, is required to be displayed on the label if the product is labeled "Alcoho-Free."
- The alcohol content is also required if the product is made with alcohol-containing ingredients/flavorings other than hops extract.
- Certificates of Label Approval (COLA) are required for interstate commerce.

Advertising

Advertising regulations are defined in 27 CFR 7.50 and are identical to those for beer and malt beverages.

Sales, Distribution, And Trades Practices

Sales, distribution, and trades practices vary by state. Most variation in sales, distribution and trades practices requirements at the state level originates with the statutory definition of beer or malt beverage in the state.

- Several states require three-tier distribution, and some require alcohol licenses, COLA registration, and monthly reporting for the distribution of non-alcohol beer.
- Direct-to-Consumer (e-commerce) sales are permitted in most states however regulations vary by state. Age restrictions on the sale of non-alcohol beer vary by state from no restrictions, to 18 or 21 plus.

While not a regulatory requirement, it is generally best practice to market non-alcohol beer as an adult beverage, which captures the same target audience as beer and malt beverage.

Conclusion

Low and non-alcohol beer production has seen a resurgence in the last few years and the category is poised for significant growth. There are a multitude of decisions to be made concerning the best process for new companies in planning to existing breweries looking to add non-alcohol beer to their current lineup. Some of the main decisions touched on include the purchase and implementation of new processing equipment, evaluating new processes and controls, and acquiring new facility permits. Food safety should also be considered since **non-alcohol beer does not have the same inherent microbiological protections as traditional beer**. Whatever stabilization technique is employed, it's critical to verify a food safe process and implement regular monitoring. Producing a low or non-alcohol beer can be quite a challenging endeavor, but the end product will be an offering that many customers are grateful for.