



SCHOOL OF LAW
TEXAS A&M UNIVERSITY

Texas A&M Law Review

Volume 8 | Issue 1

1-7-2021

Brewing Green Beer: Building a Regulatory Scheme Robust to Changes in Brewing Technologies

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Recommended Citation

Daniel Pashang Withers, *Brewing Green Beer: Building a Regulatory Scheme Robust to Changes in Brewing Technologies*, 8 Tex. A&M L. Rev. Arguendo 9 (2021).

Available at: <https://doi.org/10.37419/LR.V8.Arg.2>

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BREWING GREEN BEER: BUILDING A REGULATORY SCHEME ROBUST TO CHANGES IN BREWING TECHNOLOGIES

by: Daniel P. Withers*

ABSTRACT

New beer brewing technologies provide brewers with options to produce beer in more eco-friendly, less resource-intensive ways; however, as brewers adopt these technologies, they may find themselves straddling between the regulatory schemes of the Alcohol and Tobacco Tax and Trade Bureau (“TTB”) and the Food and Drug Administration (“FDA”). The two agencies have divided control over beers based on their ingredients, which places some beers under the TTB’s purview as “malted beverages” and others under the FDA’s purview. These distinctions have implications for the regulatory hurdles that brewers must overcome to market their products. Additional regulations that eco-friendly, green beers may face could provide higher hurdles than standard beers face, putting them at a competitive disadvantage. This Comment explores the relationships between beer brewing and the environment, new technologies that ease the environmental burden of beer brewing, and the regulatory boundaries affected by adopting these new technologies. By expanding its definition of “malted beverages,” the TTB can encourage the adoption of new eco-friendly technologies, avoid a regulatory quandary, and promote a healthy beer brewing industry.

TABLE OF CONTENTS

- I. INTRODUCTION
- II. ENVIRONMENTAL CONSIDERATIONS AND TECHNOLOGIES
 - A. *Impact of Environment on Beer*
 - B. *Impact of Beer on Environment*
 - C. *Hop-Terpene-Producing Yeast and Low-Resource-Brewing Alternatives*
- III. THE VARIOUS REGULATORY SCHEMES AFFECTING BEER
 - A. *How the TTB Defines Beer*
 - B. *How the FDA Defines Beer*
 - C. *Labeling Requirements of the TTB, FDA, and USDA*
 - D. *FDA Approval of GE Products for Human Use*
 - E. *Implications of Current Policies on the Regulation of Eco-Friendly Beer Brewing Technologies*
- IV. HOW AGENCIES AND THE INDUSTRY MIGHT MOVE FORWARD
 - A. *How the TTB and FDA Could Respond Going Forward*
 - B. *How Brewers Could Respond Going Forward*
- V. CONCLUSION

DOI: <https://doi.org/10.37419/LR.V8.Arg.2>

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I. INTRODUCTION

“[I]n all cities, markets and in the country, the only ingredients used for the brewing of beer must be Barley, Hops and Water.”

—Duke Wilhelm IV of Bavaria, 1516¹

Brewing beer begins with making a mash by mixing cereal grains, such as barley, with water and then heating that mixture to a temperature between 130°F and 155°F.² The mashing process results in a sugar-rich liquid called a wort.³ The brewer then heats the wort to boiling and adds hops.⁴ After boiling the wort, the brewer cools the liquid to around 70°F and introduces yeast to the brew.⁵ Introducing yeast to the boiled wort begins the fermentation process—in which yeast converts sugars into alcohol and carbon dioxide.⁶ Fermentation continues for several days, after which the brewer may add hop oils—hop oils add aromatic, bitter components to beer that naturally occur in hops.⁷ The addition of hop oils is specific to certain types of beers, such as India Pale Ales.⁸ Another process a brewer might use at this stage to impart aromatic flavors into the beer is dry-hopping, which consists of adding raw hops to the beer during a secondary fermentation stage.⁹ Finally, the brewer bottles the beer.¹⁰ Though the list of ingredients used to brew beer is scant—just barley, hops, water, and yeast¹¹—growing hops and barley impacts the availability of natural resources. For instance, growing hops requires about 100 billion liters of water each year in the United States.¹² With an eye toward reducing the burden of beer production on the environment, researchers have turned to developing new, eco-friendly brewing technologies.¹³

In 2018, Dr. Charles Denby¹⁴ and a team of researchers from his lab published a study revealing their use of the Clustered Regularly Interspaced Short Palindromic Repeats (“CRISPR”)

¹ Timothy R. Sloane, *Green Beer: Incentivizing Sustainability in California’s Brewing Industry*, 5 GOLDEN GATE U. ENV’T L.J. 481, 481 (2012) (citing Karl J. Eden, *History of German Brewing*, ZYMURGY, Special Ed. 1993, at 6, 7).

² *Id.* at 493–94.

³ *Id.* at 494.

⁴ *Id.*

⁵ *Id.* at 494–95.

⁶ *Id.* at 495.

⁷ *Id.*

⁸ David Ackley, *What Are Hop Oils? Explained!*, ECKRAUS (Dec. 18, 2018), <https://blog.eckraus.com/what-are-hop-oils-explained> [<https://perma.cc/U79C-SU3E>].

⁹ Lauren Buzzeo, *It’s Time to Give American Pale Ales a Chance*, WINE ENTHUSIAST (Aug. 9, 2018), <https://www.winemag.com/2018/08/09/american-pale-ales/> [<https://perma.cc/HC2S-PTEN>].

¹⁰ See Sloane, *supra* note 1, at 495–96.

¹¹ The German government added yeast to the list of ingredients in beer in the 17th century. *Id.* at 481.

¹² Charles M. Denby et al., *Industrial Brewing Yeast Engineered for the Production of Primary Flavor Determinants in Hopped Beer*, NATURE COMM’NS, Mar. 20, 2018, at 1, 2, <https://doi.org/10.1038/s41467-018-03293-x>.

¹³ See, e.g., *id.*; Stephen T. Russell et al., *Alternative Paradigms for the Production of Beer*, 114 J. INST. BREWING 349, 349 (2008).

¹⁴ Dr. Denby is a former postdoctoral fellow from the University of California at Berkeley, a co-author of *Industrial Brewing Yeast Engineered for the Production of Primary Flavor Determinants in Hopped Beer*, and founder of Berkeley Brewing Science. See Sabrina Dong, *UC Berkeley Researchers Create Genetically Engineered Beer Without Hops*, THE DAILY CALIFORNIAN, <https://www.dailycal.org/2018/03/21/uc-berkeley-researchers-create-genetically-engineered-beer-without-hops/> (last updated Mar. 22, 2018) [<https://perma.cc/9K5R-EE27>].

Cas9 system,¹⁵ a genetic engineering (“GE”) technology, to produce strains of yeast that expressed aromatic chemicals that give beer its hoppy flavor.¹⁶ Dr. Denby developed the strains to respond to concerns about how much water it takes for farmers to grow hops.¹⁷ Another group, from Dr. Charles Bamforth’s¹⁸ lab, also found itself concerned with the environmental impact of brewing beer. In 2008, the group published a study on new brewing techniques that required less resources, like water and energy, and had a lighter environmental impact than traditional brewing techniques.¹⁹ These techniques involve brewing methods such as using corn syrup instead of a barley and hop mash or taking individual constituent parts that make up beer and putting them together.²⁰

Dr. Denby went through the process prescribed by the Food and Drug Administration (“FDA”) to have his GE yeast strains assessed for potential dangers to humans.²¹ However, due to an interplay between FDA regulations and Alcohol and Tobacco Tax and Trade Bureau (“TTB”) regulations, using Dr. Denby’s yeast in conjunction with Dr. Bamforth’s less resource-intensive brewing techniques could result in a beer that is subject to the National Bioengineered Food Disclosure Standard, which does not apply to other beers that contain GE crops.²² This additional standard could put new eco-friendly beers at a competitive disadvantage compared to other beers, providing an additional hurdle for resource-efficient beer technologies before they can become popular among consumers.

This Comment explains: (1) why the government should encourage the development of resource-efficient beer technologies; (2) regulatory hurdles that may arise as these technologies develop; and (3) how the government can act to prevent these hurdles. Part II explores the interplay of the environment and beer brewing, both in how the environment impacts brewing and how brewing impacts the environment, and then proceeds with a more detailed description of the technologies developed by Drs. Denby and Bamforth. Part III discusses how the FDA and TTB have divided the subject matter of beer, how the FDA regulates GE products for human consumption, and the implications of current policies on the regulation of new beer technologies. Part IV addresses how the TTB and FDA could respond to these new technologies and how brewers could respond to the TTB and FDA regulations in using these new technologies. Finally, this Comment concludes with a summary of the issues and solutions that brewers and the TTB might face and utilize.

II. ENVIRONMENTAL CONSIDERATIONS AND TECHNOLOGIES

Beer, with its reliance on agricultural products, is both impacted by and impacts the environment. Environmental factors, such as drought, heat, and water sourcing, affect the qualities of hops, barley, and water that brewers use to make beer, subsequently affecting the beer’s flavor.

¹⁵ The CRISPR-Cas9 system utilizes a bacterial defense protein to make directed incisions in DNA, enabling its use in genetic engineering. *See generally* Le Cong et al., *Multiplex Genome Engineering Using CRISPR/Cas Systems*, 339 *SCIENCE* 819, 819 (2013), <https://doi.org/10.1126/science.1231143>.

¹⁶ Denby et al., *supra* note 12.

¹⁷ *Id.*

¹⁸ Dr. Bamforth is a Professor Emeritus in the Department of Food Science and Technology at the University of California, Davis. *See Charles W. Bamforth*, UC DAVIS, <https://foodscience.ucdavis.edu/people/charles-bamforth> [<https://perma.cc/G8QA-4BTN>].

¹⁹ Russell et al., *supra* note 13.

²⁰ *Id.*

²¹ Letter from Susan J. Carlson, U.S. Food & Drug Admin., to Charles Denby, Berkeley Brewing Sci. (Aug. 13, 2019), <https://www.fda.gov/media/131847/download> [<https://perma.cc/8AKJ-G7VZ>].

²² *See infra* Part III.

Additionally, growing hops and barley and brewing beer consume resources, affecting the environment. With an eye on the effect of beer on the environment and the effect of the environment on beer, researchers are developing brewing technologies that are less resource-intensive and more robust to environmental changes. As these technologies gain use in the industry, regulatory issues may provide obstacles that slow their adoptions. This Part delves deeper into: (1) the impact of the environment on beer; (2) the impact of the beer on the environment; and (3) the technologies developed to address these impacts.

A. *Impact of Environment on Beer*

In 2017, the United States saw a large increase in hops production, resulting in a crop valued at a record high of about \$591 million, nearly \$100 million more than the previous year.²³ About 78% of this production came from Washington.²⁴ The Pacific Northwest accounts for the majority of hops grown in the United States.²⁵ While this production appears robust, only decreasing by about 1% from 2017 to 2018,²⁶ the small geographic range of production makes the American crop susceptible to changes in environmental conditions, such as drought, heat, and storms.²⁷

First, the quality of water affects the quality of hops. The majority of the hops grown in Washington are from the Yakima Basin, and the water delivered to this region comes from melted winter precipitation from the snowcaps of the Cascade Mountains.²⁸ In 2015, the region experienced a drought, and growers concerned about the production for the year resorted to irrigation of groundwater to compensate for the dearth of water fed from precipitation.²⁹ Resorting to irrigation helped a majority of growers. However, some were left high and dry due to antiquated irrigation systems.³⁰

Second, changes in heat also affect the growth of hops.³¹ Hop growers classify varieties of hops into two groups—(1) alpha varieties and (2) aroma varieties.³² The alpha varieties contribute to the bitter flavor of beer, while aroma varieties give beers more aromatic flavors, such as citrus or herbs. In the past, hop growers have leaned toward growing mostly alpha varieties, but as preferences for beer styles shifted, demand for hops also shifted, resulting in hop growers increasing their acreage of aroma varieties.³³ In 2015, about 70% of the acreage of Washington farms growing hops was devoted to growing aroma varieties, while about 30% was devoted to growing alpha varieties.³⁴ However, the high heat of that year affected aroma and alpha varieties differently, harming aroma varieties more than alpha varieties and especially affecting early season aroma

²³ U.S. DEP'T OF AGRIC., NATIONAL HOP REPORT 1 (2018), https://www.nass.usda.gov/Statistics_by_State/Regional_Office/Northwest/includes/Publications/Hops/National%20hop_2018.pdf [<https://perma.cc/5WQJ-77P8>] [hereinafter NATIONAL HOP REPORT].

²⁴ *Id.*

²⁵ John Holl, *The Current State of Hops*, BREWING INDUS. GUIDE (Feb. 15, 2018), <https://brewingindustry-guide.com/the-current-state-of-hops/> [<https://perma.cc/7E8T-99W8>].

²⁶ NATIONAL HOP REPORT, *supra* note 23, at 1.

²⁷ Caitlyn Kennedy, *Climate & Beer*, NOAA CLIMATE.GOV (Jan. 13, 2016), <https://www.climate.gov/news-features/climate-and/climate-beer> [<https://perma.cc/6G6A-72XY>].

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² Matt Giovanisci, *The Complete List of All Hop Varieties on Earth*, BREW CABIN, <https://www.brew-cabin.com/hop-varieties/> (last updated Mar. 19, 2019) [<https://perma.cc/JGL8-GUYD>].

³³ Holl, *supra* note 25.

³⁴ Kennedy, *supra* note 27.

varieties.³⁵ While the varieties of hops grown in Washington are bred specifically to tolerate the region's climate, a shifting climate will require further breeding to adjust.³⁶ For example, Hopsteiner and the Hop Breeding Company, two hop-growing companies, specially bred, developed, and patented most hop varieties, so farmers have to seek out licenses and pay royalties whenever they have to resort to a different variety.³⁷ The U.S. Department of Agriculture ("USDA") operates a public hops breeding program, but not all varieties that come from this program will be successful.³⁸

A third problem that a shifting climate poses for beer brewing lies in the water used for actually brewing the beer.³⁹ In times of drought, brewers can find themselves having to resort to groundwater for their water supplies.⁴⁰ Groundwater typically is dense in minerals, affecting the flavor of the beer that is ultimately brewed.⁴¹ The presence of various minerals can affect the activity of enzymes at the mashing stage of brewing.⁴² Further, these minerals can affect the pH of the mash and wort, which in turn affects the extraction of molecules that impact flavor.⁴³ Finally, the mineral profile of the water used in brewing affects the fermentation and growth of yeast.⁴⁴

Brewers support initiatives to reduce human impact on the environment because they recognize the effects of shifting climates on the materials that go into their beers, lauding politicians when they take ecologically friendly stances and urging other politicians to take similar stances.⁴⁵

B. *Impact of Beer on Environment*

Brewers recognize the effects that brewing can have on the environment as well.⁴⁶ Brewers big and small take steps to decrease their carbon footprint and reduce the resources they use in brewing because they recognize the impact of the environment on their products.⁴⁷ By easing the impact of brewing on the environment, brewers act to help make a more stable product, attract eco-minded consumers, and reduce production costs.

Beer packaging has a large impact on the environment, specifically as it relates to global climate change. For example, beer packaged in glass bottles has a global warming potential⁴⁸ of

³⁵ *Id.*

³⁶ *Id.*

³⁷ Holl, *supra* note 25.

³⁸ *Id.*

³⁹ Kennedy, *supra* note 27.

⁴⁰ *Id.*

⁴¹ *Id.*; see also Alastair Bland, *California Brewers Fear Drought Could Leave Bad Taste in Your Beer*, NPR (Feb. 20, 2014, 12:38 PM), <https://www.npr.org/sections/thesalt/2014/02/19/279627234/california-brewers-fear-drought-could-leave-bad-taste-in-your-beer> [<https://perma.cc/8242-L9G8>].

⁴² See 2 J.S. HOUGH ET AL., *MALTING AND BREWING SCIENCE: HOPPED WORT AND BEER* 567 (2d ed.1982).

⁴³ See *id.* at 567–74.

⁴⁴ See *id.* at 567.

⁴⁵ See, e.g., Kirsten James, *Calling on Big Business to Step Up and Help Solve California's Water Woes*, CERES (Mar. 22, 2016), <https://www.ceres.org/index.php/news-center/blog/calling-big-business-step-and-help-solve-californias-water-woes> [<https://perma.cc/WRW9-X683>]; *CEOs of Major Companies Call on U.S. Congress to Set a National Price on Carbon*, CERES (May 22, 2019), <https://www.ceres.org/index.php/news-center/press-releases/LEAD-on-carbon-pricing> [<https://perma.cc/9SGQ-EGWD>]; Jay Richardson, *Governor's Clean Energy and Climate Plan Key to N.C. Economic Success*, WRAL.COM (Dec. 8, 2018, 5:00 AM), <https://www.wral.com/jay-richardson-governor-s-clean-energy-and-climate-plan-key-to-n-c-economic-success/18047351/> [<https://perma.cc/Q7WR-2XAH>].

⁴⁶ See James, *supra* note 45.

⁴⁷ *Id.*

⁴⁸ Global warming potential is a parameter used to measure greenhouse contributions, specifically the extent to which a mass unit can absorb infrared radiation as compared to CO₂. The closer a global warming potential is to zero,

842 grams of carbon dioxide (“CO₂”) equivalents per liter of beer bottled each day, and beer canned in aluminum and steel have global warming potentials of 575 and 510 grams of CO₂ equivalents per liter of beer canned each day, respectively.⁴⁹ The raw materials that go into brewing beer contribute to about 200 grams of CO₂ equivalents per liter of beer of the global warming potential.⁵⁰ The raw materials used in beer also account for about half of the eutrophication potential⁵¹ of beer.⁵² Production and transportation of packaging and raw materials are the areas of the beer life cycle that have the greatest environmental impact and are therefore the best targets for reducing the environmental impact of brewing beer.⁵³ Recognizing the impact of the beer industry on the environment, both large and small breweries have taken actions to reduce their environmental impacts.

Anheuser-Busch InBev, one of the largest breweries in the United States, has committed to reducing its environmental impact.⁵⁴ One way that Anheuser-Busch InBev has affected change has been through water-saving initiatives.⁵⁵ Through actions such as repurposing effluent⁵⁶ and using it for agricultural irrigation, watering public parks, and firefighting, Anheuser-Busch InBev reduced its water usage rate by 23% from 2009 to 2015.⁵⁷ This reduction accounted for a water saving of over two-and-a-half billion gallons.⁵⁸

New Belgium Brewing, a craft brewery, acts as a leader among craft breweries, pushing for and promoting the Brewers Association Sustainability Subcommittee, the Brewers Association Technical Committee, Brewers for Clean Water, the Hop Quality Group, and the Beverage Industry Environmental Roundtable.⁵⁹ Additionally, leaders at New Belgium Brewing laud the efforts of political leaders, encouraging Governor Roy Cooper when he issued an executive order to reduce carbon emissions.⁶⁰

Other craft breweries also work towards making their businesses more environmentally sustainable. In a study of seventy craft breweries, thirty-two mentioned an emphasis on water efficiency or in water conservation advocacy.⁶¹ They utilize modern equipment that uses less water and water reclamation systems to reduce their water usage as well as participate in water

the more neutral the parameter’s effect on the environment. *See Global Warming Potential*, SCI. DIRECT, <https://www.sciencedirect.com/topics/engineering/global-warming-potential> [<https://perma.cc/W6CC-45Q9>].

⁴⁹ David Amienyo & Adisa Azapagic, *Life Cycle Environmental Impacts and Costs of Beer Production and Consumption in the UK*, 21 INT’L J. LIFE CYCLE ASSESSMENT 492, 498 (2016), <https://doi.org/10.1007/s11367-016-1028-6>.

⁵⁰ *Id.* at 499.

⁵¹ Eutrophication potential is a measure of the effect a product has on fertilization runoff into water sources, resulting in an increased growth of biomass. *See Eutrophication Potential*, SCI. DIRECT, <https://www.sciencedirect.com/topics/engineering/eutrophication-potential> [<https://perma.cc/298V-ZE9Z>].

⁵² Almudena Hospido et al., *Environmental Analysis of Beer Production*, 4 INT’L J. AGRIC. RES. GOVERNANCE & ECOLOGY 152, 159 (2005).

⁵³ *Id.*

⁵⁴ James, *supra* note 45.

⁵⁵ *Id.*

⁵⁶ Effluent is wastewater produced from the brewing process. *See id.*

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Policy + the Craft Beer Industry*, NEW BELG. BREWING CO., <https://www.newbelgium.com/sustainability/community/policyandindustry/> [<https://perma.cc/Z4UH-7USF>].

⁶⁰ WRAL.COM, *supra* note 45.

⁶¹ Barry Ness, *Beyond the Pale (Ale): An Exploration of the Sustainability Priorities and Innovative Measures in the Craft Beer Sector*, 10 SUSTAINABILITY 1, 6 (2018), <https://doi.org/10.3390/su10114108>.

conservation organizations.⁶² Forty-one of the seventy craft breweries studied emphasize measures to reduce their energy use or use renewable sources of energy.⁶³ Thirty of those craft breweries employ measures to recycle their grain waste, such as by sending the grain to be used as animal feed for livestock.⁶⁴ The efforts of brewers to reduce their environmental impact—and conversely, the impact of the environment on beer brewing—have encouraged scientists to develop technologies to assist in making beer brewing more ecologically friendly and robust to environmental change.⁶⁵ Dr. Denby and Dr. Bamforth are among the scientists working to develop eco-friendly brewing technologies.

C. Hop-Terpene-Producing Yeast and Low-Resource-Brewing Alternatives

With the goal of providing brewers with a less resource-intensive alternative to hops, Dr. Charles Denby and his team published the results of a series of experiments that yielded a strain of brewer's yeast⁶⁶ that produced flavor molecules normally derived from hops.⁶⁷ The motivation for producing this strain of yeast was twofold: (1) as a response to the heavy resource use of traditional techniques that call for a large quantity of hops and (2) to provide a more reliable flavor profile than is found in traditional dry-hopping techniques.⁶⁸ The experiment utilized the CRISPR-Cas9 system to incorporate basil and mint plant genes into yeast.⁶⁹ As a result, the GE yeast successfully expressed high levels of linalool and geraniol, which are the terpenes⁷⁰ responsible for giving Cascade hops, a popular strain of hops, its signature flavor profile.⁷¹ The experiment was a success, and Dr. Denby's team then used the terpene-producing yeast strains to produce beers that were compared to a control⁷² and to a traditionally dry-hopped beer in a double-blind study.⁷³ In the double-blind study, tasters found that beers using the terpene-producing yeast strains were hoppier than the beer produced with the control yeast strain, and the tasters found one of the beers using a terpene-producing yeast strain to be hoppier than traditional dry-hopped beers.⁷⁴ However, it should be noted that the researchers still utilized hops for the initial wort stage of brewing for the experimental beer, and the researchers used terpene-producing yeast to circumvent later hop-addition steps in the brewing process.⁷⁵ Dr. Denby started Berkeley Brewing Science, which produced and sold several strains of terpene-producing yeast as well as its own beer brewed with the

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.* at 6–7.

⁶⁵ See Denby et al., *supra* note 12, at 1; Russell et al., *supra* note 13, at 349.

⁶⁶ Specifically, Dr. Denby's experiments used the strain of yeast from the species *Saccharomyces cerevisiae*. Denby et al., *supra* note 12, at 2.

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.* at 4.

⁷⁰ Terpenes are a class of organic molecule composed of isoprene units that can be used as flavor additives in food, as fragrances in perfume, and as medicine. See Priyanka P. Brahmshatriya & Pathik S. Brahmshatriya, *Terpenes: Chemistry, Biological Role, and Therapeutic Applications*, in NATURAL PRODUCTS: PHYTOCHEMISTRY, BOTANY AND METABOLISM OF ALKALOIDS, PHENOLICS AND TERPENES 2665–66 (Kishan Gopal Ramawat & Jean-Michel Mérillon eds., 2013).

⁷¹ Denby et al., *supra* note 12, at 2.

⁷² A control is an experimental group that does not receive a different treatment. In this case, it would be a beer brewed with the same recipe as the experimental beer but with a non-GE yeast strain. *Id.* at 5.

⁷³ *Id.* at 1.

⁷⁴ *Id.* at 1, 6.

⁷⁵ *Id.* at 2.

terpene-producing yeast strains.⁷⁶ Berkeley Brewing Science has since changed names to Berkeley Yeast and has shifted its focus to selling a wide variety of genetically modified yeast to craft breweries.⁷⁷

Another scientist concerned about the resource-intensive cost of beer production is Dr. Charles Bamforth.⁷⁸ He and his team tested two new beer production techniques against a traditional brewing technique to determine if they could find a less resource-intensive way to make beer.⁷⁹ One technique used hydrolyzed corn syrup to power yeast fermentation and hop extract to provide hoppy flavor, which reduced the amount of energy and water used as compared to a traditional brewing technique and produced less CO₂.⁸⁰ However, the energy and resource savings from this technique were rather minimal,⁸¹ and regulators would not consider the resulting beer to be a “malted beverage” under the Federal Alcohol Administration Act (“FAA Act”).⁸² Another technique involved mixing pure ethanol with a hop extract, water, flavoring, and a foaming agent to produce the beer.⁸³ This technique required much less energy and water than either the traditional or corn syrup methods and produced less CO₂ than the other two methods.⁸⁴ This technique also does not produce a beer that regulators would consider a “malted beverage” under the FAA Act.⁸⁵

Utilizing Dr. Denby’s and Dr. Bamforth’s techniques could help breweries reduce their impact on water usage, energy usage, and waste production. Dr. Denby’s and Dr. Bamforth’s techniques could also appeal to craft breweries because consumers are willing to pay more for beers produced with more sustainable techniques.⁸⁶ In a survey of 1,094 beer consumers, 59% responded that they would be willing to spend more on beer produced with sustainable techniques.⁸⁷ Coupled with the reduction in resource costs, using sustainable techniques could allow breweries to charge more for their products while spending less to produce them.

Brewers might be hesitant toward using Dr. Denby’s terpene-producing yeast out of fear that the prospect of consuming a genetically modified organism might repulse consumers. However, a survey of regular beer drinkers found that over 50% of respondents would drink a great tasting beer that used GE yeast.⁸⁸ These views differ from the general public, as a Pew Research Center report in 2018 found that about 49% of the general public considers GE foods to be worse for one’s health than foods without GE ingredients.⁸⁹ Further, depending on how the regulatory

⁷⁶ Robert Sanders, *Brewing Hoppy Beer Without the Hops*, BERKELEY NEWS (Mar. 20, 2018), <https://news.berkeley.edu/2018/03/20/brewing-hoppy-beer-without-the-hops/> [<https://perma.cc/B3C4-FL8V>].

⁷⁷ *Berkeley Yeast*, BERKELEY INTELL. PROP. & INDUS. RSCH. ALLS., <https://ipira.berkeley.edu/berkeley-yeast> [<https://perma.cc/T73Z-6JJZ>]; *About Us*, BERKELEY YEAST, <https://berkeleyyeast.com/about> [<https://perma.cc/9NNN-J4TE>].

⁷⁸ Russell et al., *supra* note 13, at 349.

⁷⁹ *Id.*

⁸⁰ *Id.* at 349–50.

⁸¹ *Id.* at 351.

⁸² *See infra* Part III.

⁸³ Russell et al., *supra* note 13, at 349.

⁸⁴ *Id.* at 351.

⁸⁵ *See infra* Part III.

⁸⁶ Sanya Carley & Lilian Yahng, *Willingness-to-Pay for Sustainable Beer*, PLOS ONE, Oct. 5, 2018, at 1, 10, <https://doi.org/10.1371/journal.pone.0204917>.

⁸⁷ *Id.*

⁸⁸ Michael Brotherton, Rob Trachtenberg, & Julie M. Fagan, *Proper Marketing of Genetically Engineered Products May Alleviate Opposition and Unfounded Fears Toward GMOs - A Survey*, RUTGERS UNIV. LIBRS. (2015), <https://doi.org/doi:10.7282/T3736T0H>.

⁸⁹ Cary Funk et al., *Public Perspectives on Food Risks*, PEW RSCH. CTR. (Nov. 19, 2018), <https://www.pewresearch.org/science/2018/11/19/public-perspectives-on-food-risks/> [<https://perma.cc/3QY6-WC2A>].

scheme shakes out, the brewers may not have to label their beer as containing bioengineered food anyway.⁹⁰

Another reason that brewers might turn to Dr. Denby's terpene-producing yeast strains is to counter the volatility and heavy prices of the hops market. With consumer preferences for hop varieties shifting from year to year, brewers find themselves over-ordering varieties that then go out of style before they can even use them.⁹¹ By purchasing Dr. Denby's yeast varieties, brewers can maintain stocks of several different strains of yeast and adjust more quickly as the market shifts. Both Dr. Denby's and Dr. Bamforth's experiments give brewers a means to reduce the environmental impacts of brewing while still giving consumers a crisp, refreshing beer. Even though these technologies enable brewers to make quality, eco-friendly beer, the regulatory schemes that oversee them can make them less competitive in the market, providing hurdles to the adoption of the technologies.

III. THE VARIOUS REGULATORY SCHEMES AFFECTING BEER

The acts establishing the TTB and FDA give both agencies the authority to regulate beer. The overlapping subject matter of the two agencies has led to an understanding between the agencies that delineate beers into their respective regulatory schemes depending on their ingredients. These schemes affect the labeling requirements for beer, which results in some beers having stricter labeling requirements and higher bars in the market. Brewers that utilize Dr. Denby's and Dr. Bamforth's techniques could find their beers regulated by more stringent requirements than standard beers. This Part discusses the various definitions of beers in the TTB's and FDA's regulatory schemes and the differences in regulatory requirements by the different agencies. Finally, this Part discusses the process of approval for use of GE products in beer and the effects of the policies implicated in the adoption of eco-friendly brewing technologies on brewers.

A. *How the TTB Defines Beer*

The U.S. Secretary of the Treasury has broad authority to regulate the labeling of "malt beverages" under the FAA Act,⁹² which defines a "malt beverage" as:

[A] beverage made by the alcoholic fermentation of an infusion or decoction, or combination of both, in potable brewing water, of malted barley with hops, or their parts, or their products, and with or without other malted cereals, and with or without the addition of unmalted or prepared cereals, other carbohydrates or products prepared therefrom, and with or without the addition of carbon dioxide, and with or without other wholesome products suitable for human food consumption.⁹³

⁹⁰ See *infra* Part III.C.

⁹¹ Tara Nurin, *Hop Vendors Swallow a Bitter Pill as They Confront an Oversaturated Market and Customers Who Can't Pay*, FORBES (Jan. 26, 2018, 8:02 AM), <https://www.forbes.com/sites/taranurin/2018/01/26/hop-vendors-swallow-a-bitter-pill-as-they-confront-an-oversaturated-market-customers-who-cant-pay/#572819257343> [<https://perma.cc/6RQP-Q9AE>].

⁹² 27 U.S.C. § 205(e)–(f), *invalidated in part by* *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995) (invalidating only § 205(e)(2)).

⁹³ *Id.* § 211(a)(7).

The U.S. Treasury Department regulates the alcohol and tobacco industries through the TTB's actions,⁹⁴ and accordingly, the TTB uses this same definition in its regulations.⁹⁵

The Treasury Secretary also has the authority under the Internal Revenue Code ("IRC") to tax beer brewed or produced in, or imported into, the United States.⁹⁶ Within the IRC, the Secretary of the Treasury further has the authority to regulate beer labeling.⁹⁷ The IRC defines "beer" as "beer, ale, porter, stout, and other similar fermented beverages (including saké or similar products) of any name or description containing one-half of 1 percent or more of alcohol by volume, brewed or produced from malt, wholly or in part, or from any substitute therefor,"⁹⁸ and the TTB uses a similar definition in some of its regulations.⁹⁹

These two definitions are at odds because the FAA Act definition requires the use of hops for a beverage to be a "beer," while the IRC definition does not, and the FAA Act definition requires the use of malted barley specifically for a beverage to be a "malted beverage," while the IRC definition does not. As such, a beverage can be considered a "beer" under the IRC but not a "malted beverage" under the FAA Act. To clarify this issue, the TTB published a ruling pointing out when a "beer" might not be a "malted beverage" (e.g., one that is not fermented from malted barley and is devoid of hops).¹⁰⁰ The ruling further clarified that "beers" that are not "malted beverages" do not fall under the labeling regime of the FAA Act.¹⁰¹

The Bureau of Alcohol, Tobacco and Firearms ("ATF"), the TTB's predecessor,¹⁰² determined that in order to qualify as a "malted beverage" under the FAA Act, the beverage must contain at least 25% malted barley and at least 7 1/2 pounds of hops per 100 barrels.¹⁰³ The TTB continues to use these standards but will review a request for classification by brewers of beverages that do not meet these standards and may engage in rulemaking on the issue in the future.¹⁰⁴

B. *How the FDA Defines Beer*

The Federal Food, Drug, and Cosmetic Act ("FD&C Act") gives the FDA the responsibility to promulgate rules regarding food labeling.¹⁰⁵ The FD&C Act defines "food" as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for

⁹⁴ *The TTB Story*, U.S. DEP'T OF THE TREASURY, ALCOHOL & TOBACCO TAX & TRADE BUREAU, <https://www.ttb.gov/who-we-are/about-us/our-history> [<https://perma.cc/7NBD-RRJG>].

⁹⁵ 27 C.F.R. § 7.10 (2020) (defining "malt beverage" as "[a] beverage made by the alcoholic fermentation of an infusion or decoction, or combination of both, in potable brewing water, of malted barley with hops, or their parts, or their products, and with or without other malted cereals, and with or without the addition of unmalted or prepared cereals, other carbohydrates or products prepared therefrom, and with or without the addition of carbon dioxide, and with or without other wholesome products suitable for human food consumption").

⁹⁶ I.R.C. § 5051.

⁹⁷ *Id.* § 5412.

⁹⁸ *Id.* § 5052(a).

⁹⁹ "Beer, ale, porter, stout, and other similar fermented beverages (including saké and similar products) of any name or description containing one-half of one percent or more of alcohol by volume, brewed or produced from malt, wholly or in part, or from any substitute for malt." 27 C.F.R. § 25.11 (2020).

¹⁰⁰ TTB Rul. No. 2008-3 (July 7, 2008).

¹⁰¹ *Id.*

¹⁰² 6 U.S.C. § 531(d)(3).

¹⁰³ BUREAU OF ALCOHOL, TOBACCO & FIREARMS, COMPLIANCE MATTERS, No. 94-1 (1998), <https://www.ttb.gov/public-information/comp941> [<https://perma.cc/SL6N-SNH5>].

¹⁰⁴ TTB Rul. No. 2008-3, *supra* note 100.

¹⁰⁵ 21 U.S.C. §§ 341–350(1).

components of any such article.”¹⁰⁶ Alcoholic beverages are included in this definition. An alcoholic beverage could therefore be classified as a “malt beverage” under the FAA Act and as “food” under the FD&C Act, resulting in a potential regulatory overlap between the TTB and the FDA.¹⁰⁷ However, courts have addressed this overlap by giving the TTB precedence over the FDA when it comes to the labeling of alcoholic beverages included in the FAA Act.¹⁰⁸ Further, the ATF and FDA entered into a memorandum of understanding designating labeling authority to the ATF (and now, the TTB) where the FAA Act’s definition of alcoholic beverages overlaps with the FD&C Act’s definition.¹⁰⁹ The FDA therefore regulates beers that contain less than 25% malted barley and less than 7 1/2 pounds of hops per 100 barrels. The TTB and FDA have different labeling requirements for products in their regulatory regimes, so classifying beer into one or the other’s regulatory regime impacts the requirements that brewers have to follow.

C. Labeling Requirements of the TTB, FDA, and USDA

The FAA Act requires the Treasury Secretary to enact labeling regulations to: (1) prevent deception regarding the product’s quantity or age; (2) communicate the product’s quality related to its alcohol content, net contents, and manufacturer or importer; and (3) prohibit competitor disparagement or illegal trademark use.¹¹⁰ The Secretary of the Treasury relies on the TTB to promulgate and enforce these labeling regulations.¹¹¹ The Alcohol Beverage Labeling Act of 1988 (“ABLA”) also requires that all alcoholic beverages containing more than half a percent of alcohol by volume intended for human consumption contain a government health warning statement.¹¹² The TTB has implemented regulations to satisfy this labeling requirement.¹¹³ The TTB enforces ABLA labeling regardless of whether the alcoholic product falls in the FAA Act regime or not.¹¹⁴

The TTB does not require producers to label products containing GE materials as containing those materials.¹¹⁵ It does require that GE materials used in beer be generally recognized as safe¹¹⁶ and relies upon FDA regulations for this requirement.¹¹⁷

The FDA’s labeling requirements for beers under its authority include statements of: (1) identity;¹¹⁸ (2) the net quantity of the product’s contents;¹¹⁹ (3) the name and place of the

¹⁰⁶ *Id.* § 321(f).

¹⁰⁷ U.S. FOOD & DRUG ADMIN., LABELING OF CERTAIN BEERS SUBJECT TO THE LABELING JURISDICTION OF THE FOOD AND DRUG ADMINISTRATION: GUIDANCE FOR INDUSTRY (2014), <https://www.fda.gov/media/90473/download> [<https://perma.cc/95KQ-FRBQ>].

¹⁰⁸ *See, e.g.,* *Brown-Forman Distillers Corp. v. Mathews*, 435 F. Supp. 5, 12 (W.D. Ky. 1976).

¹⁰⁹ Memorandum of Understanding Between the Food and Drug Administration and the Bureau of Alcohol, Tobacco and Firearms, MOU 225-88-2000 (Nov. 20, 1987), <https://www.fda.gov/about-fda/domestic-mous/mou-225-88-2000> [<https://perma.cc/6SKF-UQ2D>].

¹¹⁰ 27 U.S.C. § 205(e).

¹¹¹ *See Regulations*, ALCOHOL & TOBACCO TAX & TRADE BUREAU, <https://www.ttb.gov/other/regulations> [<https://perma.cc/B42H-DP8V>].

¹¹² 27 U.S.C. §§ 213–214.

¹¹³ *See* 27 § C.F.R. 16 (2020).

¹¹⁴ U.S. FOOD & DRUG ADMIN., *supra* note 107.

¹¹⁵ *See Alcohol FAQs*, ALCOHOL & TOBACCO TAX & TRADE BUREAU, <https://www.ttb.gov/resources/faqs/alcohol#alfd> [<https://perma.cc/SDY7-3ZVW>].

¹¹⁶ U.S. DEP’T OF THE TREASURY, ALCOHOL & TOBACCO TAX & TRADE BUREAU, INDUSTRY CIRCULAR NO. 2006-2, USE OF GENETICALLY MODIFIED MATERIALS AND EXPORT IMPLICATIONS (2006), https://www.ttb.gov/images/industry_circulars/archives/2006/06-02.html [<https://perma.cc/NC9Q-XP5G>].

¹¹⁷ *See infra* Section III.D.

¹¹⁸ 21 C.F.R. § 101.3 (2020).

¹¹⁹ *Id.* § 101.7.

manufacturer's business;¹²⁰ (4) ingredients;¹²¹ (5) added coloring;¹²² and (6) nutrition labeling.¹²³ The FDA does not require product labels to disclose if the product contains GE materials.¹²⁴ Instead, labeling foods that contain bioengineered substances falls to the USDA under the National Bioengineered Food Disclosure Standard.¹²⁵

The National Bioengineered Food Disclosure Standard requires food manufacturers to disclose whether their products contain bioengineered food if the food is subject to labeling requirements under the FD&C Act.¹²⁶ The Act defines bioengineered food as food “that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques” and “for which the modification could not otherwise be obtained through conventional breeding or found in nature.”¹²⁷ This definition does not require producers to label all foods that result from GE technologies as containing bioengineered food. For example, foods from GE technologies that introduce foreign DNA into the genome (which is then excised from the genome)¹²⁸ do not have to be labeled, nor do foods for which GE technologies have been used to disable a gene.¹²⁹ Further, because the FD&C Act limits the National Bioengineered Food Disclosure Standard's definition of “food,” the Disclosure Standard applies to beers that fall under the FDA's labeling regime but not beers that fall under the TTB's labeling regime. The implementation date of the National Bioengineered Food Disclosure Standard was January 1, 2020, with a mandatory compliance date of January 1, 2022.¹³⁰

The FDA regulatory regime therefore has stricter labeling requirements for beers that could slow the adoption of brewing technologies that push beer from the TTB regime to the FDA regime.

D. FDA Approval of GE Products for Human Use

Congress enacted the Food Additives Amendment in 1958, which amended the FD&C Act to require premarket approval for new uses of food additives.¹³¹ Congress broadly defined “food additives” as:

[A]ny substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in

¹²⁰ *Id.* § 101.5.

¹²¹ *Id.* §§ 101.4, 101.22.

¹²² *Id.* § 101.9.

¹²³ *Id.* § 101.

¹²⁴ See *New Plant Variety Regulatory Information*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/food-new-plant-varieties/how-fda-regulates-food-genetically-engineered-plants> [<https://perma.cc/GZ8X-V97S>].

¹²⁵ National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216, 130 Stat. 834 (2016) (codified at 7 U.S.C. §§ 1639–1639c).

¹²⁶ U.S. DEP'T OF AGRIC., NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD (2019), <https://www.ams.usda.gov/sites/default/files/media/BEFactSheet.pdf> [<https://perma.cc/BB23-N5KJ>].

¹²⁷ National Bioengineered Food Disclosure Standard § 1 (codified at 7 U.S.C. § 1639).

¹²⁸ An example of this technique incorporates genes that induce a mutation in the genome of *Arabidopsis thaliana*, a member of the mustard family. Crossbreeding then breeds out the incorporated genes while leaving the induced mutation. See Eric Wijnker et al., *Reverse Breeding in Arabidopsis thaliana Generates Homozygous Parental Lines from a Heterozygous Plant*, 44 NATURE GENETICS 467, 467 (2012).

¹²⁹ 7 U.S.C. § 1639(1).

¹³⁰ *BE Disclosure*, U.S. DEP'T OF AGRIC., AGRIC. MKTG. SERV., <https://www.ams.usda.gov/rules-regulations/be> [<https://perma.cc/2KKS-J4YW>].

¹³¹ Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958).

producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use¹³²

In the late 1960s, the FDA established a program to affirm substances that were generally recognized as safe (“GRAS”) through testing.¹³³ However, to conserve FDA resources, the agency enacted a new GRAS notification program in the late 1990s, which allows a person to voluntarily inform the FDA that a product is GRAS for its intended use rather than requiring a person to petition the FDA to affirm that a product is GRAS.¹³⁴ Through this new process, a person notifies the FDA of a substance that is believed to be GRAS, the intended use for the substance, and the basis used to determine the substance’s GRAS status.¹³⁵ The FDA will then review the notice, consult with any other agencies that may have concerns about the product, and raise any questions or concerns it may have with the notifier.¹³⁶ If the FDA has no further questions, or if the applicant responds adequately to the FDA’s questions, the FDA will issue a letter noting that it does not question the basis for the GRAS determination.¹³⁷ Importantly, the letter’s issuance is not an FDA determination that the substance is GRAS.¹³⁸ The FDA maintains the GRAS notices that go through this process on an online database.¹³⁹

The part of the “food additives” definition that the FDA has determined pertinent to its regulation of GE food products is “if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use”¹⁴⁰ As such, the FDA considers GE foods that express molecules that have already been safely used in foods at the same or similar expression levels to have a presumption of being GRAS and therefore exempt from premarket approval.¹⁴¹ If the GE food expresses a new molecule or a new form of a molecule (such as a protein with an altered amino acid profile), the FDA does not give the

¹³² *Id.* § 2, 72 Stat. at 1784 (codified as amended at 21 U.S.C. § 321(s)).

¹³³ *FDA’s Approach to the GRAS Provision: A History of Processes*, U.S. Food & Drug Admin., <https://www.fda.gov/food/generally-recognized-safe-gras/fdas-approach-gras-provision-history-processes> [<https://perma.cc/FN8V-M99X>].

¹³⁴ Paulette Gaynor, *How U.S. FDA’s GRAS Notification Program Works*, U.S. FOOD & DRUG ADMIN. (Jan. 2006), <https://www.fda.gov/food/generally-recognized-safe-gras/how-us-fdas-gras-notification-program-works> [<https://perma.cc/N478-VBHN>].

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*; *GRAS Notices*, U.S. FOOD & DRUG ADMIN., <https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices> [<https://perma.cc/BG6K-9LCW>].

¹⁴⁰ 21 USC § 321(s).

¹⁴¹ Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984-01 (May 29, 1992), 1992 WL 112827, at *22990.

food the GRAS presumption, and the food must go through premarket approval.¹⁴² Both the FDA and TTB rely on the GRAS process to determine if an ingredient may be used in beer.

E. *Implications of Current Policies on the Regulation of Eco-Friendly Beer Brewing Technologies*

Dr. Denby's hop-terpene-producing yeast has gone through the voluntary GRAS notification process by submitting a notice to the FDA indicating and justifying his belief that the yeast is safe for human consumption.¹⁴³ The FDA had no further questions for Dr. Denby, and as such, did not question the basis for Dr. Denby's GRAS determination.¹⁴⁴ Because this process does not grant a determination that a substance is GRAS, Dr. Denby would violate the FD&C Act if he allowed his yeast strain to enter into interstate commerce, but the process allows Dr. Denby's yeast to be used in "food" under FDA regulations and "malted beverages" under TTB regulations.¹⁴⁵

As small businesses, the breweries that use Berkeley Yeast's products will not be subject to the National Bioengineered Food Disclosure Standard,¹⁴⁶ but if a larger brewery decides to use Dr. Denby's yeast, or if Berkeley Yeast grows, it may be required to label its beer as containing bioengineered food (provided it also uses a brewing method that does not rely on hops in earlier brewing stages, such as the corn syrup method). This requirement could be an unintended consequence of the labeling regime set up by the interplay of "beers" as defined by the FD&C Act and "malted beverages" as defined by the FAA Act. Moreover, labeling beer to contain bioengineered food could be contrary to the public policy concerns behind reducing the beer brewing industry's environmental impact and promoting sustainability. Additionally, as hops prices continue to increase, breweries may need to utilize processes that rely less on hops, such as Berkeley Yeast's terpene-producing yeast strains.

IV. HOW AGENCIES AND THE INDUSTRY MIGHT MOVE FORWARD

As brewing technologies trend toward more eco-friendly, less resource-intensive techniques, the TTB and FDA may end up expending more resources trying to determine which of their regulatory schemes should oversee the resulting beers. Further, confusion as to which regulatory scheme breweries should follow could stifle the industry and discourage innovation. The TTB and FDA should consider reevaluating their definitions of "malted beverages" and "beer" to avoid confusion that may arise as eco-friendly technologies develop. This Part explores routes the TTB and FDA could take as well as routes brewers could take to encourage the agencies to develop a regulatory scheme that is more robust to changes in technology.

A. *How the TTB and FDA Could Respond Going Forward*

As an initial matter, the TTB could leave its rule defining "malted beverages" because, as it stands, the National Environmental Policy Act requires federal agencies to analyze the potential environmental impacts of rules they make but does not require them to strive for promulgating

¹⁴² *Id.*

¹⁴³ Letter from Susan J. Carlson to Charles Denby, *supra* note 21.

¹⁴⁴ *See id.* at 3.

¹⁴⁵ *Id.*; 21 U.S.C. § 331 (II).

¹⁴⁶ *Information for Regulated Entities*, U.S. DEP'T OF AGRIC., AGRIC. MKTG. SERV., <https://www.ams.usda.gov/rules-regulations/be/regulated-entities> [<https://perma.cc/L47X-W4M9>] (stating that food manufacturers that make less than \$2,500,000 of annual receipts are exempted from the Disclosure Standard).

rules to benefit the environment.¹⁴⁷ However, the public would benefit from a more environmentally friendly policy, and the TTB tracks the environmental impacts of alcohol producers.¹⁴⁸ Still, the TTB could leave the policy as is and simply approve eco-friendly beers that do not meet its current definition of “malted beverages” on a case-by-case basis, as it said it would do when the ATF approved the policy in the first place.¹⁴⁹ This may create confusion as to the applicability of the National Bioengineered Food Disclosure Standard, as the law applies to foods covered by the FDA via the FD&C Act,¹⁵⁰ which would normally apply to these eco-friendly beers but for the TTB’s case-by-case approval.

Another strategy the TTB could take would be to issue a legislative rule broadening its interpretation of “malted beverages.” A legislative rule would be appropriate because legislative rules impact regulated entities,¹⁵¹ and this rule would impact alcohol producers. The TTB initially issued its rule as a ruling of interpretation,¹⁵² which is a non-legislative rule.¹⁵³ The TTB could use non-legislative rulemaking again to revise its interpretation. But because the rule interplays with FDA rule interpretations that have stood since 1987,¹⁵⁴ and because the rule could be challenged by beer companies trying to out-compete other companies that utilize eco-friendly techniques, which are also more cost-effective, a legislative rule would hold up better to scrutiny than a non-legislative rule.¹⁵⁵

The TTB would proceed through formal rulemaking, notice and comment rulemaking, or negotiated rulemaking.¹⁵⁶ Formal rulemaking would require a hearing with trial-like procedures,¹⁵⁷ which may be too costly for reclassifying “malted beverages.” Notice and comment rulemaking, however, may offer the TTB a way to proceed, as it consists of publishing notice of the proposed rule to the Federal Register, which is online now, and allowing the public and other groups to comment on the proposed rule, which the TTB would then address.¹⁵⁸ This procedure is cost-effective and allows for the agency to give full notice to the public. However, due to views toward GE technologies that apply to the public at large but not necessarily to beer consumers, notice and comment rulemaking may result in an unfavorable view of the rule.

Negotiated rulemaking is a somewhat un-utilized process that the FDA has never employed.¹⁵⁹ This procedure is not mandatory, but it allows for agencies to meet with interested

¹⁴⁷ 42 U.S.C. § 4321.

¹⁴⁸ See *TTB Public Guidance: Information Regarding the Clean Water Act*, ALCOHOL & TOBACCO TAX & TRADE BUREAU, <https://www.ttb.gov/public-guidance/ttb-g-2019-1-information-regarding-the-clean-water-act> (last updated Apr. 17, 2019) [<https://perma.cc/E79U-KQ94>].

¹⁴⁹ TTB. *Rul.* 2008-3, *supra* note 100.

¹⁵⁰ National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216, 130 Stat. 834 (2016) (codified at 7 U.S.C. §§ 1639–1639c).

¹⁵¹ See generally Administrative Procedure Act, Pub. L. No. 79-404, 60 Stat. 237 (1949) (codified as amended in scattered sections of 5 U.S.C.); see also Nadav D. Ben Zur, *Differentiating Legislative from Nonlegislative Rules: An Empirical and Qualitative Analysis*, 87 *FORDHAM L. REV.* 2125, 2132 (2019).

¹⁵² TTB. *Rul.* 2008-3, *supra* note 100.

¹⁵³ Zur, *supra* note 151, at 2132.

¹⁵⁴ Memorandum of Understanding Between the Food and Drug Administration and the Bureau of Alcohol, Tobacco and Firearms, *supra* note 109.

¹⁵⁵ See Administrative Procedure Act, 5 U.S.C. § 706 (discussing the scope of judicial review for agency actions).

¹⁵⁶ *Id.* §§ 553, 561–570a.

¹⁵⁷ *Id.* § 553.

¹⁵⁸ *Id.* § 553(b)–(c).

¹⁵⁹ Julia Kobick, *Negotiated Rulemaking: The Next Step in Regulatory Innovation at the Food and Drug Administration*, 65 *FOOD & DRUG L.J.* 425 (2010).

parties to draft that rule.¹⁶⁰ The rule would then go through the notice and comment procedure of notice and comment rulemaking.¹⁶¹ While more resource intensive than notice and comment rulemaking,¹⁶² negotiated rulemaking reduces the likelihood of adversarial comments on the rule, as many different types of alcohol producers could be included in the process as well as the FDA. Negotiated rulemaking also encourages cooperation between the TTB and the beer industry, promoting a healthy, regulated industry.

If the new rule were later challenged in court, the rule would likely go through the *Chevron* two-step analysis because it would be an interpretive rule that resulted from a legislative rulemaking procedure.¹⁶³ Under *Chevron*, the first step is to analyze if there is any statutory ambiguity and if Congress delegated authority to the agency to address that ambiguity.¹⁶⁴ While the FAA Act defines a “malted beverage” as “a beverage made by the alcoholic fermentation of an infusion . . . of malted barley with hops,” the Act is silent on the quantities of malted barley and hops required,¹⁶⁵ so there is ambiguity. Additionally, the FAA Act designates regulation authority to the Secretary of the Treasury,¹⁶⁶ who oversees the TTB,¹⁶⁷ so the agency has authority to address ambiguities in the Act. Therefore, because there is an ambiguity and the agency has authority to address it, the first step of *Chevron* analysis is satisfied.

Step two of the *Chevron* analysis is to examine if the agency’s interpretation of the statutory language is “reasonable.”¹⁶⁸ This determination depends on the actual rule that results from the negotiated rulemaking process, but it would be difficult to read out the requirement that the beverage contains “malted barley with hops”¹⁶⁹ entirely, as that requirement is statutory, so the rule would have to contain some level of the two crops. A potential issue could be that courts consider consistency with prior rules. The TTB could argue, however, that the new rule is consistent with its prior rule, as the prior rule’s definition of malted barley and hops levels required for a beverage to be a “malted beverage” would still be encompassed by the new rule’s lower requirement. Cooperation between the TTB and brewers would make challenges against a new rule less likely while encouraging the adoption of eco-friendly brewing technologies.

B. *How Brewers Could Respond Going Forward*

Brewers are in an advantageous position because the technologies that could be at issue are still nascent and do not currently create the regulatory quagmire described in Part III.¹⁷⁰ Brewers could simply not worry about the issue and not use the technologies. However, there are advantages to using the technologies, which include lessening the environmental impact of brewing, reducing the economic cost of brewing, and gaining more consistent flavor profiles that are not subject to the whims of a volatile market.¹⁷¹

¹⁶⁰ §§ 561–570a.

¹⁶¹ *Id.* § 564.

¹⁶² *See id.* §§ 561–570a.

¹⁶³ *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–44 (1984).

¹⁶⁴ *Id.*

¹⁶⁵ 27 U.S.C. § 211(a)(7).

¹⁶⁶ *Id.* § 205(e)–(f).

¹⁶⁷ 6 U.S.C. § 203.

¹⁶⁸ *Chevron*, 467 U.S. at 843–44.

¹⁶⁹ 27 U.S.C. § 211(a)(7).

¹⁷⁰ *See supra* Part III.

¹⁷¹ *See supra* Part II.

If brewers were to adopt the Denby and Bamforth technologies, they could petition the TTB to include their beverages in the FAA Act regime. The potential downfalls of this strategy include that the TTB might not grant the petition, or even if the TTB granted the petition, the FDA still might assert that the beer belongs in the FD&C Act regime because the ATF memo is silent on including beverages in the FAA Act regime on a case-by-case basis.

Brewers could leave the eco-friendly beer in the FD&C Act regime. This would put the beer under the FDA labeling requirements and require labeling of the GE yeast used as per the National Bioengineered Food Disclosure Standard. However, with proper marketing, this labeling may not pose a big threat to sales. Further, brewers could challenge the National Bioengineered Food Disclosure Standard as a violation of the First Amendment,¹⁷² and beer companies have had some luck using a First Amendment argument to challenge labeling requirements.¹⁷³

Brewers could lobby Congress for a clearer definition of “malted beverages” in the FAA Act; however, this would require money and that Congress address what might be considered a niche issue in order to benefit the environment. Finally, brewers could request that the TTB issue a new rule on the matter and work with the agency in a negotiated rulemaking process. Negotiated rulemaking would provide brewers with more input than notice and comment rulemaking, allowing them to have their particular interests addressed. The regulatory roadblocks that exist for beers in the FDA regulatory scheme and slow the adoption of eco-friendly brewing techniques would be removed by a new TTB rule.

V. CONCLUSION

To reduce the impact of beer brewing on the environment, scientists like Dr. Denby and Dr. Bamforth have developed technologies that allow for less resource-intensive beer brewing. These techniques aim to reduce the amount of water and energy required by the beer brewing process. As brewers adopt these techniques to brew more eco-friendly beers, they and the TTB may soon find themselves at a crossroads. Implementing eco-friendly brewing techniques that help reduce water consumption in a process that uses a lot of water could put eco-friendly beers in a regulatory grey zone between the TTB and the FDA, which could affect how brewers must label beers and how the public ultimately receives the beers. Brewers might be slow to implement new eco-friendly brewing techniques due to concerns over discerning which regulatory regime would control their beers and how those regulatory regimes might impact the labeling requirements for, and by extension, the public perception of, their beers.

Brewers could use savvy marketing techniques to proceed under the FDA regulatory regime while producing eco-friendly beer with a label noting the GE yeast used. They could challenge the National Bioengineered Food Disclosure Standard on First Amendment grounds. They could lobby Congress to change the law to define “malted beverages” more broadly to include eco-friendly beers. Or, finally, they could work with the TTB to change the current rule defining “malted beverages,” acting in the current regulatory scheme and using a strategy familiar to regulatory agencies.

The TTB could implement any number of rulemaking techniques to address the regulatory quandary posed by eco-friendly beers and the TTB’s current “malted beverage” definition, such as issuing an interpretive ruling, engaging in formal rulemaking, utilizing the notice and comment

¹⁷² Mary Christine Brady, *Enforcing an Unenforceable Law: The National Bioengineered Food Disclosure Standard*, 67 EMORY L.J. 771, 774 (2018).

¹⁷³ *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 478 (1995).

rulemaking procedure, or using the negotiated rulemaking procedure. By engaging in negotiated rulemaking, the TTB could get ahead of this potential regulatory quagmire and enact a rule that would not likely be challenged in court due to the nature of the rulemaking procedure. Further, the TTB would be aiding the public by allowing for more leniency as brewers explore brewing techniques that ease the energy and water burdens that traditional brewing techniques have on the environment.