

Malt Beverage Formulation and Labeling: Brewers' Perceptions and Need for Resources

Introduction

While the craft brewing industry has enjoyed significant growth in recent history, this growth has translated to a substantial increase in the regulatory obligations of the associated government entities, largely the Alcohol and Tobacco Tax and Trade Bureau (TTB). This relationship between industry and government has proven difficult in some instances. Among the differences between the craft brewing segment and its macrobrewing counterpart is an intense focus on product innovation (Brewers Association, 2018). While use of unconventional brewing processes and interesting ingredients are central to the craft brewer's mission, malt beverages produced with these techniques are often associated with complicated regulatory approvals. Consequently, there exists a need to identify knowledge gaps and requisite regulatory resources for craft brewers: specifically, knowledge gaps and resources related to the TTB's labeling and formula approval process(s).

The TTB is a multi-division bureau of the United States Department of the Treasury. The TTB defines and regulates the following items: 1) required label components for beverages that meet the TTB's institutional definition of "malt beverage," 2) constructs for voluntary nutritional labeling, per TTB Ruling 2013-2, and 3) the formula approval process for malt beverages required to undergo the pre-Certificate of Labeling Approval (COLA) process (TTB, 2018).

The Advertising, Labeling, and Formulation Division of the TTB is responsible for the regulation of beverage alcohol, including malted beverages, wine, and distilled spirits through the enforcement of the Federal Alcohol Administration Act. Included in this act are requirements related to approvals for labeling and formulation of alcoholic beverages (TTB, 2018).

The purpose of this qualitative research study is to 1) explore craft brewers' comprehension and perceptions of the TTB formula and labeling approval process(s), and 2) collect brewer perceptions of the need for additional resources related to regulatory items.

Background

As is true for wine and distilled spirits, labels for malted beverages require pre-approval. Mandatory label information for malted beverages is included in Appendix A. In recent history, the TTB has produced two additional rulings with notable impact on labeling of malt beverages: 1) TTB Ruling 2008-3 itemized the entity's definition of malt beverage, which requires producers of beverages not in alignment with this definition to adhere to Food & Drug Administration (FDA) labeling standards, and 2) TTB Ruling 2013-2 provided a framework for malt beverage producers to voluntarily claim selected nutrition information on product labels (TTB, 2018b).

For many of the malt beverage products that are subject to TTB labeling regulations, a product evaluation is required to determine if the proposed label identifies the product in an

“adequate and non-misleading way” (TTB, n.d.c). There are four types of product evaluations (termed “Pre-COLA product evaluations”) to which a malt beverage may be subjected: formula, pre-import letter, lab analysis, and sulfite analysis. The evaluation of primary concern in this discussion is the formula evaluation, which is discussed in further detail as follows:

Validation of accurate labeling for products is secured through formulation approval, which must occur prior to filing for label approval through the COLA process. Generally, formula approval is required when flavoring or coloring materials are added (TTB, 2017). Any ingredient that has been identified as Generally Recognized as Safe (GRAS) - status by the FDA is allowable in malt beverage production (TTB, 2017b). Formulas are reviewed by a “Formula Specialist” (of the TTB Advertising, Labeling, and Formulation Division) to ensure that compliance with federal regulations is met (TTB, n.d.c). These pre-COLA evaluations ensure the following items: 1) prohibited ingredients (as determined by the FDA) are not used in product formulations, 2) “limited ingredients” are used appropriately, 3) appropriate tax and product classifications are made, and 4) products do not contain sulfites past the labeling declaration threshold of 10 ppm (if no label disclosure is made) (TTB, n.d.c).

“Limited ingredients” are food additives or ingredients that are “commonly or historically seen in TTB formulations” (TTB, n.d.b). The TTB has compiled a list of all “limited ingredients, along with their associated Flavor and Extract Manufacturers Association (FEMA) identification number (if applicable), relevant Code of Federal Regulations (CFR) reference, current use limit, and designated food category and/or use (TTB, n.d.b). This list is provided in

Appendix B. Use of coloring agents must adhere to the limits established in the Code of Federal Regulations, Title 21, Part(s) 73 and 74 (TTB, 2017b).

The passage of TTB Ruling(s) 2014-4 and 2015-1 limited the malted beverages that require the filing of a formula to include: 1) those that are produced using “nontraditional” processes (i.e. those processes not identified in TTB Ruling 2015-1), 2) those that contain alcohol-containing flavors or nonbeverage ingredients, 3) those that contain coloring(s) or flavoring(s) not included in the list of exemptions itemized in Attachment 1 of TTB Ruling 2015-1, and 4) those that contain food material(s) not included in the list of exemptions itemized in Attachment 1 of TTB Ruling 2015-1 (TTB, 2015b; Cornell, n.d.). To assist brewers in identifying the formula submission requirements of their product(s), the TTB developed an online tool that contains a series of prompts about the product in question and terminates in regulatory guidance (TTB, 2017).

After label approval is granted by the TTB through COLA, producers of malt beverages can make certain acceptable changes to labels without repeating the approval process. Examples of these changes include the deletion of non-mandatory label information, changing type size and font, and making appropriate changes to spelling. These changes are outlined in *TTB Form 5100.31, Section V* (Connell, 2014; TTB, n.d.d). Changes that are not included in the aforementioned form require the submission of a new COLA application (Connell, 2014).

The TTB issues “TTB Rulings” to clarify existing guidance or to state the institutional position on the “interpretation or application of a statute or of TTB’s regulations” (TTB, n.d.d).

The growth of the craft beer industry has occurred alongside a number of TTB Rulings that have manufactured considerable change on the labeling and formula approval processes associated with malted beverages. These rulings are summarized in Table 1.

Table 1

Regulations, Rulings, and Initiatives that Impact the Labeling of Malted Beverages

| <u>Date</u> | <u>Regulatory Impact</u> |
|----------------------|--|
| TTB Ruling 2008-3 | <ul style="list-style-type: none"> • Provided the TTB’s institutional definition of “malt beverage,” which include the following criteria: <ul style="list-style-type: none"> ○ Malted barley must represent no less than 25% of the fermentable ingredients ○ Hops must be present in an amount equivalent to 7.5 pounds per 100 barrels (3100 gallons) • Gave the FDA regulatory jurisdiction over beverages that do not meet the established criteria (TTB, 2008; FDA, 2014) |
| TTB Ruling 2013-2 | <ul style="list-style-type: none"> • Provided a framework for producers of malt beverages to voluntarily declare selected nutrition information • Permitted the use of Serving Facts statements on labels, which contain the following information: <ul style="list-style-type: none"> ○ Serving size ○ Number of servings per container ○ Number of calories per serving ○ Grams of carbohydrate, protein, and fat per serving • Included “Examples of Acceptable Serving Facts Statements” for malt beverage producers to use as a reference (see <i>Figure 2</i> below) (TTB 2013). |
| TTB Ruling 2014-4 | <ul style="list-style-type: none"> • Determined that the formula approval process could be avoided for products that used selected processes and 35 ingredients were “traditional” in nature |
| TTB Ruling 2015-1 | <ul style="list-style-type: none"> • Expanded on TTB Ruling 2014-4 through the inclusion of 50 additional ingredients that were determined “traditional” in nature • Provided a list of traditional ingredients and processes, “Exempt Ingredients and Processes Determined to be Traditional Under TTB Ruling 2015-1” for producers to use as a reference • Included guidance for brewers interested in adding an ingredient to the list of exemptions (TTB2015; TTB2015b) |

Regulatory and Industry Considerations for Craft Brewers

An online portal for COLAs was launched in 2003. The COLAs online portal allowed alcohol industry members (producers of malted beverages, wine, and distilled spirits) to electronically submit and subsequently track their application for labeling approval. In 2011, the TTB launched Formulas Online, which allowed for electronic submission and tracking of formula submissions. These online mediums were intended to provide industry members with a “streamlined, expedient, online paperless process to provide and obtain label and formula approval” (OIG, 2017). In TTB’s fiscal year 2014 annual report, it was reported that most industry members used the online filing programs for COLA and formula applications (94% and 84%, respectively) (OIG, 2017).

In October 2017, the Office of Inspector General, Department of the Treasury, released an audit report titled “Opportunities Exist to Enhance TTB’s COLAs and Formulas Online Programs.” The purpose of this audit was to determine if the TTB’s online medium(s) for the submission of labeling and formulation approvals improved the efficiency of the respective approval processes relative to the previous paper-based processes (Office of Inspector General [OIG], 2017). The results of the audit indicated that despite the TTB’s adoption of online submission portals and the removal of certain application approvals (discussed above under “Required Label Information”), processing times of COLA and formula applications had increased for all three beverage commodities. This increase was attributed to two primary causes: 1) industry growth, and 2) “substantial volume” of electronic resubmissions (OIG, 2017).

The audit indicated that resubmitted applications increased TTB workloads by as much as 45%. For example, in 2014, 142,000 COLA applications were submitted by alcohol industry members, however, TTB specialists processed approximately 207,000 applications, with the increase due to resubmissions of corrected electronic applications for reprocessing. Regarding management of resubmissions, TTB allows three “attempts” for COLA applications prior to rejection; four resubmissions are allowed for issues involving label image. One of the major flaws of TTB’s resubmission process identified by the OIG was priority processing of resubmissions over new applications, as processing times for error-free applications is increased due to the processing of resubmissions (OIG, 2017).

According to TTB, new industry members are primarily responsible for the additional processing time of applications, due in part because they require extensive assistance and often submit applications with errors. Furthermore, TTB officials stated that the majority of “noncompliant submissions are a result of industry misunderstanding of TTB’s regulations and/or inadvertent errors...” (OIG, 2017). Although a 2015 analysis conducted by TTB indicated a statistically significant relationship between TTB permit age and submission errors, the OIG review of this data found that new industry members had only minimally higher error rates relative to those of established industry members. Nonetheless, TTB officials recognize that increased processing times “pose a potential barrier to commerce” (OIG, 2017).

The TTB identified the three most prevalent errors in alcohol industry member applications: 1) labels containing misleading information, 2) labels that conflict with the

associated formula application, and 3) the presence of punctuation or style errors in the required Health Warning Statement (OIG, 2017). Among the OIG's recommendations to TTB regarding the results of the described audit was one related specifically to the resubmission issue: the OIG recommended that the TTB evaluate their current resubmission policy and its benefit to industry members. In general, TTB's response to this recommendation was that the office did not intend to revise the current policy, largely because it was industry misunderstanding of regulations, not TTB policy, which bears responsible for increasing processing time (OIG, 2017).

The growth and sustainability of the craft beer industry depends on appealing to the consumers through innovative ingredients and unique process(s). If the formula and label approval process(s) continue to take an exorbitant amount of time, this could hinder the ability of craft brewers to bring new product to market, which potentially represents lost revenue and/or increased operating costs associated with application submission.

Methodology

Instrument

Using a case study approach, members of the craft brewing industry were interviewed to assess their perceptions of the labeling and formula approval processes, as well as their perceived need for resources. A semi-structured interview instrument was developed to facilitate the interviews. The instrument is provided in Appendix C. Items on the interview

instrument are original items, and were developed following researcher interaction with craft brewers and TTB officials at a professional craft brewing conference.

The sample included thirteen brewers of craft beer (ten male, three female). Eleven of the study participants were affiliated with an operating brewery. The remaining two participants were previously associated with craft breweries, but had since shifted to another area of the craft brewing industry. All study participants were located in the Midwest, with participants from Missouri, Illinois, Kansas, Kentucky, and Indiana. All study participants were affiliated with microbreweries or brewpubs. See Table 2 for participant descriptions.

Table 2

Characteristics of Craft Brewers Participating in Qualitative Interviews

| <u>Brewer</u> | <u>M/F</u> | <u>State</u> | <u>Brewers Association Brewery Classification</u> | <u>Themes Identified</u> | <u>Production (BBL/Year)</u> | <u>COLA Experience (Yes/No)</u> |
|---------------|------------|--------------|---|------------------------------|----------------------------------|---|
| 1 | Male | IL | Microbrewery | 1, 2, 4, 5 | 100* | Yes |
| 2 | Female | IL | Microbrewery | 1, 2, 3, 4, 5 | 350 ⁺ | Yes |
| 3 | Male | MO | Brewpub | 2, 3, 5 | 200* | No |
| 4 | Male | MO | Brewpub | 2, 3, 5 | *** | Yes |
| 5 | Male | MO | Brewpub | 2, 3, 5 | 350 ⁺ | No |
| 6 | Male | KY | Brewpub | 2, 5 | *** | No |
| 7 | Male | MO | Brewpub | 2, 3, 5 | *** | No |
| 8 | Male | KS | Brewpub | 1, 2, 3, 4, 5 | 1750 ⁺ | Yes |
| 9** | Male | MO | Microbrewery | 2, 5 | N/A | Yes |
| 10 | Male | MO | Microbrewery | 1, 2, 3, 4, 5 | 2000* | Yes |
| 11 | Female | MO | Microbrewery | 1, 2, 3, 4 | 21,000* | Yes |
| 12** | Male | IN | Microbrewery | 1, 3, 4 | 3,000-4,000* | Yes |
| 13 | Female | MO | Microbrewery | 1, 2, 3, 4 | 10,000* | Yes |

*Reported by brewer

⁺Collected from Brewers Association website, 2017 data

**Past experience

***New brewery, no historical data available

Participants were selected for interviews using convenience sampling. Participants were sent a recruitment email that introduced the research study and requested their voluntary participation. For non-respondents that were in close geographic location to the primary investigator, a follow up phone call and/or visit was placed for recruitment purposes. All participants were given an informed consent to review and sign prior to interviewing. Additionally, written consent was obtained to quote participants without use of identifiers.

Procedure

The primary method of data collection was phone interview; face to face interviews were conducted with five brewers in close geographic proximity to the principal investigator. Interviews were conducted between July 2018 and December 2018. Interviews lasted between 20 and 40 minutes. All brewers that were interviewed via telephone consented to being audio recorded: interviews were recorded using the iPhone used to place the call. During each interview, the interviewer recorded detailed notes.

Data Analysis

Recorded interviews were analyzed using the following the five steps of familiarization: indexing, charting, mapping, identifying a thematic framework, and interpretation (Ritchie & Spencer, 2002). During the interview process sub-themes emerged. With additional data collection and interview comparisons, sub-themes were assembled into the main themes, provided in the following discussion. To ensure that the participants' responses and researcher's interpretation were in proper alignment, each participant was sent a written

summary following his/her interview to allow for correction, confirmation or expansion of any item.

Results

Main Themes

The following analysis will address the major themes identified during data collection. In some instances, subthemes were identified to capture the differences in the experiences reported by participants associated with “small” breweries versus “large” breweries. For the purposes of this study, “small” is used to define a brewery with production that is less than 1000 barrels (BBL) per year; “large” is used to define a brewery with production greater than 1000 BBL per year. These definitions have been established by the principal investigator based on the level of production at which experiences seemed to differentiate. These definitions are solely for the purpose of guiding this discussion and are not set forth by a regulatory or industry authority.

Theme 1: “On the same page.” Several brewers indicated that they perceived a disconnect between the craft beer industry and the TTB, especially with regards to craft beer “language.” In one instance, a participant stated that s/he had been challenged during a label approval over the use of the word “saison” to identify the product: “They’re [TTB] doing a disservice by not knowing what the styles are....” Another brewer mentioned that s/he had been challenged on use of the word “caramel” on a label for an amber beer that had been produced

using caramel malt, largely because the TTB reviewer was of the notion that consumers would mistakenly assume caramel was present in the product. The inclusion of the word “style” for products commonly recognized as harkening from a different country was required of multiple participants. One participant reported having to add the qualifier to the label for an Irish ale; yet another reported that the same inclusion was required for a Belgian beer. In multiple instances, brewers reported having to include “Product of the USA” on products with different countries represented in the product name. Another participant reported difficulty with use of the word “pilsner” on a label, despite it being a correct identification of the associated product. Brewers indicated that individuals reviewing labels should have more background in craft brewing as it appeared the TTB did not have a good context for beer, especially with regards to craft styles and adjuncts: “I think they need to hire people who are involved in the craft beer world...it is very apparent that they have people working there who don’t know craft beer, just because of some of the odd questions that we get.”

Likewise, the formula approval process was cited as troublesome. Generally, brewers indicated that identifying which ingredients the TTB considered appropriate as adjuncts was difficult. The use of flavoring agents rather than fresh ingredients (i.e. blueberry flavor versus fresh blueberries) was mentioned by a couple participants as a tricky process to navigate. The small brewers that had experience with formula submission described the experience as complicated and seemingly nonsensical in instances, especially when using ingredients that were not on the TTB’s exemption list. One brewer described his/her experience as so

troublesome that s/he had avoided even though there was interest in selling retail units of some of the brewery's other formulas: "We make some really creative beers, but because of the formula submittal process, it keeps us from sending that stuff outside our own walls. So, I think it definitely detracts from our brand in a way that could be seen as holding us back a little." Another brewer remarked that the timeline for formula approval process had improved, but that the information requested seemed unnecessarily tedious, especially considering the regulatory pushback on seemingly harmless ingredients (i.e. cucumber, lime, and turmeric).

Inconsistency in approvals per individual product was reported among participants associated with large breweries, as well. In multiple instances, participants reported that during submissions for label revisions, they received pushback on items that had previously been approved, such as product name and taglines. One brewer reported that during a submission of label approvals for existing products following a license change, they failed to receive bottle label approval for a product that had been in the marketplace for 10 years. One brewer described a situation in which s/he had received a rejection for a formula, and upon further investigation was told that the rejection was due to the associated product not requiring formula approval. This was especially perplexing, as this participant had been required to submit formulas for very similar products just months earlier.

Another commonly reported issue experienced by participants was inconsistency in legislative interpretation among TTB reviewers, especially as it pertained to label approval: according to participants, there are individualistic differences among TTB reviewers, and while

one reviewer may approve a label item, another reviewer may not. One participant reported that at her/his brewery, s/he had received keg label approval for a product, only to be denied approval for a bottle label because the reviews were done by different reviewers. One participant remarked that the tendency of inconsistency among reviewers was especially maddening when there was a competitor product in the marketplace that contained a label item for which the said brewery did not receive approval. Another participant instead expressed empathy for the reviewers and suggested that the inconsistencies are to be blamed on the ambiguity of the regulations: “There is some definition, but there is some broad scope to this. That might be part of why they’re seeing some of the inconsistencies here.” This sentiment seemed to be shared in part with another participant, who stated that there did not seem to have been a *clear* reading of the rules as they pertain to formula and label approvals: “The most frustrating thing is the inconsistency...Everyone is trying to follow the rules. It’s just that the rules are not consistently communicated.”

Theme 2: “Time or money?” In many of the instances discussed regarding label and formula approval, participants indicated that the disjointed communication was associated with delays in product launches or in product distribution. In several interviews, brewers volunteered their experience with the permit approval process in addition to their labeling and formula approval experiences.

Multiple brewers, especially those associated with smaller breweries, specifically mentioned that the brewer’s permit submission process was especially lengthy and required

disclosure of information that seemed unnecessarily tedious and invasive. One brewer remarked that his/her brewery waited over a year for their permit, while another indicated that s/he had been involved in opening a number of breweries, all of which were associated with processing times that were lengthier than indicated by the TTB's suggested timeline: "When they say it's going to take 120 days to process a permit, they really mean it's going to take 180-200 days." Another brewer remarked that the opening of his/her brewery was delayed due to lack of email communication from the TTB: while approval had been granted, the TTB failed to communicate the approval to the associated party(s) for months. A commonality among brewers who did not report difficulty with the permit approval process was the utilization of outside legal assistance, which represents an additional cost.

One approach used by brewers that had experienced delays in opening due to permit approval issues was using their brewery location as a craft beer bar until they had been cleared to sell their own product. This solution was described by one brewer as unfortunate, largely because profit margin(s) using this approach would be less and it delayed consumer exposure to new breweries' products: "I think that [delays in TTB permit approval] is a telltale sign that of those hoops you've got to hop through, and that period you got to wait...it stresses out the finances of people who are going out on a limb to do something for a community. They've got to get money back in the bank....getting over that hump can be stressful, financially for sure."

The labeling approval process was described as unnecessarily tedious and inefficient in some instances. Use of specific language (i.e. "IPA" versus "India Pale Ale") was cited as

common feedback from the TTB during the labeling approval process. These kind of seemingly incidental requests frustrated many of the brewers interviewed. The use of outside consulting assistance to help with labeling was mentioned by one brewer: “There is definitely expense in it [labeling approval]...we paid a guy to help us out. Could we have done it on our own? Yes. But then, what’s more important, time or money?”

Another commonly mentioned frustration was inconsistency in label feedback during the approval process, particularly during resubmissions. Multiple brewers described experiences in which they had corrected label errors identified by TTB reviewers and resubmitted, only to have new errors identified in the resubmission. In some instances, this identification of new errors took place during multiple rounds of resubmissions for the same label. One brewer remarked that the largest cost associated with label approval was the staff time associated with communicating with the TTB during these resubmissions.

Relevant to all of the processes described above is the notion of the TTB’s “queue,” to which brewers referred with frequency, particularly with regards to permit approvals: permit applications (as well as other items needing TTB approval) are processed in the order in which they are received. Arriving to the “top of the stack” is a realization desired by brewers waiting for approval of an item, although some brewers found that failing to respond to a regulatory request in an immediate manner pushed their item back to the bottom of the queue.

Theme 3: “Navigating the system.” With regards to general operations and permit approval, it was clear that most participants associated with smaller breweries received

guidance from other brewers, especially other brewers in close geographic proximity. A number of participants indicated that the nature of the craft brewing industry, particularly among small brewers, is noncompetitive and amiable: “We’re all very open and encouraging people. I’ve never met a brewer that I did not like. Because we’re all in the same boat. It’s not me versus the brewery down the street. It’s us together. It’s us as craft beer. We’re a team whether we’re wearing the same logo that day or not. I would say to anyone trying to get into the industry, talk to one of us...We are going to help anyway we can. Because that’s just the way this industry really truly is...I don’t have any competition in my mind.”

Generally, participants associated with smaller breweries indicated that in the interest of their associated local communities, their breweries exercised significant self-regulation. Several brewers indicated that among their primary motivations was serving their respective communities and providing a product that community stakeholders would appreciate. Consequently, seeking and achieving product quality was self-motivated rather than legally enforced. This was especially true among brewers who had not yet moved to larger-scale distribution or who had no intention of distribution outside their brewery, brewpub or taproom. One brewer stated that s/he perceived an absence of the “artisan” element associated with craft brewing when the focus was large scale distribution and instead wanted to focus on providing a “third space” for local community members. Furthermore, for those breweries that do not distribute product outside their state in retail packaging, their products

remain outside of TTB jurisdiction, and consequently are largely unregulated from a formal standpoint.

With regards to navigating formula and labeling regulations, multiple participants associated with larger breweries indicated that among their primary considerations was developing an internal process to satisfy regulatory requirements. One participant remarked that one of the biggest learning curves was related to establishing a timeline for production, formula approval, and label approval: s/he asserted that the end product had to be conceptualized prior to production to efficiently get approvals: “You have to have the end beer [in mind]...and everything done before you even make the beer, which is a little difficult.” Likewise, another participant stated that breweries needed to have a clear, outlined process of how to communicate internally, while collectively understanding that approvals take time. Their brewery identified that alignment between brewers, quality assurance, and labeling was imperative.

Because many of the participants associated with larger breweries had lengthier experience in the industry, and consequently working with regulations, a couple participants shared some stories of “growing pains” they had encountered. Regarding label approval, one participant stated that it s/he had developed a template of sorts to guide his/her submissions, although the template had not resulted in seamlessly receiving approvals: “Honestly, you just have to learn how it all works. Once you have an idea of what they’re looking for, from then on out I kind of have a template for a label, and I just have to make sure I check every box. That

being said...last week...3 or 4 got kicked back for corrections.” Another brewer indicated that federal labeling approval was not among the primary concerns at the time of his/her brewery’s opening; however, when distribution of the brewery’s product moved outside its respective state, a number of labels that had received state approval required revisions due to lack of alignment with federal labeling regulations, which was incredibly cumbersome.

Theme 4: “Reinvent the wheel?” Regarding the perceived need for resources, a common sentiment was that differentiation of resources would be helpful for craft brewers. One participant remarked that existing resources are nonspecific to craft beer and do not necessarily capture the more unique issues associated with craft brewing. Another participant communicated a similar judgment: differentiating resources for small breweries, midsize breweries, and large breweries would be assistive. Another participant mentioned that localization of resources would be helpful: while a number of items exist to inform brewers of labeling and formula approvals, they appear scattered across mediums.

One participant mentioned that rather than reinvent the regulatory wheel, a stepwise approach would have more utility, suggesting that it would be more helpful to designate a few of the more challenging items and provide clarification: “If you’re not taking the time to go through and read the FAQs and read the tutorials...I just don’t think that some of these guys are taking the time to do their due diligence and actually read through it...if the BA or local brewers guild had something, is there anything...that maybe the BA could push back to the TTB and say

‘Hey, here’s what we found. We need a little more clarification on these 3 items, rather than reinventing the wheel.’ ”

To address the difficulty associated with formula submission, one brewer specifically mentioned a need for guidance on the manner in which brewers should approach nontraditional ingredients, particularly those not already present on the TTB exemption list. As an addition, the same brewer stated that resource(s) that would empower brewers to expand the list would be especially useful. This same brewer remarked that in his/her interactions with other brewers, there seemed to be confusion about the utility of the TTB exemption list, especially for new brewers and/or those that weren’t distributing product outside the state in which they operated: “Even with how clear the TTB has tried to be with how ingredients can be included, and which ones need to be looked at more closely, it’s still hazy to people. I think that’s the question that gets asked the most...I understand that TTB COLA rules are place to protect the consumers, so it’s confusing to people [what requires a COLA]...so can people put whatever they want in their beer?”

Generally, participants indicated that revision(s) of current regulations were more pertinent than provision of additional, formalized resources, as interpretational variances seemed to cause the most problems. In one example, a participant indicated that s/he had discovered his/her brewery had unnecessarily spent six months been seeking federal label approval from the TTB, which was not a requirement in the associated state (this brewery was distributing instate only).

Theme 5: “Flying under the radar.” The last primary theme to emerge from the data collection described was the impact of regulation on brewery operations; more specifically, how this impact differed depending on brewery size. Many participants associated with smaller breweries indicated that they had not experienced submitting their product to the TTB, largely because they did not intend to distribute outside the state, and consequently were “flying under the radar” of the TTB, with one participant remarking, “They have nothing in place to regulate that...[breweries that are not submitting formula or label approvals because their distributing in state only].” Another participant remarked that as long as there were no complaints about their brewery, it was relatively simple to remain relatively hidden from TTB regulatory authorities: “There’s a few beers we did that with, we didn’t bother with label approval, because we didn’t have any plans to sell outside the state. But I have talked to other breweries who, over time, just stopped worrying about it [receiving TTB label approval], and just run labels. Does it find its way across state lines sometimes? Yeah, that happens.”

Discussion

While the craft brewing industry has enjoyed significant growth in recent history, the data indicate that the complicated interchange between brewers and involved regulatory parties regarding approvals translates to delays in opening brewery doors and/or bringing new products to market for retail sale. One brewer remarked that new brewers should expect

delays, and to plan accordingly. Yet another brewer remarked that brewers were simply “at the mercy of the bureaucracy.”

However, while the data collected indicate that opportunities exist to improve the relationship between the TTB and members of the craft brewing industry, it is worth noting that participants of both tiers indicated that timing of feedback on label and formula approval had improved in recent history. Some participants indicated that this may be due to additional staff, as new names had appeared on approval paperwork. Additionally, participants associated with larger breweries looked upon the TTB exemption list (TTB Ruling 2015-1) favorably. One participant remarked that the exemption list provided a means for brewers to circumvent the more complicated FDA regulations that had guided the addition of adjuncts in the past. Another participant stated that the exemption list made it clearer as to whether or not a new product required a formula.

Theoretical Implications

Regarding the need for regulatory resources among brewers, it may be useful to employ the Cognitive Flexibility Theory (CFT), especially in the context of the label and formula approval process(s). CFT is centered on learning that occurs in complex and/or poorly structured domains. According to Spiro, Coulson, Feltovich, and Anderson (1988), cognitive flexibility refers one’s ability to respond to changing contextual demands. Consequently, this theory is largely focused on context-specific learning subsequent to initial content exposure: learners

must delineate the information in a manner specific to their personal experiences/needs (Spiro et al., 1988).

While a number of online and face-to-face instructional resources exist to inform brewers of TTB regulations and expectations, the results of the data collection indicate that these resources are nonspecific and arguably difficult to navigate. While it is unrealistic for governmental and instructional entities to develop content specific to the virtually infinite number of labeling questions or concerns posed by brewers, creating brewer resources based in the guiding principles of CFT may improve comprehension of regulations. Improved comprehension of regulations will decrease the time investment required by regulatory officials, thus cultivating innovation in the craft beer marketplace.

As discussed in the results, some participants suggested that brewers formulate new products using the ultimate label as their framework, perhaps even going so far as getting formal label approval for a product in development. For new brewers or brewers that have limited experience with label approval, this practice may prevent loss of revenue or unnecessary hardship associated with developing and producing a product that subsequently is denied label or formula approval. This practice speaks specifically to the CFT principle of avoiding oversimplification of content. Regarding the TTB exemption list, it appears the most useful resources would be those that empower brewers to understand and participate in adding to the document.

Regarding educational solutions for brewers' gaps in knowledge, the resources provided by regulatory (or outside) entities should aim to be case-based, perhaps even involving opportunities for brewers to submit their current products for fictional approval. As was indicated in the results, new brewers may not have context for the COLA or formula approval process(s), especially if they are in the throes of getting state and federal approvals to begin operations. Consequently, this may lead to labeling confusion later in the lifecycle of the brewery, as was indicated by one brewer during data collection. In the future, providing resources on labeling and formula approval as part of the permit approval documentation may help mitigate confusion for breweries that find themselves interested in wholesale or retail distribution.

Strengths and Limitations

The open-ended nature of data collection in this study allowed brewers to expand on their experiences in a way that would likely be difficult to replicate using different research methods. Consequently, this approach allowed for brewers to volunteer information that otherwise may have been difficult to capture, which allowed for a comprehensive assessment that resulted in the identification of important themes.

However, this study had selected limitations. Participant recruitment was challenging, due primarily to the demanding schedule of the population of interest, which resulted in heavy dependence on convenience sampling. Additionally, this study was limited to brewers in the Midwest, so it may be inappropriate to apply the findings brewers nationwide.

Another limitation to the study was the unintentional exclusion of craft brewers associated with regional craft breweries or contract breweries. This exclusion was due primarily to recruitment challenges. Consequently, the types of craft brewers reflected in this study were limited to those associated with microbreweries and brewpubs.

As is true with qualitative data collection, the identification of themes is subjective with the potential for researcher bias. However, interview summaries were written and sent to participant's for interpretive affirmation. Following minor edits for three brewers, 100% of participants concurred with the email summary of their interview.

Suggestions for Future Research

Future research should aim to capture brewer perceptions from across the country. Additionally, using a research medium that would lend itself to quantitative analysis (i.e. survey) would provide results that may result in easier communication of the perceived needs among brewers. Specifically, an instrument that aimed to quantify the economic impact of some of the identified regulatory hurdles would be useful for informing industry, as well as government entities.

Regarding new topics for research, investigating the impact of local and state regulation would be beneficial to the craft beer industry. In multiple cases, brewers indicated local and state regulation posed just as much (if not more, in some cases) difficulty than federal regulation. Additionally, investigating the potential for threats to consumer safety may prove

valuable. As was indicated in the data collected, a significant portion of craft beer (particularly from non-distributing breweries) goes unregulated because it is not demonstrably under the TTB's purview.

Conclusion

This purpose of this review of selected regulations and qualitative research study was to identify 1) explore craft brewers' comprehension and perceptions of the TTB formula and labeling approval process(s), and 2) collect brewer perceptions of the need for additional resources related to regulatory items. While the Alcohol and Tobacco Tax, and Trade Bureau (TTB) has significant impact on the craft brewing industry, it is useful to consider regulations and initiatives arising from the Food and Drug Administration (FDA), the Brewers Association, the Beer Institute, and the United States Department of Agriculture.

Current regulations may have an economic impact on craft breweries, either through loss of potential revenue or through the absorption of additional costs. Product innovation is a pillar in the craft beer industry, and the data collected indicate that regulatory approvals may threaten the expediency with which brewers can introduce new product to market.

Additionally, brewers perceived a need for standardization of regulatory interpretation, among industry members and government officials. Data collection indicated that TTB reviewers may not have good context for craft beer, particularly the language associated with craft beer styles. This study reveals that there exist opportunities to improve existing resources

for brewers as they pertain to labeling and formula approval. Developing resources that speak particularly to craft beer production was cited as potentially helpful among participants. Last, the manner in which the TTB affects operations was dissimilar among small and large breweries. Investigating these differences may prove useful in future research.

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Appendix A

Required Label Information

Labels for malt beverages regulated by the TTB require pre-approval. Mandatory label information includes the following:

- Brand name
- Class and type designations
- Name and address of the producer or the bottler/packer
- Net contents
- Alcohol content
- Disclosure of FD&C Yellow #5 food coloring (if applicable)
- Disclosure of cochineal extract or carmine (if applicable)
- Disclosure of saccharin (if applicable)
- Sulfite declaration, if the product contains greater than 10 ppm
- Aspartame disclosure and accompanying phenylalanine disclosure (if applicable)
- Health warning statement, which must read as follows: “GOVERNMENT WARNING:(1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.”
- Country of origin (for imported malt beverages)

(TTB, 2001; FDA, 2018b)

Appendix B

Flavoring Substances and Adjuvants Subject to Limitation or Restriction

| Material | Relevant FEMA Numbers * | Reference | Current Limit | Food category and/or Use |
|------------------------|--------------------------------|------------------|----------------------------|---|
| Acacia - Gum Arabic | 2001 | 21CFR172.780 | 20.0% | Alcoholic Beverages; Function: Thickener, emulsifier, or stabilizer |
| Acetic Acid | 2006 | 21CFR184.1005 | 0.15% | All other food categories |
| Aconitic Acid | 2010 | 21CFR184.1007 | 0.002% | Alcoholic Beverages |
| Adipic Acid | 2011 | 21CFR184.1009 | 0.02% | All other food categories |
| Agar-agar | 2012 | 21CFR184.1115 | .25% | All other food categories |
| Ammonium Alginate | 2015 | 21CFR184.1133 | 0.1% | All other food categories |
| Artemisia (Wormwood) | 3114, 3115, 3116 | 21 CFR172.510 | Finished Food Thujone Free | Natural flavoring substance or natural substance used in conjunction with flavors. |
| Bakers Yeast Extract | | 21CFR184.1983 | 5% | The ingredient is used as a flavoring agent and adjuvant as defined in 21 CFR170.3(o)(12) at a level not to exceed 5 percent in food. |
| Beeswax Yellow & White | 2126 | 21CFR184.1973 | 0.002% | All other food categories |

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|--------------------------------|------|---------------|--|--|
| Benzoic Acid | 2131 | 21CFR184.1021 | 0.1% | The ingredient is used as a flavoring agent and adjuvant as defined in 21 CFR170.3(o)(12) at a level not to exceed 0.1 percent in food. |
| BHA | 2183 | 21CFR182.3169 | 0.02% of fat or oil content | This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of food, provided the substance is used in accordance with good manufacturing practice. |
| | | 21CFR172.515 | 0.5% of the essential (volatile) oil content | BHA (butylated hydroxyanisole) may be used as an antioxidant in flavoring substances whereby the additive does not exceed 0.5 percent of the essential (volatile) oil content of the flavoring substance. |
| BHT (edible fats & oils) | 2184 | 21CFR182.3173 | 0.02% of fat or oil content | This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of food, provided the substance is used in accordance with good manufacturing practice. |
| Almond, bitter | 2046 | 21CFR182.20 | free from prussic acid | Essential oils, oleoresins (solvent-free), and natural extractives (including distillates) that are generally recognized as safe for their intended use. |
| Brominated Vegetable Oil - BVO | | 21CFR180.30 | 15 ppm in the finished fruit flavored beverage | The additive complies with specifications prescribed in the Food Chemicals Codex, 3d Ed. (1981), pp. 40-41, which is incorporated by reference, except that the free fatty acids (as oleic) shall not exceed 2.5 percent and iodine value shall not exceed 16. b. The additive is used on an interim basis as a stabilizer for flavoring oils used in fruit-flavored beverages, for which any applicable |

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| | | | | standards of identity do not preclude such use, in an amount not to exceed 15 parts per million in the finished beverage. |
| Calcium Acetate | 2228 | 21CFR184.1185 | 0.0001% | All other food categories |
| Calcium Alginate | 2015 | 21CFR184.1187 | 0.4% | Alcoholic Beverages |
| Calcium Chloride | | 21CFR184.1193 | 0.05% | All other food categories |
| Calcium Sulfate | | 21CFR184.1230 | 0.07% | All other food categories |
| Camphor Tree | 2231 | 21CFR172.510 | Safrole free | Natural flavoring substance or natural substance used in conjunction with flavors. |
| Caprylic Acid | 2799 | 21CFR184.1025 | 0.001% | All other food categories |
| Cedar, White (Arbovitae) Leaves & Twigs | 2267 | 21CFR172.510 | Finished Food Thujone Free | Natural flavoring substance or natural substance used in conjunction with flavors. |
| Cherry Pits | 2278 | 21CFR172.510 | 25 ppm prussic acid | Natural flavoring substance or natural substance used in conjunction with flavors. |
| Cherry - Laurel Leaves | 2277 | 21CFR172.510 | 25 ppm prussic acid | Natural flavoring substance or natural substance used in conjunction with flavors. |
| Cinchona, Red & Yellow Bark | 2281, 2282, 2283, 2284, 2285 | 21 CFR172.510 | In beverages only: not more than 83 ppm total cinchona alkaloids in finished beverage | Natural flavoring substance or natural substance used in conjunction with flavors. |
| Corn Silk & Corn Silk Extract | 2335 | 21CFR184.1262 | 4 ppm | All other food categories |
| Dithiols - | | FEMA | 1 ppm | Total added to any food not to exceed 1.0 ppm |
| 2,3-butanedithiol | 3477 | | | |
| 1,2-ethanedithiol | 3484 | | | |
| 1,9-nonanedithiol | 3513 | | | |

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| Calcium Disodium EDTA (ethylene-diaminetetraacetate) | | 21CFR172.120 | 25 ppm | Distilled alcoholic beverages; Use: Promote stability of color, flavor, and/or product clarity |
| Elder Tree Leaves | | 21CFR172.510 | 25 ppm prussic acid in the flavor | Alcoholic beverages only; Natural flavoring substance or natural substance used in conjunction with flavors. |
| Ester Gum (Glycerol Ester of Wood Rosin) | | 21CFR172.735 | 100 ppm of the finished beverage | It is used to adjust the density of citrus oils used in the preparation of beverages whereby the amount of the additive does not exceed 100 parts per million of the finished beverage. |
| Ethyl Formate | 2434 | 21CFR184.1295 | 0.01% | All other food categories |
| Guar Gum | 2537 | 21CFR184.1339 | .5% | All other food categories |
| Gum Ghatti | 2519 | 21CFR184.1333 | .1% | All other food categories |
| Gum Tragacanth | 3079 | 21CFR184.1351 | .1% | All other food categories |
| Karaya Gum | 2605 | 21CFR184.1349 | 0.002% | All other food categories |
| Licorice and Licorice Derivates as Glycyrrhizin | 2628, 2629, 2630 | 21CFR184.1408 | 0.1% | Alcoholic beverages |
| Locust (carob) bean gum | 2648 | 21CFR184.1343 | .5% | All other food categories |
| Malic Acid | 2655 | 21CFR184.1069 | 0.7% | All other food categories |
| Mannitol | | 21CFR180.25 | 2.5% | All other food categories |
| Methylparaben | 2710 | 21CFR184.1490 | 0.1% | The ingredient is used as an antimicrobial agent as defined in 21 CFR170.3(o)(2) in a maximum level of 0.1 percent in food. |
| Oak Moss | 2795 | 21CFR172.510 | Finished Food Thujone Free | Natural flavoring substance or natural substance used in conjunction with flavors. |
| Oil of Rue | 2995 | 21CFR184.1699 | 4 ppm | All other food categories |
| Peach Leaves | | 21CFR172.510 | 25 ppm prussic acid in the flavor | Alcoholic beverages only; Natural flavoring substance or natural |

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| | | | | substance used in conjunction with flavors. |
| Potassium Alginate | | 21CFR184.1610 | 0.01% | All other food categories |
| Propylene Glycol | 2940 | 21CFR184.1666 | 5 % | Alcoholic Beverages |
| Propylparaben | 2951 | 21CFR184.1670 | 0.1% | The ingredient is used as an antimicrobial agent as defined in 21 CFR170.3(o)(2) in a maximum level of 0.1 percent in food. |
| Quinine, as the hydrochloride salt or sulfate salt | 2975, 2976, 2977 | 21CFR172.575 | 83 ppm, as quinine | In carbonated beverages as a flavor |
| Rue | 2994 | 21CFR184.1698 | 2 ppm | All categories of food |
| Sassafras Leaves | 3010, 3011 | 21CFR172.510 | Safrole free | Natural flavoring substance or natural substance used in conjunction with flavors. |
| Sodium Alginate | 2015 | 21CFR184.1724 | 1.0% | All other food categories |
| Sodium Aluminosilicate | | 21CFR182.2727 | 2% | Use: Anticaking agent |
| Sodium Benzoate | 3025 | 21CFR184.1733 | 0.1% | The ingredient is used as an antimicrobial agent as defined in 21 CFR170.3(o)(2) and as a flavoring agent and adjuvant as defined in 21 CFR170.3(o)(12) at a level not to exceed 0.1 percent in food. |
| Sodium Calcium Aluminosilicate Hydrated | | 21CFR182.2729 | 2% | Use: Anticaking agent |
| Sodium Thiosulfate | | 21CFR184.1807 | 0.00005% | Alcoholic beverages |
| Sorbitol | 3029 | 21CFR184.1835 | 12% | All other foods; Many uses |
| St. Johnswort Leaves, Flowers & Caulis | | 21CFR172.510 | Hypericin-free | Natural flavoring substance or natural substance used in conjunction with flavors. Hypericin-free alcohol distillate form only; in alcoholic beverages only |
| Stannous chloride (anhydrous and dihydrated) | | 21CFR184.1845 | 0.0015 % calculated as tin | All food categories |

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|------------------------------------|------|------------------|--|--|
| Sucrose Acetate Isobutyrate (SAIB) | | 21CFR172.833 | 300 mg/kg of the finished beverage | The total SAIB content of a beverage containing the additive does not exceed 300 milligrams/kilogram of the finished beverage. |
| Sulfuric Acid | | 21CFR184.1095 | 0.014% | Alcoholic beverages |
| Tagetes (marigold) | 3040 | 21CFR172.510 | As oil only | Natural flavoring substance or natural substance used in conjunction with flavors. |
| Tannic Acid | 3042 | 21CFR184.1097 | 0.015% | Alcoholic beverages |
| Tansy | | 21CFR172.510 | finished alcoholic beverage thujone free | Alcoholic beverages only; Natural flavoring substance or natural substance used in conjunction with flavors. |
| Woodruff, Sweet | | 21CFR172.510 | | Alcoholic beverages only; Natural flavoring substance or natural substance used in conjunction with flavors. |
| | | ATF Ruling 74-10 | 5 ppm coumarin | may wine |
| Yarrow | 3117 | 21CFR172.510 | finished beverage thujone free | Beverages only; Natural flavoring substance or natural substance used in conjunction with flavors. |

*** For more information on the Flavor and Extract Manufacturers Association of the United States (FEMA) GRAS program, visit: <http://www.femaflavor.org/gras>.**

(TTB, n.d.b).

Appendix C

Interview Guide

Opening Statement: Thank you for speaking with me today. The goal of this interview is to gather information about your experience with the pre-Certificate of Labeling Approval/Formulation approval (pre-COLA) process and the Certificate of Labeling Approval (COLA) process. I will use the information I gather from this and other brewer interviews to develop a survey to be administered to a larger volume of brewers. Ultimately, the goal is to identify where brewers could use additional resources or guidance with regards to labeling and formulation.

Name:

Brewery:

1. Do you currently bottle and/or can product for retail sale?
 - a. If yes:
 - i. Do you distribute outside the state in which you operate?
 - ii. Did you have to go through the pre-COLA process in order to get labeling approval? Describe this process.
 - iii. Describe your experience (or lack thereof) with the TTB exemption list.
 - iv. Have you submitted formulas that were not approved by the TTB? Explain.
 - a. Did you ultimately receive approval for a beer that was previously denied?
 - i. If so, do you think the delay translated to a loss of revenue and/or increased costs?
 - ii. If no, do you think the denial of this formula translated to a loss of revenue?
 2. Do you think additional guidance from the TTB (or another entity) would have prevented formula denial? Expand.

- v. Do you currently produce product that is subject to FDA labeling regulations?
 - 1. If yes, can you expand on your experience with this?
 - a. How have you navigated the FDA labeling regulations?
 - i. Do you think additional guidance would help navigating these regulations? Expand.
 - ii. Do you think that adhering to and/or adopting these regulations has translated to increased cost and/or lack of revenue?
 - vi. Do you have anything additional to add regarding your experience with formula and label approval?
- b. If no:
- i. Is bottling/canning your product something you are interested in doing in the future?
 - 1. If yes, what has kept you from bottling/canning up to this point?
 - 2. If no, why not?
 - ii. Do you sell your product directly out of your brewery and/or from a tasting room?
 - 1. If out of a brewery only: Have you submitted some/all of your formulas for approval by the TTB?
 - 2. If from a tasting room: Have you submitted some/all of your formulas for keg label approval by the TTB?
 - a. What was your perception of the process involved to get label approval for your keg(s)?
 - i. Would additional guidance have simplified this process? Expand.