The Food Safety Modernization Act: Effects on the Brewing Industry

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ABSTRACT

The Food Safety Modernization Act was a broadly impactful piece of legislation signed into law in 2011. This legislation is composed of seven core rules that together made sweeping changes to the regulations surrounding how foods are grown, harvested, and processed. These regulations affected many different industries, including the brewing industry and its supporting counterparts. Due to the expansive nature of the regulations, there have been issues with interpretations during their rollout and direct guidance from the FDA was not always immediately available. This meant that during initial years following passage of the legislation, non-government groups were left to gather information and disseminate answers to questions on maintaining compliance. A review of available literature and resources has found that even though there has now been clarification on how many of the provisions affect various industries directly from the FDA, resources on how to achieve compliance in specific areas are not always available and can sometimes be hidden behind a paid membership. Due to this, there exists a state where some resources may be unavailable to potential industry participants. There is value in providing free resources to potential participants, future research on sustainable practices with industry byproducts, and in identifying shortcomings in the legislative rollout for the benefit of future regulatory endeavors.
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Introduction

Background

The U.S. Food and Drug Administration’s Food Safety Modernization Act (FSMA) is federal legislation that was passed by Congress and signed into law on January 4th, 2011. This legislation is one of the most sweeping expanses of food safety regulation in the past 80 years, since the Food, Drug, and Cosmetic Act of 1938 [1]. In making such a leap in regulatory standards, there were far-flung effects on many industries. Included were the brewing industry and its supporting counterparts, which are industries that have a vast economic impact [22] across the state of Virginia. These regulations were put into motion during the early stages of the burgeoning craft brewing industry in Virginia – which has since seen an explosive growth of over 400% [25] in the number of craft breweries calling the state their home. To continue to encourage the growth of these industries, it is important to make sure the potential and active participants have the most reliable resources readily available to them to ensure that achieving compliance is not a daunting task.

As new regulations were rolled out following the passage of the undeniably lengthy FSMA, there were numerous unforeseen regulatory issues. Unfortunately, there was not always succinct guidance for situations that arose during regular business processes such as how certain industry byproducts like spent grains and hops would be handled for animal feed [20], or what would be considered processing for hop growers [19]. This sometimes caused confusion as to what the effects under the new regulations would be and the FDA was not always able to clarify the specifics immediately, leading to potentially drawn-out back and forth
discussions remarked by periods of open comment [20] where affected groups could voice their concerns over how implementation would affect their businesses.

During this time, resources to answer questions on specific regulations affecting individual sectors such as brewing operations or hop production had largely been left to be championed for, gathered by, and disseminated by the affected non-government associated groups including but not limited to: The Master Brewers Association of the Americas (MBAA), the Brewers Association (BA), and the Hop Growers of America (HGA). Thankfully, over the past 9 years, there has been healthy progress in clearing up previously ambiguous regulatory rules. That being said, there still exist pitfalls in navigating the regulatory framework as helpful examples to guide you through setting up compliant processes may not always be available from direct government sources and similarly are not always free to the potential or active industry participants. Therefore, these individuals or groups may still need to do extra legwork to find sources of information and verify those sources that they do receive guidance from are correct in their instruction.

**Statement of the Problem**

While there is now significantly more information available directly from the FDA as to exemptions and which establishments are affected by what regulations, the administrative rollout had a plethora of issues that are beneficial to identify and understand to help guide future endeavors in regulatory improvement. Even nearly 9 years after the passing of the FSMA, when searching for information on the FDA website, it is not uncommon to find a link that results in a dead end due to content being removed or moved. In addition, there are
shortcomings when it comes to freely available information on the specifics regarding setting up and executing standards that satisfy the requirements for Good Manufacturing Practices or Hazard Analysis Plans. As the content in the FDA documents have not always been all encompassing in their guidance, there exists a state where industry participants have sometimes needed to rely on other groups to disseminate easily digestible guidance. Unfortunately, this sometimes requires a paid association membership or access to information that may or may not be outdated.

**Purpose of the Project**

The initial intent of this project was to perform an analysis of how the transformational FSMA regulations had affected state breweries in regard to their processes for handling spent hops and grains when the regulatory fate was still undetermined or thereafter. It would have also considered what resources those breweries had used to guide them through that process. The desire was to create a single resource that combined those guiding materials/contacts into an easily digestible format to be used by interested parties to assist them in making decisions on handling the byproducts of their manufacturing processes in a sustainable fashion while keeping compliance in mind. However, due to poor response to attempted correspondence with the overwhelming majority of contacted businesses and their representatives, the project purpose had to be altered slightly. The updated purpose of this project is to perform a review of the FSMA and available resources on the requirements for regulatory compliance as they relate to the brewing industry in general and identify which regulatory aspects affect those sectors and where information can be found. Resources that are pertinent to manufacturers regarding
spent grain/hops, as well as hop producers, are emphasized. The intent is to provide an educational resource to be used by individuals seeking information regarding achieving compliance in the brewing industry and its supporting counterparts, or by students in Food Safety courses.
**Definition of Terms**

- **BA**: Brewers Association – An American trade group of over 7,200 brewers, breweries in planning, suppliers, distributors, craft beer retailers, and individuals particularly concerned with the promotion of craft beer and home brewing.

- **CGMP’s**: Current Good Manufacturing Practices – practices required to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of food and beverages, cosmetics, pharmaceutical products, dietary supplements, and medical devices.

- **CFU**: Colony Forming Unit – unit used to estimate the number of viable bacteria or fungal cells in a sample.

- **FDA**: The Food and Drug Administration is a federal agency of the Department of Health and Human Services and is responsible for protecting and promoting public health through the control and supervision of many different products, devices, and services.

- **FD&C**: Federal Food, Drug, and Cosmetic Act – set of laws passed by Congress in 1938 giving authority to the Food and Drug Administration to oversee the safety of food, drugs, medical devices, and cosmetics.

- **FSMA**: The U.S. Food and Drug Administration’s Food Modernization Safety Act – law signed on January 4th, 2011 that gave the Food and Drug Administration new authorities to regulate the way foods are grown, harvested, and processed and the powers to enforce them.

- **FSVP**: Foreign Supplier Verification Program – Verification programs that are required for each product and supplier that is being imported.

- **HGA**: Hop Growers of America – Trade association focused on grower support through technical, scientific research; trade promotion and harmonization; educational outreach; expansion of industry and USDA statistics, and more.

- **MBAA**: Master Brewers Association of Americas – Group formed in 1887 with the purpose of promoting, advancing, and improving the professional interest of brew and malt house production and technical personnel.

- **VQIP**: Voluntary Qualified Importer Program – Voluntary fee based program that provides expedited review and import entry of human and animal foods into the United States for participating importers.
Review of Literature and Resources

Economic Impact of the Brewing Industry

According to the Brewers Association, as of 2018 Virginia ranked 12\textsuperscript{th} overall in number of craft breweries per state with 236, representing an increase of over 400\% since 2012 [25]. The growth in the industry has had an exceptional effect throughout the state economically. In 2017, then Governor Terry McAuliffe stated that, “The beer industry is a significant economic driver that spans several sectors including manufacturing, agriculture, and tourism” and cited a recently released economic impact study showing that Virginia’s beer industry contributed more than $9.34 billion annually to the economy [24]. Industry impact is also evidenced by the over $1.7 billion in economic impact that the craft brewing industry had on the state in 2018, ranking 17\textsuperscript{th} overall in comparison with other states [25]. A new economic impact study that was jointly commissioned by the National Beer Wholesalers Association and the Beer Institute, released in May of 2019, shows that there are 56,126 jobs impacted by the beer industry in Virginia. These account for $2.5 billion each year in wages and benefits as well as a continued $1.7 billion annually in business, personal, and consumption taxes [22]. There is certainly no shortage of identifiable benefits as new brewing outfits of all sizes have crept into cities and towns across the state, helping to bolster tax revenue through broad economic means.

Beneficial Brewery Byproducts: Spent Grains/Hops

Spent grains and hops are natural byproducts of the brewing process that still have considerable value in several applications. Hops are the less desirable of the two, as the
residual bitterness makes them unpalatable and therefore of no use in animal food. The typical route of sustainable disposal for spent hops is as fertilizer or compost, though they have been trialed as a source of essential oils used in insect repellant [21]. Spent grains have a much higher value as a low cost alternative to feed, such as soybean, due to their high nutritional content [21]. Fortunately, there is a remarkable amount of this material as it comprises approximately 85% of all the by-products generated, 31% of original malt weight and 20 kilograms per 100 liters of beer produced [3]. These account for about 4.5 million tons of material in the U.S. on an annual basis, and 3.4 million tons in the EU [3]. Approximately 2 million tons of the EU annual output comes from Germany alone [23]. There is no hazard inherent to the spent material, as “at the point of production microbial contamination is low and the composition of the microflora can be considered microbiologically stable and within acceptable limits for use as food” [23]. However, there is a high moisture content in the spent grains, which makes it prone to spoilage within 7-10 days [3]. For smaller operations, it is much easier to pass off spent grains to local farmers – but for large operations, the disposal of this material can pose a much greater challenge.

Traditionally, the most common usage of these leftover materials has been on farms as animal feed. For small operations, farmers are able to retrieve the material themselves. Operations of considerable size typically have to contract animal feed producers to take their byproduct and process it further as the volume is just too large for other purposes [21]. However, there is evidence of several other sustainable uses. One of these alternative sustainable uses is as a lignocellulose biofeedstock in an industrial biotechnology environment [3]. Unfortunately, there are still significant challenges that must be addressed with the costs of
separation and conversion and spoilage issues due to moisture content before it could be commercially viable. Another potential avenue for sustainable use is within food products intended for human consumption, as the nutritional benefits are not just applicable to animal feeds. Of particular interest, are (1–3, 1–4)-β-d-glucan and ariboinxylan, which have respectively been shown to reduce blood cholesterol levels and postprandial glycemic responses [23]. While there are not yet any large-scale manufacturers utilizing spent grains in their food products, some current small-scale businesses are employing the practice [21].

*The Food Safety Modernization Act: An Overview*

According to FDA statistics, 1 in 6 people in the United States gets sick each year due to foodborne diseases - amounting to an astonishing 48 million people a year. In addition, some 128,000 are hospitalized due to their illness and another 3,000 illnesses are fatal in nature [2]. To address this largely preventable and massive strain on the public health system, the FSMA was signed into law by President Obama on January 4th, 2011. This legislation is one of the most comprehensive reforms of food safety law in the past 80 years, being the most broadly impactful legislative enactment by the federal government since the Food, Drug, and Cosmetic Act of 1938 [1]. It is responsible for setting up a regulatory framework that focused on a proactive, preventive strategy rather than reacting to problems after they occurred.

The aim of this legislation is to enable the FDA to better protect public health by mandating the establishment of a science-based, preventive control oriented, food safety regimen across the food supply through modernized Current Good Manufacturing Practices (CGMP’s) [2]. Included in this mandate are mandatory preventive controls for food facilities,
mandatory produce safety standards, and the authority granted to the FDA to prevent intentional contamination by issuing regulations to protect against the intentional adulteration of food products. To ensure that the mandates provisions are followed, it also provided the FDA with the tools necessary for inspecting compliance, with a mandated inspection frequency based on risk level as well as the ability to issue mandatory recalls on food products for companies that fail to voluntarily recall their unsafe wares [2]. Equally as important, the FSMA enhanced the authority of the FDA in ensuring that any foreign food facilities wishing to have their products imported are compliant with the same U.S. food safety standards applied to domestic products, and are safe for consumption by the public [2]. This legislation will affect many aspects of the brewing industry, from beer manufacturers both small and large, to breweries that maintain a combination of restaurant and tap house, as well as the growers of agricultural raw materials that are required throughout the manufacturing process.

The Seven Rules of the FSMA and the Brewing Industry

The FSMA is a union of seven regulatory rules that together form a fundamental core of the food safety principles that support an integrated national food safety system, designed to guarantee consumers safe products through proactive measures. These seven rules are as follows: 1) Produce Safety Rule, 2) Preventive Controls for Human Food Rule, 3) Preventive Controls for Animal Food Rule, 4) Foreign Supplier Verification Program for Importers of Food for Humans and Animals, 5) Accredited Third-Party Certification Rule, 6) Focused Mitigation Strategies to Protect Food Against Intentional Adulteration Rule, and 7) Sanitary Transportation of Human and Animal Food Rule. Several of these rules are of interest in various sectors of the
brewing industry, but it is first important to understand the intent and basic structure behind each of these rules.

The Accredited Third Party Verification Rule was instituted to establish a program by which third-party groups could receive accreditation by the FDA to be allowed to conduct audits of foreign suppliers and manufacturers and issue the appropriate certifications to those that meet the FDA standards for human and animal food production. This program allows the FDA to ensure that the participating third-party entities are maintaining competence by disseminating the procedures and requirements necessary to do so for both accreditation entities seeking FDA recognition as well as certification bodies seeking accreditation [9]. The certifications earned through this program have two specific purposes under the FSMA. The first is that they are an easy way for importers to establish their eligibility for participation in the Voluntary Qualified Importer Program (VQIP), which allows importers to receive expedited review on their food products during entry. The second purpose is as a preventive measure utilized to help curtail the potential for unsafe food from reaching U.S. consumers. This allows the FDA the ability to require imported foods to be accompanied by an accredited third-party certification if they deem it necessary [9].

The requirements of this rule state that Accreditation bodies must assess the third-party certification groups through periodic observation of their work and work sites to monitor performance. Reports and records on these assessments must both be stored and be provided to the FDA. Third-party certification entities must ensure that their employees are aware and well versed of all procedures to be effective during routine unannounced facility audits and in addressing any corrective actions that may arise from issues identified during those audits [9].
Foreign alcoholic beverage manufacturers are largely exempt from mandatory import certification authority established by the FSMA [9].

The Foreign Supplier Verification Rule for Importers of Food for Humans and Animals sets a requirement on importers to perform specific risk-based actions to ensure that the products they are importing meet the same safety standards that are required for domestic products designated under the preventive controls and produce safety regulations [12]. Importers are responsible for the following actions, including but not limited to: determining known or reasonably foreseeable hazards (biological/chemical/physical) with each food, evaluating risk associated with the food based on hazard analysis and supplier performance (reevaluation occurring every three years or upon new information), determining and conducting supplier performance verifications, and conducting corrective actions. These actions require established written procedures that must be followed, and FSVP’s are required for each individual food that is imported and each supplier that the imports are inbound from [12].

Importers are able to perform the required evaluation and verification duties by designing their own programs that can be customized based on the supplier characteristics or inherent food risks and can include annual on-site audits, sampling/testing, and record review. If an issue is identified during oversight processes, appropriate corrective actions must be determined and enacted to address the situation. This is done on an individual basis, as the response will always need to be tailored to the specific circumstances of that particular instance [12]. This rule does not apply to alcoholic beverages and certain ingredients used in alcoholic beverages [12] provided that some specifics be met. The regulation does not apply to imported ingredients as long as: the consumer performs the manufacturing/processing, packing, or
holding of the alcoholic beverages for which the ingredients were used; the consumer is registered (required) as a food facility under Section 415 of the FD&C Act; and the consumer is exempt from the preventive controls for human food regulation in accordance with 21 CFR 117.5(i) (21 CFR 1.501(e)(3); 21 CFR 117.5(i)) [6].

The Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration requires risk-reducing strategies to be implemented for processes in certain registered food facilities. It was conceived as a prevention measure to protect the public from intentional adulteration acts that could cause “wide-scale harm” like illness/death or a major disruption to the food supply, such as the result of a terrorist attack [13]. Since the primary focus of this rule is on the potential for an event resulting in a widespread effect, it principally covers large companies (excluding farms) whom have a broad customer base. As of September 12 in 2018, there were 3,400 covered firms operating 9,800 food facilities (domestic and foreign) [18]. Any facility that falls under the umbrella of this rule is required to formulate and enforce a food defense plan that identifies vulnerabilities and actionable process steps, mitigation strategies, monitoring procedures, corrective actions and verifications, and enforces effective training and recordkeeping practices. The finalized defense plan must be reevaluated every three years or under certain conditions such as the identification of ineffective strategies [13].

Alcoholic beverages are exempt from this rule if they meet these two conditions: Under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.) the facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type
that would require such a permit, registration, or approval if it were a domestic facility; and
Under section 415 of the Federal Food, Drug and Cosmetic Act the facility is required to register
as a facility because it is engaged in the manufacturing, processing, packing, or holding one or
more alcoholic beverages [8].

The Sanitary Transportation of Human and Animal Food Rule was designed to keep
foods safe on their journey from farm to table. Similar to other rules, it is preventive in nature
and works to counter risky transportation practices such as inadequate cleaning of holding
areas, holding temperatures, or protective measures. This is managed by a set of requirements
that governs motor and rail carriers, shippers, loaders, and receivers involved in transporting
human and animal food. The same regulations do not apply to ship or air transportation due to
limitations in the law [14]. The requirements set forth by this part of the legislation set
standards for: the design and maintenance of vehicles and transportation equipment, adequate
transportation operations such that there are no contamination or temperature control issues,
proper training of all personnel, and proper maintenance of records (retention for no longer
than 12 months) [14].

While alcoholic beverages are not entirely exempt from this rule, some exemptions are
industry applicable and there are provisions that affect exemption status. Some exemptions
that may be industry applicable include, but are not limited to: shippers, receivers, or carriers
engaged in food transportation operations with less than $500,000 in average annual revenue;
any transportation activities performed by a farm; transportation of human food byproducts
intended for use as feed for animals that will not undergo further processing; and
transportation of food that is completely enclosed by a container (except those foods that are
temperature sensitive) [14]. As cited in a comment and response exchange during the formation of this rule, the final exemption previously mentioned essentially excludes packaged beverage alcohol products from coverage under this rule [14].

The Produce Safety Rule (effective January 26th, 2016) was a major change to food safety regulations as it not only encompassed multiple aspects, but it established for the first time a set of science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables that are intended to be consumed [15]. Regarding microbial water quality, new standards require that two criteria be met: no detectable generic *E. coli* present in water used for agricultural purposes (in which it is reasonably likely that dangerous microbes that could be present would be transferred to produce through direct or indirect contact); and water that is directly applied to growing produce must have a geometric mean of \( \leq 126 \) CFU and a statistical threshold of \( \leq 410 \) CFU per 100 ml of sample water [15]. If the unfortunate event arises that water is found that does not meet these standards, there is some flexibility in the required response time. Corrective action is mandated to be implemented as soon as is practicable, but must be done no later than the following year. The rule also allows for flexibility in how to meet the criteria for water use, such as ensuring an appropriate amount of time for microbes to die between the last irrigation and harvest, or between harvest and time of storage. Microbes can also be removed during commercial activities such as washing. Of course, treatment of the water itself is always an option [15]. The Produce Safety Rule determines the frequency of testing that is required for water sources based on their type. Untreated surface water is considered the most vulnerable and requires stricter testing than untreated ground water. Untreated surface water requires an initial survey using a minimum of
20 samples collected as close to harvest time as possible over a two to four-year period, after which five new samples are required each year. Untreated ground water requires an initial survey consisting of four samples collected in a similar fashion over a growing season or one year, and only requires a minimum of one new sample a year [15].

Biological soil amendments such as manure were of notable concern to the FDA due to the potential for several dangerous microbes to be transferred to produce destined for consumption. While there is still research being performed by the FDA on the topic of raw manure handling and applications, the current guidance is that compliance with the USDA’s National Organic Program Standards is acceptable. This set of standards from the USDA calls for a 120-day interval between raw manure application and the harvest of crops that come into direct contact with the soil, and a 90-day interval for those crops that do not [15]. Microbial limits on the detectable amount of bacteria have been established for processes that are used to treat biological soil amendments and as it stands currently, “a biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54” [15]. Both domesticated and wild animals pose risks to produce, and farmers are required to make reasonable attempts during the growing seasons to identify potentially contaminated produce through visual examinations, regardless of how the product is to be harvested. The FDA has been clear that there is no requirement to exclude animals from growing areas, or destroy their habitat [15].

Lastly, but of utmost importance, the Produce Safety Rule developed requirements for the training of workers on their health and hygienic practices, and the equipment, tools, and
buildings that are utilized throughout the processes they perform. These measures are intended to prevent contamination of working surfaces or produce by workers who may have a health condition, or have poor hygienic practices. Along with the proper training, it is essential that the proper facilities be provided to both workers and visitors so that cleanliness can be maintained and contamination kept at bay. Similar standards fall onto the equipment and tools utilized when performing the job, as well as the facilities for storage. They must all be properly cleaned and maintained to prevent contamination [15].

Hops are considered covered produce under the Produce Safety Rule, and farms that grow, harvest, pack, or hold hops are expected to comply with regulations unless they are otherwise exempt [16]. Interestingly enough, hops are still not considered exempt via being established as produce that is rarely consumed raw, since the FDA could not verify that: the commodity is consumed raw by less than 0.1 percent of the population; is consumed raw on less than 0.1 percent of eating occasions; and that consumption in any form – raw, processed, or other – was reported by at least 1 percent of a weighted number of survey respondents [5]. Hops that are to be used in the making of beer are eligible for exemption due to the brewing process being deemed to adequately reduce the presence of dangerous microorganisms of public health significance [5]. However, the covered farm is required to disclose in documents that accompany the hops being sold that they are “not processed to adequately reduce the presence of microorganisms of public health significance” [16]. Hop growers are also required to obtain written assurance from their customers, or their associates who perform the processing that they are following identified written procedures that do adequately reduce the presence of microorganisms of interest [16]. The drying of hops is considered part of the
Harvesting process and is not considered manufacturing or processing unless it creates a distinct commodity [16]. This rule does not apply to grains used within the brewing process including but not limited to: barley, oats, rice, rye, and wheat [15].

In 2013, the FDA proposed a new rule that would require facilities producing feed for animals to be subjected to similar regulations to facilities used in food manufacturing. This proposal was promptly identified by those in the industry as potentially oppressive, with major implications regarding the ability of breweries to provide local farmers with cheap sources of discounted spent grains/hops. In part due to how vague the proposed rule was, there was some speculation that the proposal could require costly investment by breweries to dry and package the grain, which would instead lead to breweries making the most cost-effective decision and dumping it instead of passing it on in a more sustainable fashion as a practical feed source [20]. There was concern among the ranks of the brewers as to why there was a need for the regulation in the first place; being that there was no evidence of any contamination or illness caused from these industry byproducts [20]. This would fortunately be addressed, as the legislation would be clarified on the way to its current iteration.

The aforementioned proposal would end up as the Final Rule for Preventive Controls for Animal food, published in September of 2015. This section of the FSMA designated that animal food facilities were required to have a food safety plan that takes into account an analysis of potential hazards, identifying those that may be good candidates for prevention via risk-based controls [7]. Any facilities covered under this rule must follow CGMPs for safe animal food production. These CGMPs are designed to provide flexibility throughout the extremely diverse array of food types [10]. If a processor such as a brewery is already implementing human food
safety measures (21 CFR 117.110) [4] and they are just holding by-product for use as animal food (for example, spent grains), they are not required to implement any additional animal food related control systems (21 CFR 507) [4]. If a human food facility processes a by-product for animal food (such as in drying, pelleting, or heat-treating, then the facility must do so in compliance with CGMP’s. Unless otherwise exempt, the facility will also need to determine through hazard analysis whether any hazards require preventive controls to be established [7]. Manufacturers are also responsible for ensuring any raw materials that they receive that have been through a supply-chain-applied control are brought in from approved suppliers and that any necessary verification activities have been addressed [10].

This rule includes but is not limited to the following preventive controls: process controls that ensure parameters are maintained during processing operations such as cooking or refrigerating, and sanitation controls to maintain sanitary conditions throughout facilities and handling procedures. To ensure the effectiveness of the determined preventive controls, there are requirements around the monitoring and verification of the corrective actions that are realized. It is also essential that every animal food production facility have a recall plan ready to go in case it is needed. As with earlier regulations, all of the previously described actions need to be documented [10]. Hop growers and brewer’s associations, along with wine grape producers have raised the concern that while they are aware they will receive an exemption due to processing, they still feel the requisite paperwork and recordkeeping practices mentioned above are overbearing for their operations [17]. While there has not yet been a change, the FDA is still investigating (as of 2018) whether or not it can allow exemptions for these recordkeeping requirements for certain commodities [17].
The Final Rule on Preventive Controls for Human Food is the last of the seven central rules that comprise the foundation of the FSMA. This section resembles some of the others that have been mentioned previously in its structure and as such, if a facility was required to register with the FDA under section 415 of the FD&C it is likely covered by this rule. Any facilities that are covered are required to perform hazard analysis to identify any that may require preventive controls to be written and enforced. Much the same as previous rules, the FDA has provided flexibility in allowing these control measures to be customized to the specific hazard and environment. Some controls that may be applicable for affected facilities include the following: process controls such as temperature regulation or acidification of food products, food allergen controls such as proper packaging, and sanitation controls such as safe handling practices [11].

As with similar actions in other rules, any preventive controls that are made effective must be monitored to ensure that they are acting to help alleviate the issue they were created to address. By verifying that the implemented corrective actions are effective in minimizing hazards, processors are able to consistently adhere to regulations and stay in compliance.

Requirements for this rule also follow suit to those in the Animal Feed rule. The requirements state the need for manufacturers to have a risk-based supply-chain program to identify and control any applicable hazards that may arise on the side of their raw material suppliers. It is acceptable for other entities within the supply chain to perform verification activities as long as the manufacturer ensures proper review and assessment of those activities [11]. Manufacturers are also explicitly required to implement written recall plans that include procedures to notify consignees and the public when necessary. These procedures must also describe how to properly conduct effectiveness checks and dispose of the tainted product. As
with previous rules, effective training on food safety principles and hygienic practices [11] are important in creating a healthy culture around best practices.

Brewing operations are affected by several provisions under the Preventive Controls for Human Food Rule, regardless of their size. All facilities manufacturing and holding alcoholic beverages intended for human consumption are required to properly train their staff on food safety and hygienic practices under 21 CFR 117 Subpart A. Under Subpart B 21 CFR 117.10 they are also required to implement CGMPs that address the following (but not limited to) specific sections: personnel, plant and grounds, sanitary operations, sanitary facilities and controls, defect action levels, holding and distribution of human food byproducts, equipment and utensils, processes and controls, and warehousing and distribution [4]. Industry participants are required to annually attest to their status as a qualified facility to the FDA and make sure to document it under Subpart D 21 CFR 117.201. Subpart F requires detailed documentation on proof of training (21 CFR 117.9) and provides a basic outline on the requirements for recordkeeping [4].

There are exemptions that may be applicable, if the facility can meet certain conditions. Subparts C and G do not apply to alcoholic beverages at facilities that meet two conditions that were previously mentioned under The Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration. The first of these two conditions is that, under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.) the facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type that would
require such a permit, registration, or approval if it were a domestic facility. The second of the two conditions states that if under section 415 of the Federal Food, Drug and Cosmetic Act the facility is required to register as a facility because it is engaged in the manufacturing, processing, packing, or holding one or more alcoholic beverages, an exemption is applicable [11].
**Project Methodology**

The targeted population and participating audience for this project and report are potential or active participants in the brewing industry and its supporting counterparts, as well as students within Food Safety courses. This project was conducted by exploring available print and digital resources on the Food Safety Modernization Act and reviewing them for information regarding their effects on the brewing industry and its supporting counterparts. This project also reviewed resources regarding the statistics on the economic impact of the industry within the state of Virginia, and the uses of byproducts of the industries manufacturing processes.

**Discussion and Recommendations**

*Discussion of Project Outcome*

In the initial years following the signing of the FSMA, poorly detailed regulations led non-government bodies to do their best to gather and interpret information for those in the affected industries. In situations where guidance had yet to be received, there was some difficulty in tracking down knowledge bases on achieving compliance from resources industry participants could be comfortable in trusting, as it may not have been clear what sources of information among the slew of associations and blogs had been reviewed for completeness and accuracy. Now that there has been progress made with clarifications on regulations directly from the FDA, some aspects regarding the rules are better understood, but it has sometimes taken considerable lengths of time to achieve concise interpretations and there have even been
some updates to guidance while work was being performed on this project and report. Overall, I found that the available resources describing the applicable regulations that could be found directly from the FDA were more robust than what I had initially expected and not terribly hard to digest. There were not industry specific resources available with examples for achieving compliance with such things as HACCP plans.

While there were still helpful items on their websites, some groups like the Brewers Association and the Master Brewers Association of the Americas have a sizeable portion of their educational resources locked behind a paid membership. Some areas of these websites are outdated, such as the page on Food Safety on the MBAA’s website, which has not been updated since 2017. The Hop Growers of America have a couple of resources that are at least up to date, but things like the new risk assessment module that is part of the new ‘Good Bines’ best practices program that the HGA just rolled out earlier this year are also locked behind a paid membership. While I believe it is reasonable to assume that those that are already involved in the industry would have membership to these groups or other access to comparable resources, this could present challenges for potential industry participants who may be seeking guidance with some specificity, as that granularity is not always available directly from the FDA.

While they have some shortcomings, the resources mentioned above (along with others) are some of the best available for aspiring industry entrants albeit with varying degrees of free information. These are listed below with a short description of their contents:

- Virginia Cooperative Extension: Educational outreach program of Virginia’s universities Virginia Tech and Virginia State University and part of the National Institute of Food and Agriculture (an agency of the Department of Agriculture). The
association website has presentations, publications, services such as analytical lab analysis and soil testing, and identification of pests and diseases. No membership required. Accessed at https://ext.vt.edu/agriculture/commercial-horticulture/hops.html

- Hop Growers of America: Trade organization with primary focus on Grower Support, Statistics and Trade Promotion, and Education. The association website has resources on breeding, plant health, plant protection, various publications, training programs and more. Some resources are locked behind paid membership. Accessed at https://www.usahops.org/

- Master Brewers Association of America: Organization with the purpose of promoting, advancing, and improving the professional interest of brew and malt house production and technical personnel. The associate website has safety program templates, podcasts, webinars, and food safety resources. Many of these resources are locked behind paid membership, and some out of date convention and seminar data is present on the website. Accessed at https://www.mbaa.com/Pages/default.aspx

- Brewers Association: American trade group of over 7,200 brewers, and others involved with the promotion of craft beer and home brewing. The association website has resources on available schools, degree and certification programs, training seminars/workshops, publications, and helpful national and state statistics and data on various topics such as economic impact and sales data. Many of these resources are locked behind paid membership. Accessed at https://www.brewersassociation.org/
**Recommendations**

Considering that the brewing industry and its supporting counterparts have such a large economic footprint within the State of Virginia, it is important to make available all of the necessary resources to potential industry participants or those already involved in the sector. There is some benefit to having resources that do not require a paid membership, so those that may be expressing interest in becoming an active participant in the industry are not deterred from doing so. At the same time, it is also important to drive sustainable practices and there is a huge opportunity within the handling of brewing byproducts. There is value in future research on utilizing these byproducts in a sustainable manner such as in human food, and setting up resources for brewers and those that desire to utilize their byproducts to make it easier for both parties to interact with each other so that these valuable byproducts are not going to waste. There is also value in identifying the shortcomings of the rollout process of the FSMA, so that the same mistakes are not repeated in future regulatory endeavors.
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