

## Federal regulations and product liability in the alcohol industry

Aditi Ramesh  
Clifford Fisher

Purdue University, Indiana, USA

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### Abstract

*An alcohol manufacturer or a commercial alcohol maker produces alcohol beverages for the general public of a given society. As with any product, there follows certain liabilities of which the manufacturer must be aware. From labelling products to misinforming consumers via false or exaggerated advertising, there are lawsuits that hold the manufacturers liable for damages. Tobacco industry is akin to the alcohol industry, where there are similar regulations that are in effect, in order to maintain a certain integrity of the industry. With strict regulations, the number of manufacturers that maintain a high standard of products increases, thus resulting in a well-balanced, prosperous market.*

### Introduction

The alcohol industry is extremely strong and highly concentrated. With various mergers and acquisitions occurring in large firms throughout many countries, it is essential for a business in the industry to learn about the various legal regulations in that country prior to implementing any important strategic decisions. The alcohol industry in the United States of America has a strong base of consumers, which attracts businesses to the country and encourages many small owners to start their own businesses in the industry. Given the nature of the product, alcohol has several legal risk factors associated with it, starting with the legal drinking age, lucrative advertising of the various brands of alcohol, and further continuing into the alcohol concentration listed on the bottles. Although an alcohol manufacturer need not worry immensely about consumer behavior, it is essential to learn such behavior in order to drive sales and improve reputation in the industry.

Alcohol is a product that has the potential to be misused, and though manufacturers cannot be held liable for most consumer actions, it is highly recommended that companies be aware of the potency and the nature of the product, followed with its effects on the consumer. One might assume that alcohol products are not often targeted with product liability lawsuits, like other consumable goods. Alcohol products are only accessible for purchase by persons of legal age, and it is standard that these persons are of the rational mind and accept the risks and consequences that follow the consumption of these products. Even though alcohol is mass produced, similar to any consumable popularly demanded by the public, the regulations keep the product and the manufacturing process in check.

With clear and detailed analysis of federal and state regulations, along with various product liability statutes and precedents, this paper will guide current manufacturers and potential entrants through the current state of the alcohol industry. There will be significant parallelism between the alcohol and the tobacco industry, for the tobacco industry has been highlighted with various product liability lawsuits throughout the decades.

### Hypothetical

The following hypothetical shall aim to shine some light on how the alcohol regulations apply for both startup firms and large firms. This will also demonstrate the potential product liability concerns that must be accounted for in the industry. The arguments presented, followed by the analysis, will provide different perspectives and guide any current or potential businesses in the present state of the alcohol industry.

RiverMills is a large European firm that has had tremendous growth during the past decade as its brand of alcohol is well known and well liked throughout Europe. After some research, the CEO decided to export some alcohol to the United States, in order to scope out for potential demand for the brand. Based on the success of the sales of the River brand, RiverMills would gradually expand further in the USA market. The CEO further plans to open up either an individual, independent company in this market, or a branch of RiverMills. The River brand contains various types of alcohol beverages, ranging from beer, wine and spirits. The brand also started manufacturing other fermented beverages, like Kombucha, recently. This type of beverage is meant for health-conscious consumers, as the drink is usually made of fermented tea and sugar. The CEO has observed a high demand for fermented beverages in the US market, due to an increase in good health awareness, and aims to increase the production of this beverage.

Previously in Europe, RiverMills has been involved in a few product liability lawsuits concerning a few alcohol regulations. These lawsuits entail labeling and advertising the product, along with the purity levels of ingredients used to produce the alcoholic beverage. During one of the advertising campaigns, River Mills didn't display the accurate amount of alcohol percentage in the product and instead, focused more on targeting the audience's taste for alcohol. The concentration level was also misrepresented in the product labels, and River Mills had to recall the particular batch affected. Due to heavy media intervention, the CEO of River Mills made sure to settle these lawsuits quickly and improved the advertising and labelling standards of the products, prior to potential entry into the US market. The company has decided to seek legal advice before pursuing into the US market, in order to evaluate this strategic choice.

### **Federal Regulations**

Any alcohol manufacturer producing, packaging, selling, importing/exporting alcohol beverages in the United States must abide by the strict regulations and codes placed by the Alcohol and Tobacco Tax and Trade Bureau. River Mills must pay attention to the federal regulations placed in the alcohol industry, which are intended to benefit both the businesses and the consumers.

In such a perilous industry, where the manufacturer could potentially have immense liability and where the consumers' health is at risk with the consumption of the alcohol, the Department of Treasury steps in with the Alcohol and Tobacco Tax and Trade Bureau. The Bureau collect taxes on alcohol, tobacco, and firearms and ensures that all federal policies and regulations are met. The Federal Alcohol Administration Act (FAA) was established to provide regulations in order to protect both the manufacturers and the consumers in the alcohol industry. These regulations are enforced by the Alcohol and Tobacco Tax and Trade Bureau (TTB) to prevent unfair trade practices in the industry by regulating promotional events, consignment sales, and related practices.

The FAA Act ensures protection of the industry by thoroughly checking the businesses and individuals and ensuring that potential entrants adhere to the integrity standards set within the industry. The Act authorizes refusal to grant entrants' access to the industry if they do not follow the regulations. The Act provides for the issuance, revocation, and suspension of licenses, and can authorize TTB to penalize any alcohol manufacturer that does not adhere to the regulations. Hence, every business in the alcohol industry is completely scrutinized from the moment of entry into the alcohol market, and the behavior and actions of these businesses monitored regularly in order to avoid any legal complications, which could potentially harm either the businesses or the consumers.

The FAA Act ensures protection of consumers by ensuring the accuracy of advertising and packaging, so consumers are clearly informed at all times while consuming the product. Misleading labeling and/or advertising can lead to severe legal penalties. The alcohol bottlers and importers must abide by COLA, which stands for Certificate of Label Approval, before the product can be sold in the United States. This applies equally to both imports and locally manufactured products. Before passing the COLA requirement, the alcohol manufacturers or importers must pass the pre-COLA test. This test ensures that each ingredient present in the alcohol bottle or container is legally permissible and that no prohibited ingredient is present in the process of making alcohol.

Laboratory tests are also conducted in order to test the chemical analysis of the alcohol composition and to ensure that the composition is not harmful for consumption. After finalizing the permissible alcohol concentration, the manufacturers or importers must apply for COLA certificate. This certificate proves that the manufacturer (or importer) has gone through all the legal stages of ensuring that the product has passed the tests for permissible consumption and that the manufacturer will advertise the product using correct information with regards to concentration of the alcohol content.

The Bioterrorism Act pertains to the alcohol industry by including provisions for alcohol beverages. Under this law, the provision 'food' includes alcohol products and beverages, and manufacturers, especially importers, must take measures to abide by this act. Domestic and foreign manufacturers that produce, process, pack or hold 'food substances' must register with the Food and Drug Administration (FDA) before beginning the action of manufacturing. Importers must deliver official notice of the date of import either to the Customs and Border Protection or the FDA. The manufacturers also must maintain a clear record of non-transport sources and recipients of food and must allow full inspection authority to the FDA. Under the act, the FDA has full authority to seize any food item if it deems it to be suspicious of posing a serious risk to health of the consumers.

River Mills must comply with all the above regulations when entering the United States market. Since the firm has experience of manufacturing and selling alcohol, there won't be strict scrutiny of the manufacturing process of the product. However, based on the past mishaps regarding labelling and advertising, River Mills must be cautious of implementing warnings and preventing the marketing department from only focusing on making the advertisements lucrative to consumers. Currently, River Mills might not be allowed to enter the United States market, based on the seriousness of allegations against the manufacturer for misinforming the consumers and/or withholding information. If the Bureau requires a record of manufacture of beverages where no law is overstepped, the firm might be able to sell their products in the United States market, subject to the discretion and authority of the Bureau.

### **Product Labelling and Advertising**

In the alcohol industry, labelling the products precisely is extremely important. As with any consumable product, it is necessary for the consumers to be aware of the ingredients before deciding to consume such product. Advertising also plays a big role in spreading awareness of the potential risk to the consumer's health, albeit indirectly. Many advertisements are generally focused on attracting new target markets and keeping the current market as loyal as possible. With products such as alcohol and tobacco, advertisements can be complicated to manage.

Generally, many consumers in the alcohol and tobacco industry are young adults or teenagers, who have limited knowledge or awareness regarding the risks of consuming these products. Some are not aware that different types of alcoholic beverages could have different alcohol concentration ratio. There are a few cases regarding alcohol poisoning, where the plaintiff has alleged the manufacturer due to the product causing this injury as in *Pemberton v. American Distilled Spirits Co.* The allegation was that the alcohol poisoning was caused due to a high concentration of the alcohol content in the product, which posed unreasonable risk to the consumer's health. The Tennessee Supreme Court stated the Restatement (second) of Torts § 402A, and argued that alcohol has always been known as a toxic, evil consumable good in society, and thus a normal consumer would be aware of the risks to health, prior to consumption of the beverage.

In *Brune v Brown Forman Corp.*, however, the outcome was different. An 18 year old student died from alcohol poisoning, after consuming various shots of Pepe Lopez Tequila. The main claim stated in the lawsuit was regarding the issue of alcohol consumption awareness amongst young adults. Although it is common knowledge that alcohol is an inherently dangerous consumable product, many young adults and teenagers are unaware of the dangers of consuming huge quantity of alcohol in a short amount of time. The courts used the Restatement (second) of Torts § 402A and claimed that although the 'common knowledge' provisions protect the alcohol manufacturers, information regarding alcohol poisoning and the lethal amount of alcohol consumption is not widely known or would be known by an ordinary, reasonable consumer. Manufacturers producing alcoholic beverages that contain a higher concentration of alcohol must provide additional warnings regarding such risks of consumption.

As River Mills had a similar issue with mislabeling and misinforming the consumers about the wrong concentration levels, it must account for revisions in its current labelling process, if the firm aims to not have further lawsuits in the near future. The firm must always provide sufficient warning and clearly state that the consumption of the alcohol beverage is subject to the discretion of the consumer and that the beverage contains ingredients that pose serious health problems.

In both alcohol and tobacco industry, labelling and advertisements go hand in hand with informing the public about the risks of consumption of such products. The purpose of the Federal Cigarette Labelling and Advertising Act (15 USCS § 1331) was to establish a comprehensive federal program in order to link cigarette labelling and advertising with smoking and health. The public had to be informed of the adverse effects on health via smoking, and thus warning labels were placed both on cigarette packages and any media of advertisement (billboards, TV commercials, newspapers and magazines advertisements). This provision was set to ensure that the labelling and advertising of the tobacco products remained consistent throughout the industry and that the standards of tobacco industry remained high and that the total welfare of the industry would not succumb to the various health liability claims by tobacco consumers.

The additional provisions under the Act (15 USCS § 1333) further states the specific requirements for the labelling of tobacco products (cigarettes). The packaging and any modes of advertising must contain at least one of the following warnings.

WARNING: Cigarettes are addictive.

WARNING: Tobacco smoke can harm your children.

WARNING: Cigarettes cause fatal lung disease.  
WARNING: Cigarettes cause cancer.  
WARNING: Cigarettes cause strokes and heart disease.  
WARNING: Smoking during pregnancy can harm your baby.  
WARNING: Smoking can kill you.  
WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.  
WARNING: Quitting smoking now greatly reduces serious risks to your health.

The Alcoholic Beverage Health Warning Statement (§ 16.21) states that the on any front, back or side label that is to be placed on the alcoholic beverage, beside all other relevant and important information, the warning statement must be mentioned.

The statement reads as: 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.(27 CFR 16.21)

The tobacco manufacturers thus have a choice between any of the 9 given warnings, to be used on their products. One might argue that this could be beneficial to both the consumers and the manufacturers. If only one warning is issued on each product and each advertisement, consumers tend to ignore the warning. Since alcohol manufacturers have only one government issued warning, even if the warning is provided on the packaging and in advertising, there could be more claims against the manufacturer from consumers who would have overlooked the warning. For both tobacco and alcohol manufacturers, the Restatement (second) of Torts § 402A protect the firms from liability claims, by utilizing the 'common knowledge' test.

RiverMills must observe the advertising of the tobacco manufacturers and compare it with the alcohol industry. With the difference in issuing warnings, if multiple warnings regarding the health of the consumers is mentioned, as in the tobacco industry, the consumers might still ignore the warning or pay attention to it. However, RiverMills would have completed its duty of informing the consumers and covered its tracks by placing different types of warnings in different media of advertising, along with the labelling of the products.

### **Alcohol consumption and health concerns**

Alcohol consumption has always carried enormous weight in the field of health and safety. There is the stereotypical nature of alcohol inhibiting rational choices and encouraging rash actions amongst people. Even though there are other products similar to alcohol beverages, such as tobacco and drugs, the evils of alcohol poisoning is viewed as a more precarious symptom as opposed to the counterpart products. The other spectrum of alcohol consumption praises the quality of alcohol to enhance the health of an individual, if an alcoholic beverage is consumed in moderation. Alcohol manufacturers might assume that they need not worry about the consequences of their beverage consumption by their consumers, so as long as adequate warning is aforementioned. However, there have been various lawsuits where the plaintiffs have sued the manufactures as they alleged the manufacturers were liable for damages, after theconsumption of the beverage(s).

In *Victory over Addiction Int'l Inc. v. Am. Brands Inc.*, the plaintiff claimed that the alcoholic products manufactured by the various distilleries, breweries and wineries had aided him in his alcoholism. These manufacturers knew or should have known of the dangers of the nature of the product. The plaintiff requested remedies and restitution of about \$100 million. Both the district court and the court of appeals declared that the plaintiff had no legal standing. The alcohol beverages are intended for human consumption; certain ingredients could pose harm to the consumer, but only after repeated and/or excessive use of the product. This would hold true for any consumable product, not just alcohol.

The human body is not designed to withstand multiple amounts of any consumable 'food' item in a short period of time. Manufactures of alcohol (or any consumable) product are only liable if they were aware of a defect in the product that could bring about harm, or if one or more of the ingredients are unreasonably dangerous for human consumption. Restatement (second) of Torts § 402A revolves around this fact that manufacturers that sell defective goods and are aware of the defect, are in fact liable for damages.

Common law also states that commercial manufacturers of alcohol owes no duty of care regarding the well-known and highly functional ingredients, intended to make the product the way it is. Grapes are usually one of the key ingredients of wine; wineries are not obligated to list the potential 'harmful' aspects of consumption of grapes. Every consumer is aware of grapes and it is common knowledge that the grapes are fermented to become an alcoholic beverage.

In *Garrison v. Heublein, Inc.*, a plaintiff similarly filed a suit against an alcohol manufacturer for damages from consumption of Smirnoff vodka over the span of 20 years. The plaintiff alleged that the manufacturer failed to establish the dangerous nature of the product, especially on the consumer's mental and physical health. The District Court and the court of appeals held that the alcohol beverage's potential harm is well known to the public, and the consumption of alcohol, albeit in moderation or in excess, is up to the consumer's discretion.

In *Kenneth Hulsey v. Am. Brands Inc.*, addiction is used as a basis for claim by the plaintiff. He claimed that the manufacturers had withheld the addictive nature of tobacco and tobacco products. The district court held that the Federal Cigarette and Labelling Act preempted this claim, because claims based on fraudulent concealment were preempted by 15 U.S.C.S. § 1334(b). The district court also found that according to Tex. Civ. Prac. & Rem. Code Ann. § 82.004, there is no product liability for the manufacturers if the product is well-known by ordinary consumers to be harmful. These are a few of the many lawsuits present, regarding the consumption of alcohol and any potential 'adverse affects' it might have on the consumer's health. Although in many of these lawsuits, the courts have struck down consumers' claims and allegations, it is essential to be aware of these statements. The firm's business can be drastically affected by these claims, even when there is no liability from the alcohol manufacturer.

Consumers are more likely to use addiction as a means of seeking remedy; however, if manufacturers are following the federal regulations and codes placed for the purpose of maintaining the quality of products, such allegations will not be considered by the legal system. The manufacturers must also not use the provisions under Restatement (second) of Torts § 402A, as a means of escaping liability. Product liability is still accounted for, if the concentration of alcohol is reasonably higher than other alcoholic beverages. Manufacturers must then proceed to warn the consumers of the risks and potential danger to their health, before consuming the beverage.

### Conclusion

The federal regulations have been very clear and concise, and the instructions for filling out the forms and applications for licenses are directional and easy to follow. The businesses in the alcohol industry have the regulations to thank, for without which there would be numerous product liability lawsuits that would drain the net revenue of the entire industry in the long run. The current, completely established businesses in this industry have followed these regulations and hence, have maintained the integrity standard as intended by the FAA Act.

Furthermore, if lawsuits were to entail, strictly following regulations and guidelines would allow RiverMills to shift the burden of responsibility onto the consumer and prevent liability on their part. RiverMills must also refer to the tobacco industry in order to evaluate certain precedents about product liability lawsuits; when a company is held liable for the actions in advertising and labeling. This parallelism will provide a good indicator and foreshadow any potential lawsuits RiverMills might get involved in.

RiverMills must contact the Bureau and find out if the previous mishaps in advertising and labelling would prevent them from entering into the United States market. The Bureau would have to conduct a thorough investigation, nevertheless, and the firm can only enter the industry with the Bureau's permission. If RiverMills can provide sufficient data and reports regarding its reformed behavior in enhanced labelling and issuance of warnings to the general public, the Bureau might be inclined to oversee the previous mistakes and welcome the firm into the market. A firm as successful as RiverMills will enhance the industry's welfare, and this shall be considered and weighed heavily by the Bureau.

RiverMills can also utilize the aid of the TTB's Alcohol Beverage Advertising Program, which screens the advertising content in accordance with advertising and alcohol regulations. There is no cost to using the program, hence RiverMills would be wise to utilize this beneficial provision for a few marketing campaigns. With time, the firm would obtain a clear picture of sending a message to their consumers, along with the promotion of their specific brand of products.

If the entry of the firm into the United States market proves to be successful, it is wise to open a branch of RiverMills in the market rather than a small individual firm. As discussed previously, the alcohol industry maintains a high standard of integrity, and only firms that have prospered for a long time will be respected by both the consumers, competitors and the Bureau. It would be challenging for a smaller firm to start up an alcohol manufacturing business, in a market that is thoroughly concentrated by multinational companies. RiverMills already has a good brand name, and with consistent good performance, it can use its brand name to promote further sales in the United States market.

With regard to 'healthy' beverages that contain alcohol, such as fermented tea or Kombucha, further research must be conducted. The Bureau heavily insists that the labelling be accurate for such beverages. Any concentration of alcohol above 0.5% calls in for the regulations enlisted by the TTB to be implemented on the product. For the concentration of alcohol lower than 0.5%, the product must pass through the screening as commended by the FDA. Since the market for Kombucha is relatively new and especially niche, it is advised that RiverMills must thoroughly research the specific requirements that the Bureau insists in order to maintain a standard for regulations. Regardless of the level of alcohol concentration in this fermented beverage, the product must be manufactured in a TTB enlisted premises, complying with all the standard regulations set by the Bureau.

The regulations overall in the industry are adequate for protecting the welfare of consumers and businesses alike. Although one might think that the lack of product liability lawsuits reflects on the industry's prosperity, in fact, it is beneficial for the industry and the businesses within to have almost no product liability claims. If such claims were to fall on a business, it is easy and efficient for the courts to refer to these regulations without much confusion. The alcohol industry's well-being is protected and businesses can continue to prosper for a long period of time.

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