

CRAFT BREWERY HACCP: PREREQUISITE PROGRAMS BASED ON GOOD MANUFACTURING  
PRACTICES DEVELOPED FOR BOULEVARD BREWING COMPANY, KANSAS CITY, MO.

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## **Abstract**

The brewing industry has, historically, had little food safety regulation. In response to the September 11<sup>th</sup> attacks, new legislation culminating in the Food Safety Modernization Act of 2010 was established and reinforced food safety regulations for the brewing industry. Under this expanded regulation, breweries are required to comply with the modernized Current Good Manufacturing Practices (cGMPs). The regulatory climate for the brewing industry is very complicated. The brewing industry is regulated primarily under the jurisdiction of the Alcohol and Tobacco Tax and Trade Bureau and the Food and Drug Administration. Based upon the regulatory environment and business considerations, Boulevard Brewing Company has opted to develop a Hazard Analysis and Critical Control Point (HACCP) plan. Before a HACCP plan can be implemented a foundation of prerequisite programs, based on the FDA's cGMPs, must be in place. Prerequisite programs establish the operational and environmental conditions required for a successful HACCP plan. Failure to comply with the cGMPs can lead to fines, re-inspection fees, forced recalls, and possible criminal prosecution. Prerequisite programs were developed for the following areas: facilities, including sanitary design principles, utilities, traffic and product flow; production equipment, including preventive maintenance and calibration; receiving, warehousing, and shipping, including supplier control, chemical control, and raw material testing; pest control for insects, rodents and birds; cleaning and sanitation under a Master Sanitation Schedule; specifications, including ingredients, products, and packaging materials; personal hygiene for both employees and visitors; and lastly a system of traceability and recall. These prerequisite programs, based on cGMPs, are required to ensure regulatory compliance while minimizing regulatory and fiscal risks.

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## **Dedication**

I would like to dedicate this work to my Loving wife Anne who has supported me through this entire endeavor while shouldering the burden of working, organizing the chaos that is our household, and surviving a heart attack; and then bearing our beautiful twin boys. Also, to my children Thomas, Andrew and Nathaniel who understand that Daddy is studying. I'm done Boys! Let's go camping!

## Preface

This report contains 14 self-contained Standard Operating Procedures (SOP's) designed to establish the prerequisite programs to act as a foundation for a Hazard Analysis and Critical Control Point (HACCP) or Hazard Analysis Risk-Based Preventive Control (HARPC) Plan. The prerequisites are based upon the most up-to-date understanding of Current Good Manufacturing Practices (cGMPs), as established by the Food and Drug Administration and industry experts. The prerequisites do not confer any specific job functions or operations. They are designed to provide a framework in which job instructions and individual task instructions can be written properly to encompass the concepts and objectives defined in the cGMPs.

The 14 SOP's can be read as stand-alone documents or, as they are presented here, as a comprehensive series of foundational documents for a successful written food safety program. Accordingly, the General SOP 05-References encompasses all supporting documentation for all 14 SOP's. The references section that contains every reference used in the entire document including the Preface, Introduction, and Conclusion. The individual SOP's contain sections defining the references used in that particular document. The individual SOP's are also cross referenced to each other. All internal references to individual SOP's are underlined in the text to highlight their location.

This work is the establishment of the framework for a foundation of an effective food safety program. Further development of the individual tasks required to implement these prerequisite programs still needs to be done. Once the individual tasks are implemented and effectively in place a hazard analysis of the facility needs to be completed before implementing a risk prevention program such as a HARPC or a HACCP plan. The further development work is outside the scope of the report.



## Introduction

Craft Breweries are a difficult class to define. The microbrewery movement began in the late 70's (Microbrewery, n.d.). As microbreweries started to grow in popularity micro-brewing morphed into the concept of craft-brewing to encompass the concept of brewing as a craft (Microbrewery, n.d.). There are no hard and fast rules defining what is and is not a craft brewery. The Brewers Association, an organization of over 2000 breweries and more than 43,000 home-brewers founded in 1942, has the following definition of craft brewers (Purpose & History, 2014). A craft brewery is a small, independent, and traditional brewer whose hallmark is innovation (Purpose & History, 2014). Overall the annual production of all craft breweries is less than 6% of the total beer sales in the U.S. (Craft Brewery Defined, 2014). Craft brewers are traditional brewers of beer and specialty beer (Craft Brewery Defined, 2014). The Brewers association does not consider flavored malt beverages (FMB) to be beer even though the FMBs do meet the definition of the federal government for regulatory purposes (Craft Brewery Defined, 2014; USGPO, 2014f). Craft brewers are independent and innovative brewers re-interpreting old styles and developing unprecedented ones (Craft Brewery Defined, 2014). In keeping with the spirit of independence, two major craft breweries joined to gain market share and maintain the high quality of their product in the face of competition from large scale breweries (Alstrom, 2013). In mid-October of 2013 Brouwerij Duvel Moortgat (Duvel), a traditional Belgian craft brewer with over 127 years of experience, bought Boulevard Brewing Company, Inc. Kansas City, MO. to combine their experience and respected brand equity (Alstrom, 2013). As loose as the definition may be, Boulevard Brewing Company defines what a craft brewery is.

Brewing is an old art that has been around for 9000 years, and possibly more (McGovern, Zhang, Tang, Zhang, Hall, Moreau, Nunez, Butrym, Richards, Wang, Cheng, Zhao, and Wang, 2004). Chemical analysis of traces found on archeological artifacts indicated the brewing of grain based alcoholic beverages between 6600-7000 B.C. in a Neolithic village in Henan province, China (McGovern, et. al., 2004). The beverage was probably brewed from rice or millet and yielded anywhere from 10-15% alcohol (v/v) (McGovern, et. al., 2004). Evidence of brewing is almost as old in the Middle-East, as archeological and pictographic evidence of extensive brewing in ancient Babylon, Egypt, and Mesopotamia dates from 2500-5000 BC (McGovern, et.al., 2004). Calcium oxalate, or beer-stone, was isolated from Neolithic sites in the Middle-East and found to be chemically identical to beer-stone found in current brewery operations (McGovern, 2014). Calcium oxalate is a by-product of barley beer production (McGovern, 2014). Medieval brewers produced beer closer to what we know of as beer today. The brewers produced a barley beer with the primary change being the addition of hops

(Maddocks, 2001). Hops were written about as early as the 9th century but it was, traditionally, St. Hildegard of Binden who is credited with adding hops to beer in the 12<sup>th</sup> century (Maddocks, 2001). No discussion of beer history would be complete without discussing the Reinheitsgebot or German beer purity law of 1516 (Eden, 1993). The law established that only water, barley, and hops could be used to make beer (Eden, 1993). It was not until Louis Pasteur discovered the role of yeast in the fermentation process that yeast was added to the Reinheitsgebot in the 19<sup>th</sup> century. Modern beer was developed using the scientific understanding of brewing chemistry to bring about changes. In the 1700's English brewers developed India Pale Ales (IPAs) by adding more hops and starting with a higher specific gravity in the wort, then fermenting until the beer had a higher alcohol content, 5-7% (v/v), and the sugar had been mostly attenuated out of the finished beer (Vriesekoop, Krahl, Hucker, & Menz, 2012). The industrial revolution brought about consistency and low cost associated with mass produced beer. The craft brewing movement started in the last 40 years wherein Boulevard Brewing Company started 25 years ago in 1989 (Microbrewery, n.d.).

The brewing process imparts the characteristic flavors and anti-microbial properties associated with beer (Menz, Aldred, & Vriesekoop, 2009). The first step in the brewing process is malting of the barley. The malting process is described in the ingredients section below. The next step is preparation of the wort. The first step in wort preparation is milling. Milling is recipe dependent. Depending on how the grain is purchased it may come pre-milled; however, most grains used at Boulevard require milling. Once the desired grains are milled they are put in the mashing tun along with water and any flavorings. A tun is a brewing word for tank. In the mashing tun the grains are heated up to optimal enzyme conditions for the conversion of starch to sugar and proteins into amino acids (Wunderlich & Back, 2009). The mash will start at 40-45°C for various proteases, then cooked at ~65°C to optimize the  $\alpha$  &  $\beta$ -amylase activity, then the mash will go to the lautering tun (Wunderlich & back, 2009). The mashing step is very complex with some breweries using 10-15 thermal plateaus to optimize certain enzyme activities and denature others to extract specific flavor profiles (Wunderlich & Back, 2009; Janson, 1996). After mashing the wort drops to the lautering tun. Lautering is simply filtration using the spent grain as the filter media. The spent grains will then be sparged. Sparging is a hot water rinse in the lautering tun to extract more sugars from the spent grains. The next step is brewing or also known as the kettle boil. This process kills microorganisms, coagulates proteins, and denatures the enzymes (Wunderlich & Back, 2009). Hops is added at the brew kettle and this is where the alpha acids are converted into the desirable iso-acids useful for adding bitter and antimicrobial properties (Wunderlich & Back, 2009). Once the brewing is completed the wort is clarified using a whirlpool

clarifier, a large in-process centrifuge, and then cooled down to the ideal propagation temperatures of the desired yeast species (see the ingredient section below). The wort then goes into the fermenter. The wort has to be carefully aerated prior to pitching the yeast (Wunderlich & Back, 2009). Oxygen is critical for yeast propagation in the initial stages of aerobic growth in the fermenter (Wunderlich & Back, 2009). Along with the yeast, any flavors and dry hops are added. The fermentation starts with aerobic growth to increase viable cells, and then quickly converts to anaerobic alcohol fermentation of glucose into carbon dioxide and ethanol. Once the beer has completed the fermentation process, the green beer as it is now called, must age. Ageing allows precipitates to settle and complex flavor development to occur. At this point some beers will undergo filtration. Some beer types, like unfiltered Belgian wheat beers, do not. The next step is bottling or kegging. The finished beer is bottled into clean containers with the addition of priming sucrose and yeast. This extra sugar and yeast allows secondary fermentation to consume residual oxygen and produce carbon dioxide for carbonation inside the container. It is critical to adjust the priming sugar to match the desired finished carbon dioxide content. Too much and there will be an overabundance of carbon dioxide which can cause bottles to explode or have an excess of fermentable sugars left in the bottle removing one of the anti-microbial hurdles (Menz, et. al., 2009). Too little sugar will remove the anaerobic hurdle and leave flat beer (Menz, et. al., 2009).

The ingredients in beer are responsible for its unique flavor, nutritional, and antimicrobial properties. The ingredients included in this review are barley, the adjunct grains, flavorings, hops, water, and yeast. This review will only include European barley based malt beverages. The various rice, millet, sorghum, or corn based fermented drinks from around the world will not be considered. Taking a cue from the Brewery Institute, I will not be considering flavored malted beverages as beer (Craft Brewery Defined, 2014).

The primary dry ingredient in beer is barley. The predominant varieties being 2-row and 6-row barley (Wunderlich & Back, 2009). The Germans prefer 2-row barley for its higher extract content (Wunderlich & Back, 2009). Barley used to make beer is both malted and un-malted. Malting is the partial germination of the barley kernel to release enzymes that will breakdown the barley starch and proteins in the endosperm to release fermentable sugars and amino acids necessary for yeast metabolism (Wunderlich & Back, 2009). The straight chain amylose and the branched amylopectin found in barley compose 20-25% and 75-80%, respectively, of the starch found in the barley kernel endosperm (Jane, 2000; Wunderlich & Back, 2009). The amylose contains  $\alpha$ -1-4 glycosidic linkages which are randomly broken by  $\alpha$ -amylase (Jane, 2000; Henderson, 2000). By contrast the  $\beta$ -amylase, which is

produced only by higher plants, releases successive maltose units from the non-reducing end of the polysaccharide chain (Henderson, 2000). The amylopectin contains the  $\alpha$ -1-4 glycosidic linkages of amylose but also contains the  $\alpha$ -1-6 glycosidic linkages that form the branch structure of the carbohydrate (Jane, 2000). The combination of  $\alpha$ -amylase and  $\beta$ -amylase can, almost quantitatively, convert starch to maltose, even though neither enzyme acts on the  $\alpha$ -1-6 glycosidic linkages found in amylopectin (Henderson, 2000). The resultant wort, the sugar water made from grain that is fermented to make beer, contains 8-10% glucose, 46-50% maltose, 12-18% maltotriose, and the remaining 25-35% contains un-fermentable carbohydrates such as amylopectin, cellulose, dextrans, and oligosaccharides (Henderson, 2000; Jansen, 1996). The remaining un-fermentable carbohydrates give malted barley its distinctive sweet flavor (Wunderlich & Back, 2009). Amino acids are essential for yeast propagation and fermentation, and are released during the mashing and boiling steps (Janson, 1996; Wunderlich & Back, 2009). Free amino acids are released by enzyme action and heat denaturation, respectively (Janson, 1996; Wunderlich & Back, 2009). These free amino acids come solely from the grain (Janson, 1996).

Adjuncts, different grains to raise the starch content of the wort, may be added but are regulated all over the world (Wunderlich & Back, 2009). In the United States the Treasury Department limits adjuncts in malted beverages to less than 49% of the grain bill (USGPO, 2014f). The remaining grain must be barley to meet the definition of malt beverage, which is critical to maintain the jurisdiction of beer under The Alcohol and Tobacco Tax & Trade Bureau (TTB) and not under the Food and Drug Administration (FDA) (FDA, 2009; USGPO, 2014f). Adjuncts are primarily rice and wheat. Rice is added because it is lower cost than barley or wheat. Wheat is added for its characteristic flavor profile found in the European wheat beers. A prime example is Boulevard Brewing Company's Unfiltered Wheat Beer, their take on a typical Belgian style wheat beer.

Historically, beers were commonly flavored with spices, fruits, and anything local brewers thought made their concoction taste better (McGovern, et. al., 2004; McGovern, 2014). Beer can be flavored with anything from chocolate and coffee to saffron and ginger. Traditional European fruit beer called 'radlers' use lemon and other fruits for a refreshing flavor profile. Current trends in the U.S. have the inclusion of apple and strawberry flavors. The Reinheitsgebot, and similar laws, limit the flavoring to bittering compounds found in hops (Eden, 1993).

Hops is a very important ingredient that adds characteristics bitter and citrus notes to the flavor profile; but, also adds an anti-microbial hurdle to pathogen growth in beer (Menz, et. al., 2009; Menz, Aldred, & Vriesekoop, 2011; Vriesekoop, et.al., 2012). The addition of hops to the brewing kettle imparts the typical bitter flavor and aroma (Wunderlich & Back, 2009). In the brew kettle the hops  $\alpha$ -

acid humulone, is converted to iso- $\alpha$ -acids during the boiling step in the brew kettle (Wunderlich & Back, 2009). The cis and trans isomers of the  $\alpha$ -acid humulone impart significant bittering to the finished beer (Wunderlich & Back, 2009). Hops can also be added to the fermentation tank, in what is called dry-hopping, to impart citrus flavors to the finished beer without imparting the bitterness typical to hops because the  $\alpha$ -acids are not isomerized. The  $\beta$ -acid, lupulone, has a significantly different bittering potential since the  $\beta$ -acid has limited solubility in wort (Wunderlich & Back, 2009). The soluble iso- $\alpha$ -acids have marked anti-microbial effect on gram positive bacteria, such as *Listeria monocytogenes*, and *Staphylococcus aureus* (Menz, et. al., 2009). Those same iso- $\alpha$ -acids have little to no effect on gram negative organism such as *Salmonella typhimurium* or *Yersinia enterocolitica* (Menz, et. al., 2009). The  $\beta$ -acids, since they have low solubility in wort do little to contribute to the anti-microbial hurdles to prevent pathogen growth (Menz, et. al., 2009).

Water is a critical ingredient, since all chemical, biochemical, and biologic activity takes place in a 90-94% aqueous system (Buiatti, 2009). It is critical to have a clean source of water with the right combination of minerals required for yeast metabolism and yet not too many of those same minerals that can impart off-flavors (Jansen, 1996; Buiatti, 2009). This is why traditional water sources, like Rocky Mountain spring water for Coors, Inc., are so critical to brewing. Modern breweries, such as Boulevard, use potable city water which is then further purified by reverse osmosis and the correct concentrations of required minerals are added back.

Yeast is the most critical ingredient. Yeast strains impart characteristic flavors to the finished product (Buiatti, 2009). There are 2 main species that are important to traditional European beers. *Saccharomyces cerevisiae* is a warm temperature, 15-26°C, top fermenting yeast common to ales, porters and stouts (Wunderlich & Back, 2009). *Saccharomyces carlsbergensis* (*pastorianus*) is a cool temperature, 8-14°C, bottom fermenting yeast common to lagers and pilsners. Lagers tend to be dryer than ales due to the fermentation of raffinose by *Saccharomyces carlsbergensis* that does not happen with *Saccharomyces cerevisiae* (Jansen, 1996). *Saccharomyces carlsbergensis* can separate the fructose from the glucose-glucose of raffinose (Jansen, 1996). The fructose is fermented normally, but the  $\alpha$ -1-6 glycosidic linkages of the remaining di-saccharide can only be fermented by the lager yeast (Jane, 2000; Jansen, 1996). Yeast undergoes anaerobic alcoholic fermentation, the most important step in the beer making process. The production of two moles of ethanol and 2 moles of carbon dioxide from one mole of glucose is the critical step to impart several microbial hurdles to pathogen growth and survival in beer (Menz, et. al., 2009, Menz, et. al., 2011). The addition of the dissolved alcohol and carbon dioxide

impart a lowered pH, higher alcohol content, an anaerobic environment, and the consumption of many of the biologically available nutrients in the beer (Menz, et. al., 2009).

The brewing process and the ingredients themselves impart antimicrobial hurdles to prevent pathogen growth and kill any pathogens that may have, inadvertently, become incorporated into the finished product (Menz, et. al., 2009; Menz, et. al., 2011; Vriesekoop, et. al., 2012). The kettle boil affects all pathogens causing thermal destruction of cells (Menz, et. al., 2009; Vriesekoop, et. al., 2012). Hop bitter acids are traditionally known to have antimicrobial properties, and as mentioned before act significantly to inhibit gram positive organisms (Menz, et. al., 2009; Vriesekoop, et. al., 2012). Ironically the  $\beta$ -acid lupulone is more an effective anti-microbial agent; but, its low solubility in wort means it has little effect on pathogens (Wunderlich & Back, 2009). Beer typically has a low pH. All Boulevard beers are below a pH of 4.6, and usually closer to 4.3 pH. At this pH level the intrinsic property of the beer will inhibit the growth of organisms such as *Clostridium perfringens*, *Vibrio cholerae*, *Campylobacter jejuni*, and *Shigella sonnei* (Menz, et. al., 2009). At typical beer concentrations (3-5%), ethanol inhibits cell wall function and leads to cell lysis (Menz, et. al., 2009). Many Boulevard products are over 6% and as high as 12%. Studies have indicated that four major food pathogens *Salmonella typhimurium*, *Listeria monocytogenes*, *Staphylococcus aureus*, and *Escherichia coli* were completely inhibited at 7% (Menz, et. al., 2009). There was 57% inhibition at 4%, the lowest concentration of any boulevard product (Menz, et. al., 2009). Dissolved into solution, carbon dioxide lowers the pH and provides an anaerobic environment. The carbon dioxide compliments the antimicrobial action of hops by showing greater action against gram negative organisms (Menz, et. al., 2009). It also increases the lag phase in all pathogens (Menz, et. al., 2009). The conversion from aerobic respiration in the closed fermentation vessel to anaerobic alcoholic fermentation means the lack of oxygen has an inhibitory effect on aerobic pathogens. The lack of nutrient carbohydrates and amino acids removed either during processing or metabolized by yeast fermentation leave few nutrients for pathogen growth (Menz, et. al., 2009; Vriesekoop, et. al., 2012). The sum of all of these hurdles means that strong beer with all of the microbial hurdles mentioned is a safe and wholesome product.

Because of the intrinsic properties of the finished beer and the processing steps that beer must go through the brewing industry has, historically, had little food safety regulation. The Federal Alcohol Administration Act (FAAA) is the overarching regulation that governs the brewing industry (USGPO, 2014f). While there are sections of the FAAA that state the Treasury Department will ensure safe products, the Act deals, predominantly, with the trade and taxation of intoxicating liquors, including beer (USGPO, 2014f). The attacks on September 11<sup>th</sup> 2001, unintentionally, changed that (FDA, 2002).

On June 12<sup>th</sup>, 2002 President George W. Bush signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, or the Bioterrorism Act (BTA), which expanded the original Food Drug and Cosmetic Act of 1938 (FD&C Act)(FDA, 1938; FDA, 2002). The BTA enhanced the original FD&C Act by adding an administrative detention enhancement to the seizure clause of the original Act; and greatly expanded the facility registration, the facility inspection, records access, and record keeping requirements (FDA, 1938; FDA, 2002). Subsequently, in response to several severe food contamination cases, Congress passed new food safety legislation. (FDA, 2014a) On January 4<sup>th</sup>, 2011 President Barack H. Obama signed the Food Safety Modernization Act (FSMA) of 2010 into law. FSMA was the first major food safety legislation, since the FD&C Act of 1938, to come along in over 70 years (Wheeler, 2014). FSMA, and the subsequent final rules, will impact the brewing industry in several ways. FSMA amends the original FD&C Act by incorporating, and further enhancing, Current Good Manufacturing Practices (cGMPs), hazard analysis, preventative control measures, allergen control, sanitation, environmental monitoring, mandatory recordkeeping requirements, importer controls, employee protections, and the administrative detention clauses of the BTA (FDA, 2014a). FSMA further defines jurisdictional authorities, and provides the FDA with mandatory recall authority (FDA, 2013a). However, section 116, exempts ‘Alcoholic Beverages’, under certain conditions, from authority under certain parts of the Act (FDA, 2013c).

The regulatory climate for the brewing industry is very complicated. The brewing industry is regulated, primarily, under TTB and FDA jurisdiction. Those two agencies enforce no less than 4 separate Congressional Acts. Many of the Acts specifically exempt alcoholic beverages, in whole or in part, from their influence or specify another agencies role in enforcement of specific sections, also in whole or in part (FDA, 1938; FDA, 1995; FDA, 2002; FDA, 2013a; FDA, 2013b; FDA, 2013c; FDA, 2014a; USGPO, 2014a; USGPO, 2014f). Compiled here is an overview of the attributes from each Act and its impact on the brewing industry.

The BTA of 2002 required breweries to register their facility, allowed FDA Inspection authority of the registered facilities, and required extensive record keeping to “...identify the immediate previous source and the subsequent recipients of food” (§306(a)(b)) (FDA, 2002). These provisions were expanded further under FSMA. FSMA primarily establishes two major provisions (FDA, 2014a). The first is the Hazard Analysis and Risk-Based Preventative Controls (HARPC) provision. (FDA, 2014a) The second is the implementation of modernized cGMPs (FDA, 2005; FDA, 2014a). FSMA will require breweries to implement expanded cGMPs and further expand the provisions already set forth under the BTA (FDA, 2002; FDA, 2014a). FSMA also gave the FDA mandatory recall authority (FDA, 2014a). The

FD&C Act, FAAA, BTA and FSMA all have one thing in common. They all require that all actions be documented and records retained. Simply, the catch phrase 'if it didn't get written down it didn't happen' defines the regulatory requirements for recordkeeping.

There is some confusion about the exemptions and provisions that may exempt the brewing industry from the current final rules. Under section 116 of FSMA, alcoholic beverages (27 C.F.R. 214) are exempt from requirements related to misbranding, labeling, the reportable food registry, preventative controls and hazard analysis, allergen controls, and environmental monitoring (FDA, 2014a; FDA, 2013c). Further adding to the confusion, the following provisions do not apply to the preventative controls at Boulevard, yet. The foreign material supplier verification, food defense, and HARPC for animal food provisions are still proposed rules that have not yet been finalized, as of April 2014, and the employee protection provisions, of FSMA, are not cGMP prerequisite programs, and are outside of the scope of this report (FDA, 2014a; FDA, 2014b).

The future of the regulatory environment will only get more complicated as the FDA proposed rules are finalized. The proposed rule to Establish Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for food for Animals, may require that brewers establish a HARPC program for the spent grains routinely sold as animal food (FDA, 2014b; Bristow, 2014). The FDA acknowledges that nothing in the animal food HARPC provision exempts spent grains under Section 116, which exempts alcoholic beverages (Bristow, 2014; Crowell, 2014; ). Breweries may be required to establish expensive HARPC programs for their by-product. Several brewing industry groups are commenting on that very provision stating that for centuries spent grains from brewery operations have been used as safe and affordable animal feed (Crowel, 2014). The final impact of FSMA on the brewing industry will not be known until all of the current proposed rules are finalized.

There is a high probability that some form of HARPC will be required by a provision of FSMA. In 2013 Boulevard Brewing Company, Inc. was acquired by Duvel. Based upon discussions with representatives of Duvel, European breweries are required by law to have HACCP plans, and they want to have their US holdings follow suit. The company decided to start developing a HACCP plan for finished product at Boulevard. I volunteered, as a means to get this research, to provide the ground work to establish the foundational cGMP based prerequisite programs for the HACCP plan at Boulevard. I spent a total of four days touring the facility and innumerable hours composing e-mails discussing food safety with representatives of Boulevard and Duvel. Furthermore, readings from the book *Beer in Health and Disease Prevention* indicated that beer was an intrinsically safe product that would negate the potential for pathogens to be present in the finished product (Menz, et. al., 2009). The production steps and the



finished product introduce hurdles to microbial growth that indicated any pathogens present would be killed (Menz, et. al., 2009, Menz, et. al., 2011). The safety of the Duvel beer was proven to European authorities through a statistical analysis of the generations of product produced being safe. Menz, et. al. (2009) corroborates this information by demonstrating that  $2 \times 10^6$  CFU/ml of *Salmonella spp.* inoculated into a single bottle of beer produced a 5 Log reduction in 36 hours. In other testing *Salmonella typhimurium* survived for only seven days and demonstrated no growth (Menz, et. al., 2009). Further testing demonstrated that the most resistant pathogen was *Escherichia coli*, which survived for 3 days (Menz, et. al., 2009; Menz, et. al., 2011). The Boulevard quality control release testing requires between 7-11 days before product is even released; coupled with shipping, the earliest that product could be consumed is 8 days after kegging operations and 12 days after bottling. Research indicates that no pathogens of concern will survive to be consumed, due to the intrinsic properties of the product itself, and therefore does not pose a hazard that is reasonably likely to occur (Menz, et. al., 2009; Menz, et. al., 2011; USGPO, 2014b). Bearing that in mind with all of the regulatory constraints, suggestions, and requirements, I set out to develop the required cGMP based prerequisite programs.

The original cGMPs were modernized through the BTA, the 2005 Food cGMP Modernization guidance, and FSMA (FDA, 2002; FDA, 2005; FDA, 2014a; USGPO, 2014a). The SOPs had to incorporate the modernized cGMPs. The following categories were incorporated in to the SOPs. Personnel: deals with cleanliness, hygiene, clothing, jewelry, disease control, and the required education, training and documentation (USGPO, 2014a). Plants & Grounds: deals with the design, materials, construction, lighting, ventilation, drainage, maintenance, and upkeep of the buildings and surrounding grounds (USGPO, 2014a). Sanitary Operations: deals with housekeeping, sanitation, chemical control, and pest control (USGPO, 2014a). Equipment & Utensils: deals with the design, materials, and construction of processing equipment and utensils (USGPO, 2014a). This section also deals with production process monitoring and control (USGPO, 2014a). Warehousing & Distribution: deals with raw material control, material handling, and product work flow design (USGPO, 2014a). Lastly, Defect Action Levels deal with allowable amounts of naturally occurring debris, insect, and rodent contact products that are considered non injurious to health (FDA, 1995; USGPO, 2014a) The Defect Action Levels also deal with poisonous or deleterious substances that may be allowed in both ingredients and finished products (FDA, 2000; Navarro & Vela, 2009; USGPO, 2014a). The SOPs contained in this report address all of these considerations required to comply with FDA required cGMPs. All cGMP based prerequisite programs have one purpose. They are designed to prevent the addition of filthy putrescence, or decomposing material to the finished product, which must be held in conditions where it may not become

contaminated or become injurious to health (FDA, 1938; USGPO, 2014a). In other words, prevent the adulteration of the product (FDA, 1938; USGPO, 2014a). The SOPs also contain provisions from the TTB to comply with identity, marketing, labeling, and record retention requirements (USGPO, 2014c; USGPO, 2014d; USGPO, 2014e; USGPO, 2014g).

## **General SOP 01 Good Manufacturing Practices**

### **1. PURPOSE**

- 1.1.** This procedure defines the application of Current Good Manufacturing Practices (cGMPs) that govern production at Boulevard Brewing Company.
- 1.2.** The standards described herein reflect the FDA cGMPs and an understanding of the intrinsic properties of the product (Menz, et. al., 2009; USGPO, 2014a). The Congress, in establishing the FSMA, understood that alcoholic beverages are intrinsically safer than other food and exempted them from further controls as applied by the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food proposed rule. However, utilization of the cGMPs and record keeping requirements are required by FDA FSMA and BTA to prevent the adulteration of the product (FDA, 2002; FDA, 2012; USGPO, 2013a; USGPO, 2014a).
- 1.3.** Specific GMP's and/or prerequisite programs will be defined in separate SOP's listed in the Reference section.

### **2. SCOPE**

- 2.1.** This procedure applies to all Boulevard Brewing Company facilities.
- 2.2.** These GMP's are applicable in production areas.
- 2.3.** The administrative offices, public retail spaces, and visitor areas are excluded from these programs, except personal hygiene or when entering production areas.

### **3. RESPONSIBILITY**

- 3.1.** It is the responsibility of all personnel to understand and follow the principles outlined in this Document.
- 3.2.** It is the responsibility of the Human Resources department to provide cGMP training to all personnel working in or entering production areas of the facility.
- 3.3.** The Regulatory Affairs Officer(s), in conjunction with Corporate Counsel, are responsible for keeping this document updated.

### **4. DEFINITIONS**

- 4.1.** BTA - Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act (BTA)) amendment to the FD&C Act (FDA, 2002).

- 4.2.** cGMPs – Current Good Manufacturing Practices intended to prevent food from becoming adulterated as defined by the FDA in 21 CFR Part 110 as: “The criteria and definitions in this part shall apply in determining whether a food is adulterated... within the meaning of... the act in that the food has been manufactured under such conditions that it is unfit for food; or... in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.” (USGPO, 2014a).
- 4.3.** CIP – Clean in Place. Cleaning and sanitation of closed production equipment without requiring disassembly.
- 4.4.** FAAA – The Federal Alcohol Administration Act of 1935 partially establishing the BATFE and TTB under the U.S. Department of the Treasury (USGPO, 2014f)
- 4.5.** Facility – All Boulevard Brewing Company production, storage, maintenance, and warehousing locations, these include the surrounding grounds.
- 4.6.** FDA – Food and Drug Administration under the U.S. Department of Health and Human Services (HHS). The agency responsible for assuring a safe wholesome food supply (FDA, 1938).
- 4.7.** FDA Registered Facilities – Registration required by the FDA BTA of 2002. Boulevard Registered Facilities:
  - 4.7.1.** 13002562254 – 2501 Southwest Boulevard, Kansas City, MO.
  - 4.7.2.** 13161098130 – 1325 North Topping, Kansas City, MO.
  - 4.7.3.** 12434827500 – 3030 Roanoke, Kansas City, MO.
- 4.8.** FD&C Act – Federal Food Drug and Cosmetic Act of 1938 establishing the FDA under HHS (FDA, 1938).
- 4.9.** Food Contact Surface – Anywhere in the process where ingredients, finished product, or packaging material comes in contact. Includes tools and Utensils.
- 4.10.** FSMA – Food Safety Modernization Act of 2011 updates the 1938 FD&C Act (FDA, 2014a).
- 4.11.** Grounds - The grounds will include parking areas or structures, walkways, landscaping spaces and any open areas not covered by a permanent structure, including walkways and roads that are owned, operated, or controlled by Boulevard Brewing Company.
- 4.12.** Prerequisite Programs - The foundation for all food safety programs. Programs to enact cGMPs and keep low risk hazards from affecting the finished Product (Bernard, Parkinson, & Cheng, 2006).
- 4.13.** Production area – Any space, inside or outside of the Boulevard Brewing Company property, where production processes are performed.
- 4.14.** Product zone – All areas immediately surrounding production equipment.
- 4.15.** Sanitary Facilities –Facilities used to maintain proper personal hygiene. These include restrooms, locker rooms, hand-washing stations, hand-sanitizing stations.

- 4.16. SOP - Standard Operating Procedure.
- 4.17. TTB - Bureau of Alcohol Tobacco, Firearms and Explosives (BATFE), Alcohol and Tobacco Tax and Trade Bureau (TTB) under the U.S Department of the Treasury (USGPO, 2014f).

5. **MISCELLANEOUS CATEGORIES**

- 5.1. N/A

6. **PROCEDURE**

- 6.1. All personnel working in or entering manufacturing areas of the facility are required to attend GMP training. Refresher training is required once per calendar year.
- 6.2. Contractors and Visitors will receive cGMP training during the initial visit and will complete refresher training once per year.
- 6.3. The following suggested cGMPs "...shall apply in determining whether a food is adulterated... within the meaning... of the act..." (USGPO, 2014a).
- 6.4. Adequate signage will be employed to notify employees of cGMP requirements.
- 6.5. **Current Good Manufacturing Practices:**
  - 6.5.1. **Facilities: 21 CFR Sections 110.20, 110.35, & 110.37** (USGPO, 2014a).
    - 6.5.1.1. Guidelines governing the building design and structure at the facility including: ventilation, lighting, product flow, utility systems, etc... will be established.
    - 6.5.1.2. Maintenance and general repair guidelines will be established for the grounds and building exteriors.
    - 6.5.1.3. The facility will establish an integrated pest management system to prevent an infestation of the production, warehousing, or personal offices.
    - 6.5.1.4. Sanitary facilities such as waste management, toilets, handwashing stations, and sewers, and will be adequate to maintain sanitary conditions at the facility.
    - 6.5.1.5. A program to prevent foreign material including metal, glass and brittle plastic from entering the product or ingredient supply will be established.
  - 6.5.2. **Personnel: 21 CFR Section 110.10** (USGPO, 2014a).
    - 6.5.2.1. Supervision will be required to assure compliance to all practices.
    - 6.5.2.2. Personal hygiene standards comprised of cleanliness, handwashing, appropriate clothing, and allowable jewelry will be established.
    - 6.5.2.3. Protective equipment, including gloves and hair restraint, guidelines will be established.

- 6.5.2.4. Disease control will be established to prevent adulteration of finished product by colds, sickness, cuts, wounds, or first aid practices.
      - 6.5.2.5. Education and training guidelines in these personnel practices will be established.
- 6.5.3. **Production Equipment: 21 CFR Sections 110.35, 110.37 & 110.40** (USGPO, 2014a).
  - 6.5.3.1. The design, materials, and construction of production equipment will be such that inspections, cleaning, sanitation, and pest control will be facilitated and not offer a point of adulteration.
  - 6.5.3.2. All production equipment will have scheduled preventative maintenance programs to ensure proper operation.
  - 6.5.3.3. All necessary production and testing equipment will be on a scheduled calibration routine to ensure accuracy.
- 6.5.4. **Sanitation: 21 CFR Sections 110.35 & 110.37** (USGPO, 2014a).
  - 6.5.4.1. General housekeeping in non-production areas will be routinely scheduled.
  - 6.5.4.2. A master sanitation schedule will be developed for all location, and equipment in the facility with established schedules, verification, and record keeping.
  - 6.5.4.3. Guidelines for the use and frequency of the CIP system will be established.
- 6.5.5. **Chemical Control:** A procedure for monitoring and safely storing production, cleaning, and maintenance chemicals to ensure that no contamination of products, ingredients or equipment can occur will be established. (USGPO, 2014a)
- 6.5.6. **Raw Materials: 21 CFR Sections 110.80 & 110.110** (USGPO, 2014a).
  - 6.5.6.1. Receiving of all raw materials will follow inspection, testing, and acceptance criteria with documented traceability.
  - 6.5.6.2. Verification of vendor adherence to these same cGMPs, as allowed by law, will be enforced with audits, monitoring and record keeping.
  - 6.5.6.3. Specifications for incoming ingredients and packaging material will be established so that proper inspection and testing can be performed.
- 6.5.7. **Labelling: 27 CFR.** A program to ensure that TTB labelling requirements are designed, reviewed, delivered, and verified on finished product will be established (USGPO, 2014d).

- 6.5.8. Quality:** A positive release program, prior to shipping, with testing procedures, acceptance criteria, and disposition criteria will be implemented to ensure that no adulterated product leaves the facility.
- 6.5.9. Production: 21 CFR Section 110.37** (USGPO, 2014a).
  - 6.5.9.1.** Production processes will be established to ensure that the proper product, meeting finished product specifications, is placed in the proper packaging and is produced safely.
  - 6.5.9.2.** Product change over procedures will ensure that all production and packaging operations are cleared from one product to another.
  - 6.5.9.3.** An established procedure to control blending of substandard quality batches and disposition of batches not suitable for blending will be implemented.
- 6.5.10. Recall and Traceability: 21 CFR Section 110.80** (FDA, 2002; USGPO, 2014a)
  - 6.5.10.1.** The facility will establish a recall program capable of determining product location within 24 hours of notice.
  - 6.5.10.2.** Pursuant to the BTA all required documents will be retained (FDA, 2002).
  - 6.5.10.3.** The recall program will be supported by a unique coding, traceability, and document tracking system to facilitate the 24 hour traceability.
  - 6.5.10.4.** The recall program will be practised, reviewed, and updated on a scheduled frequency to ensure that potentially adulterated product can be retrieved quickly.

## **General SOP 02 SOP Format and Guidelines**

- 1. PURPOSE**
  - 1.1.** This procedure provides a format and guidelines for writing effective Standard Operating Procedures (SOPs).
- 2. SCOPE**
  - 2.1.** This procedure applies to all SOPs used at all Boulevard Brewing Company facilities. Procedures for approving, correcting, and maintaining SOPs are defined in the most recent version of General SOP 03 Document Control.
- 3. RESPONSIBILITY**
  - 3.1.** It is the responsibility of the author of an SOP to follow the procedure outlined in this document.
  - 3.2.** Personnel in the Quality Department will review SOPs submitted for approval to adherence to this standard.

- 3.3. Department supervision is responsible for creating accurate and current SOPs that apply to their area of responsibility. Department supervision is responsible for ensuring compliance to approved SOPs.

4. **DEFINITIONS**

- 4.1. Facility – All Boulevard Brewing Company production, storage, maintenance, and warehousing locations, these include the surrounding grounds.
- 4.2. SOP - Standard Operating Procedure.

5. **MISCELLANEOUS CATEGORIES**

- 5.1. N/A

6. **PROCEDURE**

- 6.1. All SOP's will use the Calibri font and numerical heading, as demonstrated in this SOP.
- 6.2. The SOP will include the sections listed in section 6.3 through 6.13.
- 6.3. When any section of this procedure does not apply to a task, area, or item the section should be annotated with "N/A".
- 6.4. **Header** – Every page of the SOP will have a header and footer containing the following:
  - 6.4.1. Company Name and Address: Boulevard Brewing Company, Inc. 2501 Southwest Blvd., Kansas City, MO. 64108
  - 6.4.2. Page number and number of pages.
  - 6.4.3. Title of the SOP. The title and file name MUST match.
  - 6.4.4. SOP area and SOP number. See section 6.5 below.
  - 6.4.5. Effective Date:
    - 6.4.5.1. The effective date will be the date the final version has been approved and placed in the Controlled Documents folder. The document is in full force at this time.
  - 6.4.6. The version number reflects the change history of the document and will be changed anytime a change is made to the document. The version suffix is numbered consecutively. New SOPs will be labelled 'New Procedure'.
  - 6.4.7. A document expiration date and time. All printed documents expire in 24 hours, unless they are the signed document approved according General SOP 03 Document Management. Always discard printed copies after the expiration date.
- 6.5. **SOP Number**
  - 6.5.1. The SOP number will be assigned by the Quality department administrator upon request of the author. The following number format will be followed: **AAAA SOP BB.CC**

**AAAA** - Area where the SOP is applicable.

- General
- Facilities
- Personnel
- Labelling

**BB** - SOP number for all SOP's within that area.

**CC** - The SOP revision number. A new SOP is assigned a revision number of 00. CC is incremented by 01 each time the SOP is revised.

**6.6. Purpose**

**6.6.1.** This section outlines the reason for writing the procedure. This section can also include background information and objectives relevant to the SOP.

**6.7. Scope**

**6.7.1.** This section defines the physical, departmental, legal, and regulatory areas covered by the SOP. This section can also state areas that will not be covered by the document.

**6.7.2.** Use a new line for each area of responsibility to be outlined.

**6.8. Responsibility**

**6.8.1.** This section outlines the responsibility of each individual(s) (title only) that will be affected by the document.

**6.8.2.** Use a new line for each area of responsibility to be outlined.

**6.9. Definitions**

**6.9.1.** This section is for defining terms and acroymns or decribing information that requires more detail.

**6.10. Miscellaneous Categories**

**6.10.1.** This section is for anything required to perform the procedure that is not outlined under other sections. These can include items such as frequencies, safety precautions, PPE required, special documentation requirements, etc...

**6.11. Procedure**

**6.11.1.** This section outlines the process in detail, highlighting each step clearly.

**6.11.2.** These directions may be policy guidelines or detailed step-by-step instructions. Keep text specific enough to convey information, yet, generic enough to not require changes to the document for every personnel or maintenance change.

**6.12. Reference Documents**



**6.12.1.** This section is used to list regulations, documents, or SOPs which may be used as a reference to gain additional information.

**6.12.2.** All non-SOP reference documents will include a full description and file location for easy access. The SOP number listed in **6.4.1**, and the SOP title, must be included for SOP's.

**6.13. Attachments/Forms**

**6.13.1.** Attachments that pertain to the SOP are listed here. Attachments may include forms, presentations, drawings, charts, workflows, pictures, etc.

**6.13.2.** Each attachment must be labeled and numbered as an attachment.

**6.14. Approvals/History**

**6.14.1.** The last page of the document will contain two sections.

**6.14.1.1.** The first is the approval tree containing the signature and date of the author(s) and applicable approvers from departments affected by the document.

**6.14.1.2.** The second is the change history listing the successive versions of the SOP with the dates, description of changes, and the responsible party.

## **General SOP 03 Document Management**

**1. PURPOSE**

**1.1.** This procedure provides guidelines for the management of controlled documents at Boulevard Brewing Company, Inc.

**2. SCOPE**

**2.1.** This document applies to ALL controlled documents used at Boulevard Brewing Company facilities. This guideline establishes standards for approval, and maintenance of documents. Maintenance includes: document control, record integrity, storage, retention, and destruction.

**2.2.** This procedure defines the standards for required records as defined by the FDA FD&C Act (FDA, 1938), BTA (FDA, 2002), and FSMA; and FAAA under the TTB and U.S. Department of the Treasury (TTB, 2014; USGPO, 2014c; USGPO, 2014d; USGPO, 2014e; USGPO, 2014f; USGPO, 2014g)

**3. RESPONSIBILITY**

**3.1.** It is the responsibility of every employee at Boulevard Brewing Company to comply with this SOP.

**3.2.** The Quality Department is responsible for managing all documents except HR related documents and records.

**3.3.** The Quality Department will designate the Document Administrator.

- 3.4.** The supervisor of the relevant department is responsible for creating and maintaining accurate and current SOP's. Department supervision is also responsible for ensuring compliance to approved documents.

**4. DEFINITIONS**

- 4.1.** BTA - Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act (BTA)) amendment to the FD&C Act (FDA, 2002).
- 4.2.** Controlled document – Any established document that has been approved. Refer to the latest version of General SOP 02 SOP Format and Guidelines.
- 4.3.** Document - Any written form recording operational information pertinent to any aspect of operating the facility. May exist as an electronic or hard copy.
- 4.4.** FAAA – The Federal Alcohol Administration Act of 1935 partially establishing the BATFE and TTB under the U.S. Department of the Treasury (USGPO, 2014f).
- 4.5.** Facility – All Boulevard Brewing Company production, storage, maintenance, and warehousing locations, these include the surrounding grounds.
- 4.6.** FDA – Food and Drug Administration under the U.S. Department of Health and Human Services (HHS). The agency responsible for assuring a safe wholesome food supply (FDA, 1938).
- 4.7.** FD&C Act – Federal Food Drug and Cosmetic Act of 1938 establishing the FDA under HHS (FDA, 1938).
- 4.8.** FSMA – Food Safety Modernization Act of 2011 updates the 1938 FD&C Act (FDA, 2014).
- 4.9.** HR - Human Resources
- 4.10.** Master Document List - A database of all Controlled documents and their storage location.
- 4.11.** Pending document – A Document being revised, altered, or submitted for approval. Documents are designated as pending until approved wherein they are converted to controlled documents.
- 4.12.** Reference documents – Documents necessary to clarify or support operations or quality that did not originate within Boulevard Brewing Company.
- 4.13.** Required document – Any document required by local, state, or federal regulatory or law enforcement agencies.
- 4.14.** Site Computer System – the entirety of all connected networks that contain any document.
- 4.15.** Sensitive documents – Documents of a nature that their release could cause harm to Boulevard Brewing Company.
- 4.16.** TTB - Bureau of Alcohol Tobacco, Firearms and Explosives (BATFE), Alcohol and Tobacco Tax and Trade Bureau (TTB) under the U.S Department of the Treasury. (USGPO, 2014f)

**4.17.** Uncontrolled Documents: Any document not part of the Boulevard Brewing Company production or quality departments. These may include, but are not limited to HR documents, e-mails, or memorandums, etc...

**5. MISCELLANEOUS CATEGORIES**

**5.1.** N/A

**6. PROCEDURE:**

**6.1. Document Control:**

**6.1.1.** Document control consists of the management of all documents as a facility-wide system across all functional areas.

**6.1.1.1.** Control of the format, content, retention, and destruction of documents to ensure the information is current, correct, complete and understandable.

**6.1.1.2.** Distribute documents to appropriate personnel.

**6.2. Document Flow:**

**6.2.1.** The Document Administrator will process the Controlled Documents following these guidelines:

**6.2.1.1.** The Administrator will ensure that the documents are reviewed according to the standards provided in the current version of General SOP 02 SOP Format and Guidelines.

**6.2.1.2.** The Administrator will manage the storage location and approval status in Form 03 Master Document List.

**6.2.1.3.** The Administrator will update the header and footer sections to reflect the assigned document number, title and current version.

**6.2.1.4.** The Administrator will update the footer section to reflect correct storage location by updating field information in the file name cell.

**6.2.1.5.** The Administrator will verify file information for attachments and references.

**6.2.1.6.** The Administrator will coordinate with the relevant department supervisors to assure accuracy of the document prior to approval.

**6.2.1.7.** The Administrator will coordinate the document approval process.

**6.2.2.** The Quality department will be responsible for the following:

**6.2.2.1.** The Quality department will ensure the document management procedures are effective and will schedule periodic review of the program to ensure best practices are used.

**6.2.2.2.** The Quality department will maintain the validity of documents by routinely reviewing all documents every two years or as needed.

**6.2.2.3.** The Quality department will retain records as outlined in section **6.5** below.

**6.2.2.4.** The Quality department will destroy sensitive documents and records as described in section in **6.8** below.

**6.2.3.** The author will be responsible for the following:

**6.2.3.1.** Reviewing the document and attachments to ensure the information is correct, complete and understandable prior to submitting the document for approval.

**6.2.3.2.** Ensuring that the document follows General SOP 02 SOP Format and Guidelines.

**6.2.3.3.** Making any changes or corrections identified during the approval process and resubmitting the document for approval.

**6.2.3.4.** The author, or their designee, is responsible for coordinating the training of relevant department members on the approved document.

**6.3. Approval Procedure:**

**6.3.1.** The author will submit the pending document to the Document Administrator.

**6.3.2.** The Document Administrator will assign a consecutive SOP number and category to the document.

**6.3.3.** The Document Administrator will update the Form 03 Master Document List and save an electronic version of the Document to the 'Pending Documents' Folder.

**6.3.4.** The Document Administrator will send copies to the affected department representatives listed on the approval tree at the end of the document.

**6.3.5.** The department representatives will review the document. Corrections will be noted on their copies.

**6.3.6.** The Author, Document Administrator, and all affected department representatives will meet. Corrections will be assimilated into a final document. The agreed final Document will be signed (electronic or written).

**6.3.7.** The Document Administrator will update the Form 03 Master Document List. The document will be moved from the 'Pending Documents' folder to the 'Controlled Documents' folder.

**6.4. Record Integrity**

- 6.4.1. Falsification of records is strictly prohibited by Boulevard Brewing Company, Inc.
- 6.4.2. Only blue or black permanent pens will be used on official Documents. The use of markers, pencils, erasable pens, or liquid correction fluid is not allowed.
- 6.4.3. Corrections will be made by striking through the original error with a single line. Write in the new information then initial and date the changes.
- 6.4.4. Hand written forms or work tracking sheets should be clear to define both actions that were accomplished and work that was not completed. Use of N/A is appropriate to denote non-required actions.

**6.5. Document Retention:**

- 6.5.1. The Quality Department will be responsible for assuring that records are retained to meet Boulevard Brewing Company requirements as well as, federal, state, and local regulatory requirements.
- 6.5.2. Signed copies or unique original documents must be retained.
- 6.5.3. The following document types must be retained: (FDA, 2002,), (USGPO III, 2014)
  - 6.5.3.1. Tax documents pursuant to TTB Regulations.
  - 6.5.3.2. Current food safety plan including SOPs and forms.
  - 6.5.3.3. Production documents.
  - 6.5.3.4. Analytical testing documents.
  - 6.5.3.5. Pre-shipment review testing documents.
  - 6.5.3.6. Positive release, shipping and receiving documentation.
  - 6.5.3.7. Ingredient specifications and vendor inspection documents.
  - 6.5.3.8. Customer complaints.
  - 6.5.3.9. Regulatory Inspections documents.
  - 6.5.3.10. MSS/Cleaning/Sanitation documents.
  - 6.5.3.11. Preventative maintenance documents.
  - 6.5.3.12. Integrated Pest Management documents.
- 6.5.4. All affected records must be retained for a period of not less than 2 years (FDA, 2002; USGPO, 2014c).
- 6.5.5. Once a document becomes obsolete or a new version is generated the signed hard copies must be stamped 'Archived' and retained with the current version to demonstrate the revision history.

**6.6. Electronic Document Storage**

- 6.6.1. Documents will be stored on the site computer system. Back-ups of the site computer system must be stored off site. Back-ups must be retrievable within 24 hours (FDA, 2002).
- 6.6.2. Documents are assigned to a folder according to their category type (i.e. General, Personnel, etc...)
- 6.6.3. Individual file names follow the following format: **AAAA SOP BB.CC 'SOP Title'**. Refer to the current version of General SOP 02 SOP Formats and Guidelines, for complete rules on SOP formats.
  - 6.6.3.1. Example of a file name: General SOP 03.02 Controlled Documents. That is the second revision of the third General SOP Titled 'Controlled Documents'.
- 6.6.4. It is critical for maintenance of hyperlinks that the file name remains constant throughout the revision process.
- 6.6.5. Company retained versions of electronic reference documents are stored in the 'Reference Documents' folder. Hard copies and books will be stored by the Document Administrator.
- 6.6.6. Documents that have been approved are stored in the 'Controlled Documents' folder under the appropriate categories using the criteria listed in 6.6.3 above.
- 6.6.7. Documents that have NOT been approved are stored in the 'Pending Documents' folder under the appropriate categories using the criteria listed in 6.6.3 above.
- 6.6.8. Any time changes are to be made to an approved document it must be downgraded in approval status.
  - 6.6.8.1. Documents must be removed from the 'Controlled Document' folder and moved to the same category in the 'Pending Documents' folder before any changes can occur.
  - 6.6.8.2. The Document Administrator is the only person allowed to downgrade the status of a document.
  - 6.6.8.3. Notate the changes made to the document in the 'Master Document List'.
  - 6.6.8.4. Pending documents must be approved (section 6.4 above) before being moved into the 'Controlled Documents' folder.

**6.7. Hard Copy Document Storage:**

- 6.7.1. All hard copy documents must be stored in a clean, organized manner that protects the records and prevents infestation, or damage. Storage can be on or off site, should provide easy access to documents, and must be retrievable within 24 hours (FDA, 2002).
- 6.7.2. The 'Master Document List' must be updated with all revision number changes. This is the responsibility of the Document Administrator.

**6.7.3.** Once the document is approved and the hard copies are properly stored, any electronic versions of the document must be updated. This is the responsibility of the Document Administrator to coordinate.

**6.8. Document Destruction:**

**6.8.1.** Sensitive documents, listed below in section 6.8.2, must be destroyed to prevent harm to Boulevard Brewing Company by using the approved methods listed in section 6.8.3, as allowed by law. (FDA, 2002; USGPO, 2014c; USGPO, 2014d; USGPO, 2014e; USGPO, 2014g)

**6.8.2.** The following documents are specifically included in this classification:

**6.8.2.1.** Ingredient specifications and vendor inspection documents.

**6.8.2.2.** Recipes or Ingredient Lists.

**6.8.2.3.** GMP / pre-requisite program SOPs.

**6.8.2.4.** Financial Information.

**6.8.2.5.** Recall / retrieval processes documents.

**6.8.2.6.** Customer Complaint Information.

**6.8.2.7.** Regulatory inspection documentation.

**6.8.2.8.** Financial / personal / legal information.

**6.8.3.** These documents, or any other document deemed sensitive, must be disposed of in a manner that will assure that no information can be retrieved from the destroyed document. The following procedures are acceptable.

**6.8.3.1.** Shredding – preferred method. Onsite or third party.

**6.8.3.2.** Incineration.

**6.8.3.3.** Landfill – must observe document burial by refuse or offal.

## **General SOP 04 Product Retrieval Program**

**1. PURPOSE**

**1.1.** Pursuant to sections of the FSMA and BTA producers must have procedures in place to conduct product retrieval. If, for any reason, undesirable product leaves the facility this procedure defines the market withdrawal and product recall procedure. (FDA, 2002; USGPO, 2014a)

**2. SCOPE**

**2.1.** This procedure applies to products made at all Boulevard Brewing Company facilities.

**3. RESPONSIBILITY**

- 3.1.** Senior Management is responsible for having an effective product retrieval process in place.
- 3.2.** Personnel assigned to the Company Emergency Response Team (CERT) will be responsible for managing the recall process from initiation to the final disposition of the product (Freund, Jackson, & Barach, 2013).
- 3.3.** The Quality department will be responsible for the overall product retrieval process.
  - 3.3.1.** The Quality department, in cooperation with all affected departments, will conduct bi-annual mock recalls to confirm the systems effectiveness.
- 3.4.** The procurement department will be responsible for obtaining agreements from all vendors to include a clear commitment to follow the traceability, labeling and product retrieval procedures and cooperate fully in any product retrieval.

#### **4. DEFINITIONS**

- 4.1.** cGMPs – Current Good Manufacturing Practices intended to prevent food from becoming adulterated as defined by the FDA in 21 CFR Part 110 as: “The criteria and definitions in this part shall apply in determining whether a food is adulterated... within the meaning of... the act in that the food has been manufactured under such conditions that it is unfit for food; or... in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.” (USGPO, 2014a).
- 4.2.** Chief Medical Officer (CMO) – A medical professional responsible for determining business related health decisions for Boulevard Brewing Company. The CMO may be a third party consultant (Freund, et. al., 2013).
- 4.3.** Company Emergency Response Team (CERT) – Personnel responsible for dealing with business emergencies. The team is designated in the ‘Master Contact List’. The CERT team does NOT respond to medical, security, natural or man-made disaster emergencies (Freund, et.al., 2013).
- 4.4.** Correction - “...repair modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.” (FDA, 2013d).
- 4.5.** Facility – All Boulevard Brewing Company production, storage, maintenance, and warehousing locations, these include the surrounding grounds.
- 4.6.** SOP - Standard Operating Procedure.
- 4.7.** Market withdrawal – “...a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.” (FDA, 2013d).



- 4.8. Master Contact List – Contains contact and responsibility information for all Facility personnel (Freund, et.al., 2013).
- 4.9. Prerequisite Programs - The foundation for all food safety programs. Programs to enact cGMPs and keep low risk hazards from affecting the finished Product (Bernard, Parkinson, & Cheng, 2006).
- 4.10. Product (for this SOP only) – “...an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, any tobacco product intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. Product does not include an electronic product that emits radiation and is subject to parts 1003 and 1004 of this chapter.” (FDA, 2013d).
- 4.11. Recall – “...a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery.” (FDA, 2013d)
- 4.12. Recall classification – “..the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.” (FDA, 2013d)
  - 4.12.1. Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. (FDA, 2013d)
  - 4.12.2. Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (FDA, 2013d)
  - 4.12.3. Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences. (FDA, 2013d)
- 4.13. Senior Management – The most senior executives at Boulevard Brewing Company. The specific titles are listed in the ‘Master Contact List’.
- 4.14. Stock recovery – “...a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.” (FDA, 2013d)

5. **MISCELLANEOUS CATEGORIES**

- 5.1. N/A

6. **PROCEDURE**

- 6.1. Pursuant to the BTA, records must be kept for the disposition of the immediate previous source (ingredients) and the recipient of the subsequent finished product (FDA, 2002). Refer to General SOP 01 Good Manufacturing Practices, General SOP 03 Document management, and Facilities SOP 03

Shipping Receiving and material handling for guidelines regarding required documentation procedures necessary to comply with this product retrieval procedure.

- 6.2. The goal of the product retrieval program is to get 100% of the product that is in Boulevard's direct control and the maximum amount that can be retrieved from all other sources.
- 6.3. **Required Items:** The following are to be included in the product retrieval procedure (Freund, et.al., 2013):
  - 6.3.1. The 'Master Contact List' will identify the personnel and their required duties for the product retrieval program.
  - 6.3.2. Senior Management, the CERT, the Quality department, and corporate legal counsel must develop a written product retrieval strategy that includes a procedure and description of all of the activities required for product recall, market withdrawal, and stock recovery.
  - 6.3.3. The Quality department will maintain a live regulatory contact list including local and federal emergency contact names, telephone numbers, e-mail addresses and physical addresses (Freund, et.al., 2013). This list is independent of the 'Master Contact List' as the names do not constitute employees, or contractors of Boulevard Brewing Company.
- 6.4. **Traceability.** All product produced at Boulevard Brewing Company must be marked with a unique date code that distinguishes that production batch from all other batches made at the facility (FDA, 2002; FDA, 2013d; USGPO, 2014c; USGPO, 2014d; USGPO, 2014e; USGPO, 2014g). The code must be unique for all past and future batches. Refer to General SOP 03 Document Management and Facilities SOP 03 Shipping Receiving and Material Handling for specific applications (FDA, 2002).
  - 6.4.1. All bottles and kegs must have a complete legible date code for each production unit.
  - 6.4.2. Date codes on bottles should be printed with an ink jet coder using an ink that contrasts with the bottle color.
  - 6.4.3. Date codes on kegs must be affixed to the keg in a manner that will not allow easy removal of the label with out the use of solvents or water.
  - 6.4.4. There are no regulatory requirements on font size, but the date code must be readable. (FDA, 2013d)
  - 6.4.5. There are no regulatory requirements for placement, but the date code must be visible without having to remove or alter the container or label.
  - 6.4.6. Alterations, such as erasures, covering with labels, applying white-out or writing over mechanically printed date codes with a pen or marker, are strictly prohibited.
  - 6.4.7. Containers missing the date code may be re-run to have the correct date code applied.
  - 6.4.8. Secondary packaging containers do not require a date code.

- 6.5. Identification of the issue.** Boulevard Brewing Company or a regulatory agency may initiate product retrieval (FDA, 2014a; Freund, et.al., 2013).
- 6.6. Product recovery decision.**
- 6.6.1.** If, for any reason, undesirable product leaves the facility a decision of the type of product retrieval must be made (Freund, et.al., 2013).
- 6.6.2.** Reasons for a product retrieval include product misformulation, product adulteration, or a regulatory violation. Examples respectively include (FDA, 2013d; USGPO, 2014c; USGPO, 2014d; USGPO, 2014e; USGPO, 2014g):
- 6.6.2.1.** Mislabeled product. The wrong label applied to a container that does not contain that product. May also be considered a regulatory violation.
- 6.6.2.2.** The inclusion of cleaning chemicals or glass in containers of product.
- 6.6.2.3.** Labels not containing the required information or an incorrect alcohol content. May also be considered a misformulation.
- 6.6.3.** A Stock recovery will be initiated for any product that is still within the control of Boulevard Brewing Company (FDA, 2013d). Refer to **4.13** above.
- 6.6.4.** For material that has left the company's control but has not been placed in retail sales a market withdrawal must take place (FDA, 2013d). Refer to **4.7** above. There has to be reasonable assurance that NO product was sold or left the distributor(s) or retailer(s) control.
- 6.6.5.** For any product that has left company control and made it to the retail market must be recalled (FDA, 2013d).
- 6.7. Recall procedure.** The Company Emergency Response Team (CERT) will manage the recall procedure (Freund, et. al., 2013).
- 6.7.1.** There are considerable costs associated with product retrieval. Senior Management should verify all product retrieval decisions (Freund, et. al., 2013).
- 6.7.2.** The CERT in conjunction with Senior Management, the Regulatory Affairs officer, and corporate legal counsel will conduct a review to determine if a recall is required for the situation (FDA, 2014d; Freund, et. al., 2013).
- 6.7.2.1.** The following items will be presented during the review:
- Nature of the issue.
  - Lots or batches involved.
  - Distribution information.
  - Medical hazard, regulatory and business assessments

- 6.7.2.2. If, after review, it is determined that a recall is not required, a written report will be retained with the required affected product documents. The report must include the reasoning for the decision (FDA, 2013d).
    - 6.7.2.3. If the recommendation is to recall, the recall procedures must be initiated.
  - 6.7.3. The CERT will outline the extent of the recall, including but not limited to the following: (FDA, 2013d)
    - 6.7.3.1. The nature of the issue.
    - 6.7.3.2. The affected product(s):
      - Product name(s).
      - Packaging type(s).
      - All affected batches(s).
    - 6.7.3.3. All of the ingredients in the product to be recalled.
    - 6.7.3.4. If an ingredient was used in the affected product, was it also used in any other product? If so, include those products and batches in the affected products list.
    - 6.7.3.5. The CMO must evaluate the health hazards presented by the product, if it were to be used, handled or consumed. (FDA, 2013d).
      - The CMO will draft the Medical Hazard Evaluation Report, within 24 hours, and issue that to the CERT. (FDA, 2013d).
    - 6.7.3.6. The location of all unused product in the market place. This includes the wholesale and retail market place.
  - 6.7.4. **Establish Communication:** Boulevard Brewing Company is responsible for establishing communication with customers and regulatory agencies (FDA, 2013d).
    - 6.7.4.1. Recall communications may be accomplished by personal contact, such as phone calls or e-mails, but the communication must be followed up by a telegram or First Class Letter (FDA, 2013d).
    - 6.7.4.2. The communication must convey:
      - The product(s) to be recalled (FDA, 2013d).
      - It must notify known customers of the recall (FDA, 2013d).
      - It must convey that the distribution of the product(s) must cease immediately (FDA, 2013d).
      - It must include instructions for the disposition of the affected product(s) (FDA, 2013d).

**6.7.4.3.** The communication MUST contain:

- “FOOD RECALL” in red capital letters (FDA, 2013d).
- “CRITICAL” on the envelope for Class I & II Recalls (Occasionally for class III) (FDA, 2013d).

**6.7.4.4.** Recall communication must adhere to the following guidelines:

- The communication must clear and concise (FDA, 2013d).
- The communication must identify the product size(s) date codes, secondary packaging or any other feature or description that will “...enable accurate & immediate identification of product.” (FDA, 2013d).
- Give a concise reason for the recall and a description of the hazards involved (FDA, 2013d).
- Provide a description of what to do with the product. The expectation is that the consumer should perform reasonable disposition actions (FDA, 2013d).
- Provide a “...ready means...” of contacting the company. A best practice would be to establish a 24-hour toll free hotline to allow consumers to call (FDA, 2013d).

**6.7.4.5.** Communication must NOT include irrelevant qualifications or promotional material (FDA, 2013d).

**6.7.4.6.** Recall communication should also be sent to all company sales personnel to distribute to all consumers that may be affected by the recall.

**6.7.5. Notification of Regulatory/Government Agencies:** The CERT will contact the applicable regulatory agency of the decision to conduct a recall, and will provide the recall strategy, including the Medical Hazard Evaluation Report. (FDA, 2013d; TTB, 2014)

**6.7.6. Disposition of Recalled Batches:** The CERT will coordinate the destruction of the recalled batches.

**6.7.6.1.** The CERT will establish the method for destroying the product.

**6.7.6.2.** The packaging will be recycled and NOT re-used.

**6.7.7. Preventative and Corrective Actions Taken** (Freund, et. al., 2013).

**6.7.7.1.** An investigation will be conducted to determine the root cause.

**6.7.7.2.** Corrective actions will be initiated. The corrective action(s) will be documented.

**6.7.8. Consumer Communication:** The applicable regulatory agency, depending on the severity of the issue, will notify the public (FDA, 2013d).

**6.7.8.1.** In the event that Boulevard Brewing Company would decide to make a separate public statement, the statement should be routed to the agency for review and comment (FDA, 2013d).

**6.7.8.2.** Corporate counsel will develop an appropriate communication format and establish acceptable content as part of the Recall Strategy. The communication will be distributed, as applicable, to the following media outlets (FDA, 2013d).

- National or local news media.
- Specialized news media.
- Point of sale communication.

**6.7.9. Effectiveness Checks:** The CERT will investigate and document that the product has been recalled and destroyed.

**6.7.9.1.** The CERT will determine the extent of verified communication with ALL customers that may have affected product (FDA, 2013d).

**6.7.9.2.** Follow up contact attempts must be made to customers who do not respond to initial contact attempts (FDA, 2013d).

**6.7.9.3.** Effectiveness checks must contain the name and address of the customer and the amount of product(s) they had on hand at the time of the communication (FDA, 2013d).

**6.7.9.4.** The effectiveness checks must document the amount product destroyed or returned (FDA, 2013d).

**6.7.9.5.** All effectiveness check actions must be documented. This information will be delivered to the applicable regulatory agency on a regular basis (FDA, 2013d). Refer to **6.7.10.** below.

**6.7.10. Recall Status Report:** The appropriate regulatory agency will request a regular recall status report to assess the progress of the recall. The agency will specify the frequency, usually 2 to 4 weeks. The recall status report should contain the following information (FDA, 2013d):

- The number of customers contacted and the date and method of contact (FDA, 2013d).
- The number of customers who responded to the communication and how much product was on hand at that time (FDA, 2013d).
- The number and identity of customers that did not respond to the recall communications (FDA, 2013d).
- The amount of product(s) returned by each customer who received the communication (FDA, 2013d).
- The amount of product, accounted for, in the distribution chain (FDA, 2013d).

- The results of the effectiveness checks made (FDA, 2013d).
- The estimated time to complete the recall (FDA, 2013d).

**6.7.11. Termination of Recall:** The appropriate regulatory agency will determine the termination of the recall, or the company can request termination of recall. (FDA, 2013d; USGPO, 2014g)

**6.7.11.1.** Once the agency has determined that “...all reasonable efforts have been made to remove or correct the product..” and “...it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard...” the agency will issue a written termination of recall (FDA, 2013d).

**6.7.11.2.** Once the CERT determines that the recalled batch has met the criteria listed in **6.6.10** above, the CERT will request termination of the recall by submitting a written request to the appropriate regulatory agency (FDA, 2013d).

**6.7.11.3.** The written request will also include the last status report and a description of the disposition of the recalled lot (FDA, 2013d).

## General SOP 05 References

### 1. PURPOSE

**1.1.** This documents outlines all of the references used to generate the GMP-based prerequisite programs.

### 2. SCOPE

**2.1.** This procedure applies to all SOPs used at all Boulevard Brewing Company facilities.

### 3. RESPONSIBILITY

**3.1.** It is the responsibility of the author to properly document the sources of information used to generate documents.

**3.2.** Personnel in the Quality department will review SOP’s submitted for approval to adherence to this standard.

### 4. DEFINITIONS

**4.1.** Document - Any written form recording operational information pertinent to any aspect of operating the facility. May exist as an electronic or hard copy.

**4.2.** USGPO- United States Government Printing Office.

### 5. MISCELLANEOUS CATEGORIES

**5.1.** N/A

### 6. PROCEDURE

- 6.1. Citations listed in Section 7 below should follow the APA Citation Guidelines. (APA, 2010)

## 7. **REFERENCE DOCUMENTS**

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## **Personnel SOP 01 Personal Hygiene**

### **1. PURPOSE**

- 1.1. This procedure outlines strategies to ensure that personnel are not a source of product contamination. (Bernard, Parkinson, & Chen, 2006)

### **2. SCOPE**

- 2.1. This procedure applies to personnel working, transiting, visiting, or performing contract work in the production areas of Boulevard Brewing Company operated facilities.
- 2.2. This procedure applies, in part, to office, catering and support staff whose duties do not take them into production areas.

### **3. RESPONSIBILITY**

- 3.1. It is the responsibility of all personnel on Boulevard Brewing Company property to understand and follow the principles outlined in this Document.

- 3.2. This document does not apply to non-professional visitors to the Brewery Tour, Gift Shop, or Event Spaces (Boulevard Brewing Company, 2014a; Boulevard Brewing Company, 2014b).
- 3.3. It is the responsibility of the Quality Department to determine content and format of written training materials.
- 3.4. Department supervision is responsible for monitoring adherence to this policy.
- 3.5. The Human Resources (HR) department is responsible for administering training to employees, visitors, contractors, and guests. HR is responsible for maintaining training records for all training performed. Refer to the current General SOP 03 Document Management for document retention procedures.

#### 4. **DEFINITIONS**

- 4.1. Brewery Tour – Walk-in or pre-scheduled tours of the facility with varying levels of facility access (Boulevard Brewing Company, 2014b).
- 4.2. Contractor – Any person working for a third party performing work on, or services for Boulevard Brewing Company Facilities, personnel, or equipment. This includes temporary workers.
- 4.3. Employee – Any person employed by Boulevard Brewing Company or any Duvel Moortgat holdings.
- 4.4. Event Spaces – Hospitality spaces that may be rented to provide varying levels of refreshments and catering services. The event spaces include the ‘Muehlebach Suite’, the ‘Brewhouse Bar’, and the ‘Tasting Room’ (Boulevard Brewing Company, 2014a).
- 4.5. Facility – All Boulevard Brewing Company Production, storage, maintenance, and warehousing locations, including the surrounding grounds.
- 4.6. Gift Shop – A retail location selling promotional products, prepackaged food, and bottled beers produced at Boulevard Brewing Company. Adjacent to, and accessible from, the ‘Tasting Room’ (Boulevard Brewing Company, 2014b).
- 4.7. Production area – Any space, inside or outside, where production processes are performed.
- 4.8. Product zone – All areas immediately surrounding product production equipment.
- 4.9. Sanitary facilities –Facilities used to maintain proper personal hygiene. These include restrooms, locker rooms, hand-washing stations, hand-sanitizing stations.
- 4.10. Personnel – A generic term encompassing employees, contractors, and visitors.
- 4.11. Visitor – Any person entering Boulevard Brewing Company Facilities for professional or educational purposes. Family, friends, or tour participants are not in this category.

#### 5. **MISCELLANEOUS CATEGORIES**

- 5.1. N/A

## 6. PROCEDURE

### 6.1. Personal Hygiene: (Bernard, et.al., 2006)

#### 6.1.1. **Hygiene and Grooming:**

- 6.1.1.1. Handwashing or sanitizing is required before entering production areas.
- 6.1.1.2. Handwashing is required after using sanitary facilities, including restrooms and lockerrooms.
- 6.1.1.3. Keep hands and fingernails clean. If fingernail polish, artificial fingernails, or tips are present, gloves must be worn at all times in the production area.
- 6.1.1.4. The use, or possession, of tobacco products is not allowed in production areas.
- 6.1.1.5. Spitting anywhere in the production areas is prohibited.
- 6.1.1.6. Eating, chewing gum, and drinking of any fluid other than water is not permitted in the production areas (AIB, 2013).
- 6.1.1.7. No food is allowed in production areas. Food will be confined to the break room, administrative offices, and event spaces. (AIB, 2013)
- 6.1.1.8. Toothpicks, matches, or similar objects are prohibited in production areas.
- 6.1.1.9. Makeup is not allowed in open production areas. Refer to **6.4.1.3** for areas considered open production areas (AIB, 2013).
- 6.1.1.10. Jewelry is not allowed in the production areas. Examples include the following: watches, earrings, and necklaces (AIB, 2013).
- 6.1.1.11. Plain wedding bands (without stones) and Medical Alert items are allowed (AIB, 2013).

#### 6.1.2. **Personal Health:**

- 6.1.2.1. No one affected with any disease capable of being transmitted to others may work around product, or product contact surfaces, that are reasonably likely to be contaminated. (Bernard, et.al., 2006; USGPO, 2014a)
- 6.1.2.2. All personnel will promptly inform department supervision of any illness, boils, sores, infected wounds, or other abnormal conditions that may pose a risk of product, or product contact surface, contamination.
  - 6.1.2.2.1. Personnel with such conditions are required to wear protective bandages, coverings, or other protection to minimize contamination risks while at Facility.

**6.1.2.2.2.** Bandages and coverings will be securely fastened.

**6.1.3. Clothing:**

**6.1.3.1.** Approved work clothing will consist of; full length pants, clean and in good condition; shirts with sleeves, clean and in good condition. Holes, frayed fabric, tank tops, or sleeveless shirts are not permitted. If needed, sweatshirts, insulated pants, coveralls, or jackets may be worn.

**6.1.3.2.** Clothing must be clean at the start of work and be kept as clean as possible during the shift.

**6.1.3.3.** Nothing should be stored above waist level. It may fall into the product. Shirts without pockets are preferred.

**6.1.4. Protective Equipment:**

**6.1.4.1.** Approved safety shoes will be worn, by employees in the production areas of the facility.

**6.1.4.1.1.** Shoes should be inspected regularly for cleanliness and washed when appropriate.

**6.1.4.1.2.** It is recommended that these shoes remain at the facility, and stored in personal lockers .

**6.1.4.2.** Closed-toe shoes or boots are required for visitors . No sandals or open-toed shoes may be worn in the production areas. Temporary slip-on safety shoes will be provided.

**6.1.4.3.** All personnel will wear hairnets, to contain their hair, in open production areas. Baseball caps, visors, bandanas or hardhats are not acceptable hair restraints. All hair must be tucked and covered by the hairnet. Facial hair greater than 1/8" requires a beard net. (USGPO, 2014a)

**6.1.4.3.1.** Hair restraints must be disposed of after each shift or if they become soiled.

**6.1.4.4.** Open production areas are any product zone where the primary product contact surface is open to the environment. These areas include:

**6.1.4.4.1.** Brew kettle footprint production area.

**6.1.4.4.2.** Fermentor tank tops and ingredient pitching station areas.

**6.1.4.4.3.** Brite beer tank tops.

**6.1.4.4.4.** Packaging preparation area.

**6.1.4.4.5.** Keg maintenance station.

**6.1.4.5.** Gloves must be used when working with bulk or opened ingredients.

- 6.1.4.6. Gloves used for handling ingredients must be intact and sanitary. Disposable gloves are recommended.
- 6.1.4.7. Gloves used for handling food contact surfaces must be intact and clean. Gloves should be washed if they become soiled. Gloves that are worn, or frayed must be replaced.
- 6.1.4.8. Ear protection worn in required areas will be connected to a tie string or lanyard to help prevent product contamination.
- 6.1.4.9. Ear protection must be disposed of after each shift, or if it becomes soiled.
- 6.1.5. **Personal items** are not permitted in manufacturing areas. Examples include the following: personal electronics, purses, bags, hand lotion, cosmetics, medicine, reading material, jackets, or rain gear. Some employees will be required to carry Boulevard Brewing Company approved electronic devices for business purposes (AIB, 2013).

**6.2. Required Training and Documentation:**

- 6.2.1. **Required Training:** (FDA, 2002; FDA, 2012; USGPO, 2014a)
  - 6.2.1.1. All personnel working in, or entering, production areas of the facility are required to attend GMP personal hygiene training. Refresher training is required once per calendar year.
    - 6.2.1.1.1. The personal hygiene GMP training may be combined with other GMP training.
  - 6.2.1.2. Contractors and professional visitors will receive GMP personal hygiene training at their initial visit and will attend refresher training once per calendar year thereafter.
  - 6.2.1.3. The Quality department will develop a written training program, detailing all of the points covered in this SOP.
  - 6.2.1.4. The Quality department will develop written training materials, proof of understanding testing material, and a class roster. Refer to the current Personnel SOP 03 Personnel Training and Recordkeeping.
- 6.2.2. **Required Documentation:** Required to comply with GMP and record keeping requirements of the FDA FD&C Act, BTA, and FSMA (FDA, 1938; FDA, 2002; FDA, 2012; USGPO, 2014a).
  - 6.2.2.1. All documents generated in 6.2.1.4. will be retained for 2 years past the termination date of employment, for employees, or contract termination, for contractors.



# Personnel SOP 02 Human Resources for Food Safety and Security

## 1. PURPOSE

- 1.1. This procedure defines the procedures, tools, and strategies used to manage human resources for food safety and security.
- 1.2. This procedure defines minimum standards to establish site security.

## 2. SCOPE

- 2.1. This procedure applies to personnel working, transiting, visiting, or performing contract work in the production areas of Boulevard Brewing Company facilities.
- 2.2. This procedure applies to office, catering, and support staff whose duties do not take them into production areas.
- 2.3. These procedures do not apply to tour guests and guests at the event spaces.

## 3. RESPONSIBILITY

- 3.1. It is the responsibility of all personnel on Boulevard Brewing Company property to understand and follow the principles outlined in this Document.
- 3.2. This document does not apply to non-professional guests of the Brewery Tour, Gift Shop, or Event Spaces.
- 3.3. It is the responsibility of the HR department to determine content and format of written programs, tools, and training materials.
- 3.4. The HR department is responsible for monitoring adherence to this policy.
- 3.5. The HR department is responsible for administering training to employees, visitors, contractors, and guests. HR is responsible for maintaining training records for all training performed. Refer to the current General SOP 03 Document Management for document retention procedures.

## 4. DEFINITIONS

- 4.1. Brewery Tour – Walk-in or pre-scheduled tours of the facility with varying levels of facility access.
- 4.2. Contractor – Any person working for a third party performing work on, or services for Boulevard Brewing Company Facilities, personnel, or equipment. This includes temporary workers.
- 4.3. Employee – Any person employed by Boulevard Brewing Company or any Duvel Moortgat holdings.
- 4.4. Event Spaces – Hospitality spaces that may be rented to provide varying levels of refreshments and catering services. The event spaces include the 'Muehlebach Suite', the 'Brewhouse Bar', and the 'Tasting Room' (Boulevard Brewing Company, 2014a).
- 4.5. Facility – All Boulevard Brewing Company Production, storage, maintenance, and warehousing locations, including the surrounding grounds.

- 4.6. Gift Shop – A retail location selling promotional products, prepackaged food, and bottled beers produced at Boulevard Brewing Company. Adjacent to, and accessible from, the ‘Tasting Room’ (Boulevard Brewing Company, 2014b).
  - 4.7. HR- Human Resources.
  - 4.8. Personnel – A generic term encompassing employees, contractors, and visitors.
  - 4.9. Production area – Any space, inside or outside, where production processes are performed.
  - 4.10. Product zone – All areas surrounding product production equipment.
  - 4.11. Visitor – Any person entering Boulevard Brewing Company Facilities for professional or educational purposes. Family, friends, or tour participants are not in this category.
5. **MISCELLANEOUS CATEGORIES**
- 5.1. N/A
6. **PROCEDURE**
- 6.1. **Employee Hiring Guidelines:**
    - 6.1.1. Use the attached forms to monitor and document the hiring process for all prospective employees. See Section 8 ‘**Attachments**’.
    - 6.1.2. Utilize the ‘Hiring Checklist’ (Personnel Form 01) to ensure that all steps in the hiring process are performed.
      - 6.1.2.1. Performing adequate hiring checks will help ensure that qualified candidates are chosen for the position.
      - 6.1.2.2. Qualified employees are essential to assuring an environment in which Facility security, production standards, quality standards and regulatory requirements are achieved.
  - 6.2. **Site Access Policy:** Access to the production areas of the Facility must be limited to authorized personnel to minimize exposure to tampering and maintain confidentiality.
    - 6.2.1. Lost or stolen access badges will be reported to the receptionist or HR immediately.
    - 6.2.2. Damaged, lost, or stolen badges will be replaced for a fee per badge.
      - 6.2.2.1. HR will grant access to parts of the facility that are required for the personnel to complete their job task(s).
    - 6.2.3. Employees will, as part of initial onboarding, receive a door access badge.
      - 6.2.3.1. The Employee door access badge will be uniquely colored and emblazoned with the word “EMPLOYEE” all in capital letters.
    - 6.2.4. Contractors will be granted a door access badge based upon the duration of their expected services.

- 6.2.4.1. Long-duration contractors will be issued a badge similar to the employee badge except that it will be a different color and be emblazoned with the word “CONTRACTOR” all in capital letters.
- 6.2.4.2. Short-duration contractors will be issued a visitor badge that will be a different color from either the Employee or Contractor badges and have the word “VISITOR” emblazoned on it all in capital letters.
- 6.2.5. Visitors will proceed to the receptionist desk and check in.
  - 6.2.5.1. Visitors must have an Employee contact.
  - 6.2.5.2. For visitor(s) that will move through the Facility without the Employee contact:
  - 6.2.5.3. The employee must fill out Personnel Form 08 Visitor(s) Site Access Request. Turn that form in to HR to get the required access granted as specified in section 6.2.2.1.
  - 6.2.5.4. The employee contact will meet the visitor(s) at the receptionists desk. The visitor(s) will be issued a door access badge that will have the same aspect as described in 6.2.4.2.
  - 6.2.5.5. For visitors that will move through the facility with the Employee contact, no access badge is required
- 6.2.6. **Tour Groups:** (Boulevard Brweing Company, 2014a; Boulevard Brewing Company, 2014b)
  - 6.2.6.1. Tours will follow established tour procedures.
  - 6.2.6.2. Tours will not enter production areas where open product contact areas are present. No unauthorized access to production areas will be tollerated.
  - 6.2.6.3. Access to production zones with closed production equipment is permissable.
  - 6.2.6.4. All tour groups will be escorted by an Employee.
  - 6.2.6.5. Tour groups must stay together.
  - 6.2.6.6. Tour groups have unrestricted access to Event Spaces and the Gift Shop.

## **Personnel SOP 03 Personnel Training and Recordkeeping**

### **1. PURPOSE**

- 1.1. This procedure describes the training and recordkeeping required for compliance with the FDA FD&C Act, FSMA, and BTA. (FDA, 2002; FDA, 2012; USGPO, 2014a)

- 1.2. The procedure does not describe training and recordkeeping requirements for compliance with TTB Regulation in Title 27 of the Federal code, except for Title 27 Parts 7, 13, 16, and 25: Labelling (TTB, 2014; USGPO, 2014c; USGPO, 2014d; USGPO, 2014e; USGPO, 2014g). The labelling requirements, of 27 CFR, dovetail with FDA requirements to prevent misbranding of foods. (FDA, 2002; FDA, 2012; USGPO, 2014c; USGPO, 2014d; USGPO, 2014e; USGPO, 2014g)

## **2. SCOPE**

- 2.1. This procedure applies to personnel working, transiting, visiting, or performing contract work in the production areas of Boulevard Brewing Company operated facilities.
- 2.2. This procedure applies, in part, to office, catering and support staff whose duties do not take them into production areas.

## **3. RESPONSIBILITY**

- 3.1. It is the responsibility of all personnel on Boulevard Brewing Company property to understand and follow the principles outlined in this Document.
- 3.2. The Quality department is responsible for document management, as outlined in General SOP 03 Document Management.
- 3.3. The Human Resources (HR) department is responsible for administering training to employees, visitors, contractors, and guests. HR is responsible for maintaining training records for all training performed. Refer to the current General SOP 03 Document Management for document retention procedures.
- 3.4. Department supervisors are responsible, unless otherwise specified, for content and format of training materials.

## **4. DEFINITIONS**

- 4.1. Contractor – Any person working for a third party performing work on, or services for Boulevard Brewing Company Facilities, personnel, or equipment. This includes temporary workers.
- 4.2. Employee – Any person employed by Boulevard Brewing Company or any Duvel Moortgat holdings.
- 4.3. Facility – All Boulevard Brewing Company Production, storage, maintenance, and warehousing locations, including the surrounding grounds.
- 4.4. Personnel – A generic term encompassing employees, contractors, and visitors.
- 4.5. Visitor – Any person entering Boulevard Brewing Company Facilities for professional or educational purposes. Family, friends, or tour participants are not in this category.

## **5. MISCELLANEOUS CATEGORIES**

- 5.1. N/A

## **6. PROCEDURE**

- 6.1. **Approved training programs.**

- 6.1.1. A training program will be developed for every GMP-based prerequisite program with an approved SOP.
  - 6.1.2. The department with primary responsibility for the area covered by the SOP will be responsible for the content and format of the training programs.
- 6.2. Required training components:**
- 6.2.1. All training programs will have a clearly defined curriculum. The curriculum will detail the goals, topics, and proficiency level required to prove understanding. The curriculum will include a written section. Visual aids, audio presentations, and physical examples can be added, as determined by departmental supervision.
  - 6.2.2. All training programs will have a method to demonstrate student understanding, of the concepts presented, through a 'proof of understanding' component. The 'proof of understanding' component can be a written exam, essay, demonstration of skills, or oral exam, All 'proof of understanding' components require a written Document that can stored according to General SOP 03 Document Management.
  - 6.2.3. All Training programs require a class roster to document attendance.
- 6.3. Required Training:** (FDA, 2002; FDA, 2012; Bernard, Parkinson, & Chen, 2006; USGPO, 2014c; USGPO, 2014d; USGPO, 2014e; USGPO, 2014g)
- 6.3.1.1. Employees must receive required training within one month of employment.
  - 6.3.1.2. Contractors and visitors will receive required training at the start of work and will attend refresher training once per calendar year thereafter.
  - 6.3.1.3. All personnel working in, or entering, production areas of the facility are required to attend GMP training to support the General SOP 01 Good Manufacturing Practices.
    - 6.3.1.3.1. The personal hygiene GMP training may be combined with other GMP training.
  - 6.3.1.4. All personnel that perform cleaning tasks are required to complete Cleaning and Sanitation training to support the Facilities SOP 05 Cleaning and Sanitation.
  - 6.3.1.5. All personnel in the bottling, graphic arts, and quality departments are required to complete TTB labeling training to support the Labeling SOP 01 TTB Labeling Requirements.
- 6.4. Required Documentation:** Required to comply with GMP and record keeping requirements of the FDA FD&C Act, BTA, and FSMA. (FDA, 2002; FDA, 2012; USGPO, 2014a)
- 6.4.1.1. Refer to General SOP 03 Document Management for complete guidelines on proper document storage.

**6.4.1.2.** All documents generated in **6.1**, **6.2**, and **6.3** will be retained for 2 years past the termination date of employment, for employees, or contract termination, for contractors.

## **Facilities SOP 01 Property: Structures, Grounds, Equipment, and Utilities.**

### **1. PURPOSE**

- 1.1.** This procedure describes the (re)design, materials, and maintenance of the structures, infrastructure, and grounds of the Boulevard Brewing Company.
- 1.2.** The standards described herein reflect the FDA GMP's and an understanding of the intrinsic properties of the product (Menz, Aldred, & Vriesekoop, 2009; USGPO, 2014a). The Congress, in establishing the FSMA, understood that alcoholic beverages are intrinsically safer than other food and exempted them from further controls as applied by the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food rule (FDA, 2013a). However, utilization of the GMP's and record keeping requirements are required by FDA, FSMA and BTA to prevent the adulteration of the product. (FDA, 2002; USGPO, 2013a; USGPO, 2014a)

### **2. SCOPE**

- 2.1.** These standards apply to all Boulevard Brewing Company facilities.

### **3. RESPONSIBILITY**

- 3.1.** It is the responsibility of all personnel to be familiar with the principles described in this SOP.
- 3.2.** The Engineering and Maintenance departments are responsible for applying these principals.
- 3.3.** The Quality department will be responsible for verifying certain aspects of the design parameters and maintaining all documents pursuant to General SOP 03 Document Management.
- 3.4.** The production departments will be responsible for utilizing the facilities in the manner described herein.

### **4. DEFINITIONS**

- 4.1.** BTA - Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act (BTA)) amendment to the FD&C Act (FDA, 2002).
- 4.2.** cGMPs – Current Good Manufacturing Practices intended to prevent food from becoming adulterated as defined by the FDA in 21 CFR Part 110 as: “The criteria and definitions in this part shall apply in determining whether a food is adulterated... within the meaning of... the act in that the food has been manufactured under such conditions that it is unfit for food; or... in that the

food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.” (USGPO, 2014a).

- 4.3.** CIP – Clean in Place. A system where proper cleaning and sanitation occurs, automatically, in closed production equipment.
- 4.4.** Facility – All Boulevard Brewing Company Production, storage, maintenance, and warehousing locations, including the surrounding Grounds.
- 4.5.** FAAA – The Federal Alcohol Administration Act of 1935 partially establishing the BATFE and TTB under the U.S. Department of the Treasury (USGPO VI, 2014).
- 4.6.** FDA – Food and Drug Administration under the U.S. Department of Health and Human Services (HHS). The agency responsible for assuring a safe wholesome food supply (FDA, 1938).
- 4.7.** FD&C Act – Federal Food Drug and Cosmetic Act of 1938 establishing the FDA under HHS (FDA, 1938).
- 4.8.** Food Contact Surface – Anywhere in the process where ingredients, finished product, or the inside of packaging material comes in contact. Includes utensils and tools.
- 4.9.** FSMA – Food Safety Modernization Act of 2011 updates the 1938 FD&C Act (FDA, 2014a).
- 4.10.** Grounds - The grounds will include parking areas or structures, walkways, landscaping spaces and any open areas not covered by a permanent structure, including walkways and roads that are owned, operated, or controlled by Boulevard Brewing Company.
- 4.11.** OEM – Original Equipment Manufacturer.
- 4.12.** PM – Preventative Maintenance. Pre-scheduled maintenance to ensure proper operation of equipment.
- 4.13.** Prerequisite Programs - The foundation for all food safety programs. Programs to enact GMP’s (Bernard, Parkinson, & Chen, 2006).
- 4.14.** Production area – Any space, inside or outside of the Boulevard Brewing Company property, where production processes are performed.
- 4.15.** Production equipment – Any equipment utilized to process ingredient(s) in to finished product(s) located in the Facility.
- 4.16.** Product zone – All areas immediately surrounding product production equipment.
- 4.17.** Sanitary facilities – Facilities used to maintain proper personal hygiene. These include restrooms, locker rooms, hand-washing stations, hand-sanitizing stations.
- 4.18.** SOP - Standard Operating Procedure.

- 4.19. TTB - Bureau of Alcohol Tobacco, Firearms and Explosives (BATFE), Alcohol and Tobacco Tax and Trade Bureau (TTB) under the U.S Department of the Treasury (USGPO, 2014f).

5. **MISCELLANEOUS CATEGORIES**

- 5.1. N/A

6. **PROCEDURE**

- 6.1. All audit, monitoring, preventative maintenance, verification, and calibration action(s) MUST be documented. Refer to General SOP 03 Document Management for proper documentation procedures.
- 6.2. If audits or monitoring activities find a failure, the deficiency must be immediately reported and the appropriate department notified to correct the failure. Document all corrective actions. Refer to General SOP 03 Document Management for proper documentation procedures.
- 6.3. In the event of a verification failure the equipment should be calibrated. If the calibration fails the equipment must be immediately repaired or replaced. The repaired or replaced item must be calibrated before being placed back in service. Document all corrective actions. Refer to General SOP 03 Document Management for proper documentation procedures.
- 6.4. **Plant Grounds:** The grounds surrounding the facility will be kept in a condition that will protect against the contamination of food (USGPO, 2014a).
- 6.4.1. Pest harborage and access points need to be eliminated by properly storing equipment, removing litter, cutting weeds and grass surrounding the plant structures (USGPO, 2014a).
- 6.4.2. Parking areas and walkways should be free of standing water (USGPO, 2014a).
- 6.4.3. Drainage in the grounds will be such that water is drained away from structures and production areas (USGPO, 2014a).
- 6.4.4. Security measures will be placed to ensure that unauthorized access to the grounds are prevented (USGPO, 2014a).
- 6.4.5. Ground audits will be performed regularly to ensure that the grounds meet the above standards (USGPO, 2014a). These audits must be documented. The documents will be stored in compliance with General SOP 03 Document Management.
- 6.5. **Utilities:** An uninterrupted supply of essential utilities are required to maintain sanitary conditions within the production areas (USGPO, 2014a).
- 6.5.1. All utilities must be enclosed and labeled to clearly identify the utility and allow safe access for maintenance and repair (USGPO, 2014a).
- 6.5.2. **Electricity.** A secure and uninterrupted supply of electricity sufficient to power all electrical systems at the facility is required (USGPO, 2014a).
- 6.5.2.1. Payment of accounts must be kept current to maintain this utility (USGPO, 2014a).



- 6.5.2.2. The electrical system will be on a regular PM schedule to ensure receipt of an uninterrupted supply (USGPO, 2014a).
- 6.5.2.3. These actions must be documented. The documents will be stored in compliance with General SOP 03 Document Management.
- 6.5.3. **Natural gas.** A secure and uninterrupted supply of natural gas sufficient to power all gas fired systems at the facility is required (USGPO, 2014a).
  - 6.5.3.1. Payment of accounts must be kept current to maintain this utility (USGPO, 2014a).
  - 6.5.3.2. The gas supply system will be on a regular PM schedule to ensure receipt of an uninterrupted supply (USGPO, 2014a).
  - 6.5.3.3. Regular audits of the system will inspect for leaks or damage (USGPO, 2014a).
  - 6.5.3.4. These actions must be documented. The documents will be stored in compliance with General SOP 03 Document Management.
- 6.5.4. **Water.** An uninterrupted potable water supply is critical for operation of a brewery and must be ensured (USGPO, 2014a).
  - 6.5.4.1. Payment of accounts must be kept current to maintain this utility (USGPO, 2014a).
  - 6.5.4.2. All water utilized in the brewing process must be treated on site to ensure removal of any potential spoilage microorganisms and undesirable chemicals (USGPO, 2014a).
  - 6.5.4.3. Water utilized in cleaning, boilers, and sanitary facilities must be from a municipal water supply and deemed potable (USGPO, 2014a).
  - 6.5.4.4. The water treatment system will be on a regular PM schedule to ensure delivery of an uninterrupted supply (USGPO, 2014a).
  - 6.5.4.5. These actions must be documented. The documents will be stored in compliance with General SOP 03 Document Management.
- 6.5.5. **Sewer:** Effective sewers are required to maintain an environment that does not offer the potential of adulteration. (USGPO I, 2014)
  - 6.5.5.1. Payment of accounts must be kept current to maintain this utility (USGPO, 2014a).
  - 6.5.5.2. Covered functional drains are required throughout the facility (USGPO, 2014a).
  - 6.5.5.3. The Sewer system will be on a regular PM schedule to ensure adequacy (USGPO, 2014a).

- 6.5.5.4. The sewer drains must inspected and flushed as part of a regular sewer audit (USGPO, 2014a).
    - 6.5.5.5. These actions must be documented. The documents will be stored in compliance with General SOP 03 Document Management.
  - 6.5.6. **Waste management:** Removal of waste from the facility is required to maintain an environment that does not offer the potential of adulteration. (USGPO I, 2014)
    - 6.5.6.1. Payment of accounts must be kept current to maintain this utility (USGPO, 2014a).
    - 6.5.6.2. Personnel throughout the facility will, per department supervision, be responsible for placing non-recycleable waste in appropriate receptacles. Those receptacles will be moved in timely manner to collection points.
    - 6.5.6.3. A timely pick up schedule will be determined with the third party supplier of this utility.
    - 6.5.6.4. Audits of the plant for waste and sources of waste will be performed regularly (USGPO, 2014a).
    - 6.5.6.5. These actions must be documented. The documents will be stored in compliance with General SOP 03 Document Management.
- 6.6. **Plant Construction and Design:** The following principles should be used to (re)design, construct, maintain, and operate the Facility. The facility must provide a controlled environment to prevent conditions in which "...the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." (USGPO, 2014a). If the pre-existing designs are not ideal, operational practices must be implemented to correct for design deficiencies (USGPO, 2014a).
  - 6.6.1. Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 all facilities that produce food must register with the FDA. The following are the addresses and FDA Registration numbers for all production sites for Boulevard Brewing Company. (FDA, 2002)
    - 6.6.1.1. 2501 SW Boulevard Blvd.                      FDA# 13032562254
    - 6.6.1.2. 1325 N. Topping                                      FDA# 13161098130
    - 6.6.1.3. 3030 Ronoake                                      FDA# 12434827500
  - 6.6.2. Buildings and structures will be suitable in size, materials, construction, and design to facilitate maintenance and sanitary operations. The layout should maximize process flow and minimize cross contamination (USGPO, 2014a).

- 6.6.3.** Floor, ceiling, wall and support structures must be constructed of materials that are impervious to the required cleaning chemicals. These production zone surfaces need to be free of gaps, cracks, holes, corrosion, or peeling coatings (USGPO, 2014a).
- 6.6.4.** Specifically the following extra precaution need to be followed for production zone surfaces (USGPO, 2014a; AIB, 2013):
  - 6.6.4.1.** Walls must be free from condensation built up residue.
  - 6.6.4.2.** Ceilings must provide adequate space to allow tank tops to be opened completely and allow access for cleaning or maintenance.
  - 6.6.4.3.** Windows must be solidly emplaced and free from cracks or missing panes.
  - 6.6.4.4.** Windows must be covered, when open, with appropriate size screen to prevent access.
  - 6.6.4.5.** Lighting must have a washable cover.
  - 6.6.4.6.** Doors must be of a self closing design and maintained in good working order.
- 6.6.5.** Production areas need to be (re)designed to contain and facilitate easy clean up of any intentional or unintentional releases of liquids (USGPO, 2014a).
- 6.6.6.** Production areas should be segregated from each other as much as possible. Maintain separation of ingredients from finished product and packaging materials (USGPO, 2014a).
- 6.6.7.** Maintenance and cleaning areas need to be accesible; however, they cannot impact quality or food safety (USGPO, 2014a).
- 6.6.8.** The environmental controls must be adequate to maintain a controlled environment for the entire year (USGPO, 2014a).
- 6.6.9.** Adequate lighting and ventilation will be maintained in the production areas and sanitary facilities (AIB, 2013).
- 6.6.10.** Lighting will conform to the Facilities SOP 02 Pest Control.
- 6.6.11.** All lighting used in production areas of the Facility must use a shatterproof bulb or have a shatterproof cover (AIB, 2013).
- 6.6.12.** All efforts to mitigate dust migration from milling operations and warehouses should be taken. (USGPO I, 2014)
- 6.6.13.** Ventilation equipment will be on a PM schedule to replace or maintain filters (USGPO, 2014a).
  - 6.6.13.1.** Preventative maintenance of the venitillation system will be performed on a regular basis (USGPO, 2014a).
  - 6.6.13.2.** These actions must be documented. The douments will be stored in compliance with General SOP 03 Document Management.

- 6.6.14. Ventilation will maintain positive pressure from production areas to non production areas (USGPO, 2014a).
- 6.6.15. Ventilation will maintain positive pressure from areas containing finished products to areas containing in process product to areas containing ingredients and packaging supplies (USGPO, 2014a).
- 6.6.16. Compressed air must be capable of keeping airborne lubricant levels below 3ppm and 5 microns. (AIB,2013)
  - 6.6.16.1. If the system is not capable of maintaing this level food grade lubricants must be used.
  - 6.6.16.2. The system will be on a preventative maintenance schedule based upon OEM recommendations. Preventative maintenance will also include filters and moisture traps.
  - 6.6.16.3. These actions must be documented. The douments will be stored in compliance with General SOP 03 Document Management.
- 6.6.17. Wood and other absorbent material should not be used as a construction material in the production areas. Where these materials already exist a coating will be present to ensure that effective cleaning can be performed. Ageing casks are exempt.
- 6.6.18. Only food grade silicone seals, gaskets, or sealant may be used in product zones. Special care must be taken to prevent contamination.
- 6.6.19. The buildings and structures will be audited on a regular schedule to assure compliance.
- 6.6.20. These actions must be documented. The douments will be stored in compliance with General SOP 03 Document Management.
- 6.7. **Production Equipment** should be constructed of appropraie materials for a food production area, designed to minimize accumulation of residue, and be designed to allow easy ceaning. (Bernard, et. al., 2006; Barach & Dunaif,2013; USGPO, 2014a)
  - 6.7.1. All equipment should be constructed of nonporous food-grade materials and utilize food grade lubricants and seals. All materials used in the equipment construction must be compatible with the appropriate cleaning chemicals used in the prouction area (Bernard, et.al., 2006). Ageing casks are exempt from these requirements.
  - 6.7.2. All equipment should be designed to be easlily disassemble and clean. Designs that leave 'dead spots' should be avoided. Large systems that include a CIP system are exempt from that reuirement.
  - 6.7.3. CIP systems must be verified by the Quality department for adequacy and effectiveness on a regular schedule (AIB, 2013). The Quality department will maintain the appropriate Documentation according to General SOP 03 Document Management.

- 6.7.4. All equipment will be placed on regular PM schedule. PM activities include checking for wear, damage, unauthorized modifications, or temporary repairs. The regular PM schedule will include replacing consumable or normal wear components, such as filters and seals. The maintenance schedule should be developed around OEM recommendations. Maintenance activities should be performed with approved replacement parts (AIB, 2013).
- 6.7.5. Specific production and testing equipment requires calibration to ensure that it is operating correctly. Items such as pH meters, load cells, flow meters, etc... must be placed on a regularly scheduled verification and calibration schedule. The verification can be performed by any qualified personnel. The calibrations should be performed by the Quality department or certified third party vendors.
- 6.7.6. These PM and Calibration actions must be documented. The Documents will be stored in compliance with General SOP 03 Document Management.
- 6.8. **Glass Control:** "Glass quality control programs are necessary to assure packages can be adequately sealed and processed. These programs must manage glass breakage on the processing line and prevent or detect glass fragments that could occur through manufacturing defects, distribution or processing/packaging operations." (Barach, Dunaif, 2013, p. 25; USGPO, 2014a)
  - 6.8.1. The automatic bottle wash station, on the filling line, must be verified on a very frequent schedule to ensure that it is fully functional and adequate to remove any potential for glass fragments from any bottle prior to entering the filling line
  - 6.8.2. The filling station automatic purge and rinse cycle for broken bottles, on the filling line, must be verified on a very frequent schedule to ensure that it is fully functional and adequate to remove any potential for glass fragments from entering any remotely adjacent bottle.
  - 6.8.3. These verification actions must be documented. The documents will be stored in compliance with General SOP 03 Document Management.
- 6.9. **Storage / Warehousing:** (USGPO, 2014a; AIB,2013)
  - 6.9.1. All Storage locations will have a unique storage location identification to allow traceability (AIB, 2013).
  - 6.9.2. Storage of raw materials and finished products will be maintained under conditions that will protect food against adulteration and deterioration of the product and packaging (USGPO, 2014a).
  - 6.9.3. An 18" wide Sanitary White Line will be maintained on warehouse walls adjacent to storage areas to allow for pest control access and prevent pest harborages (AIB, 2013).
  - 6.9.4. Stack ingredient(s), packaging material(s), and finished product(s) outside of the 18" Sanitary white lines (AIB, 2013).

- 6.9.5. Store all items off floor on pallets, slip-sheets or racks.
- 6.9.6. Remove and clean broken packages or spilled product immediately.
- 6.9.7. Do not use dirty or broken pallets. Do not use damaged pallets. Store pallets in areas free from filth, bird, insect, or rodent contamination. Pallets stored outside are to be inspected prior to use.
- 6.9.8. The warehouse and storage locations will be audited on a regular schedule to assure compliance.
- 6.9.9. These actions must be documented. The documents will be stored in compliance with General SOP 03 Document Management.
- 6.10. **Sanitary Facilities:** Adequate washing, sanitizing, toilet, locker room, and changing facilities must be available and properly maintained to allow adherence to personal hygiene standards and cleaning and sanitation procedures (USGPO, 2014a).
  - 6.10.1. All sanitary facilities need to follow design criteria specified in sections 6.2 and 6.3 of this document.
  - 6.10.2. Provide sufficient washing and sanitizing areas designed for cleaning and sanitizing of production equipment, tools, and utensils (USGPO, 2014a; AIB, 2013).
    - 6.10.2.1. The areas need to be designed with adequate drainage.
    - 6.10.2.2. The areas need to be large enough for complete manipulation of the equipment, tools, and utensils being cleaned and sanitized.
    - 6.10.2.3. The areas need to be provided with sink(s) of an appropriate size to handle the tasks being performed.
  - 6.10.3. Provide access to sufficient toilet, locker room, and changing locations to accommodate the number of personnel present (AIB, 2013).
  - 6.10.4. Toilet, locker room, and changing locations doors must be of a self closing design and maintained in good working order.
  - 6.10.5. All sanitary facilities will be maintained as part of the 'Master Sanitation Schedule'.
  - 6.10.6. These actions must be documented. The documents will be stored in compliance with General SOP 03 Document Management.
- 6.11. **Repairs and Maintenance:** Proper maintenance of the Facility and Utility infrastructure is critical to maintaining those systems. Regular audits of all property systems will indicate areas for repair. Reports by personnel during operation will also indicate areas of concern. Repairs must take place as soon as possible after being reported (USGPO, 2014a).
  - 6.11.1. Temporary repairs must be dated and initialed (AIB, 2013). Temporary repairs must be replaced with permanent repairs or replacements as soon as practical (AIB, 2013).

**6.11.2.** These actions must be documented. The Documents will be stored in compliance with General SOP 03 Document Management.

## **Facilities SOP 02 Pest Control**

### **1. PURPOSE**

**1.1.** This procedure outlines integrated pest management strategies to minimize or eliminate pest infestations and assure an environment free from filth and insanitary conditions that might render products adulterated.

### **2. SCOPE**

**2.1.** This procedure applies to all Boulevard Brewing Company operated facilities.

### **3. RESPONSIBILITY**

**3.1.** It is the responsibility of all personnel to be aware of the consideration in this SOP and perform any actions necessary to prevent, reduce or eliminate an infestation.

**3.2.** It is the responsibility of the engineering/design department to follow the current version of Facilities SOP 01 Properties: Structures, Grounds, Equipment, and Utilities to ensure that new and existing construction minimizes pest harborage spots.

**3.3.** It is the responsibility of the third party pest control contractor to establish, monitor and maintain the facility's written pest management system.

**3.4.** It is the responsibility of the Quality department to manage all documentation, including the written pest control program, monitoring, treatment, sighting, and audit Documents. Refer to the current General SOP 03 Document Management.

### **4. DEFINITIONS**

**4.1.** Facility – All Boulevard Brewing Company Production, storage, maintenance, and warehousing locations, including the surrounding grounds.

**4.2.** Third party pest control contractor. A registered and bonded company, providing pest control services that are compliant with local, state, and federal regulations.

**4.3.** Harborage – Any space capable of sheltering a pest. These can include lips, overhangs, pipes, cracks, crevices, holes, conduits, or access hatches. Harborage points can be as small as 0.5mm and large enough to hide a family of raccoons.

**4.4.** Integrated Pest Management Strategies: (Johnson, 2002)

**4.4.1.** Identify the extent of the problem.

**4.4.2.** Facilities design to minimize pest harborages.

**4.4.3.** Proper sanitation.

**4.4.4.** Monitor pest activity.

**4.4.5.** Utilize appropriate treatment measures, when necessary.

- 4.5. Common Pest types: (Johnson, 2002)
  - 4.5.1. Microorganisms.
  - 4.5.2. Insects, mites and arachnids.
  - 4.5.3. Vertebrate pests, including, rodents, avians, and mammals. Note that many 'pests' are actually regulated species under state or federal game laws.

5. **MISCELLANEOUS CATEGORIES**

5.1. N/A

6. **PROCEDURE**

6.1. **Mitigation strategies:**

6.2. **Facility and Equipment design.** Refer to the current Facilities SOP 01 Properties: Structures, Grounds, Equipment, and Utilities (Johnson, 2002).

6.2.1.1. The building should be designed with self closing doors, windows, screens, or vents that securely close all openings and prevent the entry of pests.

6.2.1.2. Outside lighting should be designed to avoid attracting insects near frequently used openings. Use of mercury vapor lamps should be avoided.

6.2.1.3. Production equipment and interior designs should minimize or eliminate pest harborage. If this is not possible the areas should be easily accessible for cleaning.

6.2.1.4. Outside ledges that provide bird roosts should be avoided, eliminated or modified to reduce the roosting site.

6.2.2. **Sanitation.** By eliminating waste material the attraction a given facility will be reduced. Refer to the current Facilities SOP 05 Cleaning and Sanitation (Johnson, 2002).

6.2.2.1. Regular cleaning of floors, walls, ceilings, and equipment; prompt spill cleanup; and prompt waste removal will minimize waste accumulations that can be harborage and attraction points.

6.2.2.2. Proper housekeeping of offices and break spaces will minimize food waste and reducing migration of pest from office spaces to production areas.

6.2.3. **Environmental Controls** (Johnson, 2002).

6.2.3.1. Proper environmental controls, in good repair, can maintain a constant atmosphere to prevent problems with high temperature and humidity.

6.2.3.2. Maintain storage locations as cool and dry as possible. This will minimize mold growth and inhibit insect reproduction.



**6.2.4. Monitoring pest populations** (Johnson, 2002).

**6.2.4.1.** The third party pest control contractor must have regular monitoring of environmental traps and observed pests.

**6.2.4.2.** Monitoring stations need to be placed at the perimeter of the property, outside of buildings and structures, and at ingress/egress points to monitor external pest activity.

**6.2.4.3.** Monitoring stations need to be placed at key points within the facility to monitor potential activity at critical areas.

**6.2.4.4.** Special care needs to be taken with rodent and insect infestations as they can progress rapidly from a 'first' sighting to an overwhelming infestation.

**6.2.4.5.** Use of multiple trap types for pest types will insure that all pest activity will be observed. Early detection can reveal weaknesses in other areas of the pest control system that need to be addressed. These will be addressed by the third party pest control contractor.

**6.2.4.6.** Threshold levels, to initiate treatment, will be determined by the third party pest control contractor.

**6.2.5. Treatment methods** are the sole responsibility of the third party pest control contractor. However, use of chemical controls should be minimized. Use of traps and bait stations to prevent an infestation is preferred (Johnson, 2002).

**6.2.5.1.** Pesticides utilized as part of the integrated pest management strategy must be used and stored in accordance with chemical label. Refer to the current Facilities SOP 04 Chemical Control plan.

**6.2.5.2.** The use of poison for inside interior pest control devices is prohibited.

**6.2.5.3.** Pesticide usage will be logged and tracked. Only certified applicators will be allowed to handle and apply approved chemicals.

**6.3. Personnel practices:**

**6.3.1.** Employees can have a large impact on preventing pests from entering the facility by closing windows and doors. Special attention needs to be paid to times when the climate is conducive to opening and keeping open doors and windows for personal comfort. Employee training and proper environmental control can mitigate this risk. (Johnson, 2002)

**6.4. Pest Control Audits:**

**6.4.1.** Routine pest control audits must be undertaken to note potential harborage sites or signs of infestations (Johnson, 2002).

- 6.4.2. Audit teams need to be cross function to allow different areas of expertise to observe the facility (Johnson, 2002).
- 6.4.3. All audit teams need to document the audit findings and present them to the proper area (mainenance, housekeeping, production, etc...) or to the third party pest control contractor (Johnson, 2002).
- 6.5. **Documentation:** (Bernard, Parkinson, & Chen, 2006)
  - 6.5.1. The third party pest control contractor, as part of their contract, must provide a written comprehensive pest control plan including monitoring and treatment methods.
  - 6.5.2. All monitoring activities need to be documented.
  - 6.5.3. All treatment methods need to be documented.
  - 6.5.4. All pest sightings need to be documented.
  - 6.5.5. All pest control audits need to be documented.
  - 6.5.6. These documents can be retained together with the written pest control plan.

## **Facilities SOP 03 Shipping, Receiving, and Material Handling**

### **1. PURPOSE**

- 1.1. This procedure Outlines requirements for approving vendors, establishing Ingredient specifications, receiving ingredients, receiving packaging materials, release of finished product, and shipping finished products.

### **2. SCOPE**

- 2.1. This procedure applies to all Boulevard Brewing Company facilities.
- 2.2. This procedure applies to all vendors supplying Boulevard Brewing Company.
- 2.3. This procedure applies to all ingredients and packaging materials.
- 2.4. This procedure applies to all finished product releases and shipping.

### **3. RESPONSIBILITY**

- 3.1. It is the responsibility of the Purchasing department to establish, monitor, and document a vendor verification program.
- 3.2. Personnel in the Quality department will establish, review and document the ingredient and finished product specifications.
- 3.3. It is the responsibility of the Marketing department to establish packaging specifications
- 3.4. The Quality department is responsible for verifying that product meets finished product specifications prior to release.
- 3.5. It is the responsibility of the Operations department to comply with inspection, monitoring, reporting, and documenting receiving and shipping operations.

#### 4. DEFINITIONS

- 4.1. BOL – Bill of Lading. Document that accompanies a shipment. Must have all of the information described under PO and a list of the seal numbers on the shipment.
- 4.2. BTA - Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act (BTA)) amendment to the FD&C Act (FDA, 2002).
- 4.3. Facility – All Boulevard Brewing Company Production, storage, maintenance, and warehousing locations, including the surrounding grounds.
- 4.4. FDA – Food and Drug Administration under the U.S. Department of Health and Human Services (HHS). The agency responsible for assuring a safe wholesome food supply (FDA, 1938).
- 4.5. FD&C Act – Federal Food Drug and Cosmetic Act of 1938 establishing the FDA under HHS FDA, 1938).
- 4.6. FSMA – Food Safety Modernization Act of 2011 updates the 1938 FD&C Act (FDA, 2014).
- 4.7. Material Documents – Letters of Guarantee (LOG), Certificate of analysis (COA), or any other document meant as certification of the contents of a shipment.
- 4.8. MRS Broth – de Man, Rogosa, & Sharpe broth. An ideal growth medium for *Lactobacillus* species of bacteria.
- 4.9. PO – Purchase Order. Includes vendor name, address, and telephone number; destination name and address; unique order number, and itemized list of purchased goods.
- 4.10. Shipping Documents – Any Bill of Lading (BOL), Invoice, or other document stating the name, address, telephone number, and Purchase Order (PO) of the source and destination of the products being received.
- 4.11. Vendor – Any third party supplying goods or services to Boulevard Brewing Company.

#### 5. MISCELLANEOUS CATEGORIES

- 5.1. N/A

#### 6. PROCEDURE

- 6.1. **Vendor Verification:** All vendors of ingredients for human food, even foods exempted from FSMA (Alcoholic beverages), are required to comply with both the Documentation and GMP sections of FSMA and the registration and recordkeeping requirements of the BTA. (FDA, 2002; FDA, 2012; USGPO, 2014a)
  - 6.1.1. All vendors will be inspected, on site, on a regularly scheduled frequency with allowances to increase that frequency if problems warrant greater scrutiny.
  - 6.1.2. Site audits will determine regulatory compliance and the presence, and efficacy, of an established food safety program. Required items include: (FDA, 2002; FDA, 2012; USGPO, 2014a; USGPO, 2014c; USGPO, 2014d; USGPO, 2014e; USGPO, 2014g)
    - 6.1.2.1. FDA registration number.

- 6.1.2.2. BTA compliance documentation and tracability.
  - 6.1.2.3. Established, written cGMP programs.
  - 6.1.2.4. Adherence to cGMP programs.
  - 6.1.2.5. Documentation demonstrating all of the above.
- 6.1.3. All audits, inspections and follow-up actions must be documented. Refer to General SOP 03 Document Management for proper retention and storage criteria.
- 6.2. Receiving:** (Bernard, Parkinson, & Chen, 2006; Barach & Dunaif, 2013; AIB, 2013)
- 6.2.1. All incoming production material must be inspected prior to receipt.
  - 6.2.2. All incoming production material must be handled with care to prevent damage and exposure to adverse conditions that could lead to adulteration.
  - 6.2.3. All materials must be properly labelled with a description and unique lot number attached at the lowest possible point on the box or pallet.
  - 6.2.4. Every shipment received at the facility must have the carrier inspected for damage, overall cleanliness, and pest activity.
  - 6.2.5. Every incoming shipment must have approved documentation. Approved documents must meet the following criteria.
    - 6.2.5.1. The supplied shipping documents must match the information provided by the PO.
    - 6.2.5.2. The container seals must match the ORIGINAL BOL. NO corrections allowed. A load failing this test MUST be rejected. No exceptions.
    - 6.2.5.3. Every item to be received must have the appropriate material documents enclosed.
    - 6.2.5.4. The shipment must be rejected if any the above are modified, corrected missing, or cannot be obtained from the supplier.
  - 6.2.6. All material Documents must meet or exceed the minimum requirements listed in the product specification section (6.4 & 6.5) of this Document.
  - 6.2.7. If the inspection reveals any kind of contamination, immediately notify the department supervision. Do not unload until all required testing is complete.
  - 6.2.8. Damaged, filthy, contaminated, or infested product(s) must be segregated to an area that will not pose a contamination risk to their products at the Facility, until the product disposition can be determined.
  - 6.2.9. When unloading bulk ingredient trucks, all vents will have an appropriate screen on the opening to protect the ingredient from contamination or pest infestation.
  - 6.2.10. All of the above inspection and receipt actions must be documented and the documents properly stored. Refer to General SOP 03 Document Management for proper Document retention and storage procedures.
- 6.3. Material Handling:** (Bernard, et. al., 2006; Barach & Dunaif, 2013; AIB, 2013)

- 6.3.1.** All containers must be correctly labelled correctly with the contents. Containers with no label or labelling other than the contents are strictly forbidden.
- 6.3.2.** Ingredients, packaging material, chemicals, pesticides, and finished product must be handled, maintained, and stored in a manner to prevent contamination.
- 6.3.3.** Make sure raw material bags are in good condition and outer surfaces are clean and free of contamination before taking into production
- 6.3.4.** Seal and identify contents of partially used ingredients. Identification must include the date opened and the initials of person re-sealing the container.
- 6.3.5.** Cover or seal partially used packaging material when not in use. Label the material with date opened and the initials of the person re-sealing the container.
- 6.3.6.** Store empty ingredient containers covered or inverted. Store containers away from other ingredients, packaging materials, and finished products. Keep all empty containers off the floor.
- 6.3.7.** Do not store full or empty product or ingredient containers next to containers for waste, chemicals or other non-product items.

Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed pertaining to Ingredients and By-Products.

Substance	Commodity <sup>①</sup>	Action level	Units	Reference
Aflatoxin	Animal feed	20	ppb	CPG 638.100
	Food	20	ppb	CPG 555.100
Aldrin & Dieldrin	Animal feed, processed	0.03	ppm	CPG 575.100
Aldrin & Dieldrin	Cereal grains (except buckwheat, millet, teosinte, and wild rice)	0.02	ppm	CPG 575.100
Benzene Hexachloride (BHC)	Animal feed, processed	0.05	ppm	CPG 575.100
Benzene Hexachloride (BHC)	Cereal grains (except buckwheat, millet, popcorn, teosinte, and wild rice)	0.05	ppm	CPG 575.100
Chlordane	Animal feed, processed	0.1	ppm	CPG 575.100
DICOFOL <sup>②</sup>	Animal feed, processed	0.5	ppm	CPG 575.100
DDT, DDE, & TDE	Animal feed, processed	0.5	ppm	CPG 575.100
	Hops	0.1	ppm	CPG 575.100
	Cereal grains (except buckwheat, fresh sweet corn, millet, popcorn, teosinte, and wild rice)	0.5	ppm	CPG 575.100

DIMETHYLNITROSAMINE (NITROSODIMETHYLAMINE)	Barley malt	10	ppb	CPG 578.500
	Malt beverages	5	ppb	CPG 510.600
ETHYLENE DIBROMIDE (EDB)	Grain products, intermediate (milled), must be cooked prior to consumption	150	ppb	CPG 575.100
HEPTACHLOR AND HEPTACHLOR EPOXIDE	Animal feed, processed	0.01	ppm	CPG 575.100
	Cereal grains	0.01	ppm	CPG 575.100
LINDANE	Animal feed, processed	0.1	ppm	CPG 575.100
	Rye	0.1	ppm	CPG 575.100
MERCURY	Wheat (pink kernels only)	1 ③	ppm	CPG 578.400
	Wheat (pink kernels only)	10 Kernels/500g	Ratio	CPG 578.400

Retrieved from:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetalsNaturalToxinsPesticides/ucm077969.htm>

- ① Action levels for crop groups cover all commodities specified in 40 CFR 180.34(f), unless an exception is noted.
- ② (1,1-Bis(p-chlorophenyl)-2,2,2-trichloroethanol) (Previously listed as "Kelthane," the trade name for dicofol)
- ③ 1 ppm on pink kernels

#### 6.4. Ingredient Specifications: (USGPO, 2014a)

**6.4.1.** All Ingredients must meet the regulatory guidelines for ‘Chemical Action Levels’ and ‘Defect Action Levels’ (FDA, 2000).

**6.4.2.** Chemical Action levels are listed in the FDA Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed (FDA, 2000). The following chart lists the affected ingredients used at Boulevard Brewing Company.

**6.4.3.** The FDA *Defect Levels Handbook: The Food Defect Action Levels Levels of natural or unavoidable defects in foods that present no health hazards for humans* lists the following ingredients with ‘Defect Action Levels’ (FDA, 1995):

Defect Action levels for Food pertaining to Ingredients.

Commodity①	Testing method	Defect Action Level
Hops	AOAC 967.23	≥ 2,500 aphids per 10g
Wheat	MPM-V15	≥ 32 Insect damaged kernels / 100g
Wheat	MPM-V15	≥ 9mg of rodent excreta pellets (whole or fragment) / Kg

① Action levels for crop groups cover all commodities specified in 40 CFR 180.34(f), unless an exception is noted.

Source: 51 FR 22475, June 19, 1986, as amended at 61 FR 14480, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001

Retrieved from: <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/sanitationtransportation/ucm056174.htm>  
- Defect Action levels

**6.4.4.** Further product specifications to ensure quality, but do not constitute adulteration, will be determined by Boulevard Brewing Company and will be established according to best business practices.

**6.5. Packaging Specifications:** (Bernard, et. al., 2006; Barach & Dunaif, 2013)

**6.5.1.** All labelling will conform the specification deccribed in Labelling 01 TTB Labelling Requirements.

**6.5.2.** Printed packaging materials will conform to the standard dimensions and graphic design submitted by the Engineering and Marketing departments.

**6.5.3.** Glass bottling:

**6.5.3.1.** Bottles will be packaged to minimize bottle breakage from transportation, receiving, warehousing, and unstacking.

**6.5.3.2.** Pallets will be received “as is” with up to 5 broken bottles. Breakge beyond that, up to 10% of the pallet, will be accepted but with notification of the vendor and credits applied to account. Pallets with breakage greater than 10% of the pallet will be rejected.

**6.6. Finished Product Specifications:** (Bernard, et. al., 2006; Barach & Dunaif, 2013)

**6.6.1.** Finished product will be tested for physical attributes, Documentation, sensory evaluation, and microbiological testing prior to being released for sale.  
(Proprietary Boulevard Information)

**6.6.2.** Note that during the entire brewing, mashing, lautering and fermentation process continual quality checks are performed. These final testing parameters are the verification of the continuous monitring steps througout production and are a last check to verify quality manufacture of the product.

**6.6.2.1.** Physical testing includes the following parameters: (Proprietary Boulevard Information)

6.6.2.1.1. Alcohol content on volume over volme percentage basis.

6.6.2.1.2. The plato.

6.6.2.1.3. The post conditioned CO2 content of the bottles.

6.6.2.1.4. The post fill CO2 content of the kegs.

6.6.2.1.5. The pH.

6.6.2.1.6. The haze.

6.6.2.1.7. A gas chromatographic assay to determine various trace aldehyde, ester, and specific dimethyl sulfide concentrations.

- 6.6.2.2.** Physical testing parameters, except GC analysis, are the ONLY parameters that can be out of specification and be remedied by batch blending. Blending of brewing or fermentation tanks can be performed to bring alcohol, pH, Plato, CO<sub>2</sub>, or haze into specification. Batches can also be diluted with purified water (ONLY!) to bring these specifications inline (USGPO, 2014f; Proprietary Boulevard Information).
- 6.6.2.3.** Document review verifying operation, verification, and monitoring of the automatic fill level sensor and rejection mechanism (Proprietary Boulevard Information).
- 6.6.2.4.** Sensory evaluation consisting of the following general areas of organoleptic evaluation by a trained sensory panel. Utilize Quality form 01 Tasting Profile to record the trained panel's observations (Proprietary Boulevard Information).
- 6.6.2.4.1. Afterbitter (Hang).
  - 6.6.2.4.2. Dryness (Astringency).
  - 6.6.2.4.3. Grainy, Warty.
  - 6.6.2.4.4. Cardboard, Papery (Oxidation).
  - 6.6.2.4.5. Pruney, Raisiny (Oxidation).
  - 6.6.2.4.6. Lightstruck (Oxidation).
  - 6.6.2.4.7. Drains (Mercaptan).
  - 6.6.2.4.8. Striking Match (Sulfitic).
  - 6.6.2.4.9. Rotten Egg (H<sub>2</sub>S).
  - 6.6.2.4.10. Cooked Vegetables, Canned Corn (DMS).
  - 6.6.2.4.11. Onion.
  - 6.6.2.4.12. Banana (Isoamyl acetate).
  - 6.6.2.4.13. Apple, Anise (Ethyl hexanoate).
  - 6.6.2.4.14. Pineapple (Ethyl butyrate).
  - 6.6.2.4.15. Rubber Cement (Ethyl acetate).
  - 6.6.2.4.16. Bruised Apple, Pumpkin (Acetaldehyde).
  - 6.6.2.4.17. Buttered Popcorn, Butterscotch (Diacetyl).
  - 6.6.2.4.18. Cut grass (Hexanal).
  - 6.6.2.4.19. Burnt / Roasted.
  - 6.6.2.4.20. Bubblegum, Clove (4-vinyl guaiacol; phenol).
  - 6.6.2.4.21. Spicy (Eugenol).
  - 6.6.2.4.22. Baby sick (Butyric).
  - 6.6.2.4.23. Cheesy, Goaty (Valeric, Caproic acid).



**6.6.2.5. Microbiological testing for beer spoilage organisms (Proprietary Boulevard Information).**

6.6.2.5.1. Plate samples in a MRS broth with cyclohexamide to inhibit yeasts. Incubate for 5 days. Inspect the broth for turbidity indicating the presence of *Lactobacillus* spp. beer spoilage organisms.

6.6.2.5.2. Perform PCR to verify the presence of *Lactobacillus* spp.

6.6.2.5.3. If *Lactobacillus* spp. Are present then reject the batch.

**6.6.3.** To assure that the intrinsic properties of the product can meet the hurdles to pathogen microbial growth described by Menz, Aldred, and Vriesekoop (2009 & 2011) all product prior to release will meet the following specifications (Proprietary Boulevard information):

Beer	Finished pH	IBU	%ABV	CO2
KC Pils	4.30 - 4.60	14 - 21	4.5 - 5.1	5.0 - 5.7
Unfiltered Wheat	4.30 - 4.60	9.5 - 17	4.1 - 4.7	4.8 - 5.4
80 Acre	4.30 - 4.60	14 - 22	5.2 - 5.8	4.9 - 5.7
Pop Up IPA	4.30 - 4.60	35 - 47	4.0 - 4.6	4.9 - 5.7
Pale Ale	4.30 - 4.60	29 - 39	5.1 - 5.7	4.8 - 5.6
Single Wide IPA	4.30 - 4.60	45 - 65	5.4 - 6.0	4.7 - 5.8
MidCoast IPA	4.30 - 4.60	60 - 90	5.3 - 5.9	4.9 - 5.7
Westside Rye	4.30 - 4.60	25 - 40	4.9 - 5.5	4.8 - 5.4
Bully Porter	4.30 - 4.60	45 - 65	5.7 - 6.3	4.7 - 6.0
Tank 7	4.30 - 4.60	32 - 48	8.2 - 8.8	6.2 - 8.4
Double Wide IPA	4.30 - 4.60	63 - 91	8.2 - 8.8	6.0 - 8.2
6th Glass	4.30 - 4.60	20 - 33	10.2 - 10.8	6.2 - 10
Tripel	4.30 - 4.60	19 - 29	8.9 - 9.5	6.8 - 9.1
Dark Truth	4.30 - 4.60	40 - 60	9.4 - 10.0	5.4 - 7.0
Boss Tom	4.30 - 4.60	19 - 25	5.7 - 6.3	5.1 - 5.5
Zon	4.30 - 4.60	13 - 17	4.1 - 4.7	4.7 - 5.6
Irish Ale	4.30 - 4.60	29 - 35	5.5 - 6.1	4.6 - 5.9
Bobs 47	4.30 - 4.60	26 - 33	5.5 - 6.1	4.9 - 6.0

Nutcracker	4.30 - 4.60	32 - 46	7.5 - 8.1	4.8 - 5.9
Grainstorm	4.30 - 4.60	55 - 85	7.8 - 8.4	6.0 - 10.0
Harvest Dance	4.30 - 4.60	30 - 50	9.2 - 9.8	7.1 - 9.3
Two Jokers	3.85 - 4.00	11 - 28	7.7 - 8.3	6.8 - 7.5
BBQ	3.90 - 4.30	11 - 30	11.5 - 12.1	5.9 - 7.0
Chocolate Ale	4.30 - 4.60	10 - 18	8.8 - 9.4	5.4 - 7.2
Imperial Stout	4.30 - 4.60	20 - 70	10.7 - 11.3	6.0 - 7.0
Rye On Rye	4.30 - 4.60	20 - 34	11.7 - 12.3	4.6 - 6.5
Saison Brett	4.30 - 4.60	20 - 50	8.2 - 8.8	5.1 - 7.7

**6.7. Shipping:** All outgoing finished products must be inspected prior to shipment (Bernard, et. al., 2006; Barach & Dunaif, 2013; AIB, 2013).

- 6.7.1.** All Finished product must be signed off and released by the Quality department according to section **6.6** above.
- 6.7.2.** All finished product must be handled with care to prevent damage and exposure to adverse conditions that could lead to adulteration.
- 6.7.3.** All finished product must be properly labelled and meet all TTB, Quality, and Marketing specifications (USGPO, 2014c; USGPO, 2014d; USGPO, 2014e; USGPO, 2014g).
- 6.7.4.** Every carrier must be inspected for damage, overall cleanliness, and pest activity prior to loading any finished product.
- 6.7.5.** If the inspection reveals any kind of contamination, immediately notify the department supervision.
- 6.7.6.** Damaged, filthy, contaminated, or infested carriers will not be used.
- 6.7.7.** Every shipment must have approved documentation. Approved documents must meet the following criteria.
  - 6.7.7.1.** The Supplied Shipping Documents must match the information provided by the PO.
  - 6.7.7.2.** The container seals must match the ORIGINAL BOL. NO corrections allowed. A load failing this test MUST not be shipped. No Exceptions.
  - 6.7.7.3.** The manifest must accurately describe the products in the trailer.
  - 6.7.7.4.** The shipment cannot be sent if any the above are modified, corrected missing, or cannot be provided.
- 6.7.8.** All Material Documents must meet or exceed the minimum requirements listed in the product specification section (**6.4 & 6.5**) of this Document.

**6.7.9.** All of the above inspection and shipment actions must be documented and the documents properly stored. Refer to General SOP 03 Document Management for proper Document retention and storage procedures.

## **Facilities SOP 04 Chemical Control**

### **1. PURPOSE**

**1.1.** This procedure outlines the guidelines for obtaining, using, storing and documenting chemicals at Boulevard Brewing Company Facilities.

### **2. SCOPE**

**2.1.** This procedure applies to all chemicals used at all Boulevard Brewing Company facilities. The documentation procedures are defined in the most recent version of General SOP 03 Document Control.

### **3. RESPONSIBILITY**

**3.1.** It is the responsibility of all personnel to follow the procedures outlined in this document.

**3.2.** The Industrial Hygiene officer and personnel in the Quality department will review all new and existing chemicals in all areas of the facility for adherence to this standard.

**3.3.** Department supervision is responsible for ensuring personnel compliance to this standard

**3.4.** The Industrial Hygiene officer and the Quality department will be responsible for tracking, monitoring and documenting chemical usage at the Facility

### **4. DEFINITIONS**

**4.1.** C&S - Cleaning and Sanitizing.

**4.2.** cGMPs – Current Good Manufacturing Practices intended to prevent food from becoming adulterated as defined by the FDA in 21 CFR Part 110 as: “The criteria and definitions in this part shall apply in determining whether a food is adulterated... within the meaning of... the act in that the food has been manufactured under such conditions that it is unfit for food; or... in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.” (FDA, 1986).

**4.3.** CIP – Clean in Place. Cleaning and sanitation of closed production equipment without requiring disassembly.

**4.4.** FAAA – The Federal Alcohol Administration Act of 1935 partially establishing the BATFE and TTB under the U.S. Department of the Treasury.

**4.5.** Facility – All Boulevard Brewing Company Production, storage, maintenance, and warehousing locations, including the surrounding grounds.

- 4.6. FDA – Food and Drug Administration under the U.S. Department of Health and Human Services (HHS). The agency responsible for assuring a safe wholesome food supply (FDA, 1938).
- 4.7. Food Contact Surface – Anywhere in the process where ingredients, finished product, or packaging material comes in contact. Includes tools and Utensils.
- 4.8. HAZCOM – Hazard Communication Standard. “The standard that gave workers the right to know, now gives them the right to understand.” (OSHA, 2014).
- 4.9. Incidental Food Contact Lubricants – Lubricants used in equipment with the potential to contact the food or food contact surfaces. These lubricants are required to comply with FDA 21 CFR § 178.3570 (FDA, 2013b).
- 4.10. Non-Food Contact Lubricants – Lubricant that have no to contaminate food or food contac surfaces. (FDA, 2013b)
- 4.11. OSHA –The Occupational Safety and Health Administration.
- 4.12. Production area – Any space, inside or outside of the Boulevard Brewing Company property, where production processes are performed.
- 4.13. Product zone – All areas immediately surrounding production equipment.
- 4.14. Sanitary Facilities –Facilities used to maintain proper personal hygiene. These include restrooms, locker rooms, hand-washing stations, hand-sanitizing stations.
- 4.15. SOP - Standard Operating Procedure.

5. **Hazard Communication**

- 5.1. Hazard communication is the program, administered by OSHA, to give personnel the right to know and understand the hazards presented by the chemicals they work with (OSHA, 2014).
- 5.2. MSDS are required for all boiler chemicals, C&S chemicals, pesticides, processing aides, and lubricants used within the Facility (OSHA, 2014).
- 5.3. MSDS will be available from the Industrial Hygiene officer, the Quality department and at all departmental ‘Right to Know’ Stations throughout the production areas (OSHA, 2014).
- 5.4. All personnel utilizing chemicals must be trained to OSHA HAZCOM standards. All Training must be documented according to the standard General SOP 03 Document Management.

6. **PROCEDURE**

- 6.1. **General Chemical Provisions** (AIB, 2013; Barach, & Dunaif, 2013; Swanson, K.M.J., Behling, A.R., Barach, J.T., 2013).
  - 6.1.1. Ingredients, packaging material, processing aids, cleaning chemicals, maintenance chemicals, pesticides, and finished product will be moved,

stored, handled, used, and maintained to prevent contamination of the finished product.

- 6.1.2. Containers must be labeled and contain the materials as labeled. The contents on the label MUST match. Anything else is prohibited.
- 6.1.3. A work instruction will define the proper use of each chemical on site. Personnel using these materials must be properly trained.

**6.2. Pre-Approval of Chemicals.** The approval procedure establishes a program to control chemicals and limit the chance of chemicals contaminating product (AIB, 2013; Barach, & Dunaif, 2013; Swanson, et. al., 2013).

- 6.2.1. All chemicals must have prior approval to be used at any facility. See 6.2.6 & 6.2.7. below.
- 6.2.2. All chemicals with a different MSDS must be approved separately.
- 6.2.3. The same chemical from different companies must be approved separately.
- 6.2.4. An MSDS must be available before use. (OSHA, 2014)
- 6.2.5. Prior to purchase of a new chemical a chemical approval form must be submitted for review.
- 6.2.6. The Industrial Hygiene officer, or the Quality department, will perform a hazard analysis of the chemical and make a decision on the purchase of the chemical (AIB, 2013).
- 6.2.7. The Quality department will retain the chemical approval form and all other applicable documents according to General SOP 03 Document Management.

**6.3. Inventory and Usage Logs:** (AIB, 2013; Barach & Dunaif, 2013; FDA, 2002)

- 6.3.1. Usage logs and inventory will be maintained for all chemicals in the facility.
- 6.3.2. Chemical logs and inventory will be reconciled on a monthly basis. Discrepancies will be handled on a case by case basis.

**6.4. Contractor Chemicals:**

- 6.4.1. Contractors will be notified at the initial cGMP training that all chemicals brought on site must be approved before use.
- 6.4.2. Contractors will be required to comply with this standard while at Boulevard Brewing Company facilities.

**6.5. Boiler Chemicals:** Industrial boilers require chemicals to operate properly. Steam is a part of the brewing process and may become a part of the finished product. Because of this these chemicals must be of food grade quality (FDA, 2013c).

- 6.5.1. All boiler chemicals must be FDA approved for use in food production. Note: Chemicals that are FDA approved will have this stated directly on the label. All Boiler chemicals must have this label in place, intact, and legible. All boiler chemicals must meet the requirements defined in FDA 21 CFR § 173.310. (FDA, 2013c)
- 6.5.2. Boilers must have signs, at the point where chemicals are added, stating that only USDA Approved Chemicals may be used. (FDA, 2013c)
- 6.5.3. **Cleaning and Sanitation Chemicals. Includes CIP chemicals:** (AIB, 2013; Barach & Dunaif, 2013; Swanson, et. al., 2013).
- 6.5.4. Cleaning and sanitizing chemicals must be stored in a secure designated area away from production areas. The chemical supply access will be restricted to authorized personnel.
- 6.5.5. Cleaning chemicals and their approved usage must be displayed and employees must be certified before use.
- 6.5.6. Cleaning chemical concentrations will be verified every month by the Quality department.
- 6.6. **Pesticides:** (AIB,2013; Swanson, et.al., 2013; Johnson, 2002)
  - 6.6.1. Pesticides utilized as part of the Integrated Pest Management Program must be used and stored in accordance with the chemical label (AIB, 2013; Johnson, 2002).
  - 6.6.2. The use of poison for inside interior pest control devices is prohibited.
  - 6.6.3. Pesticide usage will be logged and tracked. Only certified applicators will be allowed to handle and apply approved chemicals (AIB, 2013; Swanson, et. al., 2013; Johnson, 2002).
- 6.7. **Lubricants:**
  - 6.7.1. All lubricants must be approved by the Industrial Hygiene officer and the Quality department before receiving into facility.
  - 6.7.2. Food grade and non-food grade lubricants and maintenance fluids must be stored separately. (AIB, 2013; Barach & Dunaif, 2013; Swanson, et.al., 2013)
  - 6.7.3. Incidental food contact lubricants must be used wherever the potential exists for the lubricant to make contact with the food or a food contact surface. (FDA, 2013b)
    - 6.7.3.1. The specific type of lubricant and the maximum amount allowed to make incidental contact with the product or product contact surface must not exceed the requirements defined in FDA 21 CFR § 178.3570. (FDA, 2013b)
  - 6.7.4. Non-Food Contact Lubricants. The FDA has not established safe levels for these lubricants in food(s) or on food contact surfaces. Therefore, these lubricants can only be used where the lubricant cannot make contact with the product or product contact surfaces. Safeguards must

be in place to prevent these lubricants from contaminating food or food contact surfaces. (AIB, 2013; FDA, 2013b)

**6.7.4.1.** Adequate safeguards include drip pans, splash guards, and limiting excessive lubrication.

**6.7.4.2.** If contact with the food occurs, the product will be destroyed and the product contact surface(s) will be thoroughly cleaned and free of lubricant residue before being placed back into service.

## **Facilities SOP 05 Cleaning and Sanitation**

### **1. PURPOSE**

- 1.1.** This procedure provides guidelines for cleaning and sanitation activities required to maintain a sanitary production environment and successfully implement a Master Sanitation Schedule.
- 1.2.** This procedure also details activities that should be undertaken for general housekeeping on non-production areas.

### **2. SCOPE**

- 2.1.** This procedure applies to all Boulevard Brewing Company facilities.

### **3. RESPONSIBILITY**

- 3.1.** It is the responsibility of all personnel to understand and follow the principles outlined in this Document.
- 3.2.** The production departments will be responsible for performing the activities described herein.
- 3.3.** Personnel in the Quality department will monitor, verify and document adherence to this standard.
- 3.4.** Department supervision is responsible for ensuring adherence to this standard and initiating corrective actions when it is not.

### **4. DEFINITIONS**

- 4.1.** ATP Test kit – a simple cleaning verification tool that looks for the presence of Adenosine Tri Phosphate a key biochemical present in cells.
- 4.2.** Brewery Tour – Walk-in or pre-scheduled tours of the facility with varying levels of facility access.
- 4.3.** C&S – Cleaning and Sanitizing.
- 4.4.** cGMPs – Current Good Manufacturing Practices intended to prevent food from becoming adulterated as defined by the FDA in 21 CFR Part 110 as: “The criteria and definitions in this part shall apply in determining whether a food is adulterated... within the meaning of... the act in that the food has been manufactured under such conditions that it is unfit for food; or... in that the food has been prepared, packed, or held under insanitary conditions whereby it

may have become contaminated with filth, or whereby it may have been rendered injurious to health.” (USGPO, 2014a).

- 4.5. CIP – Clean in Place. A system where proper cleaning and sanitation occurs, automatically, in closed production equipment.
- 4.6. Cleaning - The removal of gross soil down to the bare surface being cleaned. This includes removal of hydrophobic residues and hard water deposits.
- 4.7. Event Spaces – Hospitality spaces that may be rented to provide varying levels of refreshments and catering services. The event spaces include the ‘Muehlebach Suite’, the ‘Brewhouse Bar’, and the ‘Tasting Room’. (Boulevard Brewing Company, 2014a)
- 4.8. Facility – All Boulevard Brewing Company Production, storage, maintenance, and warehousing locations, including the surrounding Grounds.
- 4.9. FDA – Food and Drug Administration under the U.S. Department of Health and Human Services (HHS). The agency responsible for assuring a safe wholesome food supply (FDA, 1938).
- 4.10. Food Contact Surface – Anywhere in the process where ingredients, finished product, or the inside of packaging material comes in contact. Includes utensils and tools.
- 4.11. Gift Shop – A retail location selling promotional products, prepackaged food, and bottled beers produced at Boulevard Brewing Company. Adjacent to, and accessible from, the ‘Tasting Room’ (Boulevard Brewing Company, 2014b).
- 4.12. MSS – Master Sanitation Schedule. A list of locations, frequencies and responsibilities describing all cleaning and sanitizing operations in a facility
- 4.13. Production area – Any space, inside or outside of the Boulevard Brewing Company property, where production processes are performed.
- 4.14. Production equipment – Any equipment utilized to process ingredient(s) in to finished product(s) located in the Facility.
- 4.15. Product zone – All areas immediately surrounding product production equipment.
- 4.16. Sanitary facilities – Facilities used to maintain proper personal hygiene. These include restrooms, locker rooms, hand-washing stations, hand-sanitizing stations.
- 4.17. Sanitizing – “...adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.” (21 CFR §110.3 (o)) (USGPO, 2014a).

## 5. **MISCELLANEOUS CATEGORIES**

5.1. N/A

## 6. **PROCEDURE**



- 6.1. General housekeeping:**
- 6.1.1.** The administrative offices, event spaces, tour areas, and gift shop will be maintained in clean and orderly condition to portray the excellence of the Boulevard Brewing Company brand.
  - 6.1.2.** Event spaces will be maintained at the required level of sanitation required for retail food service establishments in Missouri.
  - 6.1.3.** Employees and/or contractors will maintain the cleanliness of these spaces.
- 6.2. Cleaning and Sanitation Standards:** The following definitions are verbatim from the FDA. (USGPO, 2014a). Title 21: Food and Drugs, PART 110—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD.
- 6.2.1.** *“Sanitation of food-contact surfaces.* All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.” (21 CFR §110.35 (d)) (USGPO, 2014a).
  - 6.2.2.** *“(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.”* (21 CFR §110.35 (d)(1)) (USGPO, 2014a).
  - 6.2.3.** *“(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.”* (21 CFR §110.35 (d)(3)) (USGPO, 2014a).
  - 6.2.4.** *“(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.”* (21 CFR §110.35 (d)(4)) (USGPO, 2014a).
  - 6.2.5.** *“(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.”* (21 CFR §110.35 (d)(5)) (USGPO, 2014a).
  - 6.2.6.** *“(e) Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.” (21 CFR §110.35 (e)) (USGPO, 2014a).
- 6.3. Cleaning and Sanitation Guidelines** (AIB, 2103; FDA, 2000; Stone, 2013; USGPO, 2014):

- 6.3.1. C&S will constitute thorough cleaning of all surfaces to remove gross soil (USGPO, 2014a). Following cleaning, rinsing will be applied based upon manufacturer recommendations and regulatory requirements for the cleaning chemical and concentration (FDA, 2000). Only after all visible soil has been removed can food contact sanitizers be used. Sanitizers must be used according to the manufacturers instructions.
- 6.3.2. C&S activities must alternate between acidic and basic cleaning methods to remove mineral deposits that will aid in the formation of undesirable biofilms (Chen & Stewart, 2000).
- 6.3.3. C&S activities must alternate between sanitizer types to prevent organisms from gaining resistance to one sanitizer type. Refer to section 6.5 for proper monitoring of cleaning efficacy.
- 6.3.4. Immediately clean spills, dry or wet, to prevent contamination and offering a pest harborage (Stone, 2013).
- 6.3.5. All food-contact surfaces should be cleaned and sanitized before use and after any interruption where potential contamination may occur (USGPO, 2014a).
- 6.3.6. During cleaning, remove or cover all Ingredients, finished product, and packaging materials to prevent contamination (AIB, 2013).
- 6.3.7. Clean and replace food-contact gaskets on equipment as needed.
- 6.3.8. Portable equipment and utensils must be cleaned and sanitized after use and prior to being placed in storage. Storage conditions must prevent re-contamination of the items (USGPO, 2014a).
- 6.3.9. Never place clean parts, utensils, tools, or equipment on the floor.
- 6.3.10. C&S chemicals must not be used around open product zones, while they are in operation, due to contamination concerns.
- 6.3.11. Return all C&S chemicals to their approved storage location after use. Do not have C&S chemicals in production areas during operation.
- 6.3.12. C&S chemicals must be approved, labelled, used, and stored in accordance with the Facility SOP 04 Chemical Control Plan.
- 6.3.13. Store C&S equipment from the bottling area separate from all other production areas.
- 6.3.14. Store sanitary facility C&S equipment separately from any production C&S equipment.
- 6.3.15. When not in use air, and water lines will be shut off and neatly coiled and stored on labelled hangers.

**6.4. Master Sanitation Schedule:**

- 6.4.1. Daily housekeeping is part of our overall cleanliness strategy and consists of sweeping, mopping, and removing trash from non-product zone areas in the non-production areas. Daily Housekeeping is not part of the MSS.

- 6.4.2. The MSS contains a monthly schedule of required cleaning tasks for equipment and infrastructure in production areas. Cleaning tasks may be scheduled on a more or less frequent schedule. The tasks will only appear in the month that its scheduled frequency dictates.
- 6.4.3. Individual cleaning task(s) will be printed on the MSS task sheets and assigned to the responsible personnel.
- 6.4.4. Once the assigned personnel have completed the cleaning task and recorded it on the MSS task sheet. Supervisors will verify that the task has been performed up to this standard and sign off verifying the task has been completed as specified. See section 6.5 below for details on verification and monitoring.
- 6.4.5. If the task is not completed satisfactorily, the personnel will re-clean the location and proceed go back to section 6.4.3. above, until the task is completed successfully.
- 6.4.6. Completed MSS task(s) sheets will be handed into the Quality department.

**6.5. Cleaning Verification and Monitoring:**

- 6.5.1. The personnel responsible for performing MSS task(s) will verify acceptable cleaning and sanitation by utilizing an appropriate ATP test kit (Stone, 2013).
- 6.5.2. Supervisors must use ATP test kits to verify the successful completion of the assigned cleaning task.
- 6.5.3. Monitoring is required to minimize the presence of beer spoilage organisms. Even though gram positive bacteria are controlled effectively by the addition of the hops alpha acids, various process steps do not have gram positive hurdles (Menz, et. al., 2009). Thorough cleaning of product zones is required to minimize the chance of inoculating the system with beer-spoilage organisms, especially prior to fermentation and in the priming sugar tank.
  - 6.5.3.1. The ATP KIT must have a limit of detection at  $10^3$  CFU/ml for gram-negative enteric bacteria (Turner, Daugherty, Altier, & Maurer, 2010).
  - 6.5.3.2. The ATP kit must be able to detect gram-positive bacteria at  $10^2$  CFU/ml (Turner, et. al., 2010).
- 6.5.4. Monitoring, as described in Stone (2013), Bernard, et.al. (2006), and described in general terms in 21 CFR part 110 is not required for a brewery (USGPO, 2014a). The intrinsic properties in beer and the brewing process, as described by Menz, Aldred, & Vrieskoop (2009 and 2011), indicates that pathogens of concern will not survive in finished product; therefore, environmental monitoring to minimize, reduce, or eliminate pathogens are not required.

**6.6. Training**

- 6.6.1. Personnel performing cleaning activities must be trained in the proper cleaning methods to achieve the cleaning objectives.
- 6.6.2. Cleaning should be done to minimize the transfer of debris from one area to another.
- 6.6.3. This training must be documented. The Documents will be stored in compliance with General SOP 03 Document Management and Personnel SOP 03 Personnel Training and Record Keeping.

## **Labeling SOP 01 TTB Labeling Requirements**

### **1. PURPOSE**

- 1.1. This procedure provides guidance on defining, designing, and verifying TTB requirements for label design to prevent misbranded product.

### **2. SCOPE**

- 2.1. This procedure applies to all Boulevard Brewing Company facilities.

### **3. RESPONSIBILITY**

- 3.1. It is the responsibility of management to understand the label requirements as defined by the TTB.
- 3.2. It is the responsibility of the design team to understand the required elements and text that must be incorporated into the label designs. They must then verify that those designs are included on proofs and final versions of accepted label designs from the manufacturer.
- 3.3. It is the responsibility of the quality department to insure that all incoming shipments of labels meet the label requirements.
- 3.4. The receiving and production technicians are responsible for double-checking that the correct labels have been received.

### **4. DEFINITIONS**

- 4.1. Brand label - The label carrying, in the usual distinctive design, the brand name of the malt beverage. From 27 CFR Part 7 § 7.10 (USGPO, 2014d).
- 4.2. Class – The class of beer. Typical classes are ales, stouts, lagers, etc... (USGPO, 2014c).
- 4.3. COLA – Certificate of Label Approval. All Labels must be approved by the TTB, pursuant to 27 CFR section 4, 5, & 7, prior to use. Completion of TTB form 3100.31 is required (USGPO, 2014d).
- 4.4. FAAA – The Federal Alcohol Administration Act of 1935 partially establishing the BATFE and TTB under the U.S. Department of the Treasury (USGPO, 2014f).

- 4.5. Facility – All Boulevard Brewing Company Production, storage, maintenance, and warehousing locations, including the surrounding grounds.
- 4.6. FD&C Act – Federal Food Drug and Cosmetic Act of 1938 establishing the FDA under HHS. (FDA, 1938).
- 4.7. FDA Major Allergens - milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, soy (soya, soy, or soybeans), and wheat (USGPO, 2014d).
- 4.8. Malt beverage - A beverage made by the alcoholic fermentation of an infusion or decoction, or combination of both, in potable brewing water, of malted barley with hops, or their parts, or their products, and with or without other malted cereals, and with or without the addition of un-malted or prepared cereals, other carbohydrates or products prepared therefrom, and with or without the addition of carbon dioxide, and with or without other wholesome products suitable for human food consumption. Standards applying to the use of processing methods and flavors in malt beverage production appear in §7.11. From 27 CFR Part 7 § 7.10. (USGPO, 2014d)TTB - Bureau of Alcohol Tobacco, Firearms and Explosives (BATFE), Alcohol and Tobacco Tax and Trade Bureau (TTB) under the U.S Department of the Treasury (USGPO, 2014f).

5. **MISCELLANEOUS CATEGORIES**

- 5.1. N/A

6. **PROCEDURE**

- 6.1. All Labels must be approved through the COLA application process. (USGPO, 2014d)
- 6.2. **General Label Requirements:** 27 CFR Part 7 of the Code of Federal Regulations establishes the mandatory elements of label design (USGPO, 2014d).
  - 6.2.1. Required labels must be in a contrasting background color and be readily legible under ordinary conditions. Required label elements must be conspicuous if written within other text (USGPO, 2014d).
  - 6.2.2. For bottles greater than one half pint the label must have type greater, or equal to, 2mm for all required label elements (USGPO, 2014d).
  - 6.2.3. For bottles less than, or equal to, one half pint the label must have type greater, or equal to, 1mm for all required label elements (USGPO, 2014d).
  - 6.2.4. Alcohol labelling must be of the same size and not be more conspicuous than other surrounding text. For bottles under 40 ounces, and under, the text may not be larger than 3mm and for bottles larger than 40 ounces the text may not be larger than 4mm (USGPO, 2014d)..
- 6.3. **Required label elements:** 27 CFR Part 7 of the Code of Federal Regulations establishes the mandatory elements of label design (USGPO, 2014d).
  - 6.3.1. The primary or Brand Label (27CFR§7.20) (USGPO, 2014d):
    - 6.3.1.1. The brand name.
    - 6.3.1.2. The class of the beer.

- 6.3.1.3.** The legal name and address of the brewery.
- 6.3.1.4.** The net contents of container. The net contents can be on the label or imprinted on the can or bottle. All fractions must be to lowest common denominator.
  - 6.3.1.4.1.** If less than a pint it must be declared in fluid ounces or fractions of a pint.
  - 6.3.1.4.2.** If greater than 1 pint and less than 1 quart use pints and fluid ounces or fractions of a quart.
  - 6.3.1.4.3.** If greater than 1 gallon use fractions of a gallon.
  - 6.3.1.4.4.** For whole graduation use the volume. e.g. pint, quart, etc...
- 6.3.1.5.** The additional alcohol derived from alcoholic flavors or ingredients.
- 6.3.2.** The following elements can be on either the Primary or Brand label or a secondary label. The secondary label may be positioned on the front or back of the container (27CFR§7.20; 27CFR§16.21&22) (USGPO, 2014d; USGPO, 2014g).
  - 6.3.2.1.** The following Mandatory statement must appear separate and apart from all other information:

Retrieved from: <http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=a0aadf660880acdb2b8a9c1e8371e39&r=PART&n=27y1.0.1.1.12>

**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.

- 6.3.2.1.1.** The first two words: 'GOVERNMENT WARNING' must be capitalized.
- 6.3.2.1.2.** The following text sizes must be used.

Minimum required type size for warning statement	Maximum number of characters per inch
1 millimeter	40
2 millimeters	25
3 millimeters	12

- 6.3.2.1.3.** For all containers less than, or equal to 237ml (8 fl oz) the type must be greater than, or equal to, 1mm.

**6.3.2.1.4.** For all containers greater than 237 ml (8 fl oz) up to 3L (101 fl oz) the type must be greater than, or equal to, 2mm.

**6.3.2.1.5.** For all containers larger than 3L (101 fl oz) the type must be greater than, or equal to, 3mm.

**6.3.2.1.6.** The label must firmly affixed so that it cannot be removed easily without the use of water or other solvents.

**6.3.2.2.** The alcohol content on volume per volume or percent basis based upon volume. This requirement is dependant on local laws requiring this information be displayed.

**6.3.2.2.1.** This declaration is required to be in English and firmly affixed, or embossed into the container, to the container so it cannot be easily removed.

**6.3.2.3.** Declaration of the use of the FD&C approved food color Yellow #5.

**6.3.2.4.** The Prominent Declaration of the use of the FD&C approved food colorant Carmine. Must state "Contains: Carmine", "Contains: Cochineal extracts", or "Contains Carmine and Cochineal Extracts.". This statement may be displayed on a neck or strip label.

**6.3.2.5.** Declaration of added sulfites if greater than 10ppm as sulfur dioxide. Must state: "Contains: Sulfites", "Contains (a) Sulfiting Agent(s)", or a specific declaration of the sulfiting agent. This statement may be displayed on a neck or strip label.

**6.3.2.6.** Declaration of the use of Aspartame by FD&C Regulation. Must state in Capital Letters : "PHENYLKETONURICS: CONTAINS PHENYLALANINE".

**6.3.2.7.** It is optional to disclose major allergens (27CFR§7.22(a)). If it is chosen to do so the text must read "Contains: (and a list of the eight major allergens that are present in the product)" (27CFR§7.22(a)) (USGPO IV, 2014d).

**6.4. Prohibited Practices:** (27CFR§7.29) (USGPO, 2014d)

**6.4.1.** No false or misleading statements regarding (USGPO, 2014d):

**6.4.1.1.** Origin of the product, including country, state, region.

**6.4.1.2.** Type or Class of the product.

**6.4.1.3.** The Brand Name.

**6.4.1.4.** Contents.

**6.4.1.5.** Promotion of, or by, individuals or organizations.

**6.4.1.6.** Alcohol content.

**6.4.1.7.** Health Claims.

**6.4.1.8.** Statements indicating government supervision or guarantees of product identity.

**6.4.2.** No False or disparaging remarks or inferences to competitors, individuals, or organizations (USGPO, 2014d).

**6.4.3.** No use of National insignia including, but not limited to, flags, seals, coat of arms, crests, or other insignia (USGPO, 2014d).

## **Conclusion**

The future development of a HACCP plan at Boulevard Brewing Company requires that the SOP's in this report be used to develop the complete work processes required to establish the solid foundation described in the cGMP regulations. The first step is to define the job instructions described in this report. Those work instructions need to incorporate the experience from the personnel on the floor and the regulatory knowledge of the company. Management needs to develop the training and education programs to bring all personnel up to the work standards described in these documents. All of the affected personnel need to be trained and tested in their knowledge of the new requirements. All of these actions must be documented. Remember, "If it didn't get written down it didn't happen". Finally the entire corporate culture must live the principles established in these guidance documents. A successful food safety program does not come from having the best cGMP based prerequisite programs, or a perfect HACCP plan. A successful food safety program is built on a culture of support, through resources, from management indicating that food safety is as important as putting product in the market place. Obviously sales are important, for without sales there is no need for a food safety program, but a failure in the food safety program can be as lethal to a company as not putting any product to market.



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