Why Should the Malting and Brewing Industry Be Concerned About Food Safety? Part 1

Tatiana A. Lorca

Ecolab, Inc., St. Paul, MN, U.S.A.

How many of those reading remember the downfall of the Dow Brewery from Quebec City, Canada? Not many for sure. But as history tells us, food safety is a necessary agent that can save our businesses and livelihood. This event started in August of 1965 when a patient was admitted to the hospital with symptoms suggesting alcoholic cardiomyopathy. Over the next eight months 50 more cases with similar findings appeared in local hospitals within the area of the brewery, with 20 cases being fatal. After a significant review it was determined that the brewery had been adding cobalt sulfate to the beer as a foam stabilizer since July of the same year. It was also determined that the addition level in Quebec City was 10 times that in the same beer brewed in Montreal, where there were no reported cases. Would a food safety program have prevented this from occurring? There is little data to suggest resolution either way, but for sure a higher level of appreciation of the potential morbidity and mortality would have been known.

In 1990 Perrier had to face huge recalls of its products because of benzene levels in the CO_2 gas coming from their supplier. Other companies using the same CO_2 faced the same scrutiny, causing significant issues within the various beverage firms of the period. Would a food safety program have helped? Perhaps a better appreciation of their supplier operations and an analysis ahead of production might have captured the needed information before products hit the market.

One billion beers were recalled by Australian Carlton Brewery in December 2015 due to glass contamination. Would a food safety plan that took into account glass quality and traceability and perhaps a more robust recall program have made a difference?

There are more examples, few that hit this level in the beverage industry and few yet to hit the malting and brewing industry, but certainly these are attention grabbing. The brewing industry has traditionally been a very clean and good manufacturing practice (GMP) focused industry. With the traditional use of just malt, yeast, hops, and water little can go wrong. However, if you dig deeper it is easy to see the possibilities for failures within today's production. When farmers can apply a range of pesticides on grains, fungicides on hops, and poisons to control larger pests the less obvious can present itself as a possibility. Today brewers use all sorts of flavorings, spices, fruits, starches, and so on to create new beers. I have heard of soy, nuts, and shellfish entering the recipes of beers, materials all recognized as allergens within food safety guidelines in various countries. Are these all being treated as such? How many maltsters handle and brewers use sorghum to brew gluten-free products? Do they know that perhaps in the country of consumption gluten is also considered an allergen? Do they know farmers can use herbicides to stop the sorghum growth, allowing it to dry in order to facilitate harvest? How are brewers assuring themselves, and the consumers, of the safety and identity of these ingredients? These are just the tip of the preverbal iceberg; many more issues are possible and can be very real today in an industry that prides itself on delighting the palates of adventurous consumers.

Additionally, many brewers, if not most, provide spent grains as a feed source for livestock. This feed source is and should be considered a food product, because many of the livestock that it feeds are intended for human consumption down the food chain. Feed for livestock intended for human consumption is currently regulated, and more responsibility will begin to fall on the feed suppliers.

In January of 2011 the Obama Administration signed into law the U.S. Food and Drug Administration's (FDA's) Food Safety Modernization Act (FSMA). FSMA is the latest amendment to the Food, Drug and Cosmetic Act that originated in 1938, which addresses the materials and rules most breweries and other food producers function under today. FSMA is the most sweeping reform in food safety in over 70 years. It is designed and aimed at prevention of contamination rather than responding to it. This is the basis of why an understanding as well as a practice of food safety is not only important, it is now required by law.

The law is based upon five major sections:

- **Prevention:** science-based controls across the entire food supply focused on comprehensive prevention including food defense. Food defense takes the focus of prevention from unintentional acts to intentional acts such as sabotage or terrorism. This requires science-based efforts to ensure and verify potential contaminants are not intentionally added to food products.
- **Inspection and compliance:** risk-based inspections of all affected facilities.
- **Imported food safety:** to ensure products imported into the U.S. marketplace meet FSMA requirements.
- **Enhanced partnerships:** partnering with other federal, state, and local authorities for enforcement.
- **Response:** recall authority of all applicable food products.

In addition to these five major pieces the law takes into account a definition of adulteration of food that allows the re-

Tatiana Lorca, Ph.D., is the Senior Manager, Food Safety Education & Training for Ecolab, Inc. She is a member of the MBAA Food Safety Committee. She and the other members of the Food Safety Committee can be reached through the MBAA website, under Ask the Food Safety Expert.

E-mail: tatiana.lorca@ecolab.com

call of products that is a little broader than what most may be accustomed to. However, the wording states that any food product is considered adulterated under FSMA if it contains a poisonous or deleterious substance, or an unapproved food additive. Therefore, any material used in food, and now specifically in the case of beer, must be permissible by FDA standards that require the registration of all materials as generally recognized as safe (GRAS) and subsequent registration via the Tax and Trade Bureau (TTB) and the Adjunct Reference Manual.

Let's clarify one major point: alcoholic beverages are defined as an example of a food that is *regulated* by the Federal Food, Drug and Cosmetic Act (section 201(f)), and they also are addressed as products that fall under FSMA.

What Does FSMA Require?

FSMA is composed of 41 sections, 39 of which have been published in the Code of Federal Regulations (CFR) as final rules, and two are still identified as proposed rules, which are expected to be published in the first or second quarter of 2016. A more detailed review of the most embattled proposed and final rules will be addressed in a later article in the *Technical Quarterly*.

Affected facilities are required to implement current GMPs (cGMPs) (ref. 21 CFR 117, subpart B) in order to minimize adulteration (e.g., from microorganisms and from allergens). By law, manufacturers of alcoholic beverages must comply with cGMPs. The basic outline of cGMPs is as follows:

- **Personnel:** disease control, cleanliness, education, and training
- **Plant and grounds:** kept in a condition to prevent contamination
- **Sanitary operations:** general maintenance of the physical plant, control over cleaning and sanitizing substances, pest control, and sanitation of food contact surfaces
- **Sanitary facilities and controls:** water supply, plumbing, sewage disposal, hand washing, and trash removal
- **Equipment and utensils:** adequately cleanable, properly maintained, and designed, constructed, and used to preclude adulteration
- **Process and controls:** quality control, staff responsibilities, and control and management of raw materials and ingredients
- **Warehousing and distribution:** proper storage and transportation of products to minimize potential for contamination
- **Defect action levels:** natural or unavoidable defects presenting no health hazard

Affected facilities are required to document food safety plans based on undertaking a hazard analysis and risk-based control approach (ref. 21 CFR 117, subpart C). These plans will include the following:

- Evaluating the potential biological, chemical, and physical hazards that may be naturally occurring or could be introduced (intentionally or unintentionally) during the manufacture of a food. Intentional hazards may include those motivated by economic fraud that may produce a food safety hazard.
- Specifying what preventive controls will be put in place to significantly prevent such potential hazards. These may include process steps, supply chain controls, allergen controls, sanitation controls, or other controls.
- Specifying how facilities will monitor these preventive controls to ensure they are being carried out and are working.

- Maintaining routine records of monitoring.
- Specifying what actions a facility will take to correct problems that arise.
- Ensuring appropriate record keeping.

Those with broader experience in the food industry may recognize the approach above as being similar to that defined by hazard analysis and critical control point (HACCP) programs. Under FSMA, the FDA has addressed HACCP and redefined it as hazard analysis and risk-based preventive controls. It is a subtle distinction, but it contains important differences to HACCP. The hazard analysis and risk-based preventive controls approach aligns with HACCP in the design, development, implementation, and verification of the food safety plan required by FSMA. The primary difference lies in the designation of the preventive controls. Under HACCP these would typically be restricted to steps in the process identified as critical control points (CCPs), whereas under this new approach there is no such restriction. Thus, preventive controls will likely be process controls (e.g., CCPs), allergen controls, sanitation controls, supply chain controls, or other types of controls, many of which are managed by sites outside of the scope of the HACCP program but are detailed in their prerequisite programs or GMPs. This should encourage facilities to review their entire operation in a more holistic manner by managing all of the controls in place regardless of how they are classified (e.g., cGMPs, control points, or CCPs) and should allow facilities to better create food safety controls that reflect hazards within their operations. The intent here is to allow facilities to better create food safety controls that address as many hazards as possible within their operations.

Under FSMA, alcoholic beverage manufacturers do not have to develop a hazard analysis and risk-based controls program because they are exempted (21 CFR 117.5) as long as they meet the requirements under the Federal Alcohol Administration Act (27 U.S.C. 21 *et seq.*). That said, MBAA and the industry are advocating going beyond the required legal minimum and enhancing the safety of beer by advocating the development and implementation of HACCP into breweries.

Where to Start: GMPs

To help brewers work through this potentially confusing process, the MBAA Food Safety Committee constructed the MBAA food safety website designed as a roadmap on the types of programs used to develop food safety plans. Within the website we see tools like the decision tree, which helps determine what phase is most relevant depending upon the current state of food safety program adoption in a brewery. Without a doubt the foundation of a food safety program starts with GMPs.

In breweries, GMPs are also called good brewing practices (GBPs), which also work well within the malting industry. GBPs promote hygiene and cleanliness that help ensure a cleaner and safer environment for employees and ensure that products are produced, handled, and stored under safe and sanitary conditions. These practices can improve the safety and wellbeing of employees while reducing the chance of pest infestations and other costly risks that could result in a business being shut down due to public health hazards. The MBAA has released a document template for brewing-related facilities to utilize.

In turning to GMPs or GBPs, we can easily see that in order to start meeting FSMA requirements, we must first comply with GMPs.

Where to Start: HACCP

Once GMPs (GBPs) are in place, the next step for a brewery is to undertake a detailed study of the product and process in order to identify existing or needed food safety control measures to control existing or potential food safety hazards by developing and implementing a HACCP program. HACCP is a scientific, systematic, and preventive approach to identifying, analyzing, and controlling significant food safety hazards within a food production system from raw material acquisition through to consumption of a finished product. Significant food safety hazards may cause illness or injury to a consumer if not controlled. HACCP categorizes food safety hazards are as follows:
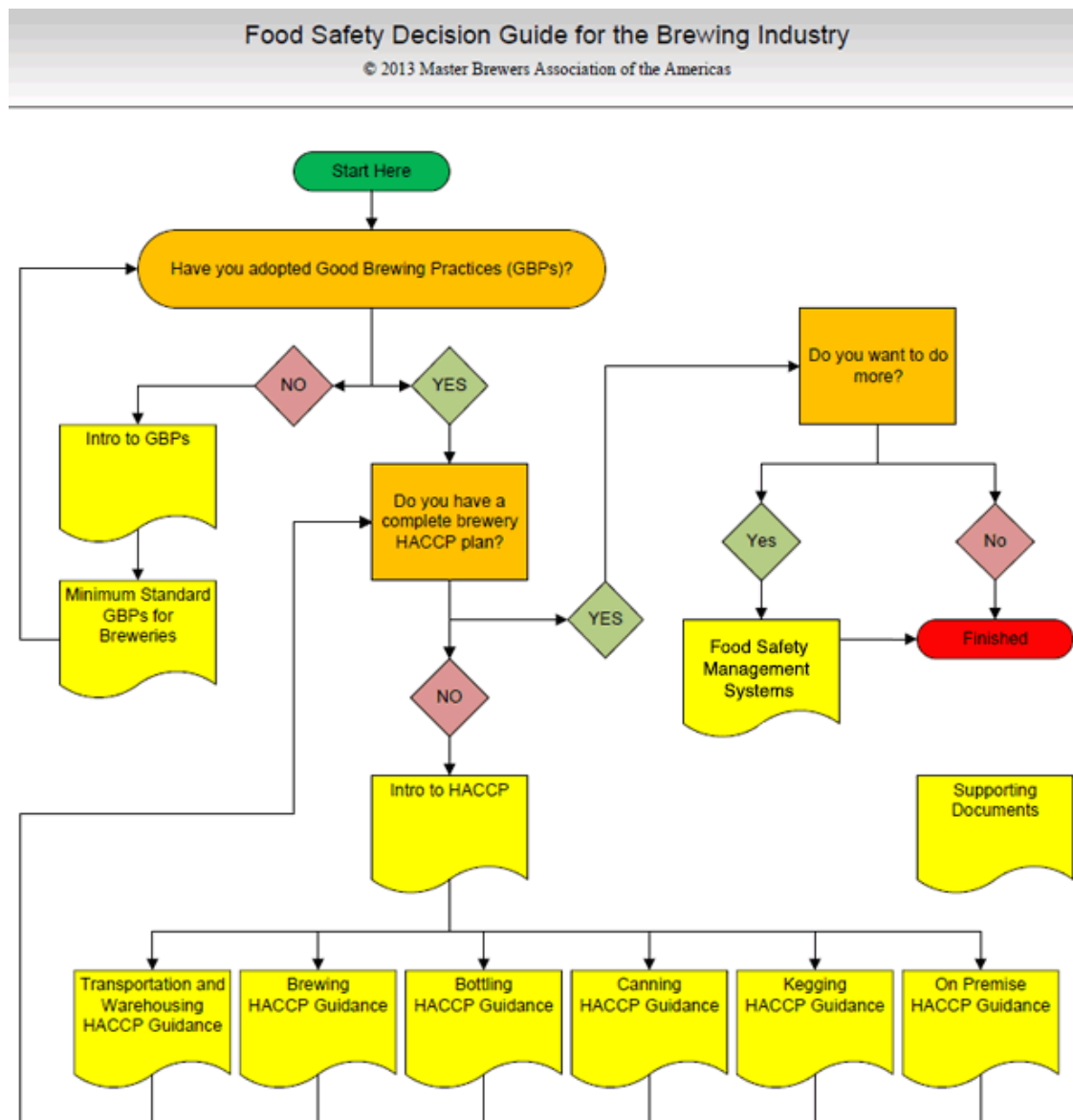
- **Biological hazards** include microorganisms such as bacteria, viruses, yeasts, molds, parasites, and protozoa with the potential to cause disease in humans, resulting in food safety and public health concerns (e.g., *Salmonella* species).
- **Chemical hazards** include toxic substances and any other chemical agents that may render a food unsafe for consumption (e.g., mycotoxin).

- **Physical hazards** include foreign material that can cause physical injury to a consumer (e.g., broken glass).

HACCP is implemented in a series of five preliminary steps and seven principles. The preliminary steps allow a site to collect information about the product and process in order to begin the HACCP study:

- Step 1: assemble HACCP team
- Step 2: describe the product and its distribution
- Step 3: describe the intended use and consumers
- Step 4: develop a flow diagram
- Step 5: verify the flow diagram

The seven principles of HACCP allow a facility to undertake a detailed study of the product and the production process from reception of the raw materials through to the distribution of the finished product in order to identify existing or needed food safety control measures to control food safety hazards. The control measures may be those classified as GMPs (or in the case of breweries, GBPs), or they may be targeted to a specific step in the process in order to eliminate a specific food safety hazard or bring it under control to an

Food Safety Decision Guide for the Brewing Industry
© 2013 Master Brewers Association of the Americas

acceptable level. The seven principles of HACCP are implemented as follows:

- **Principle 1:** *Conduct a hazard analysis.* Plants identify the potential food safety hazards that may be inherent in their inputs or introduced or made worse during the manufacture of their product. They assess their significance and identify the preventive measures the plant can apply to control these hazards.
- **Principle 2:** *Identify critical control points (CCPs).* A CCP is a location, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level.
- **Principle 3:** *Establish critical limits for each CCP.* A *critical limit* is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a CCP to prevent it, eliminate it, or reduce it to an acceptable level.
- **Principle 4:** *Establish CCP monitoring requirements.* Monitoring activities are necessary to ensure that the process is under control at each CCP. All monitoring procedures and frequencies are required to be listed in the HACCP plan.
- **Principle 5:** *Establish corrective actions.* These are actions to be taken when monitoring indicates a deviation from an established critical limit. This requires a plant's HACCP plan to identify the corrective actions to be taken if a critical limit is not met or is otherwise violated. Corrective actions are intended to ensure that no product injurious to health or otherwise adulterated as a result of the deviation enters commerce.
- **Principle 6:** *Establish procedures for verifying the HACCP system is working as intended. Validation* ensures that the plans do what they were designed to do; that is, they are successful in ensuring the production of a safe product. Plants will be required to validate their own HACCP plans. *Verification* ensures the HACCP plan is adequate, that is, working as intended. Verification procedures may include such activities as review of HACCP plans, CCP records, critical limits, corrective action records, and microbial sampling and analysis. Plants are required to ensure that the HACCP plan includes verification tasks to be performed by plant personnel. Verification of these tasks requires supporting documentation.
- **Principle 7:** *Establish record-keeping procedures.* HACCP requires that all plants maintain certain documents, including the hazard analysis and written HACCP plan, and records documenting the monitoring of CCPs, critical limits, verification activities, corrective actions taken, and the handling of processing deviations.

Under U.S. law, HACCP is required for facilities that manufacture meat and poultry products (as per the U.S. Department of Agriculture), juice products, and those that manufacture and hold seafood (as per the FDA). HACCP is also widely used within the food industry as a requirement for supplier-customer purchasing relationships.

"HACCP" Under FSMA

A key difference as noted earlier is the progression of HACCP into the hazard analysis and risk-based controls process. As we dig deeper, we see a focus on potential hazards that can occur from an intentional attempt to adulterate products. As we look at the HACCP plan, we see a greater need to focus on access to products as well as means to identify if a product may have been tampered with: for instance, a focus on facility access, perimeter barriers to access, access by people outside the facility, personnel screening for employees, safety tabs and seals for products, and so on. Digging further into our comparison of the two approaches, we add ingredient and supplier verifications to the puzzle. First, we need to consider the potential that economically motivated adulteration (food fraud) may have on the safety of the incoming materials we are using in our breweries. Are you using spices in your recipe? Did you know that 2015 saw the FDA issue health alerts and recalls of products containing cumin and related spice mixes because they were found to contain undeclared peanut powder? Industry conjuncture is that the less expensive peanut powder was used to "cut" the more expensive cumin, although investigations are still ongoing. There have been several recalls of black pepper due to high microbial levels, and current research is showing that this is common not only with pepper. What other spices are you using, and do you know how they are made, their country of origin, microbial load, and if they were recalled? Are you using milk powder in your recipe? Did you know that since March 16, 2007, more than 150 brands of pet food have been voluntarily recalled by a number of companies because they contained milk powder tainted by the industrial plasticizer melamine, and this resulted in the deaths of cats and dogs? Did you know the milk powder was supplied to these companies by ingredient suppliers in China? Breweries need to be aware of those ingredients that have been implicated in economic adulteration cases. This is a new focus under FSMA that many facilities with robust HACCP programs had not previously considered.

Breweries understand the importance of using quality ingredients in order to produce a quality product, and many have supplier approval and management programs in place to help ensure this. Let's think about food safety here. Breweries need to ensure the materials they are using in their products come from suppliers who are controlling potential food safety hazards in their own facilities. FSMA kicks this up a notch and addresses this in 21 CFR 117 subpart G by requiring facilities to implement a risk-based supply chain program for those materials that will require a supply-chain control. Not only are food manufacturers responsible for their own processes and products, but now they must verify that their suppliers are compliant as well. Although again breweries are exempted from this requirement (ref. 21 CFR 117.5), a light version of this has traditionally been part of facility GBPs, and those facilities that develop a *thorough* hazard analysis of their raw materials, ingredients, and other inputs tend to address this in their HACCP plans.

As we continue to look at the differences between the two approaches, they are similar with regard to the monitoring, corrections and corrective actions, and verification. However, when you get to the record keeping and documentation, this is where the government and the facility could have different expectations under 21 CFR 117. It becomes critical to test your plan on a regular basis and to verify that the control measures you have in place work. Additionally, this testing needs to be documented. If your plan has, which it will, specific expectations in it to test meters, counters, and so on to ensure accuracy of your measurements, you will need to do so. You will also need to be able to defend that the frequency that you execute a verification is adequate to make sure the instrument, and so on, is functioning properly 100% of the time.

The final and fairly major difference between the two plans deals with reverification frequency and any significant changes

to your processes. Traditionally, HACCP has advocated a review (or reanalysis or revalidation) of the HACCP plan a minimum of once a year or whenever there is a significant change in the product or process that may affect the safety of the product. Under 21 CFR 117.170, sites will be required to review and re-execute plans at a minimum every three years. A change in process will require a full review and restatement of that section of the plan *before* a change takes place. The key here is that this is poorly defined as to what constitutes a change. Given this vagueness it is imperative that a facility remain vigilant and focused on their plan, testing the plan, and verification that it remains compliant.

Food safety is a two-way street. We have seen in the broader food industry that retailers have been making food safety a condition of doing business. How many brewers supply big chain stores or stores of a size that require food safety plans to be in place? You may think you are exempt because of your size, but if you are providing your products to larger stores, which will normally be the case if you do any distribution at all, they will begin holding you accountable to their requirements. This means that you too will need to be compliant, not to the law, but you may be required to implement a food safety program as a condition of doing business with some of these customers.

So where can you find HACCP and FSMA information relevant to the brewing industry? To address this need the MBAA has developed and executes a HACCP training program that is typically offered a couple of times a year. These programs are available to members and nonmembers alike and are designed to help breweries address the next level of food safety planning including intentional hazards and plans to react to these, as well as testing, documentation, and change protocols. All of these will be reviewed within the materials presented. Given this new world, and the potential of issues and opportunities we face, this class is a great start to help you align your processes as required.