

SUPPLIER ASSESSMENT: A COMMITMENT TO FOOD SAFETY

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## **Abstract**

In the development of a hypothetical new food product (Beta Buzz) a company must have a thorough understanding of the associated food safety risks, and control factors needed to protect their consumers and their brand. The company must understand each of the suppliers, and take a proactive approach in determining the supplier requirements. It is critical that manufacturing risks be controlled and/or reduced through a combination of internal program compliance, government regulations, third party audit compliance, and/or customer audits and expectations with a focus on ingredients, the finished product and the manufacturing process itself. Food consumers have a right to safe food; the industry, as well as the government, has a responsibility to ensure consumers receive safe food.

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## **Chapter 1 - Supplier Assessment: A Commitment to Food Safety**

There have been many food safety incidents in recent years which have put consumers at risk, leading to additional focus on material suppliers and customer requirements. A supplier approval program takes into consideration the quality and safety associated with the finished product and is only as good as its worst ingredient. One of the tools utilized to control identified hazards is auditing. Audits can include first party, second party, third party and regulatory. When placing reliance on audits it is important to understand the underlying factors that led to the audit conclusions, including an understanding of who conducted the audit, how the audit was conducted, if there were scope limitations, and how to interpret the results. Food safety outbreaks have occurred despite third party audits, showing that these audits coupled with government regulation do not guarantee that food will be safe. Second party audits have shown to have a better track record in ensuring a safer food supply and have many benefits to the supplier approval program. As a stakeholder responsible for the review and approval of the production of Beta Buzz, it is important to look at the risks and the histories associated with the product category and dedicate sufficient resources to ensure the brand name is protected and the product is being safely produced for the consumer.

Food manufacturers have a duty to the consumer to understand risks associated with the products they produce. For example, a company preparing to produce a shelf-stable, allergen free, powdered vegetable-based beverage, such as a carrot juice health drink (Beta Buzz), would be responsible for understanding the associated food safety risks, and control factors needed to protect their consumers and their brand. Further, since consumer satisfaction can be measured by the continued purchase of products, food manufacturers have a natural interest in meeting consumer expectations of safety and quality as well as protecting their brand name and product identity. Manufacturers can achieve food safety and quality expectations by understanding the finished material they are producing, but they must also understand how each individual ingredient can affect their ability to meet safety expectations. It is critical that manufacturing risks be controlled and/or reduced through a combination of internal program compliance,

government regulations, third party audit compliance and/or customer audits and expectations with a focus on ingredients, the finished product and the manufacturing process itself.

According to the U.S. Centers for Disease Control and Prevention, 48 million people become sick, 128,000 people are hospitalized, and 3,000 die each year from foodborne diseases (CDC, 2013). Foodborne disease is largely preventable and has, therefore, gained much focus from governmental regulatory agencies and the industry itself. A number of food safety recalls, market withdrawals and consumer alerts have increased food safety concerns among consumers and stakeholders within the food industry (Peterson, 2011). Food consumers have a right to safe food; the industry, as well as the government, has a responsibility to ensure consumers receive safe food.

To prepare for the development of a new product such as Beta Buzz, one must research and understand the impacts that historical outbreaks have had in the powdered ingredient category. There are various recalls noted for improper allergen labeling, melamine, and possible physical contamination; however, the primary biological concern is *Salmonella* and possible *C. Botulinium*. It is noteworthy that a majority of recalls in this category were the result of an ingredient found by the supplier to be contaminated. Recently, Nestle USA had to recall Nesquik chocolate powder because it contained an ingredient, calcium carbonate, which had the possible presence of *Salmonella* (US FDA, 2012b). In a 2010 article by Food Safety News it was reported that three ingredients in one year had resulted in recalls of 3,306 individual products. These included products made from Peanut Corporation of America's peanut butter, Setton Pistachios, and Plainview Cooperative's powdered milk. In addition, Basic Food Flavors recalled Hydrolyzed Vegetable Protein (HVP) linked to possible *Salmonella* contamination. HVP is a common ingredient in many processed foods including soups, sauces, gravies, seasoned snack foods, dips and dressings which may have resulted in over 56 product recalls (Flynn, 2010). The quality and safety associated with the finished product is only as good as its worst ingredient.

Keeping current on food safety requirements requires a background in biological, chemical, and physical hazards, and a thorough understanding of the supply chain and the risks

associated not only with the ingredients but with each step in the manufacturing process. The ingredients for this proposed product are sourced from various suppliers and a risk assessment must be performed on each ingredient and each supplier. Beta Buzz will contain a blend of grasses, vegetables and leaves intended to provide the body with vitamins and minerals. Beta Buzz ingredients may include; lemon grass, fruit leaf, lecithin, carrot, celery, parsley leaf, tomato, and mineral complex. All of these ingredients are spray-dried and have a low water activity and moisture content. A product specification sheet has been obtained for each of the ingredients in the formula. These data sheets outline the material shelf-life, chemical properties, microbiological requirements, allergen information, and other important product attributes to be considered in the product development process. As determined through a historical review, the biological organism of concern in this category is *Salmonella*. At a minimum, each of these ingredients must be tested for *Salmonella*, Aerobic Plate Count (APC), Yeast and Mold, and Coliforms and the results reported to the customer on the certificate of analysis. Chemical hazards were identified to be cross-contamination from allergenic material. Beta Buzz ingredients do not contain allergens; therefore, a supplier approval program is a critical prerequisite to controlling this hazard because of possible cross-contamination exposure from facilities that may be processing allergenic material on the same line. Physical hazards associated with the raw materials were controlled through a supplier letter of guarantee and supplier policies which are reviewed as part of the supplier approval program.

The supplier approval program was critical to controlling the chemical and physical hazards as well as the biological hazards in the environment and finished product. The production of Beta Buzz is outsourced. Therefore, it was also critical to conduct a risk assessment of the co-manufacturer producing the material. Each supplier is assessed to determine the risks associated with their processing and facility. From the historical review of failures set forth above, it is apparent that the supplier plays a key role in ensuring that ingredients are safe for the manufacture of finished goods. As a stakeholder responsible for the review and approval of the production of Beta Buzz, it was important to look at the risks and the histories associated with the product category and dedicate sufficient resources needed to ensure Beta Buzz is being safely produced for the consumer. To this end, reliance on government standards, third party audit schemes and strong internal quality control standards, the supplier approval process was

tailored based on an overall assessment of risk, thereby yielding a safe product for the consumer and protecting the reputation of the producer of Beta Buzz. Understanding each of the approaches and audit types listed above will be important in determining what type of supplier requirements the company feels necessary to protect its brands and its consumers.

There are various ways in which government and industry are working towards a safer food system and better food for consumers. In December 2010, Congress enacted the Food Safety Modernization Act (FSMA) which updates the U.S. Food and Drug Administration's (FDA) authority to regulate food (NCSL, 2010). The FSMA was signed by President Obama on January 4, 2011. The FSMA is the most comprehensive food safety legislation since 1937. It enhances FDA the authority to regulate foods and enables FDA to proactively design measures to prevent foodborne outbreaks (National Conference of State Legislators, 2010). The FSMA applies to most food facilities except meat, poultry, and certain egg producers. Some key aspects of the act regulate prevention, inspection, response, imports and enhanced partnerships. The act requires inspection of high-risk domestic facilities within five years of enactment and no less than three years thereafter. However, in 2011, FDA only inspected 6% of domestic food producers and just 0.4% of importers. At that time FDA had no rules for how often food producers were inspected (Armour, et al., 2012). While FDA and the FSMA play an important role in food safety, the ultimate responsibility lies with industry. Further, many food manufacturers "don't believe the regulatory agencies are doing the type of job they should be doing" (Weise, 2010).

While the government plays an important role in ensuring a safe food supply, the ultimate responsibility for investing the resources and implementing appropriate internal controls lies within the food industry itself. As the company prepared to implement their supplier approval program and order materials to produce Beta Buzz, it was important for them to understand the tools used in the industry and determine what they were willing to accept or implement to control the risks. One tool the food industry utilizes is different kinds of food safety audits which aim to improve food safety. A company must consider not only regulatory requirements but many choose or require their suppliers to undertake third party, second party and first party audits. It is



important to understand the types of audits utilized by manufacturers and customers to improve food safety as well as the background and positive/negative aspects.

An internal audit program classified as a first party audit is an audit performed by the facility itself and can prove to be a useful program. The audit program should audit systems and procedures that are in place, and ensure procedures are appropriate and complied with. These audits are conducted internally by trained, competent auditors who work independently of the audited department (BRC, 2008). An example of a first party audit would be the facility quality manager auditing the preventative maintenance system and the shipping manager auditing the quality system. If implemented properly, a good internal audit program can be a key tool in ensuring the food safety compliance of a manufacturing facility. First party audits are an important piece in supporting continuous improvement and compliance and are often a requirement of third party audits.

Many companies have their own audit standards which they require suppliers to comply with. When a company is audited using customers' audit standards and expectations it is classified as a second party audit. Many times a company will have a department or employee who is responsible for auditing and ensuring these requirements are met by their suppliers. In some cases if internal resources are not available a company will utilize a second party auditor at their supplier sites to audit using the standards and expectations set forth by the company they are auditing for. Second party auditors are chosen by the company and often have knowledge of the products produced as well as the supply chain. A benefit of a second party audit is that the supplier has no influence over the auditor as second party audits are typically arranged and conducted by the supplier directly. Additionally second party audits are typically paid for by the customer and are tailored to the products supplied.

Third party audits can also be utilized to protect companies and their brands as well as public health. A number of standard industry third party audit schemes can be used (e. g., AIB consolidated standards for food safety or NSF Cook and Thurber). An example of a third party audit would be a company hiring the American Institute of Baking (AIB) to conduct an audit using the AIB consolidated standards for food safety which they would then provide to their

customers to show compliance with food safety requirements. In addition to these schemes the Global Food Safety Initiative has recently been developed and is utilized to meet third party audit requirements.

Global food industry standards and commitment to food safety and quality is evolving rapidly. The Global Food Safety Initiative (GFSI) was developed in 2000 as a result of increased food safety incidents worldwide which have put consumers at risk. GFSI is a globally recognized set of food safety standards. It is a benchmark scheme based on international food safety standards, which provides a globally accepted audit framework for food safety certification. GFSI pursues continuous improvement and increased efficiency; it is an accredited third party audit that is projected to reduce audit duplication throughout the supply chain. Nine food safety standards are accepted by a majority of food retailers that meet GFSI requirements including the British Retail Consortium (BRC), Safe Quality Food (SQF) and Food Safety System Certification 22000 (FSSC22000) (GFSI, 2012). The mission of GFSI is to drive continuous improvement in the food safety system while also increasing consumer confidence in the safety of food. The vision of GFSI is “once certified, accepted everywhere,” with the goal of reducing audit duplication so each company only needs to have one benchmarked food safety audit annually (Crandall, 2012). Both customers and suppliers must recognize and understand the requirements of the audit, who the individual is that will perform the audit, the audit scope, what the final report will contain, and the control that industry has over certification for the initiative to gain public acceptance. Many companies set aggressive goals to become compliant with these standards as a result of Wal-Mart Stores requiring that their suppliers become GFSI certified (Crandall, 2012).

When placing reliance on third party audits and GFSI audits it is important to understand the underlying factors that led to the audit conclusions, including gaining an understanding of who conducted the audit, how the audit was conducted, if there were scope limitations, and what the results mean. Auditing standards can vary greatly depending on the scope, the operation, the commodity, regulation and other factors (Costa, 2012). Therefore, the background and knowledge of the auditors play a key role in the effectiveness of an audit; consequently, auditors must keep up to date on the latest scientific developments. If the auditor is performing an

accredited third party certification audit, it means that the certification body they are auditing for is held to the stringent requirements of the accreditation body to ensure impartiality, lack of conflict, and competency requirements that aims to create confidence for the end user (Rannells, 2006). In a number of instances auditors who have had financial ties or some other conflict of interest associated with the company they are reviewing have been chosen. For example, Bloomberg Markets Magazine identified executives of Flowers Foods, Inc. serving or have served on the auditing firm AIB's board, which creates third party audit conflicts (Armour, et al., 2012). Currently almost all food producers require their suppliers to be audited and also to pay for their own audits; only in some cases will the producer provide a list of audit firms (Weise, 2010). This allows the audited supplier to choose the auditor. Ultimately, food producers rely on these auditors and "especially with critical suppliers, you're really betting your business on these guys," says Dave Theno in a USA Today Article by Elizabeth Weise (2010). In a 2011 article on third party audits, Dan Flynn shares his opinion to "certify the individual, not the company".

Auditors are often limited to auditing only what the client asks them to review, what is defined within the scope of the audit, and the documents and areas of the facility that the company specifies. The amount of time they can spend on-site is also limited. This means that audits provide a snapshot in time of what the company is doing. Consequently, some companies pass audits even though their facilities pose serious food safety risks (Powell, 2013). The audit score itself, for instance, does not indicate to the buyer whether points were lost for clerical errors in record keeping or because pest infestations have been observed. This means customers must fully understand the reports they receive and analyze the results being reported. Some of the key and inherent failures in the auditing system that have been identified include auditors lacking regulatory authority or not reporting identified problems to a regulatory authority, not ensuring that identified problems are resolved, advance notice of visits by auditors being provided to the audited party, and the failure to prioritize important food safety deficiencies.

The following food safety outbreaks have occurred despite third party audits and cast doubt on the auditing system:

- In October 1996, an outbreak of *Escherichia coli* O157:H7 leading to 64 illnesses and one death was traced to juice manufactured by Odwalla (Powell, 2013). While Odwalla had written contracts with the supplier to only provide apples from the trees rather than the ones from the ground (likely contaminated with deer feces) the company had never verified whether their suppliers were actually following the requirements (Powell, 2013).
- On January 10, 2009, Peanut Corporation of America (PCA) recalled certain types of peanut butter; this recall was further expanded over time to include more than 3,900 products from over 200 companies that were ascertained to be contaminated with *Salmonella* Typhimurium, causing this to be one of the largest recalls in U.S history (Wittenberger, Dohlman, 2010). The Centers for Disease Control (CDC) began tracking these outbreaks in November 2008 through April 2009 and 714 cases of illness were found to be linked to *Salmonella* Typhimurium and may have contributed to 9 deaths (Wittenberger, et al. 2010). The New York Times reported that an auditor from AIB had evaluated PCA and had given this company a “Superior” rating (Martin, 2009). Part of this audit may have included a review of the food safety program and microbial test results; however, it was later learned that PCA knowingly shipped products that tested positive for *Salmonella* and a criminal inquiry of the peanut company was initiated by federal officials (Martin, 2009).
- In 2010, Wright County Eggs recalled half a billion eggs that ultimately caused a *Salmonella* outbreak sickening 1,939 people (Armour, et al, 2012). In this case the company had also recently received “Recognition of Achievement” on an audit conducted by AIB. AIB said it had not been asked to audit portions of the plant where the FDA found contamination (Armour, et al, 2012).
- On August 3, 2011, Cargill recalled 36 million pounds of ground turkey after it was linked to 136 infections and one death from *Salmonella* Heidelberg (Armour, et al, 2012). In the midst of this recall the facility was awarded an “A” grade by Food Safety Net Services Ltd. using GFSI standards (Armour, et al, 2012).
- On September 14, 2011, Jensen Farms recalled whole cantaloupes due to their possible contamination with *Listeria* (US FDA, 2011). Before this outbreak,

which sickened 146 people in 28 states, killed 30, and caused a miscarriage, Jensen Farms was rated by third party audit firm PrimusLabs as “superior” with a score of a 96 percent and no-deficiencies (Acheson, 2012).

The business of food safety auditing is rapidly growing and evolving; however, the human element will always play a part in the outcome of audits. Roy Costa (2010) says “Protecting the food people eat is a shared responsibility, one way too big for even an army of auditors”.

The food industry including retailers, distributors and food service providers are requesting that their suppliers meet specific food safety and quality standards prior to buying products from them (Peterson, 2011). Some companies choose to dedicate additional resources to protect themselves and their consumers. One retailer that strengthened its requirements to reduce the risk of food contamination is Costco. This retailer, for example, pays its lettuce supplier, Earthbound, an extra 3 cents per bag for microbial testing prior to release (Armour, et al. 2012). In the previously mentioned 2009 recall of PCA's peanut butter products, it is noteworthy that they had been subject to two different second party audits by Nestle USA, for which PCA is a supplier. Nestle uses its own auditors to check suppliers and both of the second party audits in this instance had identified deficiencies at PCA, which caused Nestle to refuse using PCA products (Armour, et al.2012). Kellogg, a company that had to recall some of its peanut-containing products as a result, had received reports of acceptable third party independent audits as well as test results from PCA that indicated no positive *Salmonella* results (Martin, 2009). The audit did not raise concerns for the buyer and, consequently, the brand name and products suffered. Similarly, in a 2006 outbreak associated with *E.coli* O157:H7 found in spinach, Dole Foods had received a third party audit that did not raise concerns that would alter purchasing decisions (Powell, 2013). In the Odwalla Juice *E.coli* O157 outbreak in 1996, military personnel performed a second party audit in which they determined that the facility's sanitation program was not adequate to supply to military consumers (Powell, 2013). An advisory manager for PriceWaterhouseCoopers tells of one client who had a recall due to a tainted ingredient that was incorporated into finished product. As a result, “The manufacturer has had to implement a more rigorous inspection program for all of its suppliers to ensure they are meeting the standards of both the manufacturing company and the current regulations” (Sowinski, 2012). These cases

demonstrate that a proactive approach can work in a company's favor and help in the ultimate goal of providing safe food to consumers.

When selecting a co-manufacturing company to produce Beta Buzz it is important to understand the other products they produce and what programs they have in place to prevent cross-contamination. Although they may have a third party audit in place, there is no guarantee that their programs are sufficiently robust. In addition, the producer may have outsourced processing to other locations to which product may be transferred. Providing the internal resources for assessing the co-manufacturing supplier is critical to ensuring the food is safely produced. Internal resources will have a specific focus on the material and know the detailed requirements and risks associated with the product.

Ultimately, the company producing the food must establish its quality and safety requirements and assume the risk to its brand. While some rely solely on government standards, and some rely on third party audit schemes, a company with strong internal auditing controls and standards and a proactive approach to protecting themselves and their reputations, will ultimately better protect their brand. This review of the scientific literature has shown that third party audits coupled with government regulation do not guarantee that food will be safe. It is important that any company understand each of the suppliers, what materials they provide and what they will require of them in the supplier approval program. As this company prepares for the production of this health drink they must take a proactive approach ensuring their products are safe. These steps might include second party audits. The aim should be "encouraging an environment of shared compliance and collaboration between government and industry" (Sowinski, 2012).

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