

The Food Industry's Perception of Economically Motivated Adulteration and Related Risk Factors

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ABSTRACT

The United States of America has numerous safeguards in place to protect our food supply, including federal regulations and the food and beverage industry's dedication to food safety. One of the issues that the food and beverage industry continuously battles is the prevalence of intentional adulteration. The Food Safety Modernization Act (FSMA) specifically addresses intentional adulteration and its sub-category of economically motivated adulteration (EMA) by requiring all facilities that supply food to the US to assess the vulnerabilities within their operation in order to prevent events that could cause public harm. The purposes of this study are threefold: (1) to better understand industry's perception of EMA (2) to assess how industry determines ingredients at risk for EMA and (3) to determine the extent to which a tool that assesses ingredient vulnerability would be useful to industry.

This study surveyed individuals working for food and beverage companies in departments associated with the selection, purchase, or processing of ingredients. Questionnaire items assessed their companies' view of EMA, FSMA's impact on their companies' view on EMA, and examined their perception of EMA and ingredient safety. The data was analyzed for major themes.

Participants (n=36) overwhelmingly agreed, 88.9%, that some ingredients are at higher risk for EMA. Results show 37% of participants say that their operation is "somewhat vulnerable" to "very vulnerable" to EMA and 55.6% rank EMA as one of their company's top 5 food safety and quality assurance concerns. Specific ingredients such as "honey", "seafood", "olive oil", and "spices" were mentioned as higher risk ingredients. Other participants explained ingredients "supplied from China" and "high value and high demand raw materials" as well as "changes in the market" inflate the risk of EMA. The most common factors that impacted the

perception of risk of EMA included the originating location of the ingredient (80.6%), supplier reliability (88.9%), historic instance of EMA (88.9%), and the value of the ingredient (86.1%).

EMA is a large concern for those who completed this questionnaire. Most respondents noting that even when they feel their operation is secure against EMA, it is still a top 5 priority.

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CHAPTER 1: INTRODUCTION

Food fraud is as old as the commercialization of food. Ancient Roman law contained edicts against contamination and commercial fraud of foodstuffs. Containers used to transport wine and oil from that time period have been found bearing counterfeited Roman seals; thus illustrating the necessity for these regulations. (Armstrong, 2009; Mello, Lusuardi, Meloni, & Oddone, 1982; Purcell, 1985). Food fraud is defined by Spink and Moyer (2011) as the “collective term used to encompass the deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging; or false or misleading statements made about a product, for economic gain” (pg. 158).

Because the definition is so broad, acts constituted as food fraud need to be broken down to show the intentionality of the act, as well as their motivation, in order to best understand the result. John Hnatio (2015) explained the two criminal actors within the food fraud sphere are either individuals involved in organized crime, typically involved at the processing level, or individuals participating in a crime of opportunity. This illustrates two of the largest segments of fraudsters.

While food fraud covers a more expansive scope, intentional adulteration focuses specifically on tampering with the product and its ingredients. In the FDA’s proposed rule FDA-2013-N-1425, Focused Mitigation Strategies to Protect Against Intentional Adulteration (IA rule), intentional adulteration encompasses all types of purposeful adulteration that could possibly cause harm to the public. While the intent of the rule is to prevent acts of terrorism the proposed rule also covers economically motivated adulteration (EMA) commonly referred to as economic adulteration. EMA, which in

theory should go undetected, has caused numerous significant public health events. Food fraud is a wide-spread problem which researchers estimate cost the global food industry between \$10-15 billion annually (Hunt, 2010; Kearney, 2010; USDA, 2015).

PROBLEM STATEMENT AND PURPOSE OF STUDY

Food fraud, and more specifically, economically motivated adulteration, is a great concern within nearly all sectors of the food and beverage industry. Although the Food Safety Modernization Act (FSMA) has added regulations to help prevent public health events due to economic adulteration, industry also has a vested interest in both consumer well-being and safe-guarding brand integrity. The purposes of this study were (1) to better understand industry's perception of economically motivated adulteration (2) to assess how industry determines ingredients at risk for EMA and (3) to determine the extent to which a tool that assesses ingredient vulnerability would be useful to industry.

IMPORTANCE OF THE STUDY

The findings contained within this study will help food and beverage companies better understand EMA. As companies assess the vulnerabilities of their operation to EMA the results of this study will help guide their risk assessments. The study will also provide insight on the reported effects of federal regulations on industry behavior.

CONTEXT OF THE STUDY

The Food Safety Modernization Act passed in 2011 with the purpose of changing the culture of food safety in the United States from reactive to proactive (FDA, 2015b). The remaining final rules are scheduled for distribution in spring, 2016. Companies must be compliant within a year of the final ruling and are currently in the process of

determining how to assess the risk of EMA within the context of their supply chain. The rules directly or indirectly addressing EMA are Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR §117), Focused Mitigation Strategies to Protect Food Against Intentional Adulteration (Docket ID: FDA-2013-N-1425) and Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (21 CFR §1.500-514). However, there are indications that the final IA rule will no longer include EMA in its scope of intentional adulteration, and instead focus exclusively on acts of terrorism. This due to the final rule for FDA-2011-N-0920, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (PC Rule), which was filed in September 2015. A number of changes were made from the proposed rule including the addition of EMA to the mandatory risk assessments to food manufacturing, processing, packaging, and holding facilities.

STUDY DESIGN AND RESEARCH QUESTIONS

This exploratory survey research project is designed to better understand industry's perception of EMA and was guided by the following research questions:

1. To what extent are the FSMA rules changing industry processes versus reaffirming previously existing safe guards?
2. What factors do industry personnel weigh when considering the risk of EMA?
3. What is the current perception of EMA among industry personnel?

ASSUMPTIONS

This study was conducted under the following assumptions:

1. Participants were well informed of their companies' operations in regards to EMA.
2. Participants answered survey questions honestly and to the best of their knowledge.
3. The researcher's role in an industry funded EMA working group did not bias the survey questions or interpretation of results.

LIMITATIONS

1. Participation is voluntary and is limited to those within the email contact lists of the Grocery Manufacturers Association (GMA) and the Tennessee Food Safety Task Force.

DEFINITION OF TERMS

Food Fraud- A collective term used to encompass the deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging; or false or misleading statements made about a product, for economic gain (Spink & Moyer, 2011)

Adulterant- a substance added to a product to make it impure. (Kearney, 2010)

Adulteration- As described in 21 USC § 342 includes any addition of poisonous or deleterious substances which may render a product injurious to health, including:

- If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated, or where it may have been rendered injurious to health,
- If any valuable component has been in whole or in part omitted,
- If any substance has been substituted,
- If damage or inferiority has been concealed,
- If any substance has been added so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is (21 USC § 342)

Intentional Adulteration- The act of purposely adulterating food, for either economic gain or for public harm. Examples: Bioterrorism, revenge from a disgruntled employee, and Economically Motivated Adulteration (Federal Registrar, 2013)

Economically Motivated Adulteration (EMA)- The intentional fraudulent modification of a finished product or ingredient for economic gain (Kearney, 2010)

Unapproved enhancements: increase the apparent value, quality, or strength of a product. *Example: melamine added to milk to enhance the nitrogen value* (Kearney, 2010)

Concealment: Conceal known damage or contamination. *Example: Salmonella contagion in peanuts* (Kearney, 2010)

Non-disclosure: Intentional Good Manufacturing Practices (GMP) violations. *Example: sulfites in food to hide deterioration* (Kearney, 2010)

Mislabeleding: Reclassifying one product as another, which may include fraudulent imitation intended to be passes as genuine. *Example: sunflower oil sold as olive oil* (Kearney, 2010)

Substitution: Replace with something less valuable. *Example: use of beet sugar rather than honey* (Kearney, 2010)

Dilution: Reduce the amount of a valuable component. *Example: water used to dilute milk* (Kearney, 2010)

ORGANIZATION OF STUDY

This thesis is organized as follows. Chapter one: Introduction, including the following sections – statement of the problem, purpose of the study, importance of the study, context, research questions, assumptions, limitations, and definition of terms. Chapter two: Review of Literature, contains a review of current literature and previous research on economically motivated adulteration. The review of literature on differentiating economically motivated adulteration from food fraud and intentional adulteration, public health and economic consequences of economic adulteration, factors contributing to prominent cases of economic adulteration, relevant global laws and regulations, and current and up and coming detection methods. Chapter three: Journal Manuscript, including methodology, results, and discussion for submission to the Journal of Food Protection.

CHAPTER 2: LITERATURE REVIEW

HISTORICAL PERSPECTIVE ON ECONOMIC ADULTERATION

In 1820, Friedrich Accum wrote, *A treatise on adulterations of food and culinary poisons*, which was one of the first attempts to call out dangerous ingredients being used within the food supply to defraud consumers. In his book, Accum wrote about both harmless substitutions and toxic chemicals that he found using analytical chemistry methods common for that time. For instance, he describes his methods of testing for lead as using “water impregnated with sulphuretted hydrogen gas, which instantly imparts to the fluid containing the minutest quantity of lead, a brown or blackish tinge” (p. 51). Unfortunately, with his book he made many enemies who ended up running him out of Britain and back to his home country of Germany. As a result, his findings on food adulteration were forgotten for the next 30 years (Royal Society of Chemistry, 2016).

The next major player in the fight against food adulteration was Harvey Wiley, the Chief Chemist of the Bureau of Chemistry, which preceded the FDA (FDA Consumer Magazine, 2006). Wiley and his volunteer Poison Squad tested the effects of chemicals and adulterated foods on themselves. Under Wiley’s direction the USDA began to incorporate food standards into the food statutes. Four years after the formation of the Poison Squad their efforts culminated in the Pure Food and Drug Act of 1906 (FDA Consumer Magazine, 2006).

By the 1930s, food chemistry had progressed so far as to make the Pure Food and Drug Act obsolete which demanded a complete revision of the law. Detection methods were available for all of the food types and physical attributes listed in the Table 1 at the

time of the Food Drug and Cosmetic Act was passed in 1938 (Armstrong, 2009). Over the years, food chemists have continually pushed the boundaries for detection of ingredients as well as detection limits. Unfortunately, chemists and fraudsters on the other side of the table have had the same amount of time to circumvent the tests.

Table 1: Analytical Methods Available by 1938 when the Food Drug and Cosmetic Act was passed. (Armstrong, 2009)

Analysis	Method developed
Physical, refractometry, colorimetry, spectrometry, electrometric, viscoimeter freezing point, surface tension	1920-1937
Coloring substances	1916-1937
Preservatives	1916-1937
Metals	1924-1936
Milk analysis	1918-1936
Milk Products Analysis	1925-1935
Oils and Fats	1922-1936
Sugar Foods and Carbohydrates	1912-1935
Gums, Cereals, starches, polysaccharides, fruits, jellies and jams, vegetable products	1926-1935
Spices, Flavors, Condiments	1920-1935
Alcoholic Beverages	1928-1937

LAWS AND REGULATIONS

As discussed above, laws and regulations ensuring the purity of food have been around for centuries and across all cultures. Most ancient civilizations had bread and wine purity laws (Accum, 1820). In modern times, the federal government has an intricate series of rules and regulation to ensure the safety of our food supply.

UNITED STATES GOVERNMENTAL OVERSIGHT

In the United States, there are two principle agencies that work to protect the food supply from all types of food safety risks, the Food and Drug Administration (FDA) , the US Department of Agriculture (USDA), and the Environmental Protection Agency (EPA). Imports are inspected by Customs and Border Protection (CBP), a part of the Department of Homeland Security (DHS), in conjunction with the FDA and USDA. Food fraud also falls under the jurisdiction of the Department of Justice (DOJ), which has tried many cases of adulteration and mislabeling (Johnson, 2014). EMA is also considered an unfair method of competition as well as an unfair or deceptive act or practice. As such, the Federal Trade Commission also has concurrent jurisdiction with the FDA.

The Food Drug and Cosmetic Act of 1938 (FDCA), with some revisions, has been the laws that govern the majority of the Food and Beverage Industry's work. As defined in the FDCA, the term adulteration encompasses any addition of poisonous or deleterious substances which may render a product injurious to health, if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated, or where it may have been rendered injurious to health, if any valuable component has been in whole or in part omitted, if any substance has been substituted, if damage or inferiority has been concealed, if any substance has been added so as to increase its bulk

or weight, or reduce its quality or strength, or make it appear better or of greater value than it is (21 USC § 342). While there were many positive rulings against fraudsters in the early years of the FDCA, several of its major flaws were revealed, notably, that there is not a set standard against which to judge the food that is allegedly adulterated (Forte, 1965). This makes it easier for EMA to remain undetected.

Currently, the US is still facing an influx of products from domestic and foreign producers that are deemed by law to be adulterated. This proves that the rules and regulations are necessary. The majority of the reasons that products are refused at the port of entry into the US are all forms of adulteration such as filth or botulism in canned food (Buzby, 2008).

Food Safety Modernization Act

In 2011, the Food Safety Modernization Act was signed into law amending parts of the FDCA. While Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls (PC rule) and Foreign Supplier Verification Program for Importers of Food for Humans and Animals (FSVP rule) have published their final rules, about half of the rules, including Focused mitigation strategies to protect food against intentional adulteration (IA rule), have not yet been finalized. This leads to some confusion as to where exactly EMA will be addressed.

The proposed IA rule describes the scope of intentional adulteration as:

“acts of disgruntled employees, consumers, or competitors intended to attack the reputation of a company, and not to cause public harm, although public health harm may occur” (Federal Registrar, 2013, p. 78017).

“Economically motivated adulteration (EMA) intended to obtain economic gain, and not to cause public health harm, although public health harm may occur” (Federal Registrar, 2013, p. 78017).

“Acts intended to cause massive public health harm, including acts of terrorism” (Federal Registrar, 2013, p. 78017).

When the proposed rules were first published, EMA was to be addressed in a company’s Food Defense plan as laid out by the IA rule (Federal Registrar, 2013). However, during the rule making process, it was suggested that rather than EMA being housed under the IA rule, it should actually be contained within the PC rule.

In September 2015, the final PC rule was published in the Federal Registrar. There were several modifications from the original proposed rule, specifically the inclusion of EMA. Under the finalized rule, company food safety plans would have to consider EMA when establishing hazard analysis and risk-based preventative controls plan. The rule’s new language calls for companies to identify hazards that are “intentionally introduced for the purposes of economic gain” (21 CFR §117.130 (b)(2)(iii) which is a subtle, but important, change to disassociate EMA from intentional adulteration as is covered within the scope of the IA rule. The exact same wording is used within FSVP rule, ensuring that standard for hazard analysis is equal for domestic manufacturers as well as importers (21 CFR §1.504(b)(2)(iii)). It should also be noted that within all versions of these rules, only EMA that affects food safety is covered, EMA that alters product quality or integrity is considered to be out of scope. For produce other laws regarding pesticide usage must be followed under EPA regulation utilizing only pesticides approved for that product rather than pesticides intended for other uses for both domestic suppliers and importers.

Under the 21 U.S. Code § 342 (a)(2)(b) a food is also considered adulterated if “if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a(a) of this title”.

This change, coupled with public meetings held by the FDA regarding the IA rule, indicates that EMA will be completely housed within the PC rule for domestic manufacturers and within the FSVP rule for importers. Dr. Newkirk from the FDA spoke at a meeting about EMA’s place within FSMA saying, “We tentatively conclude that EMA is best addressed by applying a preventive control scheme when this type of adulteration is reasonably likely to occur. And therefore we feel EMA is best addressed in the human and animal preventive control rules” (McNair, 2014). Therefore, we can conjecture that the final IA rule will not include EMA in the definition of intentional adulteration and will focus exclusively on threats of bioterrorism.

The last rule that deals with EMA within FSMA is the Foreign Supplier Verification Program for Importers of Food for Humans and Animals (FSVP) rule, finalized in November 2015. As with the previous rules, this rule only addresses EMA that has the potential to cause public harm. The purpose of the rule as stated in its summary is:

“to verify that food they import into the United States is produced in compliance with the hazard analysis and risk-based preventive controls and standards for produce safety provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), is not adulterated, and is not misbranded with respect to food allergen labeling” (CFR§1.504(b)(2)(iii)).

However, there are definite complications when implementing this rule. Like any organization, the FDA and USDA operate with limited resources. Under the FSVP rule, FDA is to inspect at least 600 foreign food facilities in 2011 and, for each of the next 5 years, inspect at least twice the number of facilities inspected during the previous year (Figure 1) (Gomez, 2015). In January of 2015 the Government Accountability Office (GAO) released a study pointing out that the FDA has been unable to keep up with this mandate. The primary reason cited for the lag in inspections is staffing challenges (Gomez, 2015). As of October 2014, 44% of foreign office positions were vacant (Gomez, 2015). The GAO report recommended the FDA develop a strategic workforce plan to recruit and retain staff with the necessary skills and experience (Gomez, 2015).

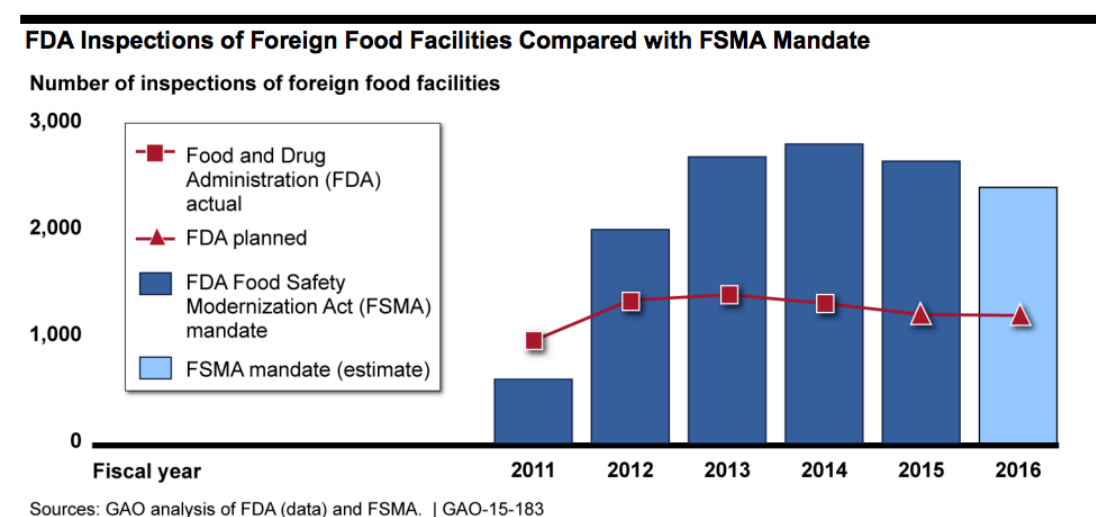


Figure 1: From the GAO analysis of FDA Inspections required by FSMA

Because of these limitations, the FDA and USDA must prioritize the most serious threats to the food system. As most cases of EMA involve only indirect health risks it is often judged to be less important than food safety incidents and bioterrorism (Karen Everstine, Spink, & Kennedy, 2013).

Tools Being Developed

As the largest concern for ingredients that may be vulnerable to EMA comes from imported ingredients it is imperative that industry utilizes tools and safeguards in addition to the government. (Kearney, 2010). The Grocery Manufacturers Association (GMA), Safe Supply of Affordable Food Everywhere (SSAFE) in conjunction with the Global Food Safety Initiative, and US Pharmacopeia are all developing tools and schemes for companies to utilize as they assess their supply chain's risk for EMA. These tools could prove to be incredibly useful as a company is preparing its hazard analysis, and risk-based preventive controls plan.

The GMA EMA vulnerability assessment tool is currently being developed by Battelle. The tool will function as a program for companies to judge the relative safety risk associated with ingredients across their specific supply chain. It will rank ingredients from highest risk of EMA to lowest risk of EMA, allowing quality assurance and food safety experts from the company to more accurately assess how to allocate their time and testing materials. It functions by pulling the latest information regarding ingredient value, scarcity, and instances of food fraud from a continuously updated database as well as allowing the user to input company specific information such as the frequency of identity testing performed. This dynamic tool will be available as an application that needs web access in order to provide up to date data.

The SSAFE/GFSI tool was released in January of 2016. It is a free tool that is available to download as an app at the Apple Store and on Google Play, as an excel document from their website, and online. The tool asks 50 questions relating to opportunities for adulteration, motivations for adulteration and control measures in place

to prevent adulteration. The benefits of this system is that it walks the respondent through a series of questions that allow the individual to assess various levels of controls within their operation so the individual can fully understand where their risk or safety stems from. The downside is that the respondent must be extremely well versed in their company's supply chain, their quality department, as well as external factors and it takes quite a bit of time to complete.

Finally, the US Pharmacopeia released a free guidance document titled "Guidance on Food Fraud Mitigation" in January of 2015. The document provides a thorough approach for assessing and preventing EMA at the ingredient level. Through a three step approach the document advises participants how to assess factors associated risk associated to EMA, assess the risk of potential impacts on public health and company revenue, and finally develop a mitigation strategy.

FOOD FRAUD, INTENTIONAL ADULTERATION, AND EMA

Economically motivated adulteration (EMA) is a specific subcategory of food fraud and intentional adulteration (Figure 2). A study on consumer product fraud conducted by A.T. Kearney defined EMA as "the intentional fraudulent modification of a finished product or ingredient for economic gain through the following methods: unapproved enhancements, dilution with a lesser-value ingredient, concealment of damage or contamination, mislabeling of a product or ingredient, substitution of a lesser-value ingredient or failing to disclose required product information" (2010, p. 3). The nature of EMA lends itself to blending in, after all the end goal is to generate more revenue so most cases of EMA only lessen the quality of the product.

A simple example of an EMA event that would not pose a threat to public health includes diluting honey with less expensive sweeteners like sugar cane or beet syrup or high fructose corn syrup (Berfield, 2013; K. Everstine, 2014). The consumer, whether that is a manufacturer using the honey in a cereal or an individual who purchases the final product, is cheated out of a significant amount of money over time and is ultimately not receiving the product they paid for.

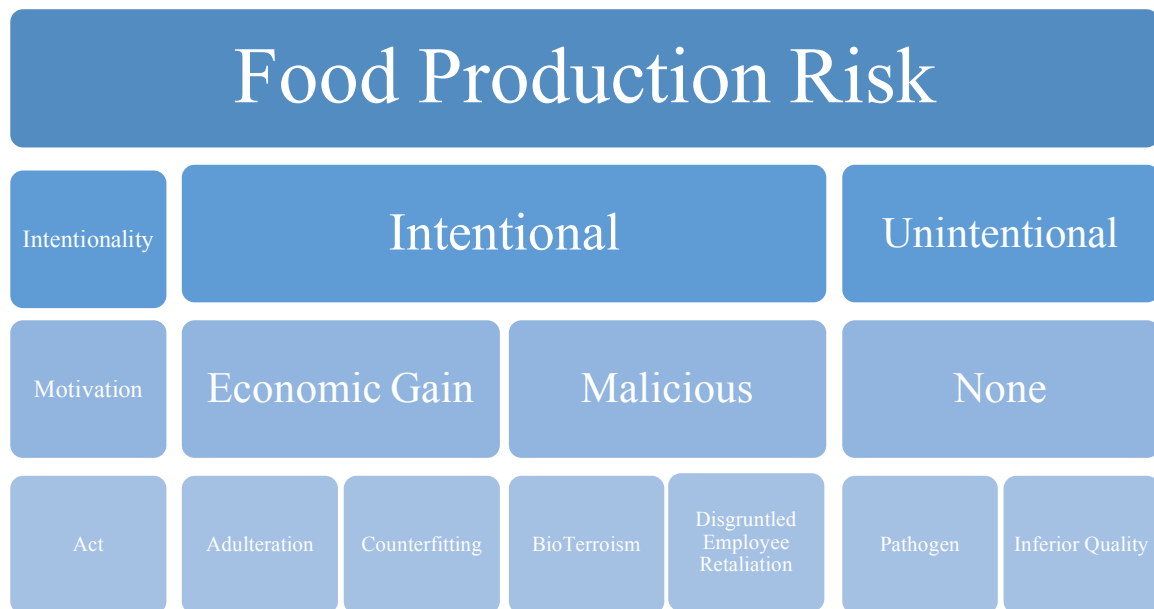


Figure 2: Umbrella of Food Production Risk

PROBLEMS CAUSED BY EMA

PUBLIC HEALTH CONCERNS

The number one concern when thinking about problems caused by EMA is the threat to public health. For those attempting EMA, blending their product in is fiscally beneficial because the longer the fraud is continued, the more money the perpetrator

generates. However not all cases of EMA are well thought out, which can cause major public health concerns.

Cases of EMA are scattered throughout history. One of the first chemists to focus of adulterants in food, Henry Accum, published *A treatise on adulterations of food and culinary poisons* in 1820 warning the public about poisonous adulterants in their tea, beer, bread, and wine. In his book he wrote, “The man who robs a fellow subject of a few shillings on the highway is sentenced to death but he who distributes a slow poison to the whole community escapes unpunished” (p. 15).

While the fraudsters who adulterate food today may not be using things like lead and mercury salts, but there are still adulterants that cause harm to the public. In late 2014 into early 2015, cumin from multiple suppliers was found to have been adulterated with ground peanuts (FDA, 2015a, 2015c; USDA, 2015). While this isn’t cause for concern to most, up to two percent of the world is allergic to peanuts, and exposure can cause symptoms from rashes to anaphylaxis (Institute, 2010). The recalls associated with the contaminated cumin pulled nearly 600,000 pounds of seasoned beef, poultry and pork products as well as over 500 spice produces off the market (Bennett, 2015). While some argue that these cases could have been unintentional, the levels of peanut protein found in the recalled cumin, up to 100,000 parts per million (ppm), were higher compared to other cumin samples that occasionally arise with 5-40 ppm (American Spice Trade Association, 2015).

Another instance of EMA with public health concerns is the use of Sudan dyes, particularly I and IV, to enhance the color of fruits, vegetables, and spices (Daood, 2005). Sudan dye I is suspected to have genotoxic effects and Sudan dyes I to IV are potential

carcinogens (European Commission, 2005) and are banned for use in foods. This has not stopped them from repeatedly surfacing to give foods such as tomatoes and red peppers a more vibrant color (Daood, 2005).

An even more immediate public health risk occurred in Britain in late 2014 when counterfeited bottles of popular vodka brands were diluted with isopropanol and sold on the grey market, meaning channels that are legal but unintended by the manufacturer. The isopropanol used to dilute the vodka can cause anything from blindness to death (Gayle, 2014). A criminal organization manufactured the counterfeit vodka right before New Year's Eve in anticipation of greater than average alcohol consumption (Gayle, 2014; Stone, 2014). The government seized the products as well as the bottles and other equipment used to produce the potentially dangerous product. Luckily there were no public health incidents related to this event because the government was able to get the products off the street quickly (Stone, 2014).

The the most infamous case of EMA was the use of melamine as an adulterant for milk powder in 2008. Melamine is a white powder that is commonly used in the plastics industry and very high in nitrogen (Lim, 2013). This is significant because nitrogen levels are used to back calculate protein levels and milk powder is priced by protein content. When consumed by humans it can cause kidney stones and renal failure, especially in children. Several dairy companies within China began adulterating their products with melamine in order to make up for the monetary loss from price gaps imposed by the Chinese government (Hunt, 2010). This crisis hospitalized over 300,000 infants and led to the death of six children under the age of four (Lim, 2013).

ECONOMIC IMPACT

There are very few published works that address the economic impact of EMA. This is due in part to corporate confidentiality, competition, brand protection as well as the abstract nature of the question. In 2010, the GMA and AT Kearney, an industry consulting group, released a study about food fraud in the market place. The report heavily focused on the economic impact of food fraud, specifically EMA, within the food industry. GMA estimates globally, food fraud may cost the industry between 10-15 billion dollars annually, affecting approximately 10% of all commercially sold food products (Kearney, 2010). It is also projected that the cost of one adulteration incident turning into a public health risk is equal to 2-15% of a company's yearly revenue (Kearney, 2010).

FACTORS LEADING TO EMA EVENTS

To understand how the Chinese melamine occurred, it is important to appreciate the chain of events leading up to the adulteration. According to surveys in the mid-2000s, the average Chinese dairy farmer had 4 milk cows or less (Hunt, 2010). They then sent their product to milk stations, which sold it to the processors, who then sent it to the distributors for consumers to buy (Hunt, 2010). In January of 2008, the Chinese government imposed price caps on milk and milk products causing the dairy industry to lose 15-20% profit compared to previous years. This did not sit well with 22 companies who ran milk stations and were looking for ways to stretch their product within the new government limitations.

Quality tests run by the Chinese government were established to ensure that milk powder meets certain specifications before it is released to the public, including a protein

level of 2.95%. While melamine does not contain protein, it is high in nitrogen. Because protein is the only macro-nutrient that contains nitrogen, quality checks for protein actually measure levels of nitrogen (Lim, 2013). This loophole allowed those perpetrating the fraud to trick the system for months. Because of censorship laws in China, specific details about the investigations of the companies or the economic impact of the scandal are not readily available.

This is not the only case where external economic factors put pressure on the supply chain and caused an EMA incident that negatively impacted public health. In 2015, an incident involving the adulteration of cumin occurred after an incredibly hot growing season in Gujarat, India, the state which produces the majority of the world's cumin, decreased the crop yield by 50% (Bawden, 2015). This sudden environmentally induced ingredient scarcity caused the prices to sky rocket and a few producers decided to take advantage of the high demand and add ground peanuts, which is visually similar to ground cumin, to their supply causing the cumin incident of 2015 described in the previous section.

CURRENT DETECTION METHODS

Detection methods are continuously advancing, but because each product can be adulterated with a vast array of adulterants there is no single way to detect adulterants in a product. Many analytical methods are available to test for specific adulterants, a few of the more common ones are listed below:

- liquid chromatography
- spectroscopy
- chromatography

- ratio mass spectrometry
- mass spectroscopy

One of the most promising fields of detection in relation to EMA is metabolomics. Although the field is relatively new, the goal of metabolomics is to create a profile of all the metabolites present in a sample (Elena Cubero-Leon, 2013). Metabolomics can determine everything from botanical and geographical origin, vintage of grapes, wine brand, tea and coffee processing variety, caffeineation, farming system, rearing system, and create unique profiles for ingredient samples. Although metabolomics still has a long way to go in order to make it a cost-effective and accurate solution for monitoring ingredient specifications, the future of assuring food authentication will likely rely heavily on this method.

It is also important to monitor databases that track instances of EMA. There are two major databases that are incredibly useful when exploring historical instances of food fraud. The Food Protection and Defense Institute's *FoodShield* database is available to anyone working with the food industry or academia. Their incidents database is incredibly thorough linking articles about events, press releases from federal agencies and any other relevant information to the event page (FoodShield, 2016).

The interesting part about the development of detection methods is that the development of a new method is generally the easiest way to tell if a company has had a "near miss". Meaning companies figure out that an ingredient has been adulterated, they ensure that batch doesn't move forward to the consumer and that the same product will not get through their system again. Food companies generally don't report near misses to

the public, but papers published describing the new methods tell enough of the story for others to infer what happened.

The United States Pharmacopeia (USP) also has a database of food fraud and EMA incidents. Their database differs from *FoodShield* in that it does not have the most detail on the incidents of EMA, but it uses inferences and deductive reasoning to ascertain near misses in the industry to give a more complete list of food fraud incidents. The USP database also has a library of detection methods to help mitigate against fraud. Together these two databases help paint a holistic picture of food fraud and EMA, which is an incredibly useful tool for industry (Moore, 2015).

SUMMARY

Economically motivated adulteration has been present since the beginning of food trade. There are multiple government agencies ensuring the US has a safe food supply and the new Food Safety Modernization Act is bringing EMA to the foreground. Industry has a vested interest in keeping our food supply safe for both consumer and brand safety. What is unknown is how industry is adapting to the new federal guidelines and expectations. The purpose of this study is to assess industry's perception of EMA and the extent to which FSMA has impacted their perception.

CHAPTER 3: JOURNAL MANUSCRIPT

INDUSTRY'S PERCEPTION OF ECONOMICALLY MOTIVATED ADULTERATION AND RELATED RISK FACTORS

ABSTRACT

The United States of America has numerous safeguards in place to protect our food supply, including federal regulations and the food and beverage industry's dedication to food safety. One of the issues that the food and beverage industry continuously battles is the prevalence of intentional adulteration. The Food Safety Modernization Act (FSMA) specifically addresses intentional adulteration and its sub-category of economically motivated adulteration (EMA) by requiring all facilities that supply food to the US to assess the vulnerabilities within their operation in order to prevent events that could cause public harm. The purposes of this study are threefold: (1) to better understand industry's perception of EMA (2) to assess how industry determines ingredients at risk for EMA and (3) to determine the extent to which a tool that assesses ingredient vulnerability would be useful to industry.

This study surveyed individuals working for food and beverage companies in departments associated with the selection, purchase, or processing of ingredients. Questionnaire items assessed their companies' view of EMA, FSMA's impact on their companies' view on EMA, and examined their perception of EMA and ingredient safety. The data was analyzed for major themes.

Participants (n=36) overwhelmingly agreed, 88.9%, that some ingredients are at higher risk for EMA. Results show 37% of participants say that their operation is “somewhat vulnerable” to “very vulnerable” to EMA and 55.6% rank EMA as one of their company’s top 5 food safety and quality assurance concerns. Specific ingredients such as “honey”, “seafood”, “olive oil”, and “spices” were mentioned as higher risk ingredients. Other participants explained ingredients “supplied from China” and “high value and high demand raw materials” as well as “changes in the market” inflate the risk of EMA. The most common factors that impacted the perception of risk of EMA included the originating location of the ingredient (80.6%), supplier reliability (88.9%), historic instance of EMA (88.9%), and the value of the ingredient (86.1%).

EMA is a large concern for those who completed this questionnaire. Most respondents noting that even when they feel their operation is secure against EMA, it is still a top 5 priority.

INTRODUCTION

Economically Motivated Adulteration (EMA) is defined by the FDA as the “fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production, i.e., for economic gain” (Johnson, 2014). EMA is subset of intentional adulteration that focuses on defrauding producers and consumers, and while it is far from a modern day phenomenon the rapid growth of science, technology, and globalization have exacerbated the issue.

EMA has been around as long as food has been commercialized. There is evidence from the roman empire that indicates that the government was protecting consumers against purchasing oil and wine that did not meet proper standards as well as seals that were counterfeit to get around the government standards (Armstrong, 2009; Mello, Lusuardi, Meloni, & Oddone, 1982; Purcell, 1985). However, research on economically motivated adulteration and its effects on public health were not a subject of focus until 1820 when Friedrich Accum wrote *A treatise on adulterations of food and culinary poisons*. In his book he outlined the ways in which food was being adulterated, the effects it caused on humans, and the scientific methods in which he proved the adulteration occurred (Accum, 1820). However, his research did not result in many changes as those that he was attempting to expose found a way to deport him from England back to his native Germany (Royal Society of Chemistry, 2016).

However, in the late 1800s Harvey Wiley and began working for the United States government on adulterants in the food supply and the dangers they posed to the public. The combination of his experiments with his team of volunteers dubbed the

Poison Squad and muckraker journalism led to the passing of the Pure Food and Drug Act of 1906 (FDA Consumer Magazine, 2006).

The Pure Food and Drug Act was later replaced with the Food Drug and Cosmetic Act (FDCA) in 1938. The one major addition to FDCA in regards to EMA was setting a thorough definition of adulteration. Up until 2011, FDCA with some revisions, has been the law that govern the majority of the Food and Beverage Industry's work. While there were many positive rulings against fraudsters in the early years of the FDCA, several of its major flaws were revealed, notably, that there is not a set standard against which to judge the food that is allegedly adulterated (Forte, 1965). This makes it easier for EMA to remain undetected.

The Food Safety Modernization Act (FSMA), passed in 2011 and is awaiting final rules, specifically addresses intentional adulteration as well as economically motivated adulteration. These new rules will require all facilities that supply food to the US to assess the vulnerabilities within their operation in order to prevent exploitations of the food supply that could cause public harm. The final rules are due to be published by the spring 2016 and companies are currently working to update their systems in order to become compliant.

The reason that EMA is concern to companies is two-fold. First and foremost, EMA poses a substantial risk to public health. While most EMA can fly under the radar without harming consumers, there have been multiple incidences in recent year that have caused illness and death.

The the most infamous case of EMA was the use of melamine as an adulterant for milk powder in 2008. Melamine is a white powder that is commonly used in the plastics

industry and very high in nitrogen (Lim, 2013). This is significant because nitrogen levels are used to back calculate protein levels and milk powder is priced by protein content. When consumed by humans it can cause kidney stones and renal failure, especially in children. Several dairy companies within China began adulterating their products with melamine in order to make up for the monetary loss from price gaps imposed by the Chinese government (Hunt, 2010). This crisis hospitalized over 300,000 infants and led to the death of six children under the age of four (Lim, 2013).

The second reason that companies are concerned about EMA is monetary. There is no published research that analyzes the amount of money companies lose by paying for a certain ingredient and losing money by paying top dollar for inferior product. However, it has been noted that any EMA incident initiating a public health risk is equal to 2-15% of a company's yearly revenue (Kearney, 2010).

MATERIALS AND METHODS

OBJECTIVE OF STUDY

Food fraud, and more specifically, economically motivated adulteration, is a great concern within nearly all sectors of the food and beverage industry. In fact, in the Food Safety Modernization Act, whose rules are in the process of being finalized, the government is requiring industry to formalize their processes of avoiding intentional adulteration including economically motivated adulteration. In 2013, The Grocery Manufacturers Association's (GMA) EMA working group tasked themselves with creating an electronic vulnerability assessment to aid industry in preventing adulterated ingredients from contaminating their products. The purposes of this exploratory study were to better understand industry's perception of economically motivated adulteration,

to better understand FSMA's role in industry decisions regarding economically motivated adulteration and to see to what extent a tool like the one envisioned by GMA would be useful to industry.

PARTICIPATION

Participants were adults over the age of 18, involved in the food safety, quality assurance, purchasing, supply chain, and procurement of ingredients for the food industry. Participants received the questionnaire by being members of working groups hosted by GMA, if they were affiliated with the Tennessee Food Safety Task Force, or if the email was forwarded to them by a colleague.

ASSUMPTIONS

This study took place under several assumptions. Firstly, that participants were well informed of their companies' operations in regards to EMA. This was combated with a knowledge check question at the beginning of the survey to ensure that participants could distinguish EMA from other forms of intentional adulteration. The second assumption was that participants answered the questions honestly and to the best of their knowledge. To ensure that participants felt they could honestly answer the questionnaire steps were taken to ensure anonymity of both the respondent and the company which they represented. The final assumption was that the researcher's role in an industry funded EMA working group did not bias the questions or interpretation of the results. To avoid bias, the researcher was advised by members of academia and industry who were not associated with the working group.

INSTRUMENT DEVELOPMENT

After attending a workshop led by the Grocery Manufacturer's Association assessing what industry would want in a tool that assessed vulnerability to economic adulteration, I conducted an extensive literature review on EMA and interviewed several experts in the field. With the information gathered, I devised the items for the questionnaire and grouped into the 5 categories listed in Table 2. To further establish construct validity the final instrument was reviewed by a panel of 8 experts. The panel was comprised of experts in survey research, food safety, EMA, and food industry personnel.

Table 2: Rationale Behind Question Categories in EMA Perception Questionnaire

Category	Purpose
Categorization	To give context to participants' perspective on ingredients.
View of EMA	To gauge the importance of EMA to the participant's company
FSMA impact	To dissect the impact of FSMA on company operations
EMA Perception	To capture industry's understanding of how EMA functions
Tool Usefulness	To determine the value of creating an industry wide EMA vulnerability assessment.

A field test of the instrument was conducted with two food production companies. Field test participants (n=6) were from different departments and were tasked with determining the clarity of questions, approximate duration, spelling, grammar, and ease of the use of the technology. The results from the field test indicated only minor changes were necessary for clarity, such as for the question "Do you perform EMA assessments in-house and/or do you use a 3rd party auditor". Previously they could have left both

boxes unchecked if they did not perform EMA assessments, but for clarity the option “We don’t perform EMA assessments” was added.

DATA COLLECTION

The final instrument was then ready for distribution with a cover letter explaining the objectives of the study. The self-report instrument was created for delivery in Qualtrics, an online survey tool. Qualtrics allowed the questionnaire to be accessed digitally, record responses immediately, and allowed for anonymous responses by automatically scrubbing IP addresses before saving the responses.

The instrument began with a consent form, approved by the University of Tennessee’s Institutional Review Board (IRB). Those who did not consent to participate were released and no data was recorded. If a participant did not complete the questionnaire their responses were automatically scrubbed from the system. All questions were ‘no response’ enabled except for the consent form, meaning that if a participant did not feel comfortable or qualified they could skip a question. The questionnaire contained 10 multiple choice questions, 8 open ended questions, 3 categorical scales, and 2 rank order scales. However, due to question flow logic, not all questions were shown to each participant. For example, Question 7 asks the respondent “With the finalization of FSMA’s rules has the way your company views EMA shifted?” to which they can either respond “Yes” or “No”. If the respondent chooses “Yes” they are directed 7.1, an open ended response question asking “How has the way your company views EMA shifted?”. Meanwhile those who select “No” are routed to question 7.2 which asks “Is there a reason that your company’s views have not shifted?”. The questions were designed with the purposes explained in Table 2. The questionnaire was active for two weeks. The data

was then downloaded, cleaned using proper data management practices (Morrow, 2013) and finally analyzed using SPSS 23.0.0 for the quantitative output and NVivo 11.1.1 for the qualitative output.

The first two questions on the instrument helped to categorize participants' perspectives and knowledge base first by industry, then by position in the company. The 16 industry sectors listed in question 1 (Appendix A) were based on *FoodSheild's*, a web database run by the Food Protection and Defense Institute that monitors cases of EMA, categories for adulterated food. The job positions listed in question 2 (Appendix A) were modified from a survey distributed by Institute of Food Technologists. The third question was designed to assess knowledge to ensure that respondents know what constitutes EMA. The four options are all versions of adulteration, but the intentionality and motivation differ.

The questions regarding risk factors relating to EMA utilized a modified list compiled by experts at the Grocery Manufacturers' Association EMA Working Group. Participants were asked to first select all factors they consider when determining risk of an ingredient, then to rank the factors they chose in order of importance.

DATA ANALYSIS

The quantitative data were analyzed using descriptive statistics, Pearson's r , and ANOVA to analyze the relationship between answers. The qualitative data collected were analyzed using a structured approach to thematic coding. Responses were organized by question and then open coding was used to identify themes. These themes were then used to find patterns and connections which attached meaning and significance to quantitative data (Taylor-Powell & Renner 2003; Elo & Kyngäs, 2008; Bazeley, 2009). Quantitative responses were analyzed for differences based on industry, participant role, and the

perception of their companies' risk of EMA. Significant differences were evaluated at the 95% confidence level ($p < 0.05$).

RESULTS AND DISCUSSION

CATEGORIZATION

Thirty-six individuals completed the questionnaire ($n=36$). Item 1 asked “Which best describes your Industry Sector (check all that apply)” (Appendix A), respondents identified themselves primarily as in the ‘Grain and Grain Product’, ‘Canned Foods’, and ‘Prepared Foods’ (Table 3). Many also chose to elaborate in the ‘Other’ box with representatives from “Food Additives”, “Food Contact Packaging”, “Snacks”, and “powder beverages”.

Participants also self-reported their position in the organization in Item 2. Individuals ($n=35$) chose between 20 options that were then broken down into 5 broader categories. Most participants in this study's positions were classified as a corporate science role (45.7%), however there was also a strong representation of plant based roles (40%). Individuals who worked in regulatory affairs or for a consulting company accounted for 11.4% of participants, one Sales or Marketing professional responded (2.9%), and there were no participants from purchasing or procurement.

Table 3: Industries represented of those who participated (n=36) in the questionnaire participants were asked to check all categories that applied to their company

Category	Total Participants (Percent)
Alcohol	0
Canned Goods	11 (31%)
Coffee and Tea	1 (3%)
Confection	3 (8%)
Dairy	4 (11%)
Eggs	3 (8%)
Fish and Seafood	3 (8%)
Fruit Juices	0
Frozen Foods	3 (8%)
Grain and Grain Products	13 (36%)
Meat	6 (17%)
Oils	4 (11%)
Pet Foods	4 (11%)
Prepared Foods	8 (22%)
Produce	0
Spice	4 (11%)
Other	11 (31%)

Item 3 had participants identify an instance of EMA 94.4% of participants correctly distinguished EMA from other forms of adulteration. One individual incorrectly responded with adulteration due to contamination and another selecting a case of bioterrorism. There could have been some confusion with the response “*Salmonella* in Peanut Butter”, which represented unintentional contamination. There was a case of contaminated peanut butter that is classified as EMA. In that case, the Peanut Butter Corporation of America shipped peanut butter that they knew was tainted with *Salmonella*, which caused hundreds to fall ill and nine deaths in 2009 (CDC, 2009).

FACTORS CONTRIBUTING TO PERCEPTION OF VULNERABILITY

Item 4 asked participants to rate their company’s vulnerability to EMA on a 6-point scale of ‘Very Vulnerable’ to ‘Very Secure.’ The majority of participants reported that they perceive their operation as somewhere in the middle with 52.7% responding ‘somewhat vulnerable’ or ‘somewhat secure’. Very few, 5.6%, saw their operation as ‘Vulnerable’ or ‘Very Vulnerable’. The rest of the participants saw their operations as ‘Secure’, 19.4%, or ‘Very Secure’, 22.2%.

Participants were then asked in Item 5 “How high a priority is protection against EMA”. While two respondents, 5.6%, don’t consider protection against EMA to be a priority, quite a few of participants consider protection against EMA to be a ‘High Priority’, 25%, or a ‘Very High Priority’, 13.9%. The largest portion of respondents, 44.4%, considered protection against EMA an ‘Average Priority’. When considering their operations in Top 5 Quality Assurance and Food Safety concerns, in Item 6, the majority of participants (55.6%) rank EMA in their top 5 (See Table 4).

Table 4: Rank of Economically Motivated Adulteration in Top 5 concerns relating to company Food Safety and Quality Assurance

Rank	Percent
1	2.8%
2	2.8%
3	19.4%
4	16.7%
5	13.9%
Not in Top 5	44.4%

THE FOOD SAFETY MODERNIZATION ACT’S IMPACT ON OPERATIONS VIEW ON EMA

According to Item 7, the new FSMA rules have not impacted the way 58.3% of participants’ view EMA. One individual summed up the major theme of how industry addresses EMA post-FSMA in stating, “The key difference is that with FSMA, EMA is required to be part of your hazard analysis [HA] now, where as before it 'should' have been part of company's HAs.”

Those whose companies’ views have shifted in regards to EMA since FMSA, 41.7%, explained how it has impacted their company in Item 7.1. Overall individuals cited changing procedures and updating hazard analysis plans. Some companies have gone even farther forming “a specific team to evaluate our vulnerability, mitigation actions in place, and which programs should be enhanced to increase the level of protection”.

Others explained why their views had not shifted in Item 7.2 by stating that “we have selected suppliers that we trust and verified that they deliver what they have promised”, “our company is at low risk for EMA”, and “There is not a clear understanding within a company how EMA alone affects a company’s overall risk profile”.

It should be noted that not everyone is up to date on latest the FSMA rules. EMA is now covered in the *Current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food* rule, which indicates some of the language used to describe mitigation strategies such as “The Food Defense/Food Security Plan is more formalized” and “We will be including this in our food defense assessment” are slightly dated. This is an opportunity for leaders in regulatory affairs, extension workers and government agencies to assist companies in understanding the updates.

Two-thirds of participants also said their company had already begun implementing focused mitigation strategies in Item 8. From content analysis of open-ended responses to Item 8.1 major themes of these strategies include increased testing, a focus on traceability of ingredients, and updating the framework of the companies’ risk analysis plans. Individuals did provide specific examples noting that they have made changes to “sampling programs for incoming grain from certain regions where EMA has been an issue in the past” and providing “training, seminars, [and] action plans” for team members. Multiple respondents (25%) indicated that their companies would work with “reputable suppliers”.

Participants were also receptive to the idea of an electronic tool proposed in Item 10 that would assist their organization in assessing the threat of EMA with 61.1% indicating the tool would be ‘Useful’, 25.0% indicating the tool would be ‘very useful’, and 25.0% indicating the tool would be ‘somewhat useful’.

RISK FACTORS

Of the total sample, 88.9% of participants believe that some ingredients are at a higher risk of EMA than other ingredients, recorded in Item 11. One participant explained why they did not perceive some ingredients to be at a higher risk of EMA in

Item 11.1 stating, “in general we consider all ingredients to be equal risk and of equal importance”.

The most mentioned ingredients at risk for being adulterated included specific examples like “seafood”, “juice”, oils including “vegetable oil” and “olive oil”, “sweeteners including honey”, “cumin”, “black pepper”, and “nuts”. Participants also mentioned ingredients “supplied from China”, “high value and high demand raw materials”, that risk varies “based on changes in the market”. One individual went so far as to explain “Whatever is most expensive at the time. Last year it would have been eggs. Milk is always a contender after the melamine as it is a white powder - any white powder that is expensive.”

Participants selected all risk factors they consider when thinking of EMA in Item 12. The number of factors selected by individuals ranged from 1 to 13, and the factors they selected were then ranked in order of importance in Item 13, with 1 being most important and n= number of factors individuals selected being the least important. The categories that consistently ranked the highest were supplier reliability, historic instance of EMA, and value of the ingredient (Table 5) throughout the quantitative and qualitative portions of the questionnaire. It is interesting to note that determining supplier reliability, which is the most subjective of all of the risk factors listed, is labeled as one of the best ways to mitigate food from being adulterated for economic gain. When looking at the importance of ingredient value to EMA risk assessments participants pointed out that ingredients with high monetary value, such as spices, as well as ingredients with high nutritive value, such as animal protein feed, are both at an elevated risk factor.

Table 5: Perceived Risk of Factors related to Economically Motivated Adulteration

Category	Total	%	Highest rank	Lowest rank	Mean	Median	Mode
Supplier Reliability	32	88.9%	1	9	3.19	3	1
Historic Instance of EMA	32	88.9%	1	9	3.23	3	1
Value of Ingredient	31	86.1%	1	8	3.40	3	1
The originating location / country/ region	29	80.6%	1	8	3.32	3	2
Volume of Ingredient	27	75.0%	2	10	5.75	6	9
Scarcity/ Surplus	26	72.2%	1	10	4.15	4	2
Frequency in Change of Ownership before product reaches facility	19	52.8%	3	12	5.89	6	6
Frequency of repacking before product reaches facility	18	50.0%	3	12	6.71	6	5
Presence of Industry Testing Database	13	36.1%	4	12	7.84	7	7
Frequency of Identity Testing	13	36.1%	2	11	7.16	8	9
Presence of Governmental Regulations	12	33.3%	2	11	8.00	9	11
Presence of Trade Associations	7	19.4%	8	13	10.42	10	8

When asked to specify areas or regions of concern in Item 13.2 the most overwhelmingly common answer was “China” with 17 individuals specifically naming China. More broad regions like “Southeast Asia” or “ASPAC region,” which include China, were also popular responses. China, infamous for the 2008 Melamine-Milk scandal, is held up as the worst case scenario for EMA. But a more holistic picture of origins industry deems to be the least trustworthy is developing countries whose food safety culture is not up to US industry or government standards. Other regions and countries of concern were “South America”, “Africa”, “India”, and “Eastern Europe”.

The issue with relying on country of origin as risk factor is that there is always the possibility that ingredients get repackaged with labels that do not accurately represent the ingredients’ origins. Traceability within a company supply chain is one of the most important ways to ensure the safety and integrity of ingredients as traceability systems would account for several risk factors at once.

It is not surprising that companies are on the lookout for ingredients that have historically been adulterated. In items 11.1 and 13.3 participants specified ingredients that they perceived to be at higher risk of adulteration. Common responses of “honey”, “spices”, “seafood”, and “juices” were in line with the list of the most common instances of EMA (Everstine, 2013).

ITEM RELATIONSHIPS

There was a moderate negative correlation between how vulnerable or secure a company felt (Item 4) in relation to EMA and the level of priority a company placed on EMA (Item 5), $r = -0.343$, $n=36$, $p=0.041$. Indicating the more vulnerable a company felt, the higher a priority it received. A moderate negative correlation was also found between the priority a company placed on EMA and the usefulness of a EMA vulnerability

assessment tool, $r = -0.379$, $n = 36$, $p = 0.023$. This correlation demonstrates that the higher a priority companies place on EMA the more likely they are to find a vulnerability assessment tool useful. There was no correlation found in how departments within the industry perceive their companies' risk to EMA, Item 4, nor was there any difference in how they ranked the risk factors.

CONCLUSIONS

This study, through surveying food industry personnel, was able to shed light on industry's perception of economically motivated adulteration, FSMA's role in industry decisions regarding economically motivated adulteration, and the usefulness of a vulnerability assessment tool. However, because of the low sample size these results are not generalizable to the food industry, only to those individuals who took the survey. Firstly, the FSMA rules reflect practices already implemented in the majority of the food industry companies that participated in this questionnaire. This follows sound logic as the FDA worked closely with industry to ensure that the new rules reflected best practices. This reflects a good working relationship between the food industry and government with the common goal of keeping our food supply safe.

Economically motivated adulteration is a large concern for the members of the food industry who completed this questionnaire, the majority of participants rank it in their top 5 Food Safety and Quality Assurance concerns. Even when a company feels their operation is secure against EMA, most still say that EMA is on their priority list. As globalization continues mitigation strategies will need to continue developed and implemented to be in order to ensure food safety.

Survey respondents are looking at EMA risk factors and judging them very consistently. Supplier reliability, ingredient origin, value of ingredient, and historic instance of EMA are the first elements they consider when evaluating the ingredients risk of EMA.

In order to obtain generalizable results, this survey should be conducted with a representative sample of the food industry. Further research should focus on the economic impact of specifically EMA, ‘near misses’ of adulterated ingredients that almost made their way into the supply chain, and continual research into detection methods.

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WORKS CITED

1. 21 USC 342 (a)
2. 21 USC 342 (b)
3. Accum, Friedrich . (1820). *A treatise on adulterations of food and culinary poisons*.
4. Armstrong, D. J. (2009). Food chemistry and u.S. Food regulations. *J. Agric. Food Chem*, 57, 8180–8186.
5. Association, A. S. T. (2015). *Frequently asked questions on cumin/allergens*. Retrieved from <http://www.canadianspiceassociation.com/wp-content/uploads/Cumin-FAQs.pdf>
6. Bawden, T. (2015, 2/13/15). New food scandal over peanuts is 'more serious' than the horsemear crisis. Retrieved from <http://www.independent.co.uk/life-style/food-and-drink/news/new-food-scandal-over-peanuts-is-more-serious-than-the-horsemear-crisis-10045725.html>
7. Bazeley, P. (2009). Editorial: Integrating data analyses in mixed methods research. *Journal of Mixed Methods Research*, 3(3), 203-207.
8. Bennett, P. (2015, 1/22/15). Peanut-contaminated cumin leads to massive allergy recall *Allergic Living*. Retrieved from <http://allergicliving.com/2015/01/22/peanut-contaminated-cumin-leads-to-massive-allergy-recall/>
9. Berfield, S. (2013). The honey launderers: Uncovering the largest food fraud in u.S. History. Retrieved from <http://www.bloomberg.com/bw/articles/2013-09-19/how-germany-s-alw-got-busted-for-the-largest-food-fraud-in-u-dot-s-dot-historySRC> - GoogleScholar
10. Buzby, J. C., Unnevehr, L. J., & Roberts, D. (2008). *Food safety and imports: An analysis of fda food-related import refusal reports*. Retrieved from Washington, D.C.:
11. CDC. (2009). Multistate Outbreak of Salmonella Infections Associated with Peanut Butter and Peanut Butter--Containing Products --- United States, 2008—2009. *MMWR* 58(04);85-90
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5804a4.htm>
12. Chemistry, R. S. o. (2016). The fight against food adulteration. Retrieved from <http://www.rsc.org/education/eic/issues/2005Mar/Thefightagainstfoodadulteration.asp>
13. Comission, E. (2005). *Questions and answers on sudan dyes contamination of certain food products*. Retrieved from http://ec.europa.eu/food/food/chemicalsafety/fraudulent/qanda_en.pdf
14. Daood, H. G., Biacs, P. A. (2005). Simultaneous determination of sudan dyes and carotenoids in red pepper and tomato products by hplc. *Journal of chromatographic science*, 43, 461-465.
15. Elena Cubero-Leon, R. P., Alain Maquet. (2013). Review on metabolomics for food authentication. *Food Research International*, 30, 95-107.

16. Elo, S., & Kyngäs, H. (2008). The qualitative content analysis process. *Journal of advanced nursing*, 62(1), 107-115.
17. Everstine, K. (2014). Economically motivated adulteration of honey: Quality control vulnerabilities in the interanational honey market. *Food Protection Trends*, 34(1), 8-14.
18. Everstine, K., Spink, J., & Kennedy, S. (2013). Economically motivated adulteration (ema) of food: Common characteristics of ema incidents. *Journal of food protection*, 76(4), 723-735.
19. FDA. (2015a). Con yeager spice company's revised voluntary recall for ground cumin and seasoning blends (containing ground cumin) due to potential undeclared peanut allergens
20. [Press release]. Retrieved from <http://www.fda.gov/Safety/Recalls/ucm435171.htm>
21. FDA. (2015b). Preventative standards. Retrieved from <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm256826.htm>
22. FDA. (2015c). Zenobia company llc. Issues allergy alert on undeclared peanut protein in "my spice sage cumin ground" [Press release]
23. FDA Consumer Magazine (2006). Pioneer consumer activist. Retrieved from <http://www.fda.gov/aboutfda/whatwedo/history/centennialoffda/harveyw.wiley/default.htm>
24. Federal Register. (2013). Focused mitigation strategies to protect food against intentional adulteration; proposed rule. 21 CFR Parts 16 and 121, 78014-78061
25. Federal Register. (2015). Foreign supplier verification program for importers of food for humans and animals. 21 CFR Parts 1, 11, and 111. 74226-74352
26. Federal Register. (2015). Current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food; final rule, 21 CFR Parts 1, 11, 16, 106, 110. 55908-56168
27. FoodSheild. (2016). Retrieved from <https://www.foodshield.org/>
28. Forte, W. E. (1965). Food and drug administration and the economic adulteration of foods, the. *Ind. LJ*, 41, 346.
29. Gayle, D. (2014, 12/28/14). Warning over killer vodka after 166 bottles of counterfeit spirits containing anti-freeze and paint remover are seized. *The Daily Mail*.
30. Gomez, J. A. (2015). Food safety: Additional actions needed to s foreign offices ensure safety of imported food. *GAO Highlights*(GAO-15-183).
31. Hnatio, J. (2015, 04/12/15). Pre-Conference Workshop: Economically Motivated Adulteration. GMA Science Forum, National Harbor, MD.
32. Hunt, T. (2010). *Global dairy outlook: Enter the giants*. Retrieved from
33. Institute, T. P. (2010). *Peanut allergy white paper*. Retrieved from http://www.peanut-institute.org/resources/downloads/peanut_allergy_whitepaper.pdf
34. Johnson, R. (2014). *Food fraud and "economically motivated adulteration"*. Retrieved from Washington, D.C.:
35. Kearney, A. T. (2010). *Consumer product fraud: Deterrance and detection*. Retrieved from Washington, D.C.:

36. Lim, V. (2013, 1/03/13). Tainted milk: Unravelling china's melamine scandal. *Think Business*.
37. Marrow, J. (2013) A Brief Introduction to the 12 Steps of Evaluation Data Cleaning. Retrieved from
38. <http://www.slideshare.net/jamorrow/brief-introduction-to-the-12-steps-of-evaluagio>
39. McCoy, K. (2015, 09/22/15). *Peanut exec in salmonella case gets 28 years*. Retrieved from <http://www.usatoday.com/story/money/business/2015/09/21/peanut-executive-salmonella-sentencing/72549166/>
40. McNair, E. (2014, 03-13-2014). *Fsma proposed rules on focused mitigation strategies to protect food against intentional adulteration and sanitary transportation of human and animal food public meeting*. Paper presented at the FDA Food Safety Modernization Act (FSMA) Public Meeting, 03-13-2014, Anaheim, CA.
41. Mello, E., Lusuardi, S., Meloni, S., & Oddone, M. (1982). Provenance studies of roman amphorae by instrumental neutron activation analysis. *Journal of Radioanalytical Chemistry*, 69 SRC - *GoogleScholar*, 259-270.
42. Moore, J. (2015, 04/12/15). Pre-Conference Workshop: Economically Motivated Adulteration. GMA Science Forum, National Harbor, MD.
43. Purcell, N. (1985). Wine and wealth in ancient italy. *Journal of Roman Studies*, 75 SRC - *GoogleScholar*, 1-19.
44. Silver, R. (2015, 04/12/15). Pre-Conference Workshop: Economically Motivated Adulteration. GMA Science Forum, National Harbor, MD.
45. Spink, J., & Moyer, D. C. (2011). Defining the public health threat of food fraud. *Journal of food science*, 76(9), R157-163.
46. Stone, J. (2014, 12/29/14). Deadly fake vodka made from anti-freeze found on sale across britain ahead of new year. *The Independent*.
47. Taylor-Powell, E., & Renner, M. (2003). Analyzing qualitative data. University of Wisconsin-- Extension, Cooperative Extension
48. USDA. (2015). Pennsylvania firm recalls chili product due to misbranding and an undeclared allergen [Press release]. Retrieved from <http://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-case-archive/archive/2015/recall-003-2015-release>

APPENDICES

APPENDIX A- QUESTIONNAIRE “INDUSTRY PERSPECTIVE ON ECONOMIC ADULTERATION”

Industry Perspective on Economically Motivated Adulteration

INFORMED CONSENT STATEMENT FOR: Participants Industry Perspective on Intentional Adulteration Survey

INTRODUCTION You are being invited to voluntarily participate in a research effort by a Master's Candidate at the University of Tennessee. The research will serve to understand and analyze Food Industry's perspective of Intentional Adulteration. The purpose of this survey is to assess the impact of the Food Safety Modernization Act (FSMA) on company's view and safety plans regarding Intentional Adulteration. **INFORMATION ABOUT PARTICIPANTS' INVOLVEMENT IN THE STUDY** Your involvement in the study would include completion of a 10-15 minute survey.

RISKS The only risk to participation is a breach in confidentiality. This risk is highly unlikely and many steps have been taken to minimize that risk including having the software not record your IP address and not asking you to identify yourself or your company.

BENEFITS Benefits to your participation include the collection of information that could be used to improve your understanding of Intentional Adulteration. Participants may also elect to receive the aggregated results of the survey. This will help the improve society's understanding of this complex topic and lead to a safer food supply.

CONFIDENTIALITY Confidentiality of participant comments will be maintained. No personal or company information will be asked and no IP address is recorded with the collection of the survey information. Data will be stored securely and only made available to the research team at the University of Tennessee.

CONTACT INFORMATION

If you have questions at any time about the study or the procedures, you may contact the one of the researchers, Lindsay Murphy, (865) 974-7107 or lmurphy9@vols.utk.edu , or Dr. Jennifer Richards, (865) 946-1089 or Jennifer.Richards@utk.edu . If you have questions about your rights as a participant, contact an IRB Compliance Officer in the University of Tennessee Office of Research and Engagement at (865) 974-7697.

PARTICIPATION Your participation in this study is voluntary; you may decline to participate without penalty. If you decide to participate, you may withdraw from the study at anytime without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed your data will be returned to you or destroyed.

CONSENT

I have read the above information. I have received a copy of this form. I agree to participate in this study.

- ☐ I agree
- ☐ I do not wish to participate in the survey

As the Food Safety Modernization Act (FSMA) Rules become finalized many people are bringing their attention to Intentional Adulteration while they work towards identifying and implementing focused mitigation strategies. The goal of this survey is to understand Industry's view of one facet of Intentional Adulteration, Economically Motivated Adulteration (EMA). EMA is defined as "The intentional fraudulent modification of a finished product or ingredient **for economic gain.**"

Thank you for your participation!

1 Which category best describes your Industry Sector (check all that apply)

- | | |
|--|---|
| ☐ Alcoholic Beverages | ☐ Grain and Grain Products |
| ☐ Canned Goods | ☐ Meat |
| ☐ Coffee and Tea | ☐ Oils |
| ☐ Confection | ☐ Pet Foods |
| ☐ Dairy Products | ☐ Prepared Foods |
| ☐ Eggs | ☐ Produce |
| ☐ Fish and Seafood | ☐ Spice |
| ☐ Fruit Juices | ☐ Other <input type="text"/> |
| ☐ Frozen Foods | |

2 What title best fits your position in the company

R&D / Quality Assurance / Scientific

- ☐ Director of Research
- ☐ Technical Director
- ☐

- ☐ Quality Assurance/Quality Control Director/Manager/Supervisor
- ☐ Quality Assurance/Quality Control (other than Director/Manager/Supervisor)
- ☐ Technical Services Director
- ☐ Laboratory Director
- ☐ Product Developer
- ☐ Chemist
- ☐ Food Engineer
- ☐ Food Scientist/Technologist
- ☐ Microbiologist
- ☐ Other

Purchasing

- ☐ Purchasing/Procurement Director/Manager
- ☐ Purchasing Agent/Buyer
- ☐ Other Purchasing

Other

- ☐ Plant Manager
- ☐ Consultant
- ☐ Government
- ☐ Sales or Marketing Professional
- ☐ Other:

3 Which of the following examples constitutes Economically Motivated Adulteration

- ☐ Salmonella in Peanut Butter
- ☐ Dilution of Juice with High Fructose Corn Syrup without disclosing the addition on the label
- ☐ A disgruntled employee contaminating beef with an insecticide
- ☐ Terrorist Contaminating the US Milk Supply with Botulism Toxin

4 How vulnerable do you think your operation is to Economically Motivated Adulteration (EMA)?

Very Vulnerable Vulnerable Somewhat Vulnerable Somewhat Secure Secure Very Secure

☐ ☐ ☐ ☐ ☐ ☐

5 How high a priority is protection against EMA

Not a priority Very Low Priority Low Priority Average Priority High Priority Very High Priority

☐ ☐ ☐ ☐ ☐ ☐

6 When considering your top 5 Quality Assurance / Food Safety concerns where does Economically Motivated Adulteration rank?

7 With the the finalization of FSMA's rules has the way your company views EMA shifted?

☐ Yes
☐ No

7.1 How has the way your company views EMA shifted?

7. Is there a reason that your company's views have not shifted?

8 Has your organization implemented any type of focused mitigation strategies in response to FSMA?

☐ Yes

☐ No

8.1 Can you provide examples?

8.2 What stage is your company at in regards to food fraud mitigation

☐ Planning Meetings

☐ Identifying measures to take

☐ Planning Implementation

☐ Other

9 Do you perform EMA assessments in-house and/or do you use a 3rd party auditor.

☐ In House

☐ 3rd Party

☐ We don't perform EMA assessments

9.1 What do you see as the benefits of in house supplier verification?

9. What do you see as the benefits of 3rd Party supplier verification?
- 2
10. To what extent would an electronic tool that Assesses Ingredients for Vulnerability to EMA be useful to your company?
- Not At All Useful Somewhat Useful Useful Very Useful
- ☐ ☐ ☐ ☐
11. Do you consider some ingredients to be higher risk for EMA?
- ☐ Yes
- ☐ No
11. Please list the ingredients you perceive to be the most vulnerable:
- 1
12. Which of these factors do you consider when thinking about EMA? (select all factors you consider)
- ☐ Value of Ingredient
- ☐ Volume of Ingredient
- ☐ Scarcity / Surplus
- ☐ Availability of Identity Tests
- ☐ Frequency your company performs Identity Tests
- ☐ Presence of Governmental Regulations preventing fraud
- ☐ Presence of Industry Testing Databases
- ☐ How frequently the ingredient changes ownership before reaching your facility

- ☐ How frequently the ingredient is repackaged before reaching your facility
- ☐ Presence of Trade Associations
- ☐ Supplier Reliability
- ☐ Historic Occurrences of EMA in a particular ingredient
- ☐ The originating location/ country / region of the the ingredient
- ☐ Other

13 Please Rank these in order of Importance (1 being the highest importance)

Value of Ingredient

Volume of Ingredient

Scarcity/ Surplus

Availability of Identity Tests

Frequency your company performs Identity Tests

Presence of Governmental Regulations preventing Fraud

Presence of Industry Testing Databases

How frequently the ingredient changes ownership before reaching your facility

How frequently the ingredient is repackaged before reaching your facility

Presence of Trade Associations

Supplier Reliability

Historic Occurrences of EMA in a particular ingredient

The originating location / country / region of the ingredient

Other stated previously

13.1 Are there any specific countries or regions of the world that create increased concern

when purchasing ingredients for your company.

☐ Yes

☐ No

13.2 Which countries and/or regions raise more concern?

13.3 Is there a specific ingredient from this country/region that raises particular concern?

Survey Powered By [Qualtrics](#)

APPENDIX B- PERMISSION TO CONDUCT RESEARCH



February 15, 2016

Jennifer Kathryn Richards,
UTIA - RES-Food Science & Technology

Re: UTK IRB-15-02671-XP
Study Title: A Survey of Industry's Perception of Economically Motivated Adulteration

Dear Jennifer Kathryn Richards:

The UTK Institutional Review Board (IRB) reviewed your application for the above referenced project. It determined that your application is eligible for expedited review under 45 CFR 46.110(b)(1), Category 7. The IRB has reviewed these materials and determined that they do comply with proper consideration for the rights and welfare of human subjects and the regulatory requirements for the protection of human subjects. Therefore, this letter constitutes full approval by the IRB of your application (version 1.1) as submitted, including Cover Letter version 1.0 (submitted in round 3) and the consent form (version 1.0, submitted in round 3) that has been dated and stamped IRB approved. Approval of this study will be valid from 02/15/2016 to 02/14/2017.

In accord with 45 CFR 46.116(d), informed consent may be altered, with the cover statement used in lieu of an informed consent interview. The requirement to secure a signed consent form is waived under 45 CFR 46.117(c)(2). Willingness of the subject to participate will constitute adequate documentation of consent.

Please note that you must replace the informed consent form that is attached to the version of the survey you submitted with the approved informed consent form that was submitted in round 3.

In the event that subjects are to be recruited using solicitation materials, such as brochures, posters, web-based advertisements, etc., these materials must receive prior approval of the IRB. Any revisions in the approved application must also be submitted to and approved by the IRB prior to implementation. In addition, you are responsible for reporting any unanticipated serious adverse events or other problems involving risks to subjects or others in the manner required by the local IRB policy.

Finally, re-approval of your project is required by the IRB in accord with the conditions specified above. You may not continue the research study beyond the time or other limits specified unless you obtain prior written approval of the IRB.

Sincerely,

Colleen P. Gilrane, Ph.D.
Chair

Institutional Review Board | Office of Research & Engagement
1534 White Avenue Knoxville, TN 37996-1529
865-974-7697 865-974-7400 fax irb.utk.edu

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VITA

Lindsay Murphy was born in Columbus, to Michael and Colleen Murphy. She is the second of three children: Patrick and Matthew. She attended elementary school through middle school in Huntley School District in Illinois, then matriculated to Marian Central High School in Woodstock, IL, before moving to Memphis, TN and graduating from St. Benedict at Auburndale in Cordova, TN. After graduation she moved Knoxville, TN to study at The University of Tennessee where she was introduced to Food Science. Lindsay completed a study abroad program in Granada, Spain in order to improve her Spanish while exposing her to different cultures. She obtained a Bachelor's of Science degree from the University of Tennessee, Knoxville in May of 2014 in Food Science and Technology. She worked as an intern for the Grocery Manufacturers Association's Science and Education foundation in the summer of 2014, which then continued during the first year of her Masters program. She accepted a graduate research assistantship at the University of Tennessee, Knoxville in the Food Science program in *the Hands On: Real World Lessons for Middle School Classrooms* Lab in which she worked as an undergraduate. Lindsay graduated with a Masters of Science in Food Science and Technology in May 2016. She accepted a position with PepsiCo in Pulaski, TN and is starting after graduation.