Chapter 1

Supply Chain Complexity and Economically Motivated Adulteration

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Globalization of our food supply increases many types of risk, not the least of which is the risk of economically motivated adulteration (EMA) or food fraud (the intentional adulteration or misrepresentation of food for economic gain). Increasing complexity reduces the ability of both regulators and industry to effectively oversee food supply chains. A brief description of each of the main themes included in this chapter is given here.

- *Regulatory and supply chain control challenges and globalization:* this section will provide a brief background and examples of some of the challenges in overseeing increasingly globalized food supply chains.
- *Economically motivated adulteration and food fraud: definitions and scope:* this section will define EMA and food fraud, discuss what is currently known about the scope of the problem given the available data, and describe various methods of perpetrating EMA.
- *Drivers of EMA opportunity and incentive:* this section will discuss the factors that drive the opportunity for EMA and the incentive behind EMA.
- *Assessing the vulnerability of foods and ingredients to EMA:* EMA risk cannot be assessed and mitigated using traditional food safety control frameworks. This section will present the general framework for evaluating EMA vulnerability in foods and ingredients, and briefly discuss one guidance document created for use by industry in conducting food fraud vulnerability assessments.
- *Future trends: legislation and EMA mitigation efforts:* the development of risk mitigation methods for industry and government, as well as new regulations for EMA control, will continue to evolve over the coming years around the world. This section will focus on recent developments in US-based legislation and one UK government-commissioned report to highlight future trends.

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1.1 REGULATORY AND SUPPLY CHAIN CONTROL CHALLENGES AND GLOBALIZATION

Our food supply is becoming increasingly globalized. Imports of food and agricultural commodities in many developed countries are rising. The US Food and Drug Administration (FDA) reported increases of 10% per year in shipments of FDA-regulated foods between 2002 and 2009 (United States Food and Drug Administration, 2011). The percentage of volume of US food consumption attributed to imports rose from 11% in 1989 to almost 17% in 2009 (http://www.ers.usda.gov/topics/international-markets-trade/us-agricultural-trade/import-share-of-consumption.aspx). A 2010 FDA report projected that future growth in imports of regulated products would exceed growth of domestic products. The European Union (EU) is the top agricultural importer, by value (European Commission, 2013). Total agricultural imports into the EU increased an estimated 24% between 2000 and 2008 (von Witzke and Noleppa, 2010). Globalization of the food supply facilitates market growth and consolidation, gives populations in many countries a year-round supply of food products that cannot be grown domestically, and can help drive down production costs. It can also result in long, interconnected, multinode and complex supply chains, which can be challenging to oversee and regulate.

The United States has less direct regulatory oversight for imported food products than those that are domestically produced. Foreign facility inspections are more expensive than domestic inspections, and the FDA performs inspections of foreign food facilities at a far lower rate than domestic facilities (United States Food and Drug Administration, 2011). Globalization of the food supply has dramatically increased the distances that food products and ingredients travel, as well as the number of intermediate parties between primary production and the ultimate consumer ("farm to fork"). In 2005, a large recall was initiated in the United Kingdom as a result of contamination of chili powder with the industrial dye Sudan 1 (http://www.theguardian.com/society/2005/feb/23/food.foodanddrink1). The chili powder supply chain involved transactions among at least six different companies in India and the United Kingdom over a time period of more than two years (http://www.telegraph.co.uk/news/uknews/1484427/Tracking-down-the-rogue-powder.html). The chili powder was subsequently used in the production of Worcestershire sauce, which was then sold as an ingredient to at least 60 manufacturers and suppliers and incorporated into more than 600 finished food products. Fig. 1.1 shows a visual representation of the complexity and breadth of the reported supply chain for the recalled chili powder. In this example, various factors contributed to the loss of oversight of the supply chain and hindered trace-back and trace-forward investigations. These factors included the number of intermediate parties, the lack of transparency throughout the supply chain, the physical nature of the product (it was sold

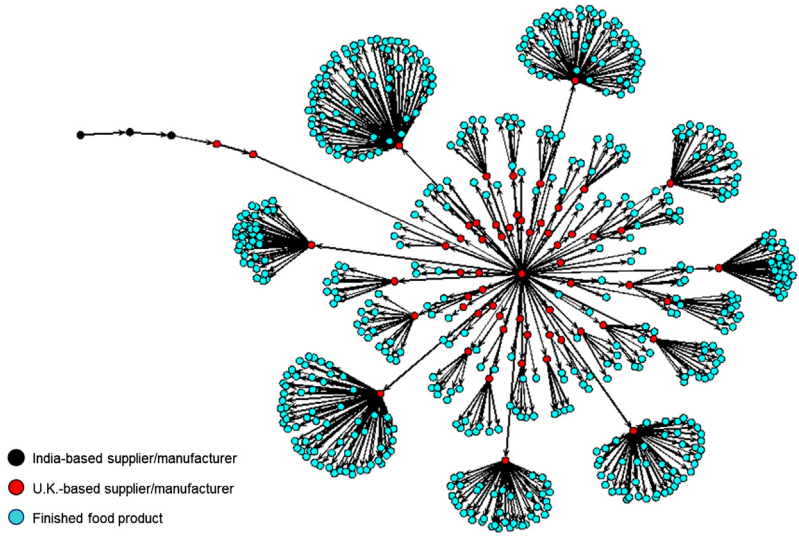

FIGURE 1.1 Visual representation of the reported supply chain for recalled chili powder. *Data sources: Food Standards Agency of the U.K. National Archives and* The Guardian.

in powdered form), and the amount of time that elapsed between production and ultimate retail sale. The recall of more than 600 finished food products cost the United Kingdom an estimated £100 million. In a separate example, the tragic 2008 incident of melamine contamination of dairy supplies in China, the resulting illnesses in hundreds of thousands of infants were confined to China. However, public health, laboratory, regulatory, and other government resources throughout the world were needed to respond to the incident, conduct product testing and recalls, and determine the risk of human exposure to melamine (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2799451/). Ultimately, food product recalls occurred in at least 47 countries.

Arguably, the increasingly complex nature of supply chains for food products increases the risk of contamination, both unintentional and intentional. It also increases the burden of ensuring authenticity along the supply chain. Routine laboratory testing of ingredients for quality assurance can be costly, and it is impractical to test food ingredients for a wide range of adulterants during each transaction along the supply chain. Therefore, one of the risks that increase when supply chain oversight and visibility are reduced is economically motivated adulteration or food fraud (Everstine et al., 2013). In a 2010 report, the FDA cited EMA as "perhaps the most serious challenge on the horizon" for the foods, drugs, and medical devices that the agency regulates (United States Food and Drug Administration, 2011). The 2013 horse meat adulteration incident in Europe prompted a UK review of the

systems that assure food integrity and outlined a number of recommendations to improve the deterrence, detection, and prevention of food fraud and food crime (HM Government, 2014). As noted in the report, "much less attention has been focused on food authenticity, food fraud and food crime" than on food safety, and there is a need to "protect consumers and honest businesses through an effective regulatory framework."

1.2 ECONOMICALLY MOTIVATED ADULTERATION AND FOOD FRAUD: DEFINITIONS AND SCOPE

FDA adopted the term "economically motivated adulteration" to refer to what is more commonly known as food fraud. The FDA proposed the following working definition of EMA: "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" (Lutter, 2009). This appears to limit the definition of EMA to incidents involving the addition or substitution of a substance. However, FDA's general definition of "adulteration" is more comprehensive and includes additional forms of misrepresentation of food. Per the US Federal Food Drug and Cosmetic Act, a food is deemed "adulterated" if it is contaminated with a potentially poisonous substance or otherwise may be "injurious to health"; if any valuable constituent has been omitted, substituted, added to increase bulk or weight, or if "damage or inferiority has been concealed in any manner"; and if it was previously denied admission into the United States (21 U.S.C.). Furthermore, food is deemed "misbranded" if it bears a false or misleading label or container, is offered for sale under another name, and does not conform to the standard of identity that it represents. Using the example of the sale of a product labeled as olive oil that actually consists of soybean oil, this form of fraud could either be viewed as adulteration of olive oil with soybean oil, or misbranding of soybean oil as olive oil. A 1966 review of legal cases of "economic adulteration" noted the overlap between the two definitions, and stated that the "statutory provisions [related to economic adulteration] in the act are general, vague, complex, and abstruse." The author reviewed multiple cases in which the courts issued "diverse and conflicting opinions" and concluded that there was a "patent and immediate need for a revised economic adulteration statute" (Forte, 1966).

The consequence of EMA and/or food fraud is that the purchaser does not have accurate information about the true identity of the product. Although the FDA definition of EMA appears more limited than the definition of food fraud, the agency ultimately has regulatory status over all forms of food misrepresentation. Furthermore, in the event of an EMA or food fraud incident, a determination of the specifics of the infraction and the type of adulteration or misbranding is typically decided by the courts. Therefore,

a clear distinction between the terms "food fraud" and "EMA" is both challenging and impractical. The Food Standards Agency of the United Kingdom and the Grocery Manufacturers Association in the United States each define food fraud as "deliberately placing food on the market, for financial gain, with the intention of deceiving the consumer" (HM Government, 2014; Grocery Manufacturers Association and Kearney, 2010). The "consumer" may be a food company purchasing from a supplier, another intermediary party along a food supply chain, or the ultimate purchaser of the product at retail. Herein, the terms "EMA" and "food fraud" will be used interchangeably to refer to the intentional adulteration or misrepresentation of foods or food ingredients for economic gain.

EMA perpetrators do not intend to cause illnesses or deaths in consumers. Health effects in consumers may result in detection of the adulteration and subsequent investigation, while the intent of the act is deception and financial gain. However, errors and misjudgments by EMA perpetrators have occurred. Concerns about fraudulent food have been increasing over the past decade, particularly in response to three incidents with broad health and economic consequences. In 2007, pet foods were recalled in the United States and other countries following melamine contamination of Chinese-produced wheat gluten used as an ingredient (http://www.ncbi.nlm.nih.gov/pubmed/18689873). Although no human illnesses were known to occur, thousands of pets in the United States became ill or died and melamine-contaminated animal feed entered the human food supply chain. Following that incident, in 2008, melamine contamination again caused widespread recalls, this time resulting from contamination of dairy supplies in China. This incident resulted in hundreds of thousands of illnesses and the deaths of at least six infants who consumed formula produced with adulterated milk (http://www.sciencemag.org/content/322/5906/1310). Most recently, in 2013, horse meat contamination of ground beef in Europe resulted in the recall of 50,000 tons of meat and affected more than 20 brands. Although no human illnesses are known to have resulted from consumption of horse meat, government health authorities expended substantial resources conducting a risk assessment for the presence of drug residues in horse meat and the potential risk for consumers.

EMA happens in a variety of ways. Research at the Food Protection and Defense Institute at the University of Minnesota defined the following methods of EMA (http://www.foodfraudresources.com/ema-incidents):

Substitution: complete replacement of a food product/ingredient with an alternate food product/ingredient. One example of substitution is the intentional misrepresentation of fish fillets as an alternate and more expensive species.

Dilution: partial replacement of a food product/ingredient with an alternate food product/ingredient. This includes the addition of an alternate

ingredient to increase the overall weight or volume. Examples include the dilution of honey with other sugar syrups and the dilution of extra virgin olive oil with lower quality or alternate oils.

Artificial Enhancement: the addition of an unapproved chemical additive to artificially enhance the quality of a product. These types of additives can include industrial dyes, fungicides, artificial ripening agents, etc. One example is the addition of Sudan dyes to chili powder to enhance the bright red color of the spice.

Mislabeling: intentional misrepresentation with respect to harvesting or processing techniques or other quality attributes. Examples include false labeling of organic and/or cage-free eggs and misrepresentation of halal or kosher processing of meats.

Transshipment/Origin Masking: misrepresentation of the geographic origin of a product. This can happen through false declaration of customs documents or mislabeling at retail. The shipment of Chinese-origin honey through intermediate countries and subsequent false labeling upon entry into the United States is one example of transshipment; this allows perpetrators to avoid antidumping duties placed on Chinese honey by the US International Trade Commission.

Counterfeit: fraudulent labeling of a product by an unauthorized party as a brand-name product. Examples include the fraudulent production, labeling and sale of brand-name infant formula.

Theft and Resale: theft of a food product and resale into commerce through unapproved channels. Theft of products can occur at retail or prior to retail ("cargo theft"). One example is the theft of infant formula from grocery stores and subsequent resale to small retail establishments or customers.

Intentional Distribution of Contaminated Product: the intentional sale of a product despite knowledge of foodborne contamination. One example is the falsification of documents and subsequent sale of *Salmonella*-contaminated peanut products that resulted in hundreds of illnesses in the United States in 2008.

EMA is a concern for many reasons. From a public health and food protection perspective, past incidents have illustrated that unintended health consequences can result and they can be catastrophic. EMA results in a loss of supply chain transparency and control, and therefore may hinder traceability efforts. Food safety programs such as Hazard Analysis and Critical Control Points (HACCP) are based on knowledge of the true identity of a food product. Therefore, EMA compromises food safety efforts and regulatory oversight. EMA can also have a negative effect on markets through evasion of antidumping duties and creation of unfair competition. Finally, EMA reduces consumers' ability to make informed food choices.

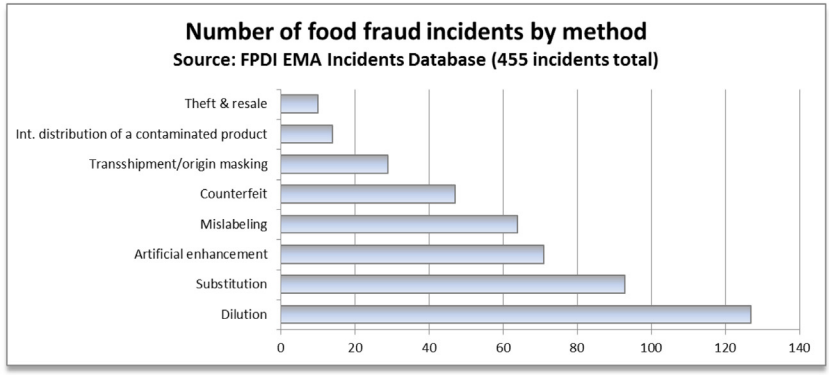

FIGURE 1.2 The number of EMA incidents by method of adulteration. *Source: FPDI EMA Incidents Database, November 2015 (http://www.foodshield.org).*

We cannot reliably estimate the true scope of EMA in foods since most incidents are likely undetected or unreported. A 2014 report based on research conducted in the United Kingdom estimated that only between 3% and 4% of fraud is detected (Gee et al., 2014). There are various databases that catalogue records of food fraud, including the FPDI EMA Incidents Database (https://www.foodshield.org/index.cfm/discover-tools-links/tools/), the United States Pharmacopeia (USP) Food Fraud Database (http://www.foodfraud.org/), the Rapid Alert System for Food and Feed (RASFF) portal (http://ec.europa.eu/food/safety/rasff/index_en.htm), and the Food Standards Agency Food Fraud Database (https://www.food.gov.uk/enforcement/enforcework/foodfraud/foodfrauddatabase). Information from the first three databases is currently either publicly available or available upon request. Each database uses different criteria for compiling records, and each provides a unique perspective on the true incidence of EMA. There is general agreement about the food product categories that appear, from available data, to be the most prone to fraud. These categories include oils, spices, milk, fruit juices, honey, seafood, alcoholic beverages, and grains (Johnson, 2014).

The FPDI EMA Incidents Database, a US-based repository, contains more than 400 records of publicly documented EMA incidents. The incidents catalogued in the database are compiled through manual searches of media sources, scientific journals, and publicly available data from regulatory agencies. The database is intended to provide contextual information about the EMA incidents, such as food product category, location of production and distribution, the number of illnesses and deaths, and the method of adulteration. Fig. 1.2 shows the number of incidents in the database attributed to each EMA method. Dilution and substitution account for about half of the total incidents and artificial enhancement accounts for about 16% of incidents.

1.3 DRIVERS OF EMA OPPORTUNITY AND INCENTIVE

There are strong economic incentives behind food fraud. In the 1980s, executives of Beech-Nut Corporation were found guilty of violating US federal laws by selling adulterated and misbranded apple juice (Buder, 1988). The company purchased fraudulent apple juice concentrate at 20–25% the price of competing products, enabling the company to maintain profitability. The addition of melamine to milk in China was an efficient and inexpensive means of increasing the apparent protein content of the milk. Melamine contains 67% nitrogen while protein contains about 16% nitrogen, and milk contains about 3.5% protein. Therefore, the addition of small quantities of inexpensive scrap melamine could substantially increase the apparent protein content of milk, and potentially allow dilution with water. This enabled producers of substandard milk that did not meet protein content requirements to continue to sell their supplies. Finally, using estimated 2013 costs of €4.00/kg for beef and €1.00/kg for horse meat, substitution of only 5% horse meat into ground beef would have saved €15,000.00 per 100,000 kg of beef.

Although the underlying motivation is economic, there are many factors that drive the incentive and the opportunity for EMA (http://www.ncbi.nlm.nih.gov/pubmed/23575142). The incentive may be driven by business or market pressures, price fluctuations, increases or decreases in rates of duty, and changes in supply or demand of ingredients. The opportunity to perpetrate EMA can be driven by many factors, including

- supply chain characteristics and oversight (e.g., the degree of vertical integration or decentralization, the number of intermediate parties involved, and the number and type of controls in place along the supply chain);
- the availability of effective analytical methods for testing food ingredients and the cost of these methods;
- the existence of federal standards of identity or other industry-wide standards;
- the prevalence of use of third-party or shared auditing programs; and
- the existence and degree of active involvement of industry trade organizations.

Given the intentional nature of EMA and the various factors that drive the incentive and opportunity for fraud, risk assessment strategies tailored toward unintentional foodborne contamination will not lead to effective risk management programs for EMA. The general consensus in recent years is that regulatory agencies and food companies should conduct EMA vulnerability assessments for food products, in order to prioritize resource allocation to those products most vulnerable to fraud.

1.4 ASSESSING THE VULNERABILITY OF FOODS AND INGREDIENTS TO EMA

EMA presents a different set of challenges from those involved in preventing either unintentional foodborne contamination or terrorism through intentional contamination of food supplies. With both unintentional foodborne contamination and terrorism, the identification of consumer illnesses or deaths prompts an outbreak investigation which leads to the identification of the contaminated food product. Recovery efforts and implementation of future preventive controls efforts may be put in place following the event. The food safety model, in particular, is based on detection of an expected set of contaminants. HACCP and other food safety programs, as well as public health disease surveillance systems, are typically built around well-characterized risks and robust sampling data.

The risk of intentional adulteration of food supplies for ideological reasons (terrorism, political protest, etc.) is usually addressed through facility-level vulnerability assessments, food sector vulnerability assessments, and the development of agent detection methods. Risk assessment for intentional adulteration usually includes an analysis of the most likely threat agents. The risk of intentional adulteration of the food supply is considered to be very low, but could cause very serious consequences.

In contrast to unintentional foodborne contamination and ideologically motivated intentional contamination, EMA involves perpetrators who are intent on evading detection (and, therefore, avoiding immediate health effects). They also usually have knowledge of the existing food safety structure. The risk of EMA in the food supply is much higher than that of intentional adulteration (based on the available data we have on each), but there are usually no immediate health consequences. Due to the intentional nature of EMA, the challenges with predicting human behavior, the use of a variety of adulterants, the potential for the introduction of unexpected adulterants, and a lack of available data on the true scope of the problem, the development of traditional risk assessment methods for EMA is not feasible. However, using what is known about the incentive and opportunity drivers of EMA, as well as additional factors, we can build methods for evaluating the vulnerability of food products and ingredients to EMA. This will allow regulatory agencies and food companies to include a consideration of fraud vulnerability into their existing food protection strategies, and devote additional resources to those products and ingredients determined to be the most vulnerable.

The first publicly available guidance for evaluating food fraud vulnerabilities was published in the *Third Supplement to the Food Chemicals Codex 9* by the United States Pharmacopeial Convention (USP) (United States Pharmacopeia, 2014). This guidance document describes a holistic strategy for qualitatively

evaluating the vulnerability of food ingredients to fraud. It is intended for use by the food industry in evaluating their ingredient supply chains. The USP guidance document advocates an evaluation of both "controllable" factors and "uncontrollable" factors that contribute to food fraud vulnerability. Controllable factors include supply chain, audit strategy, supplier relationship, history of supplier quality and safety issues, testing frequency, and susceptibility of quality assurance methods and specifications. Uncontrollable factors include fraud history and economic anomalies. "Geopolitical considerations" is the final contributing factor, which may be controllable if there are options for choosing the geographic source of an ingredient.

Application of this general framework on a broader scale using tailored sources of information and data would allow the development of regulatory agency-level EMA vulnerability assessments for the products they oversee. The results of these vulnerability assessments could then be incorporated into existing agency-level frameworks for evaluating risk and allocating regulatory resources. Academic and nongovernmental institutions are ideally positioned to bring together multidisciplinary teams of researchers to synthesize data available from a variety of sources and develop quantitative methods for evaluating each of the contributing factors to EMA vulnerability.

1.5 FUTURE TRENDS: LEGISLATION AND EMA MITIGATION EFFORTS

As a result of multiple large-scale incidents of EMA over the past decade, countries around the world have promised to increase EMA protections in the food supply. The development of risk mitigation tools and methods for both industry and government will continue to evolve over the coming years. This section will highlight, in particular, recent developments in legislation in the United States and recent recommendations to the government in the United Kingdom. These two examples demonstrate the reluctance by government agencies to impose strict EMA regulations on industry, but also the acknowledged need for innovative approaches to risk assessment and information sharing.

The US FDA Food Safety Modernization Act (FSMA) was signed into law in 2011 and was intended to be the most substantial improvement to food safety laws in the United States in 70 years (http://www.fda.gov/Food/GuidanceRegulation/FSMA/). Since passage, the FDA has released two rules that discuss or address EMA in foods for human consumption. Although the risk of intentional adulteration has typically been addressed through vulnerability assessments and corresponding mitigation strategies, the agency concluded that intentional adulteration for economic gain would be better addressed as part of food safety plans (hazard analysis and preventive controls). As stated in the proposed rule "Focused Mitigation Strategies to

Protect Food Against Intentional Adulteration" (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628.htm), "[t]he nature of economically motivated adulteration makes it difficult to identify all relevant factors to be considered in a vulnerability assessment to predict when novel events of economic adulteration are expected to occur." In September 2015, the FDA released the final rule "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (hereafter, the "FSMA PC rule") (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm). The agency included EMA mitigation efforts as part of a facility's food safety plan, indicating that EMA-associated adulterants should be included in hazard analysis, preventive controls, and supply chain programs. In addition, the agency indicated that the focus should be on those adulterants with "the potential to cause illness or injury." EMA that only affects the quality of a product, but is not a food safety hazard, was cited as outside the scope of the rule.

Following the horsemeat adulteration incident in early 2013 in Europe, the UK government requested a review of weaknesses in food supply networks and recommendations for improving the integrity of the food supply. The final report, "Elliott Review into the Integrity and Assurance of Food Supply Networks," was released in July 2014 and contained recommendations for both industry and government. Among others, these recommendations included:

- "Work with industry to ensure that opportunities for food fraud, food crime, and active mitigation are included in company risk registers"
- "Encourage industry to conduct sampling, testing and supervision of food supplies at all stages of the food supply chain"
- "Work with the industry to help it establish its own 'safe haven' to collect, collate, analyze and disseminate information and intelligence"
- "Facilitate work to standardize the approaches used by the laboratory community testing for food authenticity"
- "Work in partnership with Public Health England and local authorities with their own laboratories to consider appropriate options for an integrated shared scientific service around food standards"
- "Encourage third party accreditation bodies undertaking food sampling to incorporate surveillance sampling in unannounced audits to a sampling regime set by the standard holder" and
- "Work with industry and regulators to introduce anti-fraud auditing measures."

Most notably, the report cited the importance of the partnership among government, regulators, and industry for addressing the problem of food fraud.

The solution to the problem of EMA and food fraud must be largely industry-driven, since the food industry has primary responsibility for supply

chain control and oversight. The Elliott Review recommended limited additional food fraud regulations be placed on the food industry; similarly, the EMA provisions of the FSMA PC rule are fairly narrow in scope. However, the Elliott Review also laid out clear recommendations for how government and other organizations could best facilitate the prevention of food fraud in collaboration with industry. Recently in the United Kingdom, progress has been made toward collaborative food fraud prevention efforts. Since release of the Elliott Review, a Food Crime Unit was formed in the United Kingdom, and the BRC Global Standard for Food Safety Issue 7 was released, which included updates for minimizing fraud risk. The Elliott Review also noted that one of the most important aspects of collaboration would be the creation of a "safe haven" or protected environment for information sharing between industry and government. Compilation and analysis of anonymized industry and regulatory intelligence could be a powerful means of identifying fraudulent ingredients before they arrive at retail. There would be significant legal and cultural hurdles to overcome to implement this type of information sharing, especially in the United States. However, an integrated food protection system that proactively reduces the risk of EMA will almost certainly require it.

1.6 SOURCES FOR FURTHER INFORMATION

The United States Pharmacopeia (USP) Food Fraud Database (www.foodfraud.org) catalogs thousands of records of food fraud. The FPDI EMA Incidents database (www.foodshield.org) provides contextual information about hundreds of EMA incidents. A guidance document for conducting food fraud vulnerability assessments was published by USP in the *Third Supplement to Food Chemicals Codex 9* (http://www.usp.org/food-ingredients/food-chemicals-codex) and is also available for download at www.foodfraud.org. SSAFE provides a downloadable Excel document for conducting a food fraud vulnerability assessment at http://www.ssafe-food.org/our-projects/. Various private companies and industry groups are also developing commercial products tailored at reducing the risk of food fraud to companies.

The Global Food Safety Initiative (GFSI) released a position paper on mitigating the risk of food fraud (http://www.mygfsi.com/news-resources/news/295-gfsi-position-paper-on-mitigating-the-public-health-risk-of-food-fraud.html). GFSI also recently added new requirements for food organizations to have in place a food fraud vulnerability assessment procedure. More information about the BRC Global Standard for Food Safety Issue 7, a GFSI-approved standard which includes food fraud prevention measures, can be found here: http://www.brcglobalstandards.com/Manufacturers/Food/FoodIssue7.aspx#.Vgrov5dL1Ng. Finally, the Elliott review (available

at https://www.gov.uk/government/publications/elliott-review-into-the-integrity-and-assurance-of-food-supply-networks-final-report) describes an ambitious and well-planned national framework for preventing food fraud.

A list of additional selected publications generally addressing EMA and food fraud is given below:

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