

## General Interest

# Economically Motivated Adulteration (EMA) of Food: Common Characteristics of EMA Incidents

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## ABSTRACT

Economically motivated adulteration (EMA) of food, also known as food fraud, is the intentional adulteration of food for financial advantage. A common form of EMA, undeclared substitution with alternative ingredients, is usually a health concern because of allergen labeling requirements. As demonstrated by the nearly 300,000 illnesses in China from melamine adulteration of infant formula, EMA also has the potential to result in serious public health consequences. Furthermore, EMA incidents reveal gaps in quality assurance testing methodologies that could be exploited for intentional harm. In contrast to foodborne disease outbreaks, EMA incidents present a particular challenge to the food industry and regulators because they are deliberate acts that are intended to evade detection. Large-scale EMA incidents have been described in the scientific literature, but smaller incidents have been documented only in media sources. We reviewed journal articles and media reports of EMA since 1980. We identified 137 unique incidents in 11 food categories: fish and seafood (24 incidents), dairy products (15), fruit juices (12), oils and fats (12), grain products (11), honey and other natural sweeteners (10), spices and extracts (8), wine and other alcoholic beverages (7), infant formula (5), plant-based proteins (5), and other food products (28). We identified common characteristics among the incidents that may help us better evaluate and reduce the risk of EMA. These characteristics reflect the ways in which existing regulatory systems or testing methodologies were inadequate for detecting EMA and how novel detection methods and other deterrence strategies can be deployed. Prevention and detection of EMA cannot depend on traditional food safety strategies. Comprehensive food protection, as outlined by the Food Safety Modernization Act, will require innovative methods for detecting EMA and for targeting crucial resources toward the riskiest food products.

The nearly 300,000 illnesses and six known infant deaths in China in 2008 represent the most striking recent example of the potential for harm caused by economically motivated adulteration (EMA) of a food product (82), but the intentional adulteration of food for financial advantage has occurred throughout history (84, 102, 182). EMA of food products, also referred to as food fraud (153) or economic adulteration (173), may not necessarily be harmful to consumers. The adulterants are typically benign and used to replace more expensive ingredients or extend a product for extra profit (57, 84). Although the motivations are economic in nature, the adulteration may result in serious public health consequences when the adulterant is toxic or allergenic.

The U.S. Federal Food, Drug, and Cosmetic Act (164) declares a food adulterated “if any valuable constituent has been in whole or in part omitted . . . or if any substance has been substituted wholly or in part . . . or if damage or inferiority has been concealed . . . or if any substance has been added thereto . . . 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.” The U.S. Federal Meat

Inspection Act, which grants authority to the U.S. Department of Agriculture, contains a similar definition of adulteration (160). The U.S. Food and Drug Administration (FDA) working definition of EMA is the “fraudulent, intentional substitution or addition of a substance for the purpose of increasing the apparent value of the product or reducing the cost of its production” (166). The FDA definition of EMA encompasses food products and products such as dietary supplements, tobacco, cosmetics, pharmaceuticals, and medical devices and equipment. The more general term “food fraud” encompasses EMA and is intended to explicitly include economically motivated misbranding, theft, diversion, simulation, smuggling, and counterfeiting, which may be classified as adulteration under the Food, Drug, and Cosmetic Act but may not involve material addition or substitution (153). For the purposes of the present article, we focus on only food products and define EMA as knowingly selling a product that is not up to standards to gain an economic advantage. This adulteration includes addition of a fraudulent ingredient, dilution, substitution, simulation, and mislabeling.

EMA incidents present a particular challenge to the food industry, regulators, and consumers. Food safety

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incidents are unintentional occurrences with unintentional harm, whereas food defense incidents are intentional acts with intentional harm. EMA incidents are intentional acts with unintentional harm and are designed specifically not to be detected. For this reason, they typically involve unconventional adulterants or dilution with cheaper, benign food ingredients (122). Regulatory food safety systems and quality assurance (QA) testing methodologies are not generally designed to detect novel adulterants or low levels of dilution with inauthentic substances. Regulatory agencies such as the FDA operate with limited resources and therefore must target those resources to the most serious threats to the food system (168). Because most EMA incidents involve indirect or technical health risks (153), EMA has generally been viewed as less important than food safety incidents or incidents of bioterrorism. However, recent large-scale incidents have raised the concern about EMA incidents among regulatory agencies. The FDA traditionally has not distinguished among different motives for adulteration because it can conduct an investigation whenever it detects any form of adulteration (173). Regardless of whether the adulterant is a public health threat, EMA incidents reveal vulnerabilities in our food production and distribution system that could potentially be exploited for intentional harm.

Food safety incidents for which a food vehicle is identified are generally well described in the scientific literature. Food defense incidents are rare and also tend to be well documented because they are criminal acts and usually result in serious illnesses (59, 156). Some large-scale EMA incidents have been well documented in the scientific literature, but many other incidents have been documented only in media sources if at all. Because of this lack of consistent documentation and because we know about only those EMA incidents that are discovered, the true scope of EMA throughout history is unknown. Undoubtedly, many undetected incidents of EMA have occurred. Although media coverage of EMA incidents is important for illustrating the scope of EMA incidents, media reports often are inadequate in terms of providing useful details about the regulatory context and applicable QA methods surrounding a specific incident.

The purpose of this article is to provide an overview of documented EMA incidents in various categories of food products, to describe the common characteristics in these incidents that allowed the adulteration to happen or allowed detection of the adulteration, and to discuss these characteristics in the context of our increasingly globalized food supply and the emerging requirements of the 2011 FDA Food Safety Modernization Act. We reviewed journal articles and media reports of EMA incidents since 1980, focusing mainly on incidents that impacted U.S. consumers. Incidents were defined as documented, isolated occurrences of EMA within a defined time frame with a distinct group of perpetrators. Incidents that were difficult to isolate to a specific time frame or group of perpetrators or that had characteristics that were common among multiple perpetrators (e.g., melamine adulteration of dairy products in China) were defined as a single incident. To assist with searches, a

list of potential food categories was developed through expert elicitation and a review of media articles generally related to "economic adulteration," "food fraud," and "counterfeit food." Searches specific to each food category and adulterant were then performed in PubMed, LexisNexis, Google, the U.S. FDA Web site (169), the European Union (EU) Rapid Alert System for Food and Feed (RASFF) portal (67), the Food and Agriculture Organization of the United Nations Web site (74), and relevant industry trade group Web sites. Search terms differed by food product but generally included the name of the product along with a term such as "adulteration," "adulterate," "fake," "counterfeit," or "fraud" or the name of the adulterant. Reference lists from journal articles were additional sources of information. Food categories were reported separately when they included five or more incidents; the remaining incidents were grouped into an "other food products" category. Herein, we describe one or more incidents in each category, including the following: how the incident was detected, the ways in which any QA or regulatory processes in place at the time of the incident were evaded, and any regulatory and/or industry responses to the incident. We also identify common characteristics among these EMA incidents and discuss their relevance to detecting and preventing future EMA incidents.

## EMA INCIDENTS

Our literature search identified 137 distinct EMA incidents that could be sufficiently documented and grouped into 11 food product categories: fish and seafood, dairy products, fruit juices, oils and fats, grain products, honey and other natural sweeteners, spices and extracts, wine and other alcoholic beverages, infant formula, plant-based proteins, and other. The number of EMA incidents in each category, the number of incidents with the adulteration originating in the United States, and examples of adulterants are given in Table 1. Each of the food product categories is discussed in more detail below.

**Fish and seafood.** In a 2008 University of Guelph study, 96 samples of fish were collected from retail outlets in New York City and Toronto and compared with two global fish DNA databases. Twenty-four (26%) of the 91 samples with a barcode match in the databases were species other than those indicated on the retail label (184). One of the authors of the study conducted a larger survey in 2008 and 2009: 500 retail fish samples were compared with the Barcode of Life DNA database at the University of Guelph (94). The samples were collected from supermarkets, fish markets, and restaurants, and about 25% of the samples were misidentified or mislabeled (147). All the substituted fish were species of lower market value than the species for which they were substituted.

Multiple seafood fraud surveys have been conducted over the years with similar results. The National Seafood Inspection Laboratory found that 37% of fish samples collected over a 9-year period were mislabeled (155); the mislabeling of red snapper in the United States has been a widespread and ongoing problem (90, 91, 113); the



TABLE 1. Total number of EMA incidents, number of incidents with adulteration originating in the United States, and examples of adulterants in 11 food categories

Food category	Total no. of incidents	No. (%) of U.S.-based incidents	Examples of adulterants
Fish and seafood	24	22 (92)	Species substitution, overglazing
Dairy products	15	2 (13)	Melamine, protein additives, vegetable fats
Fruit juices	12	7 (58)	Water, beet sugar, artificial flavorings
Oils and fats	12	0	Alternative fat sources
Grain products	11	1 (9)	Organic label fraud, bulking agents
Honey and other natural sweeteners	10	4 (40)	Chloramphenicol, high-fructose corn syrup
Spices and extracts	8	0	Various bulking agents, dyes
Wine and other alcoholic beverages	7	0	Methanol, diethylene glycol
Infant formula	5	3 (60)	Counterfeit or stolen formula, substandard nutritional profiles
Plant-based proteins	5	0	Melamine, urea
Other food products	28	8 (29)	Protein powders in meat products, clenbuterol in pork, organic fraud in eggs and produce
Total	137	47 (34)	

Consumers Union found about one-third of samples were misidentified (54); inexpensive domestic fish eggs were substituted for imported Russian beluga caviar in Maryland (79, 83); sales of fake grouper have been pervasive in Florida (36, 142); and 10 to 15% of "wild-caught" salmon, sea bass, and sea bream sampled in the United Kingdom were actually farmed (69). Species adulteration, species substitution, or species swapping can occur at any point along the supply chain. The authors of one literature review concluded that "mislabeling" most often occurs at the distributor or the point of retail sale to increase profits and that the people responsible for catching or harvesting the fish do not typically benefit from the extra profit earned (97).

Species identification of fish products sold at retail is difficult because the morphological features that are typically used to identify species have been removed during processing (184). DNA barcoding is a promising method of species identification because it is time efficient, does not require a large sample, has a straightforward protocol, and is reproducible and standardized (184, 190). The Barcode of Life database uses short genetic sequences from a standard part of the genome to quickly create a "barcode" that can be matched to an existing and accessible database of almost 8,000 species of fish (94).

Other forms of seafood EMA include artificially increasing the weight of the product, misrepresenting the country of origin, and using illegal chemicals in production. Methods to increase weight include adding excess water to frozen product (overglazing), soaking products such as scallops in sodium tripolyphosphate so that they retain water, and overbreeding (e.g., frozen breaded shrimp must be at least 50% shrimp by law) (36, 55).

In a 2009 report, the U.S. Government Accountability Office (GAO) cited problems with collaboration among the three federal agencies primarily responsible for detecting and preventing seafood fraud in the United States (172). One problem was the fact that each of the three agencies has its own laboratory capabilities for species identification of seafood samples, but the agencies use different testing methodologies and do not share laboratory results. The

report recommended the development of collaborative goals for sharing resources for fraud detection and creating a federal agency-wide library of seafood species standards.

**Dairy products.** In 2008, China had a problem with infant formula when close to 300,000 children became ill and 6 children died because 22 Chinese food companies sold milk products, including baby formula, containing melamine (93). The adulteration was detected after an unusually high number of infants became ill and developed kidney stones (20, 48). The two main tests to determine the protein content of dairy products at the time both relied on determining total nitrogen content as a proxy (121). Because the tests did not distinguish between nitrogen from protein sources and nitrogen from nonprotein sources, the addition of nitrogen-rich melamine artificially inflated protein test results (82). This enabled dairy producers to dilute their milk but maintain admissible protein-level readings. The adulteration was well organized; reportedly there was a protocol for creating a solution containing melamine that was used by multiple dairy companies (187). There was no established QA mechanism for the detection of melamine in dairy products at that time because it was not an expected additive. The addition of melamine to dairy products in China was widespread and, reportedly, dated back at least 3 years (49, 109, 157). Melamine was detected in many types of products, including powdered infant formula, powdered milk products, liquid milk, yogurt, frozen dairy products, and snack foods, with a wide range of adulterant concentrations (82). The extent of the product recalls illustrated the long and complicated supply chains that existed for products made with liquid milk, the original point of adulteration. At least 47 countries received melamine-contaminated products, and many responded by banning or recalling melamine-containing food products and establishing interim limits for melamine in food. The 22 Chinese dairy companies that were found to have used tainted milk powder were ordered to recall and destroy those stocks (134).

In the report from an expert meeting convened in December 2008, the World Health Organization recom-



mended the development of “more specific, rapid and low-cost methods for protein analysis that do not include non-protein nitrogen” (185). The discussion surrounding the creation and use of protein-specific tests for food products is not a new one, but the use of nitrogen-based tests for protein remains widespread (121, 152). In 2010, China lowered the required protein level for raw milk from 2.95 to 2.8% to try and reduce the incentive for adding melamine to milk to boost protein readings (135). However, since the 2008 recalls, dairy products containing melamine have repeatedly been discovered for sale in China (134, 136, 154, 183).

In 2010, the Chinese government proposed increased control over the production of melamine and increased melamine testing by dairies and baby formula producers (138, 188). However, the adulteration of milk with substances intended to artificially inflate protein readings has already proven to be an ongoing problem. In 2009, Chinese dairy products were found to contain hydrolyzed leather protein, which is derived from animal skin and may be processed with harmful chemicals (28).

**Fruit juices.** In 1978, the Beech-Nut Nutrition Corp. became aware that the apple juice concentrate they were buying from a supplier for 20 to 25% below market price was likely adulterated with various sugars, artificial colors, and flavorings and contained little if any apple juice (53, 103, 119). However, the company continued to buy the product and market it as “100% apple juice.” At the time, no common conclusive tests existed to indicate the purity of apple juice (119, 181). Beech-Nut chemists devised new tests to detect adulterants and, based on this testing, became suspicious of their major supplier of apple juice concentrate. Because of suspicion of widespread adulteration throughout the market, a trade association was also investigating counterfeit apple juice sales (120, 158). In June 1982, an investigator tracked a shipment of counterfeit apple juice concentrate from a supplier to the Beech-Nut plant and informed the company of the findings (118, 158). In July 1982, state and federal investigators informed Beech-Nut that they had tested apple juice at retail sale and found it to be adulterated. Beech-Nut agreed to a recall of apple juice in October 1982 but continued to add the implicated concentrate to mixed juices and other products after the recall (120, 158). In November 1986, Beech-Nut and its suppliers were indicted on charges of conspiring to sell adulterated and misbranded apple juice (103). Beech-Nut eventually pleaded guilty to 215 counts and paid a \$2 million fine, and two executives were found guilty of violating federal laws (53).

The sharp increase in the demand for pomegranate juice in recent years, due to major investments in researching and advertising health claims (41), has made this juice an attractive target for adulteration. In 2008, Pom Wonderful, LLC won a case against a smaller beverage company, Purely Juice, Inc., for false advertising (85, 162). Purely Juice had advertised their product as “100% pomegranate juice” when it contained only small amounts of juice along with high-fructose corn syrup. Purely Juice reportedly sourced pomegranate juice concentrate from suppliers in

the Middle East at prices that were far below the market rate for pure juice.

Pure fruit juice is relatively expensive to produce, making the prospect of even partial dilution an attractive one because producers can gain a distinct market advantage. According to the FDA, the most common forms of juice adulteration are addition of some form of sugar and water, addition of pulp wash solids, substitution of a less expensive juice, addition of unapproved preservatives, and labeling of reconstituted juice as fresh squeezed (167). There are many other documented instances of juice companies “extending” or otherwise adulterating juice (45, 146). In a 1995 report, the GAO estimated the rate of adulteration of orange juice in the United States as ranging from 1 to 20% (171).

**Oils and fats.** In 1992, the FDA received a report claiming that a vegetable oil distributor in Ohio was blending canola oil into oil labeled as olive oil (86). A sample analyzed by the FDA contained 42 to 68% canola oil. The FDA collected evidence of widespread EMA by the distributor, including adulteration of various grades of olive oil with less expensive oils. They also found evidence that the company adulterated the products that were least likely to be tested by industry trade group or grocery chain product testing programs. Reports of internationally produced adulterated or counterfeit olive oil are common. Lower grades of olive oil (nonvirgin or olive pomace oil) have been sold as extra virgin olive oil, and other types of oils have been mixed in with olive oil (e.g., canola, hazelnut, sunflower, or colza oil) (9, 19, 81, 159). Low-grade olive oils also have been imported from other countries and repackaged as locally produced (22). In a particularly tragic case in 1981, denatured oil that was intended for industrial use was sold door-to-door as olive oil in Spain and resulted in almost 20,000 illnesses and more than 300 deaths (137). The causative agent was not definitively named, but at least two candidate etiologic agents were identified (44, 89).

Olive oil is an attractive target for EMA because of its high demand and potential profit margin. According to the International Olive Oil Council (IOOC), extra virgin olive oil must be extracted only through physical means and have a strictly defined amount of free acidity (95). Trade associations such as the North American Olive Oil Association (NAOOA) have argued that the opportunity for fraud has existed because the United States did not have strict quality standards for olive oil until recently. In 2008, the NAOOA enacted a QA program and created a seal for olive oil brands that comply with the association's requirements (128). The aim was to create more confidence among consumers in the authenticity of the olive oil that carries the NAOOA seal. In October 2010, the United States adopted olive oil standards similar to those of the IOOC (25, 124). However, more than 99% of the olive oil consumed in the United States is produced in other countries (21).

Multiple analytical testing methods for olive oil exist, and new methods are continually being developed (71, 78). Producers of fraudulent oil have kept pace with new testing methods by altering the characteristics of the adulterated oil to evade detection (39). Although olive oil appears to be the



most commonly adulterated oil, other food oils and fats have also been adulterated. In 2000, large-scale fraud involving fake butter was uncovered by the European Commission (72, 111). Nigeria has had problems with the adulteration of palm oil with water and a chemical colorant (175). More recently, the illegal reuse of potentially carcinogenic discarded kitchen oil has been a widespread problem in China (189).

**Grain products.** In 1990, the owners of a Minnesota grain company pleaded guilty to adding urea (a nitrogen-rich chemical used in fertilizer) to wheat before selling it to flour companies because it increased the price per bushel (73). The adulteration was discovered through a tip from a disgruntled former employee. Urea had routinely been added to animal feeds for nitrogen enrichment before routine urea testing was implemented (37). In 2004, a survey by the Food Standards Agency in the United Kingdom revealed that 63 (17%) of 196 samples of Basmati rice at retail contained non-Basmati rice in a proportion greater than 20% (77). As a result, they updated the Code of Practice for Basmati rice in 2005 (42, 50). In 2011, a food company in China was shut down for producing steamed corn buns that were actually produced with wheat flour, artificial colorings, and artificial corn flavoring (30). Italy uncovered a so-called "food fraud ring" in 2011 that involved false certification of foods as organic; the seized products included grains that were falsely labeled as organic (26).

**Honey and other natural sweeteners.** In the late 1990s, two brothers who ran a honey and syrup-making business in Mississippi were sentenced to prison after selling honey, maple syrup, and other syrups adulterated partially or wholly with corn syrup for more than 20 years (104). In 1995, a large honey processing firm in the United States was indicted for adulterating the "pure" honey they sold to food producers with high-fructose corn syrup to increase profits (12, 127). Adulteration and dilution of honey has also been a widespread problem in China, where tests conducted in 1999 indicated that almost one-third of the brands were adulterated with other types of sugar (47).

There is no U.S. standard of identity for honey, although in the past 2 years Florida, California, Wisconsin, and North Carolina have all adopted state standards that prohibit additives to natural honey (24). Before the development of high-fructose corn syrup in the 1970s, the adulteration of honey typically involved invert syrup, glucose syrup, or corn syrup and was easily detectable (63, 127). Because the sugar profile of high-fructose corn syrup is similar to that of honey, high-fructose corn syrup was more difficult to detect until new tests were developed in the 1980s. Honey adulteration has continued to evolve to evade testing methodology, requiring continual updating of testing methods (61, 115).

A survey of U.S. honey packers reported that 71% of the firms that tested for economic adulteration in their honey supplies had found adulterated honey (70). The average detected concentration of adulterant ranged from about 6 to 43% from 1996 through 1998. Of the adulterated honey

detected, China and Argentina were the sources of more than 90% of the adulterated honey in all three survey years.

So-called "honey laundering" is another problem that has emerged in recent years (66, 110). The use of chloramphenicol on bees in China resulted in a 2-year ban of Chinese honey in the EU and Canada, beginning in 2002 (106). Although Chinese honey is not currently banned in the United States, it is subject to additional testing for chloramphenicol at the borders (110) and high tariffs to prevent dumping on the market (133). Adding to the demand for imported honey has been a recent decrease in the U.S. domestic production of honey due to honeybee colony collapse disorder (99). In 2010, 11 people and six companies were indicted on conspiracy charges for illegally importing Chinese honey, thereby avoiding almost \$80 million in antidumping tariffs (161). There has been widespread documentation that Chinese honey has been shipped to other countries, repackaged, and reexported for shipment to the United States to avoid taxes and inspections (35, 110). In 2007, the United States imported 237 million pounds (107.6 million kilograms) of raw honey; however, many of the top countries that supplied honey appeared to be exporting more honey than their domestic bees produced (66, 106, 110, 133, 148).

Honey can be analyzed for natural soil residue to determine the country of origin (148); however, analytic capacity is low, and most honey shipments are not inspected upon arrival to the United States (149). In the most recent case of large-scale honey laundering, honey was filtered to remove pollen or soil that could be used to trace it back to its origin (110). If the importing U.S. companies return chloramphenicol-tainted honey to the supplier, there are no guarantees it will not be shipped to another buyer (148, 161). Multiple instances of chloramphenicol-tainted honey entering the EU from countries other than China have been documented, leading to similar charges of country-of-origin relabeling (17, 66).

**Spices and extracts.** In 2005, adulteration of chili powder with the dye Sudan I caused recalls of hundreds of food products worldwide. Sudan I is an industrial dye classified as a category 3 carcinogen (96). A British company imported the contaminated chili powder from India and added it to Worcestershire sauce, which was subsequently used in the manufacturing of hundreds of food products (140). Earlier that year, a new law had been put into effect in the EU requiring enhanced traceability along the food supply chain. Partly due to this enhanced traceability, the Food Standards Agency in the United Kingdom was promptly notified after the Sudan I adulteration was detected by a laboratory in Italy during testing of imported Worcestershire sauce (62). The chili powder was originally imported from India and passed through the hands of at least seven different companies in India and Britain before being bought by the makers of the Worcestershire sauce (65, 107, 116).

Although illegal, Sudan dyes are routinely detected in many types of food products. A search on the term "Sudan" in the EU RASFF Portal online searchable



database returned 64 notifications of Sudan dyes in food products from January 2009 to March 2012 (67). Contaminated food products included chili, curry, and paprika powders, palm oil, and various sauces. In a 2005 report, the European Food Safety Authority panel listed seven illegal dyes that had been found in food products in EU member states: Sudan dyes I through IV, para red, rhodamine B, and orange II (68).

Spices are particularly susceptible to adulteration because they are typically sold in powdered form, they have long and complicated supply chains, reliable and cost-effective testing methodologies for ground spices are challenging to develop, and performance losses in final food products can be difficult to detect (123). Dyes may be added to make a spice look fresher, older spices may be added to freshly ground ones to increase weight (46), nonspice material may be added as an extender, or "spent" spices with valuable constituents removed may be sold as whole spices (3). In 1994, domestic sales and exports of paprika were banned in Hungary because lower grade powdered paprika had been imported from Romania and mixed with lead oxide for color; consumption of this product resulted in more than 60 hospitalizations (10, 11). Hungarian authorities found lead in 15% of samples tested and implemented strict government controls over production and sales of the spice before allowing its sale again (114). Ten years later, Hungary again had a problem when aflatoxin was found in paprika that was marketed as domestic; however, aflatoxin-producing fungi do not grow in Hungary (14). Domestic supplies of paprika were mixed with paprika from Latin American countries that contained high levels of aflatoxin (108). Saffron is an attractive target for adulteration because of its high production costs and potential profit margin. In 2000, a Spanish producer of saffron was priced out of the British market and came to the conclusion that its competitors must be selling adulterated product (87). Samples taken by British authorities confirmed the adulteration.

**Wine and other alcoholic beverages.** In July 1985, West German authorities announced that some Austrian dessert wines were contaminated with diethylene glycol (DEG), a solvent with multiple industrial and commercial applications. By December 1985, the U.S. Bureau of Alcohol, Tobacco and Firearms (BATF) had detected DEG in 81 different brands of wine sold in the United States (170). The adulteration was discovered after an Austrian tax inspector noticed that a wine producer was claiming tax refunds on large quantities of DEG (6). Many Austrian wines were sold in bulk to West Germany (4) for blending with wines produced domestically. Multiple wines labeled as West German were found to be contaminated with DEG, indicating they had been blended with Austrian wine (7, 80). At the time, neither the BATF nor the FDA routinely tested wine for the presence of contaminants and had no reason to test wine for DEG (170). Following the incident, the Austrian Parliament adopted stricter wine laws, including new labeling requirements, a reduction in the amount of certain additives allowed, and checks to prevent doctoring (8).

Wine has a long history of containing additives and adulterants (132, 182). Consequently, multiple regulatory systems have been established for quality control, including the Appellation D'origine Contrôlée system in France, the Denominazione di Origine Controllata in Italy, the EU Protected Designation of Origin, and the American Viticultural Area system in the United States. Wine is an attractive target for adulteration because sale of desirable varieties is very profitable. The adulterated Austrian wines were sold as expensive white dessert wines. The theory at the time was that DEG was added specifically to increase sweetness. However, the quantity of DEG found in some wines apparently was not large enough to affect taste (5). A more compelling argument was that DEG was used to add body to the wine and possibly to mask the addition of sugar for sweetness (150). The use of DEG in Austrian wine was advantageous because it could be added in small quantities to have the desired effect, and because DEG was a novel wine contaminant routine QA testing methodologies for detection had not been developed. DEG also did not have any short-term health effects in the typical quantities being ingested. Presumably, the wine fraud could have continued for much longer had it not been discovered by the tax inspector.

In the Austrian wine incident, West German winemakers were also responsible for the fraud because they sold some of the contaminated Austrian wine as German wine. Examples of this type of fraud abound worldwide. Label fraud refers to the practice of mislabeling the varietal or growing area of wine (typically, labeling a cheaper wine as a more expensive one) or blending in other varietals. In 2008 and 2009, Italian officials declassified almost 2 million liters of high value wine from five wineries because it was made with unauthorized grapes (34). In 2002 in the Bordeaux region of France, large-scale fraud was discovered; producers were importing cheaper wine from other regions and selling it with the Bordeaux label (131). Although label fraud does not typically pose a danger to the health of wine consumers, those types of fraud illustrate the difficulty in assuring the authenticity of wines.

Other alcoholic beverages also are prone to adulteration. Methanol, although toxic, is commonly used to boost alcohol content because of its similarity to ethanol. Recently, Britain has had an ongoing problem with counterfeit alcohol, which can contain methanol or other chemicals (2, 117). In 2000, more than 100 people died in El Salvador after consuming liquor that was contaminated with methanol (105). A similar incident occurred in 1992 in India, when more than 200 people died (143).

**Infant formula.** In 2004, parents of malnourished infants in China sent samples of formula they were using to feed their children to the local Centre for Disease Control and Prevention. Tests on the formula indicated it contained very low levels of protein, fat, calcium, and magnesium (125, 176). High numbers of malnourished infants were showing up in hospitals and clinics in China for at least 1 year prior (192), and at least 55 brands of formula did not meet nutritional standards (98, 151). Hundreds of babies were malnourished as a result of the substandard formula,



and more than 10 died. According to news reports, small village grocery stores were at greater risk for receiving substandard formula than were large supermarket chains, which were better able to assure the quality of the formula they sold (193). Other issues cited in news reports included a lack of government oversight, lack of communication among the various agencies involved in local quality control, and the possibility of government authorities being complicit in the continued distribution of the substandard formula (98, 193). In 2006, ministry inspectors in China again found baby formula that was dangerously low in nutrients for sale in rural areas (15).

Although no incidents of health effects due to deficient Chinese-produced formula occurred in the United States, this country has had ongoing problems with counterfeit infant formula because of its high sales price and steady demand (60). The FDA considers counterfeit formula to include "products that have been diverted from normal distribution channels and relabeled" (163). In relabeled products, the age, quality, or ingredients may not be accurately represented, and diverted products may be diluted or adulterated. In 1995, the FDA seized 45,000 lb (20,430 kg) of counterfeit formula in California and uncovered 10 operations that were producing formula and packaging it with false labels (56). The counterfeiting was discovered when parents of infants began calling the maker of Similac brand infant formula to complain that the formula they had purchased looked and smelled unusual; the formula company then contacted the FDA (23, 56). The Food Marketing Institute (FMI) documented 11 separate instances of infant formula theft related to organized retail crime from 2005 through 2006 in 10 states (75, 76). In 2004, the FMI ranked baby formula fourth on the list of items that were most frequently shoplifted from grocery stores.

**Plant-based proteins.** One year before the illnesses linked to melamine adulteration of dairy products, wheat gluten and other vegetable proteins from China used in the production of pet foods and animal feed were found to be adulterated with melamine (177, 179). More than 150 brands of pet food were recalled (165). The outbreak was identified after the deaths of cats during taste trials of pet foods and resulted in the deaths of hundreds of dogs and cats in the United States due to renal failure (51). Melamine alone is not highly toxic to animals, but the combination of melamine with cyanuric acid caused the formation of insoluble crystals in the kidneys (52, 180). As with dairy products, melamine was added to vegetable proteins to make them appear to be more protein rich. At that time, no routine testing methodologies for melamine in vegetable proteins or pet food were in place among regulatory agencies or industry. Supplementing animal feeds with melamine was reportedly a long-standing practice in China; evidence was found that feed producers looking to purchase melamine scrap had advertised on the Internet (38). Evidence also suggested that producers of the contaminated vegetable proteins may have falsely labeled their shipments as nonfood products to avoid inspections (37). Melamine was detected in the feed supply of food production animals

in the United States, and some food production animals that consumed melamine in their feed most certainly entered the human food supply (1, 40, 165, 178). As a result, the FDA implemented melamine testing in vegetable proteins used in both animal feed and human food (100).

**Other food products.** Meat products have been prone to adulteration with alternative meats or nonmeat protein sources. In 1986, a beef supplier that served New York City schools was found to have adulterated its products with vegetable filler and water over at least a 5-year period (145). The company was sold to a group of investors who reported the adulteration to the FBI after finding evidence in company records. In the United Kingdom in 2009, the Food Standards Agency (FSA) detected denatured bulking agents made from porcine and bovine products that were injected into chicken products to bind water and increase weight; multiple firms were engaging in this practice (88). Because the nonchicken material was denatured, it would have passed traditional DNA tests; however, the FSA used novel scientific techniques to detect the bulking agents (88, 141). In 2011, pork in China was found to be contaminated with clenbuterol, a drug that promotes growth and reduces the percentage of fat in animals but can cause adverse human health effects (130, 186).

Coffee and tea have historically been prone to adulteration (182). Tea adulteration has been a widespread, ongoing problem in India, with much of it happening at a local level (13, 16). Adulterants tend to include plant stalks, used tea leaves, and other organic material to extend the leaves. The results of a decade-long survey conducted by the Brazilian Coffee Industry Association (ABIC) that were reported in 1998 revealed that many companies sold adulterated coffee, which was commonly bulked up with corn, barley, rye, caramel, or coffee bean husks (144). Reportedly, the rate of adulteration dropped after the ABIC introduced a quality seal program. In the mid-1990s, Britain reportedly uncovered problems with instant coffee manufactured in other countries and imported in bulk; remnants of the coffee plant and caramel were being added to increase profits (64). In 2011, teas, fruit juices, and other products produced in Taiwan were found to be contaminated with plasticizers, which replaced palm oil as a clouding agent in beverages to improve appearance (126, 139).

Multiple incidents of fraud involving the use of the ill-defined terms "natural," "free range," and "organic" have been uncovered (27, 29, 32, 58). In 2010, a Texas company settled federal allegations that they purchased old or expired food products, relabeled them with new expiration dates, and sold them to the U.S. military (92). China has had a string of additional EMA discoveries in recent years, including bean sprouts treated with banned food additives (31), the addition of Sudan dyes to duck feed to darken the resulting egg yolks (18), and the use of formaldehyde to preserve unrefrigerated cabbage (191).

## COMMON CHARACTERISTICS

The adulteration incidents described here illustrate that regulatory system controls and QA testing methodologies



employed by both industry and regulatory agencies have been evaded in a variety of ways in multiple food products for economic gain. Fortunately, these incidents have only rarely resulted in significant human illnesses. However, they reveal gaps and potential vulnerabilities in food production, distribution, and regulatory systems that will allow future EMA incidents to happen. These gaps could also be exploited for intentional adulteration with the intent to cause harm.

The GAO (173) noted in a recent report that the FDA has traditionally not distinguished EMA from other food adulteration incidents and that the importance of distinguishing among them is still being debated. An FDA official cited in the report stated that there is value in making a distinction among different motives behind food adulteration. Intentional adulteration incidents differ from traditional food safety threats in that they are not predictable by traditional food safety risk assessments and intervention strategies. EMA, which alters the identity of a food product and is designed not to be detected, makes oversight by industry and regulators very difficult. As noted by the U.S. Pharmacopeial Convention (USP), EMA incidents effectively collapse food protection into a single element: the perpetrator's scientific knowledge (112). We cannot rely on the traditional food safety paradigm for evaluating EMA risk and preventing intentional adulteration incidents. Prevention of EMA requires a holistic and systems-based approach that takes advantage of multiple disciplines and data sources. Some common themes among many of these EMA incidents can help us better evaluate the risk of EMA and devise prevention strategies. These themes reflect different ways in which regulatory systems or QA testing methodologies were insufficient for detecting EMA, successful methods of detection that we should exploit in the future, and other useful concepts related to EMA risk and deterrence. These themes are outlined below.

#### **Importance of specific, effective analytical methods.**

The two melamine adulteration incidents occurred because the commonly employed analytical method for protein content in those products was nonspecific. The use of nonspecific nitrogen tests as a proxy for protein content has been a well-recognized problem (121, 152), and the recent adulteration of dairy products with leather protein in China is an indication that this problem will continue. The use of nonspecific analytical methods for food ingredients is one known risk factor for EMA. The USP Food Chemicals Codex (174) is a compendium of monographs (full product descriptions and standard analytical profiles) for food-grade chemicals, processing aids, foods, flavoring agents, vitamins, and functional food ingredients that is widely used by suppliers and manufacturers to assure quality along the food supply chain. Continued efforts by the USP, industry, and academia to maintain updated and effective monographs for food ingredients are crucial for detecting and deterring future EMA incidents. USP advocates a compendial strategy of testing food ingredients for authenticity rather than testing for the absence of specific adulterants (122). This compendial strategy would focus on analyzing what should

be present in a sample rather than what should not be present and can potentially detect both expected and unexpected adulterants (although not necessarily at very low levels). The use of analytical methods for food product testing is certainly a tradeoff between cost and effectiveness (101) and requires a comprehensive understanding of the ingredient supply chain. Regular testing at critical points along the supply chain with targeted, specific testing methods is the first line of defense for verifying that process control systems are working and therefore is an important aspect of QA.

**Necessity of government standards.** In the case of adulterated honey and other sweeteners (12) in which the defendants were found not guilty, the jury indicated the lack of government standards for honey as one of the deciding factors in the case (24). Producers of honey and extra virgin olive oil have been pushing for strict government standards for years (21, 24). Defined standards for food ingredients give regulatory agencies more power to remove adulterated products from the market and prosecute those guilty of EMA, enable standardization within the supply chain, and may help encourage shared audit programs (84).

**Industry trade groups as a deterrent.** Just as there is an economic motivation behind EMA incidents, industry trade groups (such as the NAOOA, the Vermont Maple Sugar Makers Association, and the American Spice Trade Association) have an economic incentive to ensure customers receive an unadulterated product. Products adulterated for economic gain have an artificial market advantage, and producers of authentic products may be priced out of the market as a result. Furthermore, publicized EMA incidents erode consumer confidence and may result in a reduction in sales. Industry trade groups serve an important role in improving communication among legitimate producers, standardizing and recommending testing methods, performing regular product testing at retail, and improving customer confidence in products. In a 2010 report on consumer product fraud, the Grocery Manufacturers Association recommended implementing a clearinghouse for sharing information and audit programs (84), which could be facilitated by industry trade groups. The seal program created by the NAOOA (129) is a good example of this type of shared audit program. Producers that are part of the program must comply with the requirements of the program but in return are able to use membership in the program as a selling point for their product.

**Need for widespread access to inexpensive genetic testing methods.** Certain food products, such as fish and seafood, require genetic testing methods to definitively identify the species and source of the product. The prevention of fish fraud depends on the ability to identify species at the retail level. It is not practical to expect federal regulators to be able to perform tests with the frequency that would be required to ensure authenticity of all fish species at the retail level. Therefore, routine testing at retail requires widespread access to quick, easy, and inexpensive genetic



testing methods, combined with comprehensive databases of genetic information and explicit labeling requirements. DNA barcoding methods are being developed and show promise but currently are cost-prohibitive and not widely accessible for those stakeholders that would be informed by routine retail-level testing (184, 190). Genetic databases for fish species have been compiled at the FDA and the National Marine Fisheries Service in the United States and at the University of Guelph in Canada (43). Collaboration among different agencies to provide access to inexpensive testing and genetic databases and the rapid dissemination of results will be necessary to identify and deter seafood fraud.

**Fraud opportunities created by long and complicated supply chains.** Certain food products have long supply chains that may involve the buying and selling of ingredients multiple times before they are incorporated into a food product ready for consumption. The spice market is one example. This situation also exists for many industrial food ingredients, such as protein derivatives. Other products have evolved more complicated supply chains as a result of the attempt to avoid tariffs or benefit from subsidies, such as Chinese honey and European sugar. Food commodities with long or complicated supply chains present many challenges for detecting and preventing EMA (101). These products are often sold and transported in bulk processed form, which makes them easier to adulterate. Products that have aged during their time on the market, such as spices, may be adulterated to make them look fresher and avoid having to take a loss for them. There may be an increased incentive to adulterate industrial ingredients, such as vegetable proteins or industrial honey, which are subject to fluctuations in market prices. Adulteration of industrial ingredients is also more difficult to detect because these ingredients are diluted further by incorporation into a final product. Comprehensive and detailed knowledge of ingredient supply chains and vertical integration of the production process are important for preventing and detecting EMA incidents in these types of products (101).

**Allergenic potential of fraudulent ingredients.** The prevalence of diagnosed food allergies has increased over the past two decades (33). The vast majority of allergic reactions to foods involve milk, eggs, peanuts, tree nuts, fish, shellfish, wheat, or soy. EMA has the potential to cause serious public health consequences when allergenic ingredients are substituted for authentic ingredients. Potentially harmful substitutions include dilution of olive oil with the oil of peanuts or tree nuts, species substitution in fish and shellfish, substitution of gluten or soy protein for other vegetable proteins, or the undeclared addition of nonmeat proteins (such as soy) to meat-based products. In addition to the potential for adverse health effects, unexpected allergic reactions to food products should be considered another potential indicator of EMA.

**Use of nontraditional data sources for detection.** In the case of DEG adulteration of wines, the adulteration was uncovered through tax records. Because DEG did not cause

immediate health effects and was a novel adulterant in wine, the adulteration may have continued for much longer had it not been identified in this way. The Beech-Nut apple juice incident was an EMA incident that could potentially have been detected with market data; the company switched suppliers and was offered apple juice concentrate at 25% below typical market prices. Below-market pricing, rapid increases in supplies and sales, or known imbalances in quantities between primary production and final distribution should be regarded by producers, regulators, and consumers with skepticism. Another situation in which producers may have an increased incentive for EMA occurs when a particular food product rapidly increases in popularity. Recent examples of ingredients marketed as having health benefits are pomegranate juice, acai berry, and whey protein. Import and trade data, economic production data, and market pricing data all have the potential to provide an early indication of a potential EMA incident in a food commodity. Algorithms that incorporate analyses of non-traditional data sources into targeted laboratory testing or border inspections could improve food protection efforts with relatively few resources.

## CONCLUSIONS

EMA presents many challenges to food companies and regulators because perpetrators are specifically seeking to avoid detection and circumvent existing regulatory systems or QA testing methodologies. Therefore, risk assessment and proactive prevention strategies for EMA cannot depend solely on traditional food safety strategies. The vulnerability of the food supply to EMA will continue as long as the potential for profit exceeds the odds of getting caught and the potential consequences do not act as a deterrent. Globalization of the food supply system has made prevention and detection of adulteration more difficult. Regulators and food producers cannot test their way to complete food protection. The requirements outlined in the Food Safety Modernization Act for improved traceability and verification along the entire supply chain are necessary to make the food supply chain a less attractive target for intentional adulteration of any type. Increased information sharing among government agencies and the private sector across countries is crucial for faster worldwide response to EMA incidents. In this era of globalization of the food supply, we need creative and innovative methods for preventing and detecting EMA and for targeting crucial resources toward the riskiest food products.

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