

WHITE PAPER

THE PURSUIT OF FOOD AUTHENTICITY:

RECOMMENDED LEGAL & POLICY STRATEGIES
TO ERADICATE ECONOMICALLY MOTIVATED
ADULTERATION (FOOD FRAUD)

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RESNICK PROGRAM
FOR FOOD LAW AND POLICY



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PREFACE

This White Paper recognizes that the current political reality likely translates into less, not more federal government regulation of food. Hence, it should be noted that this paper does not advocate new administrative regulations or rules.

This paper simply recommends that the FDA enforce the existing statutory mandate against food fraud for the benefit of American consumers in a smart, efficient manner by setting enforcement priorities and by collaborating with science experts and the food industry.

This paper further recommends that the food industry eradicate food fraud by embracing the norm of authenticity and establishing self-governance rules as it has done so with sustainability.

Last, this White Paper proposes specific rules changes in litigation against food fraud that courts could take to enhance the use of the tool of litigation in combating food fraud.

LIST OF ABBREVIATIONS

CSR	Corporate Social Responsibility
EMA	Economically Motivated Adulteration
FDA	Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act
FMIA	Federal Meat Inspection Act
FSMA	Food Safety Modernization Act
GMA	Grocers Manufacturing Association
IMAS	International Multidimensional Authenticity Specification
NAD	National Advertising Division of the Council of Better Business Bureau
PPIA	Poultry Products Inspection Act
PFDA	Pure Food and Drug Act
USDA	United States Department of Agriculture
USP	US Pharmacopeial Convention

1. INTRODUCTION

Food fraud is both an old and modern problem. A major form of food fraud—referred to in modern terminology as Economically Motivated Adulteration (EMA)—includes the padding, diluting, and substituting of food product for the purpose of economic gain that may or may not affect the safety of the product. EMA harms consumers, honest merchants, and undermines the credibility of regulatory agencies that have jurisdiction over the quality and safety of food.

This form of cheating targeted wines, spices, meat, and bread, as early as in the Roman Empire. Legal responses to EMA-type fraud have historically been suited to the sensibilities for the time. During the reign of Edward the Confessor in the eleventh century, for example, brewers of poor quality beer in the city of Chester were condemned to stand in the tumbrel or dung-cart.¹ In early fourteenth-century London, the baker who sold underweight bread would have the offending loaf slung around his neck and be drawn through the dirtiest streets in town on a mobile pillory to be jeered at and targeted by flying debris hurled from fellow citizens.²

In the modern food system, trade flows of varieties of food products and ingredients from multiple locations around the world increase the level of EMA. This dynamic poses unique challenges to good governance. Enforcement against modern EMA calls for legal solutions beyond the dung-cart or mobile pillory, practical solutions that recognize the sophistication and systemic nature of the cheating and protect consumers. These practical solutions should include effective legal and policy tools and inspire new ways of thinking about food fraud.

To this end, this White Paper in four parts documents the modern problem of EMA and proposes legal and policy strategies in dealing with EMA. Part I addresses the modern problem of EMA in the United States by defining EMA, documenting the foods commonly subject

to EMA, examining the challenges of detecting EMA, and accounting for the harms of EMA. Part II surveys the legal tools currently used by the government to combat EMA, commenting on their strengths and weaknesses. Part III sets forth five specific legal and policy strategies to combat EMA. The first strategy is to put consumers first and to adhere to the statutory mandate to enforce against EMA as fraud, rather than a lower tier of adulteration that is only of interest to government agencies if there is a food safety crisis. The second strategy is to define EMA more completely in order to guide the government agencies and the food industry and to frame expectations for compliance. The third strategy is to create a high priority category for the most problematic EMA foods that would subject these foods to standards making and testing without overburdening government capacity. The fourth strategy is for the food industry to self-regulate food authenticity through corporate social responsibility

Although the definition of “authenticity” is multifaceted, especially as applied to food, this paper takes a practical approach and regards “authentic food” as food that is what it purports to be, and as food that is not subject to fraud, including economically motivated adulteration.



Source: Public Domain. <http://bit.ly/2my4007>

Food Fraud Database Lets Us All Play Detective

March 26, 2013 · 3:38 PM ET

NANCY SHUTE



Source: <http://www.npr.org/sections/the-salt/2013/03/26/175377244/food-fraud-database-lets-us-all-play-detective>

commitments and voluntary standards, thereby delivery to consumers food that is EMA-free. The fifth and last strategy recommends specific changes to class action litigation rules that would enhance the effectiveness of this tool in combatting EMA.

This White Paper acknowledges the important work being done by others in combatting EMA. US Pharmacopeial Convention (USP) in recent years has produced a guidance document on Food Fraud Mitigation, convened food fraud workshops, and created a Food Fraud Database. Michigan State University's Food Fraud Initiative includes a food fraud blog, an online course, and workshops. The newly formed International Food Authenticity Assurance Organization is creating molecular profiles for food ingredients and methodologies to determine whether food ingredients are authentic or not.

Three notable government reports that address EMA include:

1) a 2011 US Government Accountability Office (GAO) report, titled, *Better Coordination Could Enhance Efforts to Address Economic Adulteration and Protect the Public Health*;

“By now we know that not every food is what it seems.

But if you really want to get paranoid, peek into the USP Food Fraud Database. It's a searchable trove of humankind's ceaseless efforts to swindle, hoodwink and defraud with food, worldwide.

That's where I learned that hucksters sometimes use Sudan red dye to amp up paprika, which in its natural state is often a demure reddish brown. Sudan red is a potent carcinogen, banned for use in food worldwide. Eek!”

2) a 2013 report issued by the United Kingdom's (UK) Department of Environment, Food and Rural Affairs, titled *Elliott Review into the Integrity and Assurance of Food Supply Networks*;

3) a 2014 Congressional Research Service (CRS) report, titled, *Food Fraud and “Economically Motivated Adulteration” of Food and Food Ingredients*.

Articles and books in popular press have also in recent years called attention to fake food or food fraud. Examples of books include: Bee Wilson, *Swindled: The Dark History of Food Fraud, From Poisoned Candy to Counterfeit Coffee* (2008); Tom Mueller, *Extra Virginity: The Sublime and Scandalous World of Olive Oil* (2012); and Larry Olmstead, *Real Food Fake Food: Why You Don't Know What You're Eating And What You Can Do About It* (2016).

This White Paper adds to all of these efforts by addressing legal and policy strategies for the US to combat EMA.

2. THE MODERN PROBLEM OF ECONOMICALLY MOTIVATED ADULTERATION

Defining Economically Motivated Adulteration (EMA)

Defining Agencies

Defining EMA is the responsibility of the governing agencies with jurisdiction over food. Determining which government agency has jurisdiction over a particular food is often no easy task. Government regulation of food in the US is a patchwork of federal, state, and local laws. In response to food safety, integrity, and quality concerns, Congress has passed major legislation to govern food, including acts referenced in this White Paper: the 1906 Pure Food and Drug Act (PFDA); the 1907 Federal Meat Inspection Act (FMIA); the 1938 Federal Food, Drug, and Cosmetic Act (FDCA); and the 1957 Poultry Products Inspection Act (PPIA).

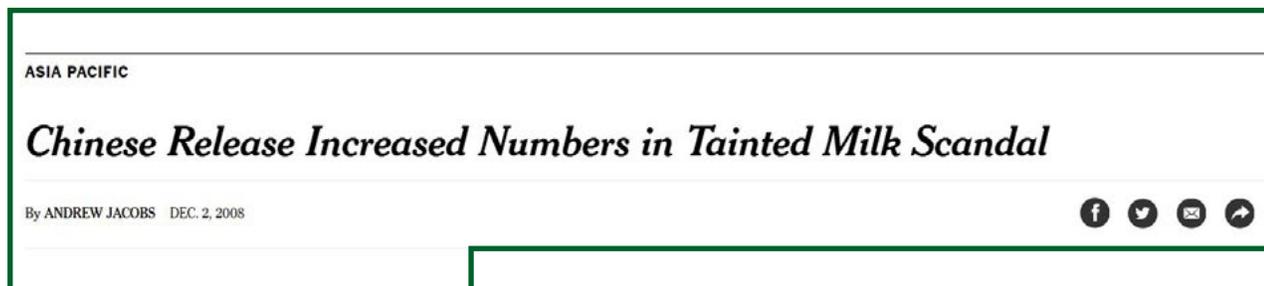
Under these and subsequent federal food acts, Congress

has delegated the bulk of federal responsibility for the direct regulation of food in the US to the Food and Drug Administration (FDA) and the US Department of Agriculture (USDA). In general, the USDA oversees meat, poultry, and eggs and administers the National Organic Program, and the FDA regulates everything else, which gives the FDA jurisdiction over most food products. The complete web of responsibilities across government agencies is much more complex, but the bulk of responsibility for defining and enforcing laws against EMA rests primarily with the FDA and secondarily with the USDA.³

The FDA's Development of a Definition of EMA

No less complicated than the organizing of the defining agencies is the actual defining of EMA and all of its component parts. Prior to 2009, the FDA had not defined EMA. It took a food scandal in 2007-08 involving Melamine being added to pet food and infant formula in China to prompt the FDA to define EMA, albeit that this definition is sparse.

Melamine is a widely used chemical found in hard plastic dishes and linings of food containers. In 2007, Melamine was added to pet food that was imported into the US in order to boost the pet food's protein content, resulting in the recall of 150 brands of pet food and in animal deaths in the US.⁴ In 2008, it was discovered that Melamine had been added to



Source: <https://nyti.ms/2jSS9Ge>

“Chinese officials on Monday issued a higher estimate for the number of children affected by tainted dairy products, saying that as many as six babies might have died and nearly 300,000 were sickened after consuming contaminated milk powder.”

infant formula by Chinese milk dealers and suppliers in an effort to increase protein content and profits, resulting in 50,000 infant hospitalizations and six infant deaths in China. In 2009, on the heels of a public outcry over these incidents, the FDA issued a Notice of Public Hearing to address EMA.⁵ The FDA's Notice of Public Hearing expressly cited these two events (as well as two drug EMA incidents) as reasons for addressing EMA. The Notice of Public Hearing also stated that the FDA's EMA Working Group had defined EMA 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. EMA includes dilution of products with increased quantities of an already present substance (e.g., increasing inactive ingredients of a drug with a resulting reduction in strength of the finished product, or watering down of juice) to the extent that such dilution poses a known or relative health risk to consumers, as well as the addition or substitution of substances in order to mask dilution.⁶

This working group definition remains the first and last definition of EMA issued by the FDA.

The EMA Working Group's definition of EMA derives from the FDCA's definition of "adulteration." The FDCA gives authority to the FDA to regulate food, drugs, and cosmetics. Section 402(b) of the FDCA (codified at 21 U.S.C. § 342(b)) lists a range of actions that constitute EMA for food products. Section 402(b) states:

A food shall be deemed to be adulterated—
...
(b) Absence, substitution, or addition of constituents
(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

(2) if any substance has been substituted wholly or in part therefor; or
(3) if damage or inferiority has been concealed in any manner; or
(4) if any substance has been added thereto or mixed or packed therewith 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.⁷

It should be noted that Section 402(b) does not expressly use the descriptor "economically motivated adulteration." It is generally accepted, as evidenced by the EMA Working Group's definition, that Section 402(b) implicitly provides that the acts enumerated in the section—substitution, addition, omission, dilution, and concealment—are intended by the adulterators to produce economic gain.

Thus, EMA is an intentional act. The most obvious way to produce economic gain is to increase profits. This may occur, for example, when a manufacturer uses cheap filler that is easily disguised to increase the product volume and in turn increase the profit margin.

The UDSA's Definition of EMA

In 1994, the FMIA was amended to prohibit expressly a category of adulteration that roughly matches the FDA's description of EMA:

The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product...if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith 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.⁸

This same definition is also found in the PPIA, an enabling statute giving authority to the USDA to inspect poultry and poultry products capable for use as human food.⁹

Additional Non-Government Definitions of EMA

As noted in the 2014 CRS Report, “[r]esearchers and industry groups working actively in this area have myriad definitions of food fraud and EMA.” For example, the Grocery Manufacturers Association (GMA) defines “economic adulteration” 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.¹⁰

GMA’s definition is consistent with Section 402(b), but also includes the intentional mislabeling of food product within the scope of EMA.

USP defines EMA of food ingredients in the following statement:

Food Fraud in the context of food ingredients refers to the fraudulent addition of non-authentic substances or removal or replacement of authentic substances without the purchaser’s knowledge for economic gain of the seller. It is also referred to as economic adulteration, economically motivated adulteration, intentional adulteration, or food counterfeiting.¹¹

USP’s definition is notable because in addition to equating EMA to food fraud, it refers to authenticity and inauthenticity as linchpins of the EMA or fraud assessment.

Delineating Statutory EMA Actions

Neither Section 402(b) nor the EMA Working Group define with specificity the EMA actions of substitution, addition, omission, dilution, and concealment. In an effort to flesh out the meaning of these terms, we group together real life examples of EMA actions. This grouping shows some overlap and blurring between the types.

• Substitution

Substitution is the most common type of EMA. Substitution occurs when a substance of less value replaces a food substance.¹² Substitution is common in fish, where tilapia, for example, is often substituted in place of more expensive fish or farmed salmon is substituted for wild salmon.¹³ Other common examples of substitution include where sugar and other sweeteners are used instead of honey,¹⁴ cow’s milk is used for more expensive sheep’s or goat’s milk, and common wheat for durum wheat. In the British Isles in 2013, the substitution of horsemeat for beef attracted widespread media attention.¹⁵ Substitution can also be linked to the false declaration of the production process, such as when food is falsely labeled or certified as organically produced or poor quality filtered honey or a honey substitute product is labeled as raw honey.¹⁶

• Addition

Food products are often sold by weight either at the register or at some point in processing. One way to increase the price of these goods is to add inexpensive material to the product to increase weight. The scandal involving the adding of melamine to infant formula in China is an obvious example.¹⁷ Other examples include the padding of cumin with ground peanut shells,¹⁸ excessive cellulose in grated Parmesan cheese,¹⁹ and “over-glazing” (adding more than the allowed amount of water to) seafood and meats.²⁰

• Omission

Omission occurs when some valuable constituent is missing from the product. An example of omission is

Ready meals with up to 100% horse meat: Shops take packets off shelves as tests ordered for animal drug

In the worst case of food contamination so far, frozen food giant Findus confirmed 15 out of 18 samples of their Italian meal tested positive for horse



BY RIJKI SAYID
07:58, 8 FEB 2013 | UPDATED 11:40, 19 FEB 2013

NEWS

The discovery of horsemeat in processed beef products sold by a number of UK supermarket chains in March of 2013 resulted in a series of product recalls and threw the spotlight on the food industry's supply chain. Source: <http://www.mirror.co.uk/news/uk-news/findus-beef-lasagne-could-100-1593248>

when Beech-Nut Corporation's "apple juice" actually contained no apple.²¹ Other examples include "100% Parmesan cheese" that is actually only imitation cheese and trimmings of Swiss, mozzarella, white cheddar, and Havarti;²² "paprika" that is actually only the leftover product after fats and flavors have been extracted for paprika-flavored extracts;²³ and "extra virgin olive oil" that is actually refined olive oil.²⁴ Some honey producers in the US and elsewhere have argued that the omission of pollen from honey should be considered an adulteration, but current US regulations do not include that requirement.²⁵

• *Dilution*

Dilution is where the amount of authentic food relative to other ingredients that may or may not be listed on the package is reduced. Dilution typically happens in concert with other forms of adulteration: a valuable ingredient might be partially removed, a less valuable ingredient added in to make up the difference, and a concealing agent applied to cover up the misdeed. For example, the addition of melamine to wheat gluten and infant formula in China was an effort to conceal the inferior protein content of diluted food products.²⁶ The most common and obvious example of dilution, however, is watered-down, under-poured alcoholic drinks in a bar or restaurant.

• *Concealment*

Concealment occurs when inferior quality is disguised through the use of some artifice, such as adding chlorophyll to olive oil to make it greener.²⁷ While it is a well-accepted purpose for food dyes and added flavors to elevate a less desirable food into a more desirable one, years ago in the US, substances were added to rancid flour and milk in order to make them whiter.²⁸

Distinguishing EMA from Food Safety Adulteration

In cases where EMA of food under the jurisdiction of the FDA causes food safety problems, the offending food company likely would be violating the food safety requirements of Section 402(a), as well as the EMA requirements of Section 402(b). Section 402(a) considers "poisonous" and "contaminated" food as adulterated. Rounding out Section 402(a) is the aggregation of food safety regulations, rules, and guidance, all of which regard food as being adulterated if it contains a harmful substance that may pose a safety risk or it contains a substance that has been intentionally added to the food but that has not been approved or otherwise sanctioned for use by statute or the FDA.²⁹

Notwithstanding the possible concurrent violation of these two sections, the statutory framework clearly distinguishes EMA, as defined in FDCA's Section 402(b), from the food safety criteria encapsulated and enumerated in the Section 402(a) (as well as in the FMIA and PPIA for meat and poultry products). EMA under Section 402(b) focuses on certain actions of economic cheating with the incidental danger to health.³⁰ To illustrate, while the intentional substituting horsemeat for beef for economic gain may be repulsive to the sensibility of many consumers, horsemeat generally was not viewed in the UK as posing a food safety hazard and thus would meet the definition of Section 402(b) rather than Section 402(a).

Distinguishing EMA from Other Forms of Adulteration and Food Fraud

EMA is distinguishable also from other forms of intentional

adulteration, such as sabotage (possibly leading to terrorist acts), the primary purpose of which is to cause physical and life-threatening harm, rather than economic gain.³¹ EMA is also distinguishable from counterfeiting, another category of food fraud, which involves the unauthorized representation of a registered trademark carried on goods similar to goods for which the trademark is registered, with the intent to deceive the purchaser into believing that they are buying the original food product.³²

Foods Most Commonly Subject to EMA

Dearth of Data

Researchers contend that the foods most often subject to EMA are fish and seafood, milk and dairy products, oils and fats (especially olive oil), meats, alcoholic beverages, fruit juices, grains, honey and other sweeteners, spices

The most egregious early example of food fraud in the US reportedly involved milk and the deaths of infants. In 19th-century New York, rapid industrialization meant the elimination of pastureland inside the city, but many Americans still relied on milk as a staple food for children and infants, especially as breastfeeding fell out of favor. Dairy farmers raised cows outside the city and shipped milk in by rail. Others raised cows inside New York City in filthy pens attached to distilleries, and the cows ate alcoholic mash—a byproduct of distilling.

“Swill milk,” as it would become known, was modified with plaster, magnesia, flour, starch, and molasses to give it the color and consistency of real milk. Real milk shipped in from neighboring counties was commonly diluted with water and given similar treatment. The practice continued for decades, and it remains hard to estimate how many children died from milk poisoning and contagion (milk pasteurization did not become common practice until the mid-1890s), but an 1858 article in the New York Times estimated 8,000 children died every year from drinking swill milk.

New York passed laws against milk adulteration and banned distillery dairies, but enforcement was rare and ineffective.

Wilson, B. (2008). *Swindled: The Dark History of Food Fraud, From Poisoned Candy to Counterfeit Coffee*, 154-63.

and extracts, produce, and coffee and tea.³³ No one knows exactly how prevalent EMA is, however, and how many products are affected.³⁴ While imported food seems to be disproportionately represented in the data that exists for EMA, this could be the result of more focused attention on imported foods. In terms of financial impact, the GMA estimates EMA costs the food industry fifteen billion dollars per year, but it is difficult to substantiate this estimate.³⁵

Summary of What We Know

The chart below identifies and briefly summarizes what is known about the foods most commonly subject to EMA.

Challenges in Detection and Testing

Detection

EMA can be very sophisticated and difficult to detect. In 1985, a massive international wine fraud was only discovered because a tax inspector noticed large deductions taken by an Austrian winery for diethylene glycol, a sweet-tasting industrial solvent that serves no purpose in winemaking.⁷² Normally, one would not inspect wine for diethylene

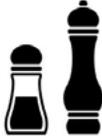
glycol⁷³ or infant formula for melamine.⁷⁴ EMA is designed, by its nature, not to be detected.

Testing

Even once specific adulterants are detected, the testing that targets these specific adulterants can quickly become obsolete when chemists working on behalf of fraudulent food producers devise new, substitute adulterants. For example, following the 2008 melamine scandal in China, officials began to test dairy products for melamine.⁷⁵ In 2009, hydrolyzed leather was found in Chinese infant formula being used for the same purpose as melamine: to boost apparent protein content.⁷⁶

Testing a food product’s authenticity, rather than focusing on a specific adulterant, can also be difficult to manage because the composition of food products often varies by location, growing conditions, production methods, and other variables.⁷⁷ Devising a test to account for these variables requires sophisticated authentication standards, such as one developed for pomegranate juice as delineated in a publication entitled *International Multidimensional Authenticity Specification (IMAS) Algorithm for Detection of Commercial Pomegranate Juice Adulteration*.⁷⁸ The

	<p>Seafood is probably the largest category of foods subject to EMA. Numerous studies have found rampant species substitution—where a lower-value fish is labeled as a higher-value fish—in restaurants, grocery stores, and fish markets.³⁶ Seafood is also subject to over-glazing: increasing the weight (and therefore price) by artificially increasing water and ice.³⁷ These problems are extremely common in the US and worldwide.³⁸</p>
	<p>Olive oil is the world’s most adulterated oil.³⁹ “Extra virgin” is the highest and most expensive grade of olive oil; it also has the most health benefits and best flavor.⁴⁰ In order to qualify as extra virgin, the oil must be separated from the fruit using only mechanical means (generally a crusher and centrifuge), have an olive fruit flavor, and be free of defects.⁴¹ Extra virgin olive oil is most often diluted with lower-grade or refined olive oil, though it is sometimes diluted with seed oils.⁴² Any addition of lower-grade oil renders the whole product lower-grade. Extra virgin olive oil is expensive to produce, but lower quality oils can be produced inexpensively in amounts that fill tanker ships.⁴³ The price premium for extra virgin olive oil is therefore extremely attractive for fraud, especially when consumers do not know that extra virgin olive oil should have a powerful bouquet of flavor. Olive oil is not the only oil subject to EMA: higher-value fats of every kind are typically diluted with lower-value fats.⁴⁴</p>
	<p>Milk adulteration has a long history in the US⁴⁵ but is now aggressively controlled.⁴⁶ However, milk and dairy adulteration is common in China, where dairy production is relatively new and domestic supply cannot meet increased demand. Infant formula is subject to EMA at such a high rate in China that it has created a grey market in illegally imported formula.⁴⁷ Cheeses are subject to adulteration worldwide, mostly by substituting lower-value cheeses for higher-value ones.⁴⁸</p>

	<p>Meat EMA takes the form of species substitution, substitution of lower-value cuts for higher-value cuts, and over-glazing.⁴⁹ Denatured pork and beef products have been injected into chicken to increase water retention, artificially increasing weight and price.⁵⁰</p>
	<p>The most common EMA of alcoholic beverages is undoubtedly water dilution and under-pouring in bars and restaurants. Many wine frauds involve the substitution of less valuable grapes or grapes from the wrong region.⁵¹ Some wine frauds involve diluting more valuable wines with less valuable wines or wines of different types.⁵² Among the most dangerous forms of EMA typically happens in combination with liquor counterfeiting: the perpetrators use methanol to increase alcohol content.⁵³ Methanol is a toxic (poisonous) alcohol and is less expensive than ethanol, the alcohol we drink.</p>
	<p>Fruit juices are particularly susceptible to EMA because their major adulterants, water and sweeteners, are present in the authentic products in large quantities. Other adulterants include pulpwash solids, unapproved preservatives, and less valuable juices; labeling reconstituted juices as fresh-squeezed is also EMA. The US General Accounting Office, in a report in 1995, estimated the rate of orange juice adulteration in the US could be up to 20%, but they also said that addressing that EMA was probably too costly.⁵⁴</p>
	<p>Grains are subject to additions like adding urea to flour or melamine to wheat gluten to fool lab tests for protein content.⁵⁵ Higher value grains like Basmati rice may be diluted with lower value grains.⁵⁶ Grains, like many other products, may also be deliberately mislabeled as organic when they are conventionally grown; the Italians uncovered an organic labelling conspiracy in 2011 that included various grains.⁵⁷</p>
	<p>Honey, like olive oil, is at the forefront of the worldwide food fraud fight. Because of rampant dilution with high fructose corn syrup and other cheap sweeteners, some countries, including the US, created tariffs on honey from China to prevent “dumping” low-cost honey on the market.⁵⁸ The European Union (EU) and Canada banned imports of Chinese honey for ten years after the discovery of chloramphenicol, a dangerous and highly controlled antibiotic, in imported honey in 2002.⁵⁹ As a result of tariffs and bans, much of the honey coming out of China is now ultra-filtered to remove all trace minerals and pollen that would allow scientists to identify the origins of honey samples.⁶⁰ Chinese honey is commonly shipped to other countries and repackaged before exporting to the US and elsewhere in order to avoid tariffs and bans; many countries export more honey than they produce.⁶¹ The US does grow its own honey adulterations: in the late 1990s, two brothers were convicted for selling honey and maple syrup diluted with corn syrup at farmers markets for more than twenty years.⁶²</p>
	<p>Spices and extracts are common targets of EMA, often at the production level (by contrast, fishers rarely see the profits from species substitutions or advanced over-glazing methods).⁶³ This is because spices are typically sold in powdered form and sourced from small producers in parts of the world with little oversight or accountability.⁶⁴ The production of “extracts” often leaves spent spice behind to be dyed and sold as if it were full strength; highly toxic industrial dyes often conceal the inferiority of spent or poor spices.⁶⁵ Non-spice bulking agents like ground peanut shells may also be used to dilute spice.⁶⁶</p>
	<p>Fresh produce is has been subject to organic labeling fraud.⁶⁷ This type of fraud is a substitution: conventionally grown produce is substituted for organically grown produce, and the culprit gains the value of the organic price premium. In the US, the USDA oversees the National Organic Program (NOP) and certification of organic food production. Because of the way the NOP works, organic labelling fraud in the US is most often a result of fraudulent documentation, especially as there are no tests to tell whether a product is organically grown.⁶⁸</p>
	<p>Coffee and tea have EMA histories as long and complex as wine.⁶⁹ Tea adulteration is ubiquitous in India.⁷⁰ Tea and coffee are both subject to the addition of organic bulking agents. In tea, that usually means spent leaves, stems and stalks, and non-tea plant matter; in coffee, it means corn, barley, rye, caramel, and bean husks.⁷¹ In the US, these adulterations are most easily avoided by buying whole-bean coffee and loose tea, though false origin and organic claims can remain.</p>

Morning Mix

Subway fires back with its own study to prove its chicken is chicken

By Ben Guarino March 2

Source: https://www.washingtonpost.com/news/morning-mix/wp/2017/03/02/subway-fires-back-with-its-own-study-to-prove-its-chicken-is-chicken/?utm_term=.c839f77c2146

IMAS algorithm serves to identify pomegranate juice authenticity and adulteration, which enables companies using these methods to identify problems in their own supply chains or adulterants in competitors' products.⁷⁹ It was developed through evaluation of a comprehensive chemical characterization of forty-five commercial juice samples from twenty-three different manufacturers in the US and samples from Iran, Turkey, Azerbaijan, Syria, India, and China.⁸⁰

For foods that have DNA, DNA testing can be used to help pinpoint the identity of the product.⁸¹ This is most useful for species substitutions in meat and fish and is actively being used by some grocery retailers to ensure the authenticity of the foods they sell.⁸² It is important to note, however, that DNA testing is expensive (often prohibitively so) and cannot be used in foods that have no DNA in them as a result of processing.⁸³ Also, as evidenced by the recent dispute over the authenticity of Subway's chicken, even when DNA testing can be used, the results are not always conclusive.

The expense of developing authoritative, public testing standards sophisticated enough to authenticate food but also affordable and accessible has helped prompt USP to get involved in standard making.⁸⁴ As a scientific nonprofit organization, USP sets standards for medicines, food ingredients, and dietary supplements.⁸⁵ USP

“The Canadian Broadcasting Corp.’s ‘Marketplace’ news program recently had a DNA lab analyze chicken meat and strips cooked in popular fast-food chains. Subway meat, the report indicated, showed significant amounts of non-chicken DNA. . .

Subway responded Wednesday with a prickly condemnation of the news report that suggested its chicken meat was diluted with unusually high levels of soy. . . ‘The stunningly flawed test by ‘Marketplace’ is a tremendous disservice to our customers,’ said Suzanne Greco, Subway president and chief executive, in a statement issued Wednesday night. . .

It bolstered its response by releasing the results of its own study, commissioned in the wake of the CBC report. . . [characterizing] the CBC report as misleading and demanded a retraction. . .

But the Canadian news company did not budge, either. It cited. . . a University of Guelph biologist, who said that although DNA ‘cannot be taken as exact mass ratios in the product,’ the genetic material could serve as a proxy for amounts of soy in the meat.”

elaborates on standards for testing the authenticity and purity of food ingredients (albeit not as sophisticated as the IMAS used for pomegranate juice authentication) in the *Food Chemicals Codex*, an internationally recognized

compendium of monographs and reference standards for food ingredients.⁸⁶ Notwithstanding USP’s expansive standards development efforts—by 2016, USP had over 1,200 testing standard monographs for food ingredients⁸⁷—testing may still miss adulterants and be expensive to administer.⁸⁸

Harms Caused by EMA

The harms caused by EMA are far-reaching. These harms include economic harms to consumers and honest food companies, potentially devastating food safety risks, and systemic harms that undermine confidence in the governance of the food system.

Economic Harms

- *Consumers*

EMA cheats consumers. When consumers buy a product, they are entitled to receive the product they agreed to buy for the price they agreed to pay—the “benefit of the bargain.”⁸⁹ When a product is adulterated, consumers miss out on the full benefit of their bargains. This harm impacts all consumers who are seeking authentic food products for whatever the reason, including for health benefits or for pure enjoyment.

- *Honest Purveyors of Food*

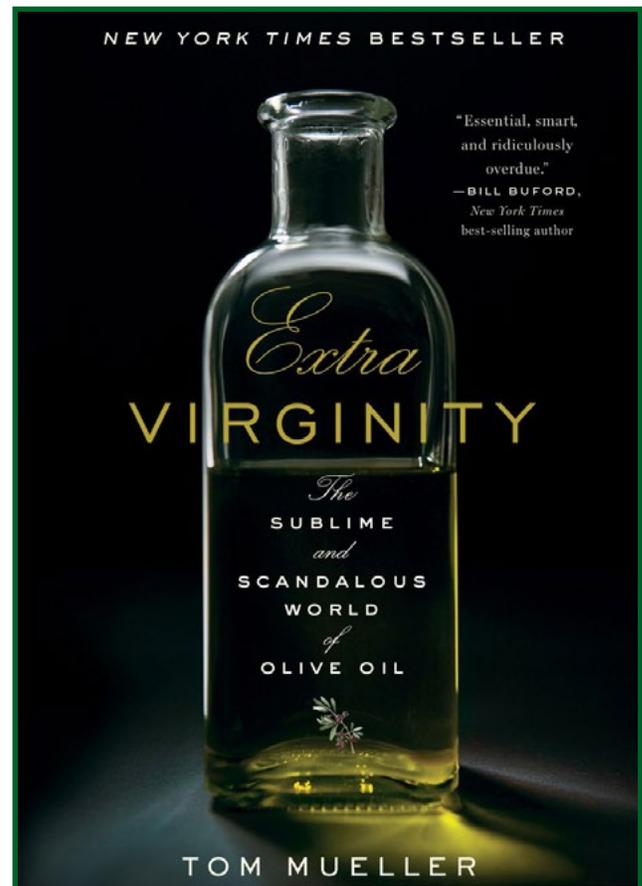
EMA also cheats honest purveyors of food. Consumers might buy a jar of honey on occasion, but food processors—companies that make more complex foods from several ingredients—buy it by the drum. They, too, lose the benefit of their bargain if the large quantities of food they buy are subject to EMA. If food producers have to compete with lower-priced frauds, they cannot make a living. Some forms of EMA are so rampant in some places that the fraudulent goods have been able to push honest producers out of the market because they cannot produce an honest product at a competitive price. In his bestselling book, *Extra Virginity: The Sublime and Scandalous World of Olive Oil*, author Tom Mueller explains this problem

in great detail as it relates to fraudulent extra virgin olive oil, a product commonly sold for prices below the price of honest production.⁹⁰ In order to compete in this and other markets, producers are compelled to participate in the “race to the bottom” or to leave the market entirely, in which case authentic food cannot be had at any price.

Food Safety Risks

- *Safety Incidents*

As previously noted, while EMA under Section 402(b) is distinctive from food safety adulteration under Section 402(a), in some cases EMA leads to serious food safety concerns. As observed by former FDA Commissioner David A. Kessler: “[i]n most cases of adulteration, it turns out to be just economic and nobody gets hurt—but there



Mueller, T. (2011). *Extra Virginity: The Sublime and Scandalous World of Olive Oil*. WW Norton & Company.

is always that potential.”⁹¹ It stands to reason that cheaters may not be very concerned about safety while adulterating a product for profit. The most obvious example is the melamine scandal in China, where the addition of melamine to infant formula resulted in hospitalizations and deaths of infants. Fraud was also a motive behind Peanut Corporation of America’s actions in connection with the Salmonella outbreak in 2009, which killed nine people and sickened 700.⁹²

A more recent example involves spices: since 2014, hundreds of food products containing “cumin” have been recalled due to undeclared peanut shells.⁹³ Although the source of the peanut shells appears to be Turkey, experts believe that cheap peanut and almond shells are being used secretly in place of cumin after a disastrous crop in India drove the spice’s price up.⁹⁴ While the shells themselves are not dangerous, they often come with pieces of peanut attached, which are potential hazards for consumers with peanut allergies.⁹⁵

Food Governance Harms

It stands to reason that non- or under enforcement against EMA undermines the credibility of government agencies entrusted to ensure the integrity and authenticity of food. This erosion of authority contributes to a growing cynicism of the modern food system and likely encourages further malfeasance and inappropriate risk-taking with food.

Many historians begin the story of modern EMA with Friedrich Accum and A Treatise on the Adulteration of Foods and Culinary Poisons, published in England in 1820.

Accum’s treatise exposed food fraud and marked how the Industrial Revolution increased the scope and sophistication of food fraud.

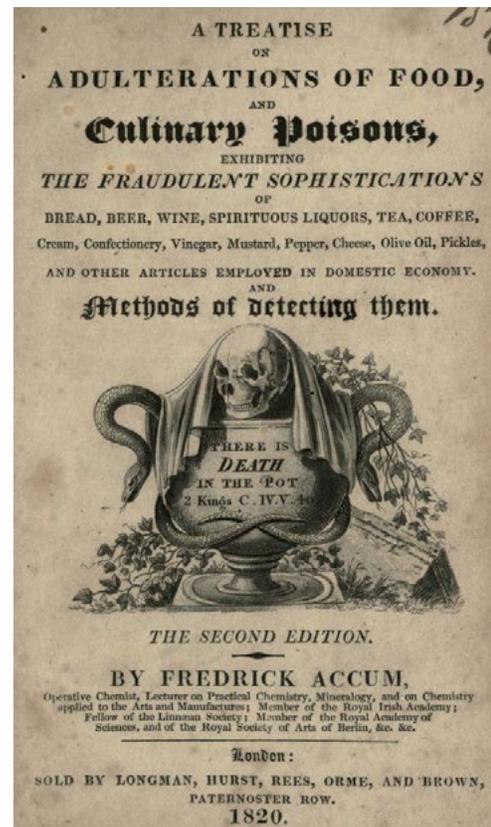


Image source: California Digital Library Internet Archive <https://archive.org/details/treatiseonadulte00accurich>

3. GOVERNMENT ENFORCEMENT AGAINST EMA

Government enforcement against EMA has changed over time in the US and abroad. Approaches have included criminal law and administrative regulation. The challenge for enforcement authorities has been to adapt to the growing sophistication of EMA and to prioritize enforcement of EMA, especially where there is no direct threat to the safety of the adulterated food. Today, enforcement is infrequent and ad hoc. What little enforcement activity there is has typically involved honest purveyors of food seeking address and not ordinary consumers who generally are not even aware of the fraud in the first place. This regulatory inertia is due to a lack of clarity about what constitutes EMA and a failure to prioritize EMA as a problem meriting enforcement in the interest of consumers.

Early Regulation

State Laws Banning Imitation Products

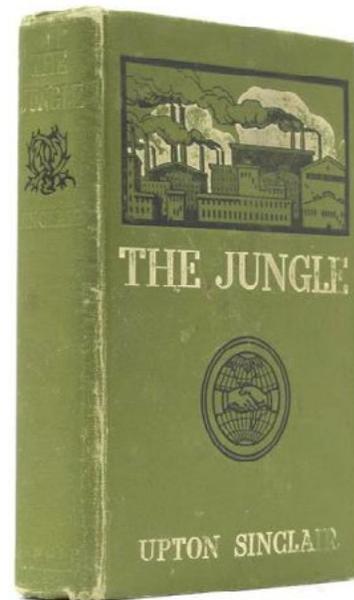
Throughout the nineteenth century, federal legislation of any kind against adulteration was rare, which left it to states to form food economic adulteration laws. A popular type of state law then concerned margarine, which is imitation butter made from vegetable oil or seed oils.⁹⁶ Before legislation banning the practice and long before comprehensive labeling laws, margarine producers dyed their products so that they could resemble—or sometimes pass for—authentic butter.⁹⁷ The Supreme Court upheld the constitutionality of these laws and the rights of states to regulate public health in this way in cases like *Capital City Dairy Co. v. Ohio*.⁹⁸

Criminal Enforcement of EMA under PFDA

In 1906, socialist muckraker Upton Sinclair published *The Jungle*, a book about the deplorable labor conditions in Chicago stockyards. In actuality, readers were appalled by the unsanitary conditions he described in the meatpacking industry. The ensuing public furor led to passage in 1906 of the PFDA and the FMIA, thus commencing the modern era of US food regulation.

“I aimed at the public’s heart and by accident hit it in the stomach.”

- Upton Sinclair



Sinclair, U. (1906). *The Jungle*. Doubleday, Page and Company.

Early enforcement of the 1906 PFDA involved frequent use of criminal misdemeanor provisions related to EMA. In *Schraubstadter v. United States*, defendants were convicted and fined \$300 each for three counts of shipping and selling carbonated wine labeled as champagne.⁹⁹ In *Union Dairy Co. v. United States*, the defendant was convicted for shipping milk diluted with water.¹⁰⁰ In *Frank v. United States*, the defendants were convicted and fined \$50 for shipping white pepper diluted with ground corn.¹⁰¹

Tapering off of Criminal Prosecution

Despite these cases and others like them,¹⁰² criminal prosecutions under the PFDA tapered off in the 1920s. One reason for the decrease was that the law failed to keep pace with new food technologies that rendered the adulteration of food more difficult to detect. Another reason is that regulators focused on prosecuting imitation products that were merely likely to mislead consumers, rather than the more typical forms of EMA, which resulted in courts curtailing the government's enforcement reach.¹⁰³ This limitation of prosecutorial authority was exemplified in the oft-cited case of *United States v. Ten Cases, More or Less, Bred Spread*, decided by the Eighth Circuit. The case involved fruit-based sandwich spread that was mostly sugar, water, and pectin and relatively low on actual fruit.¹⁰⁴ The government argued that Bred Spread was an imitation of jam, which was conventionally made of equal portions of sugar and fruit, so it had to be labeled "imitation" or it was misbranded.¹⁰⁵ The Eighth Circuit held that Bred Spread was not misbranded and did not have to be labeled an imitation because nothing on the label indicated that Bred Spread was anything other than Bred Spread.¹⁰⁶

FDCA Section 401: The Rise and Fall of Standards of Identity

Statutory Framework

The passage of the FDCA in 1938 was in part intended to remedy the perceived problem of imitation food as well as EMA in general. The principal approach under the FDCA

became the development of "standards of identity," which set out the formula or method of production required for certain foods defined by the FDA.¹⁰⁷

Section 401 of the FDCA gives the FDA broad authority to choose to develop these standards:

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container.¹⁰⁸

The enforcement provision for violating standards of identity is Section 403(g):

A food shall be deemed to be misbranded—
...
If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401 of this title, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.¹⁰⁹

Proliferation of Standards of Identity

From the enactment of the FDCA in 1938 through the 1960s, the FDA developed and enforced standards of identity for many staple foods.¹¹⁰ The result of this development effort is three hundred extant standards of identity in twenty food categories.¹¹¹

By far the largest category of food standards belongs to milk and milk products—a reasonable choice given both the centuries-long battle for safe, authentic milk

and the prevalence of dairy in the American diet.¹¹² The milk standard is extremely detailed: the “milk and cream” section of the Code of Federal Regulations is about thirty pages long and covers the range of acceptable additives for the whole spectrum of dairy products, including yogurt, buttermilk, sour cream, heavy cream, and even eggnog.¹¹³ The milk standard is extremely rigid, which is likely why milk is such a uniform product across brands and why milk EMA has become so rare in the US.

Criticism of Standards of Identity

Notwithstanding the success of standards of identity in preserving authentic categories of food, such as milk, the development of these standards by the 1970s began to lose favor with the FDA. Advances in preservatives, freezing, shipping, flavoring, and methods of cooking foods fundamentally altered the nature of artificial enhancement, and even without food technology, the variety of foods available to the modern consumer outstripped the ability of the FDA to develop standards.

The emerging view that the standards were too unwieldy and time consuming to develop was punctuated by the decade-long hearing on the identity of peanut butter that commenced in 1959 and took a decade to resolve.¹¹⁴ The issue began much earlier with the question of whether peanut butter could have ingredients other than peanuts; some people prefer peanut butter that is slightly sweetened, that does not separate, and that is easier to spread than peanuts-only peanut butter.¹¹⁵ By the time the FDA proposed developing a standard, some manufacturers sold peanut butters that were 20% non-peanut ingredients, including hydrogenated vegetable oils, which are far less expensive than peanuts and peanut oil.¹¹⁶ The FDA proposed a standard of 95% peanuts and 5% optional ingredients from a list of approved, common additives.¹¹⁷ The manufacturers of Skippy, Jif, and Peter Pan fought this proposal, and the process of public hearings, research, lobbying, and further standard development dragged out over the next ten years.¹¹⁸ The protracted process

convinced Congress and the FDA to alter many aspects of the development of new standards, but the practice never fully recovered.¹¹⁹

Any residual momentum of standards-making was grounded when Vice-President Al Gore expressed shock at learning that the FDA set forth precise standards for the shapes in which canned beans could be sold, spurring a 1995 advanced notice of proposed rulemaking to solicit comments on the viability of food standards.¹²⁰ Given the administrative and political ramifications, the FDA is no longer in the business of developing standards of identity.

The discontinuance of the development of standards of identity has not stopped a few producer groups—namely, honey and olive oil—from requesting federal standards of identity for their products lines in an attempt to eradicate EMA of imported honey and olive oil products. In 2011, on grounds that food standards are of limited use and do not benefit consumers, the FDA denied a citizen’s petition from US honey producers that requested the FDA to adopt a honey standard of identity established by the food international standards-setting body, Codex Alimentarius Commission.¹²¹ In 2012, the FDA denied a citizen’s petition by US olive oil producers to adopt an olive oil standard of identity established by the International Olive Council (IOC). It should be noted that Connecticut and California have elected to create their own standards for olive oil, including extra virgin olive oil, which follow the IOC standards.

It is important to remember that existing standards of identity for food are still enforceable law. This can cause some surprising problems for some food producers, such as when Hampton Creek received a warning letter from the FDA in August 2015, saying that the Just Mayo products, which are vegan mayonnaise substitutes, were misbranded because they did not meet the definition and standard of identity for mayonnaise.¹²² According to the FDA standard, eggs are required ingredients for mayonnaise.

Additional Enforcement Tools

In addition to fines and seizure actions for violations of the FDCA sections pertaining to EMA, honest purveyors of food in competition with cheaters have at their disposal a few other regulatory tools.

Import Alerts: FDCA Section 801

Import alerts can be an effective law enforcement mechanism for the FDA to use to prevent adulterated foods from entering the US. The FDA's authority over imported food is derived from Section 801 of the FDCA, which prescribes that a food may be refused entry into the US if it appears to be adulterated.¹²³ For example, an import alert was issued in 2009 for morel mushrooms, due both to microbial contamination and substitution of less valuable mushrooms for a portion of the morels.¹²⁴ Import alerts are the result of an administrative process, and they allow foods to be held at ports of entry without inspection.¹²⁵ Import alerts are public records and are accessible and searchable on the FDA's website.¹²⁶ While consumers conceivably could request an import alert on EMA product, the normal course of business is where a company impacted by the EMA requests the FDA to impose the alert on an offending importer.

Deceptive Advertising

Another tool for food companies harmed by EMA is to pursue a claim of deceptive advertising. An example of how this strategy works is seen through a matter involving imported Danisa® Traditional Butter Cookies, which allegedly had been diluted with an undisclosed fat ingredient, most likely a vegetable oil, Campbell Soup and its subsidiary Kelsen, Inc., argued in correspondence with FDA that use of a less expensive shortening in the butter cookies was EMA and use of the name "butter cookies" violated the standard of identity requirement that a "butter cookie" use only a butter shortening.¹²⁷ The National Advertising Division of the Council of Better Business Bureau (NAD), whose purpose it is to provide cost-effective resolution to disputes between market

competitors through voluntary enforcement mechanisms, upon request by Campbell, referred the "advertising" for the butter cookies to the FTC and FDA for further review.¹²⁸ FTC has the authority to stop "unfair methods of competition in commerce" and "unfair or deceptive acts or practices in commerce."¹²⁹ Arguably, EMA is an "unfair method of competition" and an unfair or deceptive act or practice;" however, the agency has deferred to the FDA in the handling of EMA. A Working Agreement established in 1954 between the FDA and FTC provides that unless the agencies otherwise agree, the FTC will exercise sole jurisdiction over all advertising of food and the FDA will exercise sole jurisdiction over all labeling of these products. It is likely that FTC regards EMA of food primarily as a deceptive labeling problem and thus an FDA problem, except, perhaps in cases like Danisa® Traditional Butter Cookies, where the advertising is clearly the issue.

Campbell could have brought a state claim in court against the distributor Takari (the cookies were manufactured in Indonesia and sold in packages that display Scandinavian imagery) or file a complaint directly with the FTC, but both of these paths can be cumbersome. Campbell also considered filing for an import alert, but this need was averted when Takari ceased to import the cookies into the US, presumably in response to NAD's finding that Takari had not brought its advertising into compliance with NAD's recommendations and subsequent referral of the advertising to the FTC and FDA.¹³⁰

FSMA: Focus on Safety not EMA

Heralded as the most significant food legislation in the US since the 1938 FDCA, the 2011 Food Safety Modernization Act (FSMA) introduced a new regime of food safety regulation. FSMA was passed in response to food safety concerns both to domestic and imported foods. In short, FSMA dramatically strengthened the FDA's commitment to a proactive and preventive approach to food safety.

Intentional Adulteration Provision

A provision in FSMA that dealt with intentional adulteration was initially viewed as a possible route for the FDA to develop rules on EMA; however, the provision was silent about its extension to EMA.¹³¹ Not too surprisingly, FDA's Final Rule that governs how intentional adulteration is regulated focused exclusively on what experts call "food defense."¹³² Food defense is the aspect of intentional adulteration that deals with hazards deliberately introduced to the food system, usually under political motivations, otherwise known as bioterrorism.¹³³

Preventive Controls Rule

When the FDA's Final Rule on intentional adulteration was published, the agency remarked that EMA would be handled under the food safety rule Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls

Rule). The problem with this approach, however, is that the Preventive Controls Rule focuses almost exclusively on food safety and the management of health hazards like pathogen contamination. These rules are important for food safety, but they treat EMA as a matter of regulation and enforcement only as an incidental threat to health. The Preventive Controls Rule does not address preventing EMA itself, only the health and safety hazards that may occur as a result of EMA.¹³⁴

EU Criminal Enforcement: Harbinger for the US?

Food Fraud Network

In contrast to the US approach, food fraud has become an international cooperative law enforcement agenda item in the UK and in the EU.¹³⁵ Spurred on by the



Public version of the Operation Opson IV report available at https://www.europol.europa.eu/sites/default/files/documents/report_opson_iv_public_version.pdf

horsemeat scandal in 2013, the EU established the Food Fraud Network, which is a database that operates among Member States, unifying the international approach to EMA.¹³⁶ The system is still in its early stages, but it may eventually serve to eliminate some of the problems of international transshipment of adulterated foods, at least those that flow through the EU.

Europol-Interpol Food Fraud Task Force

In some cases, EU member countries have begun acting aggressively to combat EMA: for example, Italy has stepped up its enforcement of strict criminal and civil penalties for olive oil frauds.¹³⁷ Europol and Interpol are now treating food fraud as a significant activity and source of revenue for transnational organized crime. Operation OPSON IV, the fourth iteration of the Europol-Interpol food fraud task force, resulted in the seizure of more than eleven thousand metric tons of fraudulent goods in 2015 by utilizing the cooperation of law enforcement agencies in forty-seven countries, including the US.¹³⁸

Status Quo: Minimal Enforcement Activity

Notwithstanding these various legal tools—standards of identity, import alerts, deceptive advertising claims, and the FSMA Preventive Control Rule—the prosecution of EMA is rare. Enforcement against EMA has not been a priority of the FDA or any other federal agency. Instead, EMA has been relegated as a second-tier form of adulteration that almost exclusively demands enforcement only when a food safety concern is at stake. Food companies and producer groups who are driven by market incentives to eliminate competitive food products that are adulterated in some cases after a lot of effort are able to mobilize the FDA to implement an import alert. Consumers are not so fortunate. Consumers are generally not even aware of the fraud being committed when they purchase and consume EMA food. Moreover, there is no specific formal mechanism for consumers to complain to the FDA about an EMA food product. When it comes to EMA food, the government in practice follows a laissez-

faire policy, especially when it comes to consumer interest.

4. LEGAL AND POLICY STRATEGIES

To remedy the problem of EMA food, this White Paper proposes five legal and policy strategies to be implemented by the government, the food industry, and consumer litigation.



Enforce Against EMA as Fraud: Putting the Consumers First

The FDA's failure to enforce against EMA food for the benefit of consumers is shortsighted and wrong given that the statutory thread that runs through FDCA Sections 401, 402, and 403 clearly obligates the FDA to do something more about EMA than wait for a food safety problem to arise. The FDA routinely regulates food where there is not a food safety or public health threat, as in the case of mislabeling. Moreover, the US Supreme Court has expressly acknowledged that the FDA is responsible under the FDCA to issue certain regulations to "promote honest and fair dealing in the interest of the consumer."¹³⁹

- *Treat EMA as Fraud*

EMA is by all definitions fraud and should be treated as such. The absence of a food safety consequence does not lessen the fraudulent nature of the offense. This type of fraud unabated invites an insidious form of criminality that turns into systematic fraud that is difficult to eradicate. As noted in the UK Elliott Review:

Concerns have been expressed during this review that the term food fraud creates an impression of some kind of low grade infraction of the law, of a harmless minor breach of technical regulations of the kind that many hard pressed businesses may be tempted to resort



HM Government

Elliott Review into the Integrity and Assurance of Food Supply Networks – Final Report

A National Food Crime Prevention Framework July 2014

Source: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/350726/elliott-review-final-report-july2014.pdf

to in difficult times. But the serious end of food fraud is organised crime, and the profits can be substantial. The recommendations in this report will not stop food crime, but are intended to make it much more difficult for criminals to operate in the UK.¹⁴⁰

Treating EMA as fraud would motivate the FDA and USD to prioritize the enforcement of EMA and to recognize its short-term and long-term consequences. These agencies should also follow the lead of the EU and develop a cooperative approach with other domestic and international law enforcement agencies and states in aggressive enforcement campaigns.

- *Put the Consumer First*

To facilitate the treatment of EMA as fraud, the FDA should embrace the concept advanced by the UK Elliott Review of putting the consumer first. Sparked by the horsemeat food fraud scandal in the UK, the report is a systems approach based on eight pillars of integrity. Although the pillars are interconnected, the one pillar that stands out for its novelty when applied as a norm to the food fraud problem is “Consumers First.” The preface to this pillar in the Elliott Review states: “Industry, Government and enforcement agencies should, as a precautionary principle, always put the needs of consumers above all other considerations,

and this means giving food safety and food crime prevention—i.e. the deterrence of dishonest behaviour—absolute priority over other objectives.”

Putting the consumer first will require that the FDA change its way of thinking about EMA. Too often the FDA does not view EMA in terms of the ultimate victim, both in economic and public health terms, which is the consumer. It is tempting for the FDA to view EMA solely as an economic cheat against an honest purveyor of food goods. In reality, the effect is much more pervasive. Putting the consumer first means that the FDA should define EMA with the consumer in mind, enforce vigorously against cheats in the food system, and communicate its efforts clearly and openly to consumers through the Internet, public service announcements, and social media.

Informing consumers of EMA will likely engage positive market responses favoring authenticity. For the market to respond, however, consumers have to want authentic food and be deliberate and vocal in their demands for authenticity. For consumers to demand authentic food, they need to know about food fraud in the first place and what factors lead to the likelihood of adulterants in foods. The growing food movement, evidenced by consumer interest in nutrition, local foods, and sustainability, makes it highly probable that consumers are interested in authentic food.



Define EMA More Completely

The FDA in collaboration with the USDA should define EMA. Although the definition advanced by the FDA's EMA Working Group validates that Section 402(b) adulteration is in fact economically motivated, it does not delineate the full scope of EMA or the nuances between the critical components or even the relationship between EMA and mislabeling.

- *Delineate EMA Components*

Defining EMA more expressly and completely would enable the FDA and the food industry to recognize more readily EMA, thereby allowing a more proactive approach in abating this fraud. A complete definition should capture the full range of adulteration components listed in the FDCA and distinguish between these components.¹⁴¹ It would be most helpful for the FDA to provide real and contemporary examples of what would constitute EMA, as this White Paper has attempted to do.

- *Send a message*

Providing a complete definition of EMA would also send a clear message to the food industry that the agency is serious about its statutory charge over all forms of EMA, not just EMA that raises food safety concerns. Food companies would evaluate more accurately their supply lines to ensure that their products do not violate sections 401 and 402(b).

- *Harmonization*

Given that EMA is a global menace and threat in the modern, global food system, a well-developed definition would help establish a regulatory bar that other countries could emulate and would facilitate global harmonization.



Develop High Priority List for Standards Making and Testing Strategy

A novel approach that would allow the FDA to conserve its resources and focus on the most persistent cases of EMA is to create a high priority list of food products most susceptible to EMA and to develop a strategy of testing and standards making. In addition to susceptibility, additional prioritization criteria should be consumer-based and not limited to food safety risks. This approach comports with the flexibility and prosecutorial discretion afforded by the FDCA EMA provisions.

- *Model high priority list after FSMA*

The development of a high priority list of EMA products could be modeled after the FDA's approach to high risk in food safety. Under FSMA, FDA identifies high-risk facilities and allocates resources to inspect registered facilities according to their risk profile, based on a number of food safety factors, including the known safety risks of the food manufactured, processed, packed, or held at the facility.¹⁴² FDA also inspects imported foods according to their risk profile, based on known safety risks of the imported food and of the countries or regions of origin and transport of the imported food.

- *Collaboration is key*

Developing a high priority list for EMA products could be accomplished by collaborating with credible sources, such as the USP food fraud database and the Oceana report on seafood fraud. The FDA could also confer with the USDA for possible inclusion of meat products on the list. The EMA high priority list could be refined over time through the collection of data by various means. A shared focus between the government, the food industry, and scientific organizations in obtaining data will lead to a better understanding as to the scope of the EMA problem and provide a clearer path forward to solutions. Within appropriate legal bounds, the government could provide a safe haven for food companies to self-report

and to collect and analyze data on EMA. Data could also be garnered from international sources, including the Codex Alimentarius Commission, foreign government agencies, and other credible institutions.

- *Standards, Testing, and Import Alert*

The FDA should develop standards of identity for these high priority products most susceptible to EMA and of most interest to consumers. These standards should be developed in connection with scientific bodies and other leading food testing laboratories that can help develop authenticity specifications. The FDA may find that some domestic producers, especially olive oil, spice, and honey producers, would cooperate enthusiastically with the agency in the development of standards due to their concern over imported EMA product. By utilizing the best science available, the standards should be sophisticated enough to deal with the complexities of authentication, but also flexible enough to accommodate variant imported product types.

The FDA should regularly test these high-priority products in accordance with sound science methods or develop a certification scheme where these products are tested and certified as authentic in accordance with the standard of identity. Once the high-priority EMA product meets a certain threshold of authenticity for a certain period of time, it could be removed from the priority list. At the same time, the FDA should vigorously work with industry to use the import alert tool when and where necessary against particular food companies, regions, or even, when appropriate, countries.

This focused approach would enable the FDA to enforce directly against the food products most susceptible to EMA and violative of consumer interests without having to implement new sweeping programs or rules for all food products that would drain agency resources.



Promote Authenticity as a Public Value

The Food Industry should explore using corporate social responsibility and voluntary standards (sometimes referred to as “soft law” or self-regulation) to create a social climate whereby food authenticity is diligently sought, measured, and validated by food enterprises.

- *Sustainability CSR precedence*

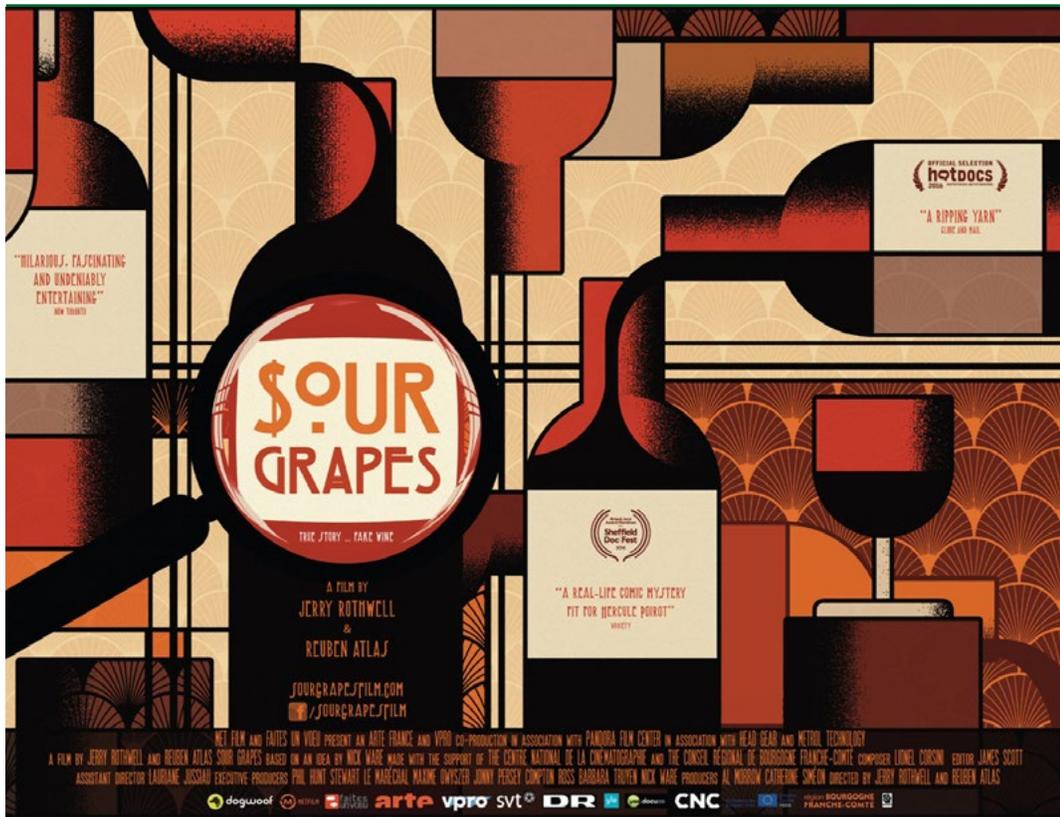
The good news is that there is precedence for this approach. In just the last decade, companies have moved from the non-acknowledgement of environmental impact of food production and manufacturing to vocal advocacy and corporate social responsibility (CSR) statements on sustainability and reducing the farm-to-fork carbon footprint.¹⁴³ Fifteen years ago, organic food in many grocery stores was a rarity, often set aside in its own tiny subsection of a produce aisle. Now, organics make up a huge chunk of the market, as do many products

“We understand that increasing numbers of consumers are seeking authentic, genuine food experiences...and we know that they are skeptical of the ability of large, long-established food companies to deliver them.”

**-Campbell Soup Co. CEO
Denise Morrison**

Source:

<http://fortune.com/2015/05/21/the-war-on-big-food/>



It is often the case where those who have resources—a competitor food and beverage enterprise or a wealthy connoisseur—are able to enforce against food fraud. For example, Rudy Kurniawan, who amassed a vast fortune in rare wines, was found to be engaged in a sophisticated wine fraud operation by Laurent Ponsot, the head of the Domaine Ponsot House, and Bill Koch, an American

billionaire, who found fake wine bottles in his collection and hired private detectives and filed a lawsuit. Finally, the FBI got involved and after a raid on Kurniawan's house, it was discovered that he had been taking cheaper wines and putting them in more expensive bottles or altering bottles to appear more valuable. In 2014, Kurniawan was sentenced to ten years in a California prison for wine fraud. A new documentary, Sour Grapes, revisits the story.

Image source: <http://www.sourgrapesfilm.com/gallery/> (c) Dogwoof Ltd. 2016

touting their GMO-free production. These sustainable concepts—reducing pesticides, avoiding GMOs, requiring environmental impact analyses—are production and market responses to values-driven consumer concerns. Sustainability now occupies a core piece of CSR for many food companies, becoming the basis in many instances for marketing and self-promotion on the part of these companies. Research demonstrates the positive effect of corporate sustainability on organizational processes and performance, giving credence to the adage, “do well by doing good.”¹⁴⁴

- *Elevation of authenticity as a value*

Authenticity of food could follow suit. Elevating authenticity to a value similar to that of sustainability in the food sector via CSR would result in food companies dedicated to producing food free of EMA. This form of internal self-regulation would mean that food companies will not tolerate adulteration of their products, and would prevent it by managing every step of production and distribution to eliminate the possibility of fraud.

The most thorough way to eliminate fraud at the enterprise level is a combination of vertical integration (where the company owns and controls every or nearly every aspect of food production, processing, packaging, and distribution) and independent audits (testing at each step and buying their own products off the retail shelf, then testing those to see if anything has been changed).¹⁴⁵ In the more likely scenario where the food manufacturer does not have the resources for vertical integration, they can ensure the authenticity of their products by assiduous attention to everyone involved with the food product before it reaches the consumer and, when possible, testing the end product for EMA.¹⁴⁶ In this manner, CSR is internal to the company, but it parallels the kind of activity one might expect from an external regulator. The food company gets the additional benefit of being able to market their self-regulation of fraud as a value in the same way they might market other values like premium quality, free trade, sustainability, and fair labor practices.



Improve Effective Use of Class-Action Litigation

Although litigation has proven thus far to be a limited tool in addressing EMA, consumer class actions and competitive lawsuits are a potentially important gap-filler tool in the absence of regulation and prosecution.

• *No private right of action under FDCA*

The FDCA does not include a private right of action to sue the FDA for enforcement of the FDCA, including its EMA-related provisions. The omission of this tool in the FDCA contrasts with its inclusion in the major environmental statutes enacted between 1970 and 1980, allowing private citizens and other interested stakeholders to bring suit against alleged violators of the statutes. These citizen-suit provisions introduce accountability into the regulation, as citizens or companies are able to take on the role of law enforcement by suing polluters and the government. Notwithstanding the application of private rights of action in federal environmental statutes, there is not any momentum to implement this tool in the FDCA.¹⁴⁷

• *Remedy for honest food companies: Lanham Act*

Due to the omission of a private right of action under the FDCA, honest food companies who hope for enforcement against food companies peddling EMA food product typically have to file a complaint with the FDA, which the agency may or may not pursue. Food companies can step into the shoes of consumers, however, via the Lanham Act, which allows for a company to sue another company for deceptive advertising.¹⁴⁸ In the recent case of *POM Wonderful v. Coca-Cola*, the US Supreme Court held that POM Wonderful was not precluded from suing Coca-Cola even when Coca-Cola had followed FDA regulations.¹⁴⁹ Thus, food companies may sue competitors for EMA even if the FDA is unwilling to take enforcement actions.

• *Remedy for consumers: class action litigation*

Absent a private right of action under the FDCA, consumers who purchase EMA products are left with suing adulterating food companies. Suing for EMA, however, requires being able to identify the adulteration in the first place, which can involve expensive tests, and the legal remedies available to successful litigants are minimal. The legal mechanism for overcoming at least the cost barrier to litigation against EMA is the collective class action, which allows consumers to sue together as a class a food company that has committed fraud.

In recent years, there has been an explosion of class action litigation over food labeling. For example, both “natural” claims and inventive ingredients like “evaporated cane juice” (otherwise known by its more conventional name, “sugar”) are being litigated in many states.¹⁵⁰ As a result of this litigation, some food manufacturers have changed their packaging, labeling, or ingredients. The cost of the litigation forces the company, to a degree, to internalize the cost of their practices: the individual consumers may only get a few dollars, but the settlement still costs the companies, which is a disincentive for further deceptions. That disincentive, along with the threat to the food product’s brand, has a market effect: other companies might not want to get sued for the same kinds of misbehavior.

The same enthusiasm for class actions over food labeling has not been extended to EMA. A lawsuit for EMA can be more complicated than a simple labeling claim for misrepresentation. In addition to finding a laboratory to verify the fraud, the plaintiffs' counsel must also deal with complicated global supply lines to determine the responsible party or parties. An ongoing case does show, perhaps, emerging interest in EMA litigation. In *Kumar v. Salov North America Corp.*, the plaintiff sued Salov, the maker of Filippo Berio brand olive oil, claiming violations of various California consumer protection statutes, common law fraud and deceit, breach of contract, and breach of the implied covenant of good faith and fair dealing. The plaintiff alleged Salov deceptively labeled its olive oil as "Imported from Italy" when the olives were not grown or pressed in Italy, and as "extra virgin" when the way the oil is bottled, transported, and stored allows it to degrade so that it may not be extra virgin by the time of sale or by the "best by" date. A federal district court in California allowed many of the putative false labeling claims against Salov to survive dismissal, suggesting, tentatively, that there may be a future for EMA litigation.¹⁵¹

Changes in the rules typically applied to class action litigation on food cases would strengthen this tool for actions against EMA. These changes involve the theory of damages, class certification, and class standing requirements.

- *Class Action Damages*

Adoption of what is known as the "full refund theory" would increase the amount of damages in an EMA case. Otherwise, even when plaintiffs win, the individual payoff can be nominal. It usually involves only the difference between what plaintiffs would have paid if they had known about the adulterant and what they actually paid—what's called the "benefit of the bargain."¹⁵² Some settlements end up giving litigants coupons for food from the company they sued.¹⁵³ This limited damages model is referred to as the premium model theory. If courts were to accept a full refund theory, requiring the food company to pay a full refund to the consumer for the product purchased—

as opposed to the premium model theory—then food companies would have a much larger incentive not to cheat.

- *Class Certification*

Another significant barrier to EMA class actions is ascertaining what portion of the consumer class received a food product that is different than they thought it would be. This difficulty makes it a challenge to certify a class under Federal Rule of Civil Procedure (FRCP) 23. This problem would be resolved if a presumption were adopted that every purchaser of a particular EMA product is harmed simply by purchasing a product where the manufacturing process creates a significant possibility of inauthenticity.¹⁵⁴ This presumption would, for example, circumvent the problem of having to obtain a sensory test, say on olive oil, for every class litigant. There likely would need to be some threshold for triggering the presumption; for example, a certain number of failed tests amongst a certain volume of food products.

How to implement this presumption, however, is problematic. The typical consumer protection statute does not have such a statutory presumption. A recent decision by the US Supreme Court in the case of *Tyson Foods, Inc. v. Bouaphakeo*, might encourage courts to create a presumption if the state statute is remedial in nature.¹⁵⁵ The Supreme Court held that a plaintiff class in a wage and hour case that sued for overtime under the Fair Labor Standards Act could rely on statistical evidence where it was impossible to prove that the class members met the overtime threshold due to a lack of time records.¹⁵⁶

Such an evidentiary presumption of liability based upon a representation sampling could have a similar dramatic impact in an EMA action. If a state were to adopt a similar presumption for EMA litigation, the presumption arguably could be applied at the federal level through FRCP 23. Also, *Tyson* suggests that a court could create the representational sampling presumption based on the remedial nature of a state consumer protection statute and its purposeful public policy.¹⁵⁷

- *Class Action Standing Requirements*

In class action lawsuits, “standing” can be one of the most fiercely litigated issues for a court to resolve in order for the suit to go forward. Under Article III of the U.S. Constitution, a plaintiff in a lawsuit has standing if he or she suffered “an injury in fact.” In EMA cases, the problem is that it is often not possible to test the specific fraudulent food product that the plaintiff consumer purchased because the consumer already consumed or discarded it. A practical solution to this problem would be for the plaintiff consumer to test similar products purchased from similar retail outlets; however, courts have held that in this scenario there is no evidence that the plaintiff consumer actually received the adulterated product and thus has no standing to sue.¹⁵⁸ In fact, a California district court has found that if a customer has paid a premium for an assurance that a food product meets certain standards, and the assurance turns out to be meaningless, the premium that the customer has paid is an actual, personal, particularized injury that is cognizable under Article III.¹⁵⁹

Authentic food is a social good that benefits consumers. Ensuring that the food supply is authentic is good governance. The pursuit of a food system that is authentic, as well as healthy and sustainable, should and can be achieved by implementing the legal and policy recommendations outlined in this report.

5. CONCLUSION

The purpose of this White Paper has been to identify and explain the problem of food fraud in the form of economically motivated adulteration and its relationship to the modern food system and to recommend legal and policy changes to address the problem. EMA has been treated as a second-tier adulteration that is viewed as a problem only if the fraud compromises the safety of the product. EMA has commanded attention as an economic crime when a particular food company’s economic interests are damaged due to the adulteration. It is rare, however, for EMA to be enforced against or prosecuted for the general welfare of ordinary consumers.

REFERENCES

- ¹ 4 WILLIAM BLACKSTONE, COMMENTARTIES 157.
- ² MICHAEL T. ROBERTS, FOOD LAW IN THE UNITED STATES 40 (2016).
- ³ *Id.* at 15-18.
- ⁴ Melamine Pet Food Recall – Frequently Asked Questions, U.S FOOD & DRUG ADMIN. (FDA).
- ⁵ FDA Notice of Public Meeting on Economically Motivated Adulteration, 74 Fed. Reg. 15,497 (April 6, 2009).
- ⁶ *Id.*
- ⁷ 21 U.S.C. § 342(b).
- ⁸ 21 U.S.C. § 601(m)(8).
- ⁹ 21 U.S.C. § 453(g).
- ¹⁰ RENÉE JOHNSON, CONG. RESEARCH SERV., R43358, FOOD FRAUD AND “ECONOMICALLY MOTIVATED ADULTERATION” OF FOOD AND FOOD INGREDIENTS 6 (2014) [hereinafter “CRS REPORT”], citing GROCERY MFERS. ASS’N, CONSUMER PRODUCT FRAUD: DETERRENCE, AND DETECTION (2010).
- ¹¹ *Id.*, citing U.S. Pharmacopeial Convention (USP), Food Fraud Database, Glossary of Terms.
- ¹² Jeffrey C. Moore et al., *Development and Application of a Database of Food Ingredient Fraud and Economically Motivated Adulteration from 1980 to 2010*, 77 J. OF FOOD SCIENCE [Moore], nr. 4 R118, R121 (2012).
- ¹³ Kimberly Warner et al., OCEANA STUDY REVEALS SEAFOOD FRAUD NATIONWIDE (Feb. 2013).
- ¹⁴ Karen Everstine et al., *Economically Motivated Adulteration (EMA) of Food: Common Characteristics of EMA Incidents*, 76 J. OF FOOD PROTECTION, nr. 4 723, 727 (2013).
- ¹⁵ *See generally* *Timeline on Horse Meat Issue*, FOOD STANDARDS AGENCY; *Q&A: Horsemeat Scandal*, BBC.COM (Apr. 10, 2013).
- ¹⁶ CRS REPORT, *supra* note 10, at 8, citing Moore, generally.
- ¹⁷ Yanzhong Huang, *The 2008 Milk Scandal Revisited*, FORBES (July 16, 2014, 10:46 AM).
- ¹⁸ *FDA Consumer Advice on Products Containing Ground Cumin with Undeclared Peanuts*.
- ¹⁹ Lydia Mulvany, *The Parmesan Cheese You Sprinkle on Your Penne Could Be Wood*, BLOOMBERG (Feb. 16, 2016, 5:00 AM EST).
- ²⁰ *E.g.* Karen Everstine, *Economically Motivated Adulteration: Implications for Food Protection and Alternate Approaches to Detection* 20 (May 2013) (unpublished Ph.D. dissertation, University of Minnesota) (citing Martin Hickman, *Chicken Injected with Beef Waste Sold in UK*, THE INDEPENDENT (June 3, 2009, at News:2); Paula Kurtzweil, *Fake Food Fight*, FDA CONSUMER (March-April 1999) (citing prosecution of executives of a seafood company that over-iced scallops).
- ²¹ *United States v. Beech-Nut Nutrition Corp.*, 871 F.2d 1181 (2d Cir. 1989).
- ²² Mulvany, *supra* note 19.
- ²³ Jeffrey C. Moore et al., *supra* note 12.
- ²⁴ *See generally* Tom Mueller, EXTRA VIRGINITY: THE SUBLIME AND SCANDALOUS WORLD OF OLIVE OIL (2012). The “omission” here is of two kinds: first, in a bottle of 100% refined olive oil, no extra virgin olive oil exists; and second, refining destroys most of the important, beneficial constituents of extra virgin oil that buyers often seek for their health benefits.
- ²⁵ *See Brod v. Sioux Honey Ass’n, Co-op.*, 927 F. Supp. 2d 811 (N.D. Cal. 2015), *aff’d* 609 Fed. Appx. 415 (9th Cir. 2015).
- ²⁶ *Questions and Answers of Melamine*, WORLD HEALTH ORGANIZATION (WHO).
- ²⁷ *See, e.g.*, María Roca et al., *Control of Olive Oil Adulteration with Copper-Chlorophyll Derivatives*, 58 (1) J. AGRIC. FOOD CHEM. 51 (2009).
- ²⁸ *E.g., U.S. v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914).
- ²⁹ MICHAEL T. ROBERTS, *supra* note 2, at 3.
- ³⁰ *See, e.g., Van Liew v. United States*, 321 F.2d 664 (5th Cir. 1963) (where the government conceded that defendant’s orange drink was just as healthy and palatable as freshly squeezed orange juice, but that the confusion caused by economic adulteration may result in dangers to health in some situations).
- ³¹ Intentional adulteration with the intent to cause harm falls under the category of “food defense” and covers a broad spectrum of activity. For more information about food defense, consider the FDA’s Food Defense category on their website (<http://www.fda.gov/food/fooddefense/>) or the many resources available from the Food Protection and Defense Institute at the University of Minnesota (<https://foodprotection.umn.edu/>).
- ³² Counterfeiting of food falls under 21 U.S.C. § 331, the list of prohibited acts under the FDCA. Counterfeiting is described as one of the forms of “misbranding” in § 343 of the Act, but there are other legal remedies and enforcement provisions elsewhere in US law that have much more severe penalties; counterfeiting is therefore usually treated under those provisions that guard trademark and other intellectual property rights.
- ³³ *See generally* Moore, *supra* note 12.
- ³⁴ *See generally* CRS REPORT, *supra* note 10.

- ³⁵ GROCERY MFRS. ASS'N ET AL., CONSUMER PRODUCT FRAUD: DETERRENCE AND DETECTION 1 (2010). The GMA report does not cite a source for its claim, and other sources cite the GMA report without following up on source information. Peer-reviewed articles from academics shy away from estimates, and most people deeply involved in EMA research say that it is extremely widespread and affects basically every food, but there is not enough data to support quantitative estimates.
- ³⁶ Everstine, *supra* note 14, at 724-25 (collecting studies, including: 2008 University of Guelph study comparing fish samples against DNA barcodes and finding 26% species substitution; a much larger study by one of those authors, finding 25% species substitution; a National Seafood Inspection Laboratory survey over nine years that found 37% species substitution; a Consumers Union study finding about one-third species substitution; and numerous other journal articles and prosecutions).
- ³⁷ *Id.* at 725.
- ³⁸ *Id.*
- ³⁹ Moore, *supra* note 12, at R121.
- ⁴⁰ Mueller, *supra* note 24.
- ⁴¹ *Id.*
- ⁴² *Id.*
- ⁴³ *Id.*
- ⁴⁴ See, e.g., Nayelli Quiñones-Islas et al., *Detection of adulterants in avocado oil by Mid-FTIR spectroscopy and multivariate analysis*, 51 (1) FOOD RESEARCH INT'L 148 (Apr. 2013) (describing ways to detect the adulteration of avocado oil with other edible oils, particularly sunflower, canola, and soybean).
- ⁴⁵ E.g. *Union Dairy Co. v. United States*, 250 F.2d 231 (7th Cir. 1918).
- ⁴⁶ 21 C.F.R. § 131.
- ⁴⁷ Liza Lin & Julie Cruz, *China's Parents Crave Illegally Imported Baby Formula*, BLOOMBERG (May 2, 2013, 3:56 PM EDT).
- ⁴⁸ See *Is There a Cheese Fraud Epidemic?*, QSR MAGAZINE (May 15, 2015); Lydia Mulvany, *The Parmesan Cheese You Sprinkle on Your Penne Could Be Wood*, Bloomberg (Feb. 16, 2016, 5:00 AM EST).
- ⁴⁹ Everstine, *supra* note 14, at 729.
- ⁵⁰ *Id.*
- ⁵¹ *Id.* at 728.
- ⁵² *Id.*
- ⁵³ *Id.*
- ⁵⁴ U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-96-18, FRUIT JUICE ADULTERATION: DETECTION IS DIFFICULT, AND ENHANCED EFFORTS WOULD BE COSTLY 1-4 (1995).
- ⁵⁵ Everstine, *supra* note 14, at 727.
- ⁵⁶ *Id.*
- ⁵⁷ *Italy cops seize 2,500 tons of false organic food*, BOSTON.COM (Dec. 7, 2011).
- ⁵⁸ Susan Berfield, *The Honey Launderers: Uncovering the Largest Food Fraud in U.S. History*, BLOOMBERG (Sept. 20, 2013 4:41 PM EDT).
- ⁵⁹ *Id.*
- ⁶⁰ Interview with Jeffrey Moore, Director, Science—Food Standards, US Pharmacopeial Convention, in Rockville, Md. (Aug. 5, 2015).
- ⁶¹ Berfield, *supra* note 58.
- ⁶² Everstine, *supra* note 14, at 727.
- ⁶³ *Id.* at 727, 725.
- ⁶⁴ *Id.* at 728 (“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.”).
- ⁶⁵ *Id.*
- ⁶⁶ *FDA Consumer Advice on Products Containing Ground Cumin with Undeclared Peanuts*, U.S. FOOD & DRUG ADMIN. (Feb. 23, 2015).
- ⁶⁷ Dan Charles, *Can You Trust That Organic Label on Imported Food?* NPR (July 23, 2014 6:14 PM ET); U.S. DEPT. OF AGRICULTURE, AGRICULTURAL MARKETING SERVICE, PESTICIDE RESIDUE TESTING OF ORGANIC PRODUCE (2012) (finding 43% of the 571 “organic” produce samples tested positive for prohibited pesticide due to either intentional mislabeling or inadequate protection from pesticide drift).
- ⁶⁸ CRS REPORT, *supra* note 10, at 37-8. See also Stephen F. Hamilton & David Zilberman, *Green markets, eco-certification, and equilibrium fraud*, 52(3) J. of Envtl. Econ. & Mgmt. 627 (Nov. 2006).
- ⁶⁹ See FREDERICK ACCUM, A TREATISE ON THE ADULTERATIONS OF FOOD, AND CULINARY POISONS 163-186 (1820).
- ⁷⁰ Everstine, *supra* note 14, at 729.
- ⁷¹ *Id.*
- ⁷² Karen Everstine & Jeffrey Moore, *Uncovering Product Vulnerability*, FOOD QUALITY & SAFETY (Dec. 12, 2014).

- ⁷³ *Id.*
- ⁷⁴ Anthony Kai-ching Hau et al., Melamine Toxicity and the Kidney, 20 J. AM. SOC. NEPHROLOGY 245, 245 (2009).
- ⁷⁵ Cf. e.g., James Neal-Kababick, *Screening for Melamine Adulteration in Protein-Based Foods by GC/MS*, FOOD SAFETY MAGAZINE.COM (Oct. 2012).
- ⁷⁶ *Possible Carcinogenic Protein Found in Chinese Dairy Products*, THE EPOCH TIMES (Oct. 1, 2015, 9:51 PM).
- ⁷⁷ Interview, Moore, *supra* note 60.
- ⁷⁸ Yanjun Zhang, et al., International Multidimensional Authenticity Specification (IMAS) Algorithm for Detection of Commercial Pomegranate Juice Adulteration, 57 (6) J. AGRIC. FOOD CHEM. 2250 (2009).
- ⁷⁹ *Id.*
- ⁸⁰ *Id.*
- ⁸¹ Everstine, *supra* note 14, at 730-31.
- ⁸² *Id.*
- ⁸³ See, e.g., Luís G. Dias, et al., *Single-cultivar extra virgin olive oil classification using a potentiometric electronic tongue*, 160 Food Chemistry 321, 322 (2014).
- ⁸⁴ Interview, Moore, *supra* note 60.
- ⁸⁵ *About USP*, U.S. PHARMACOPEIAL CONVENTION.
- ⁸⁶ *USP Food Ingredient Standards*, U.S. PHARMACOPEIAL CONVENTION.
- ⁸⁷ *Food Ingredient Reference Standards*, U.S. PHARMACOPEIAL CONVENTION.
- ⁸⁸ Dias, *supra* note 83.
- ⁸⁹ E.g. RESTATEMENT (SECOND) OF TORTS § 549 cmt. I (1977).
- ⁹⁰ Mueller, *supra* note 24.
- ⁹¹ Diana B. Henriques, *10% of Fruit Juice Sold in the U.S. Is Not All Juice, Regulators Say*, NY TIMES (Oct. 31, 1993).
- ⁹² CRS REPORT, *supra* note 10.
- ⁹³ *FDA Consumer Advice on Products Containing Ground Cumin with Undeclared Peanuts*.
- ⁹⁴ Ted Agres, *The Cumin Scandal: Accidental or Fraudulent*, FOOD QUALITY AND SAFETY (Mar. 17, 2015).
- ⁹⁵ *Id.*
- ⁹⁶ E.g. *Yellow margarine: I Can't Believe It's Not Legal!*, USA TODAY (Dec. 16, 2008, 6:02 PM).
- ⁹⁷ *Id.*
- ⁹⁸ *Capital City Dairy Co. v. Ohio*, 183 U.S. 238 (1902).
- ⁹⁹ *Schraubstadter v. United States*, 199 F. 568 (9th Cir. 1912).
- ¹⁰⁰ *Union Dairy Co. v. United States*, 250 F. 231 (7th Cir. 1918).
- ¹⁰¹ *Frank v. United States*, 192 F. 864 (6th Cir. 1911).
- ¹⁰² See e.g., *United States v. Ninety-Five Barrels More or Less Alleged Apple Cider Vinegar*, 265 U.S. 438 (1924).
- ¹⁰³ Wallace F. Janssen, *The Story of the Laws Behind the Labels*, FDA CONSUMER (June 1981).
- ¹⁰⁴ *United States v. Ten Cases, More or Less, Bred Spread*, 49 F.2d 87, 89 (8th Cir. 1931).
- ¹⁰⁵ *Id.* at 90.
- ¹⁰⁶ *Id.*
- ¹⁰⁷ Janssen, *supra* note 103.
- ¹⁰⁸ 21 U.S.C. § 341.
- ¹⁰⁹ 21 U.S.C. § 343.
- ¹¹⁰ Janssen, *supra* note 103.
- ¹¹¹ See 21 C.F.R. §§ 130-169.
- ¹¹² 21 C.F.R. § 131.
- ¹¹³ *Id.*
- ¹¹⁴ *Food Standard Innovations: Peanut Butter's Sticky Standard*, FDA (Apr. 14, 2009).
- ¹¹⁵ *Id.*
- ¹¹⁶ *Id.*
- ¹¹⁷ *Id.*
- ¹¹⁸ *Id.*
- ¹¹⁹ *Id.*
- ¹²⁰ MICHAEL T. ROBERTS, *supra* note 2, at 48.
- ¹²¹ *Id.*
- ¹²² Warning Letter from FDA to Joshua Tetrick, Founder and CEO of Hampton Creek (Aug. 12, 2015).
- ¹²³ 21 U.S.C. § 381.

- ¹²⁴ Detention without Physical Examination of Morel Mushrooms due to Adulteration and Substitution, Food and Drug Administration, FDA Import Alert 25-02 (March 18, 2011)
- ¹²⁵ *Id.*
- ¹²⁶ *Import Alerts*, FDA website (http://www.accessdata.fda.gov/cms_ia/default.html).
- ¹²⁷ Correspondence from Steven H. Armstrong, Chief Food Law Counsel for Campbell Soup Company to William H. Correll, Director of Office of Compliance, Center for Food Safety and Applied Nutrition, FDA (Mar. 17, 2015).
- ¹²⁸ NAD, *NAD Refers Advertising for 'Danish' Butter Cookie Made in Indonesia to FDA*, FTC for Further Review (Nov. 19, 2015).
- ¹²⁹ See 15 U.S.C. § 45(a)(1)-(2) and 15 U.S.C. § 45.
- ¹³⁰ Interview with Steven H. Armstrong, former Chief Food Law Counsel for Campbell Soup, in Los Angeles, CA (Feb. 2, 2017).
- ¹³¹ John Spink, *Review: Final Rules for FSMA 'Third-Party Certification,' 'Foreign Supplier Verification,' and 'Produce Rule' Regarding Food Fraud and EMA*, MICHIGAN STATE UNIVERSITY FOOD FRAUD INITIATIVE (Jan. 28, 2016).
- ¹³² Riëtte van Laack, *And Then there Were Seven: FDA Issues the Final Rule on Intentional Adulteration of Food; the Last Required by FSMA*, FDA LAW BLOG (May 31, 2016).
- ¹³³ *Id.*
- ¹³⁴ MICHAEL T. ROBERTS, *supra* note 2, at 51-52.
- ¹³⁵ AGAINST ORGANIZED CRIME: INTERPOL TRAFFICKING AND COUNTERFEITING CASEBOOK 2014, INTERPOL (2014).
- ¹³⁶ Food Fraud, European Commission, http://ec.europa.eu/food/safety/official_controls/food_fraud/index_en.htm.
- ¹³⁷ Elisabetta Povoledo, *Italy Moves to Toughen Penalties for Olive Oil Fraud*, NY TIMES (Mar. 1, 2016).
- ¹³⁸ *Record Seizures of Fake Food and Drink in Interpol-Europol Operation*, EUROPOL (Feb. 16, 2015).
- ¹³⁹ *62 Cases, More of Less, Each Containing Six Jars of Jam v. United States*, 340 U.S. 593, 596 (1951).
- ¹⁴⁰ ELLIOTT REVIEW INTO THE INTEGRITY AND ASSURANCE OF FOOD SUPPLY NETWORKS, HM GOVERNMENT (July 2014).
- ¹⁴¹ A GAO report on EMA reports that “A senior FDA official told us there is value in making a distinction between economic adulteration and other forms of adulteration to guide the agency’s thinking about how to be more proactive in addressing this issue.” U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-12-46, FOOD AND DRUG ADMIN., BETTER COORDINATION COULD ENHANCE EFFORTS TO ADDRESS ECONOMIC ADULTERATION AND PROTECT THE PUBLIC HEALTH (2011).
- ¹⁴² FSMA adds a new Section 421 to the FDCA (21 U.S.C. § 350j).
- ¹⁴³ Sammi Caramela, *What is Corporate Social Responsibility?*, BUSINESS NEWS DAILY (June 19, 2015 10:12 AM EST).
- ¹⁴⁴ Eccles, R., Ioannou, I., and Serafeim G., “The Impact of a Corporate Culture of Sustainability on Corporate Behavior and Performance,” Harvard Business School, Working Paper 12-035, November 2011
- ¹⁴⁵ USP, *Appendix XVII: Guidance on Food Fraud Mitigation*, US Pharmacopeia (Dec. 2014).
- ¹⁴⁶ See *id.*; see also Marc S. Reisch, *Momentum Builds to Keep Fraudulent Food Off of Store Shelves*, 92 (34) CHEMICAL & ENGINEERING NEWS 8 (Aug. 25, 2014).
- ¹⁴⁷ MICHAEL T. ROBERTS, *supra* note 2, at 36.
- ¹⁴⁸ See *POM Wonderful v. The Coca-Cola Co.*, 134 S. Ct. 2228 (2014).
- ¹⁴⁹ *Id.*
- ¹⁵⁰ David Schultz, *Evaporated Cane Juice: Sugar in Disguise?*, NPR, Oct. 18, 2012, 2:06 PM; Annie Wu, *What Does a 'Natural' Label Really Mean? Lawsuits Claim False Advertising*, EPOCH TIMES, June 22, 2015 (9:16 PM).
- ¹⁵¹ *Kumar v. Salov N. Am. Corp.*, Case No. 14-CV-2411-YGR (N.D. Cal., Feb 3, 2015).
- ¹⁵² *E.g.* RESTATEMENT (SECOND) OF TORTS § 549 cmt. 1 (1977).
- ¹⁵³ Michelle Singletary, *Class-action coupon settlements are a no-win for consumers*, WASHINGTON POST, Apr. 27, 2011.
- ¹⁵⁴ Interview with Adam Gutride, attorney for plaintiff in *Kumar v. Salov North America Corp.*, in Los Angeles (Sept. 12, 2016).
- ¹⁵⁵ *Tyson Foods, Inc. v. Bouaphakeo et al.*, 136 S. Ct. 1036 (2016).
- ¹⁵⁶ *Id.* at 1046.
- ¹⁵⁷ *Id.*
- ¹⁵⁸ See *Wallace v. ConAgra Foods, Inc.* 747 F.3d 1025, 1031-31 (8th Cir. 2014) (holding that customers lacked Article III standing to bring a claim based on allegedly false advertising of a product as using 100% kosher beef, where the plaintiffs could not show that the specific products they purchased contained non-kosher beef).
- ¹⁵⁹ See *McCoy v. Nestle USA, Inc.*, No. 15-CV-04451-JCS, 2016 WL 1213904, at 8 (N.D. Cal. Mar. 29, 2015).