

# Food Fraud and the Food, Drug, and Cosmetic Act: Bridging a Disconnect

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## ABSTRACT

To protect society’s food supply, the term food fraud should be replaced with the term food adulteration when used by the crusaders against food fraud. The term food fraud causes confusion from a legal perspective because it requires an *intent* to harm in order to take any protective and enforcement measures. This is backwards and needs to be corrected. Replacing food fraud with food adulteration will remove scienter as an element and replace it with a strict liability standard, so that when the food supply is harmed, that alone is enough to take action against the perpetrator of the harm. There is too much at stake when it comes to society’s health, businesses, and cultural requirements to permit a higher standard, specifically one that requires intent. Protecting society’s food supply includes many definitions. For this article, I suggest the crusaders against food fraud adopt the term food adulteration as the umbrella term that includes economic adulteration, food fraud, economically motivated adulteration, and food terrorism (food defense). I also suggest FDA eliminate its working definition of economic adulteration and revert to the definition of adulteration found in statute.

Each term is individually defined in the chart below; however, generally, the word “adulterate” is defined as “to corrupt, debase, or make impure by the addition of a foreign or inferior substance or element *especially*: to prepare for sale by replacing more valuable with less valuable or inert ingredients.”<sup>1</sup>

Food Adulteration (umbrella term)	Refers to any change in a food product that a consumer is unaware of regardless of intent.
Economic Adulteration	A type of food adulteration; a change to a food product that a consumer is unaware of that results in economic gain whether intentional or unintentional. *While economic adulteration is not a substitute for food adulteration (the two are distinct), economic adulteration is specifically described in this article because of its statutory and caselaw presence and because of its close meaning to food adulteration where adulteration itself is emphasized.

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<sup>1</sup> MERRIAM-WEBSTER DICTIONARY, <https://www.merriam-webster.com/dictionary/adulterate> (last visited Nov. 12, 2018) [<https://perma.cc/X7X3-MYHP>] (emphasis added).

Food Fraud	An intentional change in a food product that a consumer is unaware of with the purpose to deceive consumers – whether to cause harm or to economically benefit.
Economically motivated adulteration	An <i>intentional</i> change in a food product that a consumer is unaware of for economic gain.
Food terrorism (food defense)	The intentional change in a food product that a consumer is unaware of to cause intentional harm on consumers.

## INTRODUCTION

In 2013, the United Kingdom and Ireland recalled ten million pounds of hamburger marketed as “100% beef” when nearly one-third of the hamburger supply consisted of horsemeat; this event was aptly referred to as “Horsegate.”<sup>2</sup> Environment Secretary Owen Paterson stated that evidence suggested this was not accidental but instead a result of “either criminal activity or gross negligence,” and one supply chain victim stated this was even possibly “a serious case of fraud” targeting suppliers and consumers economically.<sup>3</sup> “Horsegate” occurred during the recession, a time when beef prices soared and supermarkets simultaneously sought lower prices for meat products to satisfy their economy-minded customers.<sup>4</sup> Cultural norms and attitudes in the U.K. (and the U.S.) dictate that horses are not to be eaten, and thus, the “Horsegate” incident undermined consumer confidence in supermarkets.<sup>5</sup> Customers bought and ate what they believed to be something it was not and paid more for it than they would have had they known what it was (or would not have purchased it in the first place).<sup>6</sup>

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<sup>2</sup> Food Safety Authority of Ireland, *FSAI Survey Finds Horse DNA in Some Beef Burger Products*, NEW FOOD (Jan. 15, 2013), <https://www.newfoodmagazine.com/news/9626/fsai-survey-finds-horse-dna-in-some-beef-burger-products/> [<https://perma.cc/A55L-MCYE>]; James Andrews, *Horsemeat Scandal in UK and Ireland Prompts Massive Recall*, FOOD SAFETY NEWS (Jan. 28, 2013), <https://www.foodsafetynews.com/2013/01/horse-meat-scandal-in-uk-and-ireland-prompts-massive-recall/> [<https://perma.cc/CNH3-EQF9>].

<sup>3</sup> Josh Levs & Per Nyberg, *Battle Over Blame After Horse Meat Found in Beef Products*, CNN (Feb. 15, 2013), <https://www.cnn.com/2013/02/10/world/europe/uk-horsemeat-probe/index.html> [<https://perma.cc/5DWN-AD33>].

<sup>4</sup> Felicity Lawrence, *Horsemeat Scandal: The Essential Guide*, THE GUARDIAN (Feb. 15, 2013), <https://www.theguardian.com/uk/2013/feb/15/horsemeat-scandal-the-essential-guide-104> [<https://perma.cc/C65X-P4S7>].

<sup>5</sup> Tests revealed that an antibiotic administered to horses called bute, that is unfit for human consumption, was present in six percent of the tested carcasses. See James Gallagher, *Horsemeat Scandal: Bute Found in Eight Horse Carcasses*, BBC NEWS (Feb. 14, 2013), <http://www.bbc.com/news/uk-21455419> [<https://perma.cc/3PZK-5HBP>]; see also European Commission, *Horse meat (2013-14)*, [https://ec.europa.eu/food/safety/official\\_controls/eu-co-ordinated-control-plans/horse\\_meat\\_en](https://ec.europa.eu/food/safety/official_controls/eu-co-ordinated-control-plans/horse_meat_en) [<https://perma.cc/SCM3-3YNR>].

<sup>6</sup> Ben Morris, *Horsemeat Scandal: How Tastes Changed*, BBC NEWS (Jan. 14, 2014), <http://www.bbc.com/news/business-25715666> [<https://perma.cc/C65X-P4S7>]; *Why are the British Revolted by the Idea of Horsemeat?*, BBC NEWS (Jan. 18, 2013), <http://www.bbc.com/news/magazine-21043368> [<https://perma.cc/FDC4-RQXZ>].

Honey is often adulterated so much so that a whole new honey-like product now stocks supermarket shelves, though still labeled as pure honey.<sup>7</sup> To our ignorant palettes, this new product is a perfect imitation of pure honey because it is still sweet, but it is wholly or partially made from cheap syrups such as high fructose corn syrup or glucose.<sup>8</sup> The implications of faux honey reach far beyond ignorant palettes and a few consumers' wallets. In 2001, the United States imposed anti-dumping tariffs on China for dumping Chinese-originated honey, adulterated with fillers, on the United States market at far less than fair market value, which drove many United States beekeepers out of business or into bankruptcy.<sup>9</sup> In 2016, Homeland Security Investigations (HSI) seized 60 tons of illegally imported Chinese honey worth \$200,000.<sup>10</sup> And in 2008, Chicago HSI and the Department of Justice "convicted nine

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<sup>7</sup> According to scientific honey detection tests (one of them being the "C3 Test"), pure honey registers specific levels of carbon and amino acids. See Sonia Soares, *A Comprehensive Review on the Main Honey Authentication Issues: Production and Origin*, 16 COMPREHENSIVE REVIEWS IN FOOD SCI. & FOOD SAFETY 1072, 1072–73 (2017); ROTTEN: LAWYERS, GUNS, AND HONEY (Netflix 2018) [hereinafter ROTTEN]. These specific levels are what give honey its natural sweet taste and its medicinal properties. See *Fake Food*, GASTRO POD (June 6, 2017), <https://gastropod.com/fake-food/> [<https://perma.cc/Z43V-KDSS>].

<sup>8</sup> This new honey product does not register the same carbon and amino acid levels because it is not pure honey. Hank Campbell, *Fake Honey is a Problem and Science Can Solve It—If Government Gets Out of the Way*, AMERICAN COUNCIL ON SCIENCE AND HEALTH (Jan. 17, 2018), <https://www.acsh.org/news/2018/01/17/fake-honey-problem-and-science-can-solve-it-if-government-gets-out-of-the-way-12429> [<https://perma.cc/8778-PWB8>]; Larry Olmstead, *Exclusive Book Excerpt: Honey Is World's Third Most Faked Food*, FORBES (July 15, 2016), <https://www.forbes.com/sites/larryolmsted/2016/07/15/exclusive-book-excerpt-honey-is-worlds-third-most-faked-food/-57cdd4614f09> [<https://perma.cc/7PL9-QWYC>]. See also Patrick Boehler, *China's Next Food Scandal: Honey Laundering*, SOUTH CHINA MORNING POST (June 19, 2013), <http://www.scmp.com/news/china/article/1264335/chinas-next-food-scandal-honey-laundering> [<https://perma.cc/WA4B-46H5>]. Some products labeled as honey contain no honey. Today's demand for honey is at an all-time high, and it is one in which supply cannot keep pace, yet somehow, it does. In fact, when honey production dropped in the U.S. and demand increased, supply somehow also increased. See Kim Flottum, *Imports, Exports, Production and Consumption from 2016*, BEE CULTURE (Apr. 24, 2017), <http://www.beeculture.com/u-s-honey-industry-report-2016/> [<https://perma.cc/58AF-L2AJ>]; ROTTEN, *supra* note 7.

<sup>9</sup> Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order; Honey From the People's Republic of China, 66 Fed. Reg. 63,670 (Dec. 10, 2001) (to be codified at 19 C.F.R. pt. 351); News Release, U.S. Immigration and Customs Enforcement, HSI Chicago seizes nearly 60 tons of honey illegally imported from China, (May 5, 2016), <https://www.ice.gov/news/releases/hsi-chicago-seizes-nearly-60-tons-honey-illegally-imported-china> [<https://perma.cc/7VQH-TEU9>] [hereinafter ICE News Release]; ROTTEN, *supra* note 7. As a result, the U.S. imposed tariffs on Chinese honey at three times the price sold. See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order; Honey From the People's Republic of China, 66 Fed. Reg. 63,670 (Dec. 10, 2001) (to be codified at 19 C.F.R. pt. 351). In response, China strategically shipped its adulterated honey to other countries such as Vietnam and Malaysia, where it was re-labeled in a way that indicated it originated from these countries and was then imported into the United States. See Andrew Schneider, *Asian Honey, Banned in Europe, is Flooding U.S. Grocery Shelves*, FOOD SAFETY NEWS (Aug. 15, 2011), [http://www.foodsafetynews.com/2011/08/honey-laundering/-WvG\\_49MvxTY](http://www.foodsafetynews.com/2011/08/honey-laundering/-WvG_49MvxTY) [<https://perma.cc/4VNU-MCA7>]. This was later referred to as "honey-laundering," and these countries are now known as "puddle points." The United States knows Malaysia cannot physically produce the amount of honey they export; the honey is "puddled" in Malaysia with honey from China to be then sent to the United States. See Karen Everstine et al., *Economically Motivated Adulteration (EMA) of Food: Common Characteristics of EMA Incidents*, 76 J. OF FOOD PROTECTION 723, 727 (2013); ROTTEN, *supra* note 7. The Chinese-originated honey followed a "drug dealer's playbook" when tests revealed pure honey cut with added fillers. See ROTTEN, *supra* note 7.

<sup>10</sup> ICE News Release, *supra* note 9. Smugglers shipped 195 barrels of honey into the U.S. and falsely declared them as originating in Vietnam. See Alan Harman, *Catch the Buzz—Chinese Honey Illegally Imported, Again, Labeled as From Vietnam*, BEE CULTURE (May 20, 2016),

individuals . . . in a series of global schemes”<sup>11</sup> in which nearly \$180 million in anti-dumping duties were evaded when illegally imported Chinese honey surreptitiously entered the United States honey market.<sup>12</sup> This had a huge economic impact in the United States where many beekeepers faced economic ruin as a result of these Chinese importers’ actions.<sup>13</sup> Here, unfair competition caused serious economic harm to American enterprises.

In Italy, organized crime (popularly known as the *Agromafia*) acts as the conduit for nearly the entire supply chain for extra-virgin olive oil, cured meat, cheese, and wine.<sup>14</sup> In a crackdown of what is estimated to be a \$16 billion per year industry, Italy’s “FBI of Food” seized over 59,000 tons of food for poor quality and solvent and pesticide residue contamination.<sup>15</sup> At least half of the extra-virgin olive oil bottles sold

<http://www.foodsafetynews.com/2011/08/honey-laundering/> - .WvG\_49MvxTY [<https://perma.cc/Y8FW-HZN8>].

<sup>11</sup> ICE News Release, *supra* note 9.

<sup>12</sup> News Release, U.S. Department of Justice U.S. Attorney’s Office Northern District of Illinois, Two Companies and Five Individuals Charged With Roles In Illegal Honey Imports; Avoided \$180 Million In Anti-Dumping Duties (Feb. 20, 2013), <https://www.justice.gov/usao-ndil/pr/two-companies-and-five-individuals-charged-roles-illegal-honey-imports-avoided-180> [<https://perma.cc/ZG8Y-22RS>]. The adulterated Chinese-honey contained an antibiotic (chloramphenicol) prohibited for human consumption that was traced from a German Company, Alfred L. Wolff Inc., through Russia and imported into the U.S. See Press Release, U.S. Department of Justice U.S. Attorney’s Office Northern District of Illinois, Two Chicago Executives of German Food Firm Arrested On Federal Charges For Allegedly Conspiring to Import Honey From China Containing An Antibiotic (May 27, 2008), [https://www.justice.gov/archive/usao/iln/chicago/2008/pr0527\\_02.pdf](https://www.justice.gov/archive/usao/iln/chicago/2008/pr0527_02.pdf) [<https://perma.cc/N78V-ZCDM>]. Alfred L. Wolff operated out of its Chicago office, and employees knew and intentionally sold the antibiotic infused Chinese-honey into the U.S. honey market. See Mike Hughlett, *New Charges in ‘Honey-Laundering’ Investigation*, CHICAGO TRIBUNE (May 7, 2009), [http://articles.chicagotribune.com/2009-05-07/news/0905060623\\_1\\_honey-laundering-federal-investigators](http://articles.chicagotribune.com/2009-05-07/news/0905060623_1_honey-laundering-federal-investigators) [<https://perma.cc/8U5T-K72G>].

<sup>13</sup> ROTTEN, *supra* note 7. Manuka Honey, a trendy honey ripe for adulteration, touts itself as being a honey especially high in antibacterial elements. It is found only in New Zealand and is produced from the bee-pollinated Manuka bush. See *Manuka Honey*, WEBMD, <https://www.webmd.com/a-to-z-guides/manuka-honey-medicinal-uses-1> (last visited May 6, 2018) [<https://perma.cc/239P-S33U>]. It is more expensive than those honeys deemed pure because of its healing properties. See Justina Huddleston, *Catch the Buzz—Is Trendy Superfood Manuka Honey Actually Worth Its Price Tag?*, BEE CULTURE (March 22, 2018), <http://www.beeculture.com/catch-buzz-trendy-superfood-manuka-honey-actually-worth-price-tag/> [<https://perma.cc/X5D4-Q2AH>]. Yet, many consumers do not know about the Manuka bush or that it can only be found in New Zealand. See Olmstead, *supra* note 8. If the label reads “Manuka,” then the consumer expects to consume true Manuka honey. If this honey is diluted, then many of those healing properties are removed as the amino acid content is lowered due to dilution. See ROTTEN, *supra* note 7.

<sup>14</sup> Eric Kulisch, *Compliance 360: Italy’s ‘Agromafia’ and Exports*, AMERICAN SHIPPER (Feb. 2, 2016), <https://www.americanshipper.com/main/news/compliance-360-italys-agromafia-and-exports-62865.aspx> [<https://perma.cc/7H5E-8H97>]; *‘Agromafia’: the Italian Food Mafia*, RN BREAKFAST (Jan. 6, 2016), <http://www.abc.net.au/radionational/programs/breakfast/agromafia-the-italian-food-mafia/7070200> [<https://perma.cc/9LWA-R9T2>].

<sup>15</sup> In an effort to fight back against the *Agromafia*, Italy created a panel of food experts certified by the International Olive Oil Council to certify the authenticity of food, one of those foods being extra virgin olive oil. See *60 Minutes: Agromafia* (CBS television broadcast Jan. 3, 2016) (transcript available at <https://www.cbsnews.com/news/60-minutes-agromafia-food-fraud/>) [<https://perma.cc/A4JT-M5TA>]. With a taste, panelists can tell whether an olive oil meets the official sixteen taste flaws and with that, whether an extra virgin olive oil is diluted with inferior products. See Tom Mueller, *Slippery Business: The Trade in Adulterated Olive Oil*, THE NEW YORKER (Aug. 13, 2007), <https://www.newyorker.com/magazine/2007/08/13/slippery-business> [<https://perma.cc/5WJJ-UKX8>]; see also Olive Oil Staff, *‘Extra Virginity’ Author, Tom Mueller, On Olive Oil*, OLIVE OIL TIMES (Nov. 27, 2015), <https://www.oliveoiltimes.com/olive-oil-basics/extra-virginity-author-tom-mueller-on-olive-oil/49827> [<https://perma.cc/K25J-HPY5>]. In addition to this panel, local farmers are revolting against the *Agromafia* all across Italy. In Sicily, one man

in Italy's supermarkets do not meet Italy's legal grade for extra-virgin olive oil, and under United States' standards, that percentage increases to seventy-five percent to eighty percent by conservative estimates.<sup>16</sup> Adulterated extra-virgin olive oil, as a business, is three times more profitable than selling cocaine, and it can be just as injurious to health.<sup>17</sup> The Agromafia dilutes or cuts the pure extra-virgin olive oil and adds cheaper, inferior substitutes like sunflower seed oil, canola oil, or completely rotten or lower-grade olives, just as a drug dealer cuts pure cocaine and adds fillers.<sup>18</sup> Sometimes chlorophyll is even added to give olive oil its color.<sup>19</sup> This causes economic harm to consumers because they pay far too much for the product, and the resulting profits financially support nationwide crime syndicates.<sup>20</sup>

Seafood, another example, is often misrepresented either in its weight (with consumers paying more when sellers add extra water to the fish through a chemical process) or when sellers with supposed expensive, high-quality fish market less desirable, cheaper, or more readily available fish in its place.<sup>21</sup> Studies have found that

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organized a 200-man local farmer's revolt; while in Calabria, farmers collectively created GOEL Bio to strike back against organized crime. GOEL Bio is a consortium of organic farmers who help farmers who have been victimized by organized crime in Calabria. *See 60 Minutes: Agromafia, supra*; Christopher Livesay, 'Tough Guy' Farmers Stand Up to Italian Mafia—And Win, NPR (Sept. 10, 2016), <https://www.npr.org/sections/parallels/2016/09/10/493264069/tough-guy-farmers-stand-up-to-italian-mafia-and-win> [<https://perma.cc/GY7F-TBX8>]. The Agromafia did not take well to the Sicilian revolt which threatened the \$41 million olive oil empire of a head boss in Italy, likely Matteo Messina Denaro—the boss of bosses for the Cosa Nostra. In response, the Agromafia sent a clear message to the leader of the revolt—"stay quiet"—after setting fire to his car and a portion of his home while he and his family were inside. *See 60 Minutes: Agromafia, supra*.

<sup>16</sup> *Don't Fall Victim to Olive Oil Fraud*, CBS NEWS (Jan. 3, 2016), <https://www.cbsnews.com/news/60-minutes-overtime-how-to-buy-olive-oil/> [<https://perma.cc/CB9K-2JUZ>].

<sup>17</sup> *60 Minutes: Agromafia, supra* note 15.

<sup>18</sup> 'Agromafia': *The Italian Food Mafia, supra* note 14; Everstine et al., *supra* note 9; ROTTEN, *supra* note 7. *See also* Janet Rausa Fuller, *Seven Ways to Tell If Your Olive Oil is Fake*, EPICURIUS (May 25, 2017), <https://www.epicurious.com/ingredients/seven-ways-to-tell-the-difference-between-real-and-fake-olive-oil-article> [<https://perma.cc/6GX8-JUNF>]. Pure extra virgin olive oil comes from the first press of olives and must contain no additives. *See Olive Oil Times: Extra Virgin Olive Oil*, OLIVE OIL TIMES, <https://www.oliveoiltimes.com/extra-virgin-olive-oil> (last visited May 7, 2018) [<https://perma.cc/P9C3-TQF4>]. To mask the deodorized oil from inferior blends, the Agromafia may add other oils to "give it a little color, a little flavor." One member of Italy's tasting panel stated, "It's illegal—it happens all the time." *See 60 Minutes: Agromafia, supra* note 15. This is likely commercial fraud as there appears to be clear intent to adulterate the food.

<sup>19</sup> Jon Henley, *How to Tell if Your Olive Oil is the Real Thing*, THE GUARDIAN (Jan. 4, 2012), <https://www.theguardian.com/lifeandstyle/2012/jan/04/olive-oil-real-thing> [<https://perma.cc/N8B6-D7PP>].

<sup>20</sup> For the consumer, these substitutions and omissions extend beyond pocketbooks; they can be life threatening especially if the consumer has a seed or nut allergy. Olive oil related deaths have already occurred. In Madrid 1981, 1,200 people died, and 25,000 people were hospitalized after ingesting what they believed to be olive oil but was instead rapeseed oil contaminated with an additive called aniline. The aniline was added to create industrial rapeseed oil which caused severe neurotoxin. *See* Interview with Tom Mueller, *The Heartbreak of Global Olive Oil Fraud—and What to Do About It*, GOOP, <https://goop.com/wellness/health/the-heartbreak-of-global-olive-oil-fraud-and-what-to-do-about-it/> (last visited Mar. 31, 2019) [<https://perma.cc/VE42-CGR8>]; *see also* Bob Woffinden, *Cover-up*, THE GUARDIAN (Aug. 24, 2001), <https://www.theguardian.com/education/2001/aug/25/research.highereducation> [<https://perma.cc/62QH-8G9L>].

<sup>21</sup> Kimberly Warner et al., *Oceana Study Reveals Seafood Fraud Nationwide*, OCEANA 4, 42 (2013).

as much as thirty percent of seafood is mislabeled,<sup>22</sup> with snapper and tuna sold under false and misleading labels eighty-seven and fifty-nine percent of the time respectively.<sup>23</sup> Bass, breams, or most often a species of rockfish typically substitute for snapper.<sup>24</sup> The likely motivation for this type of wrongdoing is profit<sup>25</sup> since over the last ten years, the consumer price index in the United States increased more than twenty-seven percent, creating economic incentives for seafood substitution,<sup>26</sup> which undermines consumer confidence and can also have significant adverse economic consequences on fisheries.<sup>27</sup>

Some of these types of cases have resulted in death and serious illness. In 2007, a series of reports surfaced involving the addition of “melamine to high-protein feed and milk-based products to artificially inflate protein values.”<sup>28</sup> Many dogs and cats in the United States died as a result of Chinese pet food containing a combination of melamine and cyanuric acid that forms crystals which leads to kidney failure.<sup>29</sup> Melamine was later found in infant formula that resulted in 300,000 sick Chinese babies and six infant fatalities.

These and other similar horror stories have given rise to a movement of activists seeking to combat what they broadly refer to as food fraud. Most of these crusaders against food fraud approach the problem from a fact-based rather than a legal perspective and have developed a series of terms, such as economically motivated adulteration, food fraud, and food defense, that often do not track statutory language under United States law.

This article identifies the confusion and the clarification needed between the terms food fraud and economic adulteration as used by the crusaders against food fraud versus the legal community, respectively. It also offers suggestions to bridge the gap between these two communities through the use of terminology that conforms with the Federal Food, Drug, and Cosmetic Act (FDCA) usages and adds teeth to FDA’s enforcement measures.

Part A of this article discusses food adulteration and the FDCA of 1938. It addresses the statutory history of the 1906 Pure Food and Drug Act and the 1938 Act along with certain FDA initiatives. Part B discusses anti-food fraud advocacy, its definitions, and the crusaders’ policy prescriptions. Finally, Part C discusses ways to bridge the gap.

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<sup>22</sup> Jason Holland, *Avoiding ‘Fish-gate’: Chances for Seafood Fraud Scandal Still High*, SEAFOOD SOURCE (Mar. 21, 2016), <https://www.seafoodsource.com/features/avoiding-fish-gate-chances-for-seafood-fraud-scandal-still-high> [<https://perma.cc/X7VD-68BE>].

<sup>23</sup> Warner, *supra* note 21, at 5.

<sup>24</sup> *Id.* at 36.

<sup>25</sup> LUCY ANDERSON, MARINE STEWARDSHIP COUNCIL, *FROM OCEAN TO PLATE: HOW DNA TESTING HELPS TO ENSURE TRACEABLE, SUSTAINABLE SEAFOOD* 5 (2016).

<sup>26</sup> *What is Seafood Fraud?*, OCEANA, <http://oceana.org/what-seafood-fraud> [<https://perma.cc/3CLL-PE7M>].

<sup>27</sup> ALAN REILLY, FOOD AND AGRICULTURE ORGANIZATION, *OVERVIEW OF FOOD FRAUD IN THE FISHERIES SECTOR* 3 (2018).

<sup>28</sup> RENÉE JOHNSON, CONG. RESEARCH SERV., R43358, *FOOD FRAUD AND “ECONOMICALLY MOTIVATED ADULTERATION” OF FOOD AND FOOD INGREDIENTS* 1 (2014).

<sup>29</sup> *Id.*; *see also* U.S. GOV’T ACCOUNTABILITY OFF., GAO-12-46, *FOOD AND DRUG ADMINISTRATION: BETTER COORDINATION COULD ENHANCE EFFORTS TO ADDRESS ECONOMIC ADULTERATION AND PROTECT THE PUBLIC HEALTH* 1 (2011).

**PART A***Statutory History: Food Adulteration, Specifically Economic Adulteration in the Nineteenth Century*

Food contamination and adulteration aiming to cheat consumers and/or gain an unfair advantage over competitors is not new. As far back as the Greek and Roman eras, sellers used toxic substances such as lead to sweeten wine and “correct” wine that had turned sour.<sup>30</sup> No one during these eras knew the toxic properties inherent in lead, and thus, sellers ostensibly meant to cheat but not harm consumers.<sup>31</sup> By contrast, nineteenth century scientists knew about the poisonous and toxic effects of substances such as lead and copper for over a hundred years.<sup>32</sup> Therefore, knowledge of toxic properties added to food introduced the element of intentionality to cause physical injury. This knowledge then increased sellers’ culpability from economically cheating consumers to causing physical injury.

For example, in the 1820s, when the general population sought to experience luxuries, there was a gaping opportunity to adulterate food with inferior and sometimes lethal ingredients. Because of the resulting lower prices, those of lower socioeconomic classes could drink the green tea purportedly of the wealthy and eat the whitest of bread, and their children could feed on the brightest of colored candies once available only to the wealthy. No consumer seemed to question how he or she could now afford such indulgences. At this time, the practice of economic adulteration targeted even the most innocent and naive consumers—children, whose sweet treats and other confectionaries such as red sugar drops likely contained inferior vermilion, itself adulterated by lethal red lead.<sup>33</sup> Many shopkeepers or merchants, motivated by economic gain, did not necessarily intend to harm others outright when they substituted ingredients with inferior and lethal substances to boost profits; however, harm was a known and likely byproduct of their actions.<sup>34</sup>

Even though there was proof of merchants’ intent to defraud consumers, the law in London during the nineteenth century generally did not address food adulteration or economic adulteration from a legal perspective, but rather reflected a laissez faire attitude and a policy of caveat emptor—buyer beware.<sup>35</sup>

Fredrick Accum, a chemist in the 1820s, wrote a treatise exposing these practices and instructing his readers on how to detect food adulteration in London. Accum identified a correlation between the highly industrialized London city and the food

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<sup>30</sup> FREDRICK ACCUM, A TREATISE ON ADULTERATIONS OF FOOD, AND CULINARY POISONS 137 (1820); Josef Eisinger, *Lead and Wine. Eberhard Gockel and the Colica Pictonum*, 26 MED. HIST. 279, 279 (1982).

<sup>31</sup> Milton A. Lessler, *Lead and Lead Poisoning from Antiquity to Modern Times*, 88 OHIO J. SCI. 78, 79 (1988).

<sup>32</sup> BEE WILSON, SWINDLED: THE DARK HISTORY OF FOOD FRAUD, FROM POISONED CANDY TO COUNTERFEIT COFFEE 20 (2008).

<sup>33</sup> ACCUM, *supra* note 30, at 135; WILSON, *supra* note 32, at 27; Geri Walton, *Food and Drink Adulteration in the 1700s and 1800s* (Aug. 20, 2014), <https://www.geriwalton.com/food-and-drink-adulteration-in-1700-and/> [<https://perma.cc/J3ND-JF4K>].

<sup>34</sup> ACCUM, *supra* note 30, at 135; WILSON, *supra* note 32, at 27.

<sup>35</sup> ANNE MURCOTT, Warren Belasco, & Peter Jackson, *THE HANDBOOK OF FOOD RESEARCH*, 73 (2013); WILSON, *supra* note 32, at 34.

adulterations that occurred in the nineteenth century. Specifically, Accum theorized that the more industrialized the city, the longer the supply chain, and the easier for producers to sell adulterated food to consumers and merchants whom they would probably never encounter again. Accum noted that “in a rural setting, swindling is a risky business.”<sup>36</sup> If the milk tastes sour or seems diluted, there is no question the milkman is to blame since he sold his own milk. This negatively impacts the milkman and acts as a form of accountability to his customer, not found in the industrialized city. Accum further professed, “adulteration thrives when trade operates in large, impersonal chains” because it can be difficult to determine who added the copper to make the candies the brightest of green, a color unknown in nature.<sup>37</sup>

Industrialization created long, impersonal supply chains, whereby merchants could adulterate food and remain in business. However, it also led to individuals never tasting or forgetting the taste of unadulterated food. As industrialization increased, more and more farmers moved into the city to find work. As farming decreased, people forgot the taste of untouched food. To Accum, the ultimate food detector was comparing city food to one’s vibrant memory of rural food. And now, fewer and fewer people had that baseline to apply. Few even knew what true honey tasted like because they never tasted it; they instead relied on what others told them it tasted like— “butter and sugar mixed.”<sup>38</sup>

Accum further touched on unintended human consumption and resulting unintended harm. In his treatise, he featured an account of adulterated Gloucester Cheese laden with lethal red lead. In the account, a man returning from the country experienced severe pain after eating Gloucester Cheese at an inn on three separate occasions. On each, his pain (and once violent colic) subsisted after twenty-four hours. He attributed his pain to the cheese and told the mistress, who was later told that a kitten had been “violently sick after having eaten the rind cut off from the cheese prepared for the gentleman’s supper.”<sup>39</sup> The town chemist tested the cheese and found it was contaminated with lead. The supply chain for the lead-contaminated cheese went as follows: the London dealer contacted the farmer who manufactured the cheese, and the farmer then contacted the mercantile traveler who sold him the anotto (used to color the cheese).<sup>40</sup> It was discovered that the mercantile traveler’s anotto was of inferior quality and thus colored with vermilion (a nonpoisonous dye) which was mixed with red lead.<sup>41</sup> The druggist who sold the vermilion and the purchaser who adulterated the anotto intended the product to be used in house paint. As Accum states, “through the circuitous and diversified operation of commerce, a portion of deadly poison may find admission into the necessaries of life, in a way which can attach no criminality to the parties through whose hands it has successively passed.”<sup>42</sup> Thus, Londoners were susceptible to both intentional and unintentional economic

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<sup>36</sup> WILSON, *supra* note 32, at 28 (quoting ACCUM, *supra* note 30).

<sup>37</sup> *Id.*

<sup>38</sup> *Id.* at 39.

<sup>39</sup> ALPHONSE RENÉ LE MIRE DE NORMANDY, *THE COMMERCIAL HANDBOOK OF CHEMICAL ANALYSIS* 158 (1850).

<sup>40</sup> The farmer noted the good relationship between himself and the mercantile traveler. *See* Accum, *supra* note 30, at 310–12.

<sup>41</sup> WILSON, *supra* note 32, at 30; Walton, *supra* note 33.

<sup>42</sup> ACCUM, *supra* note 30, at 312–14.



adulteration and more broadly food adulteration due to its long supply chain resulting from industrialization.

*FDA's Initiatives: How Section Seven of the 1906 Pure Food and Drug Act Addressed the Problem*

Food adulteration, and with that economic adulteration, was not isolated to London. Rather, it occurred in other industrialized cities during the Industrial Revolution as well. With the publication of Upton Sinclair's *The Jungle*, Ruth deForest Lamb's *American Chamber of Horrors*, and Dr. Wiley's *Poison Squad*, public awareness in the United States heightened and induced Congress to enact new legislation.<sup>43</sup> The 1906 Act was the United States government's first systemic response and at a minimum created a foundation from which to react to food adulteration. The Act provided FDA with authority to seize unlawful drugs and food sold in interstate commerce, but this power had its limitations. With a focus on product misbranding and no mention of pre-market approval, there was little emphasis on preventing harm to the food supply.<sup>44</sup> The emphasis was instead on seizing harmful food *after* it had already entered the food market.

Section Seven of the Act addressed food adulteration and separated it into two segments: economic adulteration and adulterated foods that impacted health. Economic adulteration, found in section seven parts one through five addressed the addition, subtraction, or substitution of ingredients (which may or may not be poisonous and deleterious ingredients) that lowered the quality, damaged, or concealed the inferiority of the resulting product deeming the product adulterated.<sup>45</sup> Section seven part six defined food adulterations from a health perspective as any food "that consists in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, whether manufactured or not, or if it is the product of a diseased animal, or one that has died otherwise than by slaughter."<sup>46</sup>

Finally, the 1906 Act section eight addressed product misbranding as a form of economic adulteration and stated that the ingredients or substances listed on the label shall not be false or misleading.<sup>47</sup> Misbranding included different types of deception

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<sup>43</sup> PETER B. HUTT et al., FOOD AND DRUG LAW CASES AND MATERIALS 469 (4th ed. 2007). Dr. Wiley's "Poison Squad" set out to determine the effects of food additives. Twelve healthy men pledged one year to the project that commonly added additives to food including borax. As a result of Dr. Wiley's Poison Squad and Dr. Wiley's advocacy, the 1906 Act was appropriately nicknamed the "Wiley Act." See DEBORAH BLUM, THE POISON SQUAD: ONE CHEMIST'S SINGLE-MINDED CRUSADE FOR FOOD SAFETY AT THE TURN OF THE TWENTIETH CENTURY (2018). See Bruce Watson, *The Poison Squad: An Incredible History*, ESQUIRE (June 27, 2013), <http://www.esquire.com/food-drink/food/a23169/poison-squad/> [<https://perma.cc/F8XF-DV32>]; *Part 1: The 1906 Food and Drugs Act and Its Enforcement*, U.S. FOOD AND DRUG ADMINISTRATION (Feb. 2, 2018), <https://www.fda.gov/AboutFDA/History/FOrgsHistory/EvolvingPowers/ucm054819.htm> [<https://perma.cc/WP6L-Q3K8>]; see generally *Doctor Wiley's Poison Squad Enlisted from Expert Toppers*, THE REPUBLIC, Dec. 6, 1903, at 12.

<sup>44</sup> DAVID G. ADAMS et al., FOOD AND DRUG LAW AND REGULATION 729 (3rd ed. 2015); *Part 1: The 1906 Food and Drugs Act and Its Enforcement*, *supra* note 43.

<sup>45</sup> Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, § 7(1-5), 34 Stat. 768 (1906) (repealed 1938).

<sup>46</sup> *Id.* at § 7(6).

<sup>47</sup> *Pure Food and Drug Act 1906*, SCHAFFER LIBRARY OF DRUG POLICY, <http://www.druglibrary.org/schaffer/history/e1900/pfda.htm> (last visited May 14, 2018) [<https://perma.cc/G8GT-NVQA>].

and prohibited foods sold as imitations or foods under other names, labeling to deceive consumers, and listing inaccurate weights. Section eight also required the labeling of eleven “dangerous ingredients” including the amount used in the product; these ingredients included alcohol, heroin, and cocaine.<sup>48</sup> Nowhere in the 1906 Act was intent or fraud specifically mentioned. The Act instead emphasized the condition of the food.

*FDA’s Initiatives: Implementation of Section Seven of the 1906 Act*

The United States Supreme Court clarified the standard of proof to be applied to section seven in two early cases. These decisions described the government’s standard of proof in adulteration cases.

In *United States v. Lexington Mill & Elevator Co.*, the Supreme Court made it clear that the government did not need to prove that a food containing poisonous or deleterious ingredients was actually injurious to public health. Instead, the burden was to prove that the added poisonous or deleterious ingredient “*may possibly* injure . . . health,” and if so, the food is considered adulterated.<sup>49</sup> According to the U.S. Supreme Court, “[i]f it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, . . . though having a small addition of poisonous or deleterious ingredients, [it] may not be condemned under the Act.”<sup>50</sup>

Similarly, in *United States v. Forty Barrels and Twenty Kegs of Coca-Cola*, the Supreme Court ruled “that it was the intention of Congress that the artificial introduction of ingredients of a poisonous or deleterious character which *might* render the article injurious to health should cause the prohibition of the statute to attach.”<sup>51</sup> These two cases were specific to section seven part five of the Act and created a standard of proof specific to injury to public health apart from economic adulteration (though found in parts one through four). Intent was not a necessary element for government enforcement in either respect. The emphasis remained on the condition of the product, not the motive of the perpetrator.

The 1906 Pure Food and Drug Act regulated foods and drugs in interstate commerce, but as stated above, the statute conferred only limited authority.<sup>52</sup> After securing many criminal convictions,<sup>53</sup> FDA pivoted in its legal enforcement against economic adulteration and instead pursued product misbranding. Misbranding under

<sup>48</sup> *Part 1: The 1906 Food and Drugs Act and Its Enforcement*, *supra* note 43.

<sup>49</sup> P. B. Hutt & P. B. Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 *FOOD, DRUG, & COSM. L.J.* 1, 57 (1984) (emphasis added).

<sup>50</sup> *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 340–41 (1914).

<sup>51</sup> *United States v. Forty Barrels & Twenty Kegs of Coca-Cola*, 241 U.S. 265, 284 (1916) (emphasis added).

<sup>52</sup> Edward A. Ayers, *What the Food Law Saves Us From: Adulterations, Substitutions, Chemical Dyes, and Other Evils*, in 14 *THE WORLD’S WORK: A HISTORY OF OUR TIME* 9316–22 (1907), <https://books.google.com/books?id=sojNAAAAMAAJ&pg=RA1-PA9316-v=twopage&q&f=false> [<https://perma.cc/JPX7-V6BS>].

<sup>53</sup> *See, e.g.*, *Frank v. United States*, 192 F. 864 (6th Cir. 1911) (pepper diluted by corn); *Union Dairy Co. v. United States*, 250 F. 231 (7th Cir. 1918) (diluted milk with water); *United States v. Frank*, 189 F. 195 (S.D. Ohio 1911) (lemon extract diluted by alcohol and water); *United States v. South Hero Creamery Ass’n.*, 1142 (D. Vt. 1925) (less than 80 percent milk fat in butter); *United States v. Atlantic Macaroni Co.*, 793 (E.D.N.Y. 1917) (macaroni dyed yellow to hide inferiority).

the 1906 Act prohibited false branding as well as foods that were an “imitation of or offered for sale under the distinctive name of another article.”<sup>54</sup> Yet, in court cases such as *United States v. 300 Cases of “Mapleine”* where the government challenged whether Mapleine contained products of the maple tree, the term’s distinctive name took on a new interpretation that later became a legal defense against claims of misbranding.<sup>55</sup> In the judge’s instructions to the jury, he defined “distinctive name” in a confusing manner: “a distinctive name is either one so arbitrary or fanciful as to clearly distinguish it from all other things, or one which by common use has come to mean a substance clearly distinguishable by the public from everything else.”<sup>56</sup> By the 1920s, section eight of the 1906 Act left many loopholes such as confusion regarding a product’s distinctive name. Eventually, this, among other reasons, led to the need for a new Act, the 1938 Food, Drug, and Cosmetic Act.<sup>57</sup>

Overall, the 1906 Act made a fair first effort to control food adulteration in a broad context, particularly by not requiring an element of intent in order to take action. But in light of challenges and advancing technology, the 1906 Act needed further clarification.

### *FDA’s Initiatives: Economic Adulteration in Section 402(b) of the 1938 Federal Food, Drug, and Cosmetic Act*

Court cases brought under the 1906 Act identified areas of confusion created by cases like *United States v. 300 Cases of “Mapleine.”* New provisions inserted in the FDCA specifically provided for increased food regulation.<sup>58</sup> For example, section 402(b) established mandatory food standards and defined adulterated food.<sup>59</sup> Foods were generally considered adulterated under section 402(a) if they contained poisonous or deleterious substances but economically adulterated under section 402(b) if any ingredient in whole or in part was omitted, substituted, damaged, or added in a way that concealed the product’s inferiority, “reduce[d] its quality or strength, or [made] it appear better or of greater value than it [was].”<sup>60</sup> The 1938 Act increased FDA’s authority to take action even if the food adulteration did not threaten public health.<sup>61</sup>

As in the 1906 Act, the 1938 Act did not confine economic adulteration to section 402(b). Instead, aspects were also addressed in section 403 Misbranded Food as well. Section 403 prohibited false or misleading statements in food labels or labeling, offers

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<sup>54</sup> Federal Food and Drugs Act of 1906 § 8.

<sup>55</sup> *United States v. 300 Cases of Mapleine*, I.S. No. 9341-a, F. & D. No. 273 (Dep’t of Agriculture Feb. 10, 1910) (Notice of Judgm., 163), [https://archive.org/stream/CAT11088278005/CAT11088278005\\_djvu.txt](https://archive.org/stream/CAT11088278005/CAT11088278005_djvu.txt) [<https://perma.cc/AD3Y-AXLF>] [hereinafter *300 Cases of Mapleine*]; *Food Standards and the 1906 Act*, U.S. FOOD AND DRUG ADMINISTRATION (2018), <https://www.fda.gov/AboutFDA/History/ProductRegulation/ucm132666.htm> [<https://perma.cc/U6PN-3BKM>].

<sup>56</sup> *See 300 Cases of Mapleine*, I.S. No. 9341-a, F. & D. No. 273 (Dep’t of Agriculture Feb. 10, 1910) (Notice of Judgm., 163).

<sup>57</sup> *Food Standards and the 1906 Act*, *supra* note 55.

<sup>58</sup> Hutt & Hutt II, *supra* note 49, at 62.

<sup>59</sup> Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 § 402(b) (1938) (codified as amended at 21 U.S.C. § 342(b) (2003)), <http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section342&num=0&edition=prelim> [<https://perma.cc/3PPA-LEKQ>].

<sup>60</sup> *Id.*

<sup>61</sup> MICHAEL T. ROBERTS, *FOOD LAW IN THE UNITED STATES* 46 (2016).

for sale under another name, imitations of food, and misleading containers. It addressed the prominence of information on the label so as to be “understood by the ordinary individual under customary conditions of purchase and use” and defined representations as to standards of quality and fill of the container.<sup>62</sup> Today, misbranding is still a viable enforcement measure through not only accurate words and visual representations, but also omissions of “facts material” to claims or representations made.<sup>63</sup>

In terms of enforcement under the 1938 Act, FDA does not require motive or intent for the Agency to take action with regard to economic adulteration,<sup>64</sup> and both civil and criminal remedies are available. First-time criminal violations are misdemeanors unless there is intent to defraud or mislead; in that case, they are felonies.<sup>65</sup> Malintent is not a prerequisite for conviction but does affect whether the crime is a felony or a misdemeanor. Enforcement measures include the ability to conduct inspections, request recalls, and take enforcement action when the Agency detects any type of adulteration or misbranding.<sup>66</sup> Such enforcement action can include injunctions, seizures, and criminal prosecution.<sup>67</sup> FDA may issue fines and in some instances prison sentences. For example, FDA permitted federal prosecutors to issue a \$100,000 fine and a five-year prison sentence for economic adulteration of forty million gallons of orange juice that occurred over eleven years, a \$120,000 fine to a seafood company for adding water to scallops to increase their weight, and a \$2.18 million fine to Beech-Nut Nutrition Corporation, a baby food manufacturer, for selling apple juice branded as 100% apple juice but was really a combination of sugar, water, and flavoring.<sup>68</sup>

#### *FDA’s Initiatives: FDA’s Implementation of Section 402(b)*

The 1938 Federal Food, Drug, and Cosmetic Act and case law that followed expanded and defined economic adulteration without naming it and never mentioned intent or fraud. This was deliberate. In addition, through case law, the 1938 Act clarified the 1906 Act’s standard of proof, specifically the proof required for FDA to take action against economic adulteration. Unfortunately, FDA ceased most of its enforcement efforts when the presence of certain additives became legally permissible in food, and FDA pivoted in its priorities away from economic adulteration and more toward safety and nutrition.

The 1938 Act did not explicitly include the term economic adulteration. Again, this was deliberate because the motivation of the perpetrator is not initially important. However, in 1943, the Supreme Court adopted the House and Senate definition of economic adulteration and applied it to the 1938 Act in FDA cases: “Economic adulteration, by which less expensive ingredients were substituted, or the proportion of more expensive ingredients diminished, so as to make the product, although not in itself deleterious, inferior to that which the consumer expected to receive when

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<sup>62</sup> Federal Food, Drug, and Cosmetic Act § 403.

<sup>63</sup> See Federal Food, Drug, and Cosmetic Act § 201(n); ADAMS et al., *supra* note 44, at 741.

<sup>64</sup> ROBERTS, *supra* note 61, at 45.

<sup>65</sup> ADAMS ET AL., *supra* note 44, at 743.

<sup>66</sup> GAO-12-46, *supra* note 29, at 9.

<sup>67</sup> ADAMS ET AL., *supra* note 44, at 743–44.

<sup>68</sup> Paula Kurtzweil, *Fake Food Fight*, FDA CONSUMER (Mar.-Apr. 1999), [<https://perma.cc/7PKY-K6NA>].

purchasing a product with the name under which it was sold.”<sup>69</sup> Again, there is no specific element of motive or intent.

The Sixth Circuit affirmed FDA’s decision that white poppy seeds artificially colored with charcoal to resemble a more expensive poppy seed constituted economic adulteration under section 402(b)(4) of the FDCA.<sup>70</sup> The section provides: “A food shall be deemed to be adulterated . . . (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.”<sup>71</sup> The artificial poppy seeds were inferior but concealed to the ultimate consumer. The court ruled that adulteration is reviewed from the perspective of the consumer because the 1938 Act is designed to protect the “consuming public,” not merchants and traders.<sup>72</sup> The consumer was likely unaware of the inferiority of the poppy seeds purchased.<sup>73</sup>

Similarly, the court stated in *United States v. 88 Cases, more or less, Containing Bireley’s Orange Beverage*, that food adulteration is determined from the perspective of the “ordinary consumer” as to whether the food appears to be superior to what it really is.<sup>74</sup> The ordinary consumer is considered a person “who is neither savant nor dolt, who lacks special competency with reference to the matter at hand but has and exercises a normal measure of the layman’s common sense and judgment.”<sup>75</sup> These two examples do not initially analyze the adulterated food from the perspective of the perpetrator but from the perspective of the consumer. The harm done to the food is of greater importance than whether it was the intent of the perpetrator to harm the food.

FDA experienced a somewhat abrupt end to its enforcement after it did not prevail in *88 Cases, more or less, Containing Bireley’s Orange Beverage*.<sup>76</sup> FDA asserted that the inclusion of yellow coal tar dyes, sugar, lactic acid, and orange oil made the orange beverage look better than it was and was thus an inferior product compared to undiluted orange juice.<sup>77</sup> FDA argued that, as a result, the addition of these ingredients sufficiently confused consumers that the orange beverage was inferior to undiluted orange juice.<sup>78</sup> The court held that undiluted orange juice is not superior to the orange beverage at issue, and FDA may only condemn “where there is confusion with a defined superior product.”<sup>79</sup> After this loss, FDA focused more on food standards and labeling requirements and nearly abandoned enforcement through litigation.<sup>80</sup>

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<sup>69</sup> Fed. Security Admin. v. Quaker Oats Co., 318 U.S. 218, 230 (1943).

<sup>70</sup> *United States v. 2 Bags, Each Containing 110 Pounds, Poppy Seeds*, 147 F.2d 123 (6th Cir. 1945).

<sup>71</sup> Federal Food, Drug, and Cosmetic Act § 402(b)(4).

<sup>72</sup> *Poppy Seeds*, 147 F.2d at 127.

<sup>73</sup> *Id.*

<sup>74</sup> *United States v. 88 Cases, more or less, Containing Bireley’s Orange Beverage*, 187 F.2d 967, 971 (3d Cir. 1951); see also Wesley Forte, *The Food and Drug Administration and the Economic Adulteration of Foods*, 41 IND. L.J. 346, 361, 365 (1966).

<sup>75</sup> *Bireley’s Orange Beverage*, 187 F.2d at 971.

<sup>76</sup> Hutt & Hutt II, *supra* note 49, at 64.

<sup>77</sup> *Bireley’s Orange Beverage*, 187 F.2d at 969.

<sup>78</sup> *Id.* at 973.

<sup>79</sup> *Id.* at 974. Here, superior orange beverage was not defined under the 1938 Act.

<sup>80</sup> Hutt & Hutt II, *supra* note 49, at 64.

In one court case following FDA's near abandonment of judicial action, the Supreme Court specified Congress's intent when it came to a verdict of "not proven" as it relates to coloring added to foods.<sup>81</sup> The Supreme Court clarified that a verdict of "not proven" still allows the government to prevent the use of those substances if found to have poisonous effects on their own.<sup>82</sup> This added clarity as to the burden of proof required in food adulteration cases as they pertain to public health risks. However, with the creation of the Food Additives Amendment in 1958 and the Color Additive Amendment of 1960, whereby Congress prohibited approval of food additives that deceived consumers economically and otherwise, the lines began to blur as to the difference between illegal adulteration and lawful inclusion of additives.<sup>83</sup>

FDA turned its attention from economic adulteration towards the health concerns associated with adulterated food. In one instance, FDA replied to the National Milk Producers Federation's (NMPF) request to enforce economic provisions of the 1938 Act by stating that due to budgetary constraints investigative and enforcement priorities were set aside.<sup>84</sup> FDA went on to state that, "Our high priorities are health hazards, filth, and nutrition. Our lowest priorities are food economics and food standards. Thus, we expect no actions in the near future concerning the cheese substitute products indicated in your letters."<sup>85</sup> Dissatisfied by FDA's response, the NMPF brought suit against FDA to compel it to take regulatory action. On appeal, the court ruled that it "found no provision which narrows or limits the discretion of the FDA to investigate, enforce, or prosecute alleged violations of the Act or its regulations."<sup>86</sup> Thus, FDA has much discretion as to whether to enforce the Act, and in most instances, it cannot be compelled to take action.

#### *FDA's Preventative Initiatives: Food Safety Modernization Act*

In a 2011 report, FDA responded to globalization and named economic adulteration as one of the most serious challenges because of its threat to physical harm as evidenced by the Chinese melamine incidents.<sup>87</sup> The 2011 Food Safety Modernization Act (FSMA) makes efforts to be preventative, but the implementation of those efforts still lacks. In section 106, "Protection Against Intentional Adulteration," measures taken are limited to intentional high-risk safety issues involving significant public harm related to food terrorism only.<sup>88</sup> Additionally, FSMA assigned "mandatory recall authority" to FDA when food companies do not comply with recommendations for voluntary recalls— not a preventative approach after contaminated food has already

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<sup>81</sup> *Flemming v. Fla. Citrus Exchange*, 358 U.S. 153, 167 (1958).

<sup>82</sup> *Id.* at 166–67.

<sup>83</sup> *Hutt & Hutt II*, *supra* note 49, at 63.

<sup>84</sup> *Nat'l Milk Producers Fed'n. v. Harris*, 653 F.2d 339, 342 (8th Cir. 1981).

<sup>85</sup> *Hutt & Hutt II*, *supra* note 49, at 72 (citing *Nat'l Milk Producers Fed'n. v. Harris*, Food, Drug & Cosm. L. Rep. (CCH) ¶ 38,045 (D. Minn. 1980)); *see also* *Hutt & Hutt II*, *supra* note 49, at 62.

<sup>86</sup> *Nat'l Milk Producers Fed'n. v. Harris*, 653 F.2d 339, 344 (8th Cir. 1981). *See also* *Heckler v. Chaney*, 470 U.S. 821 (1985) for instances in which FDA may not exercise discretion.

<sup>87</sup> Department of Health and Human Services, U.S. Food and Drug Administration, *Pathway to Global Product Safety and Quality* (2011); *see also* GAO-12-46, *supra* note 29, at 9.

<sup>88</sup> ROBERTS, *supra* note 61, at 51; *see* FDA Food Safety Modernization Act (FSMA), Pub. L. No. 111-353, § 106, 124 Stat. 3885, 3897 (2011) (codified in scattered sections of 21 U.S.C.).

likely entered the food supply.<sup>89</sup> FSMA also provided for the development, implementation, and monitoring of a “preventative controls systems to prevent outbreaks of foodborne illness” of many food processors that sell food in and into the country under the Hazard Analysis and Risk-Preventative Controls (HARBPC) program.<sup>90</sup> This is specific to intentional adulteration with an option to propose something similar for economic adulteration. Thus, there is still an economic threat to the United States’ food supply, leaving room for better preventative options.<sup>91</sup>

Within FDA’s broad adulteration prevention efforts under FSMA, there are other programs in place to detect adulteration such as FDA’s Office of Regulatory Affairs’ Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT) and FDA’s Center for Veterinary Medicine’s Pet Event Tracking Network (PETNet). PREDICT assigns risk scores to FDA-regulated products by applying risk criteria to importers’ shipment information.<sup>92</sup> PETNet is an information sharing system exchanging information about illness outbreaks and pet-food-related illnesses; its use is voluntary.<sup>93</sup> In fact, most instances of economic adulteration received by FDA are a result of industry members who become suspicious of products sold at low prices or who conduct their own testing of foods they bought and received.<sup>94</sup> Thus, FDA has few preventative measures in place to protect against economic adulteration and more broadly food adulteration generally.

## PART B

### *Crusaders Against Food Fraud: Definitions*

Those in the crusaders against food fraud community have diverse backgrounds, but most do not come from the legal community. They are academics, industry representatives, industry-oriented food-integrity practitioners, scientists, and even some consumer advocates; all of whom worry about the increasing amount of food fraud that has already affected and threatens to continue to affect our global food supply. This community includes individuals who met with FDA years ago in an effort to compel FDA to recognize food fraud as a subject of major concern. Over the years, crusaders against food fraud developed a number of definitions to facilitate their discourse and identify steps the industry can take to combat the problem. This amounted to a noble initiative but has not had any real effect on the way the law is administered and enforced.

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<sup>89</sup> ADAMS et al., *supra* note 44, at 732.

<sup>90</sup> *Id.*

<sup>91</sup> ROBERTS, *supra* note 61, at 51–52; *Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)*, U.S. FOOD AND DRUG ADMINISTRATION (Dec. 12, 2017), <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm395105.htm> (last visited May 7, 2018) [<https://perma.cc/DBX6-TFF7>]; see generally *FDA Food Safety Modernization Act: Improving Capacity to Prevent Food Safety Problems*, 21 U.S.C. §§ 2201–2206 (2011). Currently, the proposal is in the comments stage. See, Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventative Controls for Human Food, U.S. FOOD AND DRUG ADMINISTRATION (Jan. 2018), <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm> [<https://perma.cc/EX84-7J7P>].

<sup>92</sup> GAO-12-46, *supra* note 29, at 9.

<sup>93</sup> *Id.*

<sup>94</sup> Kurtzweil, *supra* note 68.

Perhaps one of the most prominent advocates fighting against food fraud is Dr. John Spink, a food-fraud expert and creator of the Food Fraud Institute at Michigan State University. Dr. Spink launched a program through an institute known as the Anti-Counterfeiting and Product Protection Program (ACAPPP), which seeks to develop strategies to combat food counterfeiting.<sup>95</sup> The Food Fraud Institute generally focuses on a wide range of what they call fraudulent practices, including adulteration, misbranding, tampering, and counterfeiting.<sup>96</sup> In multiple articles, Dr. Spink offers innovative ideas for combatting this type of food adulteration through the involvement of many disciplines. For example, he applies criminology to food science and suggests innovative strategies to curb perpetrators of fraud.

Michigan State University's (MSU) Food Fraud Initiative treats "food fraud [as] a collective term used to encompass the deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging; or false or misleading statements made about a product, for economic gain."<sup>97</sup> MSU's Food Fraud Initiative leaders state, "[f]ood fraud is a broader term than either the economically motivated adulteration (EMA) defined by the Food and Drug Administration (FDA) or the more specific intellectual property rights focused concept of food counterfeiting."<sup>98</sup>

In a Congressional Research Service report, a specialist in Agricultural Policy at the Library of Congress defined food fraud as "the act of defrauding buyers of food or ingredients for economic gain—whether they be consumers or food manufacturers, retailers, and importers" with no citation given.<sup>99</sup> Both this report and the Grocery Manufacturers Association deem economic adulteration and EMA to be a subset of food fraud.<sup>100</sup>

The United States Pharmacopeia (USP) food fraud database reports and stores food fraud incidents globally and defines food fraud as "the deliberate adulteration or mislabeling of consumable food products for the purpose of economic gain."<sup>101</sup> According to the United States Pharmacopeial Convention, "[f]ood fraud . . . refers to

<sup>95</sup> Jeneen Interlandi, *New Program Seeks Out Food Fraud*, NEWSWEEK (Feb. 7, 2010), <http://www.newsweek.com/new-program-seeks-out-food-fraud-75265> [<https://perma.cc/ESRP-ENSC>].

<sup>96</sup> Food Fraud Initiative: About, MICHIGAN STATE UNIVERSITY, <http://foodfraud.msu.edu/about/> (last visited Mar. 31, 2019) [<https://perma.cc/PNB8-A8C3>] (last visited May 6, 2018).

<sup>97</sup> JOHNSON, *supra* note 28, at 6; John Spink & Douglas C. Moyer, *Backgrounder: Defining the Public Health Threat of Food Fraud*, NATIONAL CENTER FOR FOOD PROTECTION AND DEFENSE (Apr. 30, 2011), <http://foodfraud.msu.edu/wp-content/uploads/2014/07/food-fraud-ffg-backgrounder-v11-Final.pdf> [<https://perma.cc/G888-HHUU>].

<sup>98</sup> John Spink, Food Fraud Initiative, *Introducing the Food Fraud Reference Sheet*, MICHIGAN STATE UNIVERSITY (Aug. 20, 2014), <http://foodfraud.msu.edu/2014/08/20/introducing-the-food-fraud-reference-sheet/> [<https://perma.cc/A8VR-8F3E>].

<sup>99</sup> JOHNSON, *supra* note 28, at 1, 5.

<sup>100</sup> *Id.* at 3, 6.

<sup>101</sup> *Solutions and Services: Food Fraud Database: Frequently Asked Questions*, DECERNIS <https://decernis.com/solutions/food-fraud-database/ffd-faq/> (last visited Mar. 31, 2019) [<https://perma.cc/9LZB-YVH7>]. United States Pharmacopeia (USP), recently acquired by Decernis LLC, is a Food Fraud Database that comprises thousands of ingredients and related records from scientific literature, media publications, regulatory reports, judicial records, and trade associations from around the world. See Press Release, *Decernis Acquires Food Fraud Database from USP*, DECERNIS (June 25, 2018), <https://decernis.com/decernis-acquires-food-fraud-database-from-usp/> [<https://perma.cc/NC96-QKGN>]. USP includes information about food fraud obtained through public searches of scientific literature, regulatory records, media reports, and other sources. See JOHNSON, *supra* note 28, at 11.



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."<sup>102</sup> The USP Database is limited and isolated to three types of fraud: "complete or partial replacement of a food ingredient . . . with a less expensive substitute," "addition of small amounts of a non-authentic substance to mask inferior quality ingredients," and "removal or intentional omission of an authentic and valuable constituent in a food product or food ingredient."<sup>103</sup> The USP Convention also states that food fraud is "economic adulteration, economically motivated adulteration, intentional adulteration, or food counterfeiting."<sup>104</sup>

With no reference to the statute by which it must abide, FDA defines economically motivated adulteration (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."<sup>105</sup> This definition includes dilution of products if the dilution is known to cause or could cause health risks to consumers and includes masking agents added to conceal dilution.<sup>106</sup> While FDA states this is a "working" definition for purposes of a public meeting to "stimulate and focus a discussion about ways in which the food . . . industries, regulatory agencies, and other parties can better predict and prevent economically motivated adulteration with a focus on situations that pose the greatest public health risk," this definition has already been referenced in multiple congressional research reports.<sup>107</sup> For all intents and purposes, FDA's new definition is beyond a working definition, and it appears to follow the crusaders against food fraud definitions that confuse fraud and adulteration, two distinct words.

In a 2011 U.S. Government Accountability Office (GAO) Report, FDA's working definition was adopted as the definition for economic adulteration.<sup>108</sup> However, the GAO Report distinguished economic adulteration from other forms of *intentional* adulteration like food terrorism whose primary purpose is to cause harm to others. The GAO Report also distinguished economic adulteration from unintentional adulteration including mistakes in the manufacturing process.<sup>109</sup> Food fraud is not named in the report. Fraud is only found within GAO's adopted FDA definition.

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<sup>102</sup>JOHNSON, *supra* note 28, at 6. In Mr. Moore's position as lead scientific liaison to USP's Expert Panel on Ingredient Adulterants, Mr. Moore considers "EMA to be a subset of food fraud." See Jeffrey C. Moore, *Food Fraud: Public Health Threats and the Need for New Analytical Detection Approaches*, in 209 U.S. PHARMACOPEIA: FOOD SECURITY: THE INTERSECTION OF SUSTAINABILITY, SAFETY AND DEFENSE, [http://nabc.cals.cornell.edu/Publications/Reports/nabc\\_23/23\\_5\\_3\\_Moore.pdf](http://nabc.cals.cornell.edu/Publications/Reports/nabc_23/23_5_3_Moore.pdf) [https://perma.cc/7JZ6-SS46].

<sup>103</sup>JOHNSON, *supra* note 28, at 6–7. Because USP limits and isolates its Database to three types of fraud, other types of frauds including counterfeits and simulations, gray area markets, product tampering, production over-runs, theft, smuggling, document fraud, and diversions are not reported within USP's Database.

<sup>104</sup>*Id.*

<sup>105</sup>Economically Motivated Adulteration; Public Meeting; Request for Comment, 74 Fed. Reg. 64, 15,497, 15,947–15,499 (Apr. 6, 2009).

<sup>106</sup>*Id.*

<sup>107</sup>Economically Motivated Adulteration, *supra* note 105; see also GAO-12-46, *supra* note 29, at 3.

<sup>108</sup>GAO-12-46, *supra* note 29, at 3.

<sup>109</sup>*Id.* at 7.

In response to food supply threats, Michigan State University's Dr. Spink termed food terrorism as "food defense," and he states that "a food defense incident is an intentional act with intentional harm."<sup>110</sup> It is an attempt for all consumers to lose complete faith in their food supply. Dr. Spink explains that most food fraudsters do not intend to harm others. They harm others only as a byproduct of their economic motivation. In contrast, those fraudsters who intend to harm others pose the greatest challenge because ultimately, food fraud for them is "a crime of opportunity."<sup>111</sup> Such a crime is not predictable, and fraudsters will likely strike just once rather than multiple times. A fraudster needs to enter the food supply chain undetected in just one instance to create pandemonium. So, there is no opportunity to react first then respond later to counteract future incidents.

The term food defense seems inappropriate as compared to other term names like food fraud and economically motivated adulteration that each indicate wrongful conduct. Food defense as a term to describe food terrorism does not indicate wrongful conduct but in fact the opposite, a means to stop wrongful conduct; this does not accurately describe food terrorism. Food defense is not something to discourage. Either food defense should be renamed, or it should be removed as a subcategory.

Because the 1938 Federal Food, Drug, and Cosmetic Act makes no reference to fraud, it is uncertain where the many food fraud definitions originate especially as an umbrella term that in some definitions include both economically motivated adulteration and economic adulteration.

### *Crusaders Against Food Fraud and Their Demands*

Above all else, crusaders against food fraud demand a means to protect the global food supply from food fraud and incidents of food terrorism (food defense). They recognize that a preventative approach is better than a reactive approach. They also appear to understand the government budgetary constraints FDA faces because of the many issues the agency is forced to prioritize (generally safety issues) beyond food fraud. Instead, crusaders against food fraud look to private entities and other government agencies to help share the burden and develop preventative measures to protect against food fraud culprits whose food enters our food supply.

Industry trade groups such as the North American Olive Oil Association (NAOOA), the Vermont Maple Sugar Makers Association, and the American Spice Trade Association have taken a stand against food adulteration generally. NAOOA created a shared audit program whereby producers comply with set standards, and businesses use their program membership in their advertising and communication with consumers.<sup>112</sup> Just as perpetrators have an economic incentive to adulterate food, industry trade groups have an economic incentive to ensure food is unadulterated. One of those economic incentives is to remain in business and to not lose customers and customer confidence. This was demonstrated when China laundered honey through the United States market and priced out and bankrupted many local beekeeping businesses because of economic adulteration. In addition, many industry trade groups have what FDA does not, funding. With funding comes the ability to research and

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<sup>110</sup>John Spink & Douglas C. Moyer, *Defining the Public Health Threat of Food Fraud*, 76 J. FOOD SCI. R157, R157 (2011).

<sup>111</sup>John Spink & Douglas C. Moyer, *Understanding and Combating Food Fraud*, 67 FOOD TECH. MAG. 30, 33 (2013).

<sup>112</sup>Everstine et al., *supra* note 9, at 730.

determine new testing methods, educate consumers, increase inspections within specific trade groups, and disseminate and share information.

Dr. Spink specifically calls for preventative measures when it comes to the potential for food terrorism (food defense) attacks. He says that devising prevention methods is the only way to prevent a food defense attack.<sup>113</sup> One way to address both food fraud generally and food defense is, according to Spink, to increase the risk of detection and increase the cost to circumvent detection thereby disincentivizing food fraud.<sup>114</sup> In addition, many food fraud incidents are not isolated to food product violations but also implicate other regulatory violations such as intellectual property rights, fair labeling, tampering, theft, consumer product safety, misbranding, and product importation.<sup>115</sup> Other government agencies can share the burden of fighting against food fraud.

## PART C

### *Discourse Disconnect between Crusaders Against Food Fraud and 1938 Food, Drug, and Cosmetic Act*

There is confusion between the term food fraud as used by the crusaders against food fraud and applied in FDA's working definition and the term economic adulteration as it appears in the FDCA. At first, it seemed that the two terms referred to the same idea, that of adulterated food that could cause consumers and competitors economic loss, and the crusaders against food fraud and the federal statute simply used one of the two terms exclusively. FDA's adoption of its new working definition has muddied the waters and requires clarification.

The statute does not refer to economic adulteration as food fraud because the statute does not explicitly require proof of fraud to establish a case of economic adulteration. In fact, the statute is specifically titled "Adulterated Food."<sup>116</sup> Those with a legal background know that fraud is a defined term found in caselaw and requires proof of wrongful intent, whereas adulteration focuses on the condition of the product. The ordinary meaning of "adulteration" is "to make impure, spurious, or inferior by adding extraneous or improper ingredients."<sup>117</sup> It does not require intent. Further, according to the caselaw discussed previously, even economic adulteration is specific to the condition of the product. Intent, on the other hand, is addressed second after the condition of the product because economic adulteration can be intentional or unintentional. In fact, the statute does not mention intent at all. Food fraud occurs in the opposite order: intent is ascertained first, followed by the condition of the food.

Those in the crusaders against food fraud community use the inaccurate term, food fraud, and FDA's working definition incorporates this inaccurate term. Food fraud infers the intent to harm consumers through their food, and economic adulteration is considered a subset. While the term invokes far greater emotions than economic adulteration and is catchier, fraud interchanged with adulteration changes the meaning of economic adulteration and food adulteration. It places an improper emphasis on the

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<sup>113</sup>Spink & Moyer, *supra* note 111.

<sup>114</sup>Spink & Moyer, *supra* note 110, at R161.

<sup>115</sup>*Id.* at R162.

<sup>116</sup>Federal Food, Drug, and Cosmetic Act § 402.

<sup>117</sup>Hutt & Hutt II, *supra* note 49, at 3.

perpetrator's motive and guilt, which may be difficult to prove especially in today's world where food touches many hands as it travels through the complex and extensive global supply chain. In addition, food fraud does not place enough emphasis on the condition of the food. This makes it more difficult to protect consumers. Finally, when the terms fraud and adulteration are used interchangeably, the standard of proof for adulteration seems to require intent.

In a rare occurrence, the author of a law review article misused fraud and adulteration. The author referred to all seafood adulteration as seafood fraud and defined seafood fraud as "the substitution, misrepresentation, or mislabeling of a species of seafood."<sup>118</sup> The author specifically noted intent in relation to seafood fraud: "[w]hether intentional or unintentional, [seafood fraud] is an economic, environmental, and food safety harm," and he asserted that food "fraud is not always intentional."<sup>119</sup> This is a flawed definition of fraud; fraud always requires intent on the part of the culprit to deceive the alleged victim.<sup>120</sup> Any assertion that fraud can be unintentional is an inappropriate use of the word.

In 2009, the disconnect between the use of the two terms became especially relevant when FDA released its new "working" definition for economically motivated adulteration and included both fraud and intent within that definition.<sup>121</sup> This definition may create confusion in two respects. First, FDA seems to suggest that the burden of proof for economic adulteration should be increased. For attorneys who understand the legal definition of fraud, the definition implied a new direction for FDA (because intent is included), one in which FDA action should only be taken after fraud is first proven (a difficult violation to prove). This places too much emphasis on the fraud committed (the perpetrator's motive) and too little emphasis on the condition of the food. This also suggested that FDA might be losing sight of its mission, consumer protection. Consumer protection translates to protecting consumers first from adulterated food, not first determining the perpetrator's motive and only then after protecting consumers.

Second, FDA's definition is unclear as to how it is relevant to the 1938 FDCA, which describes food adulteration and economic adulteration but does not require intent as a prerequisite for enforcement. The Agency needs to clarify its definition and also specify whether the word "fraudulent" was adopted for public effect, to bring about the necessary attention the topic deserves and perhaps also as a means to bridge the gap between both the legal community and the crusaders against food fraud community, or whether it was incorporated for some other reason. While clarification is needed, it is certain that the new definition reflects no change to the statute. Because this is a legislative issue founded in statute, all parties including the legal community and the crusaders against food fraud community should refer to the statute.

Under the 1938 Act, adulteration and intent intersect in only one instance found in 21 USCA §342(a)(7). The statute states a product is adulterated "if it has been

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<sup>118</sup>Stephen Wagner, *When Tuna Still Isn't Always Tuna: Federal Food Safety Regulatory Regime Continues to Inadequately Address Seafood Fraud*, 20 OCEAN & COASTAL L.J. 111, 112 (2015).

<sup>119</sup>*Id.* at 112, 116.

<sup>120</sup>Definition of Fraud, Black's Law Dictionary, <https://thelawdictionary.org/fraud/> (last visited May 8, 2018) (citing *Maier v. Hibernia Ins. Co.*, 67 N.Y. 283, 292 (1876)) [<https://perma.cc/T4ES-K2KN>].

<sup>121</sup>Economically Motivated Adulteration, *supra* note 105.

intentionally subjected to radiation . . . .”<sup>122</sup> In all other instances, the harm done to the product or the threat of “injurious health” is enough to prove adulteration.<sup>123</sup> This proves that Congress knows how and chooses when to require intent if it intends to do so.

Originally, courts did not address intent because it was not explicitly found in the statute. Instead, they focused on the potential harm done to the consumer rather than the guilt of the merchants and traders. FDA’s role is to protect the consumer, not the manufacturer. Thus, the mere fact that food was adulterated was enough; no intent required.<sup>124</sup> For example, in *United States v. 2 Bags, Each Containing 110 Pounds, Poppy Seeds*, the court endorsed the view that the 1938 Act was to be viewed from the consumer’s perspective, that a consumer was inexperienced and would fail to notice the differences between a higher quality and lower quality poppy seed.<sup>125</sup> The court further declared, “To set up deception of jobbers [merchants and traders] as the criterion for the determination of the issue of condemnation was, in our judgment, clearly erroneous. The express language of the pertinent provisions of the Act of Congress is reasonably susceptible of no such narrow interpretation.”<sup>126</sup> Using prior cases to support its position, the court reiterated the following words from *United States v. Thirteen Crates of Frozen Eggs*:

The Food and Drugs Act could not be enforced if the government is compelled to establish a wrongful intent on the part of those who ship prohibited articles in interstate commerce. It is enough that the articles are prohibited; and all that is necessary to be shown to justify condemnation is that the adulterated article of food has been transported in interstate commerce.<sup>127</sup>

Economic adulteration, as a subset of food adulteration, can be either intentional or unintentional, as described in the Gloucester Cheese example. The perpetrator’s intent should not be the threshold to prevent another similar incident. Further, and contrary to FDA’s working definition, economically motivated adulteration may not amount to fraud. Because unintentionally adulterated food can enter the food supply, it is imperative that FDA enforce the wrongdoing found in the condition of the food first, and in doing so, prevent harmful food from entering the food supply in the name of consumer protection without the prerequisite of proving wrongful intent. FDA should adopt food adulteration as the umbrella term that includes food fraud, economic adulteration, and economically motivated adulteration where harm is first determined. Fraud may then play a role in enforcement, but it should not play a role when assessing the condition of our food.

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<sup>122</sup>21 U.S.C. § 342(a)(7) (2003).

<sup>123</sup>Federal Food, Drug, and Cosmetic Act § 402(a).

<sup>124</sup>See *Lexington Mill*, 232 U.S. at 399.

<sup>125</sup>*Poppy Seeds*, 147 F.2d at 128.

<sup>126</sup>*Id.* at 126.

<sup>127</sup>*Id.* (citing *United States v. Thirteen Crates of Frozen Eggs*, 215 F. 584, 585 (2nd Cir. 1914)).

*How to Bridge the Gap: Solution to Resolve Definitional & Enforcement Problems in FDCA*

As for FDA's new use of the term "food fraud," it is a far cry from the longstanding definition of fraud, and it emphasizes culpability rather than the condition of the food. Thus, FDA should clarify the role of its new term and incorporate fraud only in enforcement. This will appropriately distinguish food fraud from economic adulteration and make it less difficult to protect consumers and more difficult for adulterated food to enter and remain in the food supply. It is also important for legal minds and non-legal minds to bridge the disconnect and confusion between the two terms, food fraud and food adulteration. Understandably, food fraud is a sexier term that invokes emotion and arguably makes food adulteration sound as terrible and newsworthy as it should. But if used, food fraud should be used in name only for the sole purpose of drawing attention to this issue.

Additionally, FDA should reevaluate its discretionary decisions as to whether to initiate enforcement actions against companies and individuals who economically adulterate food because consumer protection is compromised by today's economic adulteration scandals whether or not they are intentional or unintentional. However, this recommendation might not be realistic due to logistical or practical issues including budgetary restraints. In a 1997 report, GAO stated that "the existing federal system to ensure a safe food supply is fragmented, characterized by a complex maze of often inconsistent legal and regulatory requirements implemented by 12 different federal agencies, of which 6 have major roles in carrying out food safety and quality activities."<sup>128</sup> Considering the realities FDA faces, private companies may need to assume a greater role in this area, and the crusaders against food fraud community could facilitate this.

In addition, the FDCA was not created with mass production on a global scale specifically in mind. The 1938 statute was not developed for today's industrialization. It is possible the statute needs to be amended to specifically address globalization.

In terms of enforcement measures, FDA does not enforce its statutes on its own. It relies and should rely more on other agencies to support its regulatory initiatives, including the Department of Justice, through its Consumer Protection Branch.<sup>129</sup> Dr. Spink sheds light on other government agencies that can support or otherwise alleviate some of the burden on FDA. Many food adulteration incidents implicate other regulatory violations relating to intellectual property rights, fair labeling, tampering, theft, consumer product safety, misbranding, and product importation.<sup>130</sup> The DOJ is likely the agency best equipped to enforce issues that involve intent and physical harm specifically, and it can use these elements to determine appropriate penalties and remedies.

FDA must first address whether food is adulterated to isolate its investigation to the condition of the food without initial emphasis on intent. Only after FDA's determination as to whether the food is adulterated should intent and fraud play a role in enforcement decisions. It should be an element used in determining criminal and

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<sup>128</sup>Letter from Robert Robinson, Director, Food and Agricultural Issues at U.S. Gen. Acct. Off., to Congressional Committees, *Food Safety: Fundamental Changes Needed to Improve Food Safety* (Sept. 9, 1997), <https://www.gao.gov/assets/90/86979.pdf> [<https://perma.cc/5RDH-HCWH>].

<sup>129</sup>ADAMS et al., *supra* note 44, at 733.

<sup>130</sup>Spink & Moyer, *supra* note 110, at R162.

civil consequences, including remedies and penalties. If intent was a prerequisite, adulterated food would enter the food supply with no enforcement recourse and no means to protect consumers because it would be too challenging to prove. In addition, when trying to first protect consumers and remove the threat to the food supply, it is not relevant whether the perpetrator had an evil mind.

Physical harm, like intent, is an important element that should be addressed after food adulteration is initially proven because it increases the severity of the crime. Physical harm expands food adulteration beyond economic adulteration, and it reveals the serious potential impact food adulteration can have on individuals and society. It may also derive from violations of other sections of the statute. However, physical harm in this circumstance, like intent, can be difficult to prove because the proof (the food itself) is consumed and digested. Therefore, the *possible* injury to health should be enough to increase penalties.

Physical harm as a result of food adulteration is varied when it comes to public health risks. There may be immediate risks such as when a lethal or toxic substance enters the food supply, long-term exposure risks that harm public health slowly over time, and exposure risks affecting those with compromised immune systems such as the sick, the elderly, or children with allergies.<sup>131</sup> Even if a food adulteration incident does not lead to physical harm, a perpetrator's knowledge of physical harm should increase the severity of the offense, and it will also likely reduce supply chain vulnerabilities from further exploitation.<sup>132</sup> The increased severity and consequences will disincentive perpetrators. For these reasons, physical harm and intent should be incorporated in the enforcement aspect of food adulteration to increase consequences for such wrongdoings, specifically when determining punishments, penalties, and remedies.

### *How to Bridge the Gap: Methods in Place Today and Looking Toward the Future*

Previously, the best test to detect food adulteration included using senses and memory of what food tasted like in a rural setting. However, even those with firsthand knowledge find it difficult to distinguish adulterated food from unadulterated food because technology is constantly evolving to trick our senses. Food adulteration perpetrators aim to enter the food supply undetected and exploit those detection methods currently used.<sup>133</sup> And with the increased incidence of food adulteration in the world today, the threat of food defense (food terrorism) is more and more likely. For these reasons, FDA needs to take preventative measures to further protect consumers. FDA's current approach is not and will not adequately protect consumers.

As an illustration of ever-evolving technology and FDA's current strategy, consider honey-laundering. In the 1970s, honey adulteration was easily detected because of the use of invert syrups, glucose syrup, and corn syrup, but as detection methods identified the food adulteration, fraudsters changed their tactics and began to dilute honey using high fructose corn syrup instead.<sup>134</sup> The adulteration was not nearly as easy to detect

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<sup>131</sup>GAO-12-46, *supra* note 29, at 7.

<sup>132</sup>*Id.*

<sup>133</sup>Everstine et al., *supra* note 9, at 723.

<sup>134</sup>Everstine et al., *supra* note 9; Laleh Mehryar & Mohsen Esmaili, *Honey & Honey Adulteration Detection: A Review*, Conference Paper at 11th International Congress on Engineering and Food 1, 3 (May

because the sugar levels in high fructose corn syrup and honey are similar.<sup>135</sup> Today, detection methods must withstand global players and strategies; in 2013, the greatest number of adulterated honey products entered the United States market from China and Argentina.<sup>136</sup> The United States responded to these global honey players with tariffs, and to assess those tariffs and detect puddle points, the United States developed tests to analyze natural soil residue to identify the country of origin.<sup>137</sup> Again, fraudsters adapted by removing any sign of pollen or soil to trace the honey back to its country of origin.<sup>138</sup> This process continues to evolve as new adulterants enter the market. The problem is not FDA's detection methods; rather, the problem is that those who adulterate are in control of our food supply, not FDA. This is especially terrifying when considering the potential for food terrorism.

While perpetrators may currently seem to have the upper hand, there may be alternatives to predicting their next moves. For example, even though the United States currently has no designated standard to identify honey, individual states have taken action and adopted their own standards.<sup>139</sup> This could be one avenue for FDA to explore, to utilize the support of states. In addition, Dr. Spink proposes decreasing fraud opportunities by "increasing the risk of detection or increasing the costs of the necessary technology to commit the fraud and/or of developing quality levels that would attract consumers."<sup>140</sup> Here, intent and motivation could play a role. It is important to understand a perpetrator's intent and motive in order to devise tests and remain one step ahead. If FDA adopts Dr. Spink's strategies, the Agency's approach may transform into one that is more proactive.

As other federal agencies and private industry trade groups become more and more involved, the need for a shared database is important not only to record past adulteration but also to trigger warnings for future potential attacks. Some of those warning signs may include "below-market pricing, rapid increases in supplies and sales, or known imbalances in quantities between primary production and final distribution."<sup>141</sup> One solution would be to shorten the food supply chain. However, in our global world, this is not feasible on a large-scale, especially when world-wide connections are encouraged.

There are currently two food database systems in place: the USP Convention Food Fraud Database and the National Center for Food Protection and Defense (NCFPD) EMA Incident Database.<sup>142</sup> However, both are not preventative and do not take a proactive approach to ensure safe, high quality food. A congressional research service

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2011), [https://www.researchgate.net/publication/230801848\\_Honey\\_Honey\\_Adulteration\\_Detection\\_A\\_Review](https://www.researchgate.net/publication/230801848_Honey_Honey_Adulteration_Detection_A_Review) [<https://perma.cc/2MSL-8T6D>].

<sup>135</sup>Everstine et al., *supra* note 9.

<sup>136</sup>Sarah Easter Strayer et al., *Economically Motivated Adulteration of Honey: Quality Control Vulnerabilities in the International Honey Market*, 34 FOOD PROTECTION TRENDS 8, 11 (2014).

<sup>137</sup>Everstine et al., *supra* note 9. *See also* Soares, *supra* note 7, at 1072, 1088.

<sup>138</sup>Sarah Easter Strayer et al., *supra* note 136, at 9.

<sup>139</sup>Everstine et al., *supra* note 9. *See also*, Mark D. Anstoetter & Madeleine M. McDonough, *USDA to examine need for honey standard of identity*, LEXOLOGY (Aug. 22, 2014), <https://www.lexology.com/library/detail.aspx?g=0438b16a-887e-4d87-bee2-1c5e72a6709d> [<https://perma.cc/J5BZ-TLNF>].

<sup>140</sup>Spink & Moyer, *supra* note 110, at R161.

<sup>141</sup>Everstine et al., *supra* note 9, at 731.

<sup>142</sup>JOHNSON, *supra* note 28, at 10.



report stated, in reference to USP and NCFPD, that there is no way to know if the information reported through each database is accurate “because there is no single comprehensive surveillance system to detect food fraud in the United States or worldwide.”<sup>143</sup> Each database relies on submitted reports and incidents to populate its database, meaning food adulteration must have already taken place and must have already been detected in order to be recorded in each database.<sup>144</sup> Given the increasing sophistication in technology to avoid detection, it is likely each database is missing a significant number of incidents and reports of food adulteration. Thus, new technology is needed to hold each party within the supply chain accountable.

Blockchain technology is a preventative means to address both intentional and unintentional food adulteration. It is described as an “incorruptible digital ledger of economic transactions that can be programmed to record not just financial transactions but virtually everything of value.”<sup>145</sup> Blockchain technology offers accountability to the food industry and most importantly to the consumer by providing a system of checks and balances throughout the entire supply chain. As our food supply chains increase in length, it is important that we know what ingredients are added, where, and by whom. Blockchain allows for greater and quicker responses to food threats.

Blockchain technology is a shared database, public to everyone.<sup>146</sup> It is a self-auditing system that automatically updates every ten minutes in millions of computers simultaneously.<sup>147</sup> This makes information stored on the blockchain easily verifiable, transparent, and difficult for a hacker to corrupt.<sup>148</sup> In this way, information including food-product details can be stored and authenticated at every step of the supply chain. This technology will add accountability to each person involved and increase awareness as to specific products’ destinations, including recipients and for what purpose a consumer will purchase the product or ingredient. Think how this could have prevented the Gloucester Cheese incident.

Blockchain is used today to track movements within the supply chain for infant formula (recall the melamine problem) and fresh seafood through RFID tags and QR codes.<sup>149</sup> Each time the product changes hands throughout the supply chain, the QR

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<sup>143</sup>*Id.*

<sup>144</sup>JOHNSON, *supra* note 28, at 10. “Records are compiled from publicly available sources such as scientific literature, media publications, regulatory reports, judicial records and trade associations from around the world.” See *Solutions and Services: Food Fraud Database: Frequently Asked Questions*, *supra* note 101. Another food fraud database called FAIR, Food Adulteration Incidents Registry, supports food defense efforts and FSMA compilation where “data is routinely curated from publicly available sources and includes food adulteration incidents motivated by terrorism, sabotage, and fraudulent economic gain.” See Food Protection and Defense Institute, *Food Adulteration Incidents Registry* (FAIR), UNIVERSITY OF MINNESOTA, <https://foodprotection.umn.edu/fair> (last visited May 7, 2018) [<https://perma.cc/9MFC-SV3Y>].

<sup>145</sup>Ameer Rosic, *What is Blockchain Technology? A Step-by-Step Guide for Beginners*, BLOCKGEEKS (2016), <https://blockgeeks.com/guides/what-is-blockchain-technology/> [<https://perma.cc/KM8E-K5VY>].

<sup>146</sup>Sylvain Charlebois, *How Blockchain Technology Could Transform the Food Industry*, THE CONVERSATION (Dec. 19, 2017), <http://theconversation.com/how-blockchain-technology-could-transform-the-food-industry-89348> [<https://perma.cc/3C2A-HNM7>].

<sup>147</sup>Rosic, *supra* note 145.

<sup>148</sup>Lukas Schor, *Bitcoin & Blockchain Basics*, MEDIUM (Feb. 22, 2018), [<https://perma.cc/V2R9-LF3W>].

<sup>149</sup>Padraig Belton, *The Battle Against Deadly Fake Foods Goes Hi-Tech*, BBC NEWS (Dec. 5, 2017), <http://www.bbc.com/news/business-42152892> [<https://perma.cc/9PXJ-VMWB>]; Zoey Chong, *Blockchain ensures that your online baby food order is legit*, CNET (Feb. 13, 2018), <https://www.cnet.com/news/bitcoin->

code is scanned, and the information such as time, place, and content is uploaded and stored in the blockchain.<sup>150</sup> Once recorded in the blockchain, the information cannot be changed because it is in read-only format, and the labels cannot be cloned or removed without rendering the RFID useless.<sup>151</sup> This information is accessed by consumers at the shelves through an application that allows them to personally authenticate the products they buy.<sup>152</sup> Blockchain technology is not isolated to food supply chains; it is also used to trace diamonds and assure consumers that they are not buying blood diamonds.<sup>153</sup> Working in conjunction with the strategies discussed above, blockchain technology has the capacity to act as the preventative shared database system our food supply chain needs to further protect consumers both in terms of economics and health.

## CONCLUSION

From a legal perspective, adulteration remains the correct umbrella term to define and enforce appropriate food quality under the FDCA. However, the element of fraud remains relevant and should come into play after wrongdoing is established and the threat to the food supply is minimized. To bridge this gap between the two terms, FDA needs to clarify its new definition for economically motivated adulteration and whether fraud is used interchangeably with adulteration simply for effect or for another purpose. FDA also needs to more specifically address preventative measures to protect consumers and their food supply. One viable option is through the use of blockchain technology.

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technology-has-a-new-purpose-fight-food-fraud/ [https://perma.cc/55E2-ELN6]. See also ICO Oracle, *TE-FOOD, the Food Chain Sanitized by the Blockchain*, STEEMIT (Feb. 2018), <https://steemit.com/blockchain/@theicoracle/te-food-the-food-chain-sanitised-by-the-blockchain> [https://perma.cc/JU36-9KQR]; IBM also recently adopted blockchain technology, called the IBM Food Trust platform, for commercial use to trace food supply chains. Bridget van Kralingen, senior vice president for IBM Global Industries, Platforms and Blockchain said, “members of IBM Food Trust have shown blockchain can strengthen transparency and drive meaningful enhancements to food traceability. Ultimately, that provides business benefits for participants and a better and safer product for consumers.” Aaron Stanley, *Ready to Rumble: IBM Launches Food Trust Blockchain for Commercial Use*, FORBES (Oct. 8, 2018), <https://www.forbes.com/sites/astanley/2018/10/08/ready-to-rumble-ibm-launches-food-trust-blockchain-for-commercial-use/amp/> [https://perma.cc/E5VP-3M2W].

<sup>150</sup>Chong, *supra* note 149; Larry Myler, *Farm-To-Table: How Blockchain Tech Will Change the Way You Eat*, FORBES (Feb. 16, 2018), <https://www.forbes.com/sites/larrymyler/2018/02/16/farm-to-table-how-blockchain-tech-will-change-the-way-you-eat/> [https://perma.cc/5LV2-TSJS].

<sup>151</sup>Chong, *supra* note 149.

<sup>152</sup>Myler, *supra* note 150.

<sup>153</sup>Belton, *supra* note 149.