

Food Fraud and “Economically Motivated Adulteration” of Food and Food Ingredients

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Food fraud, or the act of defrauding buyers of food or ingredients for economic gain—whether they be consumers or food manufacturers, retailers, and importers—has vexed the food industry throughout history. Some of the earliest reported cases of food fraud, dating back thousands of years, involved olive oil, tea, wine, and spices. These products continue to be associated with fraud, along with some other foods. Although the vast majority of fraud incidents do not pose a public health risk, some cases have resulted in actual or potential public health risks. Perhaps the most high-profile case has involved the addition of melamine to high-protein feed and milk-based products to artificially inflate protein values in products that may have been diluted. In 2007, pet food adulterated with melamine reportedly killed a large number of dogs and cats in the United States, followed by reports that melamine-contaminated baby formula had sickened thousands of Chinese children. Fraud was also a motive behind Peanut Corporation of America's actions in connection with the *Salmonella* outbreak in 2009, which killed 9 people and sickened 700. Reports also indicate that fish and seafood fraud is widespread, consisting mostly of a lower-valued species, which may be associated with some types of food poisoning or allergens, mislabeled as a higher-value species. Other types of foods associated with fraud include honey, meat and grain-based foods, fruit juices, organic foods, coffee, and some highly processed foods.

It is not known conclusively how widespread food fraud is in the United States or worldwide. In part, this is because those who commit food fraud want to avoid detection and do not necessarily intend to cause physical harm. Most incidents go undetected since they usually do not result in a food safety risk and consumers often do not notice a quality problem. Although the full scale of food fraud is not known, the number of documented incidents may be a small fraction of the true number of incidents. The Grocery Manufacturers Association estimates that fraud may cost the global food industry between \$10 billion and \$15 billion per year, affecting approximately 10% of all commercially sold food products. Fraud resulting in a food safety or public health risk event could have significant financial or public relations consequences for a food industry or company.

There is no statutory definition of food fraud or “economically motivated adulteration” (EMA) of foods or food ingredients in the United States. However, as part of a 2009 public meeting, the Food and Drug Administration (FDA) adopted a working definition, defining 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.” Efforts are ongoing to compile and capture current and historical data on food fraud and EMA incidents through the creation of databases and repositories.

Over the years, Congress has introduced a number of bills intended to address concerns about food fraud for a particular food or food ingredient. Such legislation has not addressed food fraud in a comprehensive manner. However, although no single federal agency or U.S. law directly addresses food fraud, a number of existing laws and statutes already provide the authority for various federal agencies to address fraud. Currently, food fraud is broadly addressed through various food safety, food defense, and food quality authorities as well as border protection and import authorities across a number of federal agencies. FDA and the U.S. Department of Agriculture are the principle agencies that are working to protect the food supply from food safety risks—both unintentionally and intentionally introduced contamination—in conjunction with border protection and enforcement activities by the U.S. Department of Homeland Security. Other agencies also play a role.

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Background

Food fraud, or the act of defrauding buyers of food and food ingredients for economic gain—whether they be consumers or food manufacturers, retailers, and importers—has vexed the food industry throughout history. Some of the earliest reported cases of food fraud, dating back thousands of years, involved olive oil, wine, spices, and tea.¹ These same products continue to be associated with fraud, along with a range of other products. Overall, foods and food ingredients commonly associated with food fraud include olive oil, fish, honey, milk and dairy products, meat products, grain-based foods, fruit juices, wine and alcoholic beverages, organic foods, spices, coffee, and tea, and some highly processed foods. It is not known conclusively how widespread food fraud is in the United States or worldwide. In part, this is because those who commit fraud do not intend to cause physical harm and want to avoid detection. Most incidents go undetected since they usually do not result in a food safety risk and consumers often do not notice a quality problem. Moreover, as the motivation to commit fraud is illicit monetary gain, the type of food that might be or become adulterated is a secondary consideration (i.e., it could be any type of food or food ingredient); rather, it is the opportunity or feasibility of committing fraud that generally triggers the fraud.²

Although the vast majority of food fraud incidents do not pose a public health risk, there have been fraud cases that have resulted in actual or potential public health risks. Perhaps the most widely cited, high-profile cases have involved the addition of melamine to high-protein feed and milk-based products to artificially inflate protein values in products that may have been diluted. For example, in 2007, evidence emerged that adulterated pet food ingredients from China had caused the deaths of a large number of dogs and cats in the United States.³ This was followed by reports that melamine-contaminated baby formula had sickened an estimated 300,000 Chinese children, killing a reported 6 infants.⁴ Evidence now suggests that safety risks associated with melamine-tainted feed date back to 2003, and that melamine was first reported to be added to artificially increase protein content in feed as far back as 1982.⁵

Reports also indicate fish and seafood fraud may be widespread in some markets, consisting mostly of the mislabeling or substitution of a higher-valued species with something different from and inferior to the expected species, possibly with a fish species which could be associated with some types of food poisoning or exposure to certain allergens.⁶ Similarly, substitution of olive oil with other types of seed, legume, or nut oils could have unintended consequences, if consumed by those with certain food allergies.

Some cases might not initially appear to involve intentional adulteration, except on closer examination. Charges of fraud were part of the federal criminal indictment charging former officials of the Peanut Corporation of America with numerous offenses in connection with the *Salmonella* outbreak in 2009—which killed 9 people and sickened 700—since company officials

¹ See, for example, B. Wilson, *Swindled: From Poison Sweets to Counterfeit Coffee—The Dark History of Food Fraud*, John Murray (Publishers), 2008; T. Mueller, *Extra Virginity: The Sublime and Scandalous World of Olive Oil*, W. W. Norton & Company, 2011; and S. Foster, "A Brief History of Adulteration of Herbs, Spices, and Botanical Drugs," *HerbalGram*, Issue 92 (pp. 42-57), 2011, American Botanical Council.

² CRS communication with researchers at the United States Pharmacopeial Convention (USP), December 23, 2013.

³ For other background information, see CRS Report RL34080, *Food and Agricultural Imports from China*.

⁴ H. Bottemiller, "Chinese Authorities Seize Melamine-tainted Dairy," *Food Safety News*, April 29, 2011.

⁵ J. Moore, "The USP Food Fraud Database, and Beyond" Presentation at the USP Workshop of Economically Motivated Adulteration of Food Ingredients and Dietary Supplements, September 26–27, 2013.

⁶ For other background information, CRS Report RL34124, *Seafood Marketing: Combating Fraud and Deception*.

were found to have sold and distributed product known to be contaminated.⁷ That case resulted in one of the largest product recalls in U.S. history, including 3,912 products that contain peanut butter and peanut paste ingredients, such as cookies, crackers, cereal, candy, ice cream, pet treats, and other foods, which were manufactured by more than 200 companies.⁸

Risks from other types of fraudulent foods are not as well-documented and may be less immediate or may never be known. Generally, only those who have knowledge of the fraud are those who commit the fraud. In some cases, independent tests might uncover fraud. For example, FDA testing upon import has documented the presence of unapproved chemicals in honey, which have triggered import alerts.⁹ Reports indicate that honey from China may contain certain unapproved antibiotics or other agricultural chemicals.¹⁰ Reports also indicate that some fruit juices may be made from or diluted with juice from rotten fruit and may contain toxic mold.¹¹ In recent years, fraud involving the addition of certain food processing aids (known as "clouding agents") has raised concern given the potential public health risks and reportedly increased use in certain highly processed foods.¹² Some fraud cases might only be uncovered following an investigation in the wake of a public health event, such as when pet food adulterated with melamine caused the deaths of dogs and cats in the United States. Some fraud cases, however, might never be discovered even though they could contribute to chronic long-term health consequences.

Other food fraud concerns might not result in a public health or food safety crisis, but instead deprive the food buyer of the product they think they are getting. Most food fraud cases involve the substitution of a high-value product with a less expensive or lower quality alternative. Such cases include cheaper products mislabeled as extra virgin olive oil from Italy, wild Alaskan salmon, caviar, and pomegranate juice or juices from other "super" fruit. In another example, in Europe in early 2013, it was reported that products labeled as containing beef were found to actually contain 80%-100% horsemeat, which the meat supplier had knowingly failed to report to local authorities.¹³ Although the horsemeat incident ultimately did not result in public health consequences, initial concerns about potential health risks due to, for example, phenylbutazone¹⁴ resulted in a substantial expenditure of public resources over the course of the investigation. Such cases also erode consumer confidence and may cause other concerns for a variety of societal or cultural reasons.

The Grocery Manufacturers Association (GMA) estimates that fraud may cost the global food industry between \$10 billion and \$15 billion per year,¹⁵ affecting approximately 10% of all

⁷ Department of Justice press release, "Former Officials and Broker of Peanut Corporation of America Indicted Related to Salmonella-Tainted Peanut Products," February 21, 2013.

⁸ For other background information, see CRS Report R40450, *Penalties Under the Federal Food, Drug, and Cosmetic Act (FFDCA) That May Pertain to Adulterated Peanut Products*.

⁹ See, for example, Import Alert # 36-03 (Detention Without Physical Examination of Honey Due to Chloramphenicol), June 20, 2013, http://www.accessdata.fda.gov/cms_ia/importalert_110.html.

¹⁰ A. Schneider, "Tests Show most Store Honey Isn't Honey," *Food Safety News*, November 7, 2011.

¹¹ See, for example, FDA, "Patulin in Apple Juice, Apple Juice Concentrates and Apple Juice Products," September 2001; and "China to investigate rotten fruit juice," *China.org.cn*, September 24, 2013.

¹² USP press release, "Food Fraud Reports Up 60% Since 2010," January 23, 2013.

¹³ European Commission, "Q&A on Horsemeat," <http://ec.europa.eu/food/food/horsemeat/>; and Ireland's Department of Agriculture, Food and the Marine, "Equine DNA and Mislabeling of Processed Beef Investigation," March 2013.

¹⁴ Phenylbutazone is a non-steroidal anti-inflammatory medicine to treat musculoskeletal disorders, such as rheumatoid and arthritis, and is authorized for medicinal use in horses that are not intended for human consumption.

¹⁵ GMA, *Consumer Product Fraud, Deterrence and Detection*, 2010, <http://www.gmaonline.org/downloads/wygwam/consumerproductfraud.pdf>; and A. Kircher, NCFPD, "Tools for Protecting the Nation's Food Supply," June 5, 2012.

commercially sold food products.¹⁶ However, most researchers acknowledge that the full scale of food fraud “may be unknown or even possibly unknowable”¹⁷ even though the number of documented incidents is “most likely a fraction of the true number of incidents, since the goal of adulteration for economic gain is not to be detected.”¹⁸ Compared to the trillions of dollars spent on food and food ingredients globally each year, however, “the prevalence of food fraud is ultimately very low.”¹⁹ Fraud resulting in a food safety or public health risk event, however, could have significant financial or public relations consequences for a food industry or company. GMA estimates that fraud costs food businesses in terms of lost sales, estimated between 2% and 15% of annual revenues, as well as possible bankruptcies if adverse public health consequences occur.

The text box on the next page describes some of the types of foods and food ingredients associated with fraud based on available research and information.

Addressing food fraud concerns has become exceedingly complicated by rising U.S. imports and increased globalization of the world’s food and agricultural supplies. Increasingly, multiple product ingredients and inputs are sourced from a range of countries, both in terms of individually sourced products and ingredients between individual food companies/importers as well as in terms of internally sourced products from foreign-owned entities within a larger multinational company (such as global sourcing between parent and subsidiary). It is difficult to detect and trace not only the source of unintentional contamination and related food safety concerns, but it is often more difficult to detect and trace-back instances of intentional product fraud, especially in highly processed foods with multiple ingredients and inputs from multiple suppliers.

This report provides an overview of issues pertaining to food fraud and “economically motivated adulteration” or EMA, a category within food fraud. First, the report provides general background information on food fraud and EMA, including how it is defined and the types of fraud, as well as how food fraud fits into the broader policy realm of food safety, food defense, and food quality. Second, the report provides available information about foods and ingredients with reported cases of fraud from two databases: (1) the United States Pharmacopeial Convention (USP) Food Fraud Database and (2) the National Center for Food Protection and Defense (NCFPD) EMA Incident Database. Finally, the report describes previous and ongoing federal and congressional actions to address food fraud.

Leading Food Categories with Reported Cases of Food Fraud

Olive Oil. Olive oil is often substituted with a lower cost alternative, whether it is regular olive oil instead of higher-priced extra virgin olive oil or a less expensive variety from Greece or Turkey, instead of from Italy as the label claims. In such cases the fraud was associated with efforts to defraud the European Union’s farm support program, which subsidizes olive oil, as part of the Common Agricultural Policy (CAP). In some cases an alternate seed or nut oil may be sold as or thinned out with hazelnut, soybean, corn, peanut, sunflower, safflower, walnut, vegetable, canola, or palm oil, and in one case, lard. Some combinations contained no olive oil. The use of nut or legume oils could pose a problem for those with certain food allergies. In rare cases, non-food-grade oil may be added, such as rapeseed.

¹⁶ Estimated by the Food Standards Agency of the U.K., as reported by K. Everstine and A. Kircher, “The Implications of Food Fraud,” *Food Quality & Safety* magazine, June/July 2013.

¹⁷ J. Spink and Z.L. Fejes, “A review of the economic impact of counterfeiting and piracy methodologies and assessment of currently utilized estimates,” *International Journal of Comparative and Applied Criminal Justice*, September 2012.

¹⁸ NCFPD, “EMA Frequently Asked Questions,” <http://www.ncfpd.umn.edu/>.

¹⁹ Comments attributed to John Spink, Michigan State University’s Food Fraud Initiative, as reported by M. Oaklander, “11 Most Fraudulent Foods,” *Prevention.com*.

Fish and Seafood. Some higher-value fish and seafood are replaced with cheaper, more abundant fish. A report by Oceana found that fish samples purchased at grocery stores, restaurants, and sushi bars in major cities were often mislabeled, including red snapper (actually tilefish); white tuna and butterfish (actually escolar); wild Alaskan salmon (actually farmed Atlantic salmon); caviar (actually catfish roe); and monkfish (puffer fish). Other types of substitutions have involved halibut, sole, grouper, and striped bass. Some substitutions have involved fish or seafood associated with certain types of fish poisoning or allergens. Other substitutions are intended to evade import and other restrictions.

Milk and Milk-based Products. Milk from bovine cows has had milk from other types of animals, such as sheep, buffalo, and goats-antelopes, added to it, but also adulterated with reconstituted milk powder, urea, and rennet, among other products (oil, detergent, caustic soda, sugar, salt, and skim milk powder). Adulterated milk may also be watered down and then supplemented with melamine to artificially raise the apparent protein content and hide dilution. Melamine, an organic base chemical, is widely used in plastics, adhesives, and other consumer products, and is known to pose a public health threat. Adulterated milk might also be added into infant formula and other milk-based products. Baby formula is a common target for retail theft, often by tampering with the sell-by codes to move expired product.

Honey, Maple Syrup, and Other Natural Sweeteners. Honey might have added sugar syrup, corn syrup, fructose, glucose, high-fructose corn syrup, and beet sugar, without being disclosed on the label. Honey from a "non-authentic geographic origin" is also common, such as cases where honey from China is transshipped through another Asian country and falsely sold as honey from the second country—usually to avoid higher customs duties and tariffs that would be imposed on honey from China. Some of this honey might also contain unapproved antibiotics or other additives and heavy metals. Maple syrup is sometimes thinned out with sugar or corn syrup.

Fruit Juice. Juices might be watered down, or a more expensive juice (such as from pomegranates or other "super" fruit) might be cut with a cheaper juice (such as apple or grape juice). Some juice may be only water, dye, and sugary flavorings, although fruit is the listed ingredient on the label. Orange juice has been shown to sometimes contain added unlisted lemon juice, mandarin juice, grapefruit juice, high fructose corn syrup, paprika extract, and beet sugar. Apple juice has been shown to have added unlisted grape juice, high fructose corn syrup, pear juice, pineapple juice, raisin sweetener, fig juice, fructose, and malic acid.

Coffee and Tea. Ground coffee might be cut with leaves and twigs, as well as roasted corn, ground roasted barley, and roasted ground parchment. Instant coffee may include chicory, cereals, caramel, more parchment, starch, malt, and figs. Tea may contain leaves from other plants, color additives, and colored saw dust.

Spices. Saffron is the world's most expensive spice, and has been found to have added glycerin, sandalwood dust, tartrazine (a yellow dye), barium sulfate, and borax. Ground black pepper has been shown to have added starch, papaya seeds, buckwheat, flour, twigs, and millet. Vanilla extract, turmeric, star anise, paprika, and chili powder are other spices prone to fraud. Sudan red dyes have been used to color paprika, chili powders, and curries, but are also known carcinogens and are banned for use in foods.

Organic Foods and Products. Using fraudulent certification to market, label, or sell non-organic (conventionally produced) agricultural products as USDA-certified "organic" is a violation of U.S. law and federal National Organic Program (NOP) regulations. Products fraudulently labeled as "organic" have been detected by USDA for a range of foods and food ingredients from both domestic and international suppliers.

Clouding agents. "Clouding agents" or food processing aids "to enhance the appeal or utility of a food or food component," such as palm oil and other allowed food ingredients, are often used in fruit juices, jams, and other foods. Of particular concern is the fraudulent replacement or addition of the plasticizer Di(2-ethylhexyl) phthalate (DEHP) and other related phthalates, as a substitute for other ingredients. DEHP may also be used in food contact materials, such as seals and packaging. DEHP is associated with public health risks, including cancer and reproductive concerns.

Source: CRS compilation from information reported by USP, Michigan State University, NCFPD and researchers at the University of Minnesota, Oceana, Consumers Union, *Food Chemical News*, and the Rodale Institute. Unless otherwise indicated, "adulteration" and "misbranding" of foods is prohibited under various FDA and USDA laws.

Existing Definitions

There is no statutory definition of food fraud or "economically motivated adulteration" or EMA of foods or food ingredients, which is generally considered a subset of food fraud. However, the U.S. Food and Drug Administration (FDA) adopted a "working definition" for an April 2009 public meeting to raise awareness and solicit public input regarding economically motivated

adulteration of FDA-regulated products. For the purposes of the workshop, FDA defined “economically motivated adulteration” as the:²⁰

fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production, i.e., for economic gain. EMA includes dilution of products with increased quantities of an already-present substance (e.g., increasing inactive ingredients of a drug with a resulting reduction in strength of the finished product, or watering down of juice) to the extent that such dilution poses a known or possible health risk to consumers, as well as the addition or substitution of substances in order to mask dilution.

Other countries generally also do not have established legal definitions of food fraud. A recent European Union (EU) report on food fraud states the EU laws do not provide for a “generally acknowledged definition of food fraud” despite an extensive legislative framework focused on food safety.²¹ The only general guideline is found in EU regulations requiring that food labeling, advertising, presentation, and packaging “shall not mislead consumers.”²² However, these requirements reportedly vary among EU member states and food fraud in Europe remains largely undetected, similar to that in the United States. The United Kingdom’s Food Standards Agency (FSA) describes “food fraud” as the deliberate placement on the market, for financial gain, with the intention of deceiving the consumer, covering two main types of fraud.²³ These include the sale of food which is unfit and potentially harmful²⁴ as well as the deliberate misdescription of food, such as products substituted with a cheaper alternative.²⁵

Researchers and industry groups actively working in this area have myriad definitions of food fraud and EMA.

Broadly speaking, food fraud is a type of product fraud. According to food safety researchers at Michigan State University’s (MSU’s) Food Fraud Initiative:²⁶

Food fraud is 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.

The United States Pharmacopeial Convention (USP) states:²⁷

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

²⁰ 74 *Federal Register* 64: 15497-15499, April 6, 2009.

²¹ European Parliament, Committee on the Environment, Public Health and Food Safety draft report “on the food crisis, fraud in the food chain and the control thereof,” (2013/2091(INI)).

²² Regulation 178/2002 on general principles and requirements regarding food labeling, advertising, presentation, and packaging.

²³ FSA, “Food Fraud”, http://www.food.gov.uk/enforcement/enforcework/foodfraud/#.Un46Kz_qSSo.

²⁴ Cited examples include the recycling of animal by-products back into the food chain packing and selling of beef and poultry with an unknown origin knowingly selling goods which are past their “use by” date.

²⁵ Cited examples include farmed salmon sold as wild, and Basmati rice adulterated with cheaper varieties making false statements about the source of ingredients.

²⁶ J. Spink and in D.C. Moyer, *Backgrounder: Defining the Public Health Threat of Food Fraud*, National Center for Food Protection and Defense, April 2011.

²⁷ USP, Food Fraud Database, Glossary of Terms, <http://www.foodfraud.org/glossary-terms>.

In this context, “adulterant” is defined as “the undesirable substance” or “fraudulently added material” in a fraudulent food or food ingredient. In the case of food fraud, the adulterants used often are unconventional and designed to avoid detection through routine inspection.²⁸

According to researchers at the National Center for Food Protection and Defense (NCFPD) at the University of Minnesota:²⁹

Economically motivated adulteration (EMA) is the intentional sale of substandard food or food products for the purpose of economic gain. Common types of EMA include intentional substitution of an authentic ingredient with a cheaper product, dilution with water or other substances, flavor or color enhancement using illicit or unapproved substances, and substitution of one species with another.

The Grocery Manufacturers Association (GMA) provides the following definitions of “economic adulteration” as part of its report on consumer product fraud in the food, beverage, and consumer product industry:³⁰

Economic adulteration is defined as the intentional fraudulent modification of a finished product or ingredient for economic gain through the following methods: unapproved enhancements, dilution with a lesser-value ingredient, concealment of damage or contamination, mislabeling of a product or ingredient, substitution of a lesser-value ingredient or failing to disclose required product information.

These definitions broadly reference three types of fraud, as defined by USP and other university researchers, namely:³¹

- **complete or partial replacement** of a food ingredient or valuable authentic constituent with a less expensive substitute (or alternative animal species in the case of some meat and fish);
- **addition** of small amounts of a non-authentic substance to mask inferior quality ingredient (or excess packing ingredients, including water and ice); and
- **removal or intentional omission** of an authentic and valuable constituent in a food product or food ingredient.

Also included are false claims and non-declarations based either on geographic, species, botanical, varietal origin, and production processes in order to provide economic benefit through the substitution of a particular food or food ingredient with a lower priced or a lower quality ingredient. Fraud may also be motivated in cases where a particular food or food ingredient is in short supply, triggering the motivation to substitute one input for another. In other cases false declarations of origin are intended to evade taxes and tariffs in importing countries. Food fraud also includes smuggling, tampering, and stolen goods. The text box on the next page provides more detailed information.

²⁸ “Food Ingredients Most Prone to Fraudulent Economically Motivated Adulteration,” *Science Daily*, April 5, 2012. Unconventional adulterants may trigger food safety concerns, as they might not be approved for use in food.

²⁹ NCFPD, “EMA Frequently Asked Questions,” <http://www.ncfpd.umn.edu>.

³⁰ GMA, *Consumer Product Fraud, Deterrence and Detection*, 2010.

³¹ J.C. Moore, J. Spink, and M. Lipp, “Development and Application of a Database of Food Ingredient Fraud and Economically Motivated Adulteration from 1980 to 2010,” *Journal of Food Science*, Vol. 77, Nr. 4, 2012; and USP, Food Fraud Database, Glossary of Terms, <http://www.foodfraud.org/glossary-terms>.

Risks to Food Protection

Figure 1 provides a matrix of food protection risk and illustrates how food fraud fits into the broader policy realm of food safety, food defense, and food quality.³² Although these concepts may not always fit neatly into these categories and there may be overlap across these categories, this matrix provides a useful, and widely cited, framework for differentiating among these food protection areas.

In general, food fraud and food defense (agro-terrorism) are both intentional. Food fraud is always economically motivated. Motivation in the case of food defense includes the intention to inflict public harm or threaten consumers, and is considered to be food fraud.³³ Food fraud usually is perpetrated by actors normally involved in the food chain that have regular access to the food product (e.g., manufacturers or distributors). Problems with food defense usually are perpetrated by outsiders, including terrorists, who do not normally have access to the food product. NCFPD reports that most incidents of food fraud generally do not result in public health harm; however, sometimes perpetrators of food fraud "make mistakes and unintended health consequences result."³⁴ **Table 1** contrasts the different types of food-related risks, and provides examples, causes and motivations, primary and secondary effects, and also types of public health risks.

³² Based on work published in J. Spink and D.C. Moyer, "Defining the Public Health Threat of Food Fraud," *Journal of Food Science*, 2011, and other resources from MSU's Food Fraud Initiative (<http://foodfraud.msu.edu/>).

³³ CRS communication with Karen Everstine, NCFPD, December 27, 2013. For additional information on food defense, see section titled "Food Defense" in CRS Report R42985, *Issues in Homeland Security Policy for the 113th Congress*; and CRS Report RL34160, *The National Bio- and Agro-Defense Facility: Issues for Congress*. For more direct assistance, congressional clients may contact Jim Monke, Specialist in Agricultural Policy.

³⁴ NCFPD, "EMA Frequently Asked Questions," <http://www.ncfpd.umn.edu>.

Types of Food Fraud

(1) Replacement: Complete or partial replacement of a food ingredient or valuable authentic constituent with a less expensive substitute, usually achieved through the *addition, dilution, or extension* of an authentic ingredient with an adulterant or mixture of adulterants. Examples include addition of melamine to milk to artificially increase apparent protein contents; addition of water and citric acid to lemon juice to fraudulently increase the titratable acidity of the final juice product; and overtreating frozen fish with ice (adds extra water, potentially unsanitary). Included are false claims and non-declarations:

- False declaration of geographic, species, botanical, or varietal origin (e.g., substitution of less expensive cow's milk for sheep's or goat's milk; substitution of common wheat for durum wheat; substitution of Greek or Turkish olive oil labeled as Italian olive oil; substitution of synthetically produced vanillin for botanically derived natural vanillin); farmed salmon sold as wild; and the sale of meat from animals that have been stolen and/or illegally slaughtered, such as wild game animals that may have been poached.
- False declaration of origin to evade taxes/tariffs (e.g., U.S. imports of catfish from Vietnam labeled as grouper to avoid anti-dumping duties; transshipment of Chinese products, such as shrimp and honey, through other Asian nations to avoid anti-dumping duties or to mask the true origin of potentially unsafe product).
- False declaration of production process (e.g., fraudulent labeling of a synthetically derived flavor chemical as being "naturally" derived; food falsely labeled or certified as organically produced); or poor quality filtered honey or a honey substitute product labeled as raw honey, which reportedly has medicinal properties.

Such fraudulent practices are generally intended to provide economic benefit through the substitution of a particular food or food ingredient with a lower priced or a lower quality ingredient. In some cases, short supply of a particular food or food ingredient might trigger the motivation to substitute one input for another, for example, when horse meat was found in prepared meals as a result of a reduced European supply of beef and other meat products.

(2) Addition: Addition of small amounts of a non-authentic substance to mask inferior quality ingredient. An example is the addition of a color additive (such as Sudan Red dyes) to enhance the color of poor quality paprika.

(3) Removal: Removal or intentional omission of an authentic and valuable constituent without the purchasers' knowledge. One example is the removal of non-polar constituents from paprika (e.g., lipids and flavor compounds) to produce paprika-derived flavoring extracts, or "defatted" paprika, which lacks valuable flavoring compounds, as normal paprika. Another example is poor quality honey that has been filtered to remove pollen or other residue from the beehive, in order to make it difficult to determine the honey's botanical and geographic origin or to circumvent the ability to trace and identify the actual source of the honey.

Source: J.C. Moore, J. Spink, and M. Lipp, "Development and Application of a Database of Food Ingredient Fraud and Economically Motivated Adulteration from 1980 to 2010," *Journal of Food Science*, Vol. 77, Nr. 4, 2012; and USP, Food Fraud Database, Glossary of Terms, <http://www.foodfraud.org/glossary-terms>.

Note: "Transshipment" refers to the transfer of a shipment from one carrier or vessel to another during transit, usually to hide the identity of the port or country of origin.

In contrast, problems with food safety and food quality are unintentional. Both food quality and food safety incidents may result in an economic impact to a particular food or food ingredient industry, for example, due to reduced purchases or brand equity, but also from product recalls, process controls, and liability in the case of food safety. Food safety concerns can also cause a threat to public health and create public fear. Adulteration will cause a loss of the consumer's trust in the food supply chain, and a loss in trust among regulators, industry, and U.S. trading partners, and may result in market and trade disruptions. Unintentional adulteration involving food quality concerns might also occur due to environmental factors, and packaging, storage, and distribution issues, among other factors.

Figure 1. Food Protection Risk Matrix

Food Quality	Food Fraud (1)	<u>Motivation</u> Gain : Economic
Food Safety	Food Defense	Harm: Public Health, Economic, or Terror
Unintentional	Intentional	
<u>Action</u>		

(1) Includes the subcategory of economically motivated adulteration and food counterfeiting

Source: J. Spink and D.C. Moyer, "Defining the Public Health Threat of Food Fraud," *Journal of Food Science*, 2011.

Table 1. Food Protection Risk: Examples, Cause and Effects

Risk Type	Example	Cause and Motivation	Effect	Public Health Risk Type	Secondary Effect
Food Quality	Accidental bruising of fruit	Mishandling	Unsalable product or possible additional contamination	None, or possible food safety	Reduced product/brand equity or food safety incident
Food Fraud	Intentional adulteration of milk with melamine	Increased profit margins	Toxic poisonings	Food safety	Public fear and possible lower prices industry-wide
Food Safety	Unintentional contamination of raw vegetables with <i>E. coli</i>	Limited field protection and control during harvesting and processing	Illness and/or death	Food safety	Damaged industry, recall expense, and public fear
Food Defense	Intentional contamination of ground beef with nicotine	Revenge against the store/manager through injury to consumers	Nonlethal poisonings	Food defense	Adulterated product, damaged industry, recall expense, public fear

Source: J. Spink and D.C. Moyer, "Defining the Public Health Threat of Food Fraud," *Journal of Food Science*, 2011.

Available Data and Information Repositories

Review of Available Database Information

Efforts are ongoing to compile and capture current and historical data on food fraud and EMA incidents through the creation of databases and repositories. Although the information in these databases is not comprehensive and may contain certain limitations, it does represent the best information available and provides a first step to understand the scope and scale of food fraud as a way to further detect, combat, and prevent future fraud. The information contained in these databases is from the University of Minnesota as well as the United States Pharmacopeial Convention (USP), a long-standing scientific nonprofit organization. In addition, researchers from Michigan State University conducted further analysis of the USP databases, along with USP researchers. These databases provide a relatively new resource to examine food fraud incidents, and were first published starting in 2012 and 2013. Since then, information from these databases has been published in peer reviewed journal articles and presented at professional conferences by both academic researchers and industry leaders.³⁵ Nevertheless, because there is no single comprehensive surveillance system to detect food fraud in the United States or worldwide, it is not possible to know what portion of food fraud incidents may be captured by these databases, and whether or not the information in these databases represents the universe of potential food fraud incidents.

Information in these databases also has been widely cited by academic researchers, government officials, and the media to rank the leading foods and food ingredients that are most often associated with fraud. For example, information in the USP Food Fraud Database was used by the European Parliament to help identify the leading fraudulent foods, as part of its recent draft report calling for increased oversight of food fraud.³⁶ NDFPD's database, and preliminary analysis of information obtained from USP's database, was originally funded by the U.S. Government through funding from the Department of Homeland Security (DHS), FDA, and the U.S. Department of Agriculture (USDA), as well as funding from the private sector. USP's database and related activities are self-funded and provided in accordance with USP's mission to support public health, and are not supported by funding from any outside agency.

The two available databases are:

1. United States Pharmacopeial Convention (USP) Food Fraud Database, and
2. National Center for Food Protection and Defense (NCFPD) EMA Incident Database.

USP's database is open and publicly accessible; NCFPD's databases are accessible upon request.

Information in these databases is from available scholarly journal articles and industry analyses and lab tests (where available), as well as media reports, about foods and food ingredients that are vulnerable to fraudulent manipulation. These records are based on English-language scholarly and/or media sources. Both databases are largely global in scope and broadly represent fraud in foods and food ingredients sold commercially worldwide. Undoubtedly the information in these databases does not capture all cases of food fraud and EMA, or incidents that may occur in small-

³⁵ For example, presentations and comments at the USP Workshop of Economically Motivated Adulteration of Food Ingredients and Dietary Supplements, Rockville, MD, September 26–27, 2013.

³⁶ European Parliament, Committee on the Environment, Public Health and Food Safety draft report "on the food crisis, fraud in the food chain and the control thereof" (2013/2091[INI]).

scale markets or on a non-commercial scale or incidents that may or may not be reported in various non-English speaking information outlets.

Since those who commit fraud actively seek to avoid detection, some food fraud and EMA cases might not be captured in either database. In fact, in some cases, records in the database may be more reflective of where research is being conducted or where resources have been dedicated in a concerted effort to root out fraud, rather than provide an exhaustive accounting of all fraud cases.

Differences between these two databases, including how they were compiled and the type of records they reference, among other things, may result in differences in how different foods and food ingredients may be ranked in terms of their susceptibility to food fraud and EMA.

These databases do not address fraud involving “dietary supplements.”³⁷ Dietary supplements are a special category of food that includes finished products (e.g., a vitamin D tablet) that contain one or more “dietary ingredients” or are components of those finished products (e.g., vitamin D added to a food product such as breakfast cereal).³⁸ Like food fraud, fraud involving dietary supplements is a type of product fraud with documented concerns involving public health risks.³⁹ Additional research in this area is currently being considered, including development of a database of reported cases of dietary supplement fraud.⁴⁰

USP Food Fraud Database

The United States Pharmacopeial Convention (USP) Food Fraud Database is a public database that catalogues available analytical methods to detect and identify problematic food ingredients, which in turn provides a repository for ingredient fraud reports.⁴¹ The database is comprised of both “scholarly” and “media” reports from available food science scholarly sources (and undocumented industry analyses, where available) and mainstream English-language media. The database is not an “incidents” database where individual records have been further grouped by source and time period, but instead it catalogues reports involving detection methods and analyses of food fraud incidents.⁴² As a result, information in the database may be more representative of foods that are the most researched, and not necessarily foods that are the most adulterated. The USP database is organized by food ingredient categories and identifies the type of adulterant reported for each documented record and broadly classifies each record by the type of fraud (e.g.,

³⁷ For general information on dietary supplements, see CRS Report R43062, *Regulation of Dietary Supplements*.

³⁸ V.M. Wheatley and J. Spink, “Defining the Public Health Threat of Dietary Supplement Fraud,” *Comprehensive Reviews in Food Science and Food Safety*, Vol.12, 2013.

³⁹ D.S. Fabricant, “Dietary Supplement Adulteration”. Presentation and comments at the USP Workshop of Economically Motivated Adulteration of Food Ingredients and Dietary Supplements, September 26–27, 2013.

⁴⁰ Comments by J. Spink, MSU, November 12, 2013, as part of the massive open online course (MOOC) on food fraud.

⁴¹ USP Food Fraud Database, <http://www.foodfraud.org/>, and the USP, *Food Chemicals Codex*, 8th Edition. For information: <http://www.foodfraud.org/frequently-asked-questions>. USP is a “scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide” (<http://www.usp.org/about-usp>). Other information is at J. Moore, “The USP Food Fraud Database.” Presentation at the USP Workshop of Economically Motivated Adulteration of Food Ingredients and Dietary Supplements, September 26–27, 2013.

⁴² Detection technologies recorded in the database include high-performance liquid chromatography; standards for infrared spectroscopy; gas chromatography; isotope ratio mass spectrometry; hyphenated mass spectrometry methods; near infrared spectroscopy; polymerase chain reaction; capillary electrophoresis; enzyme linked immunosorbent assay; thin-layer chromatography; site-specific natural isotope fractionation; mid-infrared spectroscopy; Raman spectroscopy; nuclear magnetic resonance spectroscopy; high-performance anion exchange chromatography; resonance spectroscopy; high-performance anion exchange chromatography; and differential scanning calorimetry.

addition, replacement, removal), but does not provide other information such as where the product was originally produced.

The initial version of the database was published in 2012 in the USP's 8th Edition of the *Food Chemicals Codex*⁴³ and was accompanied by initial analyses of the database records published in the April 2012 issue of the *Journal of Food Science*,⁴⁴ with the support of researchers at the MSU's Food Fraud Initiative. Initial funding for MSU's contribution to the manuscript was provided by the National Center for Food Protection and Defense (NCFPD) through DHS, with other funding from FDA and USDA.⁴⁵ The USP database was updated in 2013 and now covers the period from 1980 through 2012, and contains nearly 2,100 records.

NCFPD EMA Incident Database

The National Center for Food Protection and Defense (NCFPD) EMA Incident Database is another database, which differs in that it catalogs isolated EMA incidents and is available to authorized users upon request.⁴⁶ (NCFPD is a University of Minnesota-led consortium and has been a Homeland Security Center of Excellence since July 2004.)⁴⁷ As part of the database, an "incident" is defined as:⁴⁸

a documented, isolated occurrence of EMA in a single food product or group of associated food products occurring within a defined time frame and with a distinct group of perpetrators. Incidents that are difficult to isolate to a specific time frame and/or group of perpetrators, or with characteristics common to multiple perpetrators, are entered as a single incident.

For example, the melamine adulteration of infant formula in China in 2007-2008 is recorded as one incident. Individual records therefore have been further grouped by adulterant (e.g., melamine) and time period when the incident is estimated to have occurred. The database records also do not include information on issues that might be of concern but that remain undocumented in the public domain. The database tracks EMA incidents in food products since 1980. There were 1,054 records in the database in mid-2012, covering 302 incidents.⁴⁹ The EMA Incident Database identifies the type of adulterant reported for each documented incident and classifies each by the type of adulteration (including substitution/dilution, unapproved additives, mislabeling,

⁴³ Freely available online at <http://www.foodfraud.org/>.

⁴⁴ J.C. Moore, J. Spink, and M. Lipp, "Development and Application of a Database of Food Ingredient Fraud and Economically Motivated Adulteration from 1980 to 2010," *Journal of Food Science*, Vol. 77, Nr. 4, 2012.

⁴⁵ Comments by J. Spink, MSU, November 12, 2013, as part of the massive open online course (MOOC) on food fraud. See also NCFPD, Final Report: 2007-2011, DHS Award #2007-ST-061-000003, p. 132.

⁴⁶ Information in the NCFPD EMA Incident Database is accessible via FoodSHIELD by request. For more information, see <https://www.foodshield.org/index.cfm/join-registration/membership/>.

⁴⁷ As a Homeland Security Center of Excellence, NCFPD is a multidisciplinary and action-oriented research consortium. For more information, see DHS, "Science & Technology Directorate Centers of Excellence," <https://www.dhs.gov/st-centers-excellence>; and NCFPD, "NCFPD's Mission: Defending the Safety of the Food System Through Research and Education," http://www.ncfpd.umn.edu/default/assets/File/2011-03-7_NCFPD_Flyer.pdf

⁴⁸ NCFPD, "NCFPD EMA Incidents Database," <http://ema.foodshield.org/> (may require request for access). Also see NCFPD news release, "Preventing Economically Motivated Adulteration," February 4, 2013. Cited sources include LexisNexis, PubMed, Google, FDA consumer and recall records, state reports, and the E.U. Rapid Alert System for Food and Feed (RASFF) portal.

⁴⁹ A. Kircher, NCFPD, "Tools for Protecting the Nation's Food Supply," June 5, 2012; and information compiled by CRS from records in the NCFPD EMA Incident Database (database accessed November 14, 2013).

transshipment/origin masking, and port shopping),⁵⁰ and also provides information on where the product was originally produced based on an examination of the available information.

Initial analyses of the EMA Incidents Database records were published in the April 2013 issue of the *Journal of Food Protection*.⁵¹ The database and related work to develop predictive models and case studies are intended to help characterize discrete EMA incidents to better understand the incentive behind the adulteration, including the adulterant used, how the adulteration was discovered, and how to detect and deter future incidents and protect the U.S. food supply from deliberate or intentional acts of contamination or tampering.⁵² In addition to the EMA Incidents Database, NCFPD is also developing an EMA Susceptibility Database that includes evaluations of the monographs in the USP Food Chemicals Codex for susceptibility to EMA.⁵³ NCFPD is also working with DHS on other projects, including development of an assessment tool to determine and document the most critical food and agriculture infrastructure at the state level.⁵⁴

Leading Reported Types of Fraud

These available databases provide information on the types of foods and food ingredients associated with food fraud. How these products and ingredients are ranked, however, may differ considerably among various reports. Specifically, overall product rankings of the leading reported fraudulent foods and food ingredients may differ depending on:

- database referenced (i.e., whether USP or NCFPD database);
- source or type of records referenced (i.e., in the USP database, ranking differs based on whether compiled from the “scholarly” or “media” or total records; in the NCFPD database, ranking is based on number of “incidents”);
- time period (1980 through 2010 or 1980 through 2012); and
- organization compiling the data (i.e., whether conducted by USP or NCFPD, or whether conducted by an outside organization using data from one of the databases).

USP Food Fraud Database

The initial version of the United States Pharmacopeial Convention (USP) Food Fraud database published in 2012 covered both “scholarly” and “media” records from 1980 through 2010, and was accompanied with analysis conducted by researchers at MSU and USP. This first version of the database consisted of a total of 1,305 records covering 361 discrete food ingredients that were based on 660 references (**Table 2**).

Records in the USP database indicate that the leading reported types of fraud by specific ingredient among the database’s scholarly records (1980-2010) were olive oil (16%), milk (14%),

⁵⁰ “Port shopping” refers to when exporters and importers choose a particular port on the basis of their assessment of Customs’ treatment, rather than on the quality of physical facilities and efficiency.

⁵¹ K. Everstine, J. Spink, and S. Kennedy, “Economically Motivated Adulteration (EMA) of Food: Common Characteristics of EMA Incidents,” *Journal of Food Protection*, Vol. 76, Nr. 4, April 2013. The analyses in this article covered 137 EMA incidents.

⁵² Comments by Amy Kircher, NCFPD, USP Workshop of Economically Motivated Adulteration of Food Ingredients and Dietary Supplements, September 26, 2013; and NCFPD, “EMA Frequently Asked Questions.”

⁵³ Additional information and the database is available at <http://www.foodshield.org>.

⁵⁴ DHS, “National Infrastructure Protection Plan: Food and Agriculture Sector,” and DHS, *Food and Agriculture Sector-Specific Plan: An Annex to the National Infrastructure Protection Plan*, 2010.

honey (7%), saffron (5%), orange juice (4%), coffee (3%), and apple juice (2%).⁵⁵ **Figure 2** provides a consolidated breakdown by major food ingredient category. By major food ingredient, oils (24%), milk (14%), and spices (11%) account for nearly 50% of all reported cases.

Records in the USP database indicate that the leading reported types of fraud by specific ingredient among the database's media records (1980-2010) were fish (9%), honey (6%), olive oil (4%), chili powder (4%), milk (3%), black pepper (3%), and caviar (2%). **Figure 3** provides a consolidated breakdown by major food ingredient category whereby natural flavoring complexes⁵⁶ (30%) and spices (19%) account for nearly 50% of all reported cases.

The 2013 updates to the USP Food Fraud Database added another 792 records from 264 additional references to the database, consisting mostly of new information published in 2011 and 2012. This raised the total number to 2,097 records, based on 924 references (**Table 2**).

Table 2. Scope of USP Food Fraud Database

2012 Publication and 2013 Update

Database Version	Scholarly Records	Media Records	Total
2012 Publication (1980-2010 data)			
Number of Records	1,054	251	1,305
Number of Ingredients	250	147	397
Number of References	575	85	660
2013 Update (mostly additional 2011-2012 data)			
Total Number of Records (since 1980)	1,648	449	2,097
Total Number of References (since 1980)	742	182	924

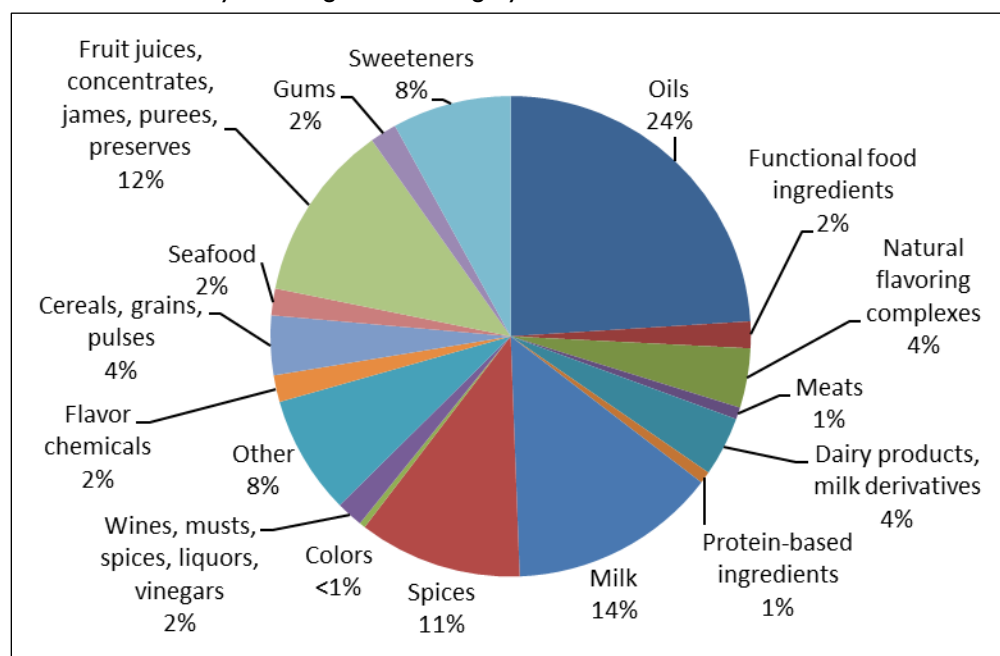
Source: As reported in J.C. Moore, J. Spink, and M. Lipp, "Development and Application of a Database of Food Ingredient Fraud and Economically Motivated Adulteration from 1980 to 2010," *Journal of Food Science*, Vol. 77, Nr. 4, 2012; and A.G. Ebert, "The Food Chemicals Codex EMA Activities: The Food Fraud Database – What's Next?" Presentation at the USP Workshop of Economically Motivated Adulteration of Food Ingredients and Dietary Supplements, September 26–27, 2013.

⁵⁵ J.C. Moore, J. Spink, and M. Lipp, "Development and Application of a Database of Food Ingredient Fraud and Economically Motivated Adulteration from 1980 to 2010," *Journal of Food Science*, Vol. 77, Nr. 4, 2012.

⁵⁶ Natural flavoring complexes refer to essential oils, oleoresin, essence or extractive, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products used as a food ingredient for flavoring.

Figure 2. Leading Reported Types of Fraud, USP Scholarly Records (1980-2010)

By Food Ingredient Category, USP Food Fraud Database

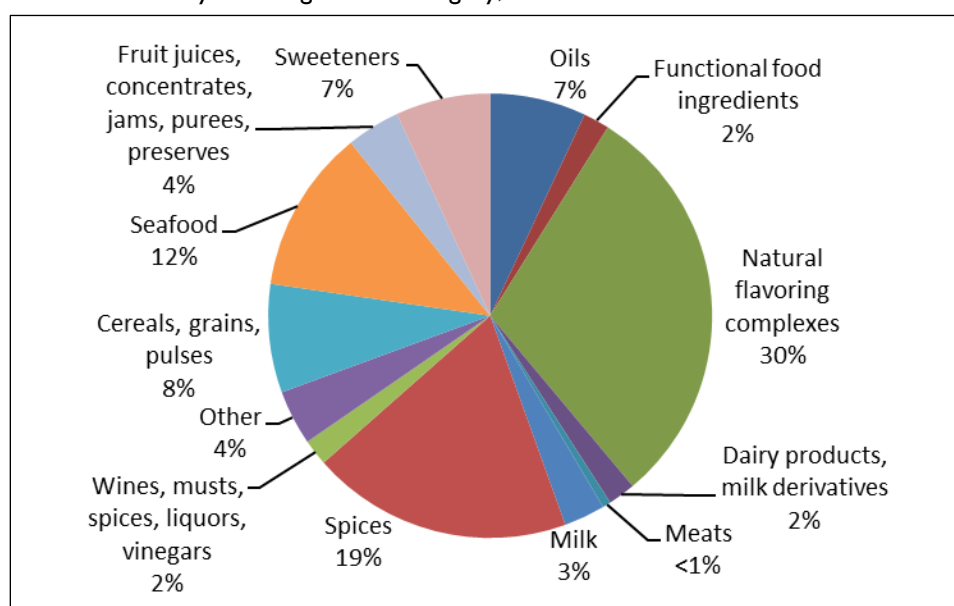


Source: USP Food Fraud Database (1980-2010), <http://www.foodfraud.org/>. As reported in J.C. Moore, J. Spink, and M. Lipp, "Development and Application of a Database of Food Ingredient Fraud and Economically Motivated Adulteration from 1980 to 2010," *Journal of Food Science*, Vol. 77, Nr. 4, 2012.

Notes: 1980-2010 data: records (1,054); ingredients (250); and references (575).

Figure 3. Leading Reported Types of Fraud, USP Media Records (1980-2010)

By Food Ingredient Category, USP Food Fraud Database



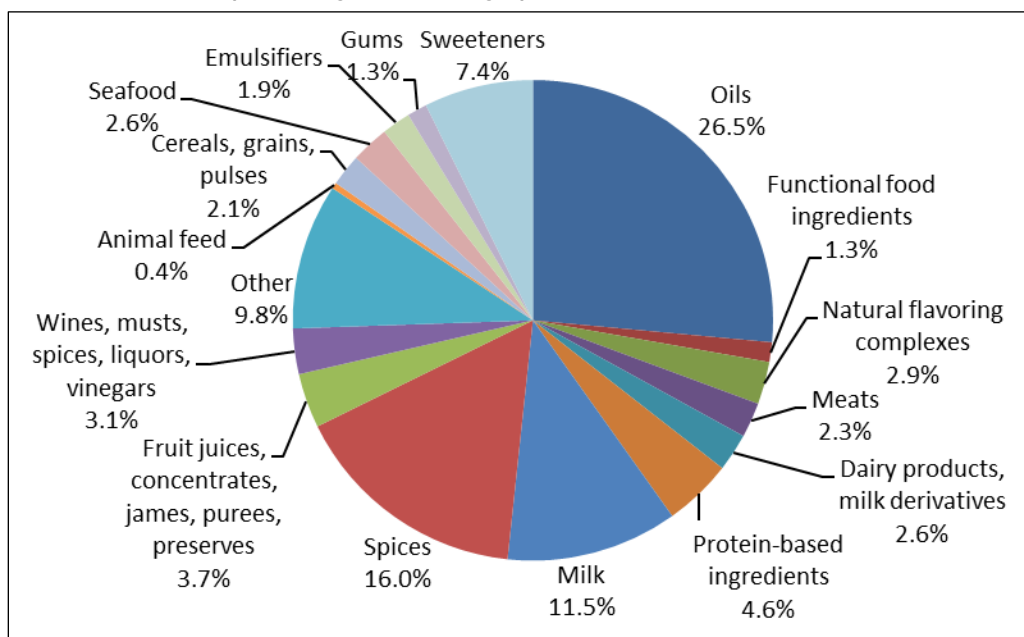
Source: USP Food Fraud Database (1980-2010), <http://www.foodfraud.org/>. As reported in J.C. Moore, J. Spink, and M. Lipp, "Development and Application of a Database of Food Ingredient Fraud and Economically Motivated Adulteration from 1980 to 2010," *Journal of Food Science*, Vol. 77, Nr. 4, 2012.

Notes: 1980-2010 data: records (251); ingredients (147); and references (85).

Figure 4 provides a breakdown by major food ingredient category, according to the databases' scholarly records following the 2013 database updates. By individual food and food ingredients, the leading reported types of fraudulent foods were olive oil, milk, saffron, honey, coffee, tea, fish, clouding agents, and black pepper. Among the new reports examined, many of the most-represented products in the database were all among the top fraudulent products reported in the initial version of the database (such as milk, fish, turmeric, chili powder, and cooking oil); however, many products were not among the top products, such as shrimp, lemon juice, maple syrup, and clouding agents.⁵⁷

Figure 4. Leading Reported Types of Fraud, USP Scholarly Records (1980-2012)

By Food Ingredient Category USP, Food Fraud Database



Source: Data from the USP Food Fraud Database (<http://www.foodfraud.org/>), 2013 update. As reported by A.G. Ebert, "The Food Chemicals Codex EMA Activities: The Food Fraud Database – What's Next?" Presentation at the USP Workshop of Economically Motivated Adulteration of Food Ingredients and Dietary Supplements, September 26–27, 2013. Data are for 2011-2012.

Notes: 1980-2012 data: records (1,648) and references (742). 2013 update included 792 additional records and 264 additional references, mostly from 2011-2012.

The 2013 updates to the USP database highlight a number of continuing and emerging issues. As reported by USP, among the leading reported types of fraud in the updated 2013 database are "watered-down and urea adulterated fluid milk in India, dilution of milk powder with fillers such as maltodextrin in South America and replacement of milk fat with vegetable oil in South America," as well as "olive oil replaced with other, less-expensive vegetable oils," and so-called "gutter oil" (waste oil repurposed as cooking oil) was documented in China.⁵⁸ The updated USP database also documents examples of the dilution or replacement of spices with less-expensive spices or fillers.

⁵⁷ FDA defines clouding agents as food processing aids "to enhance the appeal or utility of a food or food component, including clarifying agents ... , catalysts, flocculents, filter aids, and crystallization inhibitors" (21 CFR Part 1700).

⁵⁸ USP, "Food Fraud Reports Up 60% Since 2010," January 23, 2013.

The updated USP database also highlighted increasing reports of seafood fraud, reflecting previous reports by Oceana and Consumers Union.⁵⁹ Of particular concern is mislabeled fish sold in the marketplace that may cause known public health risks. These include the fish escolar (*Lepidocybium flavobrunneum*), often labeled as white tuna or butterfish, which is banned in some countries due to concerns that its high content of waxy esters may cause some types of food poisoning including gempylotoxism.⁶⁰ Another is puffer fish (*Lagocephalus scleratus*), often mislabeled as monkfish to evade import and other restrictions, and which is known to cause tetrodotoxin poisonings.⁶¹

The updated USP database also highlighted emerging concerns about food fraud involving “clouding agents.” Specifically, the USP database documents cases involving the fraudulent addition of the plasticizer Di(2-ethylhexyl) phthalate (DEHP) and other related phthalates as a substitute for more expensive palm oil or other allowed food ingredients in fruit juices, jams, and other products. DEHP might also be used in food contact materials, such as seals and packaging. DEHP is associated with public health risks, including cancer and reproductive concerns. The scope of the fraud involving clouding agents covers 877 food products from 315 companies, with 206 products exported to a reported 22 countries.⁶² Given the potential public health concerns, USP states that clouding agents might be considered the “2011 equivalent to the melamine scandal involving Chinese milk products from a few years ago.”⁶³

NCFPD EMA Incident Database

As of November 2013, about 300 “incidents” since 1980 are accessible in the National Center for Food Protection and Defense (NCFPD) EMA Incident Database.⁶⁴ Previous analyses of the incidents in the database were based on 137 incidents.⁶⁵ CRS analysis presented here is based on information from 302 incidents accessed in the EMA Incident Database, as well as other updated databases information from NCFPD.

As already noted, an incident is “a documented, isolated occurrence of EMA in a single food product or group of associated food products occurring within a defined time frame and with a distinct group of perpetrators.”⁶⁶

⁵⁹ Oceana, “Oceana Study Reveals Seafood Fraud Nationwide,” February 2013 (including previous reports in 2011); and Consumers Union, “Mystery Fish,” *Consumer Reports Magazine*, December 2011. Similar investigations were also reported by the Boston Globe newspaper in 2011, http://www.boston.com/business/specials/fish_testing/.

⁶⁰ FDA’s *Bad Bug Book: Foodborne Pathogenic Microorganisms and Natural Toxins Handbook*, <http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm071191.htm>. See also K.A. Feldman et al., “A large outbreak of scombroid fish poisoning associated with eating escolar fish (*Lepidocybium flavobrunneum*),” *Epidemiol Infect.*, 133(1):29-33, February 2005.

⁶¹ See, for example, J. Field, “Puffer fish poisoning,” *J Accid Emerg Med.* 15(5): 334–336, September 1998; and G.K. Isbister, M.C. Kiernan, “Neurotoxic marine poisoning,” *Lancet Neurol.* 4(4):219-28, April 2005.

⁶² See, for example, J.A. Tickner, et al., “Health risks posed by use of Di-2-ethylhexyl phthalate (DEHP) in PVC medical devices: a critical review,” *Am J Ind Med.*, 39(1):100-11, January 2001; and T.H. Yen et al., “Food safety involving ingestion of foods and beverages prepared with phthalate-plasticizer-containing clouding agents,” *J Formos Med Assoc.*, 110(11):671-84, November 2011.

⁶³ USP, “Food Fraud Reports Up 60% Since 2010,” January 23, 2013.

⁶⁴ Information compiled by CRS from records in the NCFPD EMA Incident Database (database accessed November 14, 2013). Accessible to FoodSHIELD.org members.

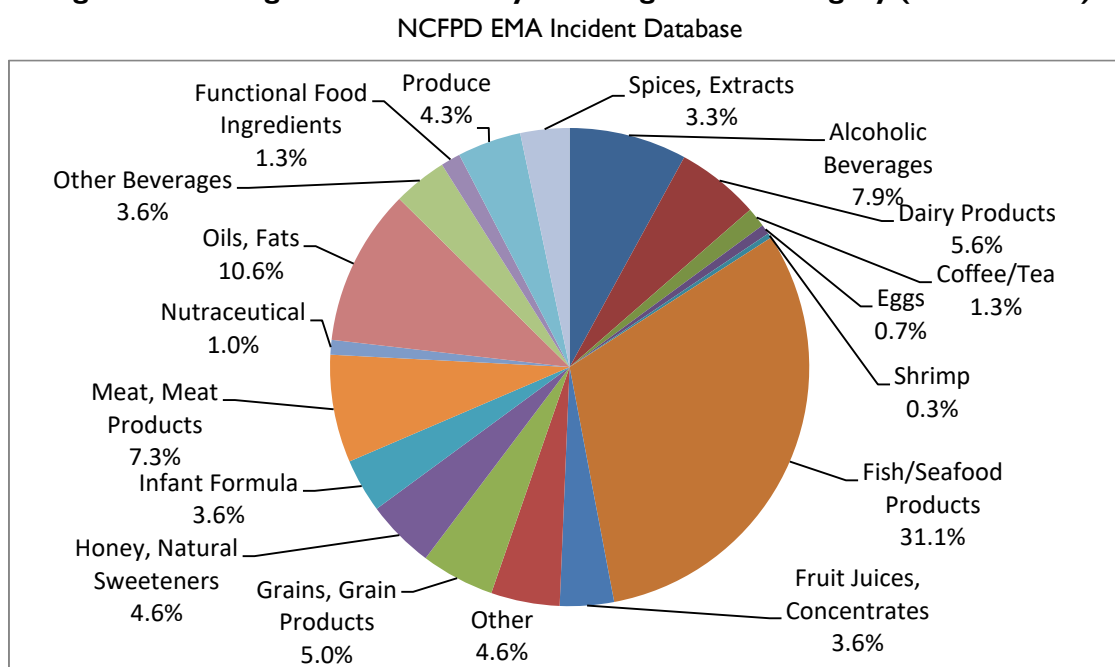
⁶⁵ K. Everstine, J. Spink, and S. Kennedy, “Economically Motivated Adulteration (EMA) of Food: Common Characteristics of EMA Incidents,” *Journal of Food Protection*, Vol. 76, Nr. 4, April 2013. The analyses in this article covered 137 EMA incidents.

⁶⁶ NCFPD news release, “Preventing Economically Motivated Adulteration,” February 4, 2013.

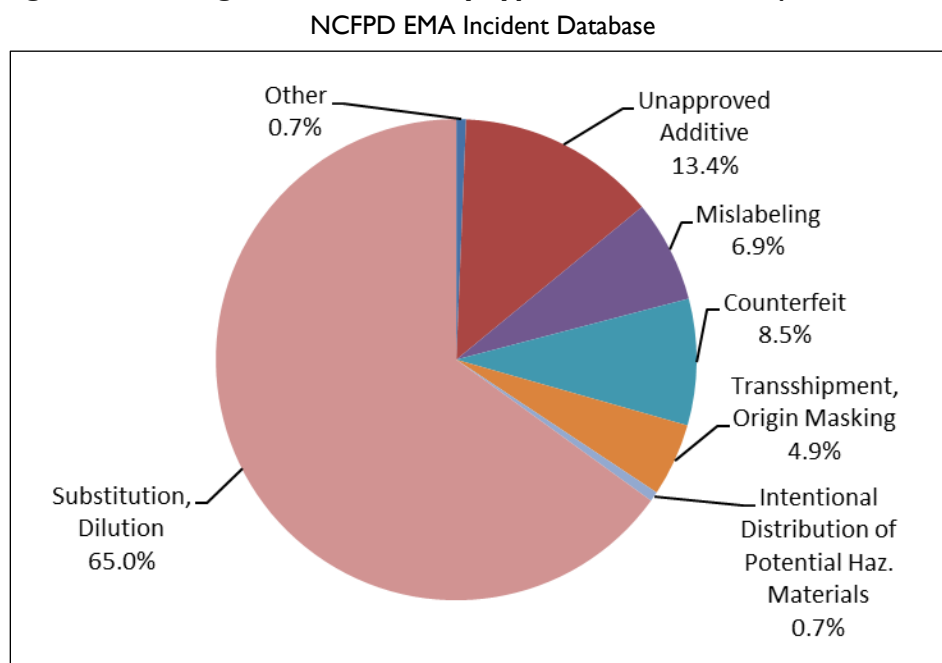
Figure 5 provides a breakdown of EMA incidents by major food ingredient category, according to the database. By individual food and food ingredients, the leading reported types of fraudulent foods were (1980 to date) fish and seafood (31%), oils and fats (11%), alcoholic beverages (8%), meat and meat products (7%), dairy products (6%), and about 5% each for grains and grain products, and honey and other natural sweeteners.

Figure 6 provides a breakdown of EMA incidents by type of adulteration, as reported in the database. Cases of EMA due to substitution or dilution accounted for 65% of the incidents, followed by 13% due to the presence of an unapproved additive. Other incidents are attributable to counterfeit goods (9%), misbranding (7%), transshipment or masking origin of product (5%), and the intentional distribution of a potentially hazardous substance (less than 1%), among other miscellaneous or unknown types of adulteration (less than 1%).

Figure 5. Leading EMA Incidents by Food Ingredient Category (1980 to date)



Source: Compiled by NCFPD CRS from records in the NCFPD EMA Incident Database (database accessed November 14, 2013) and based on 302 reported incidents. These incidents were also reported by A. Kircher, "Building Capabilities to Find and Mitigate." Presentation at the USP Workshop of Economically Motivated Adulteration of Food Ingredients and Dietary Supplements, September 26–27, 2013.

Figure 6. Leading EMA Incidents by Type of Adulteration (1980 to date)

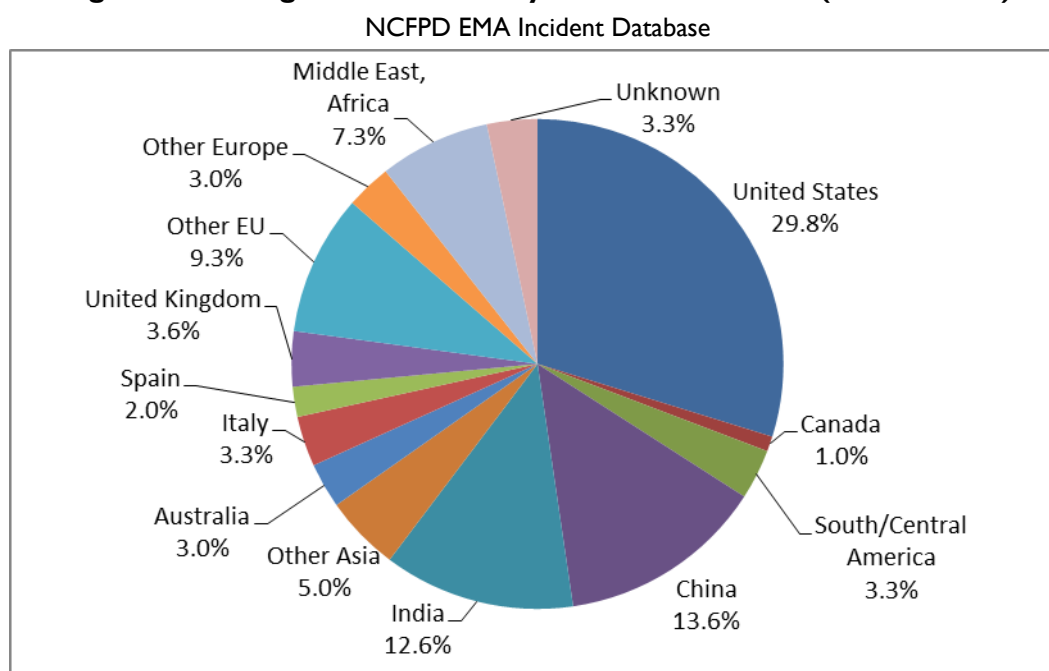
Source: Compiled by NCFPD EMA Incident Database (January 6, 2014), based on 306 reported incidents.

Figure 7 provides a breakdown of EMA incidents by location where the product is identified as being produced, as reported in the database. Among its data, the EMA Incident Database documents where the fraudulent product was originally produced based on an examination of the available information. Although the database is not restricted to conditions in the United States and is broadly reflective of fraud globally, the incidents captured in the database are based on English-language sources and may not be representative of conditions across all global commercial markets.

In addition, information in the database by location produced may mask substantial differences among countries and regions (both globally and within a particular country) in terms of their ability and dedication to detect fraud. No two countries or regions scrutinize food fraud in the same way. For example, as noted by researchers at NCFPD,⁶⁷ the relatively greater number of reported fish and seafood cases is, in part, attributable to enhanced surveillance and detection by Florida's Department of Health. This further reinforces the idea that a possible limitation of either database is that the available information may at times be more reflective of where research is being conducted or where resources have been dedicated to detect fraud.

Despite these caveats, the EMA Incidents Database indicates that nearly 30% of the EMA incidents documented involved products that were produced in the United States. Most of these were incidents involving mislabeled fish. China and India accounted for another 14% and 13%, respectively, of the documented EMA incidents. Other countries in Asia accounted for another 5% of the incidents. Combined, the European Union countries accounted for about 15% of the documented incidents, along with another 3% attributable to other non-EU European countries. About 7% of the incidents were reported to have been produced in the Middle East and Africa (**Figure 7**).

⁶⁷ Communication between CRS personnel and researchers at University of Minnesota, November 27, 2013.

Figure 7. Leading EMA Incidents by Location Produced (1980 to date)

Source: Compiled by CRS from records in the NCFPD EMA Incident Database (database accessed November 14, 2013) and based on 302 reported incidents.

Differences in Product Ranking among Databases

Reported rankings of foods and food ingredients associated with food fraud based on the USP Food Fraud Database and the NCFPD EMA Incident Database often differ. As illustrated above, how these fraudulent foods and food ingredients are ranked will differ depending on which database is referenced (i.e., whether USP or NCFPD database) and which type of record is referenced (i.e., whether based on “scholarly” or “media” or EMA “incidents”), and time period.

Rankings also differ within a database. For example, as reported in the 2013 food fraud report by the European Parliament, the “top ten products that are most at risk of food fraud” using data in the initial USP database (1980-2010) are identified (in descending order) as olive oil; fish; organic foods; milk; grains; honey and maple syrup; coffee and tea; spices (such as saffron and chili powder); wine; and certain fruit juices.⁶⁸ Comparisons, shown in **Table 3**, are intended to illustrate why different reports provide differing rankings of foods associated with fraud. The prominence of “organic foods” in the European study may be explained by the decision to distinguish organically certified products separately from all reported foods categorized by food ingredient category (which include both organic and conventionally produced foods and food ingredients). The overall prominence of “fish” in the European study may also be explained in that products may have been ranked across all records and not separated according to “scholarly” versus “media” records. Although these compilations were derived from the same database, this example illustrates why some reported compilations differ from others.

⁶⁸ European Parliament, Committee on the Environment, Public Health and Food Safety draft report “on the food crisis, fraud in the food chain and the control thereof,” (2013/2091(INI)).

Table 3. Leading Reported Types of Food Fraud, Differing Compilations

Various Years and Sources

USP Food Fraud Database: Leading Ingredient Categories, Accounting for >90% of Records (Scholarly and Media Combined)		NCFPD EMA Incidents Database: Leading Ingredient Categories, Accounting for >90% of Records (Media)		EU Report: "Top ten" products at risk of food fraud
1980-2010	1980-2012	1980-2010	1980-2012	1980-2010
(a)	(b)	(c)	(d)	(e)
Oils	Oils	Other miscellaneous	Fish, seafood	Olive oil
Spices	Spices	Fish and seafood	Oils and fats	Fish
Milk	Milk	Dairy products	Alcoholic beverages	Organic foods
Fruit juice, concentrate	Other miscellaneous	Fruit juices	Meat, meat products	Milk
Natural flavorings	Sweeteners	Oils and fats	Dairy products	Grains
Sweeteners	Fruit juice, concentrate	Grain products	Grains, grain products	Honey, maple syrup
Other miscellaneous	Natural flavorings	Honey	Honey, sweeteners	Coffee, tea
Cereals, grains, pulses	Seafood (incl. fish)	Spices and extracts	Produce	Spices
Seafood	Cereals, grains, pulses	Wine	Fruit juice, concentrate	Wine
Dairy products	Wines, musts, spirits	Infant formula	Spices, extracts	Fruit juices
Wines, spirits, vinegars	Dairy products	Plant-based proteins	Other beverages (non-alcoholic, not juice)	
	Protein-based ingred.			
	Functional food ingred.			
	Preservatives			
	Gums			
	Meats			

Sources:

(a), (b) Compiled by Jeff Moore, USP, December 22, 2013.

(c) NCFPD presentation, USP's Food Ingredients Intentional Adulterants Expert Panel, Meeting #3, October 23, 2012. Provided by Jeff Moore, USP, December 2013.

(d) Compiled by Karen Everstine, NCFPD, January 2014.

(e) As reported in European Parliament, Public Health and Food Safety draft report "on the food crisis, fraud in the food chain and the control thereof," (2013/2091(INI)), citing information obtained from the USP database.

Notes: Data from the USP Food Fraud Database and the NCFPD EMA Incident Database.

a. Clouding agents are used as food processing aids (21 CFR Part 170, Food Additives).

Federal Activities Involving Food Fraud

In the United States, no single federal agency and no single U.S. law or statute directly addresses food fraud or "economically motivated adulteration" of food and food ingredients. Instead, food fraud and intentional adulteration of food is broadly addressed through food safety authorities and border protection and import authorities and activities. Accordingly, FDA and USDA are the principle federal agencies that are working to protect the food supply from food safety risks,

including both unintentionally and intentionally introduced contamination, in conjunction with enforcement of FDA and USDA laws by the U.S. Department of Homeland Security (DHS) as part of its border inspections.

FDA and USDA are the leading food safety regulatory authorities. FDA, an agency of the Department of Health and Human Services (HHS), is responsible for ensuring the safety of all domestic and imported food products (except for most meats and poultry). USDA's Food Safety and Inspection Service (FSIS) regulates most meat and poultry and some egg products. However, the boundaries between the two agencies' jurisdictions are complex and often at odds with commonplace distinctions among food groups.⁶⁹ The laws that grant these and other federal agencies authority over foods and food ingredients also provide these agencies with the authority to govern the labeling of these products, which might also act as a further deterrent to food fraud in some cases.⁷⁰

Other federal agencies also provide product quality standards and grading, including FDA, USDA's Agricultural Marketing Service (AMS), and the National Marine Fisheries Service (NMFS), which is part of the U.S. Department of Commerce's National Oceanic and Atmospheric Administration (NOAA). State and local food safety authorities assist the federal agencies with inspection, outbreak response, and other food safety functions, among other functions. Import security measures by FDA and USDA are conducted in conjunction with border inspections by the Customs and Border Protection (CBP), which is part of DHS.

Other agencies also have played a role in food fraud prevention. The U.S. Department of Justice (DOJ) has actively pursued a number of food fraud cases in the U.S. courts involving a range of products and resulting in criminal convictions in some cases.⁷¹ In the high-profile case involving the Peanut Corporation of America, company executives were indicted in early 2013 with federal criminal charges that included fraud, conspiracy, and the introduction of adulterated food into interstate commerce with the intent to defraud or mislead.⁷² USDA's National Organic Program (NOP) has taken numerous enforcement actions against companies involving false labeling claims on organic foods, and a number of advocacy groups have filed lawsuits involving concerns about the validity of organic claims. NOAA also has conducted federal investigations and taken enforcement actions involving seafood labeling and misbranding.⁷³

The text box below provides a comparison of FDA and USDA responsibilities for food safety and regulations, and responsibilities of other federal agencies.

⁶⁹ Jurisdiction issues are addressed in a Memorandum of Understanding (MOU) between FSIS and FDA (MOU 225-99-2001), <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm117094.htm>. Other information is in CRS Report RS22600, *The Federal Food Safety System: A Primer*.

⁷⁰ "A Guide to federal Food Labeling Requirements for meat, Poultry, and Egg Products," prepared for USDA Food Safety and Inspection Service by Hogan & Hartson, LLP, August, 2007, http://www.fsis.usda.gov/wps/wcm/connect/f4af7c74-2b9f-4484-bb16-fd8f9820012d/Labeling_Requirements_Guide.pdf?MOD=AJPERES.

⁷¹ See, for example, more recent cases involving olive oil and honey as described in A. Healy, "Lawsuit over olive oil labeling will go to trial," *Food Chemical News*, November 22, 2013; and DOJ press release, "Texas Honey Broker Sentenced to Three Years in Prison for Avoiding \$37.9 Million in Tariffs on Chinese-Origin Honey," November 14, 2013.

⁷² DOJ press release, "Former Officials and Broker of Peanut Corporation of America Indicted Related to Salmonella-Tainted Peanut Products," February 21, 2013.

⁷³ See, for example, National Oceanic and Atmospheric Administration (NOAA) press release, "NOAA Investigations Into Mislabeling Seafood Protects Consumers and Fishermen," February 4, 2011.

Comparison of Selected Agency Responsibilities for Food Safety and Regulation**Agency****Responsibility****Food and Drug Administration (FDA)**

- Food (but not meat)
- Dietary supplements
- Bottled water
- Seafood
- Wild game (" exotic " meat)
- Eggs in the shell

U.S. Department of Agriculture (USDA)

- Grading of raw fruit and vegetables
- Meat and Poultry
- Eggs, processing and grading
- Certifying organic production

**National Oceanic and Atmospheric Administration
Environmental Protection Agency (EPA)**

- Grading of fish and seafood
- Drinking water
- Pesticide residues

Customs and Border Protection (CBP)

- Front-line enforcement and referral

Department of Justice (DOJ)

- Law enforcement

Federal Trade Commission (FTC)

- Advertising

Alcohol and Tobacco Tax and Trade Bureau (TTB)

- Alcohol

Source: CRS, as adapted from N. D. Fortin, *Introduction to Food Regulation in the United States*, Part I (Introductory Chapters), May 2008.

The federal government also has helped fund some of the ongoing research. These efforts were developed with the support of funding from DHS, FDA, and USDA.⁷⁴ In addition, FDA is developing a number of tools and guidance materials for the food industry to address intentional adulteration as part of its food defense strategy.⁷⁵

The U.S. Government Accountability Office (GAO) has conducted a series of investigations into food fraud cases, including fruit juice⁷⁶ and seafood.⁷⁷ GAO's most recent report addressed a wider range of fraudulent foods and issued more broad-based recommendations.⁷⁸ GAO's recommendations involving food fraud addressed the need for improved cross-agency communication and coordination and enhanced information sharing and transparency. Other recommendations called for the creation of an information clearinghouse and the need for increased oversight and inspections, and increased risk-based testing, in some cases.

A 2013 report by the U.S. International Trade Commission (USITC) cited research indicating that current standards for extra virgin olive oil are widely unenforced and result in a wide range of olive oil qualities to be labeled as "extra virgin" oil. The study further concluded that this may

⁷⁴ Comments by J. Spink, MSU, November 12, 2013, as part of the massive open online course (MOOC) on food fraud.

⁷⁵ For a listing of programs, such as Food Defense Plan Builder and Food Related Emergency Exercise Bundle (FREE-B), see FDA, "Tools and Educational Materials," <http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/>.

⁷⁶ GAO, *Fruit Juice Adulteration, Detection is Difficult and Enhanced Efforts Would be Costly*, GAO/RCED-96-18, November 1995.

⁷⁷ GAO, *Seafood Fraud, FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention*, GAO-09-258, February 2009.

⁷⁸ GAO, *Better Coordination Could Enhance Efforts to Address Economic Adulteration and Protect the Public Health*, GAO-12-46, October 2011.

lead to adulterated and mislabeled product, which could further weaken the competitiveness of U.S.-produced olive oil in the domestic market.⁷⁹

In Europe, in the wake of the horsemeat scandal, some countries have debated the need for tougher laws to protect consumers against food fraud. The European Parliament released its draft report regarding food fraud in October 2013, calling for increased enforcement and oversight regarding fraud prevention through the food supply chain.⁸⁰

HHS, Food and Drug Administration

Laws governing FDA's authority over both unintentional and intentional adulteration of both domestic and imported food—namely, the Federal Food, Drug, and Cosmetic Act—provide the agency with some of the necessary tools to pursue activities that ensure against fraud of foods and food ingredients under its jurisdiction.

Food Safety Authorities

FDA has primary responsibility for the safety of most—about 80%-90%—of all U.S. domestic and imported foods.⁸¹ The FDA is responsible for ensuring that all domestic and imported food products—except for most meats and poultry—are safe, nutritious, wholesome, and accurately labeled. Examples of FDA-regulated foods are produce, dairy products, and processed foods. FDA also has oversight of all seafood and shellfish products, and most fish products.⁸² FDA has jurisdiction over meats from animals or birds that are not under the regulatory jurisdiction of FSIS. FDA shares some responsibility for the safety of eggs with FSIS. FDA has jurisdiction over establishments that sell or serve eggs or use them as an ingredient in their products.

As described in a Memorandum of Understanding between FDA and FSIS:⁸³

FDA is responsible for implementing and enforcing the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, *et seq.*), the Public Health Service Act (42 U.S.C. 201, *et seq.*), the Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*), and parts of the Egg Products Inspection Act. In carrying out its responsibilities under these acts, FDA conducts inspections of establishments that manufacture, process, pack, or hold foods, with the exception of certain establishments that are regulated exclusively by FSIS. FDA also inspects vehicles and other conveyances, such as boats, trains, and airplanes, in which foods are transported or held in interstate commerce.

⁷⁹ USITC, *Olive Oil: Conditions of Competition between U.S. and Major Foreign Supplier Industries*, Inv. 332-537, August 2013.

⁸⁰ European Parliament, Committee on the Environment, Public Health and Food Safety draft report “on the food crisis, fraud in the food chain and the control thereof,” (2013/2091(INI)).

⁸¹ Estimated by backing out the reported 10%-20% of foods under USDA's jurisdiction. The 20% estimate is based on information reported by GAO in “Revamping Oversight of Food Safety,” prepared for the 2009 Congressional and Presidential Transition, and appears to represent proportions of total spending for food consumed at home. The 10% estimate is based on data from USDA-ERS on U.S. per capita food consumption at <http://www.ers.usda.gov/data/foodconsumption/>. See also DHS, “National Infrastructure Protection Plan: Agriculture and Food Sector Snapshot,” <http://www.dhs.gov/food-and-agriculture-sector>.

⁸² FSIS was authorized to inspect farmed catfish products under a 2008 farm bill provision (P.L. 110-246, §11016), but has not yet been implemented.

⁸³ MOU 225-99-2001, <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucml117094.htm>.

"Prohibited" Acts

FDA's food safety authorities rest primarily with the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended, requiring that foods be safe, wholesome, and accurately labeled.

"Prohibited" acts are listed in FFDCA Section 301 (21 U.S.C. §331). Along with other specified prohibited acts, the law provides that introducing adulterated or misbranded food into commerce; adulterating or misbranding food that is in commerce; or the receipt and delivery of adulterated or misbranded food in commerce is prohibited. As such, under FFDCA, two of the basic statutory components are "adulteration" and "misbranding."

FDA-regulated foods may be deemed adulterated or misbranded for a variety of statutorily prescribed reasons. For example, food may be deemed adulterated if it contains an added poisonous or deleterious substance or an unsafe food additive or if the food was prepared, packed, or held under unsanitary conditions whereby it may have become contaminated or may have been rendered injurious to health. Persons who violate FFDCA by, for example, introducing an adulterated or misbranded product into interstate commerce are subject to criminal and civil penalties.

According to FFDCA Section 402(a) (21 U.S.C. §342[a]), a food shall be deemed to be "adulterated" (and therefore prohibited) if it bears or contains or has any added "poisonous or deleterious substance" which may be "injurious to health" or is considered unsafe under the law, unless specifically exempted. Adulteration also covers food that consists of a "filthy, putrid, or decomposed substance," or if it is otherwise unfit for food or "if it has been prepared, packed, or held under insanitary conditions," or if it otherwise poses a risk to consumer health.

Perhaps more specific to food fraud, although generally less noted,⁸⁴ FFDCA Section 402(b) (21 U.S.C. §342[b]), are foods deemed to be adulterated given the "absence, substitution, or addition of constituents" including:⁸⁵

if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

Accordingly, a food may be deemed adulterated if it is missing a "valuable constituent" or if substances have been substituted wholly or in part or where damage or inferiority has been concealed in any matter, including cases where substances are added to "increase its bulk or weight" or make it appear to be higher quality.

Under FFDCA, introducing misbranded food into commerce, misbranding food that is in commerce, or the receipt and delivery of misbranded food in commerce is also prohibited. FFDCA Section 403 (21 U.S.C. §343) defines a number of conditions under which a food would be deemed to be misbranded. A food is deemed misbranded if it has a false or misleading label, is offered for sale under another name, is an imitation of another food, or is in a "misleading container" that is "made, formed, or filled to be misleading," among other types of misrepresentative packing or labeling. Similar to the definition of adulteration, numerous specific types of misbranding are also defined. These include, among others, failure to disclose specific additives or allergens in the food, and failure to provide required nutritional information. (In addition to FFDCA, FDA has regulatory authority under the Fair Packaging and Labeling Act

⁸⁴ See, for example, R. Carvajal, "USP, Food Fraud, and FSMA," *FDA Law Blog*, April 16, 2012, http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2012/04/usp-food-fraud-and-fsma.html.

⁸⁵ FFDCA §402(b) [21 U.S.C. §342(b)].

[FPLA, 15 U.S.C. §1451 *et seq.*]. FPLA establishes requirements for package labels of all consumer goods, including most foods.)

Violating the misbranding or adulteration provisions of FFDCA may invoke criminal penalties and/or product seizures. Under FFDCA Section 303 (21 U.S.C. §333), in general, any person who commits a prohibited act under FFDCA may be subject to civil or criminal penalties, including imprisonment, fines, or both. Criminal penalties provided for in FFDCA are adjusted by 18 U.S.C. Sections 3559 and 3571. Certain exceptions may be made, including for the misbranding of foods. FFDCA Section 304 (21 U.S.C. §334) also provides that FDA may order the administrative detention of foods, if a food is suspected to be adulterated or misbranded based on an inspection, examination, or investigation.

Although fraudulent activities may be illegal and enforceable under the FFDCA, FDA might not take enforcement in some cases. Practically speaking, it may not be possible for FDA and DOJ to prosecute every instance of food fraud given each agency's myriad other responsibilities and limited personnel and resources. Also, oftentimes inadequate evidence exists to effectively enforce against all alleged or suspected cases of fraud.

Other Agency Authorities and Activities

FFDCA Section 415 (21 U.S.C. §350d) requires FDA to oversee the registration of both domestic and foreign food facilities, which was part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act").⁸⁶ Under the act, facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States must be registered with FDA.⁸⁷ Domestic facilities must register whether or not food from the facility enters interstate commerce. Foreign facilities must register unless food from that facility undergoes further processing (including packaging) by another foreign facility before the food is exported to the United States. FDA also must be given advance notice on shipments of imported food. These registration and prior notification requirements might act as a further deterrent to food fraud in some cases.

Table 4 shows available data on the total number of registered domestic and foreign food facilities. The number of registered food facilities—both domestic and foreign—more than doubled from 2004 to 2012, the most recent available data.⁸⁸ Of the total number of registered facilities with FDA in 2012 (nearly 450,000), a reported 171,552 were domestic facilities and 278,307 were foreign facilities (**Table 4**).

Table 4. Registered Food Facilities, FY2004-FY2012

	FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11	FY12
All Registered Food Facilities	214,253	253,006	288,092	323,590	356,287	391,281	418,593	438,305	449,859
Domestic	92,719	104,555	115,902	129,345	141,703	154,883	166,160	167,033	171,552
Foreign	121,534	148,451	172,190	194,245	214,584	236,398	252,433	271,272	278,307

⁸⁶ P.L. 107-188.

⁸⁷ Owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack, or hold food for consumption in the U.S. are required to register the facility with FDA. See FDA, "Registration of Food Facilities," <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/default.htm>.

⁸⁸ FDA, "Registration Statistics," <http://www.fda.gov/food/guidanceregulation/foodfacilityregistration/ucm236512.htm>.

Source: Compiled by CRS from data on registered domestic and foreign facilities under FFDCA §415 (21 U.S.C. §350d); FDA's annual reporting requirements of these data are at FFDCA §1003 (21 U.S.C. §393).

Notes: Number of registrants as of November 18, 2013. Available FY2012 data are from FDA, "Registration Statistics," <http://www.fda.gov/food/guidanceregulation/foodfacilityregistration/ucm236512.htm>. FY2004-2011 data are FDA Office of Legislation (September 22, 2010, and May 7, 2012, communication); FDA, "Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices" for 2011 and 2012, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm250569.htm>; and HHS OIG, *FDA Inspections of Domestic Food Facilities* (OEI-02-08-00080).

Finally, FFDCA also broadly provides for FDA to establish voluntary food quality and grading standards, and product standards of identity (FFDCA §401 [21 U.S.C. §341]). Although not regulatory in nature, and not intended to address potential food safety or food fraud concerns, food quality and grading standards provide a product benchmark for certain foods or food ingredients. Specifically, FFDCA directs FDA to establish definitions and standards for food to "promote honesty and fair dealing" for the benefit of consumers.⁸⁹ Under the statute, FDA is authorized to establish regulations "for any food ..., a reasonable definition and standard of identity, a reasonable standard of quality, and reasonable standards of fill" of the container for any food. FDA has established roughly 300 identity standards in 20 categories of food, consisting of a range of processed foods and meat, dairy, and seafood products, as well as preserved and processed fruit and vegetable products and juices. Standards of identity cover mostly processed and value-added foods for a wide range of FDA-regulated food products.

Potential Role of the Food Safety Modernization Act

FDA has taken a series of internal actions to address intentional adulteration, including EMA.⁹⁰ In April 2009, FDA conducted a public meeting to raise awareness and solicit public input regarding economically motivated adulteration of FDA-regulated products. FDA also established, in September 2011, an internal workgroup comprised of staff from all FDA product centers (covering both food and non-food products regulated by FDA), FDA's Office of Regulatory Affairs (ORA),⁹¹ and the Office of the Commissioner. The workgroup includes risk managers, economists, regulatory counsel, policy analysts, and scientists, and uses a multidisciplinary collaborative approach to capitalize on commonalities among FDA's product centers.⁹² Part of the workgroup's mission is to address recommendations regarding EMA from the U.S. Government Accountability Office (GAO) that called for improved cross-agency communication and enhanced information sharing and transparency with stakeholders, including the regulated community.⁹³ FDA reportedly is also considering another GAO recommendation that would establish an information clearinghouse so stakeholders could share information about products that may be susceptible to economic adulteration.⁹⁴

⁸⁹ Regulations are 21 CFR Parts 130-169. 21 CFR 130 covers general requirements.

⁹⁰ For an informative overview of how EMA activities have evolved FDA, see J. Spink, "Economically Motivated Adulteration: Another Dimension of the 'Expanding Umbrella of Food Defense,'" *Food Safety Magazine*, October/November 2013.

⁹¹ ORA is the lead office for all agency field activities, and inspects regulated products and manufacturers, conducts sample analyses of regulated products and reviews imported products offered for entry into the United States.

⁹² J. Thomas, "FDA Workgroup on Economically Motivated Adulteration," Presentation at the USP Workshop of Economically Motivated Adulteration of Food Ingredients and Dietary Supplements, September 26–27, 2013.

⁹³ GAO, *Better Coordination Could Enhance Efforts to Address Economic Adulteration and Protect the Public Health*, October 2011, GAO-12-46.

⁹⁴ J. Murphy, "FDA Struggles with FSMA-Required Role in Combating Food Fraud," *Food Chemical News*, May 10, 2013.

The 111th Congress amended FFDCA by passing a comprehensive food safety law, the Food Safety Modernization Act (FSMA, P.L. 111-353).⁹⁵ FSMA aims to prevent both intentional and unintentional introduced contamination of foods through a variety of strategies to prevent food contamination and through enhanced regulatory authorities. FDA has not yet implemented many of the law's major provisions.⁹⁶ FSMA provides for increased food risk protection by creating mechanisms whereby food companies are required to identify and implement preventive controls to ensure adulterated products are not sold and then share their plan with the FDA to ensure compliance with good manufacturing practices. Having such controls in place would also allow companies to consider their responsibility regarding potentially adulterated foods involving the "absence, substitution, or addition of constituents." Some speculate that provisions under FSMA will likely result in increased detection and prevention of adulterated foods by the food companies, both under FFDCA Section 402(a) (21 U.S.C. §342[a]) and FFDCA Section 402(b) (21 U.S.C. §342[b]).⁹⁷ Since FDA could not possibly enforce every instance of food adulteration, such industry controls will be instrumental in helping to combat future adulteration before it ever reaches the marketplace.

FSMA does not directly address EMA; however, some of its provisions may have application to EMA even though some of these provisions may have originated as part of an overall food defense strategy. These FSMA provisions include:

- **FSMA Section 103 (Hazard Analysis and Risk-Based Preventive Controls).**⁹⁸

FSMA requires preventive controls for human food by domestic and foreign firms that manufacture, process, pack, or hold human food. Among the requirements are written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, identify monitoring procedures, and record monitoring results and specify what actions will be taken to correct problems that arise. These regulations would address, among other things, "hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism."

As part of its proposed rule published in January 2013, FDA states that intentional hazards, such as EMA, might require separate agency action. As part of the proposed rulemaking, FDA also has requested public comment on if and how it should address EMA:⁹⁹

FDA tentatively concludes that intentional hazards, which are not addressed in traditional HACCP¹⁰⁰ or other food safety systems, likely will require different kinds of controls and would be best addressed in a separate rulemaking ... We request comment on whether to include potential hazards that may be intentionally

⁹⁵ P.L. 111-353. For information, see CRS Report R40443, *The FDA Food Safety Modernization Act (P.L. 111-353)*.

⁹⁶ FDA's rulemaking documents are available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm>.

⁹⁷ See, for example, R. Carvajal, "USP, Food Fraud, and FSMA," *FDA Law Blog*, April 16, 2012, http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2012/04/usp-food-fraud-and-fsma.html.

⁹⁸ For more information, see FDA, "FSMA Proposed Rule for Preventive Controls for Human Food Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food," <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm> (docket#: FDA-2011-N-0920).

⁹⁹ 78 *Federal Register* 11: 3695. January 16, 2013.

¹⁰⁰ HACCP refers to "Hazard Analysis & Critical Control Points" and is defined by FDA as a management system to address food safety through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.

introduced for economic reasons ... [and] on when an economically motivated adulterant can be considered reasonably likely to occur.

- **FSMA Section 106 (Protection Against Intentional Adulteration).** FSMA requires FDA to issue regulations to protect against the intentional adulteration of food, such as “specifying appropriate science-based mitigation strategies or measures to prepare and protect the food supply chain from intentional adulteration at specific vulnerable points.”¹⁰¹ The proposal for this rulemaking was published in December 2013, and is the first time FDA has proposed a regulatory approach for preventing intentional adulteration of food.¹⁰²
- **FSMA Section 108 (National Agriculture and Food Defense Strategy).** FSMA requires that the Secretaries of Health and Human Services and Agriculture develop a National Agriculture and Food Defense Strategy, implementation plan, and research agenda. This strategy and the accompanying documents have not yet been published.¹⁰³
- **FSMA Title 3 (Improving the Safety of Imported Food).** To the extent that food fraud may be attributable to foods imported into the United States, FSMA provides for a series of requirements to ensure the safety of imported foods. Tightened import requirements may act to limit future fraud, or lend greater credibility to foods and food ingredients that are imported under these requirements. FSMA also recognizes “third party” audits or certifications, and several such entities have already started to address food fraud both in term of identifying terms or assessing implementation actions such as vulnerability assessments.¹⁰⁴ FDA’s proposed rules were published in July 2013.¹⁰⁵
- **FSMA Section 402 (Employee Protections).** FSMA expands protections for employees (whistleblowers) who provide information relating to FFDCA violations, such as testifying, assisting, or participating in a proceeding on such a violation, refusing to participate in an activity that may violate FFDCA.
- **FSMA Section 201(b) (Annual Report Regarding Food).** FSMA requires FDA to submit an annual report to Congress, covering efforts to coordinate and cooperate with other federal agencies with responsibilities for food inspections, and report information regarding facility inspections and facility registrations, among other things.¹⁰⁶

FDA has been working with other federal agencies to coordinate and cooperate on food safety activities. According to FDA’s most recent report on these types of activities, for example, FDA and the Department of Defense have “information-sharing networks and processes on facility

¹⁰¹ FDA, “Frequently Asked Questions,” <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm>.

¹⁰² For more information, see FDA, “Focused Mitigation Strategies to Protect Food Against Intentional Adulteration,” December 2013, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628.htm>.

¹⁰³ For more information, see FDA, FSMA Reports and Studies, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm271961.htm>.

¹⁰⁴ For more information, see J. Spink, C.T. Elliott, and K.P. Swoffer, “Defining Food Fraud Prevention to Align Food Science and Technology Resources,” *Food Science & Technology Journal*, Vol. 27, Nr. 4, December 2013.

¹⁰⁵ For more information, see FDA, “Food Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals,” July 2013 (docket# FDA-2011-N-01436); and “Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications,” July 2013 (docket# FDA-2011-N-01468); and “Information Required in Prior Notice of Imported Food,” May 2013 (docket# FDA-2011-N-017911), available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm>.

¹⁰⁶ Reports required under FSMA are available at <http://www.fda.gov/food/guidanceregulation/fsma/ucm271961.htm>.

audits and inspections, recalls, import alerts, laboratory findings and methods, and other food protection procedures.”¹⁰⁷ FDA officials have indicated that obtaining additional data and information would likely require enhanced public and private partnerships.¹⁰⁸

Import Authorities

Import security measures by FDA are conducted in conjunction with border inspections by CBP.¹⁰⁹ As part of this responsibility, importers of foreign food are responsible for verifying that the products obtained from foreign processors are in compliance with U.S. laws. FDA’s surveillance of imported foods consists of reviews of prior notice data, reviews of customs entry forms, physical or sensory analysis, sample collections for laboratory analysis, and detention without physical examination.

As required by the Bioterrorism Act, FDA must have received a notice for articles of food being imported or offered for import into the United States, prior to importation (FFDCA §801(m) [21 U.S.C. §381(m)]). Prior notice is required to enable the food to be inspected at U.S. ports of entry, and FDA must refuse admission to food imported or offered for import if the notice was not submitted or if the notice was deficient. Additionally, FDA may hold food at the port of entry if it is imported or offered for import by a person who was debarred under FFDCA or if it was imported or offered for import from a foreign facility that has not registered with the FDA. FDA screens the electronic shipping records of all imported food products before they enter the United States. From these records, the agency selects products for physical examination and/or testing to determine whether they contain adulterants.

Under FFDCA Section 801 (21 U.S.C. §381), FDA has the authority to refuse entry of any food import if it appears to be adulterated, misbranded, or in violation of U.S. law. In such cases, FFDCA generally provides that such a food article must be refused admission into the United States, with few exceptions, “if it appears from the examination of such samples or otherwise” that it has been “manufactured, processed, or packed under insanitary conditions,” or it is “forbidden or restricted in sale in the country in which it was produced or from which it was exported,” or it is “prohibited from introduction or delivery for introduction into interstate commerce under section 301(l)” (FFDCA §801(a)).

FDA actions on suspect imported products may be implemented through FDA’s “Import Alerts.” An alert can be issued for an import from a manufacturer, shipper, grower, geographical area, or country. An active import alert provides a signal to border inspectors to look more closely at a particular product, or a range of products from a particular producer, shipper, or importer. If the problem or condition exists on a wide scale, FDA may be instructed to detain all products of a certain kind coming from a country or a region of a country. Products that may be subject to refusal based on existing evidence (such as a history of violations) can be detained at the border and refused admission into U.S. commerce unless the importer is able to demonstrate that the

¹⁰⁷ FDA, “2012 Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices,” August 2012, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm315486.htm>

¹⁰⁸ Comments attributed to FDA Deputy Commissioner for Foods and Veterinary Medicine, Mike Taylor, reported by J. Murphy, “FDA Struggles with FSMA-Required Role in Combating Food Fraud,” *Food Chemical News*, May 10, 2013.

¹⁰⁹ FDA commissions CBP to assist FDA with examinations and investigations related to prior notice requirements for imported goods (21 U.S.C. §381(m)) at ports and other facilities and locations subject to CBP jurisdiction, under MOU 225-04-4001 (<http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115145.htm>).

products are in compliance.¹¹⁰ Import alerts may allow U.S. authorities (typically the U.S. Treasury has delegated its authority via DHS to the Customs and Border Protection) to detain, without physically examining, products that either have or potentially could violate FFDCA.¹¹¹ Detention without physical examination (DWPE), formerly known as "automatic detention," was developed to address recurrent violations.¹¹²

In FY2011, FDA reports that it physically examined (conducted field exams or analyzed samples of U.S. food imports under its jurisdiction) 243,400 food and feed import lines.¹¹³ This was out of a total of 10.4 million food import lines for FY2011.¹¹⁴ Hence, FDA physically examined 2.3% of all shipments. As noted by FDA, this physical examination was in addition to FDA's electronic screening of all import lines against a variety of risk criteria. As part of FDA's screening process, it implemented its Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) information technology system that helps target high-risk products before they enter the United States. Widely cited previous estimates of FDA food safety inspections of foreign facilities indicate that the rate of such inspections was even lower: GAO reported that, in 2000, FDA inspections covered only about 1% of the food imported under its jurisdiction.¹¹⁵ Changes to FDA's import regime under FSMA are expected to further address some of these concerns.

USDA, Food Safety and Inspection Service

Similar to laws governing FDA that may be broadly construed to provide the agency's authority over both unintentional and intentional adulteration of the food supply, the principal food safety laws governing USDA—namely, the Federal Meat Inspection Act and the Poultry Products Inspection Act—might likewise allow USDA to pursue activities to ensure against fraud of meat and poultry products under USDA's jurisdiction.

Food Safety Authorities

Excluding FDA-regulated foods, FSIS is responsible for the safety of the remaining roughly 10%-20% of foods covered by the U.S. food safety system, including meat and poultry and some egg products.¹¹⁶ As described in a Memorandum of Understanding between FDA and FSIS, FSIS's jurisdiction is as follows:¹¹⁷

FSIS is responsible for implementing and enforcing the Federal Meat Inspection Act (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451, *et seq.*), and parts of the Egg

¹¹⁰ If a shipment is refused admission, the importer may introduce evidence within 10 days to avoid the appearance of a violation. During that time, the product is held at a warehouse or with the importer and cannot be distributed. If the shipment is not proven to be safe, it must be destroyed or exported within 90 days.

¹¹¹ FDA, "Import Alerts Guard Against Unsafe Products," August 25, 2011. The database is at <http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/default.htm>.

¹¹² FDA, "Detention without Physical Examination," <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179271.htm>; and Linda Horton, "U.S. FDA Authority over Imports," <http://www.hoganlovells.com/files/Publication/a279dfd1-c81e-464e-a4f0-b26b6da16f29/Presentation/PublicationAttachment/4511545b-3ab8-4982-a2f6-ccfa2990c0a8/Horton.pdf>.

¹¹³ An entry line refers to a unique shipment.

¹¹⁴ FDA, "2012 Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices," August 2012, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm315486.htm>

¹¹⁵ GAO, *Fundamental Changes Needed to Ensure Safe Food* (GAO-02-47T), October 10, 2001, <http://www.gao.gov/new.items/d0247t.pdf>.

¹¹⁶ For more information, see CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*.

¹¹⁷ MOU 225-99-2001, <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm117094.htm>.

Products Inspection Act (21 U.S.C. 1031, *et seq.*). In carrying out its responsibilities under these acts, FSIS places inspectors in meat and poultry slaughterhouses and in meat, poultry, and egg processing plants. FSIS also conducts inspections of warehouses, transporters, retail stores, restaurants, and other places where meat, poultry, and egg products are handled and stored. In addition, FSIS conducts voluntary inspections under the Agriculture Marketing Act (7 U.S.C. 1621, *et seq.*).

The Federal Meat Inspection Act (FMIA) of 1906, as amended, requires USDA to inspect all cattle, sheep, swine, goats, horses, mules, and other equines slaughtered and processed for human consumption. The Poultry Products Inspection Act (PPIA) of 1957, as amended, gives USDA the authority to inspect poultry meat. The PPIA mandates USDA inspection of any domesticated birds (chickens, turkeys, ducks, geese, guineas, ratites [ostrich, emu, and rhea], and squab [pigeons up to one month old]) intended for use as human food. The Egg Products Inspection Act, as amended, provides USDA authority to inspect liquid, frozen, and dried egg products. Each of these laws also contain provisions governing USDA's authority to label food products under its jurisdiction.¹¹⁸

Under the authority of the Agricultural Marketing Act of 1946 as amended, USDA's FSIS may provide voluntary inspection for buffalo, antelope, reindeer, elk, migratory waterfowl, game birds, and rabbits. This type of inspection is performed by FSIS on a fee-for-service basis. However, these meat and poultry species are still within the purview of FDA under FFDCA, whether or not inspected under the voluntary FSIS program. FDA has jurisdiction over meat products from such species in interstate commerce, even if they bear the USDA inspection mark. FDA also has jurisdiction over shell eggs. In addition, the 2008 farm bill requires that FSIS inspect and grade farmed catfish products.¹¹⁹

Meat and poultry animals and products undergo continuous (i.e., 100%) inspection, which may in turn act as a deterrent to fraud in some cases. FSIS inspects all meat and poultry animals to look for signs of disease, contamination, and other abnormal conditions, both before and after slaughter ("antemortem" and "postmortem," respectively), on a continuous basis—meaning that no animal may be slaughtered and dressed unless an inspector has examined it. One or more federal inspectors are on the line during all hours the plant is operating. Processing plants visited once every day by an FSIS inspector are considered to be under continuous inspection in keeping with the laws. Inspectors monitor operations, check sanitary conditions, examine ingredient levels and packaging, review records, verify food safety plans,¹²⁰ and conduct statistical sampling and testing of products for pathogens and residues during their inspections.¹²¹

FSIS is responsible for certifying that foreign meat and poultry plants are operating under an inspection system equivalent to the U.S. system before they can export their product to the United States.¹²² Meat and poultry imports are 100% visually inspected (process-based, documentation, labeling), although physical inspections of imports may be more random. FSIS conducts evaluations of foreign meat safety programs and visits establishments to determine whether they

¹¹⁸ "A Guide to federal Food Labeling Requirements for meat, Poultry, and Egg Products," prepared for USDA Food Safety and Inspection Service by Hogan & Hartson, LLP, August, 2007, http://www.fsis.usda.gov/wps/wcm/connect/f4af7c74-2b9f-4484-bb16-fd8f9820012d/Labeling_Requirements_Guide.pdf?MOD=AJPERES.

¹¹⁹ P.L. 110-246, §11016 (Inspection and Grading). USDA has not yet finished its catfish inspection rule (76 *Federal Register* 10434, February 24, 2011), and will inspect catfish facilities when the rule is finalized.

¹²⁰ In a Hazard Analysis and Critical Control Point (HACCP) plan a facility must identify each point in its processes where contamination could occur ("critical control point") and have a plan to control it, as well as document and maintain records.

¹²¹ For more information, see CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*.

¹²² For information, see FSIS, "FSIS Import Procedures for Meat, Poultry & Egg Products," <http://www.fsis.usda.gov/>.

are providing a level of safety equivalent to that of U.S. safeguards. No foreign plant can ship meat or poultry to the United States unless its country has received such an FSIS determination.

About 1,100 of the establishments under the jurisdiction of FSIS either slaughter, or slaughter and process livestock, or poultry.¹²³ More than 4,000 facilities only process meat and poultry, and about 80 process egg products. In addition to inspecting domestic meat, poultry, and egg establishments, FSIS also performs re-inspections of imported meat, poultry, and egg products at about 140 import re-inspection facilities.

"Prohibited" Acts

FMIA and PPIA also authorize USDA to regulate labeling and packaging of meat, poultry, or processed parts to prevent false or misleading marks, labels, or containers (FMIA, 21 U.S.C. §607 and PPIA, 21 U.S.C. §457).¹²⁴ Similar to FFDCA, both FMIA and PPIA also disallow certain "prohibited" acts that involve products for use as human food that are "adulterated or misbranded at the time of such sale, transportation, offer for sale or transportation, or receipt for transportation" or products "required to be inspected ... unless they have been so inspected and passed" (FMIA, 21 U.S.C. §10; PPIA, 21 U.S.C. §458).

FSIS is responsible for developing the labeling policy to determine that meat or poultry products are wholesome, not adulterated, and properly marked, labeled, and packaged. FMIA and PPIA both define "misbranded" foods as bearing a false or misleading label, or foods that are "offered for sale under the name of another food," or are "an imitation of another food, unless its label bears, in type of uniform size and prominence," or if "its container is so made, formed, or filled as to be misleading, or is otherwise misrepresented" (21 U.S.C. §§ 453 and 601). An "adulterated" food bears or contains any "poisonous or deleterious substance which may render it injurious to health" or otherwise poses a risk to consumer health.

Perhaps more specific to food fraud, both FMIA and PPIA also define adulteration to include the following:¹²⁵

if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

Accordingly, similar to FFDCA, a food may be deemed adulterated if a "valuable constituent" is missing or if substances have been substituted wholly or in part or where damage or inferiority has been concealed in any matter, or if substances have been added to "increase its bulk or weight" (such as packing water or ice) or to raise the perceived quality of the product.

Moreover, FMIA and PPIA and federal meat and poultry inspection regulations (9 C.F.R. §§301.2 and 381.1, respectively) define "meat," "meat food product," "livestock," "poultry," and "poultry product" and do not include species of livestock or poultry other than those specifically listed. FSIS verifies the labeling, conducts species testing, and monitors the movement in commerce of all meat and poultry food products produced under federal inspection. This includes all meat and poultry products as well as other meat products (such as horsemeat and meat from various other

¹²³ FSIS' inspection directory, <http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/mpi-directory>.

¹²⁴ FSIS regulations are at 9 CFR 300. For meat products, labeling regulations are at 9 CFR 317; for poultry, regulations are at 9 CFR 381. Regulations regarding weights are at 9 CFR 442. Other information on FSIS labeling requirements is at <http://www.aamp.com/regulations/fsis-labeling/>.

¹²⁵ FMIA (21 U.S.C. §601) and PPIA (21 U.S.C. §453).

exotic animals) produced in or imported into the United States. FSIS claims that its stringent inspection process, testing capabilities, and labeling requirements effectively prevent cases such as those that occurred in the EU earlier in 2013, where horsemeat was labeled and sold as the meat of another species. FSIS claims it “conducts species tests on meat and poultry products that are produced domestically and that are imported to the United States” which are “capable of detecting beef, sheep, swine, poultry, deer and horse.”¹²⁶

Other Agency Authorities and Activities

Finally, FMIA and PPIA also broadly provide for FSIS to establish voluntary standards for meat and poultry products (FMIA, 21 U.S.C. §607[c]; and PPIA, 21 U.S.C. §457[b]). Although not regulatory in nature, and not intended to address potential food safety or food fraud concerns, food quality and grading standards provide a product benchmark for certain foods or food ingredients. Specifically, both FMIA and PPIA direct USDA to establish “definitions and standards of identity or composition” for meat and poultry products.¹²⁷ Standards of identity cover a wide range of raw, cooked, cured, and processed meat and poultry products and ingredients for USDA-regulated food products.

Import Authorities

Similar to that for FDA, various import security measures by USDA are conducted via various enforcement and border inspection activities by CBP. As part of this responsibility, importers of foreign food are responsible for verifying that the products obtained from foreign processors are in compliance with U.S. laws.

DHS, Customs and Border Protection

CBP enforces FDA and USDA regulations at ports of entry. Import security measures, in conjunction with existing CBP border inspections, are intended to address concerns about possible contaminated food imports. CBP is responsible for monitoring goods and materials in cargo shipments coming into the United States at all U.S. ports of entry, and is a regular part of inspection procedures carried out at every port of entry nationwide.¹²⁸ CBP’s border inspections are intended to address concerns about possible contaminated food imports and are not specifically designed to address intentional contamination of food and food ingredients. CBP agriculture specialists prevent the entry of harmful plant and animal pests and diseases and confront emerging threats in agro- and bioterrorism, as well as ensure that the required permits, sanitary certificates (for animal products), and phytosanitary certificates (for plant products) accompany each product shipment.¹²⁹ As part of its role in enforcing plant and animal regulations, CBP has the authority to detain, where necessary, imported or exported products pending their clearance by agency inspectors. CBP was created in 2003 through a merger of the former U.S.

¹²⁶ CRS inquiry (via FSIS at <http://www.fsis.usda.gov/wps/portal/informational/askkaren>) received December 17, 2013. Horses are not allowed to be slaughtered and horse meat is not allowed to be processed in the same facility as other species in the United States. FSIS notice on increased species sampling in response to horsemeat is at <http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/25-13.pdf>.

¹²⁷ Regulations are 9 CFR Part 319 for meat products and 9 CFR §§381.156 to 381.174 for poultry products. For corresponding labeling information, see FSIS’ “Food Standards and Labeling Policy Book,” August 2005, http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf.

¹²⁸ The authority to search, inspect, and examine merchandise entering the United States is in 19 U.S.C. §1467; regulations are at 19 C.F.R. 162.6. Other search authorities include 19 U.S.C. §§482, 1496, 1581 and 1582. These authorities rest with the U.S. Treasury that typically delegates its authority via DHS to CBP.

¹²⁹ USDA, “Importing Food and Agricultural Products into the United States,” August 2012.

Customs Service and the agricultural inspection portion of USDA's Animal and Plant Health Inspection Service (APHIS).¹³⁰

Imported products must meet the same standards as domestic goods, and must contain informative and truthful labeling in English. Existing U.S. trade laws, such as general requirements under the Tariff Act of 1930 (19 U.S.C. § 1304), require all imported articles to be marked with the English name of the country of origin.¹³¹ Other labeling requirements also apply under other laws that govern both FDA and USDA. For example, FDA requirements under FFDCA require that a food label must contain specified information. However, as noted by FDA, "The law does not specifically require that the country of origin statement be placed on the PDP [the principal display panel, PDP, or the label panel], but requires that it be conspicuous."¹³² Certain labeling requirements for meat and poultry products are also required within laws administered by FSIS.¹³³ Only plants in countries certified by USDA to have inspection systems equivalent to those in this country are eligible to export products to the United States. Regulations require that country of origin appear in English on containers of all meat and poultry products entering the United States.¹³⁴ Other USDA-administered programs also provide for additional country-of-origin requirements for certain types of foods.¹³⁵

Other Federal Food Quality or Food Safety Programs

A number of other federal agencies are involved in various food quality and food safety programs. Although these programs are not primarily focused on food fraud, product inspections under these programs might be leveraged to broadly address fraud concerns. In some cases concerns related to fraud are often a component of these programs. In other cases, such as in USDA's program certifying products that are organically produced, enforcement against fraudulent documents and certification is central to the program. Increased inspection and oversight as part of a program's product quality and marketing grades and standards may act as an added deterrent or improve detection if fraudulent marketing or related activities are happening.

USDA, Agricultural Marketing Service

Product Quality, Grading, and Standards

AMS is primarily responsible for product quality and marketing grades and standards for a range of foods, including dairy products, fruits and vegetables, livestock, meat, poultry, seafood, and shell eggs. However, AMS administers the egg surveillance program that inspects egg facilities quarterly to insure that egg handlers maintain required records and properly dispose of restricted

¹³⁰ Memorandum of Agreement (MOA), DHS Agreement# BTS-03-0001 and USDA-APHIS Agreement# 03-1001-0382-MU, March 2003, http://www.aphis.usda.gov/plant_health/moa_dhs/downloads/article1.pdf.

¹³¹ Customs and Border Protection's Guidance is at <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074567.htm>. See regulations at 19 CFR 134.

¹³² 21 CFR 101. See FDA, "Guidance for Industry: A Food Labeling Guide," October 2009, <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064872.htm>.

¹³³ FMIA (21 U.S.C. §601 *et seq.*) and PPIA (21 U.S.C. §451 *et seq.*).

¹³⁴ Regulations are at 9 C.F.R. 327.14 and 9 C.F.R. 381.205.

¹³⁵ Includes Country of Origin Labeling (COOL); see CRS Report RS22955, *Country-of-Origin Labeling for Foods and the WTO Trade Dispute on Meat Labeling*; and Perishable Agricultural Commodities Act (PACA) of 1930 and the Produce Agency Act of 1937 (7 U.S.C. §499a *et seq.*, and §1622, respectively); see CRS Report R42771, *Fruits, Vegetables, and Other Specialty Crops: Selected Federal Programs*.

eggs.¹³⁶ AMS also certifies quality programs and conducts quality grading services, generally user fee-funded. These programs are generally voluntary in nature, and in most cases do not directly address adulteration of food and food ingredients.

USDA programs establishing quality grade standards to encourage uniformity and consistency in commercial practices are provided for under the Agricultural Marketing Act of 1946 (7 U.S.C. §1621).¹³⁷ AMS develops quality grade standards for commodities as needed by the agriculture and food industry for a range of products, including cotton; dairy products; fresh and processed fruits and vegetables (and fruits and vegetables for processing); nuts and other specialty crops; livestock (including wool and mohair); poultry and eggs (including rabbits); and tobacco.¹³⁸ Under federal-state agreements, AMS-licensed state employees work where needed: in fields during harvest; at land, sea, and air ports of entry; and at packing houses, processing plants, warehouses, and federal and federal-state terminal markets. Grading is paid for by user fees and is voluntary unless the commodity is regulated for quality under a marketing order or agreement, subject to export requirements, or purchased by USDA or another federal agency for distribution (e.g., through the school lunch program or the military). Shipments of any imported commodity whose domestic production is under a marketing order or agreement must receive AMS grading to assure that the produce is comparable to the U.S. grade, size, quality, and maturity requirements.

Certified Organically Produced

AMS also oversees and enforces the USDA organic certification program, the National Organic Program (NOP). NOP is authorized under the Organic Foods Production Act of 1990, and the program's labeling and certification requirements are enforceable, and address concerns about fraud through product mislabeling.¹³⁹

NOP regulations require that agricultural products labeled as "organic" originate from farms or handling operations certified by a state or private entity that has been accredited by USDA. Administered by AMS, NOP is a regulatory program that became operational in 2002, establishing a voluntary production and handling certification program. The program specifies the methods, practices, and materials that may be used and how certified organic production is to be grown, raised, and processed.¹⁴⁰ A central part of the NOP's stated mission is to "ensure the integrity" of USDA-certified organic products according to national standards for organically produced agricultural products that "assure consumers that products with the USDA organic seal meet consistent, uniform standards."¹⁴¹ Since there are no tests that prove whether a food or ingredient is organically produced, certification relies on having the proper paperwork showing that processes were followed. Using fraudulent documents or certification to market, label, or sell non-organic (conventionally produced) food and food ingredients as USDA-certified "organic" is a violation of U.S. law and federal National Organic Program (NOP) regulations, punishable by fines of up to \$11,000 for each violation.¹⁴²

¹³⁶ Egg Products Inspection Act, as amended (21 U.S.C. §§1031-1056), 7 CFR Part 57.

¹³⁷ 7 U.S.C. §§1621 *et seq.*, 7 CFR Part 75.

¹³⁸ USDA, "USDA Quality Standards," <http://www.ams.usda.gov/standards/>.

¹³⁹ 7 U.S.C. §§6501-6522, 7 CFR Part 205. OFPA was enacted as part of the 1990 farm bill (P.L. 101-624).

¹⁴⁰ NOP regulations prohibit the use of genetic engineering, irradiation, and sewage sludge in certified organic production and handling.

¹⁴¹ For information, see USDA's website (<http://www.ams.usda.gov/AMSV1.0/nop>). See also NOP's "Fact Sheet," NOP's "2010-2012 Strategic Plan," and "National Organic Program," <http://www.ams.usda.gov/AMSV1.0/organicinfo>.

¹⁴² NOP's website lists prior and ongoing cases of fraudulent organic certificates at <http://www.ams.usda.gov/nop>.

NOAA, National Marine Fisheries Service

NOAA's National Marine Fisheries Service (NMFS) administers a number of seafood and fisheries safety and sanitation programs. NMFS's voluntary seafood and fisheries safety inspection program focuses on marketing and product quality under the authority of the Agricultural Marketing Act of 1946 (7 U.S.C. §1621 *et seq.*).¹⁴³ The program offers additional levels and types of inspection that exceed FDA requirements, which program participants also must meet. Examples include onsite NOAA inspections during production hours, certification that plants or vessels meet specified sanitation requirements, quality inspections of individual product lots, and/or laboratory testing of products, among other services. NMFS works with FDA, which helps provide training and other technical assistance to NMFS. As part of its guidance, NOAA identifies common seafood fraud consisting of the addition of water or ice to add weight to the product; use of masking agents (such as carbon monoxide in tuna) that may give the fish added color or make it seem much fresher than it actually is; and also seafood substitution or labeling and selling a less expensive fish product as a more expensive product.¹⁴⁴

Under the program, NMFS inspects a reported 20% of the seafood consumed in the United States.¹⁴⁵ Industry generally contracts with NMFS to provide the service, and NMFS personnel may inspect fishing vessels and processing plants to ensure that sanitary practices are in keeping with FDA standards. These services are provided on a fee-for-service basis and entitle participants to use various official grading and labeling marks, which are viewed as making their products more attractive to buyers. Exporters are often users of these services, in part because of foreign buyer requirements. NMFS may also periodically evaluate products at processing facilities for general condition, wholesomeness, and proper grading and labeling; and they may sample products for chemical and microbiological contamination, decomposition, and species identification.¹⁴⁶

In addition, NOAA works with FDA and other federal agencies, as well as various state agencies, under the National Shellfish Sanitation Program (NSSP). NSSP is a federal/state cooperative program recognized by FDA and the Interstate Shellfish Sanitation Conference (ISSC) to promote and improve the sanitation of shellfish—oysters, clams, mussels, and scallops—moving in interstate commerce through federal/state cooperation and to promote uniformity of state shellfish programs.¹⁴⁷ Participants include agencies from states, FDA, EPA, NOAA, and the shellfish industry, and also foreign governments. Such cooperative efforts may act as a further deterrent to fraudulent activities, or improve detection if fraud is occurring.

¹⁴³ NOAA Seafood Inspection Program, http://www.seafood.nmfs.noaa.gov/Program_Services.html. See also CRS Report RS22797, *Seafood Safety: Background and Issues*.

¹⁴⁴ See, for example, NOAA, "Identifying Seafood Fraud: A Common Practice with Serious Consequences," http://www.fishwatch.gov/buying_seafood/identifying_seafood_fraud.htm.

¹⁴⁵ NOAA, "Inspecting Seafood—A Highly Trained Nose Knows," *Fishwatch.gov*, http://www.fishwatch.gov/features/steve_wilson_10_15_12.htm.

¹⁴⁶ FDA, "2012 Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices," August 2012, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm315486.htm>.

¹⁴⁷ Information is at FDA, <http://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2006754.htm>. As part of a 1984 Memorandum of Understanding, ISSC was recognized as the primary voluntary national organization of state shellfish regulatory officials, providing guidance and counsel on matters for the sanitary control of shellfish.

Congressional Actions Involving Food Fraud

Congress has introduced a number of bills intended to address concerns about food fraud, mostly with respect to concerns about a particular food or food ingredient, but has not introduced legislation that would specifically address fraud in a comprehensive manner.

Most previous legislation in the past few years has tried to address fish and seafood fraud mostly through improved inter-agency cooperation and coordination. These include H.R. 1012/S. 520 (Markey/Begich) in the 113th Congress, S. 50 (Inouye) in the 112th Congress, and S. 3928 (Inouye) in the 111th Congress. Increased inspections of foreign seafood facilities were proposed in S. 2934 (Vitter) in the 111th Congress. Other previously introduced legislation would address fraudulent maple syrup (for example, H.R. 3363 in the 112th Congress).

Among other legislation introduced in the 113th Congress is H.R. 2400 (Capps), which seeks to improve recordkeeping and authorize investigations and enforcement actions for violations of the organic products standards. Previous congressional efforts have also highlighted concerns about fraudulently labeled “organic” products that might undermine the USDA-certified organic food industry.¹⁴⁸

In addition, both the House-passed and Senate-passed versions of the 2013 farm bill (H.R. 2642/S. 954) include a provision to require USDA to submit a report to FDA that describes an appropriate federal standard for the identity of honey. This provision relates to previous congressional effort to push FDA to create “pure honey” standards that would allow federal border agents to better combat adulteration, misbranding, and fraudulent mislabeling of honey.¹⁴⁹

A previous version of the House farm bill had also contained a provision that would establish tighter import controls on olive oil imports to enforce quality standards under the Agricultural Adjustment Act (7 U.S.C. §608e-1[a]).¹⁵⁰ This provision was removed by amendment during floor debate (H.Amdt. 213).

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¹⁴⁸ See, for example, letter from Senator Charles E. Schumer to USDA Secretary Tom Vilsack, September 20, 2010, available at http://www.schumer.senate.gov/Newsroom/record_print.cfm?id=327768.

¹⁴⁹ See, for example, Senator Schumer’s press release on June 11, 2010, regarding a letter sent to FDA Commissioner Margaret Hamburg. See also J. Pecquet, “Schumer: ‘Honey laundering’ a sticky problem that needs FDA intervention,” *The Hill*, June 12, 2010.

¹⁵⁰ H.R. 1947, §10010. See, for example, N. Flagg, “New Farm Bill Includes Olive Oil Controls,” May 20, 2013.

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