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Research Paper

Development of a Hazard Classification Scheme for Substances Used in the Fraudulent Adulteration of Foods

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ABSTRACT

Food fraud, the intentional misrepresentation of the true identity of a food product or ingredient for economic gain, is a threat to consumer confidence and public health and has received increased attention from both regulators and the food industry. Following updates to food safety certification standards and publication of new U.S. regulatory requirements, we undertook a project to (i) develop a scheme to classify food fraud–related adulterants based on their potential health hazard and (ii) apply this scheme to the adulterants in a database of 2,970 food fraud records. The classification scheme was developed by a panel of experts in food safety and toxicology from the food industry, academia, and the U.S. Food and Drug Administration. Categories and subcategories were created through an iterative process of proposal, review, and validation using a subset of substances known to be associated with the fraudulent adulteration of foods. Once developed, the scheme was applied to the adulterants in the database. The resulting scheme included three broad categories: 1, potentially hazardous adulterants; 2, adulterants that are unlikely to be hazardous; and 3, unclassifiable adulterants. Categories 1 and 2 consisted of seven subcategories intended to further define the range of hazard potential for adulterants. Application of the scheme to the 1,294 adulterants in the database resulted in 45% of adulterants classified in category 1 (potentially hazardous). Twenty-seven percent of the 1,294 adulterants had a history of causing consumer illness or death, were associated with safety-related regulatory action, or were classified as allergens. These results reinforce the importance of including a consideration of food fraud–related adulterants in food safety systems. This classification scheme supports food fraud mitigation efforts and hazard identification as required in the U.S. Food Safety Modernization Act Preventive Controls Rules.

Key words: Economically motivated adulteration; Economically motivated hazard; Food fraud

Food fraud, the intentional misrepresentation of the true identity or contents of a food ingredient or product for economic gain, can be a threat to public health. The adulteration of milk with melamine in China affected an estimated 290,000 consumers, with more than 50,000 hospitalizations and at least six deaths *(13)*. This incident cost affected companies $3 billion over the first 3 months alone *(27)*. Overall, food fraud costs the food industry an estimated $10 to $15 billion per year *(14)*. Food fraud incidents also cause secondary effects, including loss of public confidence in industry efforts to ensure the safety of the food supply and in the effectiveness of government regulatory systems. Because of its severe public health and economic costs, food fraud has received increased attention from both regulators and the food industry.

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The Codex Alimentarius Commission has not addressed the issue of food fraud, although the subject had been discussed by several Codex committees. The Global Food Safety Initiative (GFSI) *(12)*, an international initiative that provides benchmarks and guidance on food safety management systems, has undertaken work in this area, publishing revisions to GFSI Guidance Document version 7 that require a food fraud vulnerability assessment and mitigation plan. Several GFSI-recognized food safety certification programs have proposed or published revisions to address food fraud *(2, 15)*.

In Europe, the overarching food safety regulation, EC 178/2002 *(5)*, states that consumers should be protected from "fraudulent or deceptive practices," "the adulteration of food," and "any other practice which may mislead the consumer." Regulation EU 1169/2011 *(6)* (the Food Information Regulation) indicates that member states may adopt additional specific measures on the basis of protecting

registered designations of origin *(8),* implementing origin labeling, and preventing food fraud. Although there is no definition of the term "food fraud" in European Union (EU) legislation, it generally refers to the violation of statutory food requirements with the intent to deceive and motivated by economic gain *(7)* and includes forms of fraud such as counterfeiting, misbranding, and theft *(10, 20).*

The U.S. Food and Drug Administration (FDA) adopted a working definition for "economically motivated adulteration," which is 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" *(16).* U.S. regulations implementing the 2011 Food Safety Modernization Act increased the requirements for the food industry to put in place measures to prevent economically motivated adulteration. The hazard analysis and risk-based preventive controls rules for human food *(22)* and animal food *(23)* (PC rules), published in 2015, include provisions designed to help prevent the economically motivated adulteration of human and animal foods with potentially hazardous adulterants. The PC rule for human food requires that manufacturers "conduct a hazard analysis to identify and evaluate ... known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control" (21 CFR 117.130(a)) *(22).* The hazard identification must consider hazards that may be intentionally introduced for purposes of economic gain ("economically motivated hazards") (21 CFR 117.130(b)(2)(iii)). Similar provisions are found for animal food in 21 CFR 507.33 *(23).* Thus, the first step of the hazard analysis, as outlined in FDA's "Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry" *(24),* is to identify potential biological, chemical, and physical hazards, including those that could be present because they are intentionally introduced for economic gain.

The U.S. Pharmacopeial Convention (USP) is a nongovernmental organization with a mission to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. Since 2012, the USP has maintained a food fraud database *(18),* which consists of historical data records describing food ingredients that have been adulterated or could be prone to adulteration, the undeclared substances used to perpetuate fraud, scientific methods for detecting fraudulent adulteration, and additional attributes relevant to food fraud vulnerability. Information for this database is collected from media reports, the scientific literature, regulatory reports, trade associations, and other sources and is structured and coded in a manner to support robust data mining for food fraud risk mitigation. New records are regularly added to this database.

In the USP database and this article, the term "adulterant" is used very narrowly to describe a substance that is intentionally added to or substituted for a food or food ingredient for fraudulent purposes (for economic gain). Many of the adulterants described in the database and in this article are legally permissible food-grade ingredients that would not pose a concern under the conditions of use in a different context.

Following updates to food safety certification standards and publication of the PC rules, the USP recognized the value of developing a classification scheme for fraud-related adulterants as an aid in the identification of economically motivated hazards. The USP established an expert panel and undertook a project to (i) develop a scheme to classify adulterants based on their potential health hazards and (ii) apply this scheme to the adulterants in their database. Given the absence of exposure information available in the database, efforts were not made to assess the risks of these adulterants.

MATERIALS AND METHODS

A USP expert panel was formed to address the question of how to classify adulterants based on their potential to be hazardous to human health. This panel consisted of global food safety, toxicology, and regulatory experts drawn from industry, academia, and the FDA. The language (and related guidance) from the PC rules was the most applicable to this question; therefore, the work of the panel was primarily based on the language of the PC rules and the U.S. regulatory system. However, the panel's intent was for the classification scheme to be broadly applicable to food fraud mitigation efforts required by other regulatory bodies and international food safety programs.

To begin, the panel examined the approximately 800 adulterants in the USP database as of January 2016 to guide development of the framework. Categories were developed to classify the adulterants based on their potential to be hazardous by first examining the two ends of a spectrum. At one end are those materials that are themselves foods but have been used to replace more expensive ingredients for the purpose of economic gain. Examples include the undeclared addition of sugars to fruit juices and the substitution of alternative edible oils for extra virgin olive oil. Because these materials are foods, they are likely not a hazard, excluding known allergens and assuming that other food safety standards are met. At the other end of the spectrum are those adulterants that are known to have caused acute or subchronic consumer illnesses. For example, both the sale and use of industrial oil in place of olive oil and the addition of melamine to milk products caused consumer illnesses and deaths. The expert panel proposed two broad categories to capture the two ends of the spectrum and then created intermediate subcategories to further define the range of hazard potential for adulterants. Special consideration was given to the question of how to classify allergens as adulterants because these substances are generally safe for the majority of the population but pose serious health risks to a subset of consumers. Because information in the database comes from a wide variety of sources providing various degrees of detail, the panel also considered situations for which there was not sufficient information to determine the true identity of an adulterant.

The subcategories were created through an iterative process in which the panel reviewed a set of 10 to 20 adulterants in the USP database, proposed a set of subcategories based on those adulterants, then edited and refined the subcategories by applying them to an additional set of 10 to 20 adulterants. This cycle of proposal, review, and validation was repeated five times. Once the classification scheme was developed, it was applied to the 1,294 adulterants in the database as of March 2017.

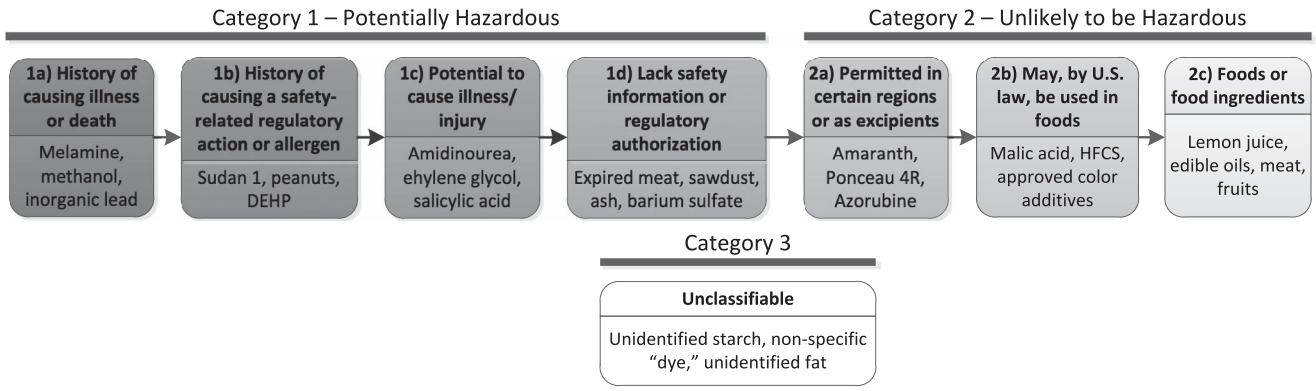

FIGURE 1. *Hazard classification scheme for food fraud–related adulterants (subcategories in bold, with example adulterants).*

RESULTS

The adulterant categories and subcategories are presented below and in Figure 1.

Potentially hazardous adulterants (category 1). Subcategories 1a through 1d describe adulterants that, if present in a food product, could result in consumer illness or death or, if detected in a food product, could result in regulatory action. This classification scheme, applied retrospectively, made use of information about regulatory actions, which are risk management decisions, for classifying potential hazards. A risk assessment that takes into account facility-specific characteristics would be required for a prospective evaluation of a suspected hazard.

Subcategory 1a. Adulterants that have a history of causing illness or death. These include industrial chemicals or by-products that are not intended for use in foods and, when fraudulently introduced for the purpose of economic gain, have resulted in illnesses or deaths. Examples of adulterants in this subcategory include melamine, methanol, and inorganic lead (lead tetroxide). In 2008 melamine adulteration of milk in China resulted in illnesses and deaths in infants *(13)*. The use of methanol in alcoholic beverages has been an ongoing challenge and routinely causes consumer illness and death *(3, 21)*. In 1994, adulteration of paprika with lead tetroxide resulted in many consumer illnesses and some deaths in Hungary *(17)*.

Subcategory 1b. Adulterants that have a history of causing safety-related regulatory action or are classified as allergens. A regulatory action may be in the form of a recall, some other market withdrawal, or a refusal to allow import. Regulatory agencies may require recalls in the absence of reports of consumer illness because of concerns that illness or other adverse outcomes could result from dietary exposure. This subcategory also includes all adulterants associated with food allergies, gluten sensitivity, or intolerances—as listed by the Codex Alimentarius Commission *(4)*—because of their history of safety-related regulatory action. Recalls due to misbranding or misleading labeling and not based on concerns about adverse health effects would not fall into this subcategory. Examples of adulterants in this subcategory include Sudan 1, peanut protein (an allergen), and diethylhexyl phthalate. Adulteration of chili powder with the industrial dye Sudan 1 caused widespread recalls in the United Kingdom in 2005 *(19)*. Peanut adulteration of cumin powder resulted in widespread recalls in both the United States and United Kingdom beginning in 2014 *(1)*. Diethylhexyl phthalate adulteration of clouding agents caused recalls of many finished food products in Taiwan in 2011 *(26)*.

Subcategory 1c. Adulterants with the potential to cause illness or injury. This subcategory includes substances that should not be used in foods because of their inherent toxicity or because they could be contaminated with toxic materials. This subcategory includes substances allowed in topical skin treatments but not authorized for use in foods and substances allowed in food contact articles (e.g., food additives, food contact substances subject to an effective food contact notification, previously sanctioned substances, substances subject to a threshold of regulation exemption, and generally recognized as safe [GRAS] substances) that are used outside the permissible conditions of use. Examples of adulterants in this subcategory include certain nitrogen-containing melamine analogs (e.g., amidinourea), which could fraudulently increase the apparent protein content of foods, ethylene glycol used as a substitute for glycerin, and salicylic acid used as a preservative in milk.

Subcategory 1d. Adulterants that lack applicable safety information or regulatory authorization. Substances without either a history of safe use or a safety profile defined by studies performed according to generally recognized protocols cannot be assumed to be safe. This subcategory includes substances permitted for use in oral drugs but not authorized for use in foods and substances that are less likely to be health hazards than those in previous subcategories but that may be associated with a history of regulatory action. Examples of adulterants in this subcategory include expired meat sold as fresh meat, materials such as sawdust and ash, which may be used as fillers in herbs and spices, and barium sulfate used to increase weight or adjust the color of ground materials.

TABLE 1. *Results of the application of the classification scheme to 1,294 adulterants in the USP database of 2,970 food fraud records*[a]

Category	Subcategory	No. (%) of adulterants
1. Potentially hazardous adulterants	1a. Adulterants that have a history of causing illness or death	26 (2)
	1b. Adulterants that have a history of causing safety-related regulatory action or are classified as allergens	325 (25)
	1c. Adulterants with the potential to cause illness or injury	136 (11)
	1d. Adulterants that lack applicable safety information or regulatory authorization	91 (7)
Subtotal		578 (45)
2. Adulterants that are unlikely to be hazardous	2a. Adulterants that, in other contexts, are substances permitted for use in foods in certain regions but not permitted for use in the United States or substances permitted for use as excipients in oral drugs without approval for food use	10 (1)
	2b. Adulterants that, in other contexts, are substances that may by law be used in foods in the United States and are not associated with a known health hazard under intended conditions of permissible use	167 (13)
	2c. Adulterants that, in other contexts, are foods and food ingredients consumed by a significant number of people for a prolonged period of time	423 (33)
Subtotal		600 (46)
3. Unclassifiable		116 (9)
Total		1,294 (100)

[a] Data current as of March 2017.

Adulterants that are unlikely to be hazardous (category 2). Subcategories 2a through 2c describe adulterants that can generally be considered unlikely to be hazardous, with the caveat that the substances meet appropriate food safety standards. Foods must be handled, processed, and stored in a controlled manner in compliance with food safety standards and must meet regulatory requirements to limit deleterious substances (e.g., heavy metals, pesticide residues, and natural toxins). Adulteration of one food ingredient with another food ingredient that does not meet appropriate safety standards could result in a hazard.

Subcategory 2a. Adulterants that, in other contexts, are substances permitted for use in foods in certain regions but not permitted for use in the United States or substances permitted for use as excipients in oral drugs without approval for food use. Although these substances may not be authorized for use in foods in certain regions, they have not been associated with illness or injury under intended conditions of use. Examples of adulterants in this subcategory include certain colors such as amaranth, Ponceau 4R, and Azorubine. (This work was primarily based on the U.S. regulatory framework; however, this subcategory could be readily adapted to apply to other regulatory frameworks.)

Subcategory 2b. Adulterants that, in other contexts, are substances that may by law be used in foods in the United States (including approved food and color additives, substances subject to a prior sanction, and GRAS substances intended for use in human foods) and are not associated with a known health hazard under intended conditions of permissible use. This includes substances permitted in foods that may also be permissible excipients in drugs. Examples of adulterants in this subcategory include malic acid, high fructose corn syrup, and approved color additives.

Subcategory 2c. Adulterants that, in other contexts, are foods or food ingredients consumed by a significant number of people for a prolonged period of time. These are foods or food ingredients that are not associated with illness or injury under intended conditions of use and are not identified as allergens by the Codex Alimentarius Commission. Examples of adulterants in this subcategory include lemon juice, edible oils (e.g., corn and canola), meat, and fruits.

Unclassifiable adulterants (category 3). This subcategory includes adulterants for which there was not sufficient information to determine the true identity of the substance. Examples of adulterants in this category include an unidentified starch, a nonspecific "dye," and an unidentified fat.

Application of this hazard categorization scheme to the 1,294 adulterants in the USP database as of March 2017 yielded the results shown in Table 1. Almost half (45%) of the adulterants in the database were classified in category 1 (potentially hazardous), with 351 (27%) of the adulterants in the database having a history of causing deaths or illnesses, being associated with safety-related regulatory action, or being classified as allergens (subcategories 1a and 1b).

DISCUSSION

Food fraud presents a unique challenge for all food protection stakeholders and has a long history involving a

wide range of adulterants—from industrial chemicals to chalk powder to sugar syrups. The PC rules have focused attention on those food fraud–related adulterants that pose a potential hazard to consumer health and are high priority for all food protection stakeholders. Given the variety and unconventional nature of adulterants used for fraudulent purposes, the identification of those adulterants that pose a health hazard is challenging. A review of data from foodborne outbreaks, recalls, and the scientific literature is often not sufficient to identify what is a "known or reasonably foreseeable" food fraud–related hazard. The classification scheme proposed here, developed using a global repository of historical food fraud records as the source for information on potential adulterants, begins to address this challenge.

The results of our application of the classification scheme to the USP database reinforce the importance of including a consideration of food fraud–related adulterants in food safety systems. An almost equal percentage of the adulterants in the database were classified in category 1 (potentially hazardous) as were classified in category 2 (unlikely to be hazardous). More than a quarter of all adulterants were known to be associated with a history of illnesses and/or deaths in consumers, associated with safety-related regulatory action, or classified as allergens. However, the global scope of food fraud is not definitively known. Based on one estimate, as few as 4% of food fraud occurrences are detected *(11),* so the true scope of the problem could be quite large. The records in the database represent a subset of the true incidence of fraud. Food fraud incidents involving potentially hazardous adulterants are most likely overrepresented in the database, because those incidents are the most likely to be detected. Nonetheless, the results presented in this study, revealing the range of hazard potential for food fraud–related adulterants, reinforce the need for food fraud mitigation efforts for both public health and brand protection.

In constructing the classification scheme, we recognized the inherent challenges associated with developing categories and applying them to substances without the benefit of contextual information regarding a particular adulteration incident (e.g., the contamination level and the nature of the exposure). The food safety risk posed by any incident of adulteration depends on many facility- and situation-specific factors. For example, the amount of adulterant present in the food, the amount of adulterant likely to be consumed, and the increased vulnerability of sensitive populations are important factors that must be considered in a risk assessment. However, because of the nature of the sources from which the data are collected for the database, information such as the quantity of the adulterant in the food and the amount of adulterant consumed generally was not available. Therefore, we were unable to assess exposure for the purposes of our work. Ultimately, a food facility or manufacturer has the burden to determine whether a full risk assessment or hazard evaluation is needed because these producers have access to the relevant information required for such an assessment.

To develop this classification scheme, we made certain assumptions that are important to consider in any risk assessment or hazard evaluation. For example, all categories falling under the broad classification "unlikely to be hazardous" were based on the assumption that the substance meets applicable food safety standards. Food facilities should consider whether such assumptions are warranted for their specific situation. Although we primarily used the U.S. regulatory framework as a basis for constructing this scheme, the scheme can be readily adapted to other regulatory frameworks. For example, subcategories 2a and 2b could be modified to focus on substances permitted for use in the EU or other regions.

This classification scheme supports the first step of what the FDA calls hazard analysis, specifically hazard identification for substances used in the fraudulent adulteration of foods. However, this scheme is not intended to serve as a hazard evaluation or hazard characterization. The FDA's draft guidance *(24),* which assists industry in complying with the PC rules, details the steps involved in conducting a hazard analysis, the first step of which is a consideration of potential hazards associated with all ingredients and with process or manufacturing steps. The subsequent determination of whether a hazard evaluation is warranted and the conduct of such an evaluation is a risk management decision that should be made by properly trained staff with appropriate expertise. With regard to hazards that may be introduced for economic gain, the FDA draft guidance recommends focusing on circumstances in which there has been a pattern of such adulteration, although past circumstances may not be associated with the specific supplier or the specific food product. Considerations should include the country of origin of an ingredient and any supplier associated with an ingredient. Based on the outcome of the full hazard analysis, a determination should be made whether a particular adulterant is a hazard requiring a preventive control or supply chain control. Although the FDA focuses specifically on food fraud–related hazards, the USP *(25)* and other organizations have developed guidance documents that identify factors to consider when broadly assessing food fraud vulnerabilities.

Although the classification scheme developed here is a useful first step, experienced risk assessors will recognize that even for substances that fall into the "unlikely to be hazardous" category further consideration of the specific circumstances of potential adulteration may be warranted. Factors to consider include whether there is reason to believe the adulterant might not be food grade, may be unstable in the food matrix, could obscure a hazardous defect in the food, or may negatively affect the nutritional profile of the finished food product. Another consideration is whether some consumers may have an intolerance or allergy to the substance even though it is not an allergen as defined by the Codex Alimentarius Commission.

Substances identified as potentially hazardous will in most cases require further assessment as part of a hazard evaluation. Factors that should be considered as part of a hazard evaluation include the toxicity of the adulterant (e.g., acute toxicity, carcinogenicity, or reproductive toxicity), the stability and purity of the adulterant, and the amount of the adulterant in the food product. Guidelines such as those

described in the "Threshold of Toxicological Concern" *(9)* can help prioritize potential health concerns.

One of the main challenges inherent in reducing the risk of food fraud is the lack of validated data on the true scope of the problem. Future work in this area should address the need for more precise estimates of the global incidence of food fraud, especially focusing on geographic regions and food products of greatest concern from a public health perspective. Much information about food fraud is privately maintained and not shared because of legal concerns. Development of mechanisms for protected means of intelligence sharing is one way to increase our understanding of the scope of the problem. The continued development of cost-effective, accessible, and validated analytical methods (especially nontargeted methods) is another important area of work for food fraud prevention. Models or templates should be created to help support hazard evaluations involving food fraud.

Food fraud cheats both ethical manufacturers and consumers. Authenticity in our food supply is a societal value that can have widespread implications beyond consumers' health and industry's bottom line. Recent developments in food regulations and food safety schemes put increasing responsibility on industry to mitigate the risk of food fraud in food supply chains. The classification scheme presented here is intended to support such food fraud risk mitigation efforts.

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