COMPREHENSIVE REVIEWS IN FOOD SCIENCE AND FOOD SAFETY



Food inauthenticity: Authority activities, guidance for food operators, and mitigation tools

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KEYWORDS

food authenticity, food fraud, vulnerability assessment

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Practical Application: Practical Application of the provided information by the food industry in selecting resources (guidance document, analytical methods etc.)

INTRODUCTION 1

Although fraud has existed since ancient times, and societal awareness is high due to the large number of food fraud incidents which have been extensively reported, there is still no international agreement on common terms and definitions relating to the phrase "food fraud." There is however movement toward a common definition; for example, the Food and Agricultural Organization (FAO) has recently defined food fraud as being when customers are deceived about the quality and/or content of the food they are purchasing, often motivated by an undue advantage for those who are selling the food (FAO, 2021). International standardization bodies such as International Standards Organization (ISO)/European Standardization Committee (CEN) and Codex have initiated work on agreeing definitions of food fraud and related subcategories such as adulteration, substitution, addition, misrepresentation, dilution, but such standardization is at an early stage and will take time to be agreed (CEN et al., 2021). The lack of such a definition is problematic not least in terms of impeding progress with respect to further transnational standardization in this area and may have significant implications for policy. For example, while it is widely accepted that food fraud is a deliberate act with intention to deceive for financial gain, early definitions of food fraud often focused on the consumer being the (sole) victim, whereas it is now widely acknowledged that food fraud often targets food businesses with the consumer often being an unfortunate "casualty" of the fraud. It is important that definitions are relevant to protecting all elements of society if food fraud is to be adequately addressed. For the purposes of this study, we propose a slight modification (bracketed) of the food fraud definition proposed by Moyer et al. (2017), "Food fraud is the illegal (intentional) deception for economic gain using food."

However, even with this clarification, the term food fraud can be used inappropriately as fraud is a legal term. Activities can only be confirmed as being fraudulent when they have been successfully prosecuted in a court of law.

In addition, there are a wide range of activities that may deem a product non-compliant or incorrectly labelled that would not be appropriate to define as food fraud. It is for this reason that we use and promote the antonym of authentic, that is, inauthentic, in this study when exploring areas where the integrity of a food might be in question. Throughout this study, we use the term "inauthenticity" except in the context of authoritative activities that are stated by those authorities as being related to "food fraud."

1.1 **The term "inauthenticity"**

Inauthentic food is presented as being something which it is not, the intentionality may be deliberate, unintentional, or unknown. There are two types of inauthenticity which will overlap in some, but not all, inauthenticity events:

- misrepresentation that a foodstuff is within the contractual arrangement between trading partners (i.e., breach
- · misrepresentation that a foodstuff is within the legal obligations of the region of intended trade (i.e., noncompliance).

In both cases, inauthenticity may concern a wide range of issues that result in incorrect information passing between trading partners or with authorities. As shown in Figure 1, inauthenticity can originate from any part of a supply chain. In the past years, attention has been devoted to deliberate acts of misrepresentation, particularly concerning ingredient identity (e.g., horse meat being misrepresented as beef). However, due to the complexity of modern supply chains, it is likely that inauthenticity events related to the suitability of production processes, or the accuracy of specifications, are occurring more frequently than those due to misrepresentation of the identity of the foodstuff being traded. Examples might include the technical details in how production processes operate compared to the process authorized within regulation, such

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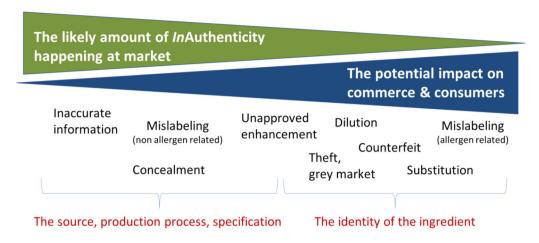


FIGURE 1 Range of possible food inauthenticity events

as the identity of microorganisms used in fermentation, or the use of extraction solvents outside of their permitted conditions of use and intentionally not included in the ingredient specification. The potential for inauthenticity is exacerbated in regions with both granular and expanding regulatory requirements, due to the difficulty of supply chain actors keeping pace with complex requirements. In regions such as the European Union, it may also be the case that authority surveillance and identification of inauthenticity events are increasing, resulting in difficulty differentiating between regulatory noncompliance and deliberate acts for the purpose of financial gain. This differentiation is important as the measures taken to rectify the inauthenticity may be different. Table 1 provides examples of the communications between trading partners and potential misrepresentation that may occur.

Due to concern over deliberate acts resulting in food inauthenticity, governmental agencies across the world have initiated activities to counter food fraud, and these are reviewed in Section 1. Food business operators have also developed a range of guidance documents in recent years, and these are reviewed in Section 2. These documents usually describe the types of deliberate acts leading to food misrepresentation, and there are several similar definitions used across available guidance which we have consolidated in Figure 2. Such acts are perpetrated at the level of ingredients, packaging, and documentation that describes the identity and characteristics of food or occur at market. It should be noted however, that in order to ensure food safety, quality, and labeling compliance, food business operators need to consider both errors and deliberate acts together in their management of food inauthenticity. When an inauthenticity incident is identified, the underlying motivation should not be assumed, unless it is obvious, without a root cause analysis. Section 3 provides an overview of available analytical tools that may be

used as a part of validation and verification of ingredient authenticity/inauthenticity.

SECTION 1: GLOBAL ACTIVITIES FOR FOOD FRAUD DETECTION AND **MITIGATION**

In order to identify and prosecute food fraud, it is usually necessary to demonstrate that the food is noncompliant to some degree with a given specification, for example, a labeling description, or a business-to-business specification. Specifications are produced to ensure foodstuffs being traded meet agreed requirements, and this facilitates food safety and quality and protects the consumer and food industry sectors or government fiscal policies from being defrauded. It is therefore of no coincidence that those countries/organizations with a long legacy of developing such specifications also have a long association with antifood fraud activities.

An example of this is the European Union's Common Agriculture Policy that provided guaranteed price levels for a wide range of European agri-food products (European Union Common Agricultural Policy, n.d.). This policy necessitated a wide and detailed range of specifications for key agri-food products in order to demarcate between the various tariffs and subsidies that were active at the time. As a result, the European Union has a long history of funding the anti-food fraud research and testing that were needed to identify the many "noncompliant" and/or fraudulent products that were attempting to take advantage of the system at the time.

Similarly, those sectors of the food industry producing high "value" products have a long history of producing detailed specifications to protect their products from fraudulent imitations. For example, the wines, spirits, and fruit juice sectors have been proactive in developing

TABLE 1 Relationship between communication and the food itself

Type of communication	Examples	Message conveyed	Examples of reasons of misrepresentation
Technical documents linked with and traded with the food.	Specifications. Technical data sheets. Certifications (e.g., production process suitability, origin, religious status). Other statements, such as on compliance status.	Explicit facts. May be used as justification for a claim, but not in themselves provided to the end consumer.	Error, e.g., change in the supply chain not reviewed by regulatory affairs department. Deliberate lack of information that is not required by regulation, but may be material to authenticity. Disinformation, the provision of some information to mislead into believing a certain status, but not the full information which would demonstrate a different status. Misinformation, the provision of frankly incorrect information.
Labeling affixed to the food.	Identity. Religious status. Geographic origin. Production method (e.g., organic). Allergen status. Date marks. Other "claims."	Explicit facts. Used as a part of the selling proposition to consumers.	Error, e.g., change in the supply chain not reviewed by regulatory affairs department. Misinformation, the provision of frankly incorrect information.
The context in which the food is presented.	Marketing imagery (e.g., looks similar to something that it is not).	Perception, based on common perceptions of foods (e.g., organic). Usually only an issue for trade to end consumers.	To promote the purchase of lower quality foods at premium prices.
IP infringement or counterfeit	Infringement in the production or appearance of foods. Frank counterfeit are a facsimile, usually only in visual appearance.	Explicit, misleading of supply chain partner or consumer.	Financial gain.

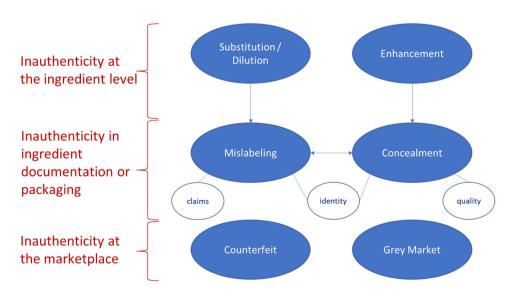


FIGURE 2 Types of deliberate act leading to food misrepresentation

specifications for their products and developing technology for assessing their compliance.

The relationship between the industry and regulators with regard to food fraud is complex and often strained, with industry requiring protection from illegal or nonconforming products on the one hand and the ability to trade freely on the other hand. This tension has varied historically, often depending on the global political agenda at the time.

The complexity of food fraud is often reflected in the fragmented nature of how it is regulated and enforced within a particular country, with those sectors providing substantial fiscal income for governments being treated differently to those that do not. The extensive tax revenue from wines, spirits, and other alcoholic beverages for example are usually the domain of specific government departments and are often separated from others concerned with other aspects of food fraud, for example, Her Majesty's Revenue and Customs (HMRC) in the United Kingdom and the Alcohol and Tobacco Tax and Trade Bureau (TTB) with respect to alcoholic beverages in the United States. While this intragovernmental demarcation is understandable, it can be an impediment if interdepartmental cooperation and communication are not optimal.

Finally, how the food fraud activity is assessed internally within government can substantially influence the compilation of statistics and data on food fraud. For example, while it is acknowledged that melamine in milk and fipronil in eggs involved aspects of food fraud due to intentionality, they are primarily classed and formally recorded as food safety incidents or regulatory nonconformance, this may result in formal governmental statistics on food fraud events being underrepresented.

Notable structures and activities to counter food fraud in different jurisdictions were collected from practitioners active in those jurisdictions through the authors' networks between 2019 and 2021. These networks included multiple stakeholder groups such as university researchers and lecturers, government employees, and employees from other food-related research institutions. The findings are summarized here:

2.1 | Europe

In Europe, several new activities related to the detection, prevention, and mitigation of food fraud have started. These include activities at the regulatory body level, the research level, in not-for-profit organizations, and private law bodies.

2.1.1 | European authoritative activities

European Commission

The European Commission (EC) has different sections known as Directorate Generals (DGs), in particular DG SANTE, which are active in preventive measures or the detection of food fraud in different ways.

The EC operates the European Anti-Fraud Office (OLAF) which is active on food fraud initiatives, and DG SANTE is linked to the food fraud activities of the EC science agency Joint Research Center (JRC). DG SANTE also maintains the Rapid Alerts for Safety of Food and Feed (RASFF) database (https://ec.europa.eu/food/safety/rasff/ portal en). This portal was predominantly created to prevent food and feed items entering the European Union which present a safety concern. However, many entries in the system are for foodstuffs that do not meet regulated specifications for residues and contaminants and are not necessarily linked to safety concern, for example, noncompliance of pesticides, veterinary drug residues, and mycotoxins. The RASFF contains a category "adulteration/fraud." Being a very useful resource, it does suffer from a lack of detail in terms of classification of type of alert. For example, mislabeling of allergens may be classed as food fraud and melamine is classed as a food safety incident even though it is also a food fraud one.

More recently, DG SANTE has invested in a dedicated Food Fraud Unit and has initiated the Food Fraud Network which is a network between competent authorities of Member States, and Europol. Europol is the EU law enforcement agency, which is active in food fraud not least via the OPSON initiatives, and recently organic products were targeted as part of the EU OPSON VIII program (Europol, 2021).

Internally within the EC and between Member States, there is a system for capturing potentially emerging food fraud incidents known as the Administrative Assistance and Cooperation System for Food Fraud (AAC-FF). Requests for information from the system are tracked, and this information demonstrates that the EC itself had the second-highest number of requests for information after Germany (Pöpping, 2020). Information has been primarily requested for the following categories: fats and oils, fish and fish products, and meat and meat products. In 2019, the number of requests for fruits and vegetables increased significantly, possibly in line with an increase in reports of organic fraud. There is an obligation for Member States to report all agri-food fraud suspicions of a crossborder nature through this portal to enable investigation by any Member State in addition to the EC. In order to better capture fraudulent incidents and to expand information beyond information gathered in authority inspections,

et al., 2017; SeaFoodplus Project, n.d.; TRACE Project, n.d.).

there is a recent requirement for Member States to set up and operate a "whistleblower" platform (Eric Marin, personal communication).

DG Joint Research Centre

At the EC level, a unit known as the Knowledge Centre for Food Fraud and Quality (KC-Food) has been established within the DG Joint Research Center. This unit is developing novel analytical methods for the detection of food fraud and providing intelligence for both EU Member States and the wider public, and performs analytical measurements for the OLAF anti-fraud investigations. At the public level, a newsletter called the "Food Fraud Reporter" is published which contains information from multiple sources including the RASFF and incidents reported by media across the world.

DG AGRI and DG MARE

DG AGRI has had a long legacy through the provision of marketing regulations of developing vertical specifications for food commodities and in developing methods of analyses for measuring compliance. An example is the Commission Regulation (EEC) No. 2568/91 which provides detailed definitions and specification for the grades of olive oils and olive-pomace oils and the relevant methods of analysis to be used to assess compliance. DG MARE's remit and activities mirror widely that of DG AGRI, but in the seafood segment.

The EC has also sponsored numerous projects and activities addressing the food fraud issue over the last 50 years, either directly through the DGs involved (e.g., adoption and support for SNIF-NMR technology for countering the illegal addition of sugar to wine and fruit juices, provision of EU wine databank, alongside the continual addition and updating of methods of analyses to support marketing standards) or/and more recently through research projects funded through EU framework programs.

EU sponsored research activities (https://cordis.europa.eu/projects/en)

One of the first EU projects dedicated to food authenticity/fraud was the FAIM project: food authenticity issues and methodologies (AIR-CT94-2452. 1994-1998) funded through Framework 4. Since then, there have been a number of projects dedicated to either developing specifically methods of analyses (e.g., methods of analyses for spirit drinks, adulteration of olive oil OLEUM) or more general multidisciplinary approaches, for example, TRACE, SeaFoodPlus, Aquatrace, Authent-net, FoodIntegrity, EU-China-Safe, FoodSmartphone that incorporate wider elements of food authenticity/fraud (AquaTrace Project, n.d.; Authent-Net Project, n.d.; EU-China Safe, n.d.; FoodIntegrity Project, n.d.; FoodSmartphone Project, n.d.; Ozulku

Labelfish was another project funded by the EC (Labelfish Project, n.d.). Different from most projects, this project was not open to private companies but only to competent authorities' organizations. The goal of this project was to identify the prevalence of fish fraud and develop methods of analysis.

2.2 **European Member States**

Several European Member States and the United Kingdom have undertaken and continue activities to prevent, detect, and mitigate food fraud.

2.2.1 | Germany

In Germany, the Bavarian authorities (LGL) initiated a project to focus their activities on high-risk commodities. This was done by developing algorithms that alert the authorities if a supply and demand ratio changes above or below an historic norm. As proof of principle, the authorities chose a change in the hazelnut commodity price to start investigating the commodity for fraud. In fact, they found several other types of nuts in ground hazelnuts that were not declared. As some consumers are allergic to certain nuts, this may also present a health hazard. More recently, the German government established the Nationales Referenz Zentrum für Authentizität (NRZ-Authent), which is the national reference center for food authenticity. Its mission is to coordinate activities that help prevent and mitigate food fraud. This includes the development of new methods and the collaboration with authorities at EC level. The NRZ-Authent is part of the Max-Rubner Institute and is decentralized across several locations in Germany with different specialisms (e.g., meat analysis and speciation in Bavaria, fish analysis in Schleswig Holstein).

In addition, the German government already had, for several decades, method working groups that deal with the authentication of animal and plant species. In addition to these, a new working group for the detection of food fraud using mass spectrometric methods was formed. The same working group also deals with the mass spectrometric detection of food allergens.

2.2.2 The Netherlands

In the Netherlands, the authorities perform regular inspections in the food industry and these inspections incorporate control against food fraud. Such inspections include targeted, analysis-based projects on authenticity in combination with food safety concerns, performed either unilaterally or in a coordinated EU plan such as the Europol coordinated operations known as OPSON. In addition, the Dutch authorities have developed administrative inspections on traceability and fraud. Different from many other EU countries, the Netherlands maintain a criminal investigations unit (NVWA-IOD) which investigates food fraud using police powers, under the authority of the Public Prosecution Office. This unit collects intelligence from a range of human and digital sources, both overtly and covertly.

The competent authorities respond to any report relating to food fraud, irrespective of if it originates from a whistle-blower, consumer, or journalist. The Netherlands competent authorities actively participate in the EU Food Fraud Network to exchange experience including on active cases.

2.2.3 Denmark

The Danish Food and Veterinary Inspection Service maintains regional offices; however, there is also a Food Inspection Task Force, otherwise known as the "Flying Squad" which performs operations across the country. These units are responsible for compliance including hygiene and labeling requirements. However, it is countering food fraud that the "Flying Squad" has become particularly well known, their tactics including intelligence-led unannounced inspections leading to successful identification and prosecution of fraudulent food operations (The Flying Squad of the Danish Food Administration, 2013).

2.2.4 - [France

France is famous for its fine food, and many French products benefit from EU quality schemes such as Protected Designation of Origin. Product origin and traceability were the top concern for French consumers according to a 2019 survey of food safety concerns (Merieux NutriSciences, 2019). This challenge is addressed by the French authorities performing regular checks to ensure food products are genuine and consumer not misled. Fighting against food fraud is managed by two governmental departments, one from the Ministry of Economic Affairs and Finance and the other from the Ministry of Agriculture and Food. Recent inspections in fish stores resulted in 52% of inspections identifying potential fraud issues (e.g., addition of water, species identity, other labeling concerns). Regarding honey, 43% of analyzed samples were not compliant.

2.2.5 | Italy

In Italy, strategic and operational aspects of food fraud prevention are separated between the relevant ministry and inspectorate. The MIPAAF (Ministero per le politiche agricole e forestali, Ministry for Agricultural and Forestry Policies) is responsible for identifying agri-food frauds, while the ICQRF (Ispettorato Centrale per il controllo della qualità e repressione frodi dei prodotti agro-alimentari, Central Inspectorate for Quality Control and Fraud Repression of Agro-Food Products) is responsible for its operating arm.

The ICQRF is one of the most active antifraud authorities in the world and is the Fraud Contact Point between Italy and the EU. ICQRF is active in all aspects of fraud detection; however, it is particularly concerned with protecting the designation of "Made in Italy." The fight against agri-food fraud is implemented through several actions such as checks on the quality and authenticity of agri-food products through six EU-accredited laboratories, supervision of control bodies in the field of Protected Designations of Origin and Protected Geographical Indications (PDO, PGI, organic), and investigations of e-commerce by working in collaboration with major e-commerce platforms.

Together with other Italian authorities (Customs Agency, State Forestry Corps, Carabinieri, etc.), the ICORF collaborates in the FALSTAFF project (Fully Automated Logical System Against Forgery Fraud) launched in 2003, and this led to the creation of a multimedia database of authentic agri-food products for the fight against their counterfeiting. Furthermore, the ICQRF maintains collaboration agreements with several public bodies, trade, and producers' associations such that there is a network of partners in the fight against attempted agri-food fraud.

The United Kingdom 2.2.6

Responsibilities for food fraud are separated broadly between operational activities led by the Food Standards Agency (FSA) and policy which is the responsibility of the Department on the Environment Food and Rural Affairs (DEFRA) together with funding of research and networking activities such as the Food Authenticity Network (www.foodauthenticity.uk). The United Kingdom has a long history of funding antifood fraud research particularly in the area of methods of analyses (http:// www.foodauthenticity.uk/research). The FSA has a dedicated resource for fighting food fraud, the National Food

Crime Unit (https://www.food.gov.uk/about-us/national-food-crime-unit). The unit is tasked with protecting consumers and the food industry from food crime within food supply chains.

The United Kingdom operates a Food Authenticity Network (FAN, www.foodauthenticity.global) which was set up in July 2015 and is coordinated by the UK Laboratory of the Government Chemist with funding support from DEFRA. The FAN is free to join and open to any interested party and was formed to raise awareness of the tools available to check for mislabeling and detecting food fraud and to ensure that the United Kingdom has access to a resilient network of expert laboratories to check for food authenticity. The FAN is a source of information for anyone involved in food authenticity testing, food fraud prevention, and supply chain integrity and contains an archive of UK projects, reports, and methods as well as links to a range of external information.

2.3 | European industry and nongovernmental initiatives

2.3.1 | International Life Sciences Institute Food Authenticity Task Force

International Life Sciences Institute (ILSI) Europe formed a Food Authenticity Task force in 2017 with the goal of compiling a toolbox for the food industry to identify and mitigate food fraud. One of major challenges recognized by the experts involved was the quantity of information available. Such data include private and government initiatives, method developments, database resources for identification of potential adulterants, and prediction of forthcoming food fraud issues. The taskforce took it upon itself to evaluate sources of information and how they might be used within business practices.

2.4 | Food Industry Intelligence Network (UK)

The Food Industry Intelligence Network (FIIN, https://www.fiin.co.uk/) was established in 2015 to help facilitate the sharing and use of industry intelligence data. FIIN is administered by the consultancy organization Campden BRI, and there is a membership fee. Membership currently includes a number of food producers and retailers. The objective is to share information between members and act as a conduit of information with authorities. Potentially commercially sensitive data are sent to a third party, anonymized, combined, and used in quarterly consolidated intelligence reports.

2.5 | North America

2.5.1 | The United States

In the United States, there are several government agencies that regulate the safety and integrity of the food supply, and each has a different approach to food authenticity. Most food products, dietary supplements, and animal foods are regulated by the Food and Drug Administration (FDA). The US Department of Agriculture's Food Safety and Inspection Service (FSIS) regulates meat, poultry, and some egg products. Within the Treasury Department, the TTB regulates alcoholic beverages. The Federal Trade Commission (FTC), generally in collaboration with the FDA, regulates aspects of food labeling.

Under FDA regulations, it is illegal to sell food that is either adulterated or misbranded. In practice, most FDA enforcement efforts under both headings are concerned with the identification and control of hazards; that is, pathogens and substances that cause direct health effects. For example, under the Preventive Controls for Human Foods rule (which are now Part 117 of 21CFR), economically motivated adulteration must be considered as a potential source of hazards that require control, but economically motivated adulteration (EMA) is not in itself necessarily considered hazardous. Under this approach, the misrepresentation of refined olive oil as virgin or extra virgin olive oil would not be considered as hazardous and no preventive controls to prevent adulteration would be required. Although the broad concept of misbranding could be seen as a tool to ensure authenticity, in fact most FDA regulatory efforts in this area also focus on direct health issues such as allergen and gluten-free labeling. The one authenticity-related issue that FDA has pursued is in fish species identification. This effort, which includes laboratory and enforcement work, has resulted in several criminal prosecutions.

FDA, FSIS, and TTB all establish standards of identity that are intended to ensure that consumers receive the products that they expect. For example, TTB defines more than 30 types of whiskey. Both TTB and FSIS have premarket label approval processes that help ensure that labels are accurate and complete.

The FTC enforces regulations that are intended to ensure that product labels and advertising claims are accurate. Because FTC responsibilities overlap with those of the FDA related to food labels, the two agencies often work together closely. In recent years, this has been particularly the case for health-related claims.

In addition to the efforts of the FSIS, US Department of Agriculture (USDA) also regulates the use of the term organic in the United States. The National Organic Program develops "rules and regulations for the production,

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handling, labeling, and enforcement" of organic foods. USDA also has issued a rule that defines how food that contain "bioengineered" ingredients should be labelled.

The National Institute of Standards and Technology (NIST), which is part of the US Department of Commerce, produces Standard Reference Materials (SRM) that are used in many laboratories as a part of their analytical quality assurance process, including authenticity testing. SRM are certified reference materials that are certified as to the level of one or more analytes. For example, NIST sells a whole milk powder SRM that is certified for 11 macroand micronutrients. Interestingly, although NIST certifies analyte levels, the identity of the matrix material is not certified. This means that caution must be taken using when NIST SRM for authenticity testing. Further, for natural substances that vary depending on location, weather, or year, NIST standards will not be representative of normal compositions.

2.6 | Canada

The Canadian Food Inspection Agency (CFIA) is responsible for regulations and guidance related to food authenticity in Canada. The Canadian provinces also play an important role in this area. This includes a large investment in a "Combating Food Fraud" program as part of the national food policy. This food fraud program includes an active testing program, inspections, risk monitoring, stakeholder engagement, and enforcement. For example, in 2018, CFIA carried out targeted surveillance sampling of honey. Of 240 samples tested, 21% did not meet Canadian standards. Interestingly, all the noncompliant samples were imported. CFIA also works with industries to ensure that effective supply chain controls are in place to mitigate the risk of fraud.

2.7 | Asia

2.7.1 | China

Chinese regulation

In the Consumer Rights Protection Law and Product Quality Law, it is stated that products are not allowed to be adulterated, and it is forbidden to use a rejected product as the legal/qualified product. The Advertising Law also has provisions prohibiting fraudulent advertising such as false publicity. In the Food Safety Law Implementation Regulation, it is defined that for foods that may be adulterated should be tested by the existing food safety testing methods or the supplementary inspection methods that are released by the Food Safety Supervision and Adminis-

tration Department of the State Council. In 2017, the draft version of Measures for Investigating and Handling Fraud in Food Safety was published. Although it is not currently active, it clearly defines fraud as a food safety concern.

There is a list of nonedible substances that are known to be illegally added to food and dietary supplements. This list is used to direct food fraud oversight. The State Administration for Market Regulation is responsible for safety oversight of food produced domestically. However, there is overlap with the Ministry of Agriculture and Rural Affairs which is responsible for the safety oversight of agricultural products. Additionally, the General Administration of Customs is responsible for the safety oversight of imported food before it enters the Chinese market. Providing a resource across these agencies is the China National Centre for Food Safety Risk Assessment which is responsible for the Food Safety Risk Monitoring Plan, risk assessment, and providing scientific advice.

2.7.2 | Malaysia

As a Muslim majority country, halal and safety aspects of meat products are a pivotal focus. Meat fraud activities such as meat adulteration, substitution, stolen livestock, gray market products, smuggling, misrepresentation, and mislabeling are against the halalan toyyiban principle.

Since the halal food industry is farm-to-table in essence, unwanted practices which culminate in halal food fraud along any part of the food supply chain is a major concern among Muslim consumers.

The Malaysia government plays a major role in ensuring halal food available for consumers. The Department of Islamic Development Malaysia (JAKIM) is the agency responsible for the Islamic affairs including halal certification in Malaysia. Therefore, JAKIM plays an important role to protect Muslim consumers in Malaysia.

For halal certification purposes, JAKIM needs to ensure every ingredient and raw materials used are halal. Laboratory analysis is used in this respect to support the technical verification of halal status.

2.7.3 | Japan

Japan currently does not have any publicly funded food fraud projects. The responsibility for accurate labeling of food product is with the Consumer Agency Affairs in the Cabinet Office, while the Ministry of Agriculture, Fisheries and Food (MAFF) deals with the quality of agricultural products. Although the agencies are aware of concerns in other jurisdictions, there are no specific concerns with food fraud known in Japan.

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2.7.4 | India

India does not currently have food fraud monitoring and reporting. There is no food fraud network nor a database similar to RASFF. However, the Food Safety and Standards Agency of India (FSSAI) has been involved in fraud-related projects, such as with the United Nations Food and Agricultural Organization to conduct a "review and analysis of food fraud and economically motivated adulteration in India." The information which resulted from this project is nonpublic. Notwithstanding, the FSSAI has published documents to raise awareness on food fraud in commodities such as meat, fish, and spices. Some documents contain information how to easily identify certain types of fraud without having to send samples to a laboratory. On the regulatory side, cases of food fraud are dealt with under the provisions relating to misbranding in the Food Safety Act of India (American Spice Trade Association, 2016).

2.8 | Latin America

Very little information was available about Latin American countries, except for Argentina and Chile.

2.8.1 | Argentina

The control of foods in Argentina is managed by several regulatory agencies which results in overlaps of responsibility.

The main official agency for food regulation is ANMAT (Federal Health Ministry of Argentina, n.d.), which is divided into two regulatory institutes: National Institute of Medicines (INAME) for medicines and National Institute of Medicines (INAME) for food. INAL oversees releasing the Argentinean food codex (código alimentario argentino), including periodic updates, giving authorizations for the operation of food businesses, including the registration of foods produced or imported to be sold in the country, controlling the food composition, safety, authenticity, and labeling. INAL has several regional offices distributed throughout the country.

In addition to ANMAT, the SENASA (National Secretary of Animal and Vegetal Sanitation of Argentina, n.d.) oversees controlling agriculture, livestock, and aquaculture products. The SENASA is responsible for verifying the integrity of foods from vegetal and animal origin exported from Argentina or traded within the country, including the suitability of agrochemicals, fertilizers, veterinary medicines, and feeds.

It should be noted that each province has subsidiary agencies and, in many cases, also at the county (municipal)

level. This complicates the effective control of food products and oversight of both ANMAT and SENASA including the communication of alerts and sharing of knowledge.

In addition to INAL and SENASA, the national institute of viticulture is in charge of controlling alcoholic beverages in Argentina, from fermented alcoholic drinks (wine, cider, etc.) to distilled liquors (Federal Agriculture Cattle and Fisheries Ministry of Argentina, n.d.).

Concerning laboratories for food control, SENASA delegates laboratory control to private and public laboratories, which are certified and recognized by the institution as the official network of laboratories for food control (SENASA).

2.8.2 | Chile

Chile has started numerous activities to combat food fraud. The leading government agency on this is ACHIPIA. Funded through different bodies, including international and European agencies such as the FAO, BfR, and International Atomic Energy Authority (IAEA), various capacity building exercises on food fraud have been and will be conducted. These include risk assessment (vulnerability assessment) of products and the development and implementation of methods for the detection of adulterants. Here, several training sessions have been held and were broadcast to a wider audience through the ACHIPIA YouTube channel, and facilitated through IICA (Instituto Interamericano de Cooperación para la Agricultura). In addition, Chile operates a rapid alert system similar to RASFF, called RIAL (Red de Información y Alertas Alimentarias). A report on the RIAL records is published on an annual basis.

2.9 | Africa

Egypt, Kenya, and Uganda are known to have staff in relevant authorities tasked with managing food fraud.

2.9.1 | Uganda

Uganda has several competent authorities dealing with different aspects of food fraud. These are Uganda Revenue Authority, Uganda National Bureau of Standards, Criminal Investigation Department of the Uganda Police Directorate, Directorate of Government Analytical Laboratory, Diary Development Authority, and the Ministry of Agriculture, Animal Industry and Fisheries. Currently there is no cross-agency taskforce to coordinate the efforts of the agencies and ministries in Uganda.



3 | SECTION 2: AVAILABLE GUIDANCE ON FOOD FRAUD AND A PROPOSED CONSENSUS PROCESS FOR MANAGING INAUTHENTICITY

3.1 | Controlling ingredient authenticity

After an ingredient has been determined to be acceptable for use within a food product at a certain concentration, it is necessary to ensure that any given upstream supply chain can consistently provide a source of the ingredient that meets the approved composition. There are three fundamental steps in this process:

- 1. Establishing the required specification of the ingredient within the commercial relationship with the supplier, including defining an appropriate source.
- 2. Managing an authenticity process to ensure that 1 is met on an on-going basis.
- Generating information to facilitate 2, in the form of both analytical data and audit information as warranted.

3.2 | Ingredient specification

As a part of a trading relationship, an ingredient specification enables the required product attributes to be agreed, and this should include parameters related to the acceptability of the ingredient in the food chain with respect to quality and safety. Fortunately, in many jurisdictions, there are established ingredient requirements, for example, specifications given in the US Code of Federal Regulations, GRAS notifications, or EU food additive purity criteria (ECFR, n.d.). There may also be regulatory requirements on contaminants and residues (such as pesticide and veterinary residues) for food commodities. In addition, there are valuable non- or pan-governmental reference sources available such as the United States Pharmacopeia (USP), Food Chemical Codex (FCC), or the documents of the Codex Alimentarius (Codex) (USP, n.d.).

The FCC provides specifications and methods for establishing the identity and purity of food grade ingredients. The Codex is a government-to-government standard development organization jointly administered by the Food and Agriculture Organization and the World Health Organization (both of which are under the auspices of the United Nations). The Codex includes food standards, guidelines, and codes of practice intended to protect food safety and quality in international commerce; therefore, inauthenticity management is implicit across the Codex documents. Codex standards are developed by multiple committees, several of which impact fraud prevention

and food integrity. For example, the Codex Committee on Food Labelling has created guidelines on the use of health claims on food labels. Standards and guidance documents developed by the many committees and regional committees frequently address authenticity and related issues by defining the important characteristics of specific foods. The Codex Committee on Food Import and Export Certification Systems (CCFICS) has created a working group on Food Integrity and Food Authenticity which is working on several aspects of food integrity, including defining a standard nomenclature that supports communication and clarity between countries.

3.3 | Published guidance on the process of authenticity management

Guidance available on the management of food authenticity, as summarized in Table 2, are those that are related to certification in-line with the Global Food Safety Initiative (GFSI), those that are provided by other standardization bodies, those that are provided by governmental organizations, and guidance that has been developed by the food industry directly.

GFSI establishes core requirements for food safety management which are then elaborated by individual certification bodies, some of which are either sector specific or region specific (e.g., BAP Seafood Processing Standard, China HACCP). Two of the most widely used certification schemes recognized under GFSI that are used by finished food companies are FSSC and IFS (FSSC, 2020; IFS, 2018). On food fraud, GFSI requires that companies have documented vulnerability assessments and mitigation plans, this is elaborated within FSSC 22000 (which draws on both GFSI and ISO 22000) which has issued a guidance on food fraud mitigation wherein types of fraud and the steps to perform a vulnerability assessment are briefly described (FSSC, 2020; GFSI, 2018). Within IFS, a more elaborated scheme is provided via a Guideline for Implementation, sources of data are described for input into a risk ranking, for both product and supplier vulnerability (IFS, 2018). Both the FSSC and IFS assessments are proposed to be performed using a quadratic matrix (familiar in HACCP evaluations where the likelihood of occurrence is compared to potential impact); however, IFS provides more detail and proposes a quantitative ranking of vulnerabilities. This enables comparison between large numbers of product/supplier combinations across the company. The product vulnerability assessment is performed by comparing likelihood of occurrence with likelihood of detection (the highest risk resulting from high likelihood of occurrence and low likelihood of detection). Similar to the IFS Standard, the BRCGS standard proposes to rank



TABLE 2 Available guidance	
Organization and guidance	Key aspects
GFSI and certification bodies The Global Food Safety Initiative, GFSI Tackling Food Fraud Through Food Safety Management Systems 2018 (GFSI, 2018).	This guidance introduces a GFSI requirement for companies to perform and document a vulnerability assessment and establish a mitigation plan (and has led to the concept of VACCP, vulnerability assessment critical control point). It is noted that fraud applies to the whole organization as opposed to being limited to manufacturing operations. Requires vulnerability assessments to identify hazard, risk, and susceptibility to the risk (likelihood). The identification of hazards should include market monitoring tools. The mitigation plan should be in the form of preventive controls.
GFSI recognized scheme: The Foundation Food Safety System Certification, FSSC. FSSC 22000 version 5 (FSSC, 2020). Guidance on Food Fraud Mitigation 2018 (FSSC, 2018).	Certification requirement: Documentation is required on the procedure to conduct a vulnerability assessment and implement mitigation measures. A documented mitigation plan is required to support the food safety management system. It is required to keep this "up to date." Guidance: Described are types of food fraud as presenting "direct risk" (e.g., acute health risk), "indirect risk" (e.g., chronic toxicity), or "technical risk" (not safety related by may result, e.g., in loss of traceability). Documented within the Food Safety Management Plan should be a vulnerability assessment and control plan which includes mitigation measures. For implementation, an identified team is required which should be trained appropriately.
GFSI-recognized scheme: International Featured Standards, IFS. Standard for auditing quality and food safety of food products Version 6.1 (IFS Food, 2017) and standard for assessing product and process compliance in relation to food safety and quality. Version 7 (IFS, 2021). Product Fraud, Guidelines for Implementation 2018 (IFS, 2018).	Certification requirement: Documentation is required on a vulnerability assessment with annual review, and mitigation plan. Guidance: In this scheme, it is proposed to "quantify" food fraud risk. The assessment should include a vulnerability assessment, which itself includes risk identification, evaluation of level of risk, and need for control measures. This feeds into the development of a mitigation plan, which should be implemented. The system should be reviewed annually by an allocated team. The document then described in detail how to undertake a vulnerability assessment, including scoring based on impact and likelihood. Risk factors for product and supplier are described, as are the types of control measures that are commonly available. A template is proposed to score vulnerabilities for prioritization and capture control measures (mitigation plan). Version 7 introduces the need for food fraud training of food operators, and requires the identification of responsible person(s) for vulnerability assessment and mitigation planning.
GFSI-recognized scheme: British Retail Consortium Global Standards, BRCGS Global Standard Food Safety Issue 8 Understanding Vulnerability Assessment 2019 (BRCGS, 2019).	Concerns vulnerability assessment. Lists sources of possible fraud and a process for reviewing against the user's portfolio. Illustrates how to chart the likelihood of occurrence, likelihood of detection (low likelihood of detection is considered higher risk), and fraud profitability. These are either placed in a simple quadratic chart for prioritization or quantitatively ranked for prioritization. Includes a brief section on mitigation (fraud controls), which include CoAs, testing of materials received, supplier audit, mass balance analysis, use of tamper seals, or use of alternative ingredients or simpler supply chains.
Other standard development organiz	
United States Pharmacopeia, USP Food Chemical Codex, Appendix XVII: Food Fraud Mitigation Guide (USP, 2016).	Scope is limited to addition of nonauthentic substances or removal or replacement of authentic substances (as per the US concept of "economically motivated adulteration"). Describes a four-step process to review an ingredient: "contributing factor assessment" (factors which contribute toward vulnerability) and "potential impacts assessment" are charted using a scale of 1–5 for each proposed element (e.g., history of supplier and economic and food safety impact). These inputs are then mapped against the two axes of another chart called "vulnerability characterization." The objective is to identify ingredients which have a high vulnerability and help identify measures to reduce to a lower vulnerability. These may not always be mitigation measures but may be actions related to input data such as having a better knowledge of the supplier.

better knowledge of the supplier.



TABLE 2 (Continued)

Other standard development organizations

Chartered Institute of
Environmental Health, CIEH.
Counter Fraud Good Practice for
Food and Drink Businesses
2016 (Chartered Institute of
Environmental Health, 2016).

British Standards Institution, BSI PAS 96:2017—Guide to protecting and defending food and drink from deliberate attack (FSA; BSI; Department of Environment Food & Rural Affairs UK, 2017).

Describes good practices to counter food fraud and improve fraud resilience. This includes a process wherein the nature and scale of fraud for the supply chains in question are investigated, based on this information, a strategy is developed and implemented which includes a description of the monitoring and actions. Considered important are an antifraud culture and an appropriate organizational structure. Methods to conduct investigations should be clear, as should performance indicators to demonstrate the value of the system.

Describes a process inspired by HACCP that combines food fraud and food defense in a system called TACCP (threat assessment critical control points). The process includes the identification of threats across both the organization and a described supply chain, risk prioritization based on likelihood and impact, and a description of critical controls.

International Standardization Organization, ISO (ISO, 2021).

FSSC 22000 uses ISO 22000 (Food Safety Management) as input. There are a number of other ISO standards that cover fraud; however, none is specific to food fraud. For example, ISO 9000 quality management, ISO 31000 risk management, ISO 22380 product authenticity, ISO 28000 supply chain security. Note that these ISO standards are referred in local standards such as BSI 10501:2014 Guide to implementing procurement fraud controls.

European committee on Standardization, CEN CWA 17369:2019 Authenticity and fraud in the feed and food chain—Concepts, terms, and definitions 2019 (CEN, 2019). The standard provides definitions of the concepts used in food authenticity and does this by relating them to each other, for example, "food fraud" can be "claim violation," "record tampering," or "product tampering."

CEN standards that describe food fraud management, vulnerability, and mitigation are not currently available.

Governmental organizations

US FDA, Food Safety Modernization Act—Economically motivated adulteration, EMA (Food and Drug Administration, 2011)

US FDA, Food Safety Modernization Act—Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry (US FDA, 2021; US FDA; Center for Food Safety & Applied Nutrition, 2019).

Codex Alimentarius (FAO; WHO, 2021).

Codex Committee on Food Import and Export Inspection and Certification (CCFICS25, 2021).

Food and Agriculture Organization, FAO, Food fraud—Intention, detection and management. Food safety technical toolkit for Asia and the Pacific (FAO, 2021; FAO; WHO, 2019). Under FSMA, EMA is specifically identified as a type of hazard. Hazards that are identified require preventative controls to be documented within a Food Safety Plan. Although there is limited guidance, what this means in practice is that there is an active vulnerability and mitigation process documented.

Requires the production of a food defense plan, and this includes a systematic process to describe manufacturing flow, and a template to identify vulnerabilities and "key activity types" for which mitigation measures should be described.

Note the food defense guidance is complemented with the FDA "CARVER and SHOCK" tool for prioritizing vulnerabilities in terms of targets for attack. https://www.fda.gov/food/food-defense-programs/carver-shock-primer

Work is on-going, chaired by the US and co-chaired by EU, Iran, and China, that aims to revise exiting standards (e.g., The Principles and Guidelines for National Food Control Systems and Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food) on how to modernize control systems to address food fraud (e.g., extension of HACCP) and the US concept of "intentional adulteration."

The FAO also has numerous antifood fraud activities, including several publications on the topic (FAO, 2020; Sylvester, 2019; UN FAO, 2016), and an expert workshop in 2019 which brought together numerous stakeholders to identify options to prevent food fraud and to detect it.

Of note, a recent FAO publication concerns food fraud in Asia and the Pacific, but the content is applicable globally. Fraud is defined widely as being when there is deception of customers on the quality and/or content of food they purchase.

Sets out a number of key actions that should be taken by governments, including actively managing food fraud, establishing a legal definition, adapting national legislation including the use of Codex provisions as a basis including labeling rules, systems to manage fraud in e-commerce, invest in analytical technology.

Beyond recommendations for governments, a VACCP approach is recommended for businesses to formally review all ingredients for vulnerability and implement appropriate controls.

TABLE 2 (Continued)

Industry guidance

Safe Supply of Affordable Food Everywhere, SSAFE, Last updated 2020 (SSAFE, n.d.).

With accompanying document from PWC: PWC China (2017).

Food Fraud Vulnerability Assessment and Mitigation. Are you doing enough to prevent food fraud?

Food Drink Europe, FDE (Food Drink Europe, n.d.).

UK Food and Drink Federation, FDF (FDF, 2014).

Food authenticity, five steps to help protect your business from food fraud.

Seasoning and Spice Association, SSA (in association with FDF & BRC) (British Retail Consortium; Food & Drink Federation; Seasoning and Spice Association, 2017).

American Spice Trade Association, ASTA (The American Spice Trade Association, 2016).

Identification and Prevention of Adulteration 2016.

Organic Trade Association, OTA (Organic Trade Association, n.d.). Organic Fraud Prevention Guide 2019.

Better Seafood Board, BSB (Task Force of Better Seafood Board & National Fisheries Institute, 2017).

Industry guidance of best practice for addressing seafood fraud 2017.

This is a vulnerability assessment tool that uses a set of 50 questions to identify and prioritize vulnerabilities. Mitigation is not in scope. The tool starts with a flow diagram to determine which part of the business to assess (and therefore which set of questions to use). It is an xl-based tool the output of which is in the form of spider-web diagrams showing areas of greater or lower vulnerability, and an output sheet showing whether and controls are low or high. The question sets are on "opportunities for fraud," "motivations," "control measures."

The PWC document sets the SSAFE tool in the wider context by describing the link to mitigation and controls, and links to GFSI requirements. Types of fraud are described as are examples of control measures.

Summarizes industry position. Refers to FDF and SSAFE but makes the following recommendations.

Companies should develop fraud risk management system, conduct vulnerability, and develop prevention processes.

Requests the rapid exchange of information between stakeholders and improved border controls.

At the product level:

- Map the supply chain
- Identify impacts, risks and opportunities
- Assess and prioritize findings (all about knowing the supplier)
- Plan of action
- Implement, track, review

Each step has key questions for consideration.

Starts with a decision tree that points to sections of the guide. The flow chart contains questions on specification, certification, form of material, market factors including price, supply chain vulnerabilities, verification of material, and rejected procedures. The separate sections describe "preventative measures" and "verification" as follows:

- Specification
- Approved supplier
- Types of products at higher risk (ground, chopped)
- Understand trading market and vulnerabilities in supply chain (complexity, history of fraud, availability of supply, restrictions in supply, economics making fraud more attractive)
- Sampling program
- Testing strategy
- Supply chain verification (e.g., predelivery validation)

Scope is limited to addition of materials or removal of constituents. Describes controls such as supply history, traceability and testing. Provides a decision tree that is linked to descriptions of the investigation and control measures as per the SSA scheme above. https://www.astaspice.org/food-safety/identification-prevention-adulteration-guidance-document/

Provides a definition of organic fraud and the need for an Organic Fraud Prevention Plan (OFPP). This includes an initial screen followed by more comprehensive vulnerability assessment, the identification and implementation of appropriate mitigation measures, including monitoring and verification, and the use of an alert system. All should be documented in a "Fraud Prevention Plan" which forms part of the "Organic System Plan." https://ota.com/OrganicFraudPrevention

Concerns fraud of seafood, so scope is limited to weight/count, species identity, origin, and labeling laws. Many of the controls concern policies for training and documentation. Species identity controls include supply chain knowledge and risk-based DNA analysis. For origin compliance, included in the recommendations are vendor approval and verification. https://www.aboutseafood.com/wp-content/uploads/2020/02/BSB-Best-Practice-Guidance-November-2017.v2.pdf

(Continues)



TABLE 2 (Continued)

Industry guidance

International Olive Council, IOC (International Olive Council, n.d.). Standards, methods and guides

Not a guidance as such but a collection of detailed trade standards, test methods and Practice Guides (e.g., for verifying conformity) for the control of olive oils. These documents thereby provide detailed mitigation methods for this specific commodity. https://www.internationaloliveoil.org/what-we-do/chemistry-standardization-unit/standards-and-methods/

Campden BRI.
TACCP/VACCP threat and
vulnerability assessments: a
practical guide 2019 (Campden BRI,
2019).

Describes a combination of TACCP as per British Standards Institution PAS 96:2017, which concerns food defense, and VACCP for food fraud, and makes a link between authenticity, quality and safety. For TACCP describes the possible sources of threat (e.g., personnel, cybercrime) and defines a scheme from prioritization.

Nestlé (Nestlé Ltd, 2016). Food fraud prevention, economically motivated adulteration. Describes types of food fraud and refers to the USP guide in terms of the fraud assessment process. Vulnerability assessment includes:

Know your materials and risks (inherent to ingredient, impact on business)

Know your suppliers

Know your supply chain (transparency) Know your existing control measures Mitigation measures include: Raw material specifications Analytical surveillance

Supplier knowledge, relationship, audit

Supply chain complexity

It is stated as essential to maintain an alert system

vulnerabilities based on likelihood of occurrence and detection; however, a third parameter of profitability is introduced to identify where motivation for fraud is highest (BRCGS, 2019). A quantitative output is also proposed to rank vulnerabilities whereby the three parameters are summed and compared for each identified vulnerability. The BRCGS standard includes a general ranking of effectiveness of controls, with risk controlled via supplier approval considered as the most effective control mechanism and analytical verification of incoming materials considered the least effective.

There are other non-GFSI associated food fraud management standards of note. The guidance in the FCC is limited in scope to the US concept of EMA which concerns only the addition of substances or removal of materials from ingredients, and this scope limitation is reflected in US trade association guidance, such as the American Spice Trade Association (American Spice Trade Association, 2016; USP, 2016). Nonetheless, the USP guidance details a vulnerability assessment process that is more prescriptive, and possibly more resource intensive than that provided in other available guidance (Gendel et al., 2020). It is presumably for this reason that work is underway to develop a more simplified screening process to enable prioritization of ingredients to scrutinize. Notwithstanding, the USP process is similar to other schemes in that both vulnerability and impact are assessed following which these elements are brought together to compare risk

across an organization, in the case of USP this is articulated via a scale of 1–5. Other non-GFSI standards are less prescriptive and more general. For example, guidance available from the UK CIEH describes the general management process (vulnerability assessment, mitigation planning followed by implementation and review) but also describes the importance of both an antifraud culture in the organization and methods to detect fraud such as whistleblowing (Chartered Institute of Environmental Health, 2016). It also highlights the importance of conducting diligent fraud investigations should an incident be identified and emphasizes the value of an authenticity management program for internal communication and awareness.

The relationship between food fraud and food defense differs across the available guidance. The US FDA has developed FSMA implementation guidance which reflects the separation between food defense (intentional adulteration) and food fraud (EMA) which are managed, respectively, via a Food Defence Plan or as a hazard within Preventive Controls. The guidance available on fraud is limited, whereas for food defense a prescriptive system is described to capture, prioritize, and mitigate risks (USFDA, 2019). Food fraud and defense are also dealt with independently in GFSI and the associated certification schemes such as FSSC, which has guidance on both; however, this is not the case for a number of other guidances wherein there is a brief description of the relationship

between fraud and defense management. For example, although the BSI guidance primarily concerns deliberate attack, it identifies EMA as one type of threat to be assessed alongside defense concerns which includes extortion and malicious contamination (FSA et al., 2017). The process for assessing food defense is known in some guidance as threat assessment critical control points (TACCP) and there have been attempts to relate this to vulnerability assessment critical control points (VACCP) which concerns food fraud, including in guidance available from both Campden BRI and Leatherhead which also describe the link to HACCP to enable holistic management of food safety and quality (Campden BRI, 2019; Wareing & Tony, 2016). HACCP concerns safety of production processes and inputs into it such as ingredients, TACCP concerns opportunities for malicious actors either internal or external, and VACCP concerns horizon scanning to identify criminal vulnerabilities in supply chains. Some recent authoritative guidances, such as the FAO Technical Toolkit for Asia and the Pacific advocate the use of VACCP which they state as including ingredient vulnerability assessment, the design and implementation of control plans, formal recording of findings and periodic review (FAO, 2021).

Food industry guidance has been developed either by consortia or trade associations and provides either guidance relevant to the whole industry or are sector specific, such as those for the herb and spice sector. Furthermore, the approach of some individual companies is available for reference as they are in the public domain. In general, trade association guidance describes the authenticity/fraud management processes, with a common approach being to map supply chains, identify risks, for the identified risks estimate the likelihood and impact, prioritize the risks, draft and implement a mitigation plan, review and update. It is also common to identify and manage risks both at the level of product (or ingredient) and supplier. Sectorial trade associations can provide more detailed guidance due to greater focus, for example, the EU and US spice associations are able to provide guidance that covers both general topics such as supplier knowledge, validation, and verification with sector-specific topics such as the types of vulnerabilities at different stages of the supply chain based on historical understanding of fraud for the sector (American Spice Trade Association, 2016; British Retail Consortium et al., 2017). A vulnerability assessment tool that is widely used to help meet the requirements of GFSI schemes, is SSAFE (SSAFE, n.d.). SSAFE contains a set of questions which are used to provide a graphical output on the degree of vulnerability for a supply chain under evaluation. The questions are in three sets relating to opportunities for fraud, motivations for fraud, and control measures.

3.4 | The management of supply chain authenticity

Based on the available guidance, we propose a generic framework for food business operators to integrate food authenticity management within their supply chain controls. The framework is intended as a starting point in that risk prioritization should be used to focus mitigation efforts. This framework is applicable to food business operators wherever they are positioned with the supply chain (Figure 4). It is intended to overcome the limitation in previously available guidance that only dealt with a subset of food authenticity, with a focus on deliberate acts. Previously, there were limited descriptions of how authenticity management fits with established operations, and authenticity management was treated in isolation. This guidance recognizes that, although there needs to be a dedicated consideration of vulnerability, the control of food authenticity, including deliberate inauthenticity such as fraud, should be viewed as an integral part of the management of suppliers and the materials supplied. The mitigation of inauthenticity needs to be integrated with both the routine validation of new suppliers or materials and on-going verification of existing supply chain arrangements. Routine verification seeks to understand whether within existing supply chain arrangements there is a new or changed potential for impact on material safety, quality or compliance, that is beyond known and controlled risks, or if such an impact has already occurred requiring corrective action.

It is inherent to normal validation and verification programs that there is an understanding of the supplied material's vulnerability to all hazards, such as vulnerability to being outside of specified or compliance requirements. For example, the likelihood that a specific crop can naturally contain a higher than specified, or regulated, content of a particular heavy metal. Vulnerability assessment for inauthenticity should be an integral part of the wider risk assessment used as a part of normal validation and verification programs. As such, although Figure 3 is a summary of food fraud management processes described in guidance, the process is common to the management of all vulnerabilities, not just deliberate inauthenticity. This is important, as to enable an effective validation or verification program all the vulnerabilities associated with the material in question should be captured, in this way there can be effective prioritization and focus of mitigation effort and resource deployed.

Food business operators do not generally maintain separate systems to manage authenticity of their supply chains, rather authenticity is integrated within the systems and processes to control safety, quality, and compliance. As

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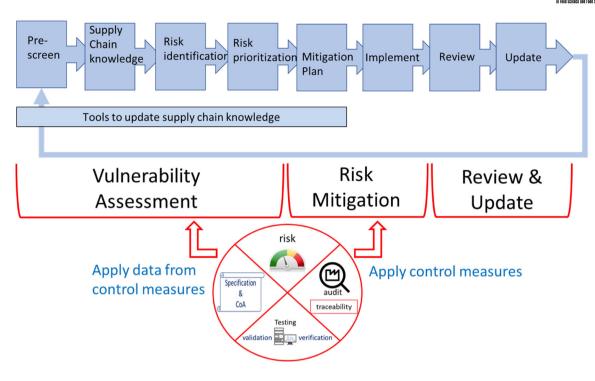


FIGURE 3 General process for managing authenticity

such, the control mechanisms that are available to food business operators, as shown in Figure 3, are used to mitigate all types of vulnerabilities including inauthenticity, and the data generated from the controls should be used in updating knowledge of vulnerability. The three principal mechanisms available are the contractual arrangements between trading partners such as the required specifications and certificates of analysis, the audit program of suppliers, and the testing of received materials. These should be applied based on the risk assessed to be associated with the supplier and material combination.

It is important to note that coordination between different departments within an individual food business can have a significant impact on the effectiveness of supply chain management including food authenticity. This is particularly important in large organizations that may be less internally connected but may hold significant knowledge on supply chain vulnerabilities. This knowledge needs to be shared between the different parts of an organization responsible for purchase decisions, external audit, and the acceptance of received raw materials. The dynamic of modern food businesses with global sourcing including spot buying increases the need for such coordination.

Vulnerability assessment 3.5

The sources of information that feed into a vulnerability assessment are different depending on the type of risk. In the case of deliberate inauthenticity or food fraud, a number of sources of information have become available in recent years. Such sources of information include:

- · National or regional networks that share information between membership which includes food business operators and in some cases authorities, see Section 1 above.
- · Commercial databases provided to paying customers by third party providers that capture authority alerts, media articles, and scientific publications enabling their analysis in various ways such as per commodity and geography.

These information sources provide input to the "prescreening" activity as shown in Figure 4 which concerns general vulnerabilities known for the material irrespective of the supplier. Elaborating on this process overview, Figure 5 illustrates how information collected from the prescreening activity can subsequently be combined with knowledge of the specific supply chain in question to enable the characterization of vulnerabilities for a specific material/supplier combination. Information on the supply chain can be used to identify so-called "vulnerability accelerators" which include aspects such as the frequency of changes within the supply chain and complexity of the material traded. This can subsequently be used for prioritization between different material/supplier combinations relevant to the food business operator. Food

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FIGURE 4 Relationship between prescreening and supply chain knowledge in the case of inauthenticity vulnerability assessment

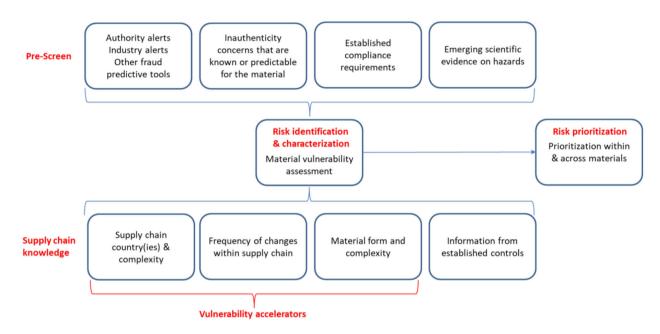


FIGURE 5 Generic process of vulnerability assessment for a material/supplier combination

business operators may undertake this activity for all vulnerabilities associated with supplied materials, including but not limited to authenticity including food fraud.

Much of the available guidance proposes the use of simple quadratic charts as a practical approach to easily capture and rank vulnerabilities both within and between supplier and material combinations. These charts usually compare likelihood with impact. In line with the available guidance, we propose that the likelihood of identified concerns is first evaluated, followed by the "prioritization" stage of the vulnerability assessment wherein the impact is incorporated. As the situation of every food business operator will be different depending upon factors such as where they sit within the supply chain and the complexity of their operations, the scheme that is used to capture and rank vulnerabilities will differ.

The "prescreen" part of the vulnerability assessment uses inputs related to recent or current authenticity issues found in authority alerts or commercial database tools, in addition to an understanding of historical or predictable inauthenticity events for the material in question, which may be found within the supplier community or their trade

association. Beyond overt authenticity concerns, it is necessary to have concise information of compliance requirements for the material in question, such that deviations can be identified (whether deliberate or not); furthermore, it is also necessary to understand emerging concerns that may lead to changed compliance requirements. All these inputs can be captured within a suitable format.

Aspects important to consider in the "supply chain knowledge" part of the vulnerability assessment include the degree to which there are specific vulnerabilities in upstream supply chains; for example, longer and more complex supply chains can be more vulnerable, especially when there is prior knowledge of concern from the prescreen activity. A comparatively high frequency of changes happening to supply chains naturally increases the difficulty of maintaining diligence and therefore potential for inauthenticity. Furthermore, forms of materials such as mixtures and powders are inherently more vulnerable to deliberate inauthenticity. However, often the most valuable input into determining vulnerability of existing supply chains is the data generated from the control measures that have been previously applied.



Type of meat Deliberate mis- representation	meat	fish	Animal origin		cereal	Spices & Herbs	Oils	Cocoa & chocolate	Additives, nutrients, minerals,	
		dairy	egg	honey					synthetic ingredients	
Substitution / dilution	X species	X species			X syrups		X	X		X
Concealment	X hygiene, shelf life	X hygiene, shelf life				X spec	х	X spec	X spec	X spec
Mislabeling	X origin	X origin	X Organic, Origin	X free- range	X source, origin	X organic	X organic, origin	X organic, origin	X origin, organic	
Enhancement	X additives		X melamine				X dyes	X additive		
			X brand (eg cheese)		X type, brand			X type, brand	X type, brand	х
Grey market	X	X eg illegal landing		X		X eg illegal pesticide	х	X	X	х
Generic risk level (frequency)	High	high	lower	med	High	lower	high	high	med	med

FIGURE 6 Example of cross-commodity prioritization based on analysis of authenticity alerts and known vulnerabilities to inauthenticity and their frequency of occurrence

Although risk prioritization for the purpose of assigning controls (i.e., mitigation) should be a fundamental part of supply chain management undertaken by all food businesses on an on-going basis, there may be elements of vulnerability assessment that necessitate the update of prioritization schemes en masse. For example, in recent years, there was a requirement from certification schemes to incorporate into vulnerability schemes deliberate inauthenticity or fraud potential. For larger food business operators with a multiplicity of supply chains, this may be a significant undertaking. In this case, as a part of the prescreen, it is possible to prioritize the update process based on the inherent vulnerability of supplied materials. Figure 6 is an example of how a prioritization might be visualized based on a review of historical food sector alerts, known vulnerabilities, and their frequency for a range of different commodities that may be of interest to the food business operator. Once the highest risk commodities are prioritized, the respective supply chains can be investigated in sequence to enable the overall risk to be determined, and this information can be fed into the risk mitigation activity.

3.6 | Risk mitigation

As discussed above, there are three principal mechanisms available to food business operators to mitigate supply chain vulnerability to inauthenticity: established requirements such as specifications and associated certificates of

analysis for batches of supplied material, testing of supplied material before it is accepted for use, and knowledge of the supply chain via audit including verification of traceability. In the case of each individual mechanism, it may often be the case that there is an underlying risk-based scheme to decide on the level of diligence applied; for example, in the case of audits decision criteria to determine the frequency of audit, however, it may be less usual for all three mechanisms to be applied together in a riskbased scheme. The emphasis that a food business operator places on the creation of analytical data compared to performing supplier audits may be partly due to company culture and accepted norms. We emphasize the need to look past established company norms and base mitigation on risk. As summarized in Table 3, there are advantages and weaknesses with each mitigation approach.

In order to be effective at mitigating potential inauthenticity, food business operators should apply the available approaches to mitigation based on risk as determined by the knowledge of the supplied material in combination with knowledge of the supplier including their upstream supply chains. Based on these factors, Figure 7 illustrates a simple scheme to enable a logical balance between control measures to be applied. For example, if there is a high knowledge of the supplied material (i.e., there is a sound basis that the material is unlikely to be inauthentic) but a low knowledge of the supplier, the appropriate focus of mitigation should be to audit the supplier. Such a scheme is general in nature and should not be used when there are specific vulnerabilities known or

TABLE 3 Advantages and weaknesses of approaches to mitigation

Approach to mitigation	Advantages	Weaknesses
Contractual arrangements such as agreed specification and CoAs	 Clarifies quality expectation. Helps to crystalize thinking on what parameters require mitigation. 	 May act as a tool to facilitate inauthenticity (parameters not specified are unlikely to be verified). Requires up front knowledge on the parameters of concern. May become unmanageable with many parameters specified. May reduce supply chain flexibility.
Testing before product acceptance	 Enables continuous verification. Can be facilitated by newer on-site or rapid technologies. 	 May act as a tool to facilitate inauthenticity (if supplier is aware of the testing being performed). If using traditional test methods, requires up-front knowledge of the parameters of concern, and due to cost and time can only be done for a limited number of parameters.
Audit	 The most effective method of verifying controls used by supplier, including how they control the upstream. Enables sharing and alignment on vulnerability and prioritization of mitigation. Enables an evolving knowledge on vulnerability. 	 Requires high level of resource and experience to perform adequately. Requires some up-front knowledge on the topics of concern.

Knowledge of Supply Chain			Focus of Mitigation		
Supplied material	Supplier incl upstream		Supplied Assurance	In-House Data	Audit
high	high	$\qquad \Longrightarrow \qquad$	low	low	low
high	med	$\qquad \Longrightarrow \qquad$	med	low	med
high	low	$\qquad \Longrightarrow \qquad$	med	med	high
med	high	$\qquad \Longrightarrow \qquad$	med	med	low
med	med	$\qquad \Longrightarrow \qquad$	med	med	med
med	low	$\qquad \Longrightarrow \qquad$	high	med	high
low	high	$\qquad \Longrightarrow \qquad$	high	med	low
low	med	$\qquad \Longrightarrow \qquad$	high	high	med
low	low	$\qquad \Longrightarrow \qquad$	high	high	high

FIGURE 7 Example scheme to determine the appropriate focus of mitigation effort for established supplier, material combinations

current market alerts which should be investigated and mitigated on a case-by-case basis.

Concerning the effort undertaken for each approach to mitigation, how "low," "medium," and "high" might be interpreted, Table 4 provides examples of the actions that might be used as a default approach.

3.7 | Inauthenticity incident management

Available guidance does not describe approaches for managing fraud or inauthenticity incidents. Here, we define "inauthenticity incidents" as when information becomes



TABLE 4 Examples of how "low," "medium," and "high" might be differentiated in the case of authenticity mitigation options

	Focus of effort	Focus of effort				
Mitigation tool	Low	Medium	High			
Supplied assurance	Contractual relationship may specify only high-level requirements such as ingredient identity and the need for compliance.	Contractual relationship has granular requirements on material sourcing and specification.	Contractual relationship has granular requirements on material sourcing and specification. Plus, batch-specific CoA is required.			
In-house data	May not be generated, limited to standard quality checks for batch acceptance. Alternatively, there may be routine verification of key parameters, within which the material is not prioritized (e.g., annual check).	Data are generated as a part of a risk-based scheme. Analytics are likely to be targeted on specific known concern(s).	Data are generated frequently perhaps batch specific, and may include a number of analytes or be non-targeted depending on a risk-based scheme.			
Audit	Audit at the minimum frequency assigned in the company audit scheme.	Audit at elevated frequency assigned in the company audit scheme.	Undertake authenticity audit at elevated frequency. Focu on verification of material specifications, supply chain knowledge and integrity, traceability.			

available that a foodstuff already within a supply chain may have been impacted with a new inauthenticity concern. Figure 8 provides a general scheme for managing inauthenticity incidents. Information that there may be a new inauthenticity concern impacting a particular supply chain can originate externally (such as information captured by commercial vulnerability databases) or from data internal to supply chain partners. To ensure the effectiveness of an incident response, a degree of formality is required including the capturing of the available information and decisions taken within a log or incident form. This can later be used when mitigation plans are reviewed or as training material for auditors.

The first response to an inauthenticity incident should be to understand whether the particular supply chain in question is impacted, and if so whether there is a potential impact on food safety in which case implicated foods should be identified and held pending further investigation and risk management decision-making. Critical to managing incidents is communication and collaboration with impacted stakeholders. In terms of both stakeholder management and effectiveness in dealing with an incident, it is helpful to have an individual assigned as the "incident coordinator" with supporting roles also made clear (e.g., regulatory affairs, toxicology) within the "incident team." As a part of the incident response wider stakeholders should be identified early with effective information provided at the appropriate time. If the underlying reason for an incident is not fully known, root cause analysis could be

used to capture what is known to enable hypotheses to be tested on the most likely underlying cause (e.g., deliberate act or error in the supply chain). This serves three purposes, first to help understand whether your supply chain may be impacted, second to enable an understanding of the characteristics of inauthenticity (how food is affected), which can then be built upon in the data gathering exercise needed for safety risk assessment, and third to provide information on how best to update supply chain controls that are effective in mitigating the issue happening in the future.

A simple method of root cause analysis is to undertake a five-step process, which can be tabulated for record keeping. First, the suspected or identified problem should be stated; second, hypotheses should be generated as to the cause of the problem; third, information should be gathered to test the hypotheses, which fourthly should be interpreted, and lastly either conclusions should be drawn, or if root cause remains unknown, new hypotheses should be generated to test.

3.8 | Summary: Guidance and consensus process

To date, published guidance on managing food fraud does not take into account that food fraud is one aspect of the wider concerns of food authenticity. Management of inauthenticity involves identifying and preventing

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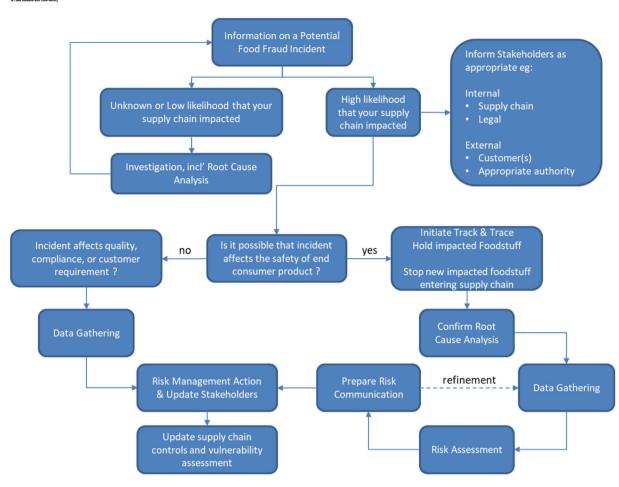


FIGURE 8 General scheme for managing inauthenticity incidents

variation from contractual or legal obligations on the identity, quality, or claims associated with an ingredient supply relationship. Food business are traditionally managing these parameters within their supply chains, and it therefore follows that fraud controls should be incorporated into these established systems. As each food business will have unique characteristics in terms of the products they produce and therefore supply chains they manage, there is no universal solution; however, as stated above, we provide general schemes for inauthenticity management that should be widely applicable.

SECTION 3: ANALYTICAL TOOLS

4.1 Notable guidance, standardization activities, and authoritative projects

A number of guidance documents are available on the application of analytical tools as a part of food fraud mitigation, notable for example is the Food Integrity "green book" from the EU-funded project of the same name (The FoodIntegrity Project, 2018). The European Standardization Committee (CEN) has established technical committee in 2019, the CEN/TC 460 on food authenticity. This committee has the remit to develop standards for food fraud detection methods. The technical committee has six working groups (WGs):

- WG1: Concepts, terms and definitions.
- WG 2: Species analyses using DNA-based methods.
- WG 3: Coffee and coffee products.
- WG 4: NMR analysis.
- WG 5: Validation concepts of non-targeted methods.
- WG 6: Stable isotope analysis.
- WG 7: LC/MS-based methods.
- WG 8: Spectrophotometric methods.

As all working groups are at the early stage, no publicly available output (standard, technical specification, or working group agreement) has been published.

Notable also is the USP—Guidance on Developing and Validating Non-Targeted Methods for Adulteration Detection which was the first guidance to provide actionable information on how to design and implement a nontargeted screen system specifically intended to mitigate

the risk of adulteration for food substances (US Pharmacopeial Convention and Food Chemicals Codex, n.d.). The information in this guidance can be used for systems that include either a single test method or multiple orthogonal tests.

The AOAC International is a not-for-profit standard development organization which established a Food Fraud Taskforce in 2018. The purpose of the taskforce was to develop method performance criteria (Standard Method Performance Requirements, SMPR®) for food fraud detection methods. The SMPR®'s defines critical performance criteria such as selectivity, sensitivity, limit of detection and/or quantification. Initially, two subgroups were formed: targeted chemistry methods and non-targeted chemistry methods. Lately, two further working groups have been added, which are targeted and non-targeted DNA-based methods. The first six SMPR® s have been published for milk, honey, and extra virgin olive oil by both the targeted and non-targeted chemistry working groups. The taskforce is now working on herbs and spices and botanicals. Method developers can submit methods to have them evaluated by an expert review panel against the minimum performance criteria. This will permit a rapid identification of methods that are appropriately suited to detect food adulterants.

The IAEA and FAO have a joint division coordinating projects on food fraud in Asia. One project seeks to enhance "Food Safety and Supporting Regional Authentication of Foodstuffs through Implementation of Nuclear Techniques." The priorities are to establish a regional consortium of science practitioners and end-users for verification of four key foodstuffs (rice, honey, tea, and dairy products) using nuclear and related complementary analytical techniques. In addition, the project seeks to establish and provide training in regionally agreed and harmonized protocols and procedures that can be used to verify the authenticity of a food sample. Also, it aims to initiate the development and initial population of a webaccessible database for archiving of food authentication information for the region.

The kick-off meeting took place on February 05–09, 2018 in Vienna. All the countries involved conducted a preliminary assessment of incidence, regulation, analytical capacity, and human resource around food authenticity and fraud as a basis for formulating their country workplans. Another project deals with the "Accessible Technologies for the Verification of Origin of Dairy Products as an Example Control System to Enhance Global Trade and Food Safe." This project will address some of the challenges that developing countries are facing in ensuring food traceability. It will develop a complete end-to-end system using dairy milk as an example commodity. This system will then be available as a template

that can be transferred to other commodities as required. The third project deals with Field-deployable Analytical Methods to Assess the Authenticity, Safety and Quality of Food. The project will identify and select appropriate analytical techniques and develop protocols to assess the authenticity, safety, and quality of food in a fielddeployable context. Milk powder and vegetable oils will be used as exemplar commodities to establish methods and guidance for "front-line" food adulteration screening. The aim is to close the gap between capabilities confined to sophisticated research laboratories, and technologies that can be utilized by various national gatekeepers in developing countries, namely national customs authorities and food regulators. The opportunity to accomplish this ambitious goal stems from a rapid and ongoing reduction in the cost of analytical equipment and a rapid increase in its portability. Throughout the last decade, the analytical instrument industry has delivered new families of handheld, portable, and transportable tools. This project will consider applications based on handheld and portable devices including (but not limited to) ion mobility spectrometry, near infrared (NIR) and X-ray fluorescence spectrometers and some bench-top laboratory instruments that have become "field" transportable including laser induced breakdown spectrometry, laser ablation molecular isotopic spectrometry, NMR spectroscopy, mass spectrometry (MS), and multispectral imaging.

4.2 | Summary of available analytical tools

Food fraud/inauthenticity mitigation approaches explained previously in this article may be supported by an analytical testing program. Detection, deterrence, and prevention are all interrelated, and testing is an excellent tool to verify that mitigation approaches are effective.

The choice for a given analytical method depends on the type of adulterant (biological, chemical, etc.), the type of product, and the type of adulteration. Some basic questions to help identify potential inauthenticity categorized below:

- 1. Are the types/amount of declared ingredients correctly labelled?
- 2. Are there likely to be any added bulking agents?
- 3. Are there likely to be any added illegal enhancers?
- 4. Do the species (plant, animal) appear to be correctly labelled?
- 5. Does the geographic origin appear to be correctly labelled?
- 6. Is the production method likely to be compliant?

TABLE 5 Overview over detection methodologies for specific types of adulteration

Type of	
inauthenticity	Technology for detection
Substitution— identity	DNA- and RNA-based methods: - (Real-time) PCR, micro arrays, biosensors - Next-generation sequencing, barcoding immunoassays - Enzyme-, fluoro-, radio-immunoassays
Substitution—origin	Stable isotope analysis - Stable isotope ratio analysis - Site-specific stable isotope ratio analysis - Isotope ratio mass spectroscopy Trace element analysis - Inductively coupled plasma mass spectrometry - Inductively coupled plasma atomic emission spectroscopy - Atomic absorption spectroscopy
Dilution Addition of bulking agents or extenders	Microscopy-Molecular spectroscopy - UV/Vis - Fluorescence - infrared - Raman Nuclear magnetic resonance
Enhancement	HPLCSpectroscopy - Near Infrared - Infrared - Mass spectroscopy

While describing each available analytical method that can be used for authenticity testing is beyond the scope of this article, the principal technologies used to detect specific types of adulterants are summarized in Table 5. Selected and illustrative examples are discussed in the proceeding text. Furthermore, based on the main inauthenticity categories of "substitution," "dilution," and "enhancement" defined in Figure 1, Table 6 provides an overview of food groups and references to analytical methods used for known inauthenticity issues previously associated with those food groups.

4.3 | Methods that are targeted or untargeted

Since the number of types of inauthenticity including known adulterants is steadily increasing, analysts are faced with the challenge of having to conduct numerous tests on the same sample for the different potential adulterants. For time and cost reasons, this is often not possible. In recent years, a newer suite of methods has been deployed: the so-called non-targeted screening approach (also referred to as untargeted screening). Instead of aiming to identify and quantify the presence of one (or a small group of) adulterant(s), this type of methods looks at the overall profile of a refence sample and compares it with the unknown sample. This is graphically depicted by Figure 9 where instead of looking for a specific individual chemical, it is the overall pattern of chemicals within a sample that is interrogated.

This allows detecting a much wider range of potential inauthenticities, even unknown ones. However, these types of method rely on high-quality and comprehensive reference databases for the identification of differences in the unknown sample under test. Types of methods that have been found to be amenable for non-targeted analysis are NIR, Fourier transform infrared (FT-IR), LC-MS/MS, and NMR.

However, the number of non-targeted methods has steadily increased. In the past 10 years, the number of studies published on this topic has exceeded 9000. The US Pharmacopeial Convention provides guidance in Annex XVIII of the Food Chemical Codex on how to develop a robust and fit-for-purpose non-targeted method. Food Integrity (European Funded Research Project) provides a white paper for validation and application of non-targeted methods as well (FoodIntegrity, 2018).

However, once a non-targeted method has identified a sample that deviates from the reference profile, the potential inauthenticity commonly needs to be identified in a second, targeted analysis. As previously mentioned, it is essential to establish that any such methods are fit-for-purpose by performing an appropriate method validation.

Method validation is also a critical component when selecting a method of any type. Typically, this is done with a "fit-for-purpose" approach, but in many cases this approach is not sufficient especially in the context of regulatory compliance. Simply put, validation ensures that a method performs the way in which it was designed. A properly functioning method will identify the analyte in the correct quantity, and as importantly, it will not mistakenly identify something else as the analyte giving a false positive result. There are many approaches to method validation. The most recognized and accepted are from internationally bodies such as ISO, AOAC, or AFNOR. Approval from organizations like these is based upon stringent validation protocols in multiple laboratories. The type and degree of validation needed varies. For example, if a laboratory uses an ISO method with known matrices, the laboratory will likely just need to verify the method operates as anticipated. If, however, a method is from a published journal article with limited published

Food groups and types of inauthenticity known to have occurred with references to analytical methods

	Substitution			
Food group	Identity	Origin	Dilution	Enhancement
Coffee beans	Arabica instead of robusta ^{3,4}			
Fish and Shellfish	Species ^{8–11}	Farmed instead of wild ⁶ Catch area ^{7,37}		
Fruit		Organic ¹²		
Herbs and spices	Species ^{13,14,38}			Coloring ¹⁵
Honey		Floral origin ^{18,19,20}	Sugar ^{16,17,21}	
Meat	Species ^{22–26} Cut ^{27–28}			
Milk and cheese		Organic ³² Geographic origin ³⁴		Nitrogen enrichment ^{29,30} Additives ³¹
Nuts	Peanuts added to almonds ^{1,2}			
Oils	Grain origin ⁵	Geographic origin ³³		
Rice	Variety ³⁵			
Salt		Sea versus rock ³⁶		
Vegetables		Organic ^{39,40}		
Vinegar	Species origin ⁴¹			

¹⁻ Esteki et al. (2017). 2- Campmajó et al. (2019). 3- Kamm et al. (2002); Pablos et al. (1999). 4- Monakhova et al. (2015). 5- Ozulku et al. (2017). 6- Anklam (1998); Fiorino et al. (2019). 7- Behrmann et al. (2015). 8- Stahl and Schröder, 2017. 9- Haynes et al. (2019). 10- Kappel et al. (2020). 11- Giusti et al. (2017). 12- Cuevas et al. (2016). ¹³ – Black et al. (2016). ¹⁴ – Delgado-Tejedor et al. (2021). ¹⁵ – Sannino and Savini (2021). ¹⁶ – Spiteri et al. (2015). ¹⁷ – Tosun (2013). ¹⁸ – Jandrić et al. (2015). 19 - Louveaux et al. (1970). 20 - Utzeri et al. (2018). 21 - Sobrino-Gregorio et al. (2018). 22 - (Ropodi et al. (2016). 23 - Rahmati et al. (2016). 24 - Rahmati et al. (2016). 25 - Cottenet et al. (2019). 26 - Prandi et al. (2019). 27 - Hu et al. (2017. 28 - Guelmamene et al. (2018). 29 - Scholl et al. (2017). 30 - Frank et al. (2017). 31 - Botelho et al. (2015). 32 - Liu et al. (2018). 33 - Gil-Solsona et al. (2016). 34 - Popping et al. (2017). 35 - Brandolini et al. (2006). 36 - Galvis-Sánchez et al. (2011). ³⁷- Li et al. (2017). ³⁸- Barbosa et al. (2019). ³⁹- Bateman et al. (2007). ⁴⁰- Mihailova et al. (2021). ⁴¹- Camin et al. (2013).



Graphical depiction of the difference between targeted and untargeted analysis (2019 Carmen Diaz-Amigo)

validation, a more in-depth validation is needed on the matrix or matrices in question. Key components to a validation include limit of detection, accuracy, reproducibility, selectivity, and measurement uncertainty.

In the following, for the main types of inauthenticity, we provide a selection of the analytical methods that have become or are becoming established to identify when inauthenticity may have occurred.

Different food matrices demand different analytical methods in order to detect and quantify the components of the food. DNA-based methods have proven invaluable in speciation of ingredients derived from plant and animal sources.

DNA is more resistant to thermal and chemical conditions than other molecules like proteins, which is an advantage when considering the analysis of highly processed food.

Even considering the existence of DNA when compared with other molecules, it is necessary to obtain DNA fragments with integrity such that it can be used in analysis. This can be particularly challenging when dealing with highly processed products where the DNA obtained is damaged and in low amounts. To be able to deal with this problem, it is recommended to use methods that allow detection and identification of small fragments (100-150 bp).

4.4 **Targeted DNA methods**

Real-time PCR 4.4.1

First applied for GMO detection and quantification (Mafra et al., 2008), several methods have now been developed and reported for meat, fish, and plants species identification. It is regarded as a principal method for species identification due its specificity and sensitivity and can be a good option when targeting a defined species. The disadvantages are the possible cross-reactivity with other species, especially in complex food products containing multiple ingredients and the limited number of targets that can be detected at any one time

4.4.2 | DNA chips

Advances in micro engineering over the last 20 years have resulted in the development of biochips (that include DNA chips), which can be described as a device made up of miniature test sites (also called microarrays) placed on a solid substrate (such as silicon, soda glass, fused quartz, plastic). This device allows performing several independent tests at one time. Various types of bioreceptors can be employed on biochips (i.e., DNA, RNA, proteins, enzymes, or antibodies) (Kappel et al., 2020).

The use of DNA microarrays (DNA chips) with speciesspecific oligonucleotide probes constitutes an alternative to real-time PCR, with the advantage to detect several species at the same time. The development of simple colorimetric DNA microarray techniques without the need

for specific fluorescence detection systems, commercial DNA chips for the identification of animal species have already been implemented in some official foods testing laboratories. However, commercial DNA chips for species identification in foods are only available for a limited number of species, which are typically meat products and more recently, some studies on fish species DNA chips (Iwobi et al., 2011; Kappel et al., 2020).

4.4.3 | DNA detecting immunoassays

Lateral flow immunoassay (LFI) strips are paper-based sensors that allow biosensing by the incorporation of bioreceptors and nanomaterials in a dry state on paper substrates. When combined with the PCR, the LFI strips can specifically react with a labelled PCR product based on biological interactions, such as antigen-antibody interaction. Test results are visualized as a color change in the strip without any specific device or equipment and can be obtained in 5-30 min. So far, the PCR-LFI tests have been used for the detection of several meat products, including horse, duck meat, and pork (Zhao et al., 2021). Besides their simplicity and low price, these tests present the great advantage of portability when instead of conventional PCR they are combined with isothermal amplification strategies which require much simpler equipment (e.g., Loop-mediated isothermal amplification(LAMP) and other similar techniques).

4.5 | Untargeted DNA methods

4.5.1 Sanger sequencing

Among the untargeted DNA-based methods, DNA sequencing is considered the gold standard for species identification. DNA barcoding based on Sanger sequencing is probably the most known method for species identification with authenticity assessment purposes and is already used by many regulatory entities (Matthes et al., 2020). Perhaps one of the most widely used barcoding methods is for fish-based products, enabling fish species identification by regulatory bodies in the United States and Europe. Species identification is performed by sequencing genomic regions with identification potential (e.g., DNA barcodes) and comparison with sequence databases. However, this method is not suitable for processed samples that contain multiple ingredients (species) as it only enables the identification of a unique species. Food products containing multiple species cannot be analyzed with this approach.



4.5.2 | Next-generation sequencing

In the last years, the emergent high throughput sequencing methods, generally next-generation sequencing (NGS), have started a new era in the food sector for traceability, safety, and authenticity.

NGS analysis delivers millions of individual sequences allowing the species identification in complex foods containing multiple ingredients. Each species present in the food product will produce unique DNA sequences that will be compared with databases resulting in species identification. This approach is usually known as DNA metabarcoding and uses some short gene regions described as presenting identification potential to differentiate species. This strategy has its origin in the previous generation of DNA barcoding, based on taxa identification by sequencing-specific and standardized gene regions using the Sanger methodology.

Presently, NGS is the only DNA-based method suitable for multispecies. Therefore, the use of this method is growing, and it is being applied by an increasing number of laboratories working on food authenticity analysis (Barbosa et al., 2019). For the most common groups of organisms (meat, fish, plants), there are many reports describing workflows, strategies, and primers. There are also some commercial products on the market to assess food authenticity by NGS metabarcoding as well as laboratories offering this type of services routinely. Public and proprietary analytical tools and databases are also available. NGS is already a reference for species identification in complex food, and feed products and several groups are working on standardization guidelines including ISO, CEN, and AOAC. Shotgun NGS has also been applied for food authenticity assessment (Akbar et al., 2021; Haiminen et al., 2019). Shotgun NGS is based on the analysis of food metagenome to determine the species content, independently from the group of organisms (meat, fish, plants, etc.). However, giving its current complexity, both on wet lab procedures and data analysis, it is not close to being used routinely.

4.5.3 | DNA method standardization

Until recently, standards supporting any DNA-based species identification method were not available. Recently, organizations such as ISO (e.g., ISO TC 34/SC 16), CEN (e.g., CEN/TC 470) and AOAC (e.g., AOAC Molecular Applications Working Group) have been working on projects to prepare and publish standards, examples include:

- ISO 20813:2019: Molecular biomarker analysis— Methods of analysis for the detection and identification of animal species in foods and food products (nucleic acid-based methods)—General requirements and definitions.
- ISO/TS 20224-2:2020: Molecular biomarker analysis— Detection of animal-derived materials in foodstuffs and feedstuffs by real-time PCR—Parts 1–7.
- CEN/TS 17303:2019: Foodstuffs—DNA barcoding of fish and fish products using defined mitochondrial cytochromes b and c oxidase I gene segments.
- · Drafts and Projects.
- ISO 22949-1:2020(E): Molecular biomarker analysis— Methods of analysis for the detection and identification of animal species in foods and food products (nucleotide sequencing-based methods)—General requirements.
- AOAC SMPR: Determination of adulterants spices and botanicals.

4.6 | Substitution related to ingredient origin: The use of isotope ratio mass spectrometry

Isotope ratio mass spectrometry (IRMS) is widely used for the investigation of geographical origin. IRMS is a specialization of mass spectrometry (see below) that allows the measurement of the relative abundance of stable isotopes in a given sample. Foodstuffs consist of chemical elements such as C, H, N, O, and S, and these elements are composed of their isotopes. Biomass is continuously being transformed from the resources of the environment, where plants are grown or animals bred, thus reflecting local nutrients, fodder, and drinking water. Although isotopic composition does vary within a limited range, it can be regarded as remaining constant and is, therefore, an "isotopic fingerprint." The isotopic fingerprint technique can be used for the detection of geographical origin of a material, the identity of batches, or the addition of synthetic material of chemically identical composition (Förstel, 2007).

IRMS instruments can be coupled to other instruments such as an elemental analyzer (EA-IRMS), gas chromatography (GC-IRMS), or liquid chromatography (LC-IRMS). Using EA-IRMS to analyze the 13 C/ 12 C ratio of different cereals has revealed significant differences (p<.05) for different geographical origins (Wu et al., 2015). A combination of 13 C/ 12 C, 2 H/ 1 H, and other isotopes can improve the quality of classification of geographical origin for different matrices.

4.7 | Dilution: The use of NMR and Benchtop IR

NMR (Nuclear Magnetic Resonance) spectroscopy is a powerful and nondestructive analytical tool.

Not only pure components but also highly complex food mixtures can be analyzed by (preferably ¹H-) NMR spectroscopy. Each component in the food sample provides a unique signal pattern used to identify that component. The ensemble of all signals in an NMR spectrum results in a characteristic "fingerprint." When combined with multivariate statistical chemometrics and suitable spectra databases, all components' characteristic signal patterns and quantities, as well as minor matrix variations can be recorded within a single run, even with only one reference sample for all samples and matrices.

However, NMR spectroscopy is not highly sensitive, which is an intrinsic property of this technique. Due to its sensitivity limitations, it cannot measure components that are in the ppb or ppt range such as residues in food products. It does offer a number of key advantages, and these strengths combine to make NMR spectroscopy an excellent and popular analytical tool. NMR is intrinsically quantitative and highly reproducible, while also being simultaneously targeted and non-targeted. Another highly useful feature of NMR is that once an NMR spectrum has been acquired, this can be reprocessed as often as necessary, meaning that users can retrospectively look at new features of interest or apply different or newly developed statistical approaches to analyze their data without having to acquire a new spectrum. NMR's ability to simultaneously analyze and quantify numerous components in complex mixtures with little sample preparation and without damaging the sample makes it a powerful and popular method in the food industry. NMR acquires the entire chemical profile or fingerprint of food products, allowing targeted quantification of specific marker components, as well as statistics-based fingerprinting for non-targeted detection of admixtures and the verification of origin and potential adulteration, all within the same experimental run. Deviations to profiles of authentic food products can be seen; hence, new adulterants or new modes of adulteration can be identified. Its high reproducibility means that NMR can be used to help build robust databases of reference spectra, allowing the different stakeholders to monitor authenticity, purity, and quality at each stage of the supply chain, from farm to fork.

Concerning IR benchtop applications, the first approaches for the validation of non-targeted methods, which include technologies like NIR and FT-IT, have been made by the AOAC Task Force for Food Authenticity Methods. From 2020 onward, this task force developed numerous Standard Method Performance Requirements

(SMPR®) for frequently adulterated commodities including milk, honey, and extra virgin olive oil for both, targeted and non-targeted methods (AOAC Food Authenticity Methods (FAM) Working Group on Non-targeted Testing, 2020a, 2020b, 2020c). More recently, there are also CEN working groups dealing with nontargeted methods performance requirements. While CEN/TC 460 WG 4 is working exclusively on NMR methods, CEN/TC 460 WG 5 seeks to define general methods performance requirements across technologies and including portable NIR devices. Both the work of the AOAC taskforce and that of CEN/TC 460 WG 5 will help to set standards and method performance requirements for non-targeted technologies like NMR and FT-IR, driving the routine implementation also for on-site food authenticity analysis.

In comparison to technologies like high-resolution mass spectrometry, infra-red technologies have a significantly lower resolution power. However, because of the size and portability of IR devices, they have been proven extremely useful in routine quality control and detecting food fraud. While the sensitivity of a standard infrared scanner is less than that of a mass spectrometer, infrared systems, especially portable ones, have proven extremely useful in routine quality control and detecting food fraud. A significant advantage of these systems is that analysis is performed in a matter of seconds with no or little sample preparation in most cases. Major food manufacturers have previously used near-infrared devices for shelf live determination (Pedro & Ferreira, 2009), and the dairy industry routinely uses FT-IR for the quality and authenticity control (Hansen & Holroyd, 2019; Scholl et al., 2017). More recently, several low(er) cost NIR-based handheld devices have been developed to determine adulterants in food and feed. Furthermore, numerous applications for food safety and food authenticity have been described for infrared-based, portable devices. In the special guest-edited section in the Journal of AOAC International, Popping and Diaz-Amigo provide an overview of current portable devices applications in relation to food fraud detection and food safety and quality analysis (Popping & Diaz-Amigo, 2020). Here, numerous authors describe the application of portable NIR technology for the authenticity of wild fish versus farmed fish (Goncalves et al., 2021), the quality control of citrus fruit (Santos et al., 2021), and the authenticity analysis of extra virgin olive oil (Weesepoel et al., 2021) and rice (McGrath et al., 2021). The United Nations Interregional Crime and Justice Research Institute (UNICRI) considers the usefulness and use of such portable applications for food fraud detection, as described in their report from 2020 (United Nations Interregional Crime & Justice Research Institute, 2020). It can reasonably be assumed that such portable tools will also be used by enforcement in the coming years to support rapid, onsite screening of samples and selecting those that are out of specification for follow-up confirmatory laboratory analysis. In the case of detection of simple fraud issues, vibrational spectroscopy (FT-IR, NIR, Raman) non-targeted screening methods can also be coupled to data analysis using chemometrics and liquid chromatography—high resolution mass spectrometry (LC-HRMS) for confirmation based on targeted biomarkers. Key enablers to the application of IR devices are the availability of high-quality, comprehensive and curated reference spectra databases and multiuser validation of such devices.

4.8 | Enhancement: The use of mass spectroscopy

Mass spectrometry is one of the most universal analytical techniques which can be used for inauthenticity investigations. From small to large biomolecules, mass spectrometry allows unlimited analytical potential in consideration of the scope of investigation (from nucleotides to DNA; from peptides to proteins; from fatty acids to fats; from simple to complex sugars). Mass spectrometry has recently been considered in the context of the double tiered approach where it is used for both screening (rapid and inexpensive untargeted approach) and confirmation (targeted approach) after validation of appropriate markers of inauthenticity.

The main limitation of MS is the cost of the mass spectrometry. However, due to the rapid evolution of the MS technology, the cost of equipment is decreasing. Advances in MS research have also led to the introduction of methods that are rapid, small size, high-throughput, and highresolution. Rapid and small size solutions are based on new ambient ionization technologies such as direct analysis in real time (DART), and atmospheric solid analysis probe where complex samples can be analyzed rapidly without the need for sample preparation or even chromatographic separation. HRMS is commonly used for residue analysis of food, gaining wide acceptance in the last decade. This development is due to the availability of rugged, sensitive, and selective instrumentation. This is one of the most promising tools when moving toward non-targeted approaches.

MS techniques as used in food authenticity testing can be divided into targeted and non-targeted methods. Targeted methods examine the presence of known molecules, whereas non-targeted MS-based methods are based on unknown molecules with the omics approach such as metabolomics and lipidomics targeting small molecules, typically below 1000–2000 Da, while peptidomics and proteomics target much larger molecules (up to 500,000 Da) (Herrero et al., 2012). Targeted methods are applicable

when there is one or more molecules to be analyzed which are related to validated markers of inauthenticity. Below are examples related to the three different main areas of mass spectrometry and case studies.

Chromatography and low-resolution mass spectrometry of cyclopropanic fatty acids in cheese are indicators of the presence of microorganisms that are related to silage feeding of cows. Chromatography combined with low resolution mass spectrometry allows for the verification of the presence of these indicators in Parmiggiano cheese (Norma UNI, 2016).

Chromatography and high-resolution mass spectrometry of the beta-casomorphin-7 in milk and dairy products as an opiopeptide indicator of presence of A1 type milk: This peptide constitutes a suitable marker to determine the presence of A1-like and/or A2-like β -casein in bovine milk. Chromatography combined with high resolution mass spectrometry allows to verify the presence of this indicator in milk and dairy products (De Poi et al., 2020).

Chromatography coupled with high-resolution mass spectrometry has also shown value in geographical origin or product of designated origin for premium products (Popping et al., 2017).

Non-targeted MS-based methods primarily focus on the detection of the widest possible pattern of components that can be subsequently transformed after method optimization and validation of suitable biomarkers, to a simpler targeted method. However, finding unique biomarkers is not always feasible, and sample classification can also be based upon the entire pattern of features (Riedl et al., 2015). This requires multivariate data analysis to establish a chemometric model.

Non-targeted methods are applicable when a list of molecules to be analyzed in relation to validated markers of inauthenticity is not known. Below are examples of mass spectrometry applied to food inauthenticity.

Chromatography and high-resolution mass spectrometry to detect inauthenticity in the red color of tuna fish: This technique has identified molecules of plant-derived dye molecules in fish muscle (as residual presence of not declared dye treatment) (De Dominicis et al., 2014).

Ambient mass spectrometry has been used to determine the floral composition of honey. DART-MS shows promising results to capture differences among the samples such as acacia honey versus multifloral honey (Damiani et al., 2020).

4.9 | Portable devices

Over the past years, numerous companies, especially startups, have developed portable food fraud and food safety testing devices which do not require skilled and scientifically trained operators. The ability to miniaturize systems in combination with cloud computing have made these developments possible. Such devices are based on different technologies, including immunology, molecular imprinting, NIR, and LAMP.

A special guest edited section of the Journal of AOAC International (2021) provides a summary of the latest developments and includes devices which allow the detection of adulterated extra virgin olive oil, identification of freshness of fruits, and the authentication of rice, using handheld, single or multisensor devices (Popping & Diaz-Amigo, 2020).

CONCLUSIONS/DISCUSSION 5

Within the landscape of food fraud, there are attempts to define consensus definitions, including what is meant by "food fraud" itself, but these are not widely adopted. Complicating the use of the term "food fraud" is that it is commonly understood to relate to deliberate acts, whereas an understanding of motivation may only be known by the presumed perpetrator. Furthermore, there are many ways in which food can be misrepresented including unintentionally. As the primary concern of food businesses is the management of misrepresented food, irrespective of the underlying motivation, and as management systems for deliberate acts are usually a part of systems to manage supply chain quality, we use the adjective "inauthentic" and noun "inauthenticity." We have reviewed three elements key to understanding the landscape of inauthenticity, the authoritative activities described as being intended to combat food fraud, available guidance documents, and analytical tools.

In our review, we discovered a hierarchy of activities across countries to combat food fraud. Although for the most part national regulations across the world do not specifically address food fraud, all countries studied have a baseline of regulations relating to the suitability of foods and not misleading consumers that are relevant to some degree to protecting against food fraud. In the case of some countries, increased concern has led to more active enforcement of these base regulations, especially in the case of commodities that are of high relevance to the country in question. In a number of countries, notably within North and South America and Europe, there are further measures taken. These fall into three categories of additional authoritative activity: namely the setup and funding of dedicated research projects aimed at enhancing fraud vigilance, for example, the development of expert systems to predict fraudulent activity based on economic indicators; the operation of laboratory infrastructure dedicated to food fraud which sometimes are formed into collaborating networks; and cross authority information sharing networks and associated tools such as alert databases. The academic activity within any particular country reflects for the most part the level of authoritative activity underway within that country, and likely therefore the amount of funding available.

It is no surprise that cross-authority networks are most prominent in the European Union, given both the nature of the single market and history of developing detailed specification requirements for commodities. This level of activity extends beyond information sharing into enforcement for example via Europol. However, given the globalized nature of food supply chains, cross-authority collaboration on food fraud has now reached the stage of being on the agenda of international fora such as the Codex Alimentarius. Despite increased authority collaboration in recent years, it remains the case that individual national projects can remain isolated and uncoordinated with other similar projects elsewhere.

Authoritative bodies often provide information on the fraudulent activities they have successfully intercepted, despite this it is not possible to determine the degree of success as measured by the fraction of deliberate inauthenticity that has been identified. Irrespective of this, there is no doubt that antifraud activities together are a powerful arsenal in making it significantly harder to commit food fraud and for ingredients that have been substituted or enhanced to go unnoticed.

Complementary to national regulations and antifraud activities, a variety of guidance is available for food businesses, from authoritative agencies, food safety certification and standardization bodies, and industry associations. Across this guidance, there is a common process; however, this process is not set within the context of the activities food businesses traditionally undertake to ensure the wider authenticity of the ingredients they purchase. We have attempted to rectify this with a simple description of combined inauthenticity management including a scheme for determining the appropriate allocation of mitigation resource and key aspects to consider when dealing with an inauthenticity incident.

Concerning the analytical tools available to validate and verify the authenticity of ingredients, recent projects, particularly the EU Food Integrity Project, have provided extensive reviews and development continues in other fora. In previous years, fraudsters and analysts have been in a battle; however, the development of more sophisticated methods for untargeted analysis for screening purposes obviates the need for knowledge on the specific fraud that may be perpetrated. These methods when applied together with vulnerability assessments and enhanced traceability will likely play a major role in reducing both the opportunity and detection of deliberate

misinformation with ingredients. The main analytical technologies of chromatography in particular coupled with mass spectrometry detection, infra-red spectroscopy, NMR and DNA sequencing provides a plethora of opportunities for both targeted and untargeted analysis. However, the advantages of untargeted methods are moderated by the need to have reference data available against which to compare. There is a need for widely accessible databases particularly for high-risk commodities.

The application of analytical tools which are suitable for the specific inauthenticity scenario in question is crucial (the problem definition and question to answer). For example, a documented claim that the origin of a wine is Chile can be verified via NMR, whereas the potential substitution of saffron with safflower can be determined via PCR. However, it is key to consider all the tools available within a toolbox approach to increase success in preventing and detecting food fraud: documentation and certificates, supply chain knowledge and traceability, and the analytical portfolio available. It is essential to bear in mind that the emphasis must be on prevention with detection using analytical methods being recognized as providing supportive data only within a wider mitigation scheme.

Food inauthenticity, in the form of misinformation between trading partners and ultimately consumers on one or more characteristics of a food, is likely to be a relatively frequent occurrence. As most stakeholders across supply chains are diligent in prioritizing safety, except in extreme cases of deliberate inauthenticity, most incidences of inauthenticity will be related to impacts on quality or compliance. Notwithstanding, the cost and impact to a brand or business of inauthenticity can be significant. To mitigate risk, the most powerful tool available to stakeholders within supply chains is to have knowledge on the upstream sourcing, processing and specification of the foodstuffs that they purchase, monitor available information resources and authoritative activities, and understand the possible causes for future inauthenticity and apply the tools described herein.

Analytical tools are key in the detection of food fraud, and the development of especially portable technologies that allow the on-site screening for suspicious material are key to combat food fraud. Still, databases for commodity screening still have to be developed. It is desirable to have such databases hosted and curated by governmental institutions for wide accessibility and open access. It would enable food manufacturers, auditors, and inspectors to deploy these easy-to-use tools to make the food supply chain safer.

In summary, it is important to understand that none of the described tools and solution, being analytical or digital, will solve the food fraud issue. Only by working in concert with each other, the described solutions will generate a synergistic effect that will lead to food authenticity through improved surveillance, preparedness, traceability and analytics.

AUTHOR CONTRIBUTIONS

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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