



FOOD SAFETY AND  
INTEGRITY SOLUTIONS

# Food Fraud Mitigation Guidance

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Appendix XVII  
General Tests and Assays



## Our Guidance

USP's Food Fraud Mitigation Guidance provides a practical framework to help your organization develop a system for identifying vulnerabilities in your ingredient supply chain and developing a control plan to mitigate risks.



## Our Services

USP customized training and advising services include:

- **Developing a Comprehensive Mitigation Plan**
- **General Training On Food Fraud Mitigation**  
One-day or partial day courses (on-site or remote) on the basic steps of food fraud mitigation
- **Advice on Existing Food Fraud Mitigation Plans**  
We will assess your existing plan and advise on every aspect, from supplier audit strategies to testing strategies.

## Our Experience

We possess the right expertise in ingredient vulnerability assessments, EMA hazard identification, supply chain and testing strategies, creating EMA preventive control plans, Hazard Analysis Critical Control Point (HACCP), Hazard Analysis and Risk-Based Preventive Controls (HARPC), FSMA and GFSI to help you meet industry needs, national and international regulatory requirements.

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## APPENDIX XVII: FOOD FRAUD MITIGATION GUIDANCE

This Appendix to the *Food Chemicals Codex* is intended to elaborate guidance frameworks and tools to assist users in the development of their own personalized preventive management system to counter food fraud.

The content in this Guidance is intended to be used as an informational tool and resource only. It is not intended to and does not constitute legal advice and is not warranted or guaranteed by USP to be accurate, complete, adequate, or current. Your use of the content in the Guidance is at your own risk. USP accepts no responsibility or legal liability for the use and/or accuracy of the Guidance or for decisions based on its content.

### TERMINOLOGY AND SCOPE

Food fraud encompasses a wide range of deliberate fraudulent acts to food.<sup>1,2,3</sup> The focus of this Appendix, however, is on one type of food fraud—the intentional and economically motivated adulteration (EMA) of foods. EMA is defined as the fraudulent addition of non-authentic substances or removal or replacement of authentic substances without the purchaser's knowledge for economic gain of the seller. This standard is therefore not intended to address the other types of food fraud such as counterfeits and simulations, gray area markets, product tampering, production over-runs, theft, smuggling, document fraud, and diversions. Lastly, the scope of this Appendix does not cover adulterations intended to cause public health harm, economic harm, or terror (i.e., food defense issues).

While risk-based preventive control systems exist for traditional food safety risks, they are not directly applicable to controlling food fraud. Food fraud and EMA are intentional acts designed to evade detection. Therefore, food fraud is deterministic in nature, and cannot be adequately addressed with probabilistic food safety risk assessment frameworks. Furthermore, food fraud incidents are more difficult to anticipate and detect than food safety incidents. Unanticipated and unintended consequences beyond traditional food safety risks must be considered in a food fraud mitigation framework. For all of these reasons, the term "vulnerability" is used instead of "risk" or "likelihood" in the context of this Appendix. This framework helps guide an assessment of food ingredients which may be more vulnerable to fraud based on a number of contributing factors. However, since the occurrence of fraud ultimately depends on intentional acts by individual perpetrators, this framework is not intended to definitively predict the likelihood of fraud.

### A. GENERAL GUIDANCE FOR FOOD INGREDIENTS

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## UTILITY AND SCOPE

Section A. *General Guidance for Food Ingredients* provides guidelines for developing and implementing a preventive management system to deal specifically with intentional, economically motivated fraudulent adulteration of food ingredients. It provides a qualitative, step-wise, and structured approach divided into four major steps for carrying out ingredient-by-ingredient assessments. The first three steps are aimed at characterizing the overall fraud vulnerabilities of an ingredient by the assessing factors contributing to fraud occurrence and the potential impacts when fraud does occur. The impacts include both public health and economic consequences. The last step provides guidance on how to use the outcome of the first three steps (the vulnerabilities characterization) to develop a mitigation strategy.

This Guidance is intended to be generally applicable to any food ingredient, and is intended to guide users to develop their own fraud management system that prioritizes and focuses mitigation resources towards the most vulnerable ingredients in the user's portfolio of ingredients. It is intended to be applicable to any user responsible for ensuring the safety and integrity of food ingredients, including both the companies purchasing food ingredients and regulatory authorities, as well as auditors and certification schemes. It is intended to be a guidance-based framework and hence must be adapted to the unique situation and needs of each user.

## LIFECYCLE AND IMPLEMENTATION

Like any management system, a food ingredient fraud management system is a continuous process as depicted in *Figure 1a*. It begins with an evaluation step to characterize food ingredient fraud vulnerabilities, followed by design and review of a mitigation strategy, and then implementation. Periodically, or as changes occur over time that may impact the vulnerabilities (e.g., a newly identified adulterant for an ingredient is reported, the supply chain for an ingredient changes, or tolerance for economic vulnerabilities changes), the entire process must be carried out again to ensure its continued effectiveness.



Figure 1a. Lifecycle for food fraud management system.

Initial implementation of an ingredient-by-ingredient fraud management system as described in this Guidance may be operationally challenging for organizations with large portfolios of ingredients and/or numerous ingredient-supplier combinations. A possible strategy for implementation in such situations is the addition of a pre-screening step to target use of this Guidance to a smaller subset of ingredients posing the greatest vulnerability to fraud to the organization, as depicted in *Figure 1b*. Below are some example pre-screening approaches that could be considered:

- One approach is to evaluate each ingredient using the first 3 steps in this Guidance but without supplier-specific factors in *Step 1* (i.e. not evaluating factors such as *Supply chain*, *Supplier relationship*, and *History of supplier regulatory, quality or safety issues*). Ingredients found to be the most vulnerable in this pre-screening evaluation could then be more carefully evaluated by the supplier by carrying out the complete assessment in the Guidance.
- Another approach is to group ingredients by class (e.g. oils, spices, dairy ingredients) and evaluating them using the first 3 steps in this Guidance but without supplier-specific factors in *Step 1* (i.e. not evaluating factors such as *Supply chain*, *Supplier relationship*, and *History of supplier regulatory, quality or safety issues*). Ingredient classes found to be the most vulnerable in this pre-screening evaluation would then be more carefully evaluated ingredient-by-ingredient using the complete assessment in the Guidance (including supplier-specific factors).
- A third approach is to prioritize ingredients sourced from countries or regions with histories of food fraud activity.
- Alternatively is the use of other tools or factors as a pre-screen that are aimed at identifying ingredients most likely to be adulterated.

Carrying out the assessments described in this Guidance will benefit from the use of multi-functional/disciplinary teams. An example team for a food producer might include functions such as procurement, quality and regulatory, audit, and food analysis functions. Additional expertise in security and corporate affairs may be helpful for geopolitical consideration assessments, and representation from a public-facing role may be helpful to characterize potential public confidence impacts.

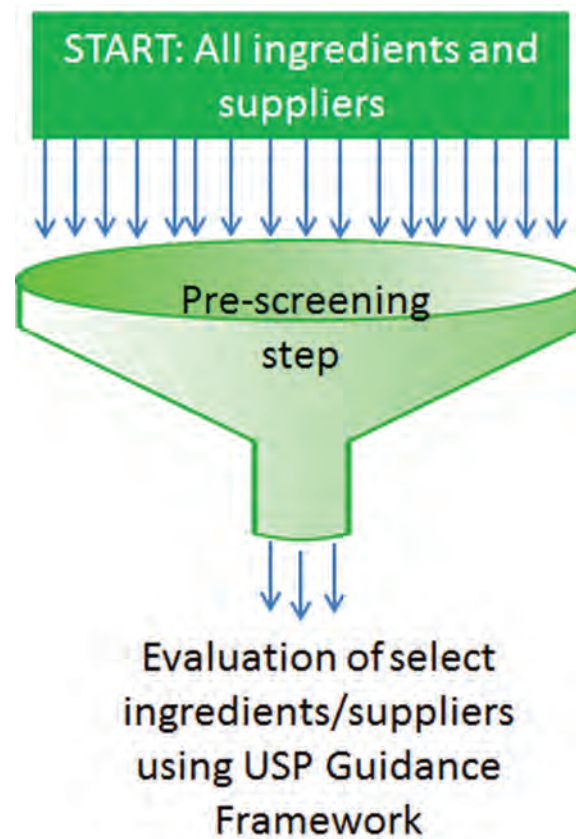


Figure 1b. Adding a pre-filter step to aid in implementation of USP Guidance Framework.

## STEP 1: CONTRIBUTING FACTORS ASSESSMENT

The first step for characterizing the fraud vulnerabilities of an ingredient is to review the factors known to be helpful in predicting fraud occurrence. These vulnerability factors are outlined in *Table 1*. They include those inherent to the ingredient, such as *Fraud history*, and factors controllable by the user such as *Testing frequency*. Users evaluating an ingredient should carefully review for each factor in *Table 1*, the provided guidance, available information sources, illustrative examples, and then estimate which vulnerability category best describes their situation. It should be noted that the vulnerability categories in *Table 1* and the corresponding details below represent points on a continuum. Users should consider "rounding up" to the next highest vulnerability category if a situation falls between scenarios. For example for the *Supply chain* factor, when ingredients are sourced from a "Firm vertically integrated" who sometimes buys raw materials from third parties, the increased vulnerability might be better described by the medium vulnerability category, "Supplier manufacturers." Some factors are interconnected, such as *Supplier relationship* and *History of supplier regulatory, quality or safety issues*, but this guidance suggests evaluating each factor individually to simplify the assessments.

### Guidance and Resources for Carrying Out Assessments of Each Factor

#### SUPPLY CHAIN

A food ingredient's vulnerability to fraud increases with the complexity of the supply chain. While this is related to the traceability of an ingredient through the supply chain, traceability in the absence of oversight and controls does not preclude the potential for fraud. This has been demonstrated by recent incidents. The vulnerability of the supply chain is related to the degree of "control" that is held by parties with a vested interest in preventing fraud at various points in the supply chain. The optimum scenario with the lowest vulnerability can be described as a single ingredient food sourced directly from a known, *trusted supplier* (See *Supplier relationship* for description of "trusted supplier"), who in turn, sources from a known, *trusted supplier*. In theory, the scenario presenting the greatest vulnerability for adulteration is when ingredients are sourced from multiple sources in an open market where there is limited knowledge about the supplier and when the ingredient, either because of storage, transportation, or processing, is handled by multiple parties and the source identity is lost or not actively tracked, as when ingredients are blended.

The following provides some explanation of the vulnerability category descriptors used in *Table 1*. These should be considered a general guideline for categorizing vulnerabilities for this factor and should be tailored to your business practices and re-evaluated on a regular basis. While not explicitly stated in the descriptions, the vulnerability of the supply chain includes consideration of whether the ingredient is a single raw material or an ingredient that is processed by more than one entity and is composed of multiple components.

- *Low: Firm vertically integrated*—The ingredient is not sourced from third parties but is sourced directly from another part of the food-producing firm. In the case of agricultural ingredients, this means that the firm produces the raw agricultural product that is used as the ingredient. For example, the firm grows the peppers, and produces the paprika that is then used as the ingredient in a product. Or, all juice is produced from fruit from company-owned farms. Assuming that policies regarding ingredient quality are uniform throughout the firm, this would present the least vulnerability for ingredient fraud. However, while this illustrates the scenario of least vulnerability, policies backed by internal audits need to be in place to ensure that all parts of the organization are acting ethically.
- *Medium-Low: Supplier vertically integrated*—The ingredient is sourced from a known, *trusted supplier* who produces the raw agricultural product that is the starting point for the ingredient. Using the example described above, the supplier owns the fields where the peppers are grown and owns the facility where the peppers are transformed into paprika. The ingredient is then sourced directly from the supplier. In this scenario, the supplier does not buy either raw or processed agricultural product from another supplier. Here the vulnerability is limited by knowledge of the supplier and trust that is verified by audits.
- *Medium: Supplier manufactures*—The ingredient is sourced directly from a primary supplier who manufactures the ingredient but buys either raw or processed agricultural products from another party. Using the example above, the supplier buys peppers from independent farmers but owns the facility that manufactures the paprika and the ingredient is sourced directly from the supplier. Here there is limited concern for possible adulteration of the raw agricultural product by parties unknown to the supplier. However the onus is on the primary supplier to ensure that his supplier (secondary supplier) has fraud prevention programs in place that are comparable to the primary supplier's own.
- *Medium-High: Upstream supplier manufactures*—The ingredient is either composed of a blend of components each manufactured by a third party, or the ingredient is subject to processing by a third party manufacturer before final processing by the supplier. This scenario might describe custom blends of juice concentrates where the supplier produces the blend from concentrates from different suppliers. Similarly, it could describe a scenario in which the supplier acts as middle man and blends, repackages, or otherwise reprocesses ingredients from other suppliers, for example, a supplier might supply a spice blend that is composed of paprika along with spices and ingredients from multiple suppliers. The degree of vulnerability increases with the number of suppliers involved in the process.
- *High: Open market*—This scenario describes the situation where an ingredient is sourced in the open market and none of the other scenarios described above can be verified as being applicable. While it is possible that an ingredient could be sourced

**Table 1. Step 1—Contributing Factors Assessment Matrix**

		Contribution to Vulnerability				
Contributing Factor		Low <sup>a</sup>	Medium-Low <sup>a</sup>	Medium <sup>a</sup>	Medium-High <sup>a</sup>	High <sup>a</sup>
Controllable Factors	Supply chain	Firm vertically integrated	Supplier vertically integrated	Supplier manufactures	Upstream supplier manufactures	Open market
	Audit strategy	Robust, onsite, with numerous anti-fraud measures	Robust, onsite, with limited anti-fraud measures	Immature, onsite, with limited anti-fraud measures	Immature onsite audit strategy with no anti-fraud measures, or strategy with limited anti-fraud measures in development	No onsite audits being used
	Supplier relationship	Trusted supplier and previously purchased ingredient(s)	Trusted supplier and new ingredient	Established supplier and some relationship	Established supplier and no prior relationship	Unestablished supplier and no prior relationship
	History of supplier regulatory, quality, or safety issues	No known issues	Few minor issues, quickly resolved	Recurrent issues or resolution concerns	Multiple persistent issues indicating lack of responsiveness to concerns; some evidence of inadequate controls	Strong evidence of quality or safety concerns; inadequate controls
	Susceptibility of QA methods and specs	More than sufficiently characterizes ingredient and can detect known and potentially unknown adulterants	Moderately sufficient to characterize ingredient and detect known adulterants	Moderately sufficient to characterize ingredient but some known adulterants may not be detected	Limited characterization of ingredient and limited screening for select adulterants	Limited to no characterization of ingredient and some known adulterants will not be detected
	Testing frequency	Intensive—every lot tested by buyer	Random lots tested by buyer	Testing done at yearly or other limited intervals as part of supplier qualification	No testing done, reliance on Certificate of Analysis	No testing done. COA either not present or not specific to lot/shipment.
	Geopolitical Considerations	Single component ingredient sourced from a single geographic origin of low concern	Ingredient comprised of two to several components sourced from geographic origin(s) of low concern	Ingredient comprised of a single to few components that have originated or transited through a region or regions with some geopolitical concerns	Ingredient comprised of several components; some originated or transited through regions with some geopolitical concerns	Ingredient comprised of one or more components that originated or transited through one or more regions exhibiting several characteristics of geopolitical concern
Uncontrollable factors	Fraud history	No reports or few known reports with no or unknown validity	Low to moderate number of reports with limited or unknown validity	Moderate number of reports with limited degree of validity	Moderate number of reports with good degree of validity; or High number with limited validity	High to moderate number of reports, some with high degree of validity, and/or evidence of an ongoing incident
	Economic anomalies	Nothing unusual	Isolated cases	Frequent but unrelated cases	Common but focused cases	Common and broad cases

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in the open market from a supplier with an integrated supply chain, this scenario assumes that a purchase on the open market limits the buyer's ability to verify that the supply chain is 1) integrated, and 2) that appropriate controls are in place to prevent fraud. This does not mean that all ingredients purchased in the open market are vulnerable to fraud; it means that the buyer has less ability to verify that procedures to prevent fraud are in place.

In summary, the amount of vulnerability presented by the supply chain is related to both the amount of control over the sourcing of the ingredient by the end user and the amount of transparency that the end user has with regard to the sourcing practices of suppliers of the ingredient. Actual control and oversight are more important than organizational or legal descriptions that may describe purchasing agreements, but which, do not in practice, reduce vulnerability.

### **Illustrative Example—Menu Foods and ChemNutra**

In 2007, clustered incidents of renal failure in pets in North America involving melamine-tainted wheat gluten resulted in one of the largest pet food recalls and fraud incidents in history. The consequences of the incident included acute renal failure for 39,000 pets in North America and an estimated 2,000 to 7,000 deaths. Most of the recalled products were produced by Menu Foods, once the largest producer of pet foods in North America. The recall involved over 60 million units of pet food at a cost of \$42 million USD, and resulted in significant litigation costs for the company.

The fraud in this case involved the addition of low purity melamine (contaminated with cyanuric acid) to inferior grade wheat gluten and other protein-rich ingredients to fraudulently boost their apparent protein content (and their economic value) by exploiting vulnerabilities of the non-specific Kjeldahl and Dumas analytical methods for estimating crude protein content. The following information is based on the criminal court case and congressional testimony records available in the U.S. (U.S. v. Miller et al., 2008; Committee on Energy and Commerce, 2007). Menu Foods purchased the tainted wheat gluten from ChemNutra, a U.S.-based supplier of imported Chinese ingredients. It was a one-time procurement from ChemNutra (although Menu Foods had used ChemNutra as a supplier for other ingredients) and was purchased at a premium price, because of a short supply of wheat gluten that started in 2006. ChemNutra was in turn supplied the tainted wheat gluten by the Chinese company Suzhou Textiles, Silk, Light Industrial Products, Arts and Crafts I/E Co., Ltd. (SSC). That company in turn had contracted the Chinese company Xuzhou Anying Biologic Technology Development Co., Ltd. (XAC) to manufacture and supply the wheat gluten SSC needed to fulfill its contract with ChemNutra. ChemNutra accepted materials based on certificates of analysis and conducted no further relevant testing on the wheat gluten. Between November 6, 2006, and February 21, 2007, XAC used SSC to export at least 13 shipments of XAC-manufactured wheat gluten to ChemNutra totaling more than 800 metric tons. Upon export from China, SSC deliberately labeled the XAC-manufactured wheat gluten using the wrong Harmonized Commodity Description and Coding System (HS) code so that the product would not be subject to compulsory and mandatory inspection by Chinese food authorities. ChemNutra was aware of the fraudulent mislabeling of the HS code and did not disclose to Menu Foods that the XAC wheat gluten had been exported out of China with the use of a tariff system code that avoided subjecting the product to mandatory inspection by Chinese authorities prior to leaving China.

Following this incident in 2007, veterinary pathologists uncovered two previous deadly pet and animal feed incidents involving renal failures that have now been attributed to melamine adulteration. This includes a 2004 incident in Asia and a 2003–2006 incident in Spain (Brown et al., 2007; Gonzalez et al., 2009).

This illustrative example points to significant supply chain vulnerabilities, in addition to other vulnerabilities such as supplier relationship, susceptibility of QA methods and specs, and economic anomalies. If information about each of these factors had been available, an assessment using this information could have provided early indication of the potential for a large-scale food fraud incident.

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### **AUDIT STRATEGY**

This factor is intended to describe the vulnerability of a supply chain to food fraud due to inadequate or undeveloped audit practices. Audits are assurance systems typically carried out to verify the compliance of a supplier with standards and specifications contracted between a buyer (customer) and supplier of goods or services. Supplier audits at the present time are mostly focused on food safety, hygiene, and GMPs, and generally do not include anti-fraud measures. The vulnerability of a supplier audit strategy to food fraud is therefore difficult to assess, but can be estimated based on a variety of inter-related factors discussed below. Generally, the most robust audit strategy is a mature program using direct audits carried onsite at a supplier's facility or facilities

by well-qualified auditors. It also includes anti-fraud measures and unannounced audits, and is performed at a frequency that is proportional to vulnerability. The least rigorous audit strategy would be paper audits (or no audit at all) performed by a third party without any anti-fraud elements. Below are factors that influence the vulnerability of an audit strategy to fraud that should be considered when assessing this contributing factor:

*Inclusion of anti-fraud measures in audits*—A variety of elements can be included along the production chain of a finished ingredient, from raw materials receiving to packaging and transport into a facility, to reduce the vulnerability to fraud. Starting with the raw materials receiving step at the supplier's facility, an audit should review the practices undertaken by individual suppliers to ensure the integrity, traceability, and security of their own supply chain (i.e., the raw materials the supplier uses). This step should focus on determining whether the supplier has implemented control measures commensurate to any potential vulnerability to ensure that their raw materials have not been fraudulently manipulated, substituted, diluted, or tampered with before reaching their facility. Documentation of a fraud vulnerability characterization and control plan, such as this FCC Guidance, could be one way for a supplier to demonstrate that they have implemented such a framework. Review of such documentation provided by the supplier should be undertaken by the auditor to verify that procedures were correctly carried out and that appropriate control measures were implemented.

After reviewing raw materials receiving, auditors should inspect the integrity of the process used by the supplier to transform raw materials into the finished ingredient purchased by the customer. For example, an auditor can do a physical walk-through of the entire processing chain to ensure that the supplier is actually processing their authentic raw materials into a finished ingredient, and not tampering with or substituting raw materials during their process chain. This should also be verified through a mass balance check by reviewing historical paperwork that documents the tonnage of raw materials received and finished product shipped. Discrepancies could indicate dilution or substitution during processing.

Additional anti-fraud measures during supplier audits could include the following:

- Perform a "should cost" analysis on an ingredient to estimate the expected cost to produce the ingredient based on market prices for raw materials and processing. This can be compared to the price being charged by the supplier and any significant cost deviations noted.
- Verify that a whistleblower policy has been implemented by the supplier.
- Conduct interviews with the supplier's staff to assess whether any suspicious or abnormal activities may be occurring.
- Collect and analyze food samples to verify supplier claims.

#### ***Illustrative Example—Sun Up Foods and the Secret Sugar Room***

From 1985 to 1990, Sun Up Foods, Inc., a processor and wholesaler of frozen juice concentrates in Kentucky, U.S., sold more than \$100,000,000 of "unsweetened" orange juice concentrate that was fraudulently diluted with 10%–20% beet medium invert sugar. Beet sugar was used in this incident instead of cane sugar to make detection of added sugar more difficult. The processing plants involved were cleverly designed and operated to conceal from inspectors the addition of beet sugar to the orange juice concentrate. An electrical control panel was uncovered in this incident (*Figure 2*) that was used as a secret door into a storage room where holding tanks were used to store the liquid beet sugar. Deliveries of the liquid beet sugar were often accepted under the cover of night when regular production and sales staff were not present. The liquid beet sugar was cleverly invoiced from a broker who billed Sun Up Foods to make it appear that they were buying "orange concentrate" instead of sugar. Additionally a stainless steel piping system was engineered to secretly connect the liquid beet sugar tanks to the seemingly legitimate processing lines by hiding them in the walls and making them appear like part of the sewage system (*Figure 3*). During inspections, the hidden line carrying sugar could be shut off and an outside pipe closed to conceal the sugar line hidden inside.

In this particular case, numerous pieces of evidence uncovered during the investigation were used to substantiate the fraudulent activities of Sun Up Foods, Inc. This included the equipment and structure of the facility designed to conceal the liquid beet sugar, records uncovering the purchase of the beet sugar, information provided by former employees of Sun Up Foods, and analytical testing results from a customer of Sun Up Foods suggesting that the product was adulterated with beet sugar. This example illustrates the ingenuity and extent of deception used to conceal fraudulent practices.

**Illustrative Example—Sun Up Foods and the Secret Sugar Room, (continued)**

Figure 2. Electrical control panel used as a secret access door to the hidden storage rooms with tanks for liquid beet sugar.



Figure 3. Hidden stainless steel pipe system used for moving liquid beet sugar from secret holding tanks to the processing line. The system was hidden inside a fake PVC drainage system.

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Lastly, audits can be used to assess the vulnerability during transportation of a finished ingredient consignment from a supplier to a facility. Use of a company's own haulers, or haulers with whom you have an established relationship can reduce vulnerability. The use of tamper-evident seals on primary packages or consignments is another measure that can help reduce vulnerabilities. For example, during the transport of a ground meat ingredient, the use of tamper-evident seals can be used, and delivery of consignments received with broken seals should be rejected.

- *Auditor qualifications*—Regardless of the type of audit conducted and the elements included, the proficiency of the auditor is critical. Documented education, training, and experience, are three key factors influencing the competency of auditors. Certification or accreditation of auditors by an independent body is one way to assess competencies.
- *Audit type*—Onsite facility audits are generally the most rigorous type of audits, especially for food fraud prevention. The mere presence of an auditor onsite can itself be a significant fraud deterrent. Other types of audits, such as paper audits, supplier staff interviews, and questionnaires can complement onsite facility audits, but cannot replace them.
- *Audit party*—Supplier audits can be carried out by a variety of parties. Customers themselves can directly audit their ingredient supplier's facility or facilities using their own qualified internal staff (called direct or second-party audits). This type of audit can significantly increase the rigor of an audit and is most likely to meet the customer's needs, especially for anti-fraud measures since the customer has the most vested interest in the integrity and safety of the finished ingredient, and will have direct access to the audit report. A potential limitation for direct audits is the use of internal staff auditors who are not qualified or who do not have competencies with anti-fraud measures. Audits can be conducted by an independent auditor that does not work for the supplier or customer (third-party audit). While wellqualified third-party audits can provide an equal level of rigor to direct audits, especially if the auditor has anti-fraud measure qualifications, third-party audits are generally considered less rigorous than direct audits. Advantages of third party over direct audits are typically economics and resources. Limitations of third-party audits may include the audit reports not addressing all the customer's needs. Audits can also be conducted under a formal or an informal shared audit program, where audit information is shared among several customers to reduce cost. A disadvantage of these audits, like third-party audits, is that the customer's needs may not be as well represented, and the customer is not typically present.
- *Onsite audit frequency*—More frequent onsite audits have the potential to decrease the vulnerability to a fraud occurrence at a supplier's facility merely based on the deterrent effect of auditors being physically present. But it typically is neither economical nor practical to conduct frequent audits. Frequency is based on the relationship established with the supplier and the history of conformance from previous audits (see sections on *Supplier relationship* and *History of supplier regulatory, quality or safety issues*). But for purposes of this Guidance, a rigorous frequency would be one that is proportional to fraud vulnerability.
- *Use of unannounced audits*—The introduction of periodic unannounced audits into an audit strategy may significantly increase the rigor of audits to deter fraud. Unannounced audits introduce an element of surprise that could be effective for uncovering fraud issues with unscrupulous suppliers. They can be performed inside or outside of regular business hours—each providing different types of information.

The above factors should be carefully considered and weighed when determining which vulnerability category best fits the scenario under evaluation. The following provides some explanation of the vulnerability category descriptors used in *Table 1*. These should be considered a general guideline for categorizing vulnerabilities for this factor, and should be tailored to your business practices and re-evaluated on a regular basis:

- *Low: Robust, onsite, with numerous anti-fraud measures*—This category describes a case where a robust and mature onsite audit strategy is in place that includes numerous anti-fraud measures.
- *Medium-Low: Robust, onsite, with limited anti-fraud measures*—This category describes a case where a robust and developing onsite audit strategy is in place that includes a limited number of anti-fraud measures.
- *Medium: Immature, onsite, with limited anti-fraud measures*—This category describes a case where an onsite audit strategy has been implemented, but is currently immature and contains limited anti-fraud measures.
- *Medium-High: Immature onsite audit strategy with no anti-fraud measures, or strategy with limited anti-fraud measures in development*—This category describes two potential scenarios; one where an onsite audit strategy with no anti-fraud has been implemented but is immature; or another scenario where an onsite audit strategy with limited anti-fraud measures is in development [supplier(s) have been notified and details regarding relevant audit factors are being assembled].
- *High: No onsite audits being used*—This category describes a case where no onsite audit strategy is being used nor is one being developed.

## SUPPLIER RELATIONSHIP

This factor is intended to describe the vulnerability of ingredients to food fraud based upon the relationship with the supplier. This factor builds on the *Supplier audits* factor and focuses on the actual relationship with a supplier. The assumption is that the closer the relationship between buyer and supplier, the more knowledge and confidence each party will have in each other. This knowledge and confidence is achieved through multiple activities experienced over a period of time.

The type of issues one encounters with a supplier including the severity of the problem and the time needed to resolve it should be considered. This helps with the identification of gaps in their processes and gaps in their depth of knowledge to resolve the problem.

An understanding of the legal structure of the supplier will assist with understanding potential issues. The liability and control may vary from country to country. This control may direct the amount of attention and resources that need to be focused on a product.

The supplier's readiness to share information on their supply chain and processes should be considered. This transparency will aid in downstream assessments. However, the supplier may be reluctant to share details beyond which are legally required

considering them proprietary. If this is the case, the supplier should have in place their own assessment of the risk potential and mitigation programs that would be shared.

The following provides some explanation of the vulnerability category descriptors used in *Table 1*. These should be considered a general guideline for categorizing vulnerabilities for this factor and should be tailored to your business practices and re-evaluated on a regular basis:

- *Low: Trusted Supplier*—This supplier is one with whom the buyer has established a partnership-type arrangement. The supplier and ingredient were on-boarded many years ago, and a high degree of confidence has been established through a long positive business relationship history, high degree of transparency and/or through testing programs. There is sharing of key information and expectations, including an understanding of key needs and controls in the both buyer and supplier processes. There is an open and responsive sharing of market intelligence and open communication on what each company is doing to protect its products. For example, if information is presented to the supplier suggesting that someone may be adulterating an ingredient from a specific country, the supplier responds that they are aware of the problem and are not sourcing from that region; that they have a vertically integrated process which avoids these issues; or that specific testing is occurring to identify any threats. This helps to assure that issues which arise are inconsequential and can be quickly resolved.
- *Medium-Low: Trusted supplier, new ingredient*—This category of supplier fulfills all the requirements of a "Trusted Supplier," with the exception that the buyer only recently began purchasing this particular ingredient from the supplier. A high degree of confidence in the supplier has already been established through purchases of other ingredients but not the one under consideration. You have on-boarded the new ingredient and implemented a testing program if required.
- *Medium: Established supplier, some relationship*—A short history of business with the supplier exists, the supplier is well respected in their market with a solid reputation, and no significant issues have been identified through discussions with other customers or public information (see *History of supplier regulatory, quality or safety issues*). The supplier has been on-boarded and a tiered testing program has been implemented.
- *Medium-High: Established supplier, no relationship*—The supplier is respected in the marketplace, has a solid reputation, and has been on-boarded; however, a business relationship and history has not yet been established.
- *High: Unestablished supplier, No relationship*—This is often a new supplier, with whom the buyer does not have any history or general industry knowledge of the supplier. The supplier may be new to a given industry or a startup firm. Relationship time frames and issue ratings should be developed based on purchaser business practices and re-evaluated on a regular basis.

On-boarding is a formal protocol for new suppliers and ingredients that typically includes a thorough background review, risk assessment, and a pre-purchase testing of the ingredient. This typically extends into a verification testing program for the supplier/product combination.

Testing is often an element in establishing the relationship and confidence in a supplier. Employment of a tiered testing regime may be warranted. Each lot (batch) would be tested for a specified period, followed by skip-lot testing with an eventual move to audit testing. Criteria for moving from individual lot testing to audit testing is directly aligned with "no issue" findings. If issues do arise, testing would revert to the lower level and full root cause and resolution protocols would be required. The testing plan would include suspect adulterants as well as key standard indicator attributes. Variance from the norm, as stated in *Testing frequency*, can be a key indicator in helping substantiate a supplier's status.

#### **Illustrative Example—Beech-Nut**

In 1988, two executives of Beech-Nut Nutrition Corporation, a company that controlled 15% of the market share in baby foods in the early 1980s, were found guilty of violating federal laws. Beech-Nut distributed adulterated apple juice marketed for consumption by infants. Although labeled as pure apple juice, the contents included water, beet sugar, cane sugar syrup, corn syrup, water, malic acid, artificial coloring, and artificial flavoring. This adulterated juice was sold over a period of at least 5 years.

Beech-Nut was under considerable financial pressure and began purchasing apple juice concentrate at belowmarket price from a different supplier—Interjuice Trading Corporation—in 1977. Estimates indicated that apple juice products accounted for about 30% of Beech-Nut sales and the adulterated concentrate was purchased for 20%-25% below market value, resulting in substantial savings.

Based on the cost of the concentrate and adulteration "rumors" in the juice market, analytical chemists within Beech-Nut began testing the concentrate for purity and quality. The chemists became suspicious of the concentrate as early as 1978, and by 1981 Beech-Nut senior management was informed by the director of research and development that the concentrate was undeniably fraudulent. However, no action was taken and the director of research and development resigned in 1982.

The Processed Apples Institute (PAI), a trade organization, simultaneously conducted its own investigation into Interjuice. A private investigator hired by PAI informed Beech-Nut in 1982 that the Interjuice concentrate was fraudulent and that a

**Illustrative Example—Beech-Nut, (continued)**

group of companies was planning to bring suit against the company. Beech-Nut executives did not cooperate with the PAI investigation or join the lawsuit. However, Beech-Nut did finally cease purchasing concentrate from Interjuice. The Interjuice operation was halted shortly afterwards by the PAI lawsuit.

After receiving incontrovertible evidence of fraud and ongoing investigations by PAI and FDA, Beech-Nut did not immediately issue a recall of products produced with the fraudulent concentrate. Facing estimated losses of \$3.5 million, Beech-Nut attempted to keep fraudulent juice products on the market as long as possible, even moving 300,000 cases of fraudulent juice across state lines to avoid seizure. Mixed Beech-Nut juice products containing the fraudulent concentrate were sold until 1983.

This example illustrates the importance of establishing a supplier relationship over time and verifying that relationship through an appropriate on-boarding and testing program. In this case, unfortunately, complicity and over-confidence on the part of senior management also played a role in perpetuation of the fraud.

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**HISTORY OF SUPPLIER REGULATORY, QUALITY OR SAFETY ISSUES**

This factor is intended to estimate the vulnerability to fraud of a food ingredient due to the lack of sufficient controls by a supplier. The idea is that there is a correlation between a supplier's ability to control quality and food safety factors, and their history of non-compliance with regulations, and the potential to allow fraudulent practices to occur in their operations. Sources of information to carry out such an assessment should include direct knowledge and public records.<sup>4</sup> Examples of sources for public records are provided in the *Information Resources* section at the end of this Guidance. Direct knowledge can include food safety or compliance information resulting from third-party audits, onsite visits conducted by the purchasing company, or results from ingredient QA testing conducted by the purchaser. Public records can include on-going and historical alerts by regulatory agencies, recalls, or other information disseminated by governmental agencies responsible for overseeing the food supply.

Both the frequency and the extent of any quality or safety issues should be considered as an indicator of whether or not adequate controls are generally in place, and how quickly and completely any issues are resolved. Although these quality and safety issues may be more related to food safety threats (such as microbiological contamination) than food fraud, they can still shed light on the vulnerability of a supplier to fraudulent practices based on an overall lack of adequate controls, as in the case of the illustrative example below.

The following provides some explanation of the vulnerability category descriptors used in *Table 1*. These should be considered a general guideline for categorizing vulnerabilities for this factor and should be tailored to your business practices and re-evaluated on a regular basis:

- *Low: No known issues*—The buyer has no direct knowledge of quality or safety issues on the part of the supplier, and a review of public records did not identify any. Audits indicate very robust food safety and quality control systems that meet or exceed peer company systems.
- *Medium-Low: Few minor issues which were quickly resolved*—Very few and/or minor issues that were adequately resolved by the supplier within a reasonable time frame. Food safety and quality issues are either relatively infrequent but rapidly and sufficiently addressed or are very infrequent and aggressively addressed, especially if they pose real public health or product performance risks.
- *Medium: Recurrent issues or issues which were not resolved quickly or adequately*—Persistent quality or safety issues or those which were not resolved adequately. Firms that respond to food safety or quality issues but fail to do so consistently without additional failures would indicate a basic capability problem that could make the supplier more susceptible to EMA even if it does not suggest that they would knowingly do so.
- *Medium-High: Multiple persistent issues indicating lack of responsiveness to concerns or some evidence that adequate controls are not in place*—This could include examples where the time to report or correct food safety or quality concerns compares poorly with the purchasing company's expectations or supplier peer group performance. Evidence of not notifying the purchaser when an enforcement action has been taken by a regulatory authority would also indicate a lack of responsiveness.
- *High: Numerous uncorrected/continuing issues or undeniable evidence that the extent of quality or safety concerns is unacceptable*—This would be evidenced by repeated citations for the same basic failure food safety or quality standards in audits, regulatory agency enforcement actions or repeated rejections for the same problem. A consistent pattern of not notifying

<sup>4</sup> Examples of Public Records on Food Safety and Integrity are provided in the *Information Resources* section.

the purchaser when an enforcement action has been taken by a regulatory authority would also indicate an unacceptable lack of control or awareness of its importance.

This factor has very close ties to the *Supplier relationship*. Care should be taken to determine under which factor issues should be classified. As with the *Supplier relationship*, issue ratings should be developed based on current business practices and re-evaluated on a regular basis.

#### **Illustrative Example—Peanut Corporation of America**

In 2008, a large, multi-state foodborne outbreak investigation involving illnesses caused by *Salmonella typhimurium* implicated peanut products produced by the Peanut Corporation of America (PCA). While this example does not involve the fraudulent addition of non-authentic substances, it illustrates a connection between persistent quality and safety issues and fraudulent practices. *Salmonella* was not intentionally introduced into the peanut products; however, investigations revealed prior unreported knowledge of microbial contamination on the part of PCA executives. At least 700 people were sickened during the outbreak, and four PCA executives were charged with the intentional "introduction of adulterated food into interstate commerce with intent to defraud or mislead." The fraud occurred over a period of at least 5 years.

Court documents related to a plea agreement on the part of the operations manager documented evidence of various types of fraud. Many lots of peanut products were intentionally shipped to customers after microbiological testing conducted at contract laboratories indicated the presence of *Salmonella* or coliform levels above those indicated as acceptable per customer specifications. PCA produced and provided to customers fraudulent certificates of analysis that reported either misleading, incomplete, or false testing results. Upon receipt of positive confirmation of *Salmonella* contamination of peanut products that had already been shipped, PCA intentionally neglected to inform their customers of the contamination so that they could take appropriate measures. PCA executives and employees misrepresented the location of production of certain peanut products provided to customers, and in some instances misrepresented the country of origin of the peanuts. Finally, PCA shipped peanut products that had previously been rejected by customers for not meeting specifications or containing foreign material.

Reports suggest that PCA did have a history of quality and safety issues before this incident from private audits findings and from inspection findings from state authorities. For example, one buyer refused to purchase product from PCA based on failed audits of PCA's processing facilities dating back to the 1980s. In another example, a customer rejected PCA as a supplier based on sanitary issues identified through external audits in 2002–2006. Lastly, inspection reports from State authorities showed a history of inspection violations, including at least eight consecutive inspections from November 2005 to August 2007, all with documented violations but none that were individually egregious enough to take enforcement action. This illustrative example points to the potential role that knowledge of a supplier's safety and quality issues, if available, in conjunction with assessments against other vulnerability factors, could play in identifying food fraud vulnerabilities.

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### **SUSCEPTIBILITY OF QUALITY ASSURANCE (QA) METHODS AND SPECIFICATIONS**

This factor is intended to describe the vulnerability of ingredients to food fraud based on a lack of sufficient analytical methods and specifications. A simple approach for making this estimation is to determine how well a method and specification or suite of methods and specifications characterizes an ingredient and how effectively the combination of method(s) and specification(s) will exclude or detection adulteration. This can be done by considering two factors:

1. *Compositional difficulties*—The compositional complexity (very simple to very complex ingredient) and accepted variability (highly consistent to highly variable) of the ingredient or components thereof. Typically the more complex and variable an ingredient, the more susceptible it is to fraud because of the inherent difficulties in characterizing it analytically.
2. *Testing power*—How comprehensively and precisely the employed QA methods and specifications assess the ingredient's composition (i.e. authenticate the ingredient) and can detect or exclude adulteration. Factors to consider when making this assessment depend upon the type of testing approach used:
  - o When using traditional targeted analytical methods and specifications to measure the composition of a food ingredient (e.g. compendial tests used in FCC monographs), this can be assessed with regard to the number of analytes measured or orthogonal measurements made, the associated specificities of the methods used, and how tight the specification ranges are.
  - o When using non-targeted methods (e.g. spectroscopic fingerprinting methods aimed at measuring the similarity or dissimilarity of an ingredient compared to a reference fingerprint or library of fingerprints) as a strategy to screen raw materials, this can be assessed by considering performance characteristics relevant to non-targeted methods such as the

false-negatives rate of the method at the desired sensitivity level. Factors affecting the false-negative rate include the sufficiency of the samples used to calibrate the method relative to the universe of authentic samples, the variability of the method itself relative to the specification range, and the natural variability inherent in the universe of the authentic ingredient. [NOTE—False-positives, while perhaps seeming to be a non-issue from detecting food fraud, are undesirable in as much as faith in the nontargeted method being employed will soon be lost and the use of the method discontinued.]

- o While the use of targeted adulterant detection methods to measure or screen known adulterants (e.g. LCMS/ MS to measure melamine in wheat gluten) does improve the *Testing power*, these types of tests only detect what is tested for and thus cannot detect unknown adulterants. In cases where targeted adulteration detection methods are used, the improvement in *Testing power* should be based on the number of adulterants tested and the sensitivity of the measurements.

It should be noted that for some specific ingredient uses, the functional performance of the ingredient can be a deterrent to economic adulteration. In other words, if an ingredient must perform in a certain manner and an added adulterant or lack of an authentic component affects that performance, the likelihood of detection of the adulteration is significantly increased.

Conceptually, the *Compositional difficulties* of an ingredient (factor 1) should be at least balanced or outweighed by the *Testing power* of the methods and specifications (factor 2) to provide a high degree of confidence in the authenticity (and hence low vulnerability) of the ingredient. Careful consideration of both factors and their relative balance can provide a good estimation of the fraud vulnerability contribution originating from QA methods and specifications (see *Figure 4*).

The following provides some explanation of the vulnerability category descriptors used in *Table 1*. These should be considered a general guideline for categorizing vulnerabilities for this factor and should be tailored to your business practices and re-evaluated on a regular basis:

- *Low*—Non-targeted method(s) (and/or combination of multiple orthogonal targeted methods for composition) in conjunction with specifications are more than sufficiently powerful relative to the compositional difficulties of the ingredient to characterize the ingredient and confidently exclude or detect both known and potentially unknown adulterants.
- *Medium-Low*—Non-targeted method(s) (and/or combination of multiple orthogonal targeted methods for composition) in conjunction with specifications are sufficiently powerful relative to the compositional difficulties of the ingredient to characterize the ingredient; but some limited examples can be identified where non-targeted and compositional methods and specifications may not be able to detect or exclude adulterants, and targeted tests are used to detect those adulterants.
- *Medium*—Non-targeted method(s) (and/or combination of multiple orthogonal targeted methods for composition) in conjunction with specifications are moderately powerful to characterize the composition of the ingredient; and some limited examples can be identified where non-targeted and compositional methods and specifications may not be able to detect or exclude adulterants, and targeted methods are NOT available or NOT used to test for those adulterants.
- *Medium-High*—Neither non-targeted nor targeted adulterant detection methods are used; and limited targeted methods for composition along with specifications are used and are moderately powerful relative to the compositional difficulties of the ingredient to characterize the ingredient.
- *High*—Neither non-targeted nor targeted adulterant detection methods are used; and targeted methods for composition along with specifications are used but have low power relative to the compositional difficulties of the ingredient to characterize the ingredient; and examples can be identified where adulterants could be added and pass the tests used.

Below are some illustrative examples to demonstrate this concept.

*Example 1. Whey Protein Ingredients*

Whey ingredients are a combination of lactose, several proteins, and several minerals, and therefore they would be classified as very complex. The composition of whey protein concentrates would be considered highly variable because of the wide ranges of protein, lactose, and minerals. A powdered whey protein concentrate specification comprised solely of a total (crude) protein level of 25.0% to 89.9% as determined with the Kjeldahl nitrogen method would be categorized as highly vulnerable to adulteration given the complexity of the ingredient and the variability allowed by the specification. Most importantly, the lack of selectivity and specificity of Kjeldahl nitrogen methodology for protein nitrogen in general (and whey protein in particular) dramatically increases the vulnerability. Whey protein isolate with a crude protein specification of NLT 90% would also be categorized as high vulnerability if that specification is based on the Kjeldahl nitrogen method, because the lack of selectivity and specificity of this method could fail to identify non-whey protein nitrogen adulterants such as vegetable proteins or other highly nitrogenous compounds (e.g., melamine, urea, cyanuric acid). An alternative suite of methods and specifications that includes an infrared identification test, an amino acid fingerprinting identification test, a nontargeted nonprotein nitrogen test (See *Appendix XVI, Nonprotein Nitrogen Determination for Skim Milk Powder and Nonfat Dry Milk* as an example) in addition to a traditional Kjeldahl protein method to address the lack of specificity of the latter, an HPLC method for lactose coupled with a relevant lactose specification, and a weight loss on drying test coupled with a specification of NMT 6% would move the QA method and specification combination from the highly vulnerable to the medium-low or low vulnerability category.

*Example 2. Fruit Juice Concentrate*

A fruit juice concentrate purchased on the basis of methods and specifications for only Brix, pH, and visual color would be highly vulnerable to adulteration as shown in *Table 2*. Utilizing additional tests and specifications with increased selectivity and specificity will decrease the vulnerability to economic adulteration.



Ingredient	Compositional Difficulties	÷ Testing Power	Vulnerability
Rebaudioside A (high purity steviol glycoside)	<ul style="list-style-type: none"> <li>• Simple</li> <li>• Not variable</li> </ul>	<ul style="list-style-type: none"> <li>• 2 strong tests (IR and HPLC) plus screening for other sweeteners</li> </ul>	<p>Low</p>
Fruit juice concentrate	<ul style="list-style-type: none"> <li>• Complex</li> <li>• Variable</li> </ul>	<ul style="list-style-type: none"> <li>• 2 weak tests (%Brix and Hunter color)</li> </ul>	<p>High</p>
Fruit juice concentrate	<ul style="list-style-type: none"> <li>• Complex</li> <li>• Variable</li> </ul>	<ul style="list-style-type: none"> <li>• 7 tests including %Brix, pH, visual color, sugars profile, titratable acidity, organic acids, UV</li> </ul>	<p>Medium</p>
Fluid milk	<ul style="list-style-type: none"> <li>• Complex</li> <li>• Variable</li> </ul>	<ul style="list-style-type: none"> <li>• Percentages fat, protein, and solids-non-fat, all by methods such as Kjeldahl with low selectivity</li> </ul>	<p>High</p>
Fluid milk	<ul style="list-style-type: none"> <li>• Complex</li> <li>• Variable</li> </ul>	<ul style="list-style-type: none"> <li>• Compositional testing and validated non-targeted screening methods, both by IR</li> </ul>	<p>Low</p>

Figure 4. Examples of Analytical Method Susceptibility.

**Table 2. Example QA Methods and Specs Vulnerability Scenarios Based on Combinations of Methods Used**

Low	Medium Low	Medium	Medium High	High
BRIX pH Visual color Sugars and sugar alcohols profile (including sugar ratios) Titratable acidity Organic acids (including ratios) UV-visible spectrometry Amino acids profile Mineral profile (including ratios) C <sup>13</sup> /C <sup>12</sup> ratio O <sup>18</sup> /O <sup>16</sup> ratio Pigment profile Artificial sweeteners	BRIX pH Visual color Sugars and sugar alcohols profile (including sugar ratios) Titratable acidity Organic acids (including ratios) UV-visible spectrometry Amino acids profile Mineral profile (including ratios)	BRIX pH Visual color Sugars and sugar alcohols profile (including sugar ratios) Titratable acidity Organic acids (including ratios) UV-visible spectrometry	BRIX pH Visual color Sugars and sugar alcohols profile (including sugar ratios) Titratable acidity	BRIX pH Visual color

Vulnerability can be most effectively reduced using a combination of test methods. In this example, the selectivity and specificity of the tests increases as one moves from right to left in the table. [NOTE—Although one could argue that one only need to run the most specific test or tests in the left most column, in practice, analysts in the fraud detection arena find that developing an "authentic fingerprint" of characteristic values by a number of tests on authentic samples to use for comparison with the characteristics of a sample in question using most or all of the tests is the most effective means of detecting adulteration present in a sample.]

Additional examples regarding the vulnerability of food ingredients to fraudulent adulteration based on analytical methods and specification can be found in the "EMA Susceptibility" database, available at [www.FoodSHIELD.org](http://www.FoodSHIELD.org) (registration required). This database is a compilation of evaluations of monographs from the 7th edition of the *Food Chemicals Codex* with respect to EMA susceptibility.<sup>5</sup> The evaluations were conducted based on the factors described above, including the complexity and variability of the food ingredients, the selectivity and specificity of the associated analytical methodologies, and the function of the ingredient in the final food product. The results of those evaluations were used to group ingredients into EMA susceptibility categories. Organizations interested in evaluating the vulnerability of sourced ingredients can use this database as a starting point to consider an ingredient's attributes and the associated analytical methodologies that may increase or decrease this vulnerability.

**TESTING FREQUENCY**

This factor is intended to describe the vulnerability of ingredients to food fraud based on application and frequency of laboratory testing of the ingredients. In preventative food safety plans like Hazard Analysis Critical Control Points (HACCP), testing is considered as verification that the plan is working and it should be considered to be the same in programs addressing food fraud.

The vulnerability indicated by the frequency of testing is thus a continuum, for example:

- The vulnerability to fraud is probably minimal when every lot that is purchased is supported by a Certificate of Analysis (COA), from the supplier, a buyer testing program, from a supplier that is trusted, and when the audit programs are robust.
- The vulnerability increases when the buyer depends on the COA, but does not require a specific COA for every lot purchased and does not conduct any verification of the test results.
- The highest degree of vulnerability occurs when there is no testing done, either through a COA or by the buyer. Even if the supplier is trusted and the audit programs are robust, testing needs to be done in order to provide verification that the quality systems are working.

Some may consider buyer-conducted testing to be redundant when the supplier provides a COA. However, independent testing provides not only some assurance of the accuracy of the COA, but also assurance that nothing "unusual" has happened to the ingredient between the time of analysis by the supplier and the time of receipt of the ingredient by the buyer. Buyer conducted testing is inherently validation of the analytical results provided by the supplier in a COA. However a key consideration is whether the testing is done in a laboratory that is certified to conduct the tests and whether validated methods are available and used. This is done not only for purpose of detecting adulteration but is also frequently done to detect quality related issues that may arise between the time of purchase of an ingredient and the time when it is actually received by the buyer.

<sup>5</sup> The evaluations are based on information from the Food Chemicals Codex 7th Ed., 3rd Supplement, published on 8/31/2011, and does not necessarily reflect the information in the most recent publication.

Table 3 provides some explanation of the vulnerability category descriptors used in Table 1. These should be considered a general guideline for categorizing vulnerabilities for this factor based upon a company's current testing program and should be tailored to your business practices and re-evaluated on a regular basis: In Table 3,  $S_t$  and  $S_d$  represent *trusted* and *developing* supplier, and  $A_r$  and  $A_i$  represent a *robust* audit program or *immature* audit program. For the purposes of this table, the concept of trusted and developing supplier is an amalgam of the previous factors previously discussed in the section on *Supplier relationship*. A *trusted* supplier is one with whom you have a partnership-type arrangement, a high degree of confidence based upon a long positive history, and the sharing of key information relevant to the prevention of food fraud. All other supplier relationships are categorized as *developing*, i.e., working toward establishing a trusted relationship. As explained previously, the elements of a *robust* audit program includes considerations of anti-fraud measures as part of the audit that is conducted by experienced auditors in the field at the most appropriate frequencies and times.

**Table 3. Vulnerability Categories and Characteristics Relating to Testing Frequency**

Low	Medium-Low	Medium	Medium-High	High
$S_t A_r I$ and COA	$S_t A_r R$ and COA	$S_d A_i M-R$ and COA	$S_d A_i$ , COA only	$S_d A_i$ , no testing or COA
With a trusted supplier and an audit process that is robust, testing can provide verification that all processes are working as planned. Frequent testing provides verification that the processes are working when the methods are capable of detecting "suspicious" activity, and serves as both deterrence and early warning for follow up.	Routine testing provides limited assurance that the processes are working, and provides limited deterrence but does not provide enough information to spot trends.	In this scenario testing may be performed with high frequency in an attempt to overcome the shortcomings of Supplier development and the development of Audit processes. High frequency testing in this scenario provides assurance about all lots of ingredients used in production. The high frequency of testing may allow for the spotting of trends or suspicious activity. Because of the heavy emphasis on testing to mitigate vulnerability, gaps due to limitations of methodology rise in importance.	While this is better than no testing, testing in this scenario provides assurance about the tested lot and some benefit of deterrence. Very limited information will be available to spot suspicious activity.	In this scenario the purchaser has no assurance of identity or purity of the ingredient

$S_t$  stands for *trusted* supplier (see section on *Supplier relationship*)  
 $S_d$  stands for *developing* supplier (has not achieved trusted supplier status, see section on *Supplier relationship*)  
 $A_r$  stands for *robust* audit program  
 $A_i$  stands for *immature* audit program  
 $I$  stands for intensive testing frequency  
 $R$  stands for routine testing frequency  
 $M$  stands for minimal testing frequency  
 $M-R$  stands for minimal to routine testing frequency  
 COA stands for certificate of analysis

Some examples of considerations that go into assessing the vulnerability addressed by the testing program include:

- Do routine tests or alerts from the industry indicate that there is a need for more intensive testing? For example, if tests for total volatile oil content are out of line with historical or expected results, that might highlight a need for additional testing, including tests that might be more sensitive to detect adulteration. Spices are routinely tested for volatile oil; if the volatile oil range from a specific region changes significantly, it would be wise to conduct more detailed testing. Changes in total oil content might indicate the addition of spice extracts, i.e. spent spice material (material from which the oil has been removed).

- If the material is accepted on a COA, what is the confidence in the laboratory doing the testing, and what is the confidence that the sample being tested by the laboratory accurately represents the ingredient being purchased by the buyer? Is the laboratory certified to conduct the analysis? Are results of proficiency testing available to review? Is the sampling procedure sound and is the "Chain of Custody" documented? What programs are in place to verify the COA?
- Have there been any changes in price; is there geopolitical unrest in the source area; has there been any significant environmental issue in the source region (see sections on *Economic anomalies* and *Geopolitical considerations*)?

A final consideration is whether the testing program is well integrated with purchasing, audit, and quality operations. Often, suspicions are detected in one operational unit ahead of the others. Testing frequency should be informed by information from the other operational areas, and those areas should be informed by test results.

### GEOPOLITICAL CONSIDERATIONS

This factor is intended to describe the vulnerability of ingredients to food fraud based on a lack of food control system/food safety regulatory/enforcement frameworks and other geopolitical factors that ensure food safety and sustainability and prevent food fraud in any region of the world. The *Geopolitical considerations* factor attempts to articulate circumstances in which, based on factual evidence of adulteration history, economics, complexity of the food supply chain, demographics, and stage of development, food ingredients may be more susceptible to fraud. The factor is integrally tied to the number of raw materials (or components of ingredients) used to produce the finished ingredient, the geographic sources of the ingredients, and the number of geographic regions through which the ingredients and components of those ingredients may transit. It is critical to note that this Guidance has no intention to focus on or disparage any specific country/region of the world. It is also important to consider not only the immediate geographical source of the ingredient, but also any regions where the ingredient or component of the ingredient may have been sourced, transited and/or manipulated. This includes differences in the import requirements and tariff restrictions in the exporting country relative to potential original source countries.

Food fraud may be more likely to occur where several factors/conditions operate in combination. Such factors/conditions may include:

- The level of development of the food control system/food safety regulatory and enforcement framework in a country/region. It is likely that there could be a greater food fraud vulnerability in countries/regions where food control systems/food safety regulatory and enforcement frameworks are not well advanced. At least one resource is currently available to provide this type of information by region.<sup>6</sup>
- The prevalence of corruption and organized crime in a particular region. The more prevalent corruption and organized crime are in a region, the more plausible it is that a fraudulent ingredient will pass through any food control systems in place in the region. Several resources are currently available to provide corruption and organized crime indices by region, along with crime threats assessments.<sup>7</sup>
- The stage of general development of the country/region may also increase the plausibility of food fraud. In some developing countries, there may be other more pressing political imperatives, such as food security, that take priority over developing advanced food control systems/food safety regulatory and enforcement frameworks.
- Gross Domestic Product (GDP). The GDP correlates highly with overall food security in a country and the ability of a people to afford food. A lower GDP may also be associated with increased motivation to sell foods at lower prices while still generating a profit.
- Number of countries/regions/places through which the original ingredient has been processed or transited. The more steps through which an ingredient has been put through, the more opportunity there has been for fraudulent activity on the ingredient. Geopolitical consideration should be considered for both the origins of each raw material used as components of the finished ingredient and each region through which the component of the ingredient has been transited.
- System disruptions in a region or country that may limit supply availability and increase the vulnerability to food fraud. Natural system disruptions include incidents such as drought, hard freezes, and floods.
- System disruptions may also be man-made: terrorism and political instability may decrease the ability of a region's food safety net to protect the food supply against food fraud. Issues observed in regions of geopolitical unrest include: sabotage and terrorism, strikes, riots and/or civil commotion, malicious damage, insurrection, revolution and rebellion, mutiny and/or coup d'état, war, and/or civil war. Analytical tools and maps have been developed by companies that specialize in risk management, allowing analysis of the history of countries/regions, and comparison of different countries/regions against each other over time and with respect to different risk icons.<sup>8</sup>
- Cultural/business ethics considerations are also likely to make a contribution to food fraud vulnerability. Many different cultures across the regions of the world mean that historically and culturally, attitudes/tolerance to corruption, including food fraud, are diverse. What may be regarded as a corrupt business practice/ethic in one region of the world is not necessarily

<sup>6</sup> Regional food safety indices are one component used to compute the Economist Intelligence Unit (EIU) Global Food Security Index. Indices are available at <http://foodsecurityindex.eiu.com/>.

<sup>7</sup> Transparency International's Corruption Perception Indices available at <http://cpi.transparency.org/cpi2013/results/#myAnchor1> and at <http://www.transparency.org/country>. Another resource on the composite organized crime index is Van Dijk, Jan. "Mafia markers: assessing organized crime and its impact upon societies." *Trends in Organized Crime* 10.4 (2007): 39–56. Available as an open source article at: <http://link.springer.com/article/10.1007/s12117-007-9013-x#page-1>. A transnational crime threats assessment is available from the United Nations Office on Drugs and Crime at <https://www.unodc.org/unodc/en/data-and-analysis/TOC-threat-assessments.html>

<sup>8</sup> One example is the Political Risk Map and Terrorism Risk Map hosted by Aon at [www.aon.com/terrorismmap](http://www.aon.com/terrorismmap)

the same in another, and in fact may be regarded as the normal business procedure. Cultural/business ethics considerations are intimately associated with relevant indexes for fraud, regions of political unrest, and many of the other factors above.

From the perspective of geopolitical consideration, the optimal scenario would be one in which a single ingredient product is sourced from within a country that has a relatively low population density, a high GDP, a strong food safety system, no corruption, and where the food does not transit through another country prior to reaching the location in which it will be sold. A higher level of vulnerability would be associated with multi-ingredient foods for which each ingredient may be sourced from a different country, some with many of the vulnerability factors listed above, and where corruption/crime may be endemic and where some or all of the ingredients in the final product may have transited through several countries which may have varying levels of the vulnerabilities listed above.

The following provides some guidance to the vulnerability category descriptors used in *Table 1*. These should be considered only as a general guideline for categorizing vulnerabilities for this factor and should be tailored to your business practices and re-evaluated on a regular basis:

- *Low*—Single component ingredient sourced from a single geographic origin of low concern: Ingredient is a single component that has been sourced from a single geographic origin that is considered to have low vulnerability to food fraud. Such a region could be described by a combination of factors, including but not limited to: political stability; developed region of stable population size and growth, with a relatively low level of poverty and good GDP rating; source region places a high priority on a well-developed food control system/regulatory and enforcement framework; little or no history of instances of food fraud, and with a low prevalence of organized crime and corruption (e.g., as indicated by relevant indices). It should be noted that even if all of these indicators would indicate a lower potential for food fraud, it does not preclude the possibility of food fraud: e.g., "Horsegate" in Europe in 2013 (fraudulent adulteration or substitution of ground beef with horse meat) which likely would have been detected through other factors in this Guidance.
- *Low-Medium*—Ingredient is composed of two to several components sourced from geographic origin(s) of low concern: Ingredient is composed of multiple components that may have been sourced from several geographic origins that are all considered to have low vulnerability to food fraud as described in the "low susceptibility" category. None of the components would have originated from or transited through a region considered to have a medium vulnerability to food fraud but there have been additional opportunities for food fraud to take place over and above the low category.
- *Medium*—Ingredient with a single or few components that have originated or transited through a region or regions with some geopolitical concerns: A geographic origin considered to have medium vulnerability to food fraud could be described as being in between the two extremes (low, high), where a combination of factors might include a transition from developing to developed economy, occasional political and social unrest, but where some priority is given to substantial improvement in the established food control system/food safety regulatory and enforcement framework, a population/GDP/political system leading to a medium level of poverty, and where organized crime and corruption does exist to a medium extent (again based on indices), leading to some instances of food fraud, but where such fraud is also a priority that is seriously addressed.
- *Medium-High*—Ingredient is comprised of several components; some originated or transited through regions with some geopolitical concerns: Ingredient has several components, many of which have originated in or transited through one or more countries or regions that experience some of the vulnerabilities listed above. None of the components would have originated from or transited through a region considered to be highly vulnerable to food fraud.
- *High*—One or more components of the ingredient originated or transited through one or more regions exhibiting several characteristics of geopolitical concern: Ingredient contains one or many components, any of which may have originated in a region that experiences many of the vulnerabilities listed above, or one or more of the ingredient's components have transited through such a region. A geographic origin considered to have high vulnerability to food fraud might be described as still developing, possibly politically and socially unstable or at least have the potential to be so based on history, with a large and increasing population (unstable growth compared to GDP and poverty measures; government and social systems unable to cope leading to high poverty rate), where there is a low priority placed by government on a well advanced food control system/food safety regulatory and enforcement framework (due to many other social and political priorities), and consequently a high prevalence of organized crime and corruption and a substantial history of occurrence of food fraud instances.

#### ***Illustrative Example—Chili Powder from India Adulterated with Sudan I Found in United Kingdom Worcestershire Sauce***

The following example is meant to illustrate some of the geopolitical considerations that may come into play when sourcing ingredients as well as the importance of looking at not only the country of origin for the immediate ingredient but also the origins and transiting countries/regions for any of the components of ingredients or verification that the supplier of the ingredient has done this work. No inference should be drawn from this example about the countries mentioned, as this particular example was chosen solely on the basis of having published literature available that addressed the subject of geopolitical factors.

In May 2003, chili powder in the European Union was found to be adulterated with the dye Sudan I. The chili powder originated from India. Sudan I is a dye that is used to color leather and textiles but is not allowed in foods. Sudan I has been

**Illustrative Example—Chili Powder from India Adulterated with Sudan I Found in United Kingdom Worcestershire Sauce, (continued)**

classified as a category 3 carcinogen (suspected human carcinogenic) by the International Agency for Research on Cancer. Based on this incident and several other adulterations of various ingredients from India with various non-permitted colors, several controls were brought into place in both the European Union and in India. Despite these controls, in 2005, Sudan I was found in Worcestershire sauce produced in the UK. It was determined that the source of the Sudan I was from adulterated chili powder imported by the Worcestershire sauce manufacturer from India in 2002. Because of the aging process for Worcestershire sauce, the sauce did not end up on the market until 2004–2005, long after the original incident had ended. The finding of the Sudan I in the Worcestershire sauce resulted in a huge number of recalls across Europe and around the world for both of the sauce itself (shipped to at least 15 countries on two continents) and the foods in which the sauce had been used as an ingredient (see Figure 5), highlighting the need to know the history of not only ingredients, but also the components of the ingredients. In the UK alone, over 600 products were recalled over eight months with an estimated cost of £200 million.

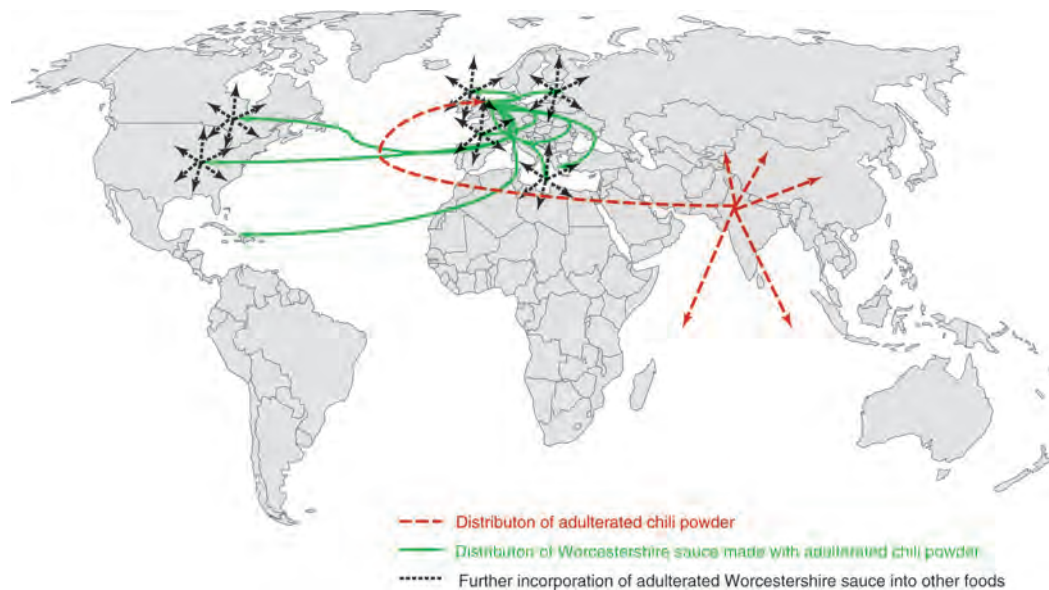


Figure 5. Partial map of distributed chili powder adulterated with Sudan I, which in turn, was incorporated and distributed in Worcestershire sauce in 2005.

The Government of India has published warnings for common adulterants in foods sold in India including the use of unapproved colors in spices. Many of the reasons given for food adulteration in the country are geopolitical in nature. Some of the reasons identified in the media and peer-reviewed literature from the region are: that many consumers cannot afford branded foods that may have more QA controls, or that such foods are simply not available in many locations. In addition, several authors claim that although the government had appropriate legislation in place, there was little regulatory activity at that time at the ground level to monitor or detect adulterated foods in the market or to punish the culprits. Another reason presented by literature from the region is that, like many developing countries, India is more focused on resolving food security issues. The Government of India has asserted on its website that adulteration of food for financial gain is common in developing countries, but that if adequate precautions are taken by the consumer at the time of purchase of the product they can avoid consuming these foods. This of course places the burden of detecting adulteration on the buyer. This example, while not intended to point to any weaknesses in one particular region, highlights the intricacies of knowing what is going on in both the places that an ingredient is imported from and also where the components of that ingredient may have been derived.

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## FRAUD HISTORY

This factor is intended to generally characterize the potential for fraud in an ingredient based on the pattern and history of reported fraud occurrences for that ingredient, and the validity or degree of evidence available to substantiate the legitimacy of the fraud reports.

The history of fraud for a particular ingredient can be indicative of future vulnerabilities. Just as the legitimate science of food sourcing, processing, and safety are shared within the food science community, so too are illegitimate practices often shared amongst the perpetrators of food fraud such as supply chain vulnerabilities and existing and new adulterants that can be used to exploit those vulnerabilities. This sharing of information can lead to the recurrence of the same fraud issue over time if countermeasures such as detection methods cannot be developed or are not used by ingredient purchasers. In other cases where countermeasures are developed and implemented to detect and deter fraud, criminals may exploit the same vulnerability, but use a different adulterant that is not targeted by the countermeasures.

### *Illustrative Example—Milk Fraud: Déjà Vu and the Analytical Battle*

Milk has historically been one of the most defrauded foods and its pattern of adulteration has been influenced over time by geopolitical factors (see *Geopolitical considerations* section). Adulteration of milk in the USA was commonplace in the 19th and early 20th centuries. One of the earliest frauds for fluid milk was to dilute it with water—an easy way to dilute milk simply sold on a weight or volume basis for illicit profits. A 1913 report on milk analyzed in the State of Georgia suggested that more than 50% of the milk tested was diluted with water (Bassett, 1913). Another milk fraud reported at that time in the U.S. was adulteration with formaldehyde. This adulterant was added to milk as a preservative, especially in dairy-producing regions where cold storage and/or milk processing facilities were not commonplace. A 1903 milk survey report in the city of Detroit, Michigan, U.S., found that more than 6% of tested samples were adulterated with formaldehyde (Alvord and Pearson, 1903; Rice, 1946). These types of milk frauds in general are no longer a problem in the U.S. due to the drastic improvements in industry practices and regulatory and enforcement frameworks. Similar problems have reappeared recently, however, in geographic regions with less developed dairy economies and food regulatory and enforcement frameworks. For example, a 2012 investigation reported that more than 80% of milk samples tested in a specific region in India were watered down (Deepa P. and Kannappan, 2012). Similarly, a government survey in India in the same year indicated that more than 60% of samples surveyed across the nation were noncompliant with national standards rendering them adulterated, and almost half of the nonconformances were consistent with watering down of the milk (FSSAI, 2012). Fraudulent addition of formaldehyde has also resurfaced in other regions. A study in 2003 investigating milk in Northern India reported that formaldehyde was detected in approximately 0.4% of samples tested, and a more recent 2011 study of UHT milk in Brazil suggested that more than 44% of tested samples were adulterated with formaldehyde (Arora et al., 2004; Souza et al., 2011).

Analytical detection methods to combat milk adulteration have proven a continuous battle with ingenious criminals constantly developing new ways to circumvent the latest adulteration detection methods. An early tool used to detect the addition of water to milk was the lactometer, an instrument for measuring the specific gravity of milk. Other useful tools for detecting watered milk include measuring solids with a refractometer and also freezing point depression using a cryoscope. Criminals did not take long to devise clever ways to circumvent these tools. Refractometer testing, for example could be circumvented by simply adding solids, such as glucose, to watered milk to increase the apparent solids. Scientists eventually recognized these vulnerabilities in the test methods. As early as 1913, for example, a scientific report highlighted how the addition of glucose could fraudulently increase apparent solids when measured refractometrically (Long and May, 1913). This struggle between the science of detection and the science of deception continues even today, especially for difficult to test and characterize foods and ingredients.

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**Illustrative Example—Cassia Oil Criminals Evolving to Circumvent New Detection Methods**

Cassia oil (*Cinnamomum aromaticum* or *Cinnamomum cassia*), a cinnamon-like oil, was once thought to be commonly adulterated with rosin, a practice that was detected by purchasers through the use of optical rotation and specific gravity specifications. This countermeasure was soon circumvented by criminals through the addition of kerosene to rosin-adulterated materials to adjust the optical rotation and specific gravity to fall within the range of authentic materials. This practice was later stopped through the development and use of a direct detection method for rosin. Criminals then adopted the practice of adding synthetic cinnamaldehyde (a chemically derived equivalent to the cinnamaldehyde naturally present in cassia oil) to cassia oil, a practice that was stopped through the use of radio carbon analysis. Later use of <sup>14</sup>C-enriched synthetic cinnamaldehyde by criminals to trick radiocarbon analysis is now detected through the use of SNIF-NMR. This example points to a long history of fraud for cassia oil which suggests that it is prone to adulteration, even when new detection methods are developed.

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The volume of fraud reports and incidents related to an ingredient is one factor to consider when assessing its vulnerability. The other factor to consider is the validity or degree of evidence to substantiate the legitimacy of reported fraud issues. Carrying out this assessment is often difficult to do using the limited information available in public reports, and when considering the often disconnected nature among different reports on the same issue. The best guidance is an explanation of the different types of reporting mechanisms—both public and private—and the limitations and motivations of each in terms of validity:

**Food industry reports**—One type of reporting mechanism is the discovery of a potential issue by the food industry, typically from surveillance studies, analytical or supply chain intelligence information, or via a trade association. This type of information likely carries a significant weight, especially when supported by analytical data, but often is not made publicly available. Immediate public dissemination of such information may not happen unless there is a legitimate food safety concern because of trade concerns and/or legal liabilities. However, the information may be leaked, and reported through the media or other outlets, without supporting documentation.

**Peer-reviewed scientific journal articles**—Peer-reviewed scientific reports can offer two types of information related to food fraud history.

One is scientifically documented incidents of food fraud, which can have a high degree of legitimacy, but typically are reported with a significant delay after the incident. Often these documented incidents in scholarly journals lack incident details, such as the origin or producer of the fraudulent product—information that is often withheld from scholarly publications due to legal liability concerns from the study authors. The legitimacy of the analytical results reported in scientific reports tend to carry increased weight compared to most other report types, depending on the strength of the peer review process.

A second type of fraud history information in peer-reviewed scientific articles is the reporting of "common" adulterants and fraud issues, often to introduce the fraud history of a food and the need for a newly reported analytical method. These reports can be used to indirectly infer fraud issues that might be occurring in the marketplace, but can vary considerably in substantiating weight (validity).

**Regulatory surveillance and compliance testing, and judicial records**—Another possible route for dissemination of fraud issues is through routine surveillance or compliance testing performed by regulatory authorities. Information resulting from these testing programs is typically only publicized through media outlets if there is an identified food safety threat, but is not often accompanied in the media by sufficient scientific data to independently verify the weight of evidence. Issues not considered a public health threat may not be widely publicized by the regulatory authority, but are sometimes revealed in media or other outlets with very limited details. Depending on the national or regional laws, food fraud issues uncovered by regulatory authorities including data to verify the weight of evidence may be releasable to the public through mechanisms such as through Freedom of Information Act requests in the U.S., but typically can only be successful if sufficient information is disclosed by the regulatory authority to the public to identify the fraud issue. If criminal convictions are pursued by regulatory authorities, court case records can provide another source of information. If convictions are successful, that can also add an additional weight of evidence that fraud actually occurred.

**Media reports**—Media reports about food fraud can result from any of the mechanisms listed above. Media reports may also not indicate how information about a food fraud incident or report was obtained, making the legitimacy of the incident more difficult to assess. Lastly, it is important to consider the possibility of unsubstantiated fraud issues being reported in the media or other outlets based on false or misconstrued reports (hoaxes).



**Illustrative Example—The Cardboard Bun Hoax**

In July of 2007, an undercover media report surfaced in China alleging that local street vendors were fraudulently producing and selling pork buns filled with a mixture containing 60% caustic soda-soaked cardboard and 40% fatty pork. Investigations by local health authorities did not find evidence of the fraudulent buns in the marketplace. It was later reported the story was a hoax by a young journalist who was under the pressure of a performance evaluation. A police investigation concluded that the report was a hoax and the journalist was finally sentenced to one year in jail and a fine of \$132. This example illustrates that the validity of reports should be carefully considered when evaluating fraud reports.

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The following are the vulnerability category descriptors used in *Table 1*. These should be considered a general guideline for categorizing vulnerabilities for this factor and should be tailored to your business practices and reevaluated on a regular basis:

- *Low*—No reports or few known reports with no or unknown validity.
- *Medium-Low*—Low to moderate volume of reports with limited or unknown validity.
- *Medium*—Moderate volume of reports with limited degree of validity.
- *Medium-High*—Moderate volume of reports with good degree of validity; or high volume of reports with limited validity.
- *High*—High to moderate number of reports, some with high degree of validity, and/or evidence of an ongoing incident.

Two useful resources are available that compile public reports on food fraud and can be used to help carry out assessments against this fraud history factor. The *USP Food Fraud Database* is one resource that is published in the *Foods Chemicals Codex* and publicly available online in digitally searchable form at [www.foodfraud.org](http://www.foodfraud.org). The USP database compiles information on scientific and media reports into entries categorized by type of ingredient, type of or identified adulterant, and analytical detection methods reported. References are provided for each database entry. The NCFPD EMA Incidents Database is another searchable database that is available online through [www.FoodSHIELD.org](http://www.FoodSHIELD.org) (access is available by registration). The NCFPD EMA Incidents Database describes discrete incidents of food fraud (in many cases, the database circumscribes several reports related to a single incident), and provides contextual information such as a brief incident summary, the locations of production and distribution of the final food products, perpetrator information (if available), and known public health effects. Combining the information available in each of the databases for a particular ingredient can provide insight into the history of food fraud for an ingredient. The *USP Food Fraud Database* in general covers a wider range of reports (not only documented incidents of food fraud but also fraud issues reported in literature) and is particularly useful for identifying reported adulterants, along with the analytical detection methods. The NCFPD EMA Incidents Database is useful for exploring discrete food fraud incidents within a food product category, and adds supporting information about perpetrators, incentives, and the regulatory environment for a particular incident. Although the true history of food fraud in a particular ingredient will never be fully documented, taken together, a review of documented incidents along with information inferred from published literature on research into detection methods and reported adulterants provides a good picture of the scope of food fraud.

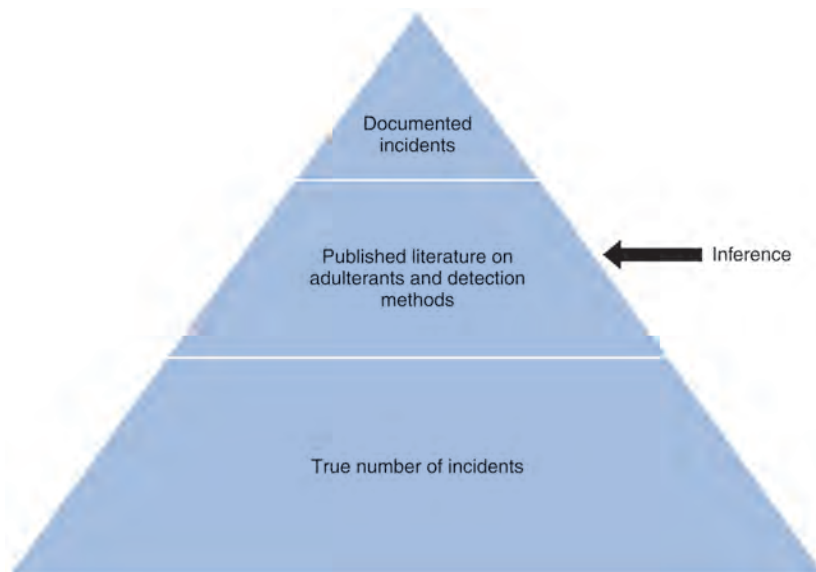


Figure 6. Assessing the history and scope of food fraud for a particular ingredient

**Illustrative Example—Using Available Databases to Construct a Fraud History**

To illustrate how to correctly use the information available in the *USP Food Fraud Database* and the NCFPD EMA, this example uses a search on "apple juice concentrate". This search resulted in one incident in the EMA Incidents Database—the 1980's Beech-Nut case (see *Illustrative Example—Beech-Nut*)—a documented incident with a very high degree of substantiating evidence based on a criminal court case conviction in the U.S. A search on "apple juice concentrate" in the *USP Food Fraud Database*, and a subsequent filtering by ingredient "apple" resulted in 27 records. Twenty-four of these records are based on scholarly articles from 1988 to 2011 that discuss methods for detection of apple juice adulteration and discuss 18 unique potential adulterants for apple juice concentrate. Although most of the scholarly articles do not specifically reference a known incident of fraud, it can be inferred from the research surrounding analytical methods for detecting fraud in apple juice that undocumented incidents have occurred. Three of the USP records are each a separate media article report about the Beech-Nut incident. Combining the results of the two databases suggests a moderate volume of fraud relating to apple juice concentrate adulteration continuing to date, and a high degree of substantiating evidence from the Beech-Nut case suggesting that fraud did indeed occur, albeit more than 2 decades ago in the U.S.

In addition to publicly available databases that catalog documented food fraud incidents, it is helpful to incorporate other public sources of knowledge about potential quality and safety concerns for the ingredient of interest.<sup>2</sup> For example, notifications about quality and safety issues detected by regulatory authorities may provide some insight into potential ingredient adulteration (see *History of supplier regulatory, quality or safety issues*).

**ECONOMIC ANOMALIES**

This factor is intended to describe the vulnerability of ingredients to food fraud based on economic anomalies happening in the marketplace for the ingredient. Given that food fraud is driven by economic opportunity, anomalies in the economics of particular foods or food sources can be an indicator of potential problems. Less-than-market pricing, especially for products where costs are rising or supplies are tight, has been an indicator in prior food fraud cases including animal and vegetable protein products. In some cases, the price advantage of the fraudulent product may even be larger than the probable profit margin of competitors, making it more suspicious but potentially easier to identify. When prices are uneven or are rising unequally across a class of foods—animal proteins for example—it provides an opportunity for product substitution such as pork or horse into beef or mutton. The 2013 European horse meat scandal was a result of firm(s) substituting horse meat for ground beef, in some cases entirely, to take advantage of the low value of horse meat given its limited consumer demand. Stable pricing and ready supply when there has been a poor harvest or other disruption may also indicate food fraud, such as poor quality apples for premium apples after a poor harvest or stable shrimp supplies and pricing after a natural disaster.

Less obvious would be a firm or groups of firms exhibiting unusual price stability relative to competition. The ability to maintain significantly more stable pricing than competition, especially in commodity markets that are historically volatile, may indicate artificially low input costs as the result of EMA or food fraud. Country-specific low prices or price stability relative to predominant market prices could indicate a gap in oversight or enforcement in the country-of-origin that could increase the opportunity and incentive for fraud. Melamine contamination of wheat gluten may have been identified earlier if the unusual price stability of wheat gluten from China relative to other countries-of-origin had been identified before the recall. Trade data, including the most recent year, quantity of import/export and value by country are available from sources such as COMTRADE (<http://comtrade.un.org/>) as well as from country-specific portals such as the USDA Global Agricultural Trade System Online (GATS) <http://apps.fas.usda.gov/gats/default.aspx>.<sup>9</sup> A step-by-step guide for how to obtain pricing data from GATS is provided in the Information Resources section at the end of this Appendix. Comparing the value by weight of a specific commodity by country can identify understandable variation such as value-added variants (honey from Germany), as well as unusually low pricing for one or more countries (honey from China). Market uncertainty of appropriate pricing can be another indicator, in some cases identifiable by larger spreads in future pricing forecasts or more rapid turnover, or shorter duration, of futures contracts, for product for which such data are available.

**Illustrative Example—The Vanilla Price Spike**

Extreme weather conditions in Madagascar and Indonesia, two of the world's major vanilla producing regions, along with other market conditions in the early 2000s resulted in an unprecedented spike in the price of vanilla, the second-most expensive spice behind saffron. Several cyclones in Madagascar's vanilla-growing northeastern region in the early 2000s destroyed a significant percentage of standing crop and stocks vanilla. Extreme droughts in Indonesia resulting in production being halved in 1999 (McGregor, 2005). Additionally, the demand for vanilla was outstripping supply during this period due to increasing consumer demand for natural vanilla instead of synthetic vanilla. These factors combined contributed to a significant increase in vanilla prices. Prices were typically under \$80/kg from the 1970s until the late 1990s and then increased to more than \$600/kg in 2004 (see *Figure 7*). Prices were sustained at a high level for several years due to civil war in Madagascar, another cyclone in Madagascar in 2004, the launch of Coca-Cola's "Vanilla Coke" product, and speculative demand during

<sup>9</sup> Canada <http://strategis.gc.ca/eic/site/tdo-dcd.nsf/eng/Home>, U.S. <http://apps.fas.usda.gov/gats/ExpressQuery1.aspx>, United Kingdom <https://www.uktradeinfo.com/Pages/Home.aspx>.

**Illustrative Example—The Vanilla Price Spike, (continued)**

this time period (McGregor, 2005). Some documented and anecdotal evidence suggests that adulteration of vanilla did occur during this period of time, likely motivated by this economic anomaly along with the inherent fraud susceptibility of vanilla due to its high price, and the analytical difficulties to authenticate vanilla due to its complex and variable composition and selectivity challenges of available analytical methods. One report with substantiating evidence reported that lots of chopped Indonesian vanilla beans were likely fraudulently injected with elemental mercury in the early 2000s to increase the weight (and purported value) of the beans (IFF v. Day et al., 2005). The source of the elemental mercury was thought to be the local gold mining industry where it was widely used and available. Testing revealed levels of mercury ranging from 37 ppm to 411 ppm in the adulterated lots (IFF v. Day et al., 2005). The purchaser of this ingredient claimed more than \$5 million USD in damages for losses associated with using 5 tons of contaminated beans to produce vanilla extract, including losses due to the value of contaminated vanilla extract shipped to customers, value of material not yet shipped to customers, and costs associated with remediation and de-contamination of its processing equipment.

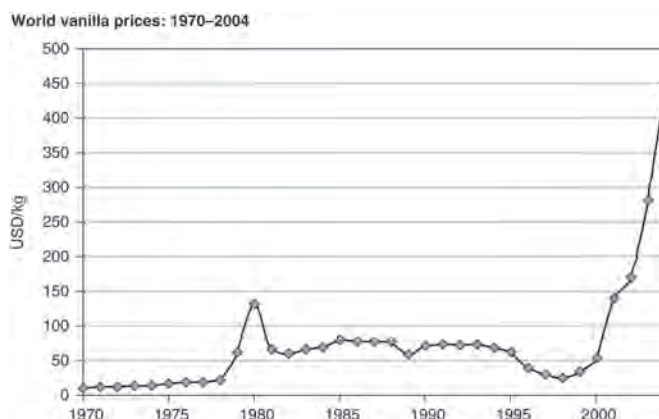


Figure 7. World Vanilla Prices 1970-2004. Source: Food and Agriculture Organization of the United Nations, 2005, McGregor, A., Diversification into high-value export products: Case study of the Papua New Guinea vanilla industry <ftp://ftp.fao.org/docrep/fao/008/j6561e/j6561e00.pdf>. Reproduced with permission.

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Geographic differences in standards, stringency of regulations, or industry oversight are other factors that can provide an opportunity for food fraud that may be identified by economic anomalies. For example, honey from countries where excessive antibiotic residues are a known problem have been trans-shipped through third countries, apparently to evade bans, limits, or testing, and sometimes intentionally mislabeled as originating in an approved country. If the volume or cost of products supplied from a particular country or region are inconsistent with the production and general availability in that area, it may also indicate food fraud. For example, if a country that has minimal production and consumption of beef is a source of imports, while other more likely sources have quality or disease concerns, it suggests the potential for fraud. For many commodities, the production by country is available from FAOSTAT (<http://faostat3.fao.org/faostat-gateway/go/to/home/E>), which also contains commodity balances that can be used to identify inconsistencies in total availability as compared to production and trade flows.

An evaluation of economic anomalies can include any number of relevant data sets available to the team conducting the vulnerability assessment, including supplier prices, aggregated trade data, and futures prices. Some of the indicators to look for include changes in the absolute value of the unit price above what appears to be the normal trend (as illustrated with the vanilla example, above), unusually rapid changes in the market price for a commodity, trends in the market price over time from a firm or region that are inconsistent with other factors, a comparison of the price quoted by a particular supplier relative to other sources of data on typical market prices, and unusual stability or instability in the prices for commodities from a particular supplier or region. This evaluation will depend, in part, on the personal judgment of those conducting the vulnerability assessment, and will benefit tremendously from the solicitation of input from subject matter experts in procurement, business, markets and economics.

The following provides some explanation of the vulnerability category descriptors used in *Table 1*. These should be considered a general guideline for categorizing vulnerabilities for this factor and should be tailored to your business practices and re-evaluated on a regular basis:

- *Low: Nothing unusual*—No examples of unusual economic behavior are available.
- *Medium-Low: Isolated anomalies*—While there are some unusual economic indicators, they appear to be random with no consistent pattern by geography, commodity/product, or company. These could be one-off attempts or reflect temporary imbalances such as early or late harvest of a fresh produce item resulting in limited pricing changes.
- *Medium: Frequent but unrelated anomalies*—Anomalies are not uncommon but show no commonality by geography, commodity/product or company. These may represent opportunists taking advantage of predictable market dynamics such as seasonal shifting of sourcing or post-natural disaster supply chain disruption. As one example, following a tsunami in 2011 that decimated the Chilean scallop beds, there were cases of fraudulently labeled seafood cut to appear to be scallops, but no widespread fraud was identified.
- *Medium-High: Common but focused anomalies*—Anomalies are common, but only with respect to a geography, commodity/product, or company. These can represent specific companies utilizing fraud as an acceptable business practice or lax oversight of a specific commodity/product in a country. The melamine adulteration of dairy products in China in 2008 is an example where pricing for milk and dairy products across China was below comparable levels in the rest of the world while production was increasing at a rate much faster than the rest of China's agriculture production.
- *High: Common and broad anomalies*—Anomalies are not confined to one country, one commodity, or one company. These can represent systemic fraud, either as a result of a broad lack of effective oversight, a general lack or inconsistent awareness to the potential for fraud, or the dissemination of a fraudulent ingredient broadly through complicated supply chains. The European horsemeat scandal, potentially identifiable by the significant difference between the price of horsemeat relative to beef, was magnified by the utilization of the low cost, fraudulent ground meat by many companies in a broad range of products.

## STEP 2: POTENTIAL IMPACTS ASSESSMENT

While all foods and food ingredients have some potential to be the targets of food fraud, not all of them represent foods and food ingredients where food fraud has the potential to have a substantial impact on public health, an economic impact, or an impact on confidence in regulatory authorities. An assessment of the range of potential impacts is thus a necessary component of an overall food fraud vulnerability characterization. This step therefore provides guidelines for developing an approach to assess each of the impact areas for their potential severity.

**Table 4. Impact Evaluation Matrix**

	Low		Moderate		High
<b>Food Safety</b>	Food grade-known safe	Food grade-No known risks	Food grade-known sub-population risks	Non-food/non-food grade-unknown risks	Non-food/non-food grade-known risks
<b>Economic Impact</b>	No significant balance sheet impact		Operational Risk		Enterprise risk
<b>Potential Multipliers</b>					
<b>Focused Consumption</b>	No focused consumption	Temporally focused	Low level	Potential target populations	At-risk populations
<b>Nutritional Sufficiency</b>	No sufficiency impacts		Important micro-nutrient food	Core food for a sub-population	Primary/critical sub-population food
<b>Public Confidence</b>	Specific food	Specific commodity	Industry sector	Industry wide	Authorities & industry

One approach is to consider the potential impacts of a food fraud event as the combination of the two primary concerns (food safety and economic impacts) and a small set of potential multipliers (focused consumption, nutritional sufficiency, public confidence) that could amplify impacts as depicted in *Table 4*. The public health impacts should play a dominant role, but for a firm to remain viable, the economic impacts may come close in importance. The potential multipliers are those aspects that may be harder to quantify or anticipate but would serve as a useful means of discriminating between apparently equal negative primary impacts. Users evaluating an ingredient should carefully review for each factor in *Table 4* and the guidance provided below and then estimate which category best describes their situation.

### Public Health Impact—Food Safety

The traditional food safety risks associated with food fraud where the adulterant has the potential to cause illness or death are the most obvious public health impact concerns. While those who commit food fraud do not intend to cause illness or death, those who commit the fraud do not always understand the potential harmful effects of the adulterating material. Melamine adulteration of dairy proteins, denatured rapeseed oil adulterated olive oil, and methanol contamination of vodka are all examples where the perpetrators might have lacked awareness of the potential consequences, including significant morbidity and mortality. There are several steps and considerations when determining if there is a likely food safety risk associated with food fraud.

A first step for assessing the public health impact is to identify potential adulterants for the ingredient under evaluation. One publicly available tool for this purpose is the *USP Food Fraud Database* available at [www.foodfraud.org](http://www.foodfraud.org). It contains adulterants by ingredient that have been reported in documented fraud incidents as well as those adulterants reported as common adulterants in literature. In addition, users should identify adulterants based on their own supply chain intelligence, and potential new adulterants should be identified based on the inherent characteristics of the ingredient and availability of other materials that could be used as a substitute.

Once potential adulterants have been identified, the user should determine if they could cause harm. For some specific foods there are readily identifiable adulterants, either due to historic use or inherent characteristics, which have an established potential for causing public health harm (e.g., lead chromate in turmeric). In this case, the potential severity and nature of the public health harm from the consumption of one or more of the identified, hazardous adulterants is the driving force behind prioritizing the potential impact and this can be assessed considering the toxicity of the adulterant and the potential adverse health outcomes resulting from consumption of the adulterant. As noted before, individuals who engage in food fraud generally do not intend to cause illness or death, but through the addition of adulterants to foods they sometimes introduce unforeseen health hazards. It may be difficult or require specialized knowledge to assess, *a priori*, the potential health impact of adulterants. But adulterants that are themselves only available as food-grade materials are likely to pose less of a public health threat than potential adulterants that are not allowed to be used in foods (e.g., industrial chemicals like lead chromate in turmeric or Sudan dyes in spices) as well as those adulterants that are allowed in foods but also have non-food grade equivalents (e.g., technical grade of ingredient available). For example the public health impact of the adulteration of honey with sugar syrup is expected to be less than the adverse impact of the adulteration of milk with melamine. Of course, food or food ingredients used for adulteration could pose unknown public health hazards if they are themselves adulterated, of substantially substandard quality, or pose

unique hazards such as allergens. A possible way of systematically assessing the potential public health impact is to consider the basic nature of the potential adulterants, incorporating information on their specific potential public health impacts when available. While the following are phrased in terms of toxicity, it is important to note that infectivity is also of concern as was the case with PCA peanut paste and *Salmonella*. The type or nature of adulterant can be broadly considered in four major categories:

- If the adulterant is a food or recognized food ingredient, the toxicity might not present a substantial public health impact in terms of causing illness or death unless it is a known allergen.
- If the adulterant is a food or recognized food ingredient containing a known allergen, it presents a considerable concern of causing serious illness or death for sensitive consumers unknowingly consuming the allergen.
- If the adulterant is available in food and technical or other grades, the potential for harm increases since technical or other grades of materials may not be of a purity that is suitable for consumption.
- If the adulterant is not allowed for use in foods, the threat of causing serious illness or death increases substantially.

A more detailed analysis of the potential public health impact requires information on the toxicity or infectivity of the adulterant and potential levels of consumer exposure. The information on toxicity should include not only acute health effects but also chronic health impacts such as carcinogenicity, reproductive toxicity, and chronic exposure toxicity and should address the vulnerability of the most sensitive population that is likely to be exposed to the adulterant. While these analyses are most often performed retroactively to assess the public health impact for the consumers from a food fraud incident, they can be performed proactively for impact ranking or scenario planning, given sufficient available expertise. In that case, it may also be useful to differentiate between adulterants that are more likely to result primarily in illness and those that are likely to also cause death. The absence of obvious, anticipatable, negative health impacts does not mitigate the legal and ethical responsibility of the manufacturer to maintain the purity of his products.

### POTENTIAL FOOD SAFETY IMPACT MULTIPLIERS

*Focused consumption multiplier*—The potential public health impact is increased if the consumption profile of the final food increases the amount or frequency of consumption (exposure) so that even lower levels of a harmful adulterant could have a significant public health impact. The adulteration of foods that comprise the major, sole, or necessary component of a diet substantially raise the potential public health impact of food fraud. Pet food, infant formula, and baby food are examples where the consumption pattern, limited diet diversity, and increased frequency of consumption, have already demonstrated their potential for public health harm through food fraud. Final foods that have these or similar consumption profiles that may result in higher overall exposure to the adulterants (i.e., nutritional supplements, specialized nutrition foods, military MREs, etc.) increase the potential public health impact of any of the ingredients included in them. A means of categorizing them includes:

- Highly concentrated consumption profile by *At-risk populations* (i.e., infants, children, senior citizens, immune-compromised, etc.).
- Frequent consumption profile (i.e., vitamins, nutritional supplements, specialized nutrition foods/nonimmune compromised, etc.)
- Frequent consumption profile among *Target populations*. While food fraud is not generally intended to cause public health harm, it can also be a means of demonstrating the ability to deliver intentional adulteration to specific target populations such as the military (MREs), patients that require medical foods, groups with specific non-medically required dietary restrictions (Kosher, Halaal), and others.
- *Temporally focused consumption* profile where due to holidays, seasonality, or other events the consumption of the final foods may be expected to spike among certain populations, thus increasing potential exposure to the adulterant and the public health impact (i.e., pumpkin pie filling, etc.).

*Nutritional sufficiency multiplier*—There have been cases where either through dilution or total substitution, the nutritional content of the final food has been reduced to the point of posing a public health impact among the target population, specifically infant formula. Any final foods that serve a critical role in baseline nutrition for a sub-population increase the potential public health impact of food fraud due to insufficient nutrition, not due to food safety.

### Economic Impact

The economic impact of a food fraud event that is identified can be broken down into direct and indirect costs to the firm, the industry segment, and authorities. The economic impact of a food fraud event that is not identified is impossible to discern, but may be equally damaging over the long term if it degrades the consumer acceptance, customer performance, or regulatory confidence associated with the final food or ingredient. These can more specifically be considered in terms of *Direct costs* and *Indirect costs*, both of which will increase depending on the breadth of products and production facilities impacted by the food fraud event:

- *Direct costs*: During the time that the fraudulent food or ingredient was received by the impacted firm there is a quantifiable cost of overpayment for inferior product, but that is a relatively insignificant cost compared to dealing with the consequences of an identified event. What is the cost of recalling adulterated product and returning to market? This includes cost of product, personnel, disposal, plant reconditioning, supplier re-qualification, post-event marketing/promotions, public relations, and litigation. After a food fraud event, the incremental costs of marketing and promotions to regain shelf space and consumer confidence can be significant. The *Direct costs* increase is in proportion to the total amount of product impacted

by the food fraud event and may include unusual costs of ingredient/supplier replacement if it is a critical ingredient for any particular product.

- Indirect costs: These costs following a food fraud event can have sustained effects thus maximizing their impact. The loss of confidence by investors, customers, consumers, or authorities can be far more damaging than any direct economic impact as has been seen in both traditional food safety events and food fraud. The loss of confidence can result in a significant drop in market value of the firm, loss of important customers, reduced shelf space, consumer purchasing profile shifts, and other similar impacts. This includes loss of access to export markets that, while a decision of regulatory authorities, is another means of damaging customer confidence. If the response by regulatory authorities results in substantial operational inefficiencies, this can also be a significant indirect cost, such as time to clear products for import or export. While anticipating the degree to which stakeholders will view the firm as also being a victim or instead as culpable due to negligence is uncertain at best, the efforts expended by the firm to prevent food fraud before the event occurs can dramatically reduce such indirect costs. These *Indirect costs* can increase much more rapidly if the food fraud event spans a broad range of products or if it is a critical ingredient for some products.

### POTENTIAL ECONOMIC IMPACT MULTIPLIERS

*Public confidence multiplier*—The impact of a loss in consumer confidence is included in the indirect economic (above) impact of a potential food fraud event. What is not included, however, is the extent to which a food fraud event can impact public confidence in the food supply more broadly. Some may result in loss confidence for a specific food (*Specific food*), a specific agricultural or food commodity (*Specific commodity*), an entire sector of the industry (*Industry sector*), industry as a whole (*Industry wide*), or industry segment and government authorities (*Authorities and industry*) in the wake of a food fraud event. Prior food safety and animal health failures provide illustrative examples of the far reaching impacts of such incidents. The 1980s Bovine spongiform encephalopathy and the 2001 foot-and-mouth disease crises in the United Kingdom resulted in a reorganization of the overall food and animal agriculture regulatory system. Similar changes have happened in several other countries. Even if a food fraud event does not lead to an overhaul of the overall regulatory system, it can still result in new regulations, demands on authorities, and overall food system burdens. While not a firmspecific economic impact, the degree to which a food fraud event could trigger such responses is also important to consider. Traditional media such as television shows and newspaper articles continue to be important drivers of public confidence, but new media (social media and internet) can be equally or more impactful in forming public opinion. When considering public confidence, it is important to consider whether a potential incident would be considered to be noteworthy by traditional media and whether they would devote resources to “investigating” the incident and possible reasons for the incident. New media, however, can be far more critical. While “pink slime” (the term used to describe meat trimmings called finely textured beef) was not a true food fraud incident, the 2012 episode well illustrates the power of new media in driving a loss in public confidence. The product posed no food safety risk and it contributed to both holding costs down and providing a lower fat content for hamburgers for the school lunch program. The product’s one weakness was that it was easy to describe in visceral terms with the resulting consumer outrage driven by social media causing the destruction of a product and a company. The “pink slime” example also illustrates that the potential impact of a firm appearing to fail in protecting consumers can be equally severe as when a firm actually fails to protect consumers.<sup>10</sup>

#### ***Illustrative Example—The Economic Impact of Apple Juice Fraud***

The following description of the events surrounding the Beech-Nut apple juice food fraud event illustrates that the substantial damage to a brand can be not only expensive but long lasting. Following indictment as a result of the long-running fraud, Beech-Nut's market share dropped from more than 20% in early 1986 to 16% in 1987. Most of this drop was the result of plummeting apple juice sales, which fell about 20% within a few months of the indictment. Although sales figures were not released, sources told *Business Week* that Beech-Nut racked up near-record losses in 1987.

Beech-Nut quickly undertook a new promotional campaign that stressed the quality of the Stages line of baby food and was designed to appeal to the increasing number of older first-time mothers. All baby food manufacturers had long since followed Beech-Nut's lead in removing salt and artificial flavors from their products. After the indictment, Beech-Nut became the first major firm to remove modified starch, the ingredient that had long been responsible for the creamy consistency of most baby food. The company spent millions trying to recapture consumer confidence, urging mothers to read the labels of their products and compare them with their competitors. By 1989, Beech-Nut had succeeded in regaining some of its lost market share, but the cost of the campaign virtually wiped out profit margins, according to industry analysts.

#### **References**

- <http://www.answers.com/topic/beech-nut-nutrition-corporation#ixzz3DgIW5kac>

<sup>10</sup> [http://www.slate.com/articles/news\\_and\\_politics/food/2012/10/history\\_of\\_pink\\_slime\\_how\\_partially\\_defatted\\_chopped\\_beef\\_got\\_rebranded.html](http://www.slate.com/articles/news_and_politics/food/2012/10/history_of_pink_slime_how_partially_defatted_chopped_beef_got_rebranded.html)

### STEP 3: OVERALL VULNERABILITIES CHARACTERIZATION

In order to prioritize efforts in controlling fraud for a food ingredient, it is important to consider both the contributing factors assessment (step 1) as well as the potential consequences of a food fraud event (step 2). A highly vulnerable food or food ingredient for which food fraud would have no public health impact and an entirely manageable economic impact represents an overall benign threat to the company and the public. Conversely, a less vulnerable food or food ingredient, if subject to specific types of food fraud, could cause grave public health and economic impacts. Such a scenario would be far more threatening and thus a higher priority. This step provides an approach for combining steps 1 and 2 to generate an overall vulnerabilities characterization.

While any individual company's assessment will vary, a basic interaction matrix can be used to categorize the overall food fraud vulnerabilities composed of results from step 1 (contributing factors assessments) and step 2 (impact assessment). An example evaluation matrix is provided below (see Table 5), but the matrix is less important than the decision-making process used in the overall process prior to this point. After working through each element of the vulnerabilities and the impacts, the areas of focus should be readily categorized as to their importance to public health, the firm, and all other stakeholders. In the example provided in Table 5, characterizations falling into a red area of the matrix would be considered the highest priority for mitigation, whereas characterizations falling into the green area would be of lowest priority.

**Table 5. Example Vulnerability Characterization Matrix**

			Contributing Factors (Composite of Step 1)				
			1	2	3	4	5
			Low	Medium-Low	Medium	Medium-High	High
Potential Impact (Composite of Step 2)	A	Low Economic	New controls optional	New controls optional	New controls optional	New controls optional	New controls should be considered
	B	Moderate Economic	New controls optional	New controls should be considered	New controls should be considered	New controls should be considered	New controls strongly recommended
	C	Low Public Health/High Economic	New controls optional	New controls should be considered	New controls should be considered	New controls strongly recommended	New controls strongly recommended
	D	Moderate Public Health/High Economic	New controls optional	New controls should be considered	New controls strongly recommended	New controls strongly recommended	New controls strongly recommended
	E	High Public Health/High Economic	New controls optional	New controls strongly recommended	New controls strongly recommended	New controls strongly recommended	New controls strongly recommended

General Tests and Assays



## STEP 4: MITIGATION STRATEGY DEVELOPMENT

Upon completion of the overall vulnerability characterization (Step 3), the next step is to develop an appropriate mitigation strategy. The objective is to move the vulnerability to an acceptable level based on potential food safety implications as well as the business environment as it pertains to economic impacts.

It is expected that developing a mitigation strategy would be an iterative process whereby a company would consider options to mitigate vulnerability, implement those options, and then determine if the vulnerability has been reduced through a subsequent vulnerabilities characterization. If the characterization indicates that there are still vulnerabilities that should be addressed, the cycle would be performed again, as illustrated in *Figure 1*.

It should be noted that the vulnerability characterization is not static. Changes in any of the factors (e.g., economics surrounding the ingredient, change in supply chain, change in geopolitical status for a region) may all indicate the need for an updated vulnerability characterization.

After reviewing the results of the overall vulnerabilities characterization (Step 3; e.g., *Figure 8*), three possible actions can be taken.

- If the result of the initial vulnerabilities characterization is green, i.e., "new controls optional", then documentation of the assessment may be all that is necessary.
- If the result is orange, i.e., "new controls should be considered", then the user needs to consider if the vulnerabilities are acceptable, and if not, determine where to apply food fraud mitigation resources to yield an acceptable level of vulnerabilities.
- If the result is red, i.e., "new controls strongly suggested", then the user needs to determine how and where to apply food fraud mitigation resources to help move them from red to orange or green.

The approach for addressing the issues raised under orange and red outcomes starts with reviewing the controllable factors highlighted in Step 1 and determining the most effective controls to employ based on the user's situation. The inclusion of some type of cost-benefit analysis for the top "controllable" factor should be part of the review to determine where costs for the user can yield the most improvement per dollar. Other considerations include:

- Prioritize potential actions by considering factors (see *Table 1*) most in your control, and therefore capable of influencing the overall (composite) contribution of contributing factors to vulnerability. For example, some vulnerability areas like *Geopolitical considerations* might be partially inherent vulnerabilities to the ingredient hence less controllable by the user (e.g., ingredient can only be sourced from one region), whereas testing frequency and audit strategy may be completely controllable by the user.
- Consider whether there are other mitigating/compounding factors that may affect the level of control on the ingredient. For example, an ingredient used extensively in production may warrant greater attention than one used in a single low margin item. One might consider that the use of a vulnerable item in a low margin product is not worth the risk and therefore discontinue the item or find an alternate ingredient.
- Consider company resources to address identified vulnerabilities—e.g., testing may be less resource-intensive than developing a comprehensive auditing program.
- Consider possible use of external resources to help address any identified vulnerabilities. These might include trade associations or groups of companies that have already organized food fraud mitigation programs around the same ingredients. Examples include the Grocery Manufacturers Association (Washington, DC, U.S.), and the Technical Committee for Juice and Juice Products (<http://www.tcjip.org/index.html>), which is a group of analytical chemists interested in analytical methods to detect food fraud in juices and juice products.

For users considering QA method and specifications as a tool to mitigate food fraud vulnerability, the monographs in the *Food Chemicals Codex* provide a valuable resource. Additionally, the *USP Food Fraud Database*, [www.foodfraud.org](http://www.foodfraud.org), is a resource that compiles food fraud detection methods reported in literature.

### **Illustrative Example—Implementing a Mitigation Strategy Plan**

The following demonstrates a theoretical situation in which a finished food manufacturer has recently switched suppliers for imaginary ingredient, "Z" based on the new supplier's more competitive pricing, and the finished food manufacturer decides to carry out the steps recommended in this Guidance. In performing the contributing factors assessment (Step 1), the manufacturer of the final product identified some potential vulnerabilities to fraud for the ingredient:

- "Z" is a high-value ingredient processed and grown in only one region of the world; civil unrest has erupted into violence in that region over the last two years and the market price of the ingredient has increased two-fold during this time.
- "Z" is being sourced from the new supplier (an established ingredient broker with whom the finished food manufacturer has no relationship) on the open market. Research into the new supplier's manufacturer has uncovered some minor but reoccurring sanitation violations from inspection reports.
- Recently there have been several published and well-substantiated incidents where "Z" has been diluted with a lower value component so that apparently lower prices could be offered by specific suppliers.

**Illustrative Example—Implementing a Mitigation Strategy Plan, (continued)**

- The manufacturer has historically invested limited-to-no resources into QA testing "Z" and has begun developing (but not implemented) an onsite audit strategy for the ingredient.

The manufacturer's vulnerabilities assessment for ingredient "Z" is presented in Figure 8.

		Contribution to Vulnerability				
		Low	Medium-Low	Medium	Medium-High	High
Controllable factors	Supply chain					X
	Audit strategy				X	
	Supplier relationship				X	
	History of supplier issues					X
	Methods and specs				X	
	Testing frequency					X
Uncontrollable factors	Geopolitical considerations					X
	Fraud history					X
	Economic anomalies					X

Figure 8. Step 1—Results of the Contributing Factors Assessment for ingredient "Z". Based on the contributing factors assessment, the manufacturer then performed an impact assessment (Step 2), and determined that the potential impacts on economic impact are high, but that potential food safety implications are moderate as presented in Figure 9.

	Low		Moderate		High
<b>Food Safety</b>	Food Grade-Known Safe	Food Grade-No Known Risks	Food Grade-Known Sub-Population Risks	Non-Food/Non-Food Grade-Unknown Risks	Non-Food/Non-Food Grade-Known Risks
<b>Economic Impact</b>	No Significant Balance Sheet Impact		Operational Risk		Enterprise Risk
<b>Potential Multipliers</b>					
<b>Focused Consumption</b>	No Focused Consumption	Temporally Focused	Low Level	Potential Target Populations	At-Risk Populations
<b>Nutritional Sufficiency</b>	No Sufficiency Impacts		Important Micro-Nutrient Food	Core Food For a Sub-population	Primary/Critical Sub-Population Food
<b>Public Confidence</b>	Specific food	Specific commodity	Industry sector	Industry wide	Authorities & Industry

Figure 9. Step 2—Results of the Impacts Assessment for ingredient "Z". Based on the integration of the contributing factors and impacts assessments, the manufacturer of the final product performs a vulnerabilities characterization (Figure 10), noting that new controls are strongly indicated.

**Illustrative Example—Implementing a Mitigation Strategy Plan, (continued)**

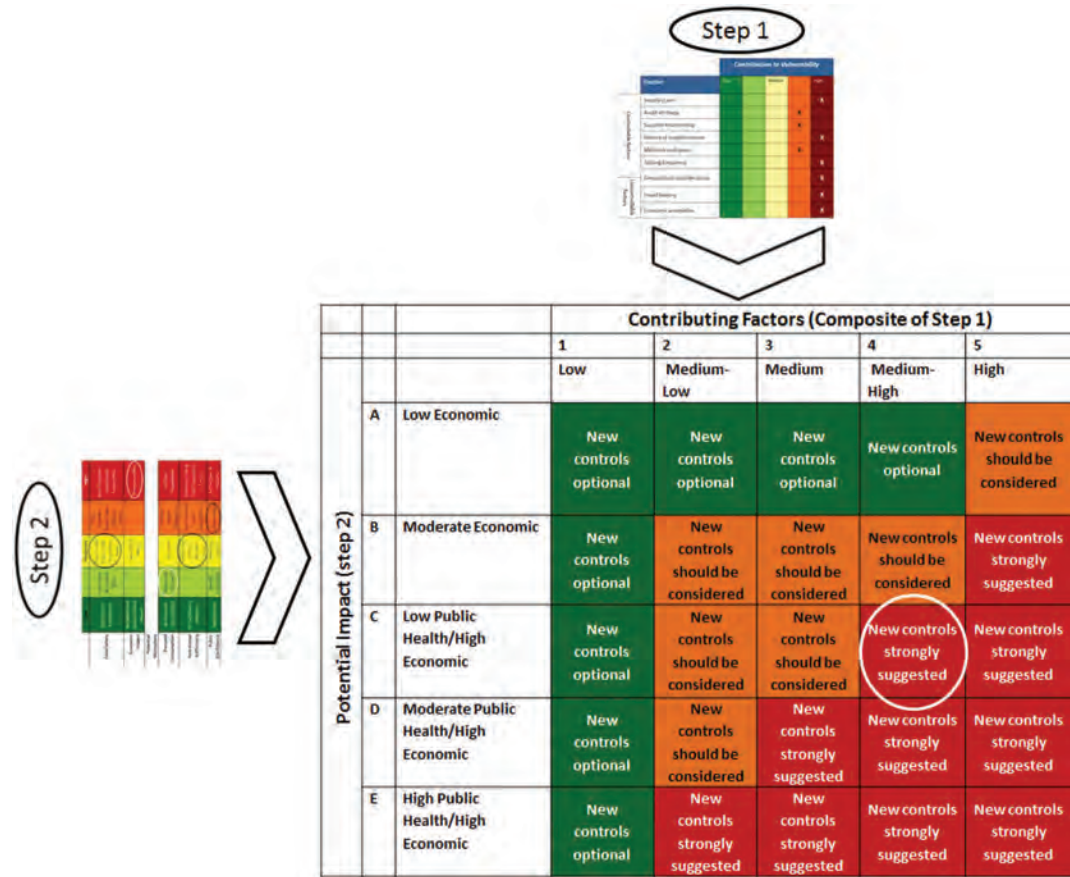


Figure 10. Step 3—Vulnerabilities characterization of ingredient "Z"

The following changes were made to the mitigation strategy:

- The new supplier was further researched to see if there were any warning flags such as other customer complaints regarding the quality of ingredients, as well as looking into the controls on ingredient quality that the supplier had.
- Based on some red flags in this research, a decision was made to return to the previous supplier who was a trusted and vertically integrated supplier for the food manufacturer.
- Testing frequency of the ingredient was increased strategically.
- QA methods and specifications for ingredient "Z" were changed to better characterize the ingredient.
- Audit strategy was enhanced by more frequent audits and the addition of onsite audits of the supplier.
- The supplier agreed to transition to a supply chain with greater oversight.
- No changes to the region from which the ingredient is sourced were possible, but this was documented.

The resulting change to the vulnerabilities assessment is presented in *Figure 11*.

*Illustrative Example—Implementing a Mitigation Strategy Plan, (continued)*

		Contribution to Vulnerability				
		Low	Medium-Low	Medium	Medium-High	High
Controllable factors	Supply chain		X			
	Audit strategy		X			
	Supplier relationship	X				
	History of supplier issues		X			
	Methods and specs	X				
	Testing frequency	X				
Uncontrollable factors	Geopolitical considerations					X
	Fraud history					X
	Economic anomalies					X

Figure 11. Effect of mitigation strategies on Step 1: Contributing Factors Assessment.

In this situation, as there has been no change to the formulation of the final product (no change to the ingredient exposure), the impact assessment will not change and this was documented.

The resulting change in the vulnerabilities characterization may look something like that shown in Figure 12.

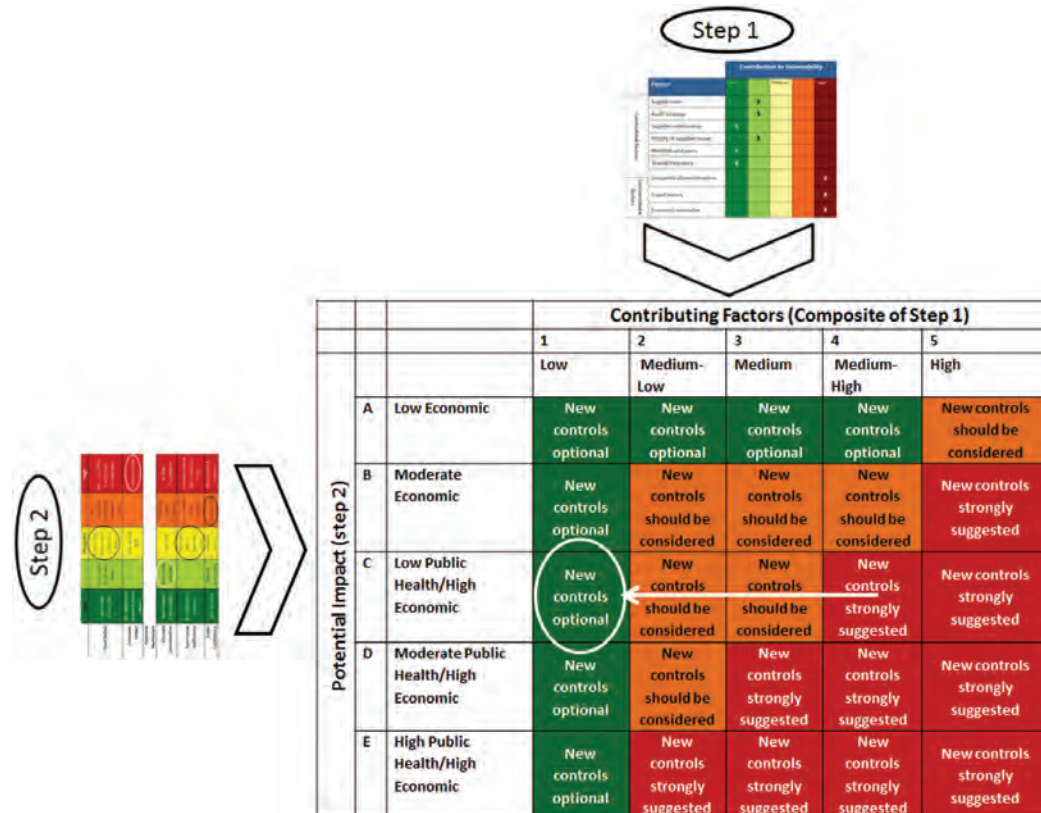


Figure 12. Step 3—Vulnerabilities characterization after mitigation strategies applied.

All conclusions and actions should be documented.

Include an ongoing program to assure that there are no changes or trends in the assumptions that were used for the assessments. For example:

- Keep assessing changes in fraud history and geopolitical situation using horizon scanning or other tools.
- Monitor vendor performance using scorecard indicators or other tools.
- Routinely review audits and analytical findings.

Individuals familiar with the assessment process may be able to define threshold values which would trigger a vulnerabilities review.

The process as referenced above is a dynamic one. Changes can be detrimental or beneficial. The review should not be a one-time activity. Ownership should be assigned and maintained.

The user should also keep in mind that in many countries, the legal and regulatory requirements for documenting and validating plans to address food fraud threats that could result in food safety risks are quite stringent. Therefore the user may want or be required to integrate regulatory considerations in the review of the mitigation plan.

## INFORMATION RESOURCES

[NOTE—This is not intended to be a comprehensive list nor an endorsement of any particular products or services.]

**Table 6. Useful Information Resources**

Factor	Name	Web Address
Fraud history	USP Food Fraud Database	<a href="http://www.foodfraud.org/">http://www.foodfraud.org/</a>
Fraud history	NCFPD EMA Incidents Database	<a href="https://www.foodshield.org/">https://www.foodshield.org/</a>
Fraud history	European Union Rapid Alert System	<a href="http://ec.europa.eu/food/safety/rasff/index_en.htm">http://ec.europa.eu/food/safety/rasff/index_en.htm</a>
History of supplier issues	USA-FDA Recalls and Enforcement Reports	<a href="http://www.fda.gov/Safety/Recalls/default.htm">http://www.fda.gov/Safety/Recalls/default.htm</a>
History of supplier issues	USA-FDA Import Alerts and Refusals	<a href="http://www.fda.gov/ForIndustry/ImportProgram/default.htm">http://www.fda.gov/ForIndustry/ImportProgram/default.htm</a>
History of supplier issues	USA-FDA Warning Letters	<a href="http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm">http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm</a>
History of supplier issues	European Union Rapid Alert System	<a href="http://ec.europa.eu/food/safety/rasff/index_en.htm">http://ec.europa.eu/food/safety/rasff/index_en.htm</a>
History of supplier issues	Canada Recalls and Alerts	<a href="http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php">http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php</a> <a href="http://www.inspection.gc.ca/about-the-cfia/newsroom/food-recall-warnings/complete-listing/">http://www.inspection.gc.ca/about-the-cfia/newsroom/food-recall-warnings/complete-listing/</a>
History of supplier issues	Australia and New Zealand	<a href="http://www.foodstandards.gov.au/science/surveillance/Pages/default.aspx">http://www.foodstandards.gov.au/science/surveillance/Pages/default.aspx</a>
History of supplier issues	Czech Agriculture and Food Inspection Authority	<a href="http://www.szpi.gov.cz/en/IstDoc">http://www.szpi.gov.cz/en/IstDoc</a> .
History of supplier issues	The Department of Food Safety, Govt of N.C.T of Delhi	<a href="http://dcwestrev.delhigovt.nic.in/pfa/newweb/CompleteListFood-Category.asp?SessNull=0">http://dcwestrev.delhigovt.nic.in/pfa/newweb/CompleteListFood-Category.asp?SessNull=0</a>
Geopolitical considerations	Regional food safety indices from Economist Intelligence Unit (EIU)	<a href="http://foodsecurityindex.eiu.com/">http://foodsecurityindex.eiu.com/</a> .
Geopolitical considerations	Transparency International's Corruption Perception Indices	<a href="http://ec.europa.eu/food/safety/rasff/index_en.htm">http://ec.europa.eu/food/safety/rasff/index_en.htm</a>
Geopolitical considerations	Transnational crime threats assessment by UN	<a href="https://www.unodc.org/unodc/en/data-and-analysis/TOC-threat-assessments.html">https://www.unodc.org/unodc/en/data-and-analysis/TOC-threat-assessments.html</a>

Factor	Name	Web Address
Geopolitical considerations	Political Risk Map and Terrorism Risk Map hosted by Aon	<a href="http://www.riskmap.aon.co.uk/Terrorism_Risk_Map.aspx">http://www.riskmap.aon.co.uk/Terrorism_Risk_Map.aspx</a>
Economic anomalies	Canadian trade data	<a href="http://strategis.gc.ca/eic/site/tdo-dcd.nsf/eng/Home">http://strategis.gc.ca/eic/site/tdo-dcd.nsf/eng/Home</a>
Economic anomalies	USA trade data	<a href="http://dataweb.usitc.gov/">http://dataweb.usitc.gov/</a>
Economic anomalies	USDA Foreign Agricultural Service's Global Agricultural Trade System (GATS)	<a href="http://apps.fas.usda.gov/gats/default.aspx">http://apps.fas.usda.gov/gats/default.aspx</a>
Economic anomalies	UK trade data	<a href="https://www.uktradeinfo.com/Pages/Home.aspx">https://www.uktradeinfo.com/Pages/Home.aspx</a>
Economic anomalies	COMTRADE international trade data	<a href="http://comtrade.un.org/">http://comtrade.un.org/</a>
Impact assessment	USP Food Fraud Database	<a href="http://www.foodfraud.org/">http://www.foodfraud.org/</a>
Impact assessment	NCFPD EMA Incidents Database	<a href="https://www.foodshield.org/">https://www.foodshield.org/</a>

### Guide for Accessing Pricing Data from GATS

In addition to data that may be available from company sources or trade associations, aggregated pricing data at a country or regional level can be accessed from various public trade registries. One way is the USDA Foreign Agricultural Service's Global Agricultural Trade System (GATS). GATS data is updated on a monthly basis with a 4–6 week lag, but since analysis at this level is trying to identify cases of systematic EMA, that is still very valuable in knowing when something warrants further investigation. The following illustrates how to use the tool:

1. Access the system at <http://apps.fas.usda.gov/gats/default.aspx>.
2. Click on Standard Query on the left side of the screen.
3. It opens with base settings. For ingredients that are significantly imported, select Imports – General from the Product Type dropdown menu.
4. Product Groups are the level of aggregation of materials. For specific ingredients, select Harmonized HS-6, HS-8 or HS-10 from the Product Groups dropdown menu.
5. Enter the name for the material of interest in the Commodity Search box and click the Go button (e.g., “Vanilla”).
6. In the center Products box, a list of product choices will come up. Choose the product(s) you are interested in (e.g. 095000 Vanilla Beans).
7. In the Statistics box, select FAS Non Converted or FAS Converted. FAS converts some of the quantity data from that recorded at entry to quantities that are more consistent.
8. In the Dates box, choose the date range that you are interested in.
9. Click on the Retrieve Data button and a table and control buttons like the one below in *Figure 13* will be on the bottom of the screen. Clicking the Other Formats button will take you to a screen to export the data as an Excel file.

Area/Partners of Origin		January - December															
And General Commodities Imported		Quantities/Values in Thousands of Dollars															
		2000		2001		2002		2003		2004		2005		Period/Period % Change (Value)		Period/Period % Change (Qty)	
Partner	Product	UOM	Value	Qty	Value	Qty	Value	Qty	Value	Qty	Value	Qty	Value	Qty			
World Total	09050000 - Vanilla Beans	MT	43,772	1,304.7	126,449	1,469.9	162,527	1,117.4	289,411	1,509.6	202,254	669.2	48,351	1,505.6	-76	125	
Grand Total		MT	43,772	1,304.7	126,449	1,469.9	162,527	1,117.4	289,411	1,509.6	202,254	669.2	48,351	1,505.6	-76	125	

**Notes:**  
 1. Data Source: U.S. Census Bureau Trade Data  
 2. All zeroes for a data item may show that statistics exist in the other import type, Consumption or General.  
 3. Users should use cautious interpretation on QUANTITY reports using mixed units of measure. QUANTITY line items will only include statistics on the units of measure that are equal to, or are able to be converted.  
 4. Product Group : Harmonized

Figure 13. Example Output from GATS.

### Acknowledgments

USP would like to acknowledge Jerry Phares, Deputy Clerk, U.S. District Court, Western District of Kentucky for his assistance identifying available court case records relevant to the Sun Up Foods, Inc. case; and Leonard Jay Farr, retired compliance officer with the US FDA Cincinnati District Office, Cincinnati, OH for his contributions to the Sun Up Foods, Inc. illustrative example.





## FOOD SAFETY AND INTEGRITY SOLUTIONS

For more information about USP's Food Safety and Integrity Solutions please go to [www.foodfraud.org](http://www.foodfraud.org) or contact us at [foods@usp.org](mailto:foods@usp.org).

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### **USP-Brazil**

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### **USP-Ghana**

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### **USP-Philippines**

Muntinlupa City

### **USP-Nigeria**

Lagos