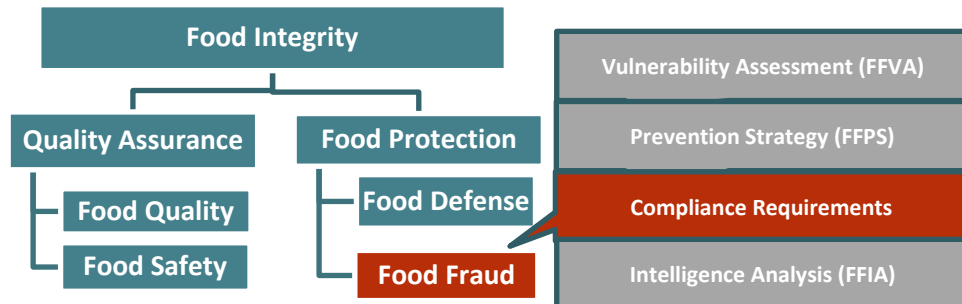




# Food Fraud Prevention THINK TANK

Primer on Food Fraud Compliance

MAY 2023



## Food Fraud Compliance Requirements (2023)

As Food Fraud has become more of a focus, there are evolving expectations – whether explicit or implicit – for meeting regulatory or standards compliance. The first step in addressing a vulnerability or risk is considering the urgent and most basic minimum requirements. There are a range of laws, regulations, certifications, and standards that apply. These include the Global Food Safety Initiative (GFSI), Food Safety Modernization Act (FSMA), Food Drug & Cosmetics Act (FDCA or FD&C), Sarbanes-Oxley Act (SOX or Sarbox), ISO, Codex Alimentarius, and others. FSMA compliance has been a priority activity for food companies, but the FDCA sections on “Adulterated Foods” and “Misbranded Foods” are still in effect. After an incident and during an investigation, a question would be, “How did you define this NOT to be a ‘hazard that requires a preventive control?’” Addressing all hazards from any source is a requirement for food laws. Specifically, all types of Food Fraud have been illegal in the U.S. since at least the Food Drug and Cosmetics Act of 1938 which included sections on “Adulterated Foods” and “Misbranded Foods.” Though not explicitly stated or defined in FDCA, conducting a Food Fraud Vulnerability Assessment (FFVA) and Food Fraud Prevention Strategy (FFPS) has been a requirement. Sarbox expanded the requirement to business equity risks in 2002. As of January 1, 2018, the Global Food Safety Initiative (GFSI) requirements now include an FFVA and FFPS for all types of fraud and for all products. Since Food Fraud Prevention is new, the first requirements are very simple in seven “yes or no” questions include: (1) conduct an FFVA, (2) it is written, (3) conduct an FFPS, (4) it is written, (5) document and demonstrate implementation, (6) include executive-level sign-off, (7) at least update the FFVA annually, (8) implement a method to review incidents, and cover the GFSI scope of (9) all types of fraud and for (10) all products. The GFSI compliance appears to address the other regulatory and standards requirements.

Food Fraud – intentional deception for economic gain using food – is an urgent food industry issue. While the most important strategic goal is to protect the product, the most pressing tactical issue is meeting compliance requirements for laws, regulations, certifications, and standards. Without meeting the compliance requirements thoroughly and on time, the company’s products will be illegal or de-certified and prohibited from selling or buying. This **Primer on Food Fraud Compliance** will address the details of those compliance questions.

**The most pressing and urgent issue is the GFSI requirement, which was due on January 1, 2018. Not being GFSI compliant on January 1, 2018, could lead to a poor audit score and GFSI de-certification. GFSI certification is a requirement to be able to sell to most companies.**

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**Compliance Requirements:** There are a range of compliance requirements, including the Food Safety Modernization Act (FSMA), Food Drug and Cosmetics Act (FDCA), Codex Alimentarius (CODEX), Chinese Non-Traditional Food Safety Issues (CFDA), Sarbanes-Oxley Act (SOX or SARBOX), International Standards Organization (ISO), European Union (E.U.), Global Food Safety Initiative (GFSI), and others. The bottom line is that generally, all types of food fraud (from adulterant-substances to stolen goods and counterfeits) and all products (from raw ingredients to consumer-packaged goods that are at retail locations) are illegal or unacceptable under one law or another. Whether Food Fraud is an inspection or enforcement priority, the product is illegal, and after an incident, a logical question would be, “How did you determine this NOT to be a ‘hazard that requires a preventive control?’”

**Requirements – Source and Dates:** This will help prioritize the timing and intensity of work (Table 2).

- **Global Food Safety Initiative (GFSI)** – January 2018 – Consequence: De-certified. Possibly not be allowed to sell your products.
- **Food Safety Modernization Act (FSMA)** – September 2016 – Consequence: see FDCA section below
- **Food Drug and Cosmetics Act (FDCA)** – 1938 – Consequence: All types of fraud for all products are illegal, so the consequence is a recall or regulatory penalties after an incident.
- **Sarbanes-Oxley Act (SOX)** – 2002 – Consequence: This is beginning to be an audit item leading to regulatory penalties and possible criminal charges.
- **Codex Alimentarius (CODEX)** – Several Years – Consequence: A discussion paper addressing definitions and Food Fraud prevention management systems. Generally, “fraudulent activities” are covered.

**GFSI - Requirements – Details and Actions:**

Several specific requirements for GFSI appear to equate to compliance with the other laws and regulations (See Table 1). Answering “yes” to the seven questions appears to confirm GFSI compliance. ANY “no” response would NOT lead to GFSI compliance and possible de-certification. There is a criticism that an Audit with only “yes or no” questions is just a checklist. While this is true, it is also the most efficient and effective role of the auditor at this stage. Food Fraud Prevention is only just being implemented. By the auditors asking the questions, the companies being certified will begin a chain of events to address and approve the Food Fraud Prevention activities. The “yes or no questions” for the GFSI requirements will start harmonized implementation, allowing sharing of best practices and more advanced and optimized countermeasures and control systems.

<b>Table 1: GFSI Food Fraud Compliance Requirements<sup>1</sup> – Answer “Yes” to All Questions to Confirm Compliance</b>	
<b>1)</b>	<b>Have you conducted a Food Fraud Vulnerability Assessment? (Y/N)</b>
<b>2)</b>	<b>Is it written – how soon could you show it to me? (Y/N)</b>
<b>3)</b>	<b>Have you created a Food Fraud Prevention Strategy? (Y/N)</b>
<b>4)</b>	<b>Is it written – how soon could you show it to me? (Y/N)</b>
<b>5)</b>	<b>Can you Demonstrate Implementation – is it documented?</b>
<b>6)</b>	<b>Do you have an Executive Level Sign-off (an officer of your company)?</b>
<b>7)</b>	<b>Have you minimally conducted an annual Food Fraud Incident Review? (Y/N)</b>
<b>8)</b>	<b>Do you have a method to review your incidents and general market incidents?</b>
<b>9)</b>	<b>Plus: Confirm this does address all types of Food Fraud. (Y/N)</b>
<b>10)</b>	<b>Plus: Confirm this addresses all products from incoming goods (e.g., ingredients) and outgoing goods (e.g., finished goods) to the consumer. (Y/N)</b>

**How to Achieve Compliance – Minimum Requirements:** The current compliance requirements are very simple in the absence of clear regulatory or standards guidance. To satisfy a GFSI auditor, there is no detail or specification on how long or the level of detail regarding the vulnerability assessment or the prevention strategy. From the details provided by GFSI, there are only “yes or no” questions as to whether the documents exist, that they are written, and that they cover the full “GFSI scope.” That said, not meeting any of those minimum, simple requirements would not pass an audit and eventually lead to GFSI Food Safety Management – not just the food fraud section of the code – de-certification.

**FDCA/ FSMA – Requirements – How to Achieve Compliance:** Essentially, the U.S. food laws – both the Food Safety Modernization Act of 2011 (FSMA) and the foundational Food Drug and Cosmetics Act of 1938 (FDCA) address all hazards for any “agent” [physical agent] that causes a “hazard that requires a preventive control” regardless of the source including from acts that are “economically motivated.”<sup>ii</sup> FSMA/FDAC does not require a company to do anything specific to address Food Fraud<sup>iii</sup>, but they hold the company accountable for any problem or hazard that could occur. This means that there are no prescribed tasks to address FF/EMA, but after an incident, a logical question from an FDA Office of Criminal Investigation or FBI investigator would be, “How did you determine this NOT to be a ‘hazard that requires a preventive control.’” This has also been addressed in the Preventive Controls for Human Food Qualified Individual Training (PCHF-QI).<sup>iv</sup> These requirements expect all hazards to be assessed and managed:

- **“The hazard analysis must be written regardless of its outcome” [21CFR507.33 (a)(2)]/ 21CFR117.130).”**
- **“(iii) The hazard may be intentionally introduced for purposes of economic gain.”**

Table 2: Summary of Compliance Requirements Regarding Food Fraud		
Requirement	Effective Date	Scope
Food, Drug & Cosmetics Act – Section on “Adulterated Foods” and “Misbranded Foods”	1938	All types of food fraud are illegal, unfit for commerce, and regardless of the investigation or enforcement priority, they are subject to a recall. Not addressing Food Fraud could be <u>literally</u> criminal. <b>Requirement:</b> assess and address ‘hazards that require a preventive control’ – they do not specifically mention or address food fraud. <b>Consequence:</b> illegal products could be subject to recall and financial penalties.
Sarbanes-Oxley Act	2002	All types of business fraud that could lead to a negative economic impact on revenue or equity; the annual report states that all risks are with the risk tolerance or reported; not reporting is a federal crime <b>Requirement:</b> address or disclose risks to revenue <b>Consequence:</b> not an enforcement priority, but non-compliance could be a felony crime.
FSMA Preventive Controls	September 2016	All types of food fraud that lead to a ‘hazard that requires a preventive control’ (to determine this, all food fraud types must be assessed) <b>Requirement &amp; Consequence:</b> see FDCA
GFSI Version 7 (including certification programs such as FSSC, SQF, etc.)	January 2018	All types of food fraud must be assessed, and prevention plans for health hazards. <b>Requirement:</b> conduct and document annually a (1) food fraud vulnerability assessment, (2) food fraud prevention strategy, and (3) address the GFSI scope. Note: FFVA – and food defense vulnerability assessment – must be separate from the food safety assessment. <b>Consequence:</b> non-compliance will lead to being de-certified.
GFSI Certification Programs Organizations (CPOs)	January 2018	The core requirements are from GFSI, and each CPO has some additional requirements or details. <b>Requirement &amp; Consequence:</b> see GFSI

**How to Achieve Compliance – First Step:** To achieve a specific objective, the first step is to define the scope of “what is a success.” For Food Fraud Compliance, if the scope is “GFSI Compliance,” then it appears the final product will also achieve compliance with most if not all, other requirements.

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<sup>i</sup> Food Safety Magazine, Feb 2017, “Food Fraud Vulnerability Assessment and Pre-filter for FSMA, GFSI and SOX Requirements”, <http://www.foodsafetymagazine.com/magazine-archive1/februarymarch-2017/food-fraud-vulnerability-assessment-and-pre-filter-for-fsma-gfsi-and-sox-requirements/>; New Food Magazine, Feb 2017: Food Fraud Prevention – how to start and how much is enough?”, <http://www.newfoodmagazine.com/33890/new-food-magazine/past-issues/issue-1-2017/issue-1-2017-digital-version/>

<sup>ii</sup> Spink, John (2015). Review: Final Rule for FSMA Preventative Controls Regarding Food Fraud and EMA (FSMA-PC), <http://foodfraud.msu.edu/2015/10/08/review-final-rule-for-fsma-preventative-controls-regarding-food-fraud-and-ema-see-15-page-preliminary-report/>

<sup>iii</sup> Or the term still used by FDA is Economically Motivated Adulteration or EMA. This is a confusing term since the law address all types of fraud in the FDCA sections on “Adulterated Foods” and “Misbranded Foods” but the “FDA working definition” of EMA is a “substance” for “economic gain” with a “health hazard.” Using this FDA working definition then the horsemeat incident would not be “EMA.”

<sup>iv</sup> Preventive Controls Qualified Individual Training, Chapter 5, Section on Economically Motivated Hazards (FDA and FSMA) [FDA] – FDA/FDCA/FSMA requirement: <https://www.youtube.com/watch?v=ZqMHhfSbvek>