

FFI Report

Review – New FSSC 22000 Version 4 Regarding Food Fraud and Food Defense

December 23, 2016

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SUMMARY

On December 22, 2016, FSSC 22000 released their new “Food Safety System Certification 22000” Version 4. This will be required after an “appropriate transition period for certified organizations to adapt to the implementation of the new requirements” or reportedly by January 1, 2018. This is one of the first systems or programs that explicitly addresses and emphasizes “Food Fraud *Prevention*.”

Aligned with GFSI, the standard requires a separate (1) Food Fraud Vulnerability Assessment and (2) Prevention Strategy for **all** types of fraud, **all** products, and across the food supply chain from raw materials to finished goods supplied to end users.

They also require a separate Food Defense threat assessment and control plan for all types of attacks – e.g. tampering and disgruntled employees not just the FSMA Intentional Adulteration scope of terrorist-type “wide scale [human] public health harms.”

Most food companies are **not** currently compliant and will need to expand their Food Fraud vulnerability assessments and prevention strategies. That said there are many resources already available. See the SSAFE organization [Food Fraud Guidance](#), the published MSU [Food Fraud Initial Screening Tool](#) (FFIS), and our MSU Food Fraud Initiative Executive Education Short-courses or the Food Fraud MOOC [Massive Open Online Course](#).

FSSC 22000 – based on the ISO 22000 Food Safety Management – is one of several Global Food Safety Initiative (GFSI) recognized standards. GFSI essentially sets the food safety management system expectation for most of the food industry. This standard essentially defines what the food industry **will** do.

CONCLUSION

Current Food Fraud Vulnerability Assessments and prevention plans appear to be compliant as long as the scope covers **all** types of fraud, **all** products, and **all** the way to the end user – some systems or programs only cover ingredient, only adulterant-substances, or combine Food Fraud and Food Defense assessments.

1. Conducting a Food Fraud vulnerability assessment is **not** optional
2. Implementing a separate Food Fraud prevention strategy is **not** optional.
3. There must be a separate assessment for Food Fraud and another for Food Defense.



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Introduction

This is the full, detailed review of the new FSSC 22000 Food Safety System Certification 22000” Version 4. A detail Line-by-Line assessment is provided.

The following is a section-by-section review of the FSSC 22000 Version 4 as it relates to *Food Fraud* and the related application to Food Defense. For reference purposes, coding has been added to each pertinent section. Codes have three components:

- The first digit refers to the FSSC 22000 Part. There are five parts and then appendices.
- The next three digits refer to the source document page number
- The final digit (after the decimal) identifies a separate concept addressed on that page.
- “FFI Comment” sections are included, numbered, and authored by MSU Food Fraud Initiative researchers.
- For example, ‘88.3’ refers to page 88 with a specific note of the 3rd concept on that page. (Note: Any in-text emphasis (e.g., underlining) is added by the authors.)

Definitions

Key definitions are for Food Defense and Food Fraud Prevention:

FSSC-0-005.2: “Food Defense - The process to prevent food and feed supply chains from all forms of ideologically or behaviorally motivated, intentional adulteration that might impact consumer health.”

- **FFI Insight 1:** A key for the general Food Defense concept is intent to harm. This definition would include Food Fraud.
- **FFI Insight 2:** While later in FSSC 22000 Food Fraud is identified as a separate assessment and control plan, here the Food Defense definition technically covers all intentional acts including fraud.
- **FFI Insight 3:** An interesting grammatical note is that the document uses British or European spelling except for the phrase ‘Food *Defense*’ rather than ‘Food *Defence*.’ For example, ‘flavourings’ versus flavorings and ‘prioritises’ versus prioritizes.

FSSC-0-005.1: “Food Fraud Prevention -The process to prevent food and feed supply chains from all forms of economically motivated, intentional adulteration that might impact consumer health.”

- ***FFI Insight 4:** This is one of the first times that Food Fraud Prevention has been clearly identified in a scheme.

- **FFI Insight 5:** The standard mentioned avoided potential translation or regulatory interpretation confusion by not using “economically motivated adulteration” but “economically motivated, economically motivated, intentional adulteration.”

FSSC-0-006.X: “Food Fraud” – no definition. Later they refer to GFSI compliance.

The GFSI definition of Food Fraud was included in the GFSI position paper.

From GFSI: “Food fraud... is deception of consumers using food products, ingredients and packaging for economic gain and includes substitution, unapproved enhancements, misbranding, counterfeiting, stolen goods or others.”

- ***FFI Insight 6:** Though Food Fraud was not explicitly defined in this scheme the adherence to GFSI would lead to a definition that includes all types of fraud including adulterant-substances, stolen goods, and counterfeiting.

Other important definitions:

FSSC-0-005.1: “Food - Any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes amongst others:

- a) drink,
- b) chewing gum and
- c) any substance that has been used in the manufacture, preparation or treatment of “food” .”

FSSC-0-006.2: “Food/Feed Safety - The policies, processes and procedures, materials, facilities and monitoring systems applied to Food or Feed products to ensure they will not cause harm to humans or animals or adversely affect their health when utilized according to their intended purpose.”

- **FFI Insight 7:** The scheme does not limit harm or hazard within a manufacturing facility or within the proprietary supply chain. All types of hazards – and all types of fraud – would be in-specification all the way to the end user.

FSSC-0-006.3: “Food/Feed Safety Hazard - Biological, chemical, physical agent or allergen in food/feed, or condition of food/feed, with the potential to cause an adverse health effect to humans and/or animals (ISO 22000, section 3.3).”

- **FFI Insight 8:** Applying to Food Fraud, the phrase “or condition of food/feed” applies to stolen goods that are mishandled that leads to spoilage that creates a health hazard. This is in agreement with consistent with UK Food Standards Agency, European Commission Resolution on Food Fraud, UK DEFRA Elliott Review, GFSI and others.

Assessments

There were specific sections and requirements for 'Food Fraud Vulnerability Assessment' and 'Food Defense Threat Assessment.' They did not use the terms TACCP or VACCP.

Food Fraud Requirement

FSSC-2-007.1: "2.1.4.6 Food Fraud prevention

2.1.4.6.1 Vulnerability assessment

- 1) The organization shall document, establish and maintain a documented procedure for food fraud vulnerability assessment that:
 - a) identifies potential vulnerabilities,
 - b) develops preventive measures, and
 - c) prioritises them against the vulnerabilities.
- 2) In order to identify the vulnerabilities, the organization shall assess the susceptibility of its products to potential acts of food fraud.

2.1.4.6.2 Preventive measures

- 1) The organization shall put in place appropriate preventive measures to protect consumer health. These processes shall;
 - a) be controlled within the scope of the food safety management system;
 - b) be in compliance with applicable legislation.

2.1.4.6.3 Annual review

- 2) The food fraud prevention procedure shall be reviewed;
 - a) after each actual or potential failure of a preventive measure, and
 - b) at least annually."

- **FFI Insight 9:** The scheme refers to the Food Fraud activity as a "vulnerability assessment" consistent with the previous GFSI mentions of Vulnerability Assessment and Critical Control Plan or VACCP. TACCP was not specifically mentioned in this scheme.
- ***FFI Insight 10:** The scheme requires – it is not optional – to have a "documented procedure" that includes identifying and implementing "preventive measures."
- ***FFI Insight 11:** The scheme requires – it is not optional – to assess **all** types of Food Fraud to "assess the susceptibility of its products."

Food Defense Requirement

FSSC-2-006.1: “2.1.4.5 Food defense

2.1.4.5.1 Threat assessment

1) The organization shall document, establish and maintain a documented procedure for food defense threat assessment that:

- a) identifies potential threats,
- b) develops preventive measures, and
- c) prioritises them against the threats.

2) In order to identify the threats, the organization shall assess the susceptibility of its products to potential acts of:

- a) sabotage,
- b) vandalism, and/or
- c) terrorism.

2.1.4.5.2 Preventive measures

The organization shall put in place appropriate preventive measures to protect consumer health impacts. These processes shall;

- a) be controlled within the scope of the food safety management system;
- b) be in compliance with applicable legislation.

2.1.4.5.3 Annual review

1) The food defense procedure shall be reviewed:

- a) after each actual or potential failure of a preventive measure, and
- b) at least annually.”

- **FFI Insight 12:** The scheme refers to the Food Defense activity as a “threat assessment” which is consistent with the previous GFSI publications regarding “threat” and “TACCP.” TACCP was not specifically mentioned in this scheme.
- **FFI Insight 13:** The scope of the scheme is broader than the Food Safety Modernization Act (FSMA) intentional Adulteration Rule – wide-scale intention health hazard, essentially terrorist attacks -- and appears consistent with the GFSI requirements. A separate or modified Food Defense plan may be needed – or preferred – for FSMA-IA compliance.
- **FFI Insight 14:** There may be confusion between the GFSI and US Food Safety Modernization Act Intentional Adulteration rule (FSMA-IA) Food Defense requirements. FSMA-IA addresses a “vulnerability assessment.” This confusion was unavoidable since the global industry, association, and academic activities – including in the USA – has referred to a Food Fraud assessment as a “vulnerability assessment.” There is a clarity of three different types of assessments for the three different concepts: Food Safety has a “hazard assessment” which is consistent with “HACCP,” Food Fraud has a “vulnerability assessment,” and Food Defense has a “threat assessment.” The “threat assessment” – and TACCP – is also consistent with UK Publically Available Standard 96 Food Defence (PAS96).

Due to the narrower FSMA-IA scope a modified Food Defense plan may be needed for FSMA-IA compliance.

Additional Definitions

FSSC-0-006.4: “Ingredient - A processed or unprocessed component of food, feed or packaging.

FSSC-0-007.1: “Raw Material – A component of food, feed or packaging that has not undergone processing.

FSSC-0-006.X: “Finished or Packaged Goods” – no definition

FSSC-2-007.2: “2.1.4.9 Product labelling - The standard shall ensure that the finished product is labelled according to the applicable food regulations in the country of intended sale.”

FSSC-0-007.2: “Retail - Preparation, packaging, storage, serving, vending, selling or otherwise providing food for consumption direct to the public.”

FSSC-0-007.3: “Risk - The product of the probability of an adverse health effect and the severity of that effect, consequential to hazard in food when prepared and consumed according to its intended use.

A FSSC defined “risk” could be present that does not create a hazard that would require a preventive control. The FSSC definition of “risk” is similar but different from ISO 31000 Risk Management/ Guide 73 Risk Terminology which states:

From ISO 31000: “Risk – The effect of uncertainty on objectives. NOTE 1: An effect is a deviation from the expected — positive and/or negative”

The FSSC definition implies only a negative consequence. (A more detailed term could have been “food hazard risk”).

Auditor Requirements

The auditors and auditor requirements are an important component:

FSSC-0-004.1: “Auditor qualification - The process applied to confirm auditor competence.”

FSSC-A5-003.1: “Annex 5: Auditor Competence
3.2 Initial Training

The CB shall provide initial training in the following areas if the auditor does not already meet the requirements detailed in the section specific specifications:

- 1) HACCP training – minimum 16 hours;
- 2) Food Safety Management Training – minimum 40 hours, as lead auditor in ISO 22000 or in FSSC 22000;
- 3) Sector specific training in relevant PRPs;
- 4) FSSC 22000 Scheme requirements, and
- 5) ISO/TS 22003; ISO 19011 and ISO 17021-1.”

FSSC-A5-006.1, 009.1, 011.1, 013.1: “4 - Practical Assessment -

- 1) Successful completion of supervised training through 5 audits or 10 audit days at a number of different organizations.
- 2) Previous ISO 22000 and/or GFSI recognized audits are considered applicable for meeting the practical assessment.
- 3) Final assessment by a competent assessor/supervisor during FSSC 22000 audit (qualifying witnessed audit) - to cover the following:
 - a) Knowledge of
 - i) Food safety;
 - ii) HACCP;
 - iii) PRPs;
 - iv) Food fraud prevention;
 - v) Food defense, and
 - vi) Applicable laws/regulations/codes.”

- **FFI Insight 15:** The training or requirements for Food Defense and Food Fraud are undefined.
- **FFI insight 16:** Again, Food Fraud and Food Defense are identified as separate topics requiring separate expertise.

Scope of the Standard

The scope is very important to clearly understand what is or isn't required:

FSSC-1-004.1: “2 Scope - The Scheme is intended for the audit, certification and registration of food safety management systems for the following scopes and product categories:

- 1) Farming of animals Farming of animals for meat, milk, eggs and honey but excluding trapping, hunting and fishing.
- 2) Manufacturing of food products
 - a) Production of perishable animal products (e.g. meat, poultry, eggs, dairy and fish/seafood products).

- b) Production of perishable plant products (e.g. fruits, fresh juices, vegetables, grains, nuts and pulses).
 - c) Processing of perishable animal and plant products (mixed products; e.g. pizza, lasagna, sandwich, dumpling, ready-to-eat meal).
 - d) Production of products with long shelf life at ambient temperature (e.g. canned products, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar, food-grade salt).
 - e) Production of (bio)chemicals (i.e. food and feed additives, vitamins, minerals, bio-cultures, flavourings, enzymes and processing aids) but excluding pesticides, drugs, fertilizers and cleaning agents.
- 3) Manufacturing of food packaging and packaging material (e.g. direct, indirect contact with the food)
 - 4) Manufacturing of food and feed for animals (e.g. pet food, pet food for dogs and cats, animal feed, fish feed)
 - 5) Transport and storage services (e.g. storage and transport activities across the food supply chain)
 - 6) Catering Preparations, storage and, where appropriate, delivery of food for consumption, at the place of preparation or at a satellite unit.
 - 7) Retail/wholesale Provision of finished food products to a customer (e.g. retail outlets, shops, wholesalers)."
- ***FFI Insight 17:** While the scheme does not explicitly state the scope to cover finished goods – raw materials and ingredients are named – the scope includes through “transportation and storage” as well as to “catering” or “retail.”
- FSSC-1-003.1:** “1 Background - 1.1 Aim of the Scheme - The aim of the FSSC 22000 certification Scheme (hereafter the Scheme) is to ensure that the Scheme continuously meets international requirements resulting in certification that assures the provision of safe products to consumers worldwide. ... The value added for a certified organization lies in the oversight by the Foundation to ensure that the integrity of the entire certification process is in line with the Scheme requirements recognized by GFSI.”
- **FFI Insight 18:** The ‘provision of safe products to consumers’ emphasizes the last step in the supply chain which includes handing finished or packaged goods to the final user.
 - **FFI Insight 19:** The scheme clearly defines the scope to meet GFSI requirements which include Food Defense and Food Fraud.
 - **FFI Insight 20:** The scheme aligns with the GFSI Food Fraud scope that includes any action that could lead to a food safety hazard including from raw materials through ingredients to finished or packaged goods. This also includes controls over the entire supply chain from manufacturing through transportation and storage to the final delivery to the user.

FSSC-2-005.1: “2.1.4 Additional requirements - To meet the needs of the key stakeholders and to ensure an adequate control of food safety, specific additional FSSC requirements for the food safety management system are included in the Scheme. ... These may be elaborations of the clauses in ISO 22000 and technical specifications for sector PRPs or additional requirements as outlined below. ... The additional Scheme requirements are:

- 1) Management of services
- 2) Supervision of personnel
- 3) Management of supplied materials
- 4) Management of natural resources (for animal production only)
- 5) Food defense
- 6) Food fraud prevention
- 7) Formulation of products (only for pet food for dogs and cats)
- 8) Management of allergens
- 9) Product labelling
- 10) Environmental monitoring
- 11) Logo use [of the FSSC logo].

- ***FFI Insight 21:** Food Defense and Food Fraud are clearly separated as separate functions or requirements.

Conclusion

The FSSC 22000 Version 4 is clear and direct in their coverage of Food Defense and Food Fraud. This is consistent with other GFSI requirements including the GFSI Guidance Document Issue 7 that is due to publish in two months in February 2017. **FFI**

Reference:

- FSSC 22000, Food Safety System Certification 22000, Edition 4, January 2017 (published December 22, 2016) [Accessed December 22, 2016], URL: <http://www.fssc22000.com/documents/support/downloads.xml?lang=en>

MSU’s Food Fraud Initiative will continue to inform global stakeholders as to the relationship between Food Fraud and Economically Motivated Adulteration, Food Crime, Food Integrity, and Food Authenticity in order to encourage a global set of terms and definitions that are consistent.

Note: MSU’s Food Fraud Initiative (FFI) conducts a wide range of teaching, research and outreach projects. The “FFI Report” series was created to review specific emerging topics or recent laws, regulations, certifications, standards, or best practices. The summary and insight is not legal advice and is not intended to replace the counsel of a food law expert.

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