



FOOD SAFETY SYSTEM CERTIFICATION 22000

GUIDANCE DOCUMENT: FOOD DEFENSE

CONTENTS

REVISION HISTORY 1

1. BACKGROUND 2

2. DEFINITION 2

3. FSSC 22000 SCHEME REQUIREMENTS 3

4. IMPLEMENTATION 4

5. FOOD DEFENSE TEAM AND TRAINING 5

6. AUDITING 6

7. REFERENCES 7

REVISION HISTORY

Date Published	Issue	Changes
May 2019	1	First publication
July 2023	2	Updates made in line with Version 6 of the FSSC 22000 Scheme

1. BACKGROUND

Food defense is a crucial element in protecting your business and consumers from internal and external threats. It encompasses a range of potential threats, from relatively common tamper hoaxes to less probable terrorist attacks. Searching the web for “product tampering” or “product tampering employee” gives numerous examples illustrating that the threat is REAL. Supply chain or manufacturing threats can often be mitigated to reduce a wide range of threats. For example, putting a locking lid on a vat can facilitate a wide range of potential intentional attacks.

Food Defense Programs shall be developed to reduce the risks from internal and external threats to protect your customers.

The FSSC 22000 Additional Requirements contain a specific requirement on Food Defense. Although this topic is addressed in ISO/TS 22002-1:2009 clause 18, the FSSC 22000 Additional Requirement 2.5.3 is aligned with GFSI requirements and taken to the management system level, making it a part of the management responsibility process.

2. DEFINITION

There are many different definitions of food defense which are in nature very similar. Some even conflict with the GFSI definition, such as including food fraud within the scope of food defense. It is essential to realize that food fraud is a separate topic and a different requirement in the FSSC 22000 Scheme.

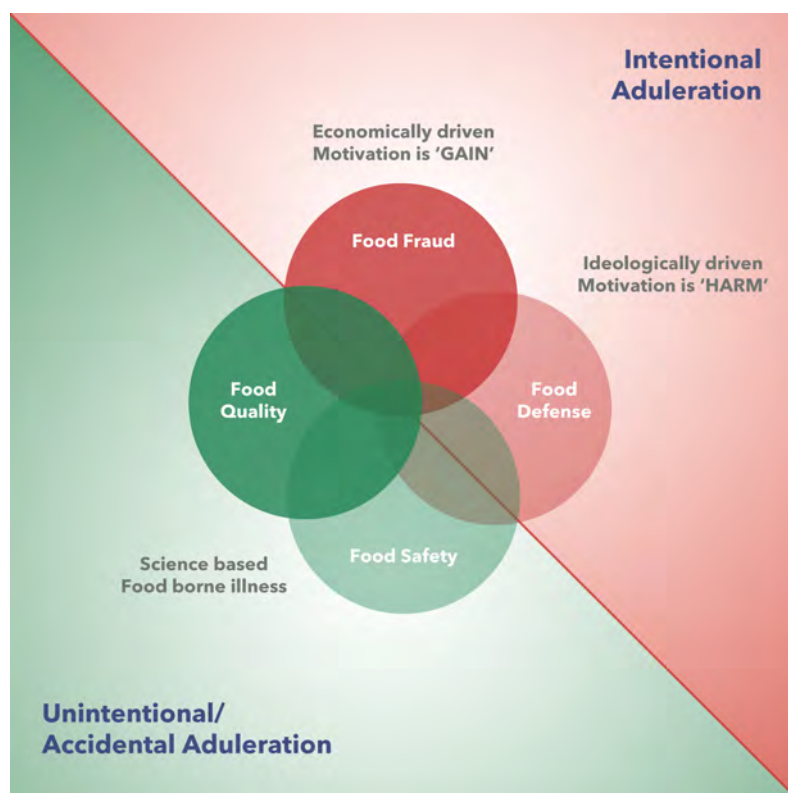
The GFSI definition of Food Defense is: “The process to ensure the security of food, food ingredients, feed, or food packaging from all forms of intentional malicious attack including ideologically motivated attack leading to contamination or unsafe product.” (GFSI 2020.1)¹.

Other frequently used definitions are:

- PAS 96:2017 - Food Defense: procedures adopted to ensure food and drink security and supply chains from malicious and ideologically motivated attacks leading to contamination or supply disruption (PAS 96:2017)².
- FDA (FSMA-Intentional Adulteration Rule): Food Defense is the effort to protect food from intentional adulteration from acts intended to cause wide-scale harm to public health, including acts of terrorism targeting the food supply (FDA Food Defense fact sheet)³.

Industry and regulators have developed Food Safety Management Systems based on Hazard Analysis Critical Control Point (HACCP) principles which have proven effective against unintended food safety hazards. HACCP principles, however, have not been routinely used to detect or mitigate deliberate attacks and are therefore not relevant to Food Defense.

The motivation or root cause for food defense is the intent to cause harm to consumers or companies. This is different from the motivation for food fraud which is exclusively for economic gain. Therefore, food defense prevention requires a different approach than the control of unintentional food safety hazards (HACCP) and food fraud prevention.

Figure 1. Intentional vs. unintentional adulteration⁹

3. FSSC 22000 SCHEME REQUIREMENTS

Part 2 – Requirements for organizations to be audited V6:

2.5.3 FOOD DEFENSE (ALL FOOD CHAIN CATEGORIES)

2.5.3.1 THREAT ASSESSMENT

The organization shall:

- a) Conduct and document the food defense threat assessment, based on a defined methodology, to identify and evaluate potential threats linked to the processes and products within the scope of the organization; and
- b) Develop and implement appropriate mitigation measures for significant threats.

2.5.3.2 PLAN

- a) The organization shall have a documented food defense plan based on the threat assessment, specifying the mitigation measures and verification procedures.
- b) The food defense plan shall be implemented and supported by the organization's FSMS.
- c) The plan shall comply with applicable legislation, cover the processes and products within the organization's scope, and be kept up to date.
- d) For food chain category FII, in addition to the above, the organization shall ensure that its suppliers have a food defense plan in place.

4. IMPLEMENTATION

To implement the FSSC 22000 Food Defense requirements, a logical, systematic, and risk-based approach should be followed. It must be noted that there are many approaches, and FSSC leaves the choice to the organization. However, the most widespread methods are TACCP (Threat Assessment Critical Control Points; BSI/PAS 96 recommended), CARVER+Shock, and FDA “Food Defence Plan Builder” (FDA)⁴.

To assist in implementing the clauses of FSSC 22000, the following way of working is recommended:

- 1) Establish a food defense team;
- 2) Conduct a threat assessment (e.g., TACCP), identify and evaluate potential threats linked to the processes and products within the scope of the organization;
- 3) Define the significant threats;
- 4) Identify, select, and implement appropriate mitigation measures for significant threats;
- 5) Document the threat assessment, mitigation measures, verification, and incident management procedures in a Food Defense Plan supported by the FSMS; and
- 6) Develop a practical training and communication strategy and implement the Food Defense Plan.

In relation to mitigation measures, this needs to address both preventative and control measures.

When determining the scope of your assessment, it is important to realize that the threat level has been shown to be at its highest at production facilities^{4,7}. Make sure your site (including staff) is covered but do not limit yourself to your premises only and include the supply chain as well.

You need to implement a system that logically assesses the threats for which several tools are available (e.g., TACCP, CARVER+Shock, FDA Food Defense Plan Builder FDBP⁴). The tool is up to the organization and must be appropriate for their business.

In essence, the food defense approach aims to answer the following key questions:

- Who might want to attack us?
- How might they do it?
- What is the potential public health impact?
- How can we prevent this from happening?

Familiarize yourself with which food processing attributes may make your food a target (e.g., large batches or ease of access intend to increase the risk). Include external risks (elsewhere in the supply chain) AND internal risks (e.g., site/equipment access, disgruntled employees, etc.).

It is important to note that every threat identified will NOT automatically be determined to be significant and will NOT automatically be required to be addressed by a mitigation measure. Identifying as many threats as possible is important so they can be assessed. After repeated or severe incidents, a subsequent threat assessment may determine that an additional mitigation measure is required.

When conducting the threat assessment, it is allowed to initially group materials (e.g., similar raw materials or similar finished products). A more in-depth analysis may be required when significant risks are identified within a group.

When defining a food defense strategy, the potential threats identified shall be assessed for their significance. A risk matrix similar to HACCP can be used (e.g., likelihood of occurrence x impact/consequence). Other factors such as accessibility, likelihood of detection, and recognizability may be used as further indicators. A prevention strategy for the significant risks shall be developed and documented. To help identify preventive measures, the FDA has published a database with preventive measures for different activities throughout the whole food chain (FDA)⁵.

The plan shall be integrated into and supported by the organization's FSMS for all its products. It should contain elements such as control measures, verification activities, corrections and corrective actions, responsibilities, record keeping, and continuous improvement. In addition, the FSMS needs to include the food defense element in policies, internal audits, management reviews, etc.

The effectiveness of control measures and protection against potential threats largely depends on people. These may be external (e.g., suppliers) or internal (your associates). Therefore, a training and/or communication program is essential.

In addition, Category FII organizations for brokering and trading must ensure that their suppliers have a food defense plan in place. This can be established in several ways, e.g., by having suppliers complete a supplier questionnaire confirming whether the supplier has a food defense plan in place, as well as requesting a copy of the suppliers' food defense plan or evidence of the supplier having a GFSI-recognized or approved certification in place.

5. FOOD DEFENSE TEAM AND TRAINING

The threat assessment is performed by a multidisciplinary team with a wide range of expertise (e.g., HR, Security, Quality, IT, Production, Facility Manager). The composition of the food defense team will likely differ from that of your HACCP team and food fraud vulnerability assessment team. The team's composition may evolve over time as the understanding of food defense develops, and external expertise may be required.

Training of the team is required. Many trainings are available from a wide range of organizations. An example is Food Fraud Prevention Think Tank which provides free web-based courses on food defense (Food Defense Threat Audit Guide MOOC= massive open online course)⁶.

The FDA provides free online training materials, and although it is US/FDA regulatory compliance focused, this training assists in educating the food industry on ways to help protect the food supply from deliberate acts of contamination or tampering (FDA)⁸.

Note: The FDA training was developed to meet FDA compliance. It is important to note that the FDA scope, specifically for the FSMA intentional adulteration rule, is narrower than the GFSI scope. Therefore, FSMA-IA compliance does not necessarily equate to GFSI compliance.



Figure 2. Differences between HACCP, TACCP, and VACCP (GFSI)

6. AUDITING

Auditors should assess the threat assessment and identification and implementation of mitigation measures is adequate by asking the following questions:

- Is there a team with the correct competencies/knowledge?
- Has a threat assessment been performed and documented?
- Are relevant threats identified?
- Breadth of the threat assessment (has the whole supply chain been assessed and not just its own site)?
- Is there a methodology to determine the significance of threats?
- When significant threats are identified, is there a documented food defense plan?
- How are training and communication addressed?
- Is the performance of the food defense plan evaluated in line with ISO 22000:2018, Clause 9 on performance evaluation?
- Is the analysis regularly reviewed, and is the frequency adequate?
- Is the emergency response team prepared (ISO 22000:2018 clause 8.4)?
- Are all of the above effectively implemented through the organization's FSMS (e.g., records, awareness of people, site security, internal audits, and management reviews)?

7. REFERENCES

- 1) GFSI Benchmarking Requirements version 2020.1
- 2) BSI PAS 96:2017. Guide to protecting and defending food and drink from deliberate attack.
- 3) FDA Food Defense fact sheet:
<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM503566.pdf>
- 4) FDA Food Defense Plan Builder:
<https://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm349888.htm>
- 5) FDA database of mitigation strategies:
<https://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm295898.htm>
- 6) Food Fraud Prevention Think Tank course:
<https://foodfraudpreventionthinktank.com/courses/food-defense-threat-audit-guide-mooc-ffpd/>
- 7) Nina Puhač Bogadi, Mara Banović and Ivona Babić. Food defense system in food industry: perspective of the EU countries. Journal of Consumer Protection and Food Safety, March 2016.
- 8) FDA Food Defense Training and Education: <https://www.fda.gov/food/food-defense/food-defense-training-education>
- 9) GFSI position on mitigating the public health risk of food fraud, July 2014. [Food-Fraud-GFSI-Position-Paper.pdf \(mygfsi.com\)](#)