

	GUIDANCE ON FOOD DEFENSE	Ed: 4/ Sep 23
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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 22002-1:2013 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 GFSI definition such including Food Fraud within the scope of Food Defense.

It is important to realize that Food Fraud is a separate topic and a different chapter 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).

Other frequently used definitions are:

- PAS 96:2017: **Food defense: procedures adopted to assure the security of food and drink and their supply chains from malicious and ideologically motivated attack leading to contamination or supply disruption** (PAS 96:2017).
- 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).

Industry and regulators have developed Food Safety Management Systems based on Hazard Analysis Critical Control Point (HACCP) principles which have proven to be 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 than the motivation for Food Fraud that 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.

Intentional vs unintentional adulteration

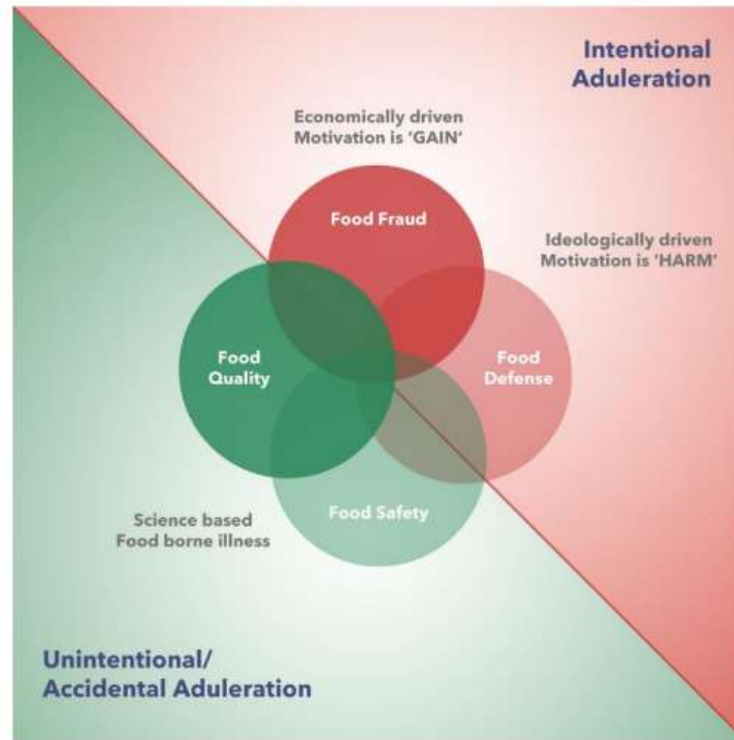


Figure 1. Intentional vs. unintentional adulteration⁹

3. FSSC 22000 scheme requirements

Part 2 – requirements for certification V6

2.5.3 FOOD DEFENSE

2.5.3.1 Threat assessment

The organization shall have a documented procedure in place to:

- a) Conduct a threat assessment to identify and assess potential threats;
- b) Develop and implement mitigation measures for significant threats.

2.5.3.2 Plan

- a) The organization shall have a documented food defense plan specifying the mitigation measures covering the processes and products within the FSMS scope of the organization.
- b) The food defense plan shall be 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.

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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 wide-spread approaches are TACCP (Threat Assessment Critical Control Points; PAS96 recommended), CARVER+ Shock and FDA Food Defense Plan Builder (FDA).

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 and select appropriate control measures for significant threats;
- 5) Document the threat assessment, control measures, verification and incident management procedures in a Food Defense Plan supported by the Food Safety Management System
- 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. 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 FDBP). 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 both external risks (elsewhere in the supply chain) AND internal risks (e.g., site/equipment access, disgruntled employees).

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 control measure. It is important to identify as many threats as possible so they can be assessed. After repeated or severe incidents, a subsequent threat assessment may determine that a control measure is required.

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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).

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 protecting yourselves is largely depending on people. These may be external (e.g., suppliers) or internal (your own 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 (e.g. TACCP, CARVER + Shock, FDBP) is performed by a multidisciplinary team with wide range of expertise (e.g. HR, Security, Quality, I.T., Production, and Facility Manager).

The composition of the Food Defense team is likely to be different than that for your HACCP and/or Food Fraud Vulnerability Assessment teams. The composition of the team may evolve over time as the understanding of Food Defense evolves. External expertise may be required.

Training of the team is required. Many trainings are available from a wide range of organizations. An example being Michigan State University which provides free web-based courses (MOOC Food Defense audit guide – MOOC = massive open online course).

The FDA provides free on-line training materials (Food Defense Awareness for Food-Professionals), and although it is US/FDA regulatory compliance focused, this training gives a good overview (FDA).

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.

Differences between HACCP, TACCP and VACCP



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

6. Auditing

Auditors should assess the risk assessment and identification and implementation of preventive actions is adequate through asking the following questions:

- is there a team with the correct competencies/knowledge?
- has a risk assessment been performed and documented?
- are relevant threats covered?
- breadth of the risk assessment (whole supply chain assessed and not just own site)?
- is there a methodology to determine the significance of threats?
- when significant threats are identified, is there a written Food Defense plan?
- how are training and communication addressed?
- Is the performance of the Food Defense Process evaluated in line with ISO 22000:2018 Clause 9 (Performance Evaluation)?
- Is the analysis regularly reviewed and is the frequency adequate?
- is the Emergency Response Team prepared (ISO 22000:2018 paragraph 8.4)?
- is all of the above effectively implemented through the organization's FSMS (e.g. records, awareness of people, site security, internal audits, management reviews)?

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7. REFERENCES

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