Guidance on Food Defense

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1. Background

Food Defense is an important 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 to illustrate that the threat is real. Often supply chain or manufacturing threats can be mitigated to reduce a wide range of threats. For example, putting a locking lid on a vat can reduce a wide range of potential intentional attacks. Food Defense Programs shall be developed to reduce the risks from both internal and external threats in order to protect your customers.

The FSSC 22000 scheme v4.1 has been extended with clauses related to Food Defense. Although in ISO 22002-1 chapter 18 this topic was addressed, it is now aligned with new GFSI requirements and taken to the management system level, making it a part of the management responsibility process.
The new FSSC requirements have become mandatory from January 1, 2018.

2. Definitions

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 and drink from all forms of intentional malicious attack including ideologically motivated attack leading to contamination." (GFSI 2017)[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)[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 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.
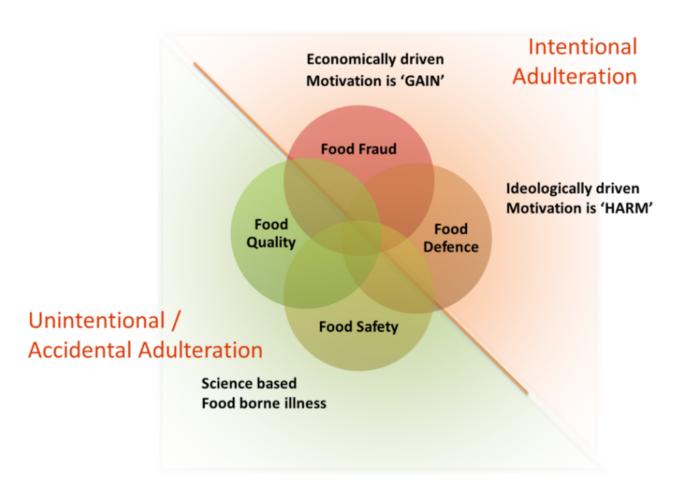
Figure 1. Intentional vs unintentional adulteration[4]

3. FSSC 22000 scheme Requirements

Part II – Requirements for certification v4.1

2.1.4.3 Food defense
2.1.4.3.1 Threat assessment
1) The organization shall have a documented and implemented threat assessment procedure in place that:
a) identifies potential threats,
b) develops control measures, and
c) prioritizes them against the identified threats.
2) To identify the threats, the organization shall assess the susceptibility of its products to potential food defense acts.
2.1.4.3.2 Control measures
The organization shall put in place appropriate control measures to reduce or eliminate the identified threats.
2.1.4.3.3 Plan
1) All policies, procedures and records are included in a food defense plan supported by the organization's Food Safety Management System for all its products.
2) The plan shall comply with applicable legislation.

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 Defence Plan Builder (FDA)[5].

Note: PAS96 covers both Food Defense and Food Fraud prevention, take care when using this document.

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

1) Establish a Food Defense team
2) Conduct a Threat Assessment, identify and evaluate potential threats and vulnerabilities
3) Identify and select proportionate mitigation measures
4) Document the threat assessment, mitigation measures, verification and incident management procedures in a Food Defense Plan supported by the Food Safety Management System
5) Develop an effective training and communication strategy and implement the Food Defense Plan.

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[5,8]. Make sure your own site (including staff) is covered but do not limit yourself to your own premises only and also consider IT security and the supply chain.

Ad 1/2. You need to implement a system that logically assesses the Threats for which a number of tools are available (e.g. TACCP, CARVER+Shock, FDA Food Defense Plan Builder FDBP[5]). Whatever tool is used, is up to the organization.
In essence, a Food Defense approach tries 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 mitigation 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 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). When significant risks are identified within a group, a more in-depth analysis may be required.

Ad 3/4. When defining a Food Defense strategy, the potential threats identified under 1 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 should be developed and documented. To help with identifying preventive measures, FDA has published a database with mitigation measures for different types of activities throughout the whole food chain (FDA)[6].

Ad 4. The plan should be supported by the organization's Food Safety Management System for all its products (clause 2.1.4.3.3) meaning that it should contain elements such as mitigation measures, verification activities, corrections and corrective actions, training, responsibilities, record keeping and continuous improvement. In addition, the FSMS needs inclusion of the Food Defence element into e.g. policies, internal audits, management review, etc.

Ad 5. 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.

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, 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 Defence audit guide – MOOC = massive open online course)[7].

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)[9].

6. **Auditing**

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

- is there a team with the correct competencies/knowledge?
- has a threat assessment been performed and documented?
- are relevant threats covered?
- breadth of the threat 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 there a verification system present in line with ISO 22000 paragraph 8.4?
- Is the analysis regularly reviewed and is the frequency adequate?
- is the Emergency Response Team prepared (ISO 22000 paragraph 5.7)?
- is all of the above effectively implemented through the organization's FSMS (e.g. records, awareness of people, site security, internal audits, management reviews, etc.)?

References

1) GFSI Benchmarking requirements version 7.2 (draft 2017)
2) PAS 96:2017. Guide to protecting and defending food and drink from deliberate attack.
3) FDA Food Defence fact sheet:
   https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM503566.pdf
4) GFSI Position Paper on mitigating the public health risk of food fraud (2014)
   https://www.mygfsi.com/files/Technical_Documents/Food_Fraud_Position_Paper.pdf
5) FDA Food Defense Plan Builder:
   https://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm349888.htm
6) FDA database of mitigation strategies:
   https://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm295898.htm
7) Michigan State University courses: http://foodfraud.msu.edu/mooc/
8) 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.
9) FDA Food Defence 101 training: https://www.accessdata.fda.gov/scripts/FDTraining/index.cfm