



# FOOD DEFENSE

Food defense is the effort to protect the food supply against intentional adulteration that is intended to cause harm to public health. A food defense plan is a written program that identifies possible threats within the supply chain, manufacturing process and facility. It establishes mitigation strategies to reduce or eliminate these threats.

In recent years, food safety regulations such as the Food Safety Modernization Act in the U.S. and GFSI-benchmarked schemes such as SQF and BRCGS have introduced the requirement for sites to develop a food defense plan. There is no standardized format for the food defense plan. However, the following key elements should be included:

1. Designated food defense team and senior management person
2. Threat assessment
3. Mitigation strategies
4. Product protection plan
5. Annual challenge exercise and review

The following information provides guidance on each element and helps sites successfully develop and implement a food defense plan to meet regulatory and third-party certification requirements.

## 1. Food Defense Team

The food defense team will depend on the size of the operation. Ideally, the team should be cross-functional and include personnel from different departments such as production, sanitation, maintenance, transport, etc. to better identify possible threats. A senior management person must also be responsible for and involved in food defense.

## 2. Threat Assessment

A threat assessment evaluates each step, point or procedure in the operation to identify points with a risk of intentional adulteration that could cause wide-scale public health harm. Different methods can be used to conduct a threat assessment. One method developed and described by the Food and Drug Administration is the Key Activity Type (KAT) method. This method is based on four activities that have been ranked by the FDA as the most vulnerable, regardless of food commodity, to intentional adulteration intended to cause wide-scale public health harm. The KAT method is an appropriate method for conducting threat assessments because it takes into consideration an inside attacker and the three required elements of a threat assessment:

1. The potential public health impact (e.g., severity and scale) if a contaminant (biological, chemical, or physical) was introduced
2. The degree of physical access to the product
3. The ability of an attacker to successfully contaminate the product



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Each process step is assessed to determine if the activity fits within one or more of the KATs. Process steps that fit within one or more of the KATs are actionable steps and require mitigation strategies to minimize or prevent intentional adulteration. The four KATs are:

1. Bulk Liquid Receiving and Loading – Includes opening inbound/outbound transport vehicles, opening vent hatches or other access points, attaching any pumping equipment or hoses, and unloading/loading the bulk liquid. This is a KAT because it involves a large volume of product, physical access to the product, and the contaminant can easily go undetected as it mixes within the liquid.
2. Liquid Storage and Handling – Includes bulk or non-bulk liquids in storage or handling tanks, silos, totes, or any containers where the tamper-evident seal is broken. This is a KAT because the contaminant can easily go undetected as it mixes within the liquid.
3. Secondary Ingredient Handling – Includes any point, step, or procedure where dry or liquid secondary ingredients are manipulated by human contact prior to or during the addition to the product flow. This includes opening ingredients, preparing ingredients such as measuring, weighing, premixing, adding ingredients, or reworking product. It also includes the storage of partially used, open containers of secondary ingredients where the tamper-evident packaging has been broken. This is a KAT because it involves a potentially large volume of product being contaminated, and the ingredient is easily accessible by employees.
4. Mixing and Similar Activities – Includes mixing, homogenizing, grinding and coating. Equipment associated with these activities includes mixers, blenders, homogenizers, mills, grinders and other similar equipment. This is a KAT because the contaminant can be easily mixed into the product and go undetected, and it may potentially contaminate a large volume of product.

### 3. Mitigation Strategies

Mitigation strategies are procedures established to minimize or prevent intentional adulteration at each KAT. For each mitigation strategy, monitoring procedures must be defined, including what will be monitored, how it will be monitored, how often it will be monitored, and who is responsible for monitoring. Monitoring procedures are recorded, and corrective and preventive actions must be established in the event of a deviation. The mitigation strategies will be specific to the facility, and the KAT identified. Some examples of mitigation strategies may include:

<ul style="list-style-type: none"> <li>✓ Security cameras and proper CCTV signage</li> <li>✓ Adequate lighting surrounding the premises, especially around entrances and shipping/ receiving areas</li> <li>✓ Controlled access to the facility and off-site storages (e.g., key fob system, security fencing)</li> <li>✓ Protection of chemicals, packaging, ingredients, and air, gas and water supplies</li> <li>✓ Protection of sensitive data systems and the data (e.g., labels, specifications, formulations)</li> <li>✓ Control visitors (including contractors) through a visitor policy and sign in sheet</li> </ul>	<ul style="list-style-type: none"> <li>✓ Inspect vehicles to ensure vehicles are locked, and seals are intact and match shipping records, and if there is any evidence of tampering</li> <li>✓ Securely storing raw materials and finished product and maintain an inventory</li> <li>✓ Use tamper-evident packaging</li> <li>✓ Development and implementation of an approved supplier program</li> <li>✓ Raw material and final product testing</li> <li>✓ Employee integrity screening</li> <li>✓ Employee training on food defense</li> <li>✓ Providing employees with a method to anonymously report suspicious behaviour, etc.</li> </ul>
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Below is an example of one way to document a food defense plan:

Process Step	KAT (1,2,3,4) & Explanation	Mitigation Strategy & Explanation	Monitoring Procedure	Deviation Procedure	Verification Procedure	Associated Records
Brining	3 – Secondary ingredient handling. Contaminants could be added when employee is mixing the brine solution.	Brine solution is mixed by trained authorized personnel only and salt is stored in a tamper-evident or sealed container. The employee responsible for preparing the brine solution records how much salt was used and signs their name.	Who: Production Manager  Frequency: Daily  How: Inspect salt container and storage area. Observe employee mixing the brine solution.	If the salt container appears to be tampered with (i.e., seal is broke), Production Manager must report to the Food Safety Manager immediately and initiate the Product Hold procedure. Corrective Action Record to be completed.	Who: Food Safety Manager  Frequency: Weekly  How: Verify Brine Mixing Record and Daily Inspection Record to ensure they are completed.	Brine Mixing Record  Daily Inspection Record  Corrective Action Record

#### 4. Product Protection

A plan must be established to protect customers from potentially contaminated products in the event of a food defense crisis. When there is any uncertainty regarding product safety, the product must be placed on hold and segregated. Decisions on release must be made by authorized personnel. Any incident involving a recall will be handled as outlined in the site’s recall program.

#### 5. Annual Challenge Exercise and Review

The food defense plan is monitored regularly through facility inspections; however, an annual food defense challenge exercise must be completed and documented. An example of a challenge exercise may involve having an outside visitor attempt to enter the facility without following proper protocol to determine how employees react to an unfamiliar person or situation. The record of the challenge exercise should include the date and time, who was involved, the situation, how the employee(s) reacted, a summary, and any corrective and preventive actions. The food defense plan must be reviewed annually to ensure it is up to date.

#### References and Further Reading:

Food and Drug Administration. (March 2019). Draft Guidance for Industry: Mitigation Strategies to Protect Against Intentional Adulteration. Retrieved May 7, 2021 <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-mitigation-strategies-protect-food-against-intentional-adulteration>

Food and Drug Administration. (February 2020). Supplemental Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration. Retrieved May 7, 2020 from <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/supplemental-draft-guidance-industry-mitigation-strategies-protect-food-against-intentional-adulteration>

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