IFS Food

IFS Food Defense Guideline

ENGLISH

IFS Food v. 6 Food Defense Guidelines for Implementation

1 Background

The IFS Food v. 6 guidelines for implementing Food Defense have been written by the North American IFS Working Group in order for IFS Food certified suppliers around the world to understand the intent of the Food Defense requirements, and to gain an understanding of implementation practices and considerations.

Developed by retailers and manufacturers together, the IFS Food v. 6 Food Defense requirements have been implemented to meet the requirements of the Global Food Safety Initiative (GFSI) Guidance Document Sixth Edition. IFS Food previously offered 13 additional requirements on an optional basis (now 8 mandatory), and primarily for companies exporting to, or using the IFS Food standard within, the United States of America (USA). The IFS requirements were developed originally based on the regulatory requirements deployed by the US Food and Drug Administration (FDA) and United States Department of Agriculture (USDA).

The IFS Food v. 6 Food Defense Guidelines for Implementation provide a further establishment of practices for implementing the requirements developed around:

- Who is responsible within an organization for implementation of the criteria,
- What should be considered during the food defense hazard analysis and assessment of associated risks and/or implementation of the requirement,
- Where each requirement should be considered within a facility,
- When implementation or checks of the implementation should be carried out,
- Why each requirement is important to the facility and/or organization implementing the criteria, and
- How the requirement can be implemented in a practical, effective way.

By following guidelines, IFS has provided to assist with implementation of the IFS Food v. 6 Food Defense requirements, the facility and its employees will be better prepared and equipped to prevent and manage the possibility of food contamination and thereby reduce the associated risks.

Though these requirements and procedures were originally developed for use in the USA, they will enhance the capabilities of all companies around the globe who will implement them per the IFS Food certification.

The intention of this document is to provide guidance for facilities to implement the IFS Food v. 6 Food Defense requirements. The elements in this document are not intended to provide further specific definition of the requirements. Auditors should be familiar with the guidance provided to facilitate training and understanding.

2 Definitions of Food Defense

Food Defense does not have an international and unique definition but below are two definitions offered by United States authorities that describe their intent behind a Food Defense strategy.

Food Defense is the collective term used by the US Food and Drug Administration (FDA), United States Department of Agriculture (USDA), Department of Homeland Security (DHS), etc. to encompass activities associated with protecting the nation's food supply from deliberate or intentional acts of contamination or tampering. This term encompasses other similar verbiage (i.e., bioterrorism (BT), counter-terrorism (CT), etc.)[1]

The USDA Food Safety and Inspection Service define Food Defense as "the protection of food products from intentional adulteration by biological, chemical, physical or radiological agents.[2]

A misconception of Food Defense is to consider it a synonym of Food Security. Food Security is defined below.

Food Security – When all people at all times have both physical and economic access to enough food for an active, healthy life. Food security includes both physical and economic access to food that meets people's dietary needs and food preferences.

The purpose of a HACCP system is to identify unintentional physical, chemical and biological hazards which are significant to food safety. The purpose of a Food Defense plan is to identify, mitigate, and monitor possible sources of intentional contamination of food. While Food Safety and Food Defense programs stand independently, there are common elements. (e.g.—the sealing of transportation vessels)

Key Points

There is no singular defined structure for a Food Defense plan. The plan should be developed considering different factors which may include:

- Surroundings and construction/design of the facility (geographic layout, adjacent facilities, criminal index of the zone …).

- Accessibility to the facility:
  - Enclosed production buildings are less vulnerable than facilities where part of the production is done in the exterior;
  - Use of contract and temporary employees may be a major risk in facilities where the number of employees is low and with low turnover.
- The nature of some food products may make them more vulnerable to intentional adulteration than others. Characteristics may include:
  - Large production batch size;
  - Uniformity;
  - Product categories;
  - Shelf life;
  - Accessibility to the product.
- Situational factors could increase the risk of intentional adulteration. Such factors include:
  - Disgruntled employees;
  - National, political, business, personal, or other differences;
  - Changes in organizational culture;
  - Economic disruption/financial gain;
  - Public fear;
  - Harm to others.

Structure of the Plan

Food Defense programs typically include the following criteria which may be modified depending upon the country, organization, and regulatory requirements.

- Clear roles and responsibilities, management commitment and employee awareness.
- Hazard analysis and assessment of associated risks of the products, facility, and facility surroundings in order to identify vulnerabilities.
- Identification of vulnerabilities and the determination of control measures.
- Implementation and sustainability of the program.
- Internal audits of the entire Food Defense program.
- Continual improvement of the system.

3 Guidelines for chapter 6 of IFS Food version 6

6.1 Defense Assessment

A Food Defense team or a single person, with accountability to the facility management team, shall be established with defined roles and responsibilities. Defence is the responsibility of top management and is, therefore, a "management issue."

The team shall have access to the management and shall have experience in the area of security. Competence can be gained through training and/or relevant experience in this area.

Finally, the auditor shall perform an assessment of competence regarding the implementation of the hazard analysis, the assessment of associated risks and other relevant documentation.

IFS does not define how the hazard analysis and assessment of associated risks shall look like. The company is free to develop its own tools. Several tools are available, e.g. CARVER (which allows the company to record conclusive data that flows into a food defense plan) or VACCP method (vulnerability analysis critical control point—"weak points" analysis and identification of critical control points, which is structured analogous to the classic HACCP; however, its focal point is comprehensive site security).

Regardless of how the applied method looks, all relevant security aspects of the location shall be taken into account. In some cases, this could also be a checklist for inventory; however, this shall always account for operational conditions and characteristics and shall be enough detailed.

Records are evidences of effective implementation and provide information about the extent to which the food defense plan is confirmed.

In some cases, a site registration is mandatory in different countries (e.g. Bioterrorism Act and the FDA registration of US exporters).

Requirement 6.1.1:

Responsibilities for food defense shall be clearly defined. Those responsible shall be key staff or shall have access to the top management team. Sufficient knowledge in this area shall be demonstrated.

WHY

A Food Defense team, with accountability to the facility management team, shall be established with defined roles and responsibilities reviewed on a regular basis.

HOW

"Those responsible" could be a team or one person.

In case of team, this team should include cross-functional employees from all levels within the organization. They should possess the knowledge and expertise to identify program requirements and propose the best course of action. A team leader should be identified whom is responsible for the coordination, development, implementation, maintenance and improvement of the system.

If applicable (if food defense matters are applicable in the production and destination countries of products), there should be a designated contact and process for communicating with the local and national authorities.

Food Defense training should be provided to employees appropriate to their duties. Senior management review should include the Food Defense program.

QUESTIONS THAT THE AUDITOR SHOULD ASK AND THAT THE COMPANY SHOULD BE ABLE TO REPLY TO:

1. Who has the accountability for the food defense program?
2. What are the competence and qualifications demonstrated for the person(s) responsible for the food defense program?
3. What is the position of the person(s) responsible for the food defense program with respect to the management team?
4. How do management teams support the person(s) responsible for the food defense program?
5. Where are the responsibilities clearly defined?
6. Was this communicated to the members of the company? How?

Requirement 6.1.2:

A food defense hazard analysis and assessment of associated risks shall have been performed and documented. Based on this assessment, and based on the legal requirements, areas critical to security shall be identified.

Food defense hazard analysis and assessment of associated risks shall be conducted annually or upon changes that affect food integrity.

An appropriate alert system shall be defined and periodically tested for effectiveness.

First part of the requirement: A food defense hazard analysis and assessment of associated risks shall have been performed, documented and risks evaluated. Based on this food defense hazard analysis and assessment of associated risks, and based on the legal requirements, areas critical to security shall be identified.

WHY

Food defense hazard analysis and assessment of associated risks are defined as: The identification, evaluation, and estimation of the levels of risk involved in a situation, their comparison against historical and anticipated events, and determination of an acceptable level of risk including i) hazard identification, ii) hazard characterization, iii) exposure assessment, and iv) risk characterization. (Source: FAO/WHO)

One of the criteria for performing a food defense hazard analysis and assessment of associated risks can be the production and destination countries of the finished products.

HOW/WHAT RISKS?

Competence in the process, packaging, storing, transportation and warehousing in order to introduce the contaminant agent at the most convenience and less controlled stages.

Access to the method of adulteration without discovery. Ability to perform the intentional act without discovery. Likelihood and severity of occurence.

Potential access to raw materials, utilities, process or final products with the sufficient amount of time to alter the product in an unacceptable physical or economic manner.

Several resources are available in order to assist organizations to perform their hazard analysis and assessment of associated risks. Resources could include general and sector specific Food Defense checklists, software that determines level of risk for different factors, rules needed to be implemented in case of exporting products to some countries.

Second part of the requirement: food defense hazard analysis and assessment of associated risks shall be conducted annually or upon changes that affect food security.

WHY

The result of the food defense hazard analysis and assessment of associated risks should be an identification of conditions that pose a risk of intentional acts to the process, materials and product resulting in adulteration.

HOW

In order to identify vulnerabilities, the Food Defense team should consider the following (not an exhaustive list):

Exterior

- Are doors, windows and roof areas kept secure?
- Is a perimeter fence or wall necessary? If a perimeter fence or wall exists, is it in good condition?
- Is there adequate lighting?
- Is there controlled access of people and vehicles?
- Are there back-up sources of critical utilities, such as electrical, water, information technology (computer data), and refrigeration systems available, in case of emergency?
- Are parking areas controlled and monitored?
- Are ventilation systems adequately protected?
- Are bulk receiving and storage areas secured?

Interior

- Are surveillance methods utilized – such as cameras, staff supervision, or security services?
- Are there systems that effectively alert employees in case of security breach?
- Is access controlled?
- Are hazardous materials or controlled substances managed?
- Is access of staff limited to appropriate work location, job function and working hours?

Shipping and Receiving

- Are transportation vessels sealed/locked?
- Are drivers providing appropriate credentials?
- Are deliveries and shipments scheduled?
- Are transportation vendors part of the vendor approval program?
- Are any missed or delayed deliveries investigated?
- Are returned goods permitted? If so, are they managed?

Raw Materials

- Are water, ice and steam sources secure and monitored?
- Are all raw materials secured and monitored when not in use?
- Are there means to verify integrity and chain of custody?
- Are packaging materials and product labels controlled?

Personnel

- Are personal background checks necessary or performed, if allowed by law?
- Is the potential for retaliatory actions by terminated employees assessed?
- Are the reasons for an employee's departure reviewed?
- Are personnel supervised?
- Are employees trained in Food Defense awareness and identifying/reporting unusual or suspicious behavior?
- Are lockers inspected?
- Are cameras allowed?
- Are personal items restricted in processing areas?
- Is there a policy written to address legal or illegal weapons and drugs?

Once the organization identifies risks and vulnerabilities, appropriate control measures should be developed and implemented based on the elimination, mitigation, and maintenance of risk to an acceptable level.

Last part of the requirement: An appropriate alert system shall be defined and periodically tested for effectiveness.

WHY

A program to implement identified control measures will help the organization in defining the schedule and resources necessary to maintain the program. Higher risks should be prioritized.

HOW

The Food Defense program becomes an established part of the internal audit process.

Once the system is implemented, identified vulnerabilities controlled, and deficiencies rectified, it is time to improve.

The regular review of the process ensures that it remains current and relevant. Risk should be reassessed annually or upon a significant change.

QUESTIONS THAT THE AUDITOR SHOULD ASK AND THAT THE COMPANY SHOULD BE ABLE TO REPLY TO:

1. What are the legal/customer food defense requirements applicable to the company?
2. How can the company demonstrate compliance with such requirements?
3. What is the process/procedure used to perform the hazard analyisis and assessment of associated risks?
4. Is the hazard analysis in line with legal and/or customer needs and/or expectations?
5. How do the systems assist the company to identify critical or high risk areas?
6. How often is a review of the food defense program performed?
7. What criteria does the company consider in order to determine the frequency to perform the hazard analysis, if is not done annually?
8. How is the company alerted of any food defense breach?
9. How does the company evaluate the effectiveness of the food defense program?

Requirement 6.1.3:

If legislation makes registration or onsite inspections necessary, evidence shall be provided.

WHY

Regulatory requirements dictate whether or not registrations or onsite inspections are necessary. If they are necessary, then evidences should be available for review that indicate the appropriate regulations have been complied with.

HOW

The appropriate regulatory documentation whether local or national should be compiled and stored in general as the other documents required in the IFS Food standard.

This requirement is not applicable (N/A) if no legislation exists in the country where the audit is done and where the products are sold.

QUESTIONS THAT THE AUDITOR SHOULD ASK AND THAT THE COMPANY SHOULD BE ABLE TO REPLY TO:

1 What are the legal/customer food defense requirements applicable to the company?

2 Based on legal requirements in the country where the plant is located or by the country where the product is consumed, is it required to apply for formal registration?

3 If registration is required, who has this information? Could the company demonstrate compliance?

4 Is there any requirement for periodic inspection? If yes, then:

- a) Who performs it?
- b) Against what standard?
- c) When was the last inspection?
- d) What was the result of the inspection?
- e) Is it required to provide evidence that deviations have been solved? (Corrective Actions)
- f) What are the implications if a major breach is identified?

Source:

1. FDA Food Defense Acronyms, Abbreviations and Definitions
   http://www.fda.gov/Food/FoodDefense/Training/ucm111382.htm
2. FSIS Homeland Food Defense 03/17/09
   http://www.fsis.usda.gov/PDF/Food_Defense.pdf
3. Food Defense Plan Security Measures for Food Defense
   http://www.fsis.usda.gov/PDF/General-Food-Defense-Plan-9-3-09%20_2_.pdf
4. United States Department of Agriculture food safety and inspection service
   Food Defense verification procedures and national terrorism advisory system alert response for the office of field operations

http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5420.1.pdf

6.2 Site Security

Requirements for site security can also be found in Chapter 4.9 **Constructional requirements for production and storage areas** of IFS Food version 6.

These requirements are supplemented with additional requirements relevant to security. In this way, effective and concrete security measures have been established, which make it impossible for unauthorized persons to gain uncontrolled access to all areas of processing and storage.

Easily accessible raw materials, intermediate and finished products or even chemicals (cleaning agents, acids, lye, flammable liquids etc.) could be stored in specific areas. Classic points to be considered are the outside storage of materials, unlocked doors or other installations that limit access. The overall goal of food defense is site security. Fences can help in this task, but are not mandatory if security can be achieved through other measures. For instance, visual surveillance or security personnel could be just as effective. Uncontrolled access in storage and production areas is in no case acceptable.

If critical areas were identified in the hazard analysis and assessment of associated risks, they can be monitored with specific construction measures, such as security doors or access with chip cards. Specific attention should be paid to raw materials, equipment and materials that are stored outside, which must be protected from unauthorized access in case of possible product hazard through manipulation.

Controls for incoming and outgoing goods such as seals and labels can provide additional security.

Requirement 6.2.1:

Based on a hazard analysis and assessment of associated risks, identified areas critical to security shall be adequately protected to prevent unauthorized access.

Access points shall be controlled.

First part of the requirement: Based on a food defense hazard analysis and assessment of associated risks, identified areas critical to security shall be protected adequately to prevent unauthorized access.

WHY

To prevent unauthorized access to product, ingredients and services that could adversely affect the content or safety of the food.

HOW

Physical barriers, procedures and systems should be established that prevent unauthorized access to areas external to the plant, internal to the plant, to laboratories handling chemicals and reagents, to waste disposal areas where potentially hazardous materials are disposed of and to service areas such as water, gas, electric, refrigeration systems, etc. Such barriers and procedures should, taken in their entirety, provide adequate protection of food and systems used to manufacture and store it. Measures established should be appropriate to effectively manage the associated risk. The key to establishing such measures is to assure they are effective and appropriate. There are many ways to manage risk and many types of situations that create risk of unauthorized access. Examples of methods used to control unauthorized access can include fencing, guards, security alarms, electronic pass keys, locked doors, windows that do not open, cameras. In general, such measures should protect food that is stored both inside the plant and external to the plant. Storage bins/silos would be included. Computer systems are often fire-walled and password protected. Procedures such as sign in procedures, keeping doors locked, etc. can supplement or substitute for physical barriers.

Second part of the requirement: Access points shall be controlled.

WHY

To prevent unauthorized personnel from entering the facility or storage areas and gaining access to ingredients or food products.

HOW

Through a combination of physical barriers, procedures and systems that work together to prevent unauthorized access.

Access points should be controlled. Not all entries are access points. If a door is locked at all times, it is not an access point. If windows are continuously locked, they are not necessarily an access point. Control may be maintained through basic procedures and/or high tech systems that could be equally effective.

Generally this clause applies to access from the outside to the inside of the facility but also applies to external storage vessel and vehicles access, as well as access from one critical area in a plant to another.

QUESTIONS THAT THE AUDITOR SHOULD ASK AND THAT THE COMPANY SHOULD BE ABLE TO REPLY TO:

1. Based on the hazard analysis and assessment of associated risks, what areas have been identified as critical?
2. What control measures are in place in order to control the entrance to those areas?
3. How does the company maintain control over who enters to the premises and critical areas?

4 What are the access controls applicable to the following people?

- Temporary employees
- Contractors
- Visitors
- Employees
- Carrier drivers

Requirement 6.2.2:

Procedures shall be in place to prevent tampering and/or allow identification of signs of tampering.

WHY

To assure that products have not been tampered with.

Product tampering can take many forms. In general, tampering involves the malicious and willful damage to or adulteration of finished product or raw materials.

HOW

Employees should be trained to understand what tampering is and how to identify signs of tampering. If possible and practical, finished products should have tamper evident seals or devices on individual units. Manufacturing systems should be either closed or closely monitored where a risk is determined. Other plant systems such as filtration, metal detection, screens should be maintained in proper working order to detect and remove adulterants.

Monitoring for tampering is a continuous process but occurs most actively during manufacturing and at time of loading for shipment.

QUESTIONS THAT THE AUDITOR SHOULD ASK AND THAT THE COMPANY SHOULD BE ABLE TO REPLY TO:

1 Does the company define procedures to identify tampering of raw materials, Works in Process (WIP) and final goods?

2 Are there means to verify if products have been tampered?

3 Are employees trained in the identification of tampered products?

4 Does the design of packaging material include the identification of tamper evident measures? Is it required by law in the country of origin or destination?

5 Are there tests to verify that measures against tampering are properly applied and working properly?

6.3 Personnel and Visitor Security

In order to protect against misuse, the company shall limit and control access to the premises, especially sensitive areas.

In addition to registering visitors and service providers on the premises, adequate briefing and supervision should take place. This also includes equipment and materials brought from outside. For example, chemicals, knives with retractable blades, lubricants or even workers themselves must all be considered.

Employees shall participate at regular food defense training. Concretely, this means conducting documented training on main food defense aspects at least once a year. Main goal is to increase sensitivity of employees to food defense aspects. Employee surveys is a way to assess if employee are sensitive or still unfamiliar to the subject.

The managers responsible for food defense should attend at more intensive training. A difficult and sensitive subject is the employee background check, because this is differing to countries and customs. For example, in the USA, reviewing criminal records and other documents by specialized firms and drug tests are common, whereas such measures are legally very limited or sometimes even prohibited in other countries. Finally, another concern is that a company is able to ensure that new employees are trustworthy, reliable and pose no security risk. If background checks are not possible or unwanted, other references can be, for example, job references, telephone interviews of former employers, recommendations, or a police clearance certificate depending on the position.

Requirement 6.3.1:

Visitor policy shall contain aspects of food defense plan. Delivery and loading staff in contact with the product shall be identified and shall respect the access rules of the company. Visitors and external service providers shall be identified in areas with product storage and shall be registered at the time of access. They should be informed about the site policies and their access controlled accordingly.

WHY

To ensure everyone entering the property and facility are aware of and adhere to the Food Defense requirements for the facility.

HOW

A policy should be written that is linked (key elements) to the food defense plan. Records that provide evidence all visitors and contractors receive necessary introduction

to facility requirements related to Food Defense should be available. This may include a registration log or register, signed introductory forms, or similar record.

The evidence should clearly indicate this introduction to Food Defense requirements occurs before visitors or contractors are permitted on-site.

QUESTIONS THAT THE AUDITOR SHOULD ASK AND THAT THE COMPANY SHOULD BE ABLE TO REPLY TO:

1. Do visitor/contractor access policies include controls to avoid that no members of the company are able to move freely without escorts inside the premises?
2. Are visitors and contractors informed of the food defense rules and their scope while inside company premises?
3. Does the company have defined means to ensure that contractors who will spend a long time inside the plants are properly identified, supervised and escorted inside critical areas?
4. Are there controls to ensure that truck drivers who load or unload products/materials are restricted to defined areas inside and outside the building and company premises? Are there means to watch the movements of non-employees once they enter company premises? (E.g. cameras or guards at defined areas? Other procedures?)
5. If contractors and visitors are provided with access keys, are those keys programmed to limit the access to specified and selected areas?
6. If escorts are required to guide visitors and contractors at all times, are there arrangements to have defined guides at all shifts?
7. Are security/guards aware of how to deal in cases where there are no escorts available at any particular moment?

Requirement 6.3.2:

All employees shall be trained in food defense with respect to the product requirements and the training needs of the employees or when significant program changes occur. The training sessions shall be documented.

Employee hiring and employment termination practices shall consider security aspects as permitted by law.

First part of the requirement: All employees shall be trained in food defense with respect to the product requirement and the traiing needs of the employees or when significant program changes occur. The training sessions shall be documented.

WHY

To ensure all employees are aware of, comprehend, and adhere to the Food Defense requirements for the facility.

HOW

Employee training records should ensure that Food Defense is part of the training. There should also be evidence of attendance at the training, and verification of the training's effectiveness (e.g. exams with score requirements). (Reference training requirement 3.3in IFS Food v. 6)

Evidence should clearly indicate that the training is based on the product requirements and the needs of employees to be trained and it was conducted after any significant change as noted above, or as part of new employee orientation.

Second part of the requirement: Employee hiring and employment termination practices shall consider security aspects as permitted by law.

WHY

To provide greater assurance that employees entering the property and facility are aware of and adhere to the Food Defense requirements for the facility. Food Defense is also considered when existing employees are terminated.

HOW

It may be difficult to review actual employee records for this requirement due to legal reasons. A discussion with Human Resources or plant management will clearly indicate what can and cannot be shared.

The program should clearly indicate all precautions are taken prior to the employee entering the workforce, and immediately upon termination. Interviews of employees upon termination can help a management team identify possible issues. Additionally, if the company uses a badge system or other access device for entering and leaving the property, each of these elements should be immediately eliminated from the terminated employee's control.

QUESTIONS THAT THE AUDITOR SHOULD ASK AND THAT THE COMPANY SHOULD BE ABLE TO REPLY TO:

1. Does the annual training program include food defense?
2. How is food defense and associated controls explained to new employees?
3. Are there records that demonstrate that employees received food defense training?
4. Is training updated according to changes in the Food Defense program?
5. How are employees informed of major changes in the food defense program?

6 Does the system evaluate training effectiveness?

7 Does training include controls of knowledge acquired from the last version of the food defense training?

8 What controls are implemented at the time of hire/termination of an employee or creation/termination of a service by a contractor?

9 Are access controls updated at the time of termination of an employee or when the work is finished on the part of a contractor?

6.4 External Inspections

The inspections procedure should describe the methods and responsibility for managing inspections and regulatory visits. This requirement is not applicable (N/A) if no legislation exists in the country where the audit is done which ask for external inspections and/or regulatory visits or if the company doesn't export to the US and no FDA inspection could happen.

Requirement 6.4.1:

A documented procedure shall exist for managing external inspections and regulatory visits. Relevant personnel shall be trained to execute the procedure.

WHY

As a part of the Food Defense program, this procedure ensures that sufficient resources are devoted to regulatory compliance and customer inspections. It also ensures that only authorized personnel have access to manufacturing, storage areas, and sample collection.

HOW

This procedure should describe the methods and responsibility for managing inspections and regulatory visits.

This procedure should be utilized any time an external inspection or regulatory visit is conducted and reviewed on an annual basis or more frequently as necessary.

QUESTIONS THAT THE AUDITOR SHOULD ASK AND THAT THE COMPANY SHOULD BE ABLE TO REPLY TO:

1 Is there a documented procedure that defines the criteria to follow in case an external organization requires access to the company's premises?

2 Are there clearly defined levels of authority to provide access to external organizations at all times?

3 Does the procedure define the means to proceed if or when a regulatory body requests access to the premises?

4 Are relevant functions aware of their responsibilities under such conditions?

5 Are levels of authority defined with respect to the kind of information that is allowed to be provided?

6 Are there means to ensure a complete record of activities done and details of the visit?

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