



FOOD AND DRUGS AUTHORITY

GUIDELINES FOR THE ESTABLISHMENT OF A FOOD PROCESSING PLANT

Document No.	: FDA/FID/GL-FPF/2020/01
Date of First Adoption	: 1 st February 2013
Date of Issue	: 20 th May 2020
Version No.	: 02

Contents

- 1. INTRODUCTION 4
- 2. GLOSSARY..... 4
- 3. REQUIREMENTS..... 5
 - 3.1 LOCATION..... 5
 - Establishment..... 5
 - Equipment..... 5
 - 3.2 PREMISES AND ROOMS..... 5
 - Design and layout..... 5
 - Internal structures and fittings (walls, floors, doors, ceiling/overhead fixtures) 6
 - 3.3 EQUIPMENT 6
 - Condition of equipment..... 6
 - Food control and Monitoring equipment 6
 - Maintenance programme 7
 - 3.4 FACILITIES..... 7
 - Water supply..... 7
 - Drainage system..... 7
 - Lighting and Ventilation 7
 - Storage..... 7
 - 3.5 CONTROL OF FOOD HAZARDS..... 8
 - General..... 8
 - Control of foreign objects/metal detection 8
 - 3.6 QUALITY CONTROL/ HYGIENE CONTROL SYSTEMS 8
 - Time and temperature control 8
 - Quality assurance system 8
 - 3.7 RAW MATERIAL REQUIREMENTS 9
 - Incoming material requirements..... 9

- 3.8 DOCUMENTATION AND RECORDS 9
 - General..... 9
- 3.9 MAINTENANCE AND CLEANING..... 9
 - General..... 9
 - Cleaning Programmmes..... 10
- 3.10 PEST CONTROL SYSTEMS..... 11
 - Eradication..... 11
 - Housekeeping standards..... 11
 - Pest control records 11
- 3.11 WASTE MANAGEMENT 11
- 3.12 WORKERS /PERSONNEL STANDARDS..... 12
 - Staff training 12
 - Personnel Protective Equipment..... 12
 - Hand washing discipline 12
 - Medical needs (Pre-employment health checks) 13
 - Visitors screening 13
 - Ancillary facilities 13
- 3.13 TRANSPORTATION..... 13
- 3.14 PRODUCT INFORMATION AND CONSUMER AWARENESS..... 14
 - Labelling..... 14
 - Product recall 14
- 3.15 DEFINITION OF RESPONSIBILITY..... 14
- 4. SANCTIONS 15
- 5. PENALTIES..... 15

1. INTRODUCTION

In exercise of the powers conferred on the Food and Drugs Authority (FDA) by Public Health Act, 2012, Act 851, Part Seven, Section 148, these guidelines shall serve as requirements for the establishment of food processing plants and the pre-requisite for the licensing of a food processing plant by the FDA unless there are specific requirements for a given food category factories.

Notwithstanding the above, food processors shall comply with any other existing National Statutory Requirements for food processing plants.

Where a company operates a Food Safety Management System (FSMS), such as Hazard Analysis and Critical Control Points (HACCP) or ISO 22000 or their equivalent, these guidelines may serve as the pre-requisite programmes (PRPs) for the given FSMS.

The purpose of these guidelines for the establishment of Food Processing Plants is to:

1. Ensure that operations and facilities of Food Processing Plants conform to current Codes of Good Manufacturing Practices (cGMPs) that will promote safe food processing environment and the production of safe food.
2. Facilitate the licensing of Food Processing Plants in accordance with Part Seven, Section 130 & 131 of the Public Health Act, 2012, Act 851.

This guideline is hereby promulgated for information, guidance and strict compliance by all concerned.

2. GLOSSARY

For the purpose of these guidelines the following definitions shall apply:

Cleaning: The removal of soil, food residue, dirt, grease or other objectionable matter.

Contaminant: Any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability.

Contamination: The introduction or occurrence of a contaminant in food or food environment.

Disinfection: The reduction, by means of chemical agents and/or physical methods of the number of micro-organisms in the establishment, to a level that does not compromise food safety or suitability.

Establishment: Any building or area in which food is handled and the surroundings under the control of the same management.

Food hygiene: All conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

HACCP: A system which identifies, evaluates, and controls hazards which are significant for food safety.

Food handler: Any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements.

Food safety: Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Food suitability: Assurance that food is acceptable for human consumption according to its intended use.

Primary production: Those steps in the food chain up to and including, for example harvesting, slaughter, milking, fishing.

3. REQUIREMENTS

3.1 LOCATION

Establishment

- 3.1.1. The plant shall be located away from environmentally polluted areas and where industrial activities would pose a threat of contaminating food.
- 3.1.2. Unless adequate safeguards are provided, a food processing plant shall not be sited in areas prone to flooding or pest infestation.
- 3.1.3. A food processing plant shall not be sited in an area where solid or liquid waste cannot be removed effectively.

Equipment

- 3.1.4. Food processing equipment shall be located such that it facilitates:
 - adequate cleaning and maintenance,
 - good hygienic practices including monitoring.
- 3.1.5. Equipment must be properly designed for its intended use.

3.2 PREMISES AND ROOMS

Design and layout

- 3.2.1. The flow of raw materials, finished products, and personnel movement through the factory shall provide protection against cross-contamination.

Internal structures and fittings (walls, floors, doors, ceiling/overhead fixtures)

Internal structures must be designed to withstand the rigorous activities of the production processes, be easy to clean and disinfect. The following specific conditions shall be satisfied to protect the suitability of the food:

- 3.2.2. Surface of floors, walls and partitions shall be even and impervious with no toxic effect in intended use.
- 3.2.3. Junctions/joints such as floor-wall junctions shall be coved to facilitate cleaning.
- 3.2.4. Where notices are required, they shall not be nailed, pinned or taped to walls. Self-adhesive notices or food grade painted notices are recommended in production areas.
- 3.2.5. All doors to production areas shall be self-closing and shut firmly. Doors shall have smooth, non-absorbent surfaces, and be easy to clean.
- 3.2.6. Ceiling and overhead fixtures shall be constructed and finished to minimize the build-up of dirt and condensation, and the shedding of particles.

3.3 EQUIPMENT

Condition of equipment

- 3.1. All food equipment surfaces shall be smooth, impervious, and easy to clean.
- 3.3.2. Food grade lubricants must be used where there is potential contact with food.
- 3.3.3. Equipment and containers shall be made of materials with no toxic effect in intended use.
- 3.3.4. Pallets for internal use must be made from plastic or non-corroding metal. Wooden pallets are allowed for fully protected final products.

Food control and Monitoring equipment

- 3.3.5. Equipment used to cook, heat treat, cool, store or freeze food shall be designed to achieve the required food temperatures as rapidly as necessary and maintain them effectively.
- 3.3.6. Equipment shall allow temperature to be monitored and controlled. Temperature recording equipment shall be regularly checked and calibrated.

Maintenance programme

3.3.7. All equipment shall have a written maintenance and overhaul programme, which is adequate for the process.

3.4 FACILITIES

Water supply

3.4.1. Water used in food handling and processing must be potable (based on latest WHO Guidelines for Drinking Water Quality). Non-potable water used for other activities where it will not contaminate food such as steam production, fire control etc. shall have a separate system, be identified and shall not connect with or allow reflux into potable water systems.

Drainage system

3.4.2. The drains shall be designed and constructed such that the risk of contaminating food is avoided. Example:

- the capacity of the drains must be adequate to cope with the process requirement.
- the inlets and outlets of the drains must be pest-proof and debris traps provided.

Lighting and Ventilation

3.4.3. Ventilation systems shall be constructed so that air does not flow from contaminated areas to clean areas.

3.4.4. Windows shall be constructed to minimize the build-up of dirt and shall be easy to clean; those required to be opened to enhance ventilation, must have the total opening area fitted with insect-proof screens.

3.4.5. Throughout the production and inspection areas, adequate lighting must be provided. Fluorescent tubes and other lighting fixtures shall be protected by shatterproof covers to avoid glass contamination of product.

Storage

3.4.6. Adequate facilities for the storage of products shall be made available.

The storage facilities shall be designed and constructed such that:

- The products in storage are protected from contamination.
- Cleaning and maintenance activities can be effectively done.
- Pests are denied access into the facility.

3.4.7. Non-food compounds such as cleaning agents, agricultural compounds and their associated application equipment shall be stored in separate, secure areas.

- 3.4.8. It is recommended that all materials shall be kept off the floor. Products shall be packed on clean pallets at least 50cm away from the wall to facilitate adequate cleaning, pest control and product ventilation.
- 3.4.9. Incoming materials, work in progress and finished products must be clearly identified and stored in separate designated areas.
- 3.4.10. All raw materials require storage under the correct conditions of temperature, lighting and ventilation, dependent on their nature and substance. Monitoring and control systems must be in place.

3.5 CONTROL OF FOOD HAZARDS

General

Hazards shall be controlled through the use of food safety management systems (FSMS) such as HACCP. Expert advice may be appropriate to achieve a sound FSMS.

Control of foreign objects/metal detection

- 3.5.1. Product protection must be effected by the use of in-line equipment, such as magnets, sieves, metal detectors and other appropriate techniques and process design features. Sieves, filters and magnets etc. must be checked and cleaned regularly.
- 3.5.2. No glass item shall be taken into any production area; a “glass policy” shall be in place.
- 3.5.3. Pencils, pins/staples and pen tops which are potential hazard materials shall not be permitted in the food production area.
- 3.5.4. Where practical, all conveyors carrying open food, raw materials or open containers shall be protected from overhead contamination by suitable covers.

3.6 QUALITY CONTROL/ HYGIENE CONTROL SYSTEMS

Time and temperature control

- 3.6.1. Where temperature and time are critical to the process. E.g. during cooking, chilling, they shall be monitored and recorded.
- 3.6.2. Temperature control systems shall take into account factors such as the nature of the food e.g. its water activity, the intended product shelf –life etc.
- 3.6.3. Temperature recording devices must be regularly checked and calibrated.

Quality assurance system

- 3.6.4. The company shall have a comprehensive system of quality assurance and monitoring, to ensure the consistent production of safe, legal product in compliance with the agreed specification or standards.

3.6.5. The company shall have sufficient properly trained personnel with clearly defined responsibilities to maintain agreed quality standards, covering all aspects of the operation.

3.6.6. The Quality Assurance Department shall be independent from the Production and Purchasing functions, although they must liaise with each other to achieve the required product specification.

3.7 RAW MATERIAL REQUIREMENTS

Incoming material requirements

3.7.1 Incoming materials and goods shall be inspected and monitored to minimize the likelihood of pest infestation and limit the need for pesticides.

3.7.2. Incoming raw materials shall at least have the following details:

1. Records of delivery
2. Date coding and indication of shelf life where applicable
3. Batch identification system to facilitate good stock rotation and complete traceability of the end product
4. Source of raw material/or country of origin

3.7.3 The batch identification system for the raw material shall be used throughout the process, on all documentation to guarantee traceability.

3.7.4 The stock rotation of raw materials shall be strictly controlled to ensure that each product is used within its storage life.

3.7.5 Where regular auditing of a supplier is a challenge, products are to be accompanied by Certificates of Analysis.

3.8 DOCUMENTATION AND RECORDS

General

3.8.1 Appropriate records of processing, production, and distribution shall be kept for a period that exceeds the shelf-life of the product.

3.9 MAINTENANCE AND CLEANING

General

3.9.1 Establishments and equipment shall be kept in an appropriate state of repair to:

- Facilitate all sanitation procedures
- Function as intended, particularly at critical steps
- Prevent contamination of food, e.g. from splinters, flaking plaster, debris and chemicals.

3.9.2 Cleaning shall remove food residues and dirt which may be a source of contamination. The necessary cleaning methods and materials depend on the nature of the food business. Disinfection may be necessary after cleaning.

3.9.3 Cleaning chemicals shall be handled and used carefully and in accordance with manufacturer's instruction, and stored, where necessary, separated from food, in clearly identified containers to avoid the risk of contaminating food. **Cleaning procedures and methods**

3.9.4 Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, vacuum cleaning or other methods that avoid the use of water, and chemical methods using detergents, alkalis or acids.

3.9.5 Cleaning procedures will involve, where appropriate:

- removing gross debris from surfaces;
- applying detergent solution to loosen soil and bacterial film and hold them in solution or suspension;
- rinsing with potable water to remove loosened soil residues of detergent;
- dry cleaning or other appropriate methods for removing and collecting residues and debris; and where necessary, disinfection with subsequent rinsing unless the manufacturer's instructions indicate on scientific basis that rinsing is not required.

Cleaning Programmes

3.9.6 Cleaning and disinfection programmes shall ensure that all parts of the establishment are appropriately clean, and shall include the cleaning of cleaning equipment.

3.9.7 Cleaning and disinfection programmes shall be continually and effectively monitored for their suitability and effectiveness and where necessary, documented.

3.9.8 Where written cleaning programmes are used, they shall specify:

- Areas, items of equipment and utensils to be cleaned;
- Responsibility for particular tasks; - Method and frequency of cleaning; and

- Monitoring arrangements.

3.10 PEST CONTROL SYSTEMS

Eradication

- 3.10.1 The company shall contract the services of an Environmental Protection Agency (EPA) certified personnel or organization to implement the Pest Control Program of the facility.

Housekeeping standards

- 3.10.2 An effective approach towards infestation control is by maintaining good housekeeping standards i.e. controlling accumulation of food and packaging debris, keeping passages clear and uncluttered, removing redundant equipment and materials from the manufacturing area and ensuring good stock rotation.
- 3.10.3 Domestic animals e.g. cats and dogs must be excluded from the production environment. Staff shall never feed or encourage stray animals to come on site.

Pest control records

- 3.10.4 Detailed records of the pest control activities must be maintained. (Documentation relating to the safety and application of approved baits and pesticides must be available).

3.11 WASTE MANAGEMENT

- 3.11.1 The external facility for the disposal of waste shall be located well away from production areas, preferably in its own enclosed building, to minimize the danger of pest infestation or other hazards.
- 3.11.2 Suitable provision must be made for the storage and removal of waste. If the waste facility is not enclosed, disposal receptacles with close fitting lids must be provided. Waste disposal and effluent treatment must be monitored.
- 3.11.3 Disposal of plant effluent shall comply with the requirements of the relevant legislation (contact Environmental Protection Agency [EPA]).

3.12 WORKERS /PERSONNEL STANDARDS

Staff training

- 3.12.1 All personnel shall be appropriately trained in food hygiene disciplines, relevant to the job they do. Training records shall be kept and the effectiveness of training assessed to confirm that designated procedures are being followed.

Personnel Protective Equipment

- 3.12.2 Suitable protective clothing, hair restraints and footwear shall be worn by all food handling operatives and persons who enter food preparation areas. It is recommended that protective clothing be free of loose fastenings such as buttons, and top pockets. Any internal pockets provided in the garment must be at hip level.
- 3.12.3 Management shall ensure adequate supply of laundered protective clothing is available for use.
- 3.12.4 Personal effects such as jewelry, watches and pins shall not be worn or brought into food handling areas. Nail polish shall not be worn as it presents a potential foreign body risk to the product. Strong perfumes are not allowed because of possibility of tainting the food product.
- 3.12.5 Where ear plugs or ear muffs are worn, they shall be accounted for at the end of each shift.

Hand washing discipline

- 3.12.6 Adequate hand washing and hand drying facilities shall be provided in toilet areas and at each entrance to the production area.
- 3.12.7 Suitable, well equipped hand washing stations shall be provided at designated places within the food processing area.
- 3.12.8 Where appropriate, non-perfumed barrier creams or alcohol based hand sanitizers shall be provided. Hands shall be washed:
1. Immediately before commencing work, or entering production areas.
 2. After handling debris, refuse or food waste.
 3. If they become soiled or visibly contaminated.
 4. After visiting the toilet.

Medical needs (First aid)

- 3.12.9 First aid equipment shall be available and treatment given by trained staff. No person having untreated sores, cuts or grazes shall be allowed to work directly in contact with food. All such injuries must be reported and suitably treated.

Medical needs (Pre-employment health checks)

- 3.12.10 All company employees shall undertake appropriate medical examination prior to commencing work. The employees (food handlers) shall be screened for communicable diseases namely Typhoid, Hepatitis A and Tuberculosis.
- 3.12.11 Persons suffering from infectious illnesses (particularly gastro-intestinal disorders, such as vomiting, diarrhoea must not be permitted to work in food production areas.

Visitors screening

- 3.12.12 There must be adequate screening of all visitors to the factory or manufacturing premises.
- 3.12.13 Visitors entering production areas must wear protective clothing and adhere to other personal hygiene provisions.

Control of smoking, food and drink.

- 3.12.14 Smoking and the use of tobacco shall not be permitted in food production areas.
- 3.12.15 Eating and drinking shall not be permitted in production areas. Only designated places shall be used.
- 3.12.16 Where drinking is permitted, a drinking fountain is the preferred source of water supply.

Ancillary facilities

- 3.12.17 Preventative pest control systems consistent with those adopted in other areas of the processing facility shall be established in canteens and rest room areas.
- 3.12.18 Separate, adequately equipped male and female rest rooms (toilets, hand washing facilities, resting areas and changing rooms) shall be provided for the workers.

3.13 TRANSPORTATION

- 3.13.1 Food must be adequately protected during transport. Storage containers or conveyances shall be designed and constructed such that they:
- Do not contaminate food or packaging;
 - Can be effectively cleaned and disinfected;
 - Provide effective protection from contamination including dust and fumes;
 - Can effectively maintain the temperature, humidity, atmosphere and other conditions necessary to protect food from harmful or undesirable growth and deterioration.

3.14 PRODUCT INFORMATION AND CONSUMER AWARENESS

Labelling

- 3.14.1 Prepackaged foods shall be labelled with clear instructions to enable consumers to handle, display, store and use the product safely.

Traceability

- 3.14.2 Where the process involves a “resting” stage or delay with work in progress (partly processed materials), a reference code must be issued.
- 3.14.3 The Company shall have adequate documentation which ensures that batches of finished products can be correlated with the individual deliveries of raw materials used in manufacturing and with the corresponding laboratory records.

Product recall

- 3.14.4 It is recommended that the company shall have a formalized, product recall procedure.
- 3.14.5 The company must have a formalized, complaint procedure.
- 3.14.6 All complaints shall be recorded when received and investigated accordingly.

3.15 DEFINITION OF RESPONSIBILITY

- 3.15.1 A major responsibility of managers is to ensure compliance with all appropriate legislation.
- 3.15.2 It is recommended that personnel at all levels throughout the organization shall have a job description which explains their duties and responsibilities. Management level requires a more detailed job description which includes their specific tasks, reporting procedures and any specific safety requirements.
- 3.15.3 Persons allocated responsible positions shall have sufficient authority to discharge their responsibilities effectively. The Quality Assurance Manager in particular must have the authority to accept or reject raw materials, packaging materials or finished products that are out of specification.
- 3.15.4 The Production Manager and Quality Assurance Manager shall work independently but must collaborate to achieve the required quality specification.

4. SANCTIONS

Failure on three counts of caution on non-adherence to this code of practice will result in suspension or revocation of license.

5. PENALTIES

Where non-adherence to this code of practice results in exposure of consumers to a food safety hazard, the FDA will impose an administrative fine in accordance with Public Health Act, 2012, Act 851, Section 148, Sub-section 4 and 5.