



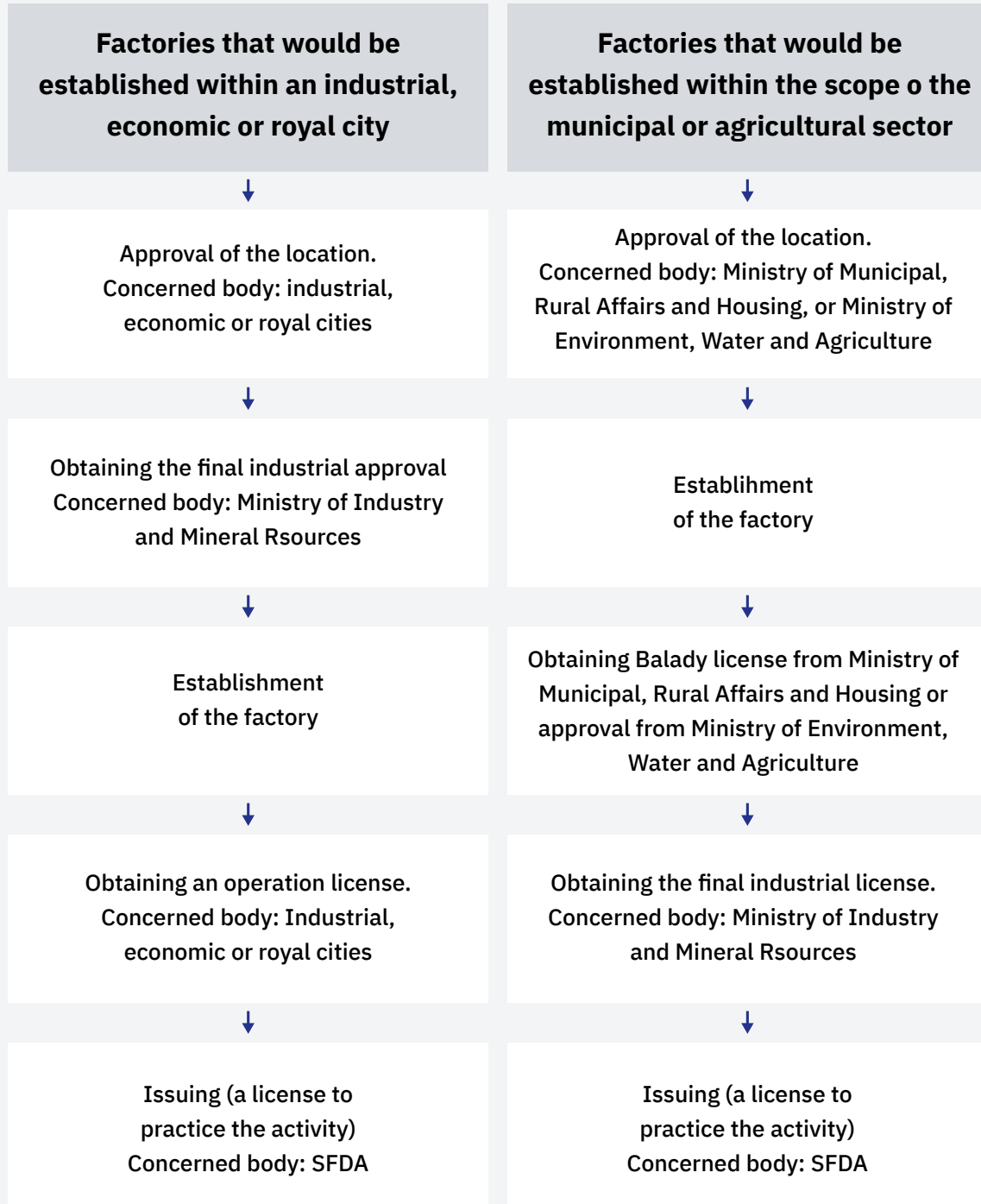
Kingdom of Saudi Arabia  
Saudi Food & Drug Authority



## Guidance on Technical Requirements

# for Food and Water Manufacture

# Journey to Obtain a License to Practice an Activity



The above are without prejudice to the Specification (SFDA FD.21:2018): Health Conditions to be fulfilled by Food Manufacture and their Workers, and all relevant Specifications.

## Site

---

01

**01** - It must be far from any other non-food industrial establishment that has a negative impact on the environment.

**02** - It is strictly prohibited for a factory to connect to another factory unless the same is explicitly stated in the license of either of them.

**03** - It is strictly prohibited to change the factory area by increase or decrease unless obtaining the SFDA's approval.

## Used Well

---

02

**01** - A closed, brick-roofed room must be built around the well.

**02** - The floor of the well room must be made of cement concrete.

**03** - The height of the wellhead above the ground must be 10 to 20 cm.

**04** - Wellhead must be covered tightly with a plastic or metal (stainless) cover.

## Building Status

---

03

**01** - The building must be made of brick and cement, and the roof must be made of reinforced concrete. False Ceiling can be used (they must be smooth and easy to clean).

**02** - Materials of heat-insulating type that are impermeable or water-absorbent must be used in construction.

**03** - It must be taken into account that there are no cracks in the factory and all its facilities to avoid the entry of insects and rodents.

## Size and Area

04

- 01** - The area must be spacious and appropriate.
- 02** - The areas must be proportional to the factory construction plan approved by the SFDA.
- 03** - The building must be designed with a sufficient size that satisfies the purpose for which it was prepared and designed without causing crowding in equipment, machinery, workers, or materials.
- 04** - The building should include sufficient areas, including (warehouses - production halls - staff quarters - laboratory - maintenance - administrative offices).

## Design

05

- 01** - The building's design must be proportional to the type of activity.
- 02** - The design must be tight to prevent dirt, dust, insects, rodents, and pollutants.
- 03** - The production hall must be isolated from the external environment when designing the building.
- 04** - Factory areas must be separated and isolated from each other to prevent interference and pollution, and to maintain flow and arrangement.
- 05** - The design ensures that there are no suitable conditions for condensation above the production lines.
- 06** - The design ensures easy cleaning, disinfection and maintenance inside the establishment.
- 07** - The design of devices, equipment and machines must fulfill the safety and security rules for installation, cleaning and use.
- 08** - The design of the factory takes into account the future expansion of the factory and how the shape of the building surface is suitable for the expansion of production lines in the future.
- 09** - The design takes into account the factory's service facilities, such as electricity, cooling, heating, and gas units, depending on use.

**10** - Worker's accommodations are not permitted within the factory.

**11** - The design shall allocate and plan areas for the safety of workers or visitors (determining areas in which walking is allowed, designated for means of transportation, etc.).

**12** - The design shall consider organization and arrangement when determining the areas of tools, equipment and machineries in the factory.

## Celling

---

06

**1** - Celling should be painted a light color (preferably white) to be easy to clean.

**2** - In the case of a false ceil, it must be made of healthy materials that do not absorb moisture, and are easy to clean, and have no protrusions or corners.

**3** - No plumbing connections be installed above the false ceil.

**4** - There are no openings in the ceilings that allow insects and rodents to harbor and pollutants to collect on top of the ceiling.

**5** - The angles between ceilings and walls should not be sharp, and it is preferable for them to be rounded or inclined at an angle of  $(45)^\circ$  to be easy to clean and disinfect, and to prevent the accumulation of pollutants.

**6** - Celling must have a suitable slope to prevent the accumulation and leakage of rainwater, dirt, and cleaning water.

**7** - The ceiling of the manufacturing halls must be heat insulated.

**8** - The height of the factory ceilings must not be less than (6 meters).

## Walls

---

07

**1** - Walls must be painted with a suitable light-color, and be smooth and easy to clean.

**2** - All interior walls of the factory, except for the warehouses, shall be covered with smooth ceramic, free of wrinkles, of a light color, with a height of no less than (3 meters) and commensurate with the quality of production.

- 3 - Walls must be made of heat-insulating bricks and is not permeable or water-absorbent.
- 4 - Walls must be resistant to acids and alkalis (depending on the type of product and cleaning and sterilization materials).
- 5 - The corners between walls and floors must be concave (not sharp) to facilitate the cleaning process.
- 6 - Walls must be free of cracks and fissures.

## Floors

---

08

- 1 - Floors must be made of materials that are impermeable, non-absorbent, and easy to clean, such as tiles, rough ceramic, or epoxy.
- 2 - Factory's interior floors, except for warehouses, must be made of rough ceramic with a light color and a slight slope toward the drainage holes.
- 3 - Providing a suitable slope for easy drainage of water into ground sewers with a minimum of (2%).
- 4 - Floors must be made of materials resistant to acids, alkalis, and cleaning and sterilization materials.
- 5 - Floors must be free of cracks and be easy to clean.
- 6 - Floors must be solid, resistant to weights and vibrations, of appropriate thickness and non-slip.
- 7 - If the site locates within agricultural lands, the factory floor must be elevated above ground level to prevent the entry of water from the outside into inside, and to prevent dust and pests.

## Doors

---

09

- 1 - Doors must be made of aluminum or unbreakable glass, impermeable to water, non-absorbent, with smooth surfaces, tightly self-closing, and made of rust-resistant material.
- 2 - Providing air or plastic curtains at the main (external) entrances.

**3** - Doors leading into the factory must be double (consisting of two doors approximately one meter apart) and open to the outside in order to ensure that insects and rodents do not enter while opening them.

**4** - Providing sufficient numbers of doors in the establishment, and the internal doors in the establishment must be self-closing.

## Windows and other Openings

10

**1** - All openings in the factory must be tightly sealed, covered with unbreakable glass, and easy to clean.

**2** - If there are windows in the factory attachments, they must be equipped with easy-to-move metal mesh covers made of a stainless steel and tightly sealed.

**3** - Edges must be sloped to prevent it from being used as shelves and to prevent the accumulation of dirt.

**4** - Frame must be made of a stainless and non-water-absorbent material.

## Lighting

11

**1** - Lighting must be suitable, natural or artificial, so that production processes can be carried out effectively and do not result in shadows or intense brightness throughout the establishment.

**2** - Providing appropriate protection for the industrial lighting units to prevent any physical risks resulting from their breakage.

**3** - Natural or artificial lighting should be sufficient.

**4** - Lighting bulbs installed and suspended above the production lines or one of its stages must be of the safe type (providing covers for bulbs) to avoid any contamination of food if they are broken.

**5** - Using types of bulbs that do not increase the temperature inside the factory.

## Ventilation and Air Conditioning

---

12

- 1 - The building must be well ventilated to prevent increasing temperature and to ensure that fumes or dust do not condense.
- 2 - Ventilation and air conditioning system must be capable of purifying air (installing a number of extraction fans and air conditioners commensurate with the area of the establishment and the purpose of each section, as well as with the size and quantity of production).
- 3 - Ventilation openings must be covered from the outside with a metal mesh to prevent the entry of insects and rodents.
- 4 - Ventilation must be made using an air intake system to prevent the accumulation of condensed steam and dust and expel polluted air (regular maintenance of air conditioning and filters).
- 5 - Air direction must not be from polluted areas to other less polluted areas.
- 6 - A thermal control system must be available in the establishment to prevent high temperature that affect the quality of the product.

## Changing Rooms/Restrooms (Bathrooms and Hand Sinks/Shower Areas).

---

13

- 1 - Changing rooms for workers must be provided in the food establishments, but they shall not directly connect to the production area. Changing rooms shall be equipped with stainless steel cupboards to keep workers' belongings and uniform.
- 2 - Workers' restrooms and bathrooms must be completely isolated and not directly connected to the production area.



**3** - Workers must have bathrooms equipped with hot and cold water in sufficient numbers (according to the table) and equipped with appropriate cleaning materials and not opened directly to the production areas.

**4** - The main entrance to the bathrooms shall be equipped with a self-closing door.

**5** - Bathrooms must be well-lit and ventilated.

**6** - Providing hand sinks in sufficient numbers in every place where they are required, and be equipped with hot and cold water, liquid soap, and drying devices. It is preferable to use disposable paper tissues.

**7** - Taking-off personal clothing, and taking shower and wearing the work uniform inside the factory.

**8** - It is preferable to use self-operating faucets in hand sinks.

**9** - All waste containers must be of the foot-opening type and tightly closed.

**10** - It is preferable to use an automatic flushing system in bathrooms.

**11** - Workers must have showers equipped with hot and cold water in sufficient numbers (according to the table).

Individuals	Toilets	Hand Sinks	Showers
1-10	2	2	2
11-20	4	4	4
21-40	6	6	6
41-60	8	8	8
61-80	10	10	10
81-100	12	12	12
More than 100	Toilet, hand sink or shower for every 10 additional persons		

## Staff Access Area

---

14

- 1 - Staff access must not open directly onto the production hall and must include two entrances with a sufficient distance between them to place the equipment for the staff entrance.
- 2 - Providing a sufficient number of automatic hand sinks.
- 3 - Providing hand sinks with self-operating hot and cold water and odorless, anti-bacterial liquid hand soap.
- 4 - Providing the staff area with a designated place for head and mouth coverings, hand gloves, shoes, and hand sanitizers.
- 5 - Providing single-use paper dryers.
- 6 - Providing a waste container that cannot be opened with hands.
- 7 - Place an air or plastic curtain at the entrance leading to the production hall.
- 8 - It is preferable to install a special device to ensure that all workers carried out the cleaning and sterilization process before entering the production hall.

## Machineries, Tools and Equipment

---

15

- 1 - Equipment must be at least two meters away from walls.
- 2 - Adjacent equipment must be at least 4 meters apart from each other.
- 3 - When installing tools, equipment and devices, they must be raised off the ground by an appropriate amount to facilitate cleaning.
- 4 - Tools and equipment must be made of corrosion-resistant materials that can withstand washing and disinfection.
- 5 - Equipment belts must be made of a material that is easy to clean and is not absorbent to water and liquids.

6 - Devices and tools must be designed and installed in a way that prevents health damage and can be easily cleaned and sterilized.

7 - Considering quality, safety and periodic calibration requirements.

## Laboratories

16

**1 - If there is a laboratory inside the factory, then the following must be available:**

- Conducting chemical, microbial, and physical analyzes for raw materials used in manufacturing, as well as for the products manufactured within the factory.

- Providing the appropriate devices and equipment to conduct tests and calibrate them periodically.

- The technician/s working in the laboratory must be competent and qualified.

- Analyzing periodic samples representative of production, equipment, devices, and machines to ensure their safety and compliance with standard specifications, while maintaining special records of the analysis.

**2 - In the event that there is no laboratory within the factory, then tests shall be made by private laboratories nominated and approved by the SFDA during the year.**

## Warehouses

17

**1 - The warehouse must be designed in a tightly sealed manner to prevent the entry of insects, rodents and birds.**

**2 - Chilled foods (less than 4°C), frozen foods (-18°C), and dry foods (25°C) must be stored and registered periodically in special registers.**

**3 - Food items are stored separately and covered to avoid cross-contamination.**

**4 - Raw materials (raw + packaging materials) must be stored separately from the final product.**

- 5 - Food must be separated from packaging materials when stored.
- 6 - Materials used for cleaning and disinfection must be separated in a separate warehouse.
- 7 - Raw materials must be inspected and sorted at the beginning of the manufacture line and in an appropriate location so that only clean and sound materials are used in the manufacturing process.
- 8 - Washing raw materials, if necessary, to remove dust and contaminants before they enter the production line.
- 9 - When storing food, it must be elevated above the ground by no less than 30 cm and away from the walls by no less than 45 cm (a sufficient distance for ventilation and cleaning), and not to reach the ceiling (it is preferable to use plastic pallets)
- 10 - Stored materials shall not be accumulated inside the warehouse in a manner that negatively affects the efficiency of ventilation and air conditioning.
- 11 - The warehouse must be equipped with the appropriate lighting, ventilation, air conditioning, and fire-fighting tools and equipment.
- 12 - All parts of the warehouse and stored materials must be clean.
- 13 - The warehouse design should not allow air pollution.
- 14 - All warehouses must be constructed of non-flammable materials that resist high loads and temperatures.

## **Chemicals Warehouse**

---

18

- 1 - Chemicals shall be stored in a separate area designated for this purpose, well protected and labeled.
- 2 - Chemicals should only be handled by a competent person.
- 3 - Providing a register of chemical materials specifying the type of materials, characteristics, and the handling method.
- 4 - Additives shall be stored in a separate room designated for this purpose.

## Used Water

---

19

- 1 - Providing a safe and healthy water source for drinking water or used water, to be approved by the Ministry of Water and Electricity. A double filter shall be installed on the tanks and the filters shall be changed periodically.
- 2 - The water used must comply with the Gulf standard specifications for non-bottled drinking water No. (SFDA.FD/GSO 149:2014).
- 3 - The water used must be subjected to regular laboratory tests and the results must be kept.
- 4 - Providing the necessary quantity of water to prepare the product, personal hygiene of workers, and cleanliness of the site.
- 5 - Water tanks must be tightly closed to prevent pollution, easy to clean, made of stainless steel and far from sources of pollution.
- 6 - Water tanks and pipes must be made of materials that do not interact with water, and resistant to leakage and rust. Tanks and pipes shall not interact or affect water whatsoever.

## Cleaning and Disinfection/ Cleaning and Disinfection of Equipment, Machines, Tools/ Equipment

---

20

- 1 - Providing a complete program for cleaning equipment, tools and facilities.
- 2 - Documenting cleaning and disinfection processes in special registers.
- 3 - Allocating a qualified person for each establishment to carry out and supervise cleaning processes within the establishment.
- 4 - This person must have permanent assistants who are well trained to reinstall cleaning equipment and are aware of the seriousness of the pollution.
- 5 - Giving sensitive sites, devices, and materials special attention.
- 6 - Providing appropriate cleaning and sterilization machines.

- 7 - Providing a cleanliness system (CIP) on site, when required.
- 8 - Using clean water that conforms to Gulf standard specifications for cleaning, disinfection and sterilization processes.
- 9 - Storing cleaning materials in closed rooms that are used only for this purpose.
- 10 - Storing cleaning equipment in designated places that are used only for this purpose.
- 11 - All detergents and disinfectants used must be approved and have a certificate proving the same.

## Cooling and Freezing Rooms

21

- 1 - Providing vertical type refrigeration units equipped with appropriate shelves made of safe anti-rust materials, along with an external easy-to-read temperature gauge.
- 2 - Cooling and freezing rooms must be clean and designed to prevent contamination.
- 3 - Materials used in the cooling and freezing rooms must be clean and easy to clean.
- 4 - Area of cooling and freezing rooms should be sufficient to prevent overcrowding.
- 5 - Doors of cooling and freezing rooms must be tightly closed.
- 6 - Lighting of cooling and freezing rooms must be appropriate.
- 7 - Temperature of cooling rooms should be between (1-4)°C.
- 8 - Temperature of freezing rooms should be -18°C.
- 9 - An alarm system must be available in the cooling and freezing rooms.

## Raw Materials

---

22

- 1 - Raw materials shall be stored away from sources of pollution, insects and rodents.
- 2 - Raw materials shall not be susceptible to corruption.
- 3 - Raw materials shall be stored in good storage conditions, and appropriate humidity and temperature.
- 4 - Raw materials shall be stored separately from the final product.
- 5 - Raw materials shall be separated from packaging materials when stored.
- 6 - Raw materials shall be inspected and sorted at the beginning of the manufacture line and in a suitable location so that only clean and sound materials enter the manufacture process.
- 7 - Temperature of cooling rooms should be between (1-4) °C.
- 8 - Temperature of freezing rooms should be -18°C.

## Food Contact Surfaces

---

23

- 1 - The equipment surfaces in contact with the food product must be made of a stainless steel and non-toxic material that does not produce an unacceptable odor or taste and is easy to clean.
- 2 - The equipment surfaces in contact with the food product must be resistant to corrosion and not susceptible to interaction with the product (suitable for food use), and must withstand repeated washing and disinfection and be free of pits, cracks and paint peels.
- 3 - The equipment surfaces must be smooth, non-absorbent, free of cracks, scratch-resistant, without sharp edges and corners, and easy to clean.
- 4 - Wiping tests must be conducted for all surfaces in contact with the product as an important factor to ensure the safety and health of the factory.

## Washing and Preparation Processes

24

**1** - Raw materials should be washed, if necessary, to remove dust or other contaminants, and the water used for this purpose should not be reused until after it has been treated to make it in a condition that does not cause any risk to health.

**2** - Preparation and packaging processes must be timed quickly and sequentially under conditions that prevent the product from being exposed to contamination, spoilage, or growth of pathogenic microorganisms or poisoning, while taking random samples from the production line and from the final product to ensure the safety of production

## Production Halls

25

**1** - Using modern technological methods for the manufacture process and not having intersections in production lines to prevent cross-contamination.

**2** - Manufacturing and packaging processes should be carried out automatically as much as possible or by using devices, machines and equipment that prevent any contamination of the final product. It is not permitted to use hands to touch food except in cases of extreme necessity to complete the work, and tools, such as gloves, spoons, forks and knives should be used instead of touching the product.

**3** - All production processes must be carried out under conditions that prevent contamination, gradual deterioration, or the formation of pathogenic or spoilage-causing microorganisms.

**4** - Hand washing means should be available in all production and manufacture departments and halls, including hot and cold water, soap, and effective sanitary means for drying hands.

**5** - Belts of machines used in food Manufacture should be made of a suitable material that is easy to clean and does not allow food liquids to be absorbed.

**6** - Devices and tools must be designed and installed in a way that prevents health damage and allows for easy cleaning and sterilization.



## Sorting and Screening

---

26

- 1 - Providing sufficient space for screening and sorting.
- 2 - Screening and sorting place must not be susceptible to contamination.
- 3 - Raw materials shall be inspected and sorted at the beginning of the manufacture line in a suitable location so that only clean and sound materials are used in the manufacture process.
- 4 - Raw material shall not be accepted if it already contains toxic decomposition products or unknown materials that cannot be removed to an acceptable extent through normal sorting, processing or manufacture processes.

## Packing and Packing Material

---

27

- 1 - Preservation methods ensure that the product is protected from pollution, spoilage factors, infection, and anything that poses a threat to public health.
- 2 - Packaging materials must not contain any substances that may cause unwanted organic sensory changes, and the packaging materials must be non-absorbent, tasteless and odorless, and must not interact with the product.
- 3 - Unused packing materials should be stored in a place away from the production area and should be protected from dust and contamination.
- 4 - Packing materials used in production and packaging must be from an authorized and approved source.

## Explanatory Data

---

28

- 1 - It must fully comply the standard specification for packaged foodstuffs label (SFDA.FD/GSO 9:2013).
- 2 - The product's nutritional label must contain a barcode.

**3** - The explanatory data on the food label must include (product name - brand - manufacturer name - net weight - production and expiration date - batch number - product numbering).

**4** - Adherence to technical regulations, specifications and circulars related to the food product.

**5** - Data must be printed clearly on the product in a way that is difficult to change and remove.

## **Product**

---

29

**1** - The product shall be periodically inspected according to the standard specifications for each product.

**2** - The products must conform to the standard specifications for the product type.

**3** - The products shall be stored properly.

**4** - The final product should be numbered for easy tracking

## **Food Means of transporting within the Production Area and Warehouses**

---

30

**1** - Using a forklift that runs on electricity or gas.

**2** - The means of transportation used inside production halls and warehouses must not emit any high heat or odors.

**3** - All means of transportation used must be clean and easy to clean effectively.

## **Roads and Yards in the Manufacture**

---

31

**1** - The site shall be designed in a manner that prevents intersections in production lines and intersections between food and non-food items.

**2** - The roads and yards inside the establishment must have strong surfaces suitable for the movement of vehicles and trucks, with drainage and cleaning means available.

**3** - Designating areas for movement of cranes and means of transportation within the production halls.

## Disposal of Waste

32

**3** - Waste containers must be tightly closed, opened and closed with the foot, while using bags to collect waste.

**2** - Providing two separate drainage systems, one connected to bathrooms and toilets and the other for the establishment's general drainage (floor drains, manufacturing equipment, liquid waste).

**3** - Providing appropriate slopes for water drainage.

**4** - Providing underground sewers with odor traps, appropriate ventilation, and airtight covers.

**5** - Drainage lines must not pass through or over production areas.

**6** - Perishable waste shall be kept in separate refrigerated rooms.

**7** - Waste is disposed of regularly so that it does not become a source of pests and insects.

**8** - Cleaning and disinfecting containers and sewer lines regularly.

**9** - Providing a primary treatment unit for wastewater far from the manufacture area.

**10** - Draining waste and water into the sewage network or into a absorption pit (pit) located no less than ten meters away from underground drinking water tanks and at a level half a meter lower.

**11** - Manholes openings are not permitted in the workplaces.

## Staff Health Status

33

- 1 - All workers inside the manufacture must have valid health certificates.
- 2 - Medical examination shall be conducted periodically for the workers, once a year or more as needed, to ensure their health and safety and that no worker has an epidemic disease. The establishment shall bear all examination procedures.
- 3 - Workers returning from vacations abroad shall subject to examination before resuming their work.
- 4 - Workers with contaminated wounds, sores, or any contagious disease are excluded until they treated.
- 5 - First aid must be available in the factory according to the potential dangers (antiseptics, bandages, drugs for wounds and burns...etc.). Further, workers trained and qualified in first aid works shall be available in the site.

## Staff Hygiene

34

- 1 - Workers must sanitize their hands before and after each manufacture process.
- 2 - Maintaining the cleanliness of the work uniform and procedures for covering the head, hands and legs.
- 3 - Nails should be trimmed. Wearing jewelry is not permitted during work, and workers shall take shower before entering work.
- 4 - It is preferable to have a regular and periodic program of medical swab tests for workers.

## Staff Uniform

35

- 1 - Taking-off personal clothing.

**2** - It is preferable to use a uniform for workers according to the nature of the work, such as production and maintenance workers, etc., while adhering to wearing designated protective clothing, according to the nature of the work and reasons for use.

**3** - Maintaining cleanliness of the uniform throughout working hours.

## Health Instructions Board

36

**1** - Placing health guidance boards to prevent eating, drinking, smoking, spitting, blowing the nose, chewing gum, and using aromatic perfumes, etc. during the production processes.

**2** - Guidance boards shall be written in Arabic and English, or languages related to the workers' nationalities, to make it easy for them to understand the written phrases.

**3** - Placing guidance boards on how to wash and disinfect hands and how to wear head coverings, mouth coverings, and gloves.

**4** - Placing guidance boards of health requirements inside the establishment.

## Training

37

**1** - The establishment must have a comprehensive training program for all employees.

**2** - Providing a system to inform and educate workers about the health conditions that must be met in the food establishment, the sources of pollution and how to avoid pollution.

**3** - Organizing programs and workshops for workers on a regular basis (seminars, films, lectures, posters, etc.) that explain the importance of food handling safety.

**4** - Providing qualified staff to carry out the training process, whether inside or outside the establishment.

## Record Keeping

---

38

- 1 - The establishment must preserve and document all relevant records related to the manufacture of food products within the factory, as of receiving raw materials to the distribution of the final product to the consumer.
- 2 - Maintaining records of all medical examinations for all employees.
- 3 - Preparing records for all training courses for employees.
- 4 - Establishing records for pest and rodent control.

## Quality Management

---

39

- 1 - It is preferable for the establishment to have a control and quality system.
- 2 - Quality department shall be responsible for self-monitoring, inspection and auditing of the establishment.
- 3 - Quality department personnel must have appropriate educational qualifications.
- 4 - It is preferable for the establishment to implement a food safety system.

## Means of Transportation

---

40

- 1 - All means of transportation must be completely covered so that the food product is not exposed to any influence of temperature or other climatic conditions.
- 2 - Means of transportation should be designed in a way that prevents food contamination or spoilage.
- 3 - Means of transportation must be washed, cleaned and disinfected periodically.

4 - Means of transportation designated for transporting food products may not be used to transport any other materials.

5 - Means of transportation must be equipped in a way that enables it to secure the freezing and/or cooling temperature determined according to the type of food being transported, regardless of the distance or period of transportation.

6 - Refrigerated or frozen vehicles must be equipped with electronic devices to measure temperatures while transporting refrigerated or frozen foods.

## Administrative Offices

41

1 - Administrative offices must be separated from the rest of the factory.

2 - Administrative departments shall not have access to the production halls.

3 - Administrative buildings shall not be used as accommodation for the workers.

The Establishment may access to all related technical regulations, specifications and circulars on the SFDA's website:

[www.sfda.gov.sa](http://www.sfda.gov.sa)

please contact the Call Center 19999



Saudi\_FDA

[www.sfda.gov.sa](http://www.sfda.gov.sa)