

# **Investor Journey to Obtain a License for Food Manufacture or a Bottled Water and Ice Manufacture**

Third edition

This document is a draft, therefore, it is subjected to alteration and modification.  
Disclaimer: The English version is a translation of the original in Arabic for information purposes only. In case of a discrepancy, the Arabic original will prevail.

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## 1<sup>st</sup> Chapter

### Introduction

Based on SFDA Law issued by Royal Decree No. (M / 6) dated on 25/1/1428 AH. Article 5 of the law stated, “The Authority shall initiate all the organizational, executive and oversight tasks necessary to achieve its objectives and objectives to be achieved ... etc.”. In Paragraph No.4 organizational tasks are included, “The Authority shall lay the right foundation for food, medicinal manufacturing and the health requirements that shall be met in the establishment and manufacturer, including food establishments and their workers, facilities and water manufacturer”.

This guide distributed in purpose of clarifying all procedures related to licensing food, bottled water, local ice and specific controls including conditions for obtaining the initial approval (for manufacture located within the municipal area) and the final license to practice the activity.

## 2<sup>nd</sup> Chapter

### Definitions

The following terms and expressions, wherever mentioned herein, shall have the following meanings unless the context requires otherwise.

#### **Investor:**

An individual or group (a company) willing to invest and establish a manufacturer in the field of manufacturing or packing foodstuffs, bottled water, and ice. Whether the investor is Saudi, Gulf, or foreign.

#### **Food establishments:**

A building/s combined, dispersed or part of thereof used for production, operation, manufacturing, packaging, trading and storage its raw materials/ products. Including the surrounding area that is subject to the control of the manufacture.

#### **Bottled Water Manufacture:**

Industrial establishments that produce potable water, packed in sanitary containers of varying capacities, tightly sealed, and meet the Saudi standard specifications for bottled potable water and the label of packaged foodstuffs.

#### **Ice Manufacture:**

Industrial establishments that convert water into ice for human consumption.

### **Technical License (Activity Practice License):**

The license issued by the competent authority to establish food, bottled water or ice manufacture after reviewing the technical and engineering designs, and approving the manufacturing and packaging means.

### **Municipal License:**

The license issued by the Ministry of Municipal and Rural Affairs& Housing to establish a food manufacture.

## 3<sup>rd</sup> Chapter

### Field and Applicability

This guide applies to the investor who is willing to obtain an activity practice license for food, bottled water, or ice establishment for industrial activities (ISIC) that subject to the Authority. This license enables the manufacture to produce and sell in the local markets and import raw materials for manufacturing. Therefore, it is issued after all documents and requirements of the concerned government agencies are fulfilled, as follows:

- Saudi Food and Drug Authority.
- Ministry of Municipal and Rural Affairs.
- Ministry of Environment, Water and Agriculture.
- Ministry of Commerce.
- Ministry of Investment.
- Saudi Arabian General Investment Authority
- Ministry of Industry and Mineral Resources.
- Saudi Authority for Industrial Cities and Technology Zones
- King Abdullah Economic City.
- Royal Commission for Jubail and Yanbu.

\* The ISIC activities herein can be found on SFDA website

<https://www.sfda.gov.sa/ar/oper/RegistrationAndLicencing/Documents/EconomicActivitiesSFDA.pdf>

## 4<sup>th</sup> Chapter

### Itinerary to Obtain an Activity License

1. The investor journey to obtain a license to practice an activity varies depending on the manufacture establishment site. The investor who wishing to establish the manufacture in one of the industrial areas affiliated with the Ministry of Municipal and Rural Affairs or on agricultural land with natural raw materials, natural sources, and animal/agricultural production, shall apply to SFDA for obtaining the approval to review the relevant government agencies:

- The Ministry of Municipal and Rural Affairs to obtain approval for the site based on what stated in Council of Minister Law No. (181)
- Civil Defence.
- Ministry of Environment, Water and Agriculture - General Administration of Water quality standards and Regulation to obtain its approval of the water source and disposal of the return only for bottled water and ice manufacture.
- Ministry of Industry and Mineral Resources to obtain the final industrial license.

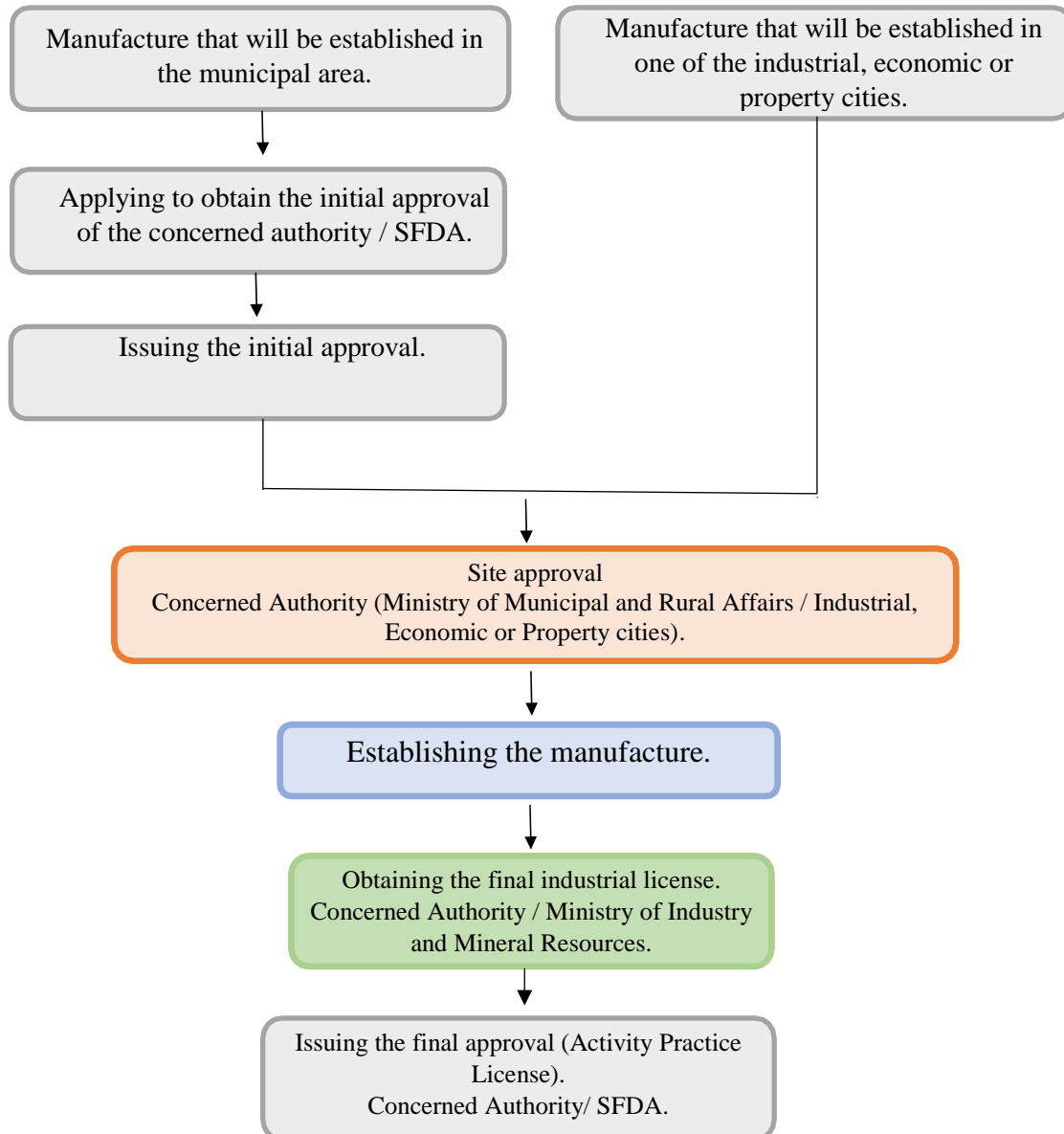
If the factory is established in an industrial, economic city, or in the Royal Commission for Jubail and Yanbu, the investor is not required to obtain initial approval and apply directly to the concerned authorities for obtaining the approval of the site other government agencies.

2. After the establishment obtains the approvals of the concerned government agencies, the investor establishes and equips the manufacture with the necessity to apply the technical requirements mentioned in the guideline for the technical requirements (the guide can be obtained via the link below) in addition to the requirements of the site granting authority such as the Ministry of Municipal and Rural Affairs or Industrial or Economic Cities.

<https://www.sfda.gov.sa/ar/food/eservices/Documents/food-Inspection-887.pdf>

3. Register in the electronic system for registering and licensing establishments and local food products after attaching all the approvals from the concerned government agencies as aforesaid in clause No. (1).
4. Obtaining the final approval (Activity Practice License) by SFDA.

## Itinerary to Obtain an Activity License





## 5<sup>th</sup> Chapter

### Issuing a license to Practice Activity (Final License)

#### **Conditions for obtaining a license to practice activity:**

- 1- Obtaining the necessary licenses and approvals from the relevant government agencies as aforesaid in Chapter Four.
- 2- Apply the technical requirements mentioned in the guideline for technical requirements.  
<https://www.sfda.gov.sa/ar/food/eservices/Documents/food-Inspection-887.pdf>
- 3- Commitment to the following standard specifications:
  - Gulf standard specification No. (21/1984 A.D) related to “health conditions in Food manufacture and their workers”.
  - Gulf Standard No. (9/2013 A.D) for “Labelling of packaged foodstuff”.
  - Gulf Standard Specification No. (168/1994 A.D) related to "requirements for stores the preserving dry and canned foodstuffs."
  - Adherence to the standard specifications and the approved related technical regulations of the establishment and the food products to be produced. Approved specifications and technical regulations can be obtained either through the website of the Gulf Standardization Organization [www.gso.org.sa](http://www.gso.org.sa) or through the website of Saudi Standards, Metrology and Quality Organization (SASO) [www.saso.gov.sa](http://www.saso.gov.sa)

#### **Mechanism for Obtaining a Final License (License to practice activity)**

Applying for a license to practice the activity electronically completed by the following steps:

1. Entering the following service link:  
<https://frcs.sfda.gov.sa/Account/RegisterAccount.aspx?enc=YmnZnGScyVI>
2. Filling out the application and the authorization form.
3. Receiving the activation code for the account via email, then activate the account.
4. Complete all information in the food establishment registration form in seven steps:

**First step:** Establishment information.

**Second step:** Head office address.

**Third step:** Establishment activities.

**Fourth step:** Production Information.

**Fifth step:** Food Safety Systems.

**Sixth step:** Official documents.

**Seventh step:** Approval.

5. The food establishment registration application is sent via the system.
6. Fill out all the information in the food product registration form.

**Documents required in the electronic system:**

All official documents required in the sixth step shall be completed when registering in the online system, which are as follows:

1. Site map.
2. A copy of the valid municipal license and the industrial license if the site is outside the industrial cities / or a copy of the industrial license if the site is inside the industrial cities.
3. Attach the Ministry of Environment, Water and Agriculture approval.
4. A copy of a valid Civil Defence license for manufacture outside the industrial cities or a valid operating license for manufacture located inside the industrial and economic cities.
5. For the commercial agency, a copy of the commercial agency certified by the Chamber of Commerce is required.
6. A copy of the national identity, family record, passport or residency of the authorized person.
7. A declaration signed by the manufacture owner certified by the Chamber of Commerce in which the authorized person is authorized.
8. A copy of the legal agency or an authorization certified by the Chamber of Commerce for the responsible person.

### **Financial Compensation:**

The Authority collects the financial compensation for the services it provides in the field of registering, licensing and inspecting food, bottled water and ice manufactures, as follows:

<b>Financial Compensation</b>			<b>Services</b>
Category A	Category B	Category c	
1000 Riyals			Registration and licensing food, bottled water or local ice manufactures.
3000 Riyals	2000 Riyals	1000 Riyals	Inspection fee for food, bottled water or local ice manufactures.

### **Method of calculating fees:**

Fees for issuing a license to practice activity are collected according to the manufacture category and the licensing years.

Licensing fees = (registration and licensing fees 1000 riyals) + (inspection fees by category x number of years) with minimum of one year and a maximum of 3 years.

## Mechanism for licensing manufacture according to

### degree of risk:

After registering in the electronic system for registration and licensing of food establishments, the application is reviewed and the activities mentioned in the industrial license are reviewed by which the degree of risk of the manufacture is determined according to the National Guide for Economic Activities "ISIC" and the degree of risk of each activity, which was determined by the Authority. **To view the activities degree of risk that fall within SFDA jurisdiction, please see the following link:**

<https://www.sfda.gov.sa/ar/oper/RegistrationAndLicencing/Documents/EconomicActivitiesSFDA.pdf>

### First/ Establishments with low-risk activities:

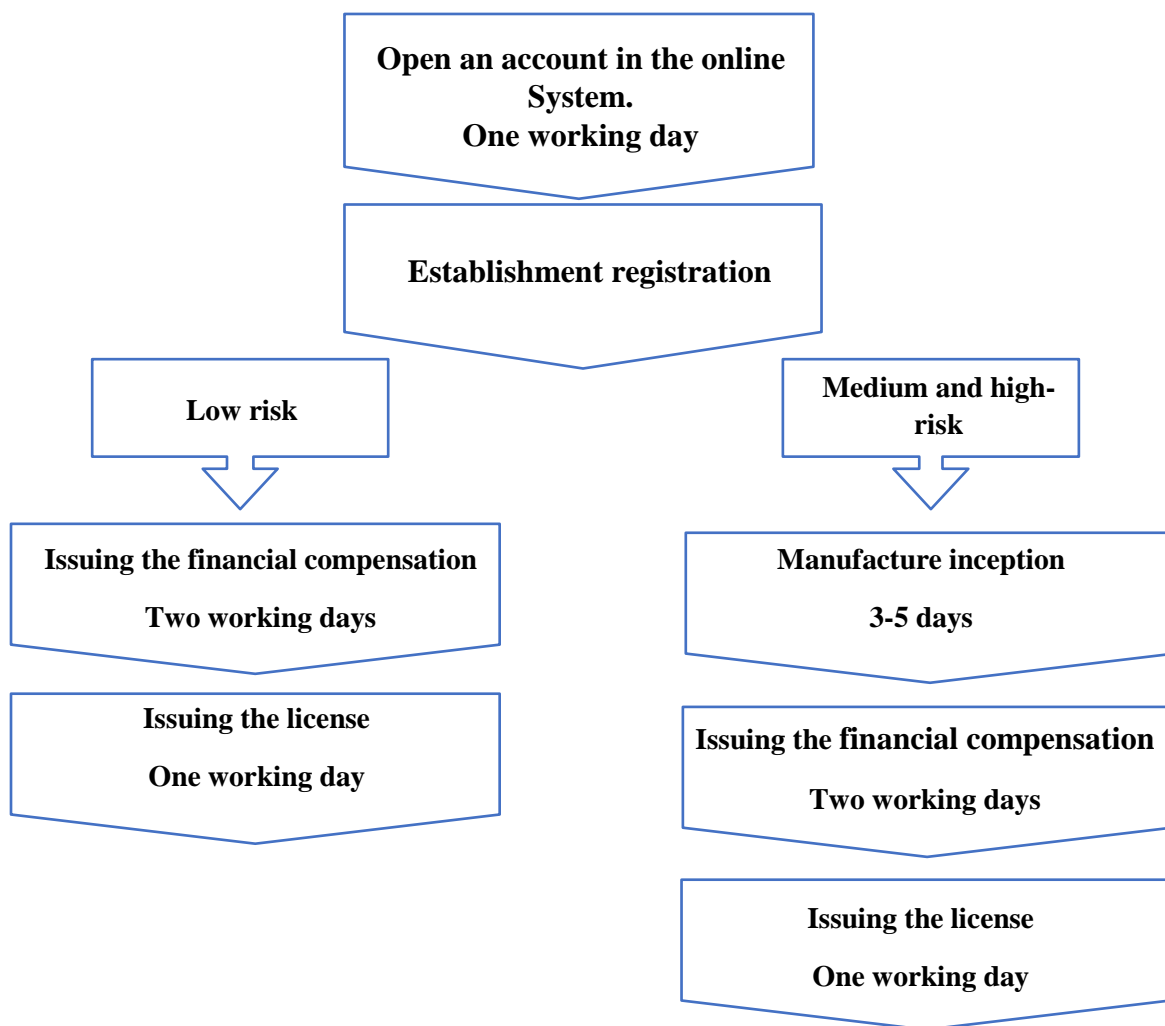
The license to practice the activity is issued to low-risk food manufacture immediately after the completion of the registration in the electronic system and the payment of the financial compensation. Provided that the inspection process is carried out later to ensure the manufacture applies the technical requirements and withdraw samples for laboratory analysis.

### Second / Medium and high-risk factories:

- Applications for licenses to practice activity for food, bottled water and medium and high-risk manufactures are referred to inspection to ensure that the manufacture meets the technical requirements.
- The manufacture shall perform the laboratory analysis in one of the private laboratories accredited by the Authority and obtain the test results before carrying out the inspection visit. The list of accredited private laboratories can be obtained via the following link: [https://www.sfda.gov.sa/ar/food/about/administration/management\\_regulations/Pages/Licensed\\_Private\\_Food\\_Laboratories.aspx](https://www.sfda.gov.sa/ar/food/about/administration/management_regulations/Pages/Licensed_Private_Food_Laboratories.aspx)
- The manufacture provides a copy of laboratory analysis results of the products it produces at the factory to the inspection team.
- The manufacture operates production lines (for laboratory analysis only) and analyzes 80% of the products manufactured inside the manufacture at the time of the visit.

- The inspector has the right to take samples and send them to the laboratories of the Authority. If the results of the laboratory analysis show that the manufacture is not in conformity, the necessary measures shall be taken according to the list of violations and penalties. The list of violations and penalties can be found at the following link:  
<https://www.sfda.gov.sa/ar/food/about/regulations/Documents/Food2102018.pdf>

### Obtaining the Final License Duration



## 6<sup>th</sup> Chapter

### Guide to Renew a License

#### First/ Mechanism for renewing a license to practice activity:

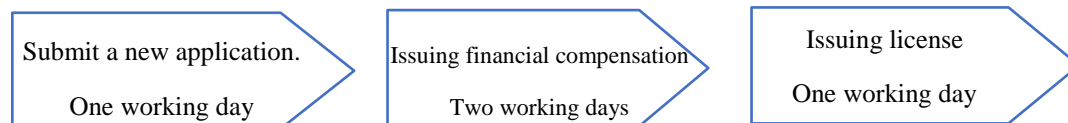
The administration is contacted via e-mail ([sa.gov.sfda@food.lmrdr](mailto:sa.gov.sfda@food.lmrdr)) and the documents below shall be attached with the license renewal application:

- The final industrial license.
- Civil Defence permit - for manufactures outside industrial cities.
- Manufacture operation license - for manufactures located inside industrial cities.
- License to practice activity issued by the Food and Drug General Authority to be renewed.

All attachments shall be in PDF format.

#### Second/ The process of renewing a license to practice an activity:

- The renewal application will be submitted by the company via e-mail.
- The renewal application is transferred to inspection.
- After approval of the inspection, a financial compensation for the renewal will be issued.
- The establishment financial compensation is sent by e-mail.
- The establishment pays and provides the Authority with the payment receipt.
- The new establishment license will be issued.



## 7<sup>th</sup> Chapter

### Expanding and Adding Production Lines

Food, bottled water, and ice manufacture that wishing to expand the establishment or add production lines shall obtain SFDA approval before establishing the expansion or addition work. The manufacture shall not start actual production before obtaining SFDA approval and adding the activity in the license if it is not previously added.

- Mechanism to obtain the approval:

- The establishment submits an official letter to the Authority stating its desire to expand the establishment or add new production lines with attaching the following documents:

<https://www.sfda.gov.sa/ar/oper/RegistrationAndLicencing/Documents/op1462020aaaaa.docx>

- Acknowledgment of compliance with the terms of expansion or addition. The declaration can be obtained through the following link:
- Engineering drawings for expansion or addition of production lines.
- SFDA studies the application.
- Respond to the establishment with approval or not via e-mail.
- The manufacture is carrying out expansion or addition works.
- After completing the expansion or addition, the establishment informs the Authority by an official letter via e-mail ([sa.gov.sfda@food.lmrdr](mailto:sa.gov.sfda@food.lmrdr)) declaring that the work has been completed.
- The Authority shall inspect the establishment to ensure that the expansion or addition works conform to the standard specifications.
- After inspection approval, the Authority informs the facility to start the actual production process.



## 8<sup>th</sup> Chapter

### Mechanism for Transferring Ownership or Changing the Location of the Manufacturer

In case of changing the commercial registry, the manufacturer shall register a new one and be considered as a new manufacture as mentioned in Chapter Five. But if the commercial registry is just as it is, the Authority shall be notified by an official letter to that effect, with the following documents attached:

- Commercial Register.
- The final industrial license.
- Civil Defence permit (for manufacture outside the industrial cities).
- Municipality license (for manufactures located outside the industrial cities).
- Manufacturer operation license (for manufactures located inside industrial cities).

All of them shall be in the name of the new owner.

- Mechanism for relocating a food manufacture:

Submit a letter to the Authority confirming the transfer of the manufacture and attach the following documents:

- Commercial Register.
- The final industrial license.
- Civil Defence permit (for manufacture outside the industrial cities).
- Municipality license (for manufactures located outside the industrial cities).
- Manufacturer operation license (for manufactures located inside industrial cities).

And they are modified for the new location.