



# SFDA Facilities Self-Assessment Programme

*A New Initiative Supporting Inspections of Factories and Establishments*

**SFDA Facilities Self-Assessment Programme:**  
**A New Initiative Supporting Inspections of Factories and Establishments**

The SFDA is currently expanding a new initiative designed to assist with the inspection process for factories and establishments that fall under the authority's purview. In late 2019 the SFDA launched the facilities self-assessment programme, which is one of the initiatives under the authority's strategic plan. The programme encourages establishments to self-assess their processes regularly to identify the extent to which they are adhering to national standards, requirements and regulations, while deepening their knowledge of these regulations. It helps establishments identify areas of non-conformity and spurs them to take corrective action. By conducting self-assessments, establishments will be more prepared for routine site inspections by the SFDA.

The programme covered food and bottled water factories as of early 2022, but the authority will expand it to other establishments over the course of the year. This article provides an overview of the new self-assessment programme and how it fits into the broader SFDA inspection process.

**SFDA Responsibilities**

The SFDA has a range of responsibilities and functions. When it comes to regulating factories and their products, the authority is responsible for issuing operational licences for establishments under its purview; registering products; and clearing imported products that pass through Saudi Customs points. It monitors establishments and products for compliance, and imposes legal penalties on violators.

The authority's work includes inspecting local and international manufacturers of food, drugs and medical devices, as well as retailers of these products. It strives to ensure all food, animal feed, pesticides, drugs, cosmetics, and medical equipment and products made in or imported to the Kingdom comply with regulations, safety standards and consumer requirements.

**Inspections**

The authority inspects both imported and locally manufactured goods. Saudi Arabia imports 80% of its food, 60% of its medications and more than 90% of its medical devices. Ensuring that only safe products enter the market is of paramount importance.

The SFDA regularly inspects factories through routine scheduled inspections. The frequency of inspections depends on whether a factory produces high-, medium- or low-risk products. The SFDA grades factories on a scale from "A+" to "D" to determine the frequency of visits required. Factories rated "A+" require fewer inspections, such as one to two routine inspections per year, while a "D"-rated establishment requires four to six visits. In addition to routine inspections, the SFDA conducts visits for licensing, responding to complaints, sampling products, supporting requests to export products and other reasons.

For imported goods, routine factory inspection is the responsibility of the national regulator of the source country. However, the SFDA will conduct visits to overseas facilities in certain cases in order to ensure compliance with standards in the Saudi market.

**Facilities Self-Assessment**

The SFDA's facilities self-assessment programme encourages factories to evaluate their performance in areas related to hygiene, production lines, personnel, maintenance and visitors. Once factories are

registered with the programme, representatives of the factory are encouraged to complete an electronic form every three months that measures compliance with SFDA standards. The form has around 100 multiple-choice questions through which the representative ranks the performance of various areas from 1 to 5, with 5 being the best. The assessment looks at topics such as cleaning plans, safety requirements for personnel and health cards for workers. The assessment helps to ensure the factory is producing safe products and is taking all measures to avoid any contamination during manufacturing.

Once the form has been completed, representatives will be notified of the areas where corrective actions are needed and told which, if any, are priority areas to address at the soonest possible opportunity. If factories do not meet certain standards, the SFDA typically gives them time to implement corrective actions. Once the actions are completed, factories will inform the SFDA and the authority will assess whether the moves were sufficient; if not, the factory will be notified of further actions to take. Corrective actions may include informational courses for workers, installing new signs, and ensuring workers have the correct equipment such as gloves and hair nets.

The programme facilitates more efficient site inspections. When SFDA inspectors go to factories, they open previously submitted self-assessment forms and check when the last self-assessment was conducted. This allows them to see any previous areas of non-conformity and ask what corrective actions were taken.

The self-assessment programme was particularly helpful during 2020, when regular site inspections were not possible due to the Covid-19 pandemic.

### **Scope of the Programme**

When fully operational, the self-assessment programme will cover the following areas:

1. Food factories, including bottled water factories
2. Animal feed factories
3. Food, animal feed, pesticide, drug, medical device and cosmetic warehouses
4. Science offices and consulting offices related to the SFDA's areas of work

The self-assessment programme is currently optional for factories. The SFDA is working to raise awareness of the programme by sharing content on social media that informs the industry about the programme and its benefits. When visiting factories, the SFDA informs representatives about the programme and lets them know that registration and regular participation will make it easier for them to deepen their knowledge of SFDA regulations.

### **Food Factories**

There are currently 930 licensed food factories in Saudi Arabia that are under the SFDA's jurisdiction. As of February 2022, 756 factories had registered for the self-assessment programme. It is hoped that all of the country's food factories will soon be registered under the programme. As more operators open factories in Saudi Arabia, the SFDA will encourage them to join the programme.