A Guide Control of Handling Manufactured Breastmilk Substitutes and Supplementary Milk Products and Infant Food for Special Medicinal Use

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Operation Sector

Saudi Food and Drug Authority

For more information, please visit the website:

www.sfda.gov.sa

Questioned Documentation:

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Definitions

The following terms and expressions, wherever they may occur in this document, shall have the meanings assigned thereto, unless the context requires otherwise.
SFDA: The Saudi Food and Drug Authority.

Formulated Breast Milk Substitute: refers to milk-based foods manufactured as a substitute for breastmilk to provide full term infants with the necessary nutrition they need during the breastfeeding period.

Complementary Feeding: milk-based foods, which complement breastfeeding, and are specifically prepared for feeding newborns, infants throughout the weaning period, and children above six months old.

I**nfant and Child Formula for Special Medicinal Use**: foods manufactured in such a way to meet special nutritional needs, and administered under medical supervision for patients with undermined ability to digest (some ingredients present in) ordinary food, or patients with specific nutritional needs which can only be satisfied through modifications to ordinary diet or food with special nutritional uses or both.

Food handling: all aspects of the operations which food undergoes throughout the entire food chain.

Product/s: Maternal milk substitutes for infants, complementary milk foods and infant formula for special medicinal uses from birth to 36 months.

Food establishment: Any legal entity that carries out food business at any production stage throughout the food chain except for household kitchens.

Infants: babies under the age of 12 months.

Toddlers: Children between 12 and 36 months old.

First: Scope

This guide applies to establishment producing or manufacturing breastmilk substitutes, complementary feeding products and infant foods for special medicinal uses from birth to the age of 36 months.

Second: Date of Implementation

This guide comes into force on March 1st 2020 A.D.

Third: Food Production Controls

1. Without prejudice to the provisions laid down under the Regulation for Marketing of Breast Milk Substitutes as amended by the Minister of Health's decision No (100493) dated 19/2/1440 A.H, pursuant to SFDA Food Act and Implementing Regulation promulgated by SFDA Board decision No. (3-16-1439 dated 9/4/1439 A.H), the importers and producers of breastmilk substitutes, complementary feeding products, and infant formulas of special medicinal uses for babies from birth to 36 months of age, are required to comply with the following::
    - For importer, to obtain a valid warehouse license from SFDA excluding premises in relation to which restrictions have been imposed by relevant regulations.
    - As far as domestic products are concerned, to obtain a valid factory license from SFDA.
    - Not to sell except from SFDA authorized warehouses or sale points licensed by the relevant government bodies.
    - To ensure that a traceability system in place starting from manufacturing
    - To ensure that the product has already passed Life Shelf Testing.
    - To maintain a record-keeping system in which the SFDA approved distribution zones are clearly identified, and to acknowledge full responsibility, including commitment to incur financial costs, to recall any products cleared by SFDA and announce the recall in local newspaper in case such products have undergone any change substantiating the recall...

•To import only from establishments approved by SFDA for the export to the Kingdom of Saudi Arabia of breastmilk substitutes and complementary feeding products and infant food for special medicinal uses.

- Not to import directly except from the manufacturer.
- To register the product with SFDA after ensuring conformity with SFDA technical regulations and standards.
- To register with SFDA whether the premises are in Saudi Arabia or abroad.

2) All the detailed nutritional information about the manufacturer's products circulated in the Saudi market shall be provided, including the period analyses conducted on these products by accredited laboratories.

3) A statutory agent qualified in science shall be appointed by the establishment to act as a representative for the company in Saudi Arabia and to do the following:

A. Provide any information requested by SFDA about the company's products traded in the Saudi market.
B. Follow up on the registration of the company's products in Saudi Arabia.
C. Follow-up on the company's products after registration and commit to informing the SFDA promptly about any regulatory or precautionary measure undertaken by any International control agency applicable to the company's products or any observations regarding the safety and quality of the product.
D. Inform the SFDA immediately when the food establishment becomes aware or under the suspicion that the food does not comply with SFDA requirements and take the necessary product recalls and withdrawals.

Fourth: Foreign establishment registration.

When intending to export their products to Saudi Arabia, manufacturers of breastmilk substitutes and complementary feeding products, and infant formulas for special medicinal uses are required to register with SFDA through the following link:

https://www.sfda.gov.sa/ar/food/eservices/Pages/FERS1.aspx

Fifth: Products Registration

The importer or producer shall register its products in accordance with the relevant procedures set out in the Food Investor's Guide at the following link:

https://www.sfda.gov.sa/ar/Documents/FoodInvestorGuide.pdf

They shall also adhere to what is stated in the approved Technical Regulations and standard specifications.

Sixth:

SFDA shall consider the approval of the competent authority in the exporting countries that supervise regulate and undertake the registration of businesses involved in the production of breastmilk substitutes, complementary feeding products, and infant formulas for special medicinal uses. For that matter, the competent authority in the exporting country shall communicate with SFDA, which in turn and upon satisfaction of the import and accreditation requirements, shall include the competent authority and the establishment to the list of countries and list of establishments respectively.