FSSAI (Food Safety and Standards Authority of India) Act and Rules

FSSAI Act and Rules: brief overview

Introduction

- In the field of pharmacy, food supplements (also known as dietary supplements or nutraceuticals) occupy a unique position.
- They are not classified as drugs, but are often sold in pharmacies, and are widely used to support health, immunity, and nutrition.
- This gives rise to overlapping regulatory concerns between food laws and pharmacy ethics.
- To regulate the safety, efficacy, and quality of such products, the Food Safety and Standards Authority of India (FSSAI) was established under the Food Safety and Standards Act, 2006.
- This Act, along with various rules and regulations notified under it, forms the legal foundation for ensuring the safety, manufacture, storage, labeling, sale, and distribution of all food products in India, including food supplements.

Origin and Purpose of FSSAI

Legal Foundation:

- **Act Name**: Food Safety and Standards Act, 2006
- **Enforced by**: Food Safety and Standards Authority of India (FSSAI)
- **Nodal Ministry**: Ministry of Health and Family Welfare, Government of India

Objectives:

1. Consolidate various food laws into one single legislation.
2. Create a single point of reference for all matters related to food safety and standards in India.
3. Lay down science-based standards for food items.
4. Regulate the manufacture, distribution, sale, storage, and import of food to ensure consumer safety.
5. Promote public health through safe and wholesome food.
6. Establish procedures for enforcement, penalties, and consumer grievance redressal.

Scope of the FSSA, 2006

- The Act applies to all categories of food products, including:
  - Primary and processed foods
  - Packaged foods and beverages
  - Health supplements, nutraceuticals

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- Functional and novel foods

Key Definitions under the FSSA, 2006

Food (Section 3(1)(j))

- "Food" refers to any substance, whether processed, partially processed, or unprocessed, intended for human consumption. It includes:
  - Primary food (grains, vegetables, etc.)
  - Processed food
  - Health and dietary supplements
  - Beverages, chewing gum, etc.

Food Supplements / Health Supplements

- These are regulated under specific provisions of the Act and are defined as:
- Foods intended to supplement the normal diet and are a source of nutrients such as vitamins, minerals, amino acids, or other substances with nutritional or physiological effects.
- They may come in the form of:
  - Tablets
  - Capsules
  - Powders
  - Granules
  - Liquids

Note:

- These supplements must not be confused with **medicines or drugs**, which fall under the **Drugs and Cosmetics Act, 1940**.

Role of FSSAI in Regulations Related to Food Supplements

- FSSAI regulates food supplements through specific categories and detailed regulations to ensure their **safety, quality, labeling, and claims**.
- These products are **not treated as drugs**, but their use is closely monitored under food law.

Categories Regulated by FSSAI

- Health Supplements
- Nutraceuticals

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- Foods for Special Dietary Uses (FSDU)
- Foods for Special Medical Purposes (FSMP)
- Functional Foods
- Novel Foods

Relevant Regulations

1. **Food Safety and Standards (Health Supplements, Nutraceuticals, FSDU, FSMP, Functional Foods, and Novel Foods) Regulations, 2022**
    - ➢ Primary regulation governing composition, claims, labeling, usage, and safety of food supplements.
2. **Food Safety and Standards (Labelling and Display) Regulations, 2020**
    - ➢ Governs the presentation, labeling, and mandatory declarations on packaging.
3. **Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011**
    - ➢ Mandates licensing for manufacturers and sellers of food supplements.

Key FSSAI Regulations for the Manufacture of Food Supplements

1. Licensing and Registration

- ➢ Manufacturers must obtain appropriate authorization based on their business scale:
    - **Basic Registration**: For businesses with an annual turnover up to ₹12 lakhs.
    - **State License**: Required for businesses with turnover between ₹12 lakhs and ₹20 crores.
    - **Central License**: Mandatory for businesses with turnover exceeding ₹20 crores, those operating in multiple states, or those involved in import/export activities.

2. Manufacturing Premises

- ➢ Facilities must adhere to hygiene and sanitation norms outlined in **Schedule 4** of the FSS (Licensing and Registration) Regulations.
- ➢ **Good Manufacturing Practices (GMP)** and **Hazard Analysis and Critical Control Points (HACCP)** protocols must be followed.
- ➢ Premises are subject to routine inspections by designated Food Safety Officers.

3. Ingredients and Product Formulation

- ➢ Only ingredients approved by FSSAI may be used, in accordance with the Indian Pharmacopoeia, Ayurvedic Pharmacopoeia, or Codex standards.

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- The use of banned substances such as **steroids**, **hormones**, **sibutramine**, and **phenolphthalein** is strictly prohibited.
- Nutrient content must comply with defined limits (e.g., vitamins should not exceed 1 RDA unless specifically permitted).
- **Drug-like claims** on products are not allowed.

4. Product Approval

- Products containing **novel ingredients**—those not previously approved or commonly used—must obtain pre-market approval from FSSAI.
- The application should include:
  - Safety and toxicity data
  - Clinical or toxicological studies
  - Nutritional profile
  - Details on manufacturing process and ingredient sourcing

5. Quality Control

- Each batch of food supplements must be tested in an **FSSAI-recognized laboratory**.
- Tests must cover:
  - Contaminants
  - Heavy metals
  - Microbiological safety
  - Pesticide residues
  - Consistency of nutritional content

Aspects Related to Storage of Food Supplements (As per FSSA 2006 and FSSAI Regulations)

Storage Conditions

- Products must be stored to prevent **contamination, spoilage, temperature fluctuations, moisture**, and **sunlight exposure**.
- Conditions should preserve product **integrity until expiry**.
- **Cold storage** is mandatory for temperature-sensitive items (e.g., probiotics).
- Labels must clearly state storage instructions (e.g., “Store in a cool, dry place”).

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