

## Chapter-9 | FSSAI | Pharmacy Law & Ethics

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**FSSAI (Food Safety and Standards Authority of India) Act and Rules: brief overview and aspects related to manufacture, storage, sale and labelling of Food Supplements**

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

- The Food Safety and Standards Authority of India (FSSAI) Act, 2006 and its rules and regulations are the legal framework for food safety and standards in India.
- The Act establishes the FSSAI as the central regulatory authority responsible for laying down science-based standards for articles of food and regulating their manufacture, storage, distribution, sale, and import to ensure that they are safe and fit for human consumption.
- Under the FSSAI Act, all food business operators (FBOs) must be registered or licensed with the FSSAI and comply with the food safety and standards lay down by the Authority.
- The Act also provides for the appointment of food safety officers and enforcement of penalties for non-compliance.
- The FSSAI has framed regulations on various aspects of food safety and standards, including standards for food products, labeling and packaging requirements, hygiene and sanitation requirements for food businesses, and rules for food imports and exports.
- Some of the major regulations framed by the FSSAI include the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011, the Food Safety and Standards (Packaging and Labeling) Regulations, 2011, and the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011.
- The FSSAI Act and its rules and regulations provide a comprehensive legal framework for food safety and standards in India and are aimed at protecting the health and well-being of the country's citizens.

### **Food supplements:**

- Food supplements are defined as concentrated sources of nutrients or other substances with a nutritional or physiological effect, intended to supplement the normal diet.
- They are typically marketed in the form of capsules, tablets, powders, soft gels, gels, drops, liquids, or bars and are taken by mouth as a supplement to the normal diet.
- Food supplements are commonly used to address deficiencies in the diet, improve overall health and well-being, or meet specific health needs such as for weight management, sports nutrition, or heart health. Some examples of common food supplements include vitamins, minerals, amino acids, herbal products, and probiotics.

### **Manufacture of Food Supplements:**

The manufacture of food supplements is a regulated industry, with strict standards in place to ensure the safety and quality of these products for human consumption. The regulations vary from country to country, but in general, the following are some of the key aspects of food supplement manufacturing:

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1. **Good Manufacturing Practices (GMP):** Food supplement manufacturers must comply with Good Manufacturing Practices (GMP) standards, which lay down guidelines for the production, control, and storage of food supplements to ensure their safety and quality.
2. **Raw Material Sourcing:** Food supplement manufacturers must source high-quality raw materials from reputable suppliers and ensure that the materials meet the required standards for purity, potency, and quality.
3. **Production Processes:** Food supplement manufacturers must follow strict production processes to ensure that the supplements are made in a clean and hygienic environment and are free from contamination and deterioration.
4. **Testing and Quality Control:** The manufacture of food supplements must be accompanied by regular testing and quality control measures to ensure that the finished product meets the required standards for safety and quality.
5. **Packaging and Labeling:** The packaging and labeling of food supplements must comply with the regulations set by the relevant authorities, including the use of appropriate warning and caution statements, if necessary.

The manufacture of food supplements is a highly regulated industry, with strict standards in place to ensure their safety and quality for human consumption. Food supplement manufacturers must comply with these standards to protect the health and well-being of consumers.

## **Storage, Sale and Labelling Of Food Supplements:**

In India, the storage, sale, and labeling of food supplements are regulated by the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards Act, 2006 and its associated regulations. The following are some of the key aspects of the regulation of food supplements in India:

1. **Storage:** Food supplements must be stored in a clean and hygienic environment and must be protected from contamination and deterioration. Proper storage conditions, such as temperature and humidity controls, must be maintained to ensure the safety and quality of the food supplements.
2. **Sale:** Food supplements must be sold only by registered food business operators (FBOs) and must comply with the labeling and packaging requirements laid down by FSSAI.
3. **Labeling:** Food supplements must be labeled with all relevant information, including the name and address of the manufacturer, the name of the food supplement, the list of ingredients, and the recommended daily dose. The label must also carry appropriate warning and caution statements, if necessary, and must comply with the Food Safety and Standards (Labelling and Display) Regulations, 2011.