

ESU 009 - Regulatory issues for nutraceuticals and functional foods

Lecture 41



Regulation of nutraceuticals

Issues with regulatory regime before FSSA-

- Nine different laws and eight different ministries was governing the food sector
- Laws framed by different Ministries/Depts. With different perspective and enforcement approach
- Overlapping laws with different quality standards & labelling requirements

Need for new law (FSSA)-

- Removal of multiple regulations
- Harmonizing with international law
- Framing regulatory requirements based on science and risk analysis
- Facilitating trade without compromising consumer safety and bringing in innovation in foods

Food Safety and Standard Act

Manufacture, storage, distribution, sale and import of Nutraceuticals in India are regulated under the Food Safety and Standards Act, 2006. This Act consolidated the laws relating to food and established the Food Safety and Standards Authority of India for laying down science based standards for articles of food.

- The Prevention of Food Adulteration Act, 1954**
- The Fruit Products Order, 1955**
- The Meat Products Order, 1973**
- The Vegetable Oil Products (Control) Order, 1947**
- The Edible Oils Packaging Order, 1998**
- The Solvent Extracted Oil, De oiled Meal, and Edible Flour (Control) Order, 1967.**
- The Milk and Milk Products Order, 1992**

FSSAI & Nutraceuticals

Chapter IV section 22 of the Act addresses nutraceuticals, functional food, dietary supplements.

- According to it “foods for special dietary uses or functional foods or nutraceuticals or health supplements” means:
 - foods which are specially processed or formulated to satisfy particular dietary requirements and the composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist, and may contain one or more of the following ingredients, namely:-
 - ❖ plants or botanicals or their parts in the form of powder, concentrate or extract in water, ethyl alcohol or hydro alcoholic extract, single or in combination;

Salient feature of the act

- **Movement from multi-level and multi-department control to a single line of command.**
- **FSSAI as a single reference point for all matters relating to Food Safety and Standards, Regulations and Enforcement.**
- **Integrated response to strategic issues like Novel foods, Health Foods, Nutraceuticals, GM foods, international trade etc.**
- **Decentralization of licensing for manufacture of food products.**
- **Achieve high degree of consumer confidence in quality & safety of food.**
- **Investor's friendly regulatory mechanism with emphasis on self regulations and capacity building.**

New provisions under the act

- **Regulation of food imported in the country**
- **Provision for food recall**
- **Surveillance**
- **New enforcement structure**
- **Envisages large network of food labs**
- **New justice dispensation system for fast track disposal of cases**
- **Harmonization of domestic standards with international food standards**
- **Covering Health Foods, supplements, Nutraceuticals**
- **Issuing Licenses within a time frame of 2 months**
- **Provision of Improvement Notice by Designated Officers**

Registration of food business

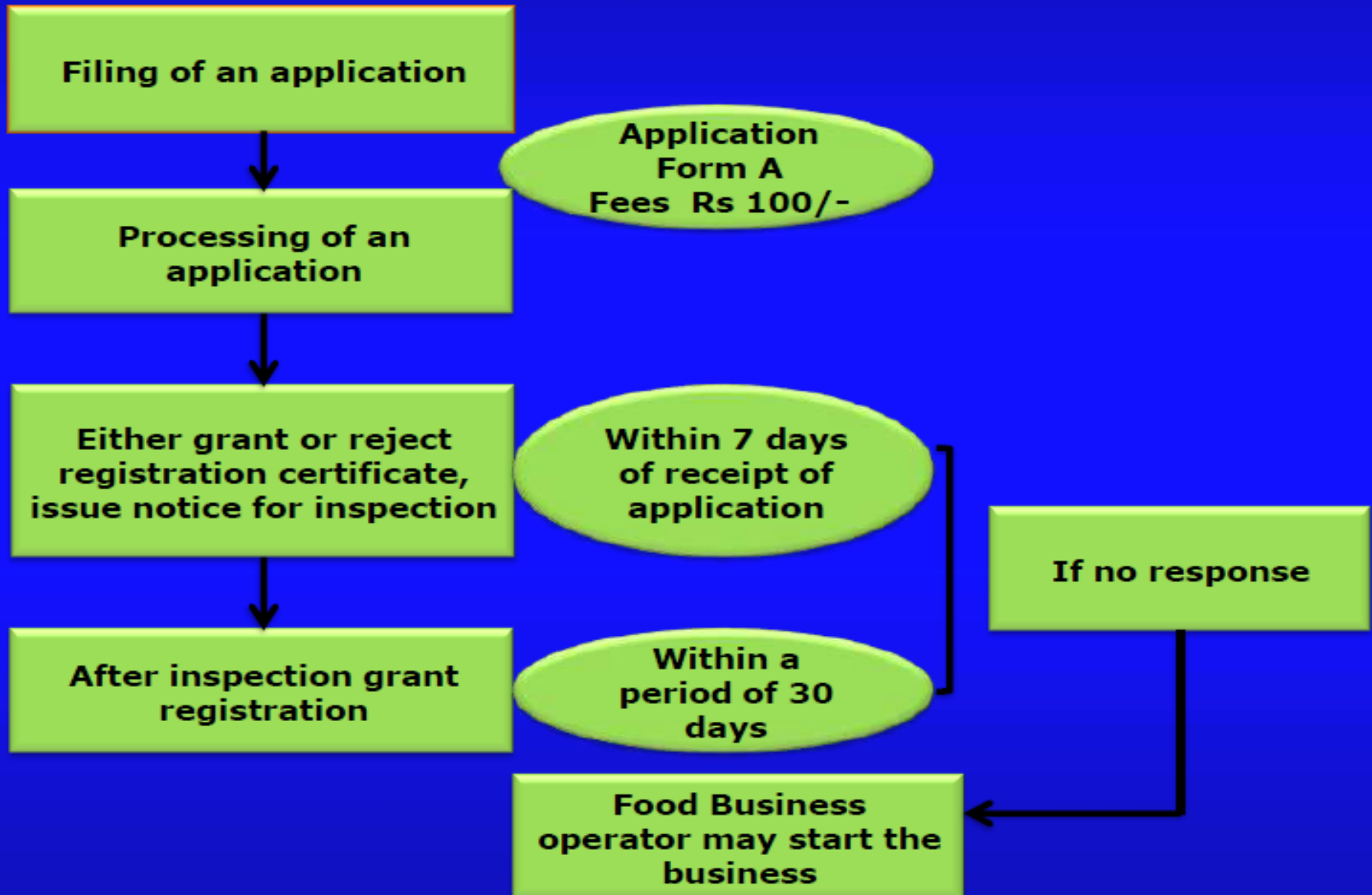
Registration is required only for “Petty Food Manufacturer” means any food manufacturer, who

- manufactures or sells any article of food himself or a petty retailer, hawker, itinerant vendor or temporary stall holder; or distributes foods including in any religious or social gathering except a caterer; or
- such other food businesses including small scale or cottage or such other industries relating to food business or tiny food businesses with an annual turnover not exceeding Rs 12 lakh and/or whose
 - production capacity of food (other than milk and milk products and meat and meat products) does not exceed 100 kg/ltr per day or
 - procurement or handling and collection of milk is up to 500 litres of milk per day or
 - Slaughtering capacity is 2 large animals or 10 small animals or 50 poultry birds per day or less.

Procedure for registration

- **Registration shall not be refused without giving the applicant an opportunity of being heard.**
- **On completion of the procedures and grant of registration, A registration certificate and a photo identity card shall be issued which shall be displayed at a prominent place.**
- **The Registering Authority or any officer or agency specifically authorized for this purpose shall carry out inspection of the registered establishment.**

procedure for registration of food business



Procedure for licensing

- **No person (other than petty food businesses) shall commence any food business without obtaining a valid license.**
- **Existing Operator holding valid license/registration shall be granted a license within one year of notification of this Regulation.**
- **No license fee for the remaining period of the validity of the earlier license.**
- **License for businesses mentioned under Schedule 1, shall be granted by the Central Licensing Authority and all others by State licensing Authority.**
- **Importers of food items shall obtain a license from the Central Licensing Authority in addition to license taken for any other food business.**

Packaging and labeling

Labeling is required in the manner as may be specified by regulations:

- Provided that the labels shall not contain any statement, claim, design or device which is false or misleading in any particular concerning the food products contained in the package or concerning the quantity or the nutritive value implying medicinal or therapeutic claims or in relation to the place of origin of the said food products.
- Every food business operator shall ensure that the labeling and presentation of food, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, does not mislead consumers.

Advertisement

Supreme Court of India has held that commercial advertisement is a fundamental right available to every citizen under Article 19 (1) (a) of the Constitution of India subject to the requirements of Article 19 (2) of the Constitution.

The Advertising Standards Council of India (ASCI) has drafted and implemented a Code for Self-Regulation in Advertising (ASCI Code) in India.

Advertisement guideline provides that-

- It should not be misleading or deceptive.**
- Advertisements should not disparage good dietary practice or the selection of options, such as fresh fruit and vegetables that accepted dietary opinion recommends should form part of the average diet.**

- **Advertisements should not encourage excessive consumption or inappropriately large portions of any particular food.**
- **Ensure advertisements do not mislead as to the nutritive value of any food.**
- **The nature of the audience should be taken into account.**
- **Claims shall be specific to the promoted product/s and accurate.**
- **Claims in an advertisement should not be inconsistent with information on the label or packaging of the food.**

Panalties

- ✘ **Substandard food: Upto Rs. 2.00 lakhs**
- ✘ **Misbranded: Upto Rs. 3.00 lakhs**
- ✘ **Misleading advertisement : Upto Rs. 10.00 lakhs**
- ✘ **Food with extraneous matter: Upto Rs. 1.00 lakhs**
- ✘ **Fail to meet the requirements as directed by FSO: Upto Rs. 2.00 lakhs**
- ✘ **Unhygienic / unsanitary preparations: Upto Rs. 1.00 lakhs**
- ✘ **Adulterant not injurious to health: Upto Rs. 2.00 lakhs**
- ✘ **Adulterant injurious to health: Upto Rs. 10.00 lakhs**
- ✘ **Unsafe food – but does not cause immediate injury : 6 months imprisonment with fine of Rs.1.0 lakh**

Thank you

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