CHAPTER 3

Food Standards

Under the Food Safety and Standards Act, 2006 FSSAI is responsible for framing standards for food products and for food safety. The scientific risk assessment and setting of standards is carried out on the basis of latest developments in food science along with various factors including emergence of new additives, changes in processing technology, identification of new risks associated with a food or an additives in respect of metallic contaminants, toxins, residues of pesticides and veterinary drugs, microbiological contaminants, food consumption pattern, nutritional aspects, advancement in analytical methods, and regulatory impact.

This entire process is carried out in a transparent manner involving all stakeholders. For this purpose, FSSAI has constituted scientific bodies, namely, a Scientific Committee and 17 Scientific Panels under the provisions of Food Safety and Standards Act for development of standards. 17 Scientific Panels and a Scientific Committee comprising of more than 220 subject independent experts/scientists of eminence.

Formulation of standards of any article of food involves several stages. After recommendation by the Scientific Panel, following the due process laid down including validation by the Scientific Committee a standard is then approved by the Food Authority. After which draft notification is issued for inviting public comments and finally notified as standards.

Further, considering the needs of the Indian population, for promoting innovation by the Industry and to bridge the gap between National and International best practices, FSSAI has constituted eight Standard Review Groups for various vertical group of commodities viz. Oils & Fats; Milk & Milk Products; Cereals & Cereals Products; Fruits, Vegetables & their Products; Sweets & Confectionery; Meat & Fish Products; Beverages including Alcoholic Beverages; and Nutraceuticals. These groups, which consist of representatives from the Industry associations, would review the existing standards, identify gaps and propose development of new standards taking into account the Indian and international scenario, for minimizing the regulatory burden, while reflecting advancement in scientific knowledge in areas of food processing and technology, nutrition, toxicology and prepare and forward note justifying revision of existing standards or development of new standards for food commodities.

Category of Standards

Standards can be broadly categorized into Horizontal Standards and Vertical Standards. Horizontal standards cut across foods or categories of foods like Food Safety and Standards (Contaminants, Toxins and Residues) Regulations-2011 and Food Safety and Standards (Packaging and Labelling) Regulations-2011. Vertical Standards mainly include identity and compositional standards of specific food products like Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011 and Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016

Important Food Standards

Contaminants, Toxins, Residues & Biological Hazards: The Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011 relates to safety of food products with respect to Contaminants, Toxins and Residues. The limits for microbiological contaminants have been prescribed at Appendix-B of Food Safety and Standards (Food Products standards and Food Additives) Regulations, 2011. These Regulations prescribe the maximum permissible limits of the following contaminants:

i) **Metal Contaminants:** Such as Lead, Copper, Arsenic, Tin, Cadmium, Mercury, Methyl Mercury, Chromium and Nickel. The requirement of heavy metals has been prescribed for all food categories.

- ii) **Insecticide/Pesticide Residues:** Maximum residue level of about 149 insecticides/pesticides. Maximum residue level of nearly 70 new pesticides are at various stages of notification.
- iii) Antibiotic and other Pharmacologically Active Substances: Such as Tetracycline, Oxytetracycline, Trimethoprim and Oxolinic acid for fish and fish products and 10 antibiotics for honey have been prescribed. Maximum residue level of nearly 119 antibiotics and veterinary drugs are at various stages of notification.
- iv) Crop Contaminants: Such as Aflatoxins, Ochratoxin A, Patulin and Deoxynivalenol.
- v) Naturally Occurring Toxic Substances: Such as Agaric acid, Hydrocyanic acid, Hypericine and Saffrole.
- vi) Other Contaminants: Such as Melamine in Powdered infant formula, Liquid infant formula and for other foods, Histamine in fish and fishery products.
- vii) **Microbiological Contaminants:** Safety and hygiene requirements have been specified for majority of food categories. More standards in this area are at various stages of notification.

Labelling, Packaging & Claims: The link between food packaging, labelling and consumer protection is of high significance. To safeguard the interests of the consumer and the society at large, Food Safety and Standards Authority of India has notified Food Safety and Standards (Packaging and Labelling) Regulations, 2011. These Regulations are now being split into three parts, namely:

- 1. Food Safety and Standards (Packaging) Regulations;
- 2. Food Safety and Standards (Labelling) Regulations;
- 3. Food Safety and Standards (Advertisement and Claims) Regulations.

The proposed packaging Regulations deal with the various types of packaging standards such as plastics, metal & metal alloys, paper, paper board and glass. For the sake of innovation with different types of packaging material available globally, the list of safe packaging materials has also been broadened in the proposed regulation. These Regulations prescribe the general requirements for containers used in the preparation, packaging & storing of food and product specific packaging requirements to be followed by the FBOs. It also provides a suggestive list of packaging materials for different food categories.

The proposed labelling Regulations prescribes the general and specific labelling requirements for pre-packaged food articles. The information required to every FBOs to declare on the label of pre-packaged food has also been specified.

Labelling regulations further prescribe the mandatory provisions, developed based on WHO model, for Front of Pack nutritional labelling for energy, total fat, trans fat, added sugar and sodium along with their per serve % contribution to RDA. The same would also be applicable to Foods containing high fat, sugar and salt (HFSS).

The proposed Regulations also provides for labelling of Genetically Engineered (GE) foods.

While framing the Labelling Regulations overlapping provisions with Legal Metrology (Packaged Commodities) Rules, 2011 have been removed. Legal Metrology (Packaged Commodities) Rules, 2011 has given exemption in respect of packages containing food articles wherever appropriate and in such cases, the requirements of Food Safety and Standards Act would apply.

Food Safety and Standards (Advertisement and Claims) Regulations prescribes general principles for claims and provides conditions for specific claims like nutritional claims, non-addition claims, health claims, claims related to dietary guidelines or healthy diets, conditional claims and prohibited claims. Further, it includes the schedules for approved Nutrition claims, Health claims for disease risk & fortified foods, claims regarding use of words like natural, fresh, pure, original traditional premium realets.

Provision has also been made for restricting the advertisements and/or claims for food articles that undermines the products of any other manufacturer for the purpose of promoting their products or influencing consumer behavior.

- Food Additives: The provisions for use of food additives is given under the Food Safety and Standards (Food Products standards and Food Additives) Regulations, 2011. These Regulations specify an updated/expanded list of food additives, largely harmonized with Codex standards, and their criteria for use in foods, including specifications for the identity and purity of food additives. The revised regulation also provides hierarchical food category system with 16 major categories and subcategories in line with the codex food categorization system.
 - The updated/expanded food additive provisions provide a wide choice of additives to food manufacturers for improving the quality of food products by use of food additives that are technologically best suitable for the product.
- Food Category System: In compliance with the guiding principles specified in the Food Safety and Standards Act, 2006 and India's commitments towards WTO, FSSAI created a Food Category System (FCS), in harmony with the Food Categorization System adopted in Codex General Standard for Food Additives (GSFA).

There are 16 Main categories of food. One more category numbered '99' is included for substances added to food which are 'not for direct consumption as food' under the Food Categorization Code. These are:

- 01. Dairy products and analogues
- 02. Fats and oils, and fat emulsions
- 03. Edible ices, including sorbet
- 04. Fruits and vegetables (including mushrooms and fungi, roots and tubers, fresh pulses and legumes, and aloe vera), seaweeds, and nuts and seeds
- 05. Confectionery
- 06. Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses, legumes (fresh pulses and legumes are covered in category 4.2) and pith or soft core of palm tree, excluding bakery wares of food category 07.0
- 07. Bakery products
- 08. Meat and meat products, including poultry
- 09. Fish and fish products, including molluscs, crustaceans, and echinoderms
- 10. Eggs and egg products
- 11. Sweeteners, including honey
- 12. Salts, spices, soups, sauces, salads and protein products
- 13. Foodstuffs intended for particular nutritional uses
- 14. Beverages, excluding dairy products
- 15. Ready-to-eat savouries
- 16. Prepared foods
- 17. Substances added to food which are 'not for direct consumption as food'

Most of the standards for food products under categories such as milk and milk products, oils and fats, and fruits and vegetable products have already been established. However, a few remaining products under Cereal, Fish, Meat & Egg

and their products are at various stages of development. The Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011 initially prescribed standards for 377 products/product categories. Since, then additionally standards for 134 products have been finalized and notified and an equal number of the product standards are in the process of being finalized.

 Health Supplements and Nutraceuticals: Standards for Health supplements and Nutraceuticals are specified under Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food, and Novel Food) Regulations, 2016. The enforcement of these regulations shall commence with effect from January 1, 2018.

The regulations cover eight categories of Functional foods, namely, Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Specialty food containing plant or botanicals, Foods containing Probiotics, Foods containing Prebiotics and Novel Foods. It provides for the general conditions for manufacture and sale of these foods, requirements related to claims, besides providing details of each type of above foods individually regarding its essential composition, specific labeling requirements and permitted use of additives. The regulations do not allow the use of hormones or steroids or psychotropic ingredients in any of the articles of food.

Furthermore, these regulations provide various Schedules containing list of vitamins and minerals, amino acids, schedule for minimum and maximum values for vitamins and minerals for FSDU and FSMP category, list of ingredients of plants or botanical origin, nutraceuticals, probiotics and prebiotics. A comprehensive schedule of additives, divided into various sub-categories for use in different foods is also included.

For ingredients which are in use for a number of years with history of safe consumption in India and/or abroad, which have not been included in said regulations, as well as novel foods, FBOs will have to apply to FSSAI for approval as per Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017.

 Fruits & Vegetable Products: Standards for 'Fruit & Vegetable Products', and those of 'Salt, spices, condiments and related products' are prescribed under sub-regulation 2.3 and 2.9 respectively of Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011.

These regulations covers more than 50 products such as Thermally Processed Fruits, Thermally Processed Vegetables, Thermally Processed Fruits Juices, Thermally Processed Vegetable Juices, Soup Powders, Tamarind Pulp/Puree and Concentrate, Fruit Bar/ Toffee, Fruit/Vegetable, Canned Tomatoes, Tomato Juice, Jams, Fruit Jellies & Marmalades, Table Olives, Inclusion of Ethylene gas for ripening (revision), Cinnamon whole and powder, Pickles, Nuts and Raisins, and spices such as caraway, cardamom, chillies and capsicum (Lal Mirchi), Cinnamon, mustard, nutmeg, pepper black, poppy, saffron, turmeric, curry powder, iodized salt, iron fortified iodized salt (double fortified salt), and many more.

These regulations prescribed the quality parameters for the product. The safety parameters have been separately prescribed under The Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011.

Some new standards which are under the process of development are Date Paste, Fermented Soybean Paste, Harrisa (Red Hot Pepper Paste), Quick frozen French fried potatoes, Vegetable Protein Products, Cocoa mass/cocoa cake, Canned Chestnut and Chestnut Puree, Edible Fungus Products, Mixed Spices(Powder), Oleoresins, Almond Kernels, Coconut Milk Powder, Tejpat, Star Anise, Water Chestnuts Flour, Dried Oregano – Whole and Powder, Pimento (Allspice) – Whole and Powder, Laurel (Bay Leaf) - Whole and Powder.

- Milk and Milk Products: With the large-scale development and changing needs of the dairy industry in the country, and to bring in consistency with the globally recognized standards, the standards for milk and milk products have recently been revised in a comprehensive manner. The revised regulations include a general standard for milk and milk products which provides comprehensive definitions of milk/milk products and heat treatments used in dairy processing, conditions for use of dairy terms in the nomenclature of food products etc. The Regulations also include revised individual identity standards for various products, namely, milk; flavoured milk; evaporated or concentrated Milk; sweetened condensed milk; khoa; cream and malai; fermented milks; milk powders; partially dehydrated milks (condensed milks); cheeses; indigenous dairy products; milkfat products (butter, ghee etc.); whey powder; ice cream; frozen desserts etc. New standards for edible lactose, dairy whitener, flavoured dahi fermented milk drinks and camel milk have also been included therein.
- Infant Food Products: The standards for different infant products are specified under 2.1.9 of Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011. These Regulation contains standards for mainly two categories of products that is infant milk substitute and infant foods. They prescribe the limits of various nutrients such as protein, fat, vitamins and minerals etc. along with the source of mineral salts and vitamin compounds to be used, and list of additives with their permissible limit.
 - Further, as per Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 no person shall manufacture, sell, store or exhibit for sale, an infant milk food, infant formula and milk cereal based weaning food, processed cereal based weaning food and follow up formula except under Bureau of Indian Standards certification mark.
- Cereal & Cereal Products: Standards for Cereals and Cereals Products are prescribed under Regulation 2.4 of FSS
 (Food Product Standards and Food Additives) Regulations, 2011. These regulation covers products like Atta, Maida,
 Semolina, Besan, Pearl Barley, Foodgrains, Cornflour, Corn flakes, Custard Powder, Macaroni products, Malted and
 Malt Based Foods, Rolled Oats, Solvent Extracted Flours, Starchy Foods, Bakery Products, Instant Noodles, Oats,
 Pasta and many more.
 - Some new standards which are under the process of development are Sago, Durum wheat, Durum Wheat Semolina and Whole durum wheat semolina, Durum Wheat Maida, Pearl Millet Flour, Sorghum Flour, Soybean, Soy Protein Products, Quinoa, Finger Millet, Amaranth, Wheat Protein Products Including Wheat Gluten, Whole Maize (Corn) Flour, Degermed Maize (Corn) Flour and Maize (Corn) Grits, Couscous, Tempe, Textured Vegetable Protein (Soya Bari), Tofu, Edible Sago Flour, Decorticated Pearl Millet Grains (Bajra), Basmati Rice, Chia seeds, Gari, Edible Cassava Flour, Chana Sattu, Ragi Flour, Wheat bran etc.
- Alcoholic Beverages: Regulations on Alcoholic beverages is in the final stage of notification. It covers all alcoholic
 beverage containing more than 0.5 per cent alcohol. These Regulations includes following types of alcoholic
 beverages:
 - i) Distilled alcoholic beverages: Brandy (grape, blended), Country Liquors (Plain, Fenny, Blended), Gin, Pot distilled spirits, Rum (rum, white rum), Liqueur or cordials, Vodka, Whisky (single malt, blended).
 - ii) Wine and other Fermented Beverages: Table/grape wine (white and red), Fortified Wine, Wine with carbon dioxide, Fruit Wine (fruit wine, cider, Perry), Wine from other agricultural and plant sources.
 - iii) Beer: Beer (strong and regular), Draught Beer (strong and regular).

FSSAI is also in the process of notifying a list of additives which would be allowed to be used in manufacturing of above alcoholic beverages. This list is aligned with the OIV list of food additives.

- Packaged Drinking Water: Standards for packaged drinking water have been prescribed under sub regulation "2.10.8 of Food Safety and Standards (Food Products standards and Food Additives) Regulations, 2011. It provides for manufacture of packaged drinking water from various sources such as surface water or civic water supply or underground water or sea water or any other consistent source of water. Various types of treatments such as decantation, filtration, combination of filtration, aerations, filtration with membrane filter depth filter, cartridge filter, activated carbon filtration, demineralization, remineralization, reverse osmosis etc. has also been specified. The regulation also provides for the types of packaging.
- Proprietary Food: The regulation on proprietary food covers those foods which are not standardized in any of the Regulations notified by FSSAI. This regulation provides for ingredient based concept as against the recipe based approval of food products followed earlier by FSSAI. As per this regulation any food product prepared using those ingredients which are either standardized or permitted to be used in standardized products does not require any product approval. Further, FSSAI is in the process of extending the scope of this provision by considering the food or ingredients included in Indian Food Composition Tables by National Institute of Nutrition thereby allowing food 528 key food ingredients representing all major food groups that could be utilized by the FBOs manufacturing proprietary food which would also not require any separate product approval. Relevant FSSR and their amendments including the definition for proprietary food has covered a majority of food products for which NOC/product approvals were required earlier (http://www.fssai.gov.in/home/fss-legislation/fss-regulations.html).
- Non-Specified Food Products Approval Mechanism: For the FBOs whose product which have not been standardized in any of the Regulations, FSSAI has recently Notified Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017. These regulations lay down the procedure for grant of prior approval of non-specified food and food ingredients whereby FBOs are required to submit application as prescribed along with necessary documents such as the safety data, history of safe use, a certificate of analysis in respect of the chemical, physical, microbiological and nutritional parameters etc. along with a fee of Rs. 50000/-. The approval for these products are granted by the Authority after the risk analysis is carried out by the Scientific Panels.
- Food Fortification: Regulations on fortification of foods namely Food Safety and Standards (Fortification of Foods) Regulation have been operationalized since October, 2016. These regulation provides for fortification of staples such as Wheat flour, Rice, Edible oil & Vanaspati, Milk and salt with micronutrients like Vitamin A, Vitamin D, Iron, Folic Acid, Vitamin B12, Zinc, Thiamine, Riboflavin, Niacin and Pyridoxine and their salts with the permitted levels as specified under the regulation. Further, the regulation prescribes the '+F' logo that may be used by FBOs for Fortified Food Products Procedure for use of +F logo is also available on website.

 (http://ffrc.fssai.gov.in/ffrc/licence_registration).
- Organic Food Products: Standards to regulate manufacture, distribution, sale or import organic foods have been
 prescribed under Food Safety and Standards (Organic Foods) Regulations, 2017. These Regulations recognizes two
 systems of certification i.e. Participatory Guarantee System (PGS) implemented by Ministry of Agriculture and
 Farmers Welfare and National Programme for Organic Production (NPOP) implemented by Ministry of Commerce
 and Industry. As such FSSAI will be regulating transport, storage, processing, distribution, retail and imports of all
 organic products.

The Regulation which is at the final stage of notification will be able to provide the integrity of the Organic food products and control the unscrupulous practices of Organic Foods in the market. The Regulation will also ensure credibility of Organic Products amongst the consumers thus benefitting the farmers by way of increasing their income.

FSSAI is also in the process of developing online database having details of Organic Food Business Operators with their products and geographical areas in which such products are available for the benefit of the other Food Business Operators and Consumers.

• Irradiated Foods: Irradiated foods are food and agricultural commodities preserved by radiation processing. Radiation processing of food or food irradiation, is a physical process in which food and agricultural commodities in pre-packaged form or in bulk, are exposed to a controlled amount of radiant energy from a gamma, X-ray or electron beam source, to achieve desirable technological objectives such as inhibition of sprouting, delay in ripening, killing of insect pests, parasites, pathogenic and spoilage microorganisms. FSSAI has published Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2016, on the use of irradiation for sanitary and phyto-sanitary purposes. The regulations provide for radiation processing of different classes of food products and the limits of radiation dose. The regulations also provide for the dose limits recommended for radiation processing of allied products such as packaging materials, food additives, health foods, dietary supplements and nutraceuticals, incorporating the relevant provisions of Atomic Energy (Radiation Processing of Food & allied Products) Rules, 2012. In conjunction with Plant Quarantine (Regulation of Import into India) Order, 2003, these regulations enable use of irradiation as a phyto-sanitary or quarantine measure for import or export of produce for overcoming quarantine barriers and getting market access. For sanitary applications, the technology has been used in India for microbial decontamination of exportable spices since 2000. Since 2007 Indian mangoes have found market access in USA by using irradiation as a phyto-sanitary measure.

Nutrition and health portfolio

Food Fortification Resource Centre (FFRC): The Food Fortification Resource Centre has been set up as a Resource
and Support Centre, in collaboration with Tata Trusts, to promote large-scale fortification of food across India. This
centre works closely with government departments at the Centre and States, development partners, food
businesses, premix suppliers, equipment manufacturers and consumer representative organisations to address any
issue in the effective implementation of food fortification programme.

The objectives of FFRC is to Sensitize states about fortification of food and promote fortified foods in state nutrition programmes, to provide technical support especially to small scale food manufacturers to enable them to produce fortified foods; to educate people about the benefits of fortification and consume fortified foods; to train and build capacity for large-scale fortification of foods and provide tools for monitoring and evaluation of fortification programmes, to provide communication material, technical, scientific and financial support to promote large-scale fortification of foods.

An online portal of the Food Fortification Resource Centre has been set up to aid in realisation of these objectives. The portal provides all information pertaining to fortification of food such as scientific evidence, latest fortification technology, national and international experience and best practices.

• IFS Quick Access: FSSAI has developed a system integrating all Food Safety Standards and Regulations for providing a quick access to the vertical as well as the horizontal standards. This is aimed at minimizing ambiguity in the interpretation of regulations and facilitating FBOs in smooth operations of their business. Quick Access would provide all relevant information about a food product at a single glance. It would facilitate a user to access the information relating to all permitted food additives; HS Code; Food Category Code; contaminants, pesticide residues, metallic contaminant, product-specific quality standards; licensing and imports related requirements. (http://117.239.180.188:8080/IFSquickaccess/).

Packaging and Labelling of Foods

- The Food Safety and Standards (Packaging and labelling) Regulations, 2011 provides the manner in which food
 products are to be packed and labelled. Section 24 of the Food Safety & Standards Act, 2006 talks about
 restrictions of advertisement and prohibition as to unfair trade practices and Regulation 2.5 of Food Safety &
 Standards (Packaging and Labelling) Regulations, 2011 also relates to restriction on advertisement.
- All packaged food products has to be labelled in the manner as may be specified by the regulations. The labels
 should 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 has to ensure that the labelling 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.

A. Important Definitions –

- "Best before" means the date which signifies the end of the period under any stated storage conditions during
 which the food shall remain fully marketable and shall retain any specific qualities for which tacit or express
 claims have been made and beyond that date, the food may still be perfectly safe to consume, though its quality
 may have diminished. However the food shall not be sold if at any stage the product becomes unsafe.
- 2. "Date of manufacture" means the date on which the food becomes the product as described;
- "Date of packaging" means the date on which the food is placed in the immediate container in which it will be ultimately sold;
- 4. "Infant" means a child not more than twelve months of age;
- 5. "Lot number" or "code number" or "batch number" means the number either in numericals or alphabets or in combination thereof, representing the lot number or code number or batch number, being preceded by the words "Lot No" or "Lot" or "code number" or "Code" or Batch No" or "Batch" or any distinguishing prefix by which the food can be traced in manufacture and identified in distribution.
- 6. "Multi-piece package" means a package containing two or more individually packaged or labelled pieces of the same commodity of identical quantity, intended for retail either in individual pieces or packages as a whole.
- 7. "Non- Vegetarian Food" means an article of food which contains whole or part of any animal including birds, fresh water or marine animals or eggs or products of any animal origin, but excluding milk or milk products, as an ingredient;
- 8. "Pre-packaged" or "Pre-packed food", means food, which is placed in a package of any nature, in such a manner that the contents cannot be changed without tampering it and which is ready for sale to the consumer.
 - Note: The expression "package" wherever it occurs in these Regulations, shall be construed as package containing pre-packed food articles.
- 9. "Principal Display Panel" means that part of the container/package which is intended or likely to be displayed or presented or shown or examined by the customer under normal and customary conditions of display, sale or purchase of the commodity contained therein.

- 10. "Use by date" or "Recommended last consumption date" or "Expiry date" means the date which signifies the end of the estimated period under any stated storage conditions, after which the food probably will not have the quality and safety attributes normally expected by the consumers and the food shall not be sold;
- 11. "Vegetarian Food" means any article of Food other than Non-Vegetarian Food as defined in regulation 1.2.1(7).
- 12. "Wholesale package" means a package containing
 - (a) a number of retail packages, where such first mentioned package is intended for sale, distribution or delivery to an intermediary and is not intended for sale direct to a single consumer; or
 - (b) a commodity of food sold to an intermediary in bulk to enable such intermediary to sell, distribute or deliver such commodity of food to the consumer in smaller quantities.

B. Packaging

General Requirements

- (a) Utensil or container made of following material or metal used in the preparation, packaging and storing of food shall be deemed to render it unfit for human consumption if:
 - (i) containers which are rusty;
 - (ii) enamelled containers which have become chipped and rusty;
 - (iii) copper or brass containers which are not properly tinned
 - (iv) containers made of aluminium not conforming in chemical composition to IS:20 specification for Cast Aluminium & Aluminium Alloy for utensils or IS:21 specification for Wrought Aluminium and Aluminium Alloy for utensils.
- (b) Containers made of plastic materials should conform to the Indian Standards Specification, used as appliances or receptacles for packing or storing.
- (c) General packaging requirements for Canned products
 - (i) All containers shall be securely packed and sealed.
 - (ii) The exterior of the cans shall be free from major dents, rust, perforations and seam distortions.
 - (iii) Cans shall be free from leaks.

Product Specific Requirements

(a) Packaging requirements for Milk and Milk Products

- (i) Bottling or filling of containers with heat-treated milk and milk product shall be carried out mechanically and the sealing of the containers shall be carried out automatically.
- (ii) Wrapping or packaging may not be re-used for dairy products, except where the containers are of a type which may be re-used after thorough cleaning and disinfecting.
- (iii) Sealing shall be carried out in the establishment in which the last heat-treatment of drinking milk or liquid milk-base products has been carried out, immediately after filling, by means of a sealing device which ensures that the milk is protected from any adverse effects of external origin on its characteristic. The

sealing device shall be so designed that once the container has been opened, the evidence of opening remains clear and easy to check.

(iv) Immediately after packaging, the dairy products shall be placed in the rooms provided for storage.

(b) Packaging requirements for Edible oil/ fat:v

Tin Plate used for the manufacture of tin containers for packaging edible oils and fats shall conform to the standards of prime grade quality contained in B.I.S. Standards No. 1993 or 13955 or 9025 or 13954 as amended from time to time and in respect of Tin containers for packaging edible oils and fats shall conform to IS No. 10325 or 10339 as amended from time to time. v

(c) Packaging requirements for Fruits and Vegetables Products

- (i) Every bottle in which any fruit product is packed shall be so sealed that it cannot be opened without destroying the licensing number and the special identification mark of the manufacture to be displayed on the top or neck of the bottle.
- (ii) For Canned fruits, juices and vegetables, sanitary top cans made up of suitable kind of tin plates shall be used.
- (iii) For Bottled fruits, juices and vegetables, only bottles/jars capable of giving hermetic seal shall be used.
- (iv) Juices, squashes, crush, cordials, syrups, barley waters and other beverages shall be packed in clean bottles securely sealed. These products when frozen and sold in the form of ice shall be packed in suitable cartons. Juices and Pulps may be packed in wooden barrels when sulphited.
- (v) For packing Preserves, Jams, Jellies, and Marmalades, new cans, clean jars, new canisters, bottles, chinaware jars, aluminium containers may be used and it shall be securely sealed.
- (vi) For Pickles, clean bottles, jars, wooden casks, tin containers covered from inside with polythene lining of 250 gauge or suitable lacquered cans shall be used.
- (vii) For Tomato Ketchups and Sauces, clean bottles shall be used. If acidity does not exceed 0.5% as acetic acid, open top sanitary cans may also be used.
- (viii) Candied fruits and peels and dried fruits and vegetables can be packed in paper bags, cardboard or wooden boxes, new tins, bottles, jars, aluminium and other suitable approved containers.
- (ix) Fruits and Vegetable products can also be packed in aseptic and flexible packaging material having food grade quality conforming to the standards laid down by BIS.

(d) Packaging requirements for Canned Meat Products

- (i) New sanitary top cans made from suitable kind of tin plate shall be used. The cans shall be lacquered internally; they shall be sealed hermetically after filling. The lacquer used shall be sulphur resistant and shall not be soluble in fat or brine.
- (ii) Cans used for filling pork luncheon meat shall be coated internally with edible gelatin, lard or lined with vegetable parchment paper before being filled.
- (iii) Meat products packed in hermetically sealed containers shall be processed to withstand spoilage under commercial conditions of storage and transport.

(e) Packaging requirements for Drinking Water (Both Packaged and Mineral Water)

It shall be packed in clean, hygienic, colourless, transparent and tamperproof bottles/containers made of polyethylene (PE) (conforming to IS:10146 or polyvinyl chloride (PVC) conforming to IS:10151 or polyalkylene terephthalate (PET and PBT) conforming to IS:12252 or polypropylene conforming to IS:10910 or food grade polycarbonate or sterile glass bottles suitable for preventing possible adulteration or contamination of the water.

All packaging materials of plastic origin shall pass the prescribed overall migration and colour migration limits.

C. Labelling

(a) General Requirements

- (i) Every pre-packaged food shall carry a label containing information as required here under unless otherwise provided, namely,
- (ii) The particulars of declaration required under these Regulations to be specified on the label shall be in English or Hindi in Devnagri script:
 - Provided that nothing herein contained shall prevent the use of any other language in addition to the language required under this regulation.
- (iii) Pre-packaged food shall not be described or presented on any label or in any labelling manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect;
- (iv) Label in pre-packaged foods shall be applied in such a manner that they will not become separated from the container;
- (v) Contents on the label shall be clear, prominent, indelible and readily legible by the consumer under normal conditions of purchase and use;
- (vi) Where the container is covered by a wrapper, the wrapper shall carry the necessary information or the label on the container shall be readily legible through the outer wrapper and not obscured by it;
- (vii) License number shall be displayed on the principal display panel in the following format, namely:-



Provided that the existing products of a unit shall comply with the requirement of this clause on and after the six months of commencement of the Food Safety and Standards (packaging and labeling) Amendment Regulation, 2013.]

(b) Labelling of Pre-packaged Foods

In addition to the General Labelling requirements specified above every package of food shall carry the following information on the label, namely,

- (i) The Name of Food: The name of the food shall include trade name or description of food contained in the package.
- (ii) List of Ingredients
- (iii) Nutritional information
- (iv) Declaration regarding Veg or Non veg
- (v) Declaration regarding Food Additives
- (vi) Name and complete address of the manufacturer
- (vii) Net quantity
- (viii) Lot/Code/Batch identification
- (ix) Date of manufacture or packing.
- (x) Best Before and Use By Date
- (xi) Country of origin for imported food:
- (xii) Instructions for use

(c) Manner of declaration

- (I) Any information or pictorial device written, printed, or graphic matter may be displayed in the label provided that it is not in conflict with the requirements of the Regulations.
- (ii) Every declaration which is required to be made on package under the regulations shall be:
 - (aa) Legible and prominent, definite, plain and unambiguous
 - (ab) Conspicuous as to size number and colour,
 - (ac) as far as practicable, in such style or type of lettering as to be boldly, clearly and conspicuously present in distinct contrast to the other type, lettering or graphic material used on the package, and shall be printed or inscribed on the package in a colour that contrasts conspicuously with the background of the label.

Provided that -

- (i) Where any label information is blown, formed or moulded on a glass or plastic surface or where such information is embossed or perforated on a package, that information shall not be required to be presented in contrasting colours:
- (ii) Where any declaration on a package is printed either in the form of a handwriting or hand script, such declaration shall be clear, unambiguous and legible.
- (iii) No declaration shall be made so as to require it to be read through any liquid commodity contained in the package.

- (iv) Where a package is provided with an outside container or wrapper, such container or wrapper shall also contain all the declarations which are required to appear on the package except where such container or wrapper itself is transparent and the declarations on the package are easily readable through such outside container or wrapper.
- (v) Labels not to contain false or misleading statements: A label shall not contain any statement, claim, design, device, fancy name or abbreviation which is false or misleading in any particular concerning the food contained in the package, or concerning the quantity or the nutritive value or in relation to the place of origin of the said food:

Provided that this regulation shall not apply in respect of established trade or fancy names of confectionery, biscuits and sweets, such as, barley, sugar, bull's eye, cream cracker or in respect of aerated waters, such as, Ginger Beer or Gold-Spot or any other name in existence in international trade practice.

(d) Principal display panel:

- (a) The information required under these Regulations shall be given on the principal display panel of the package or container and such information may be given in the following manner.
 - (i) All information should be grouped together and given at one place. OR
 - (ii) The pre-printed information be grouped together and given in one place and
- (b) Online information or those not pre-printed be grouped together in another place.
- (c) Area of the principal display panel and the height of numeral in the declaration shall be as prescribed in the Regulations.
- (e) Specific restrictions on Product labels
 - (i) Labels not to contain reference to Act or rules or regulations contradictory to required particulars.
 - (ii) Labels not to use words implying recommendations by medical profession
 - (iii) Unauthorized use of words showing imitation prohibited
 - (iv) Any fruit syrup, fruit juice, fruit squash, fruit beverages, cordial, crush or any other fruit products standardised under Food Safety and Standards (Food Products standards and Food Additives) Regulations, 2011 which does not contain the prescribed amount of fruit juice or fruit pulp or fruit content shall not be described as a fruit syrup, fruit juice, fruit squash, fruit beverages, cordial, crush or any other fruit product as the case may be.
 - (v) Any food product which does not contain the specified amount of fruit and is likely to deceive or mislead or give a false impression to the consumer that the product contains fruit, whether by use of words or pictorial representation, shall be clearly and conspicuously marked on the label as

"ADDED" '(NAME OF THE FRUIT) FLAVOURED'.

(vi) Any food product which contains only fruit flavours, whether natural flavours and natural flavouring substances or nature identical flavouring substances, artificial flavouring substances as single or in combination thereof, shall not be described as a fruit product and the word "ADDED"

- (vii) Carbonated water containing no fruit juice or fruit pulp shall not have a label which may lead the consumer into believing that it is a fruit product.
- (viii) Any fruit and vegetable product alleged to be fortified with vitamin C shall contain not less than 40 mg. of ascorbic acid per 100 gm. of the product.
- (ix) Imitations not to be marked "pure"
- (x) Labelling prohibitions for Drinking Water (Both Packaged and Mineral Water)
 - (aa) No claims concerning medicinal (preventative, alleviative or curative) effects shall be made in respect of the properties of the product covered by the standard Claims of other beneficial effects related to the health of the consumer shall not be made.
 - (ab) The name of the locality, hamlet or specified place may not form part of the trade name unless it refers to a packaged water collected at the place designated by that trade name.
 - (ac) The use of any statement or of any pictorial device which may create confusion in the mind of the public or in any way mislead the public about the nature, origin, composition, and properties of such waters put on sale is prohibited.

(f) Restriction on advertisement

There shall be no advertisement of any food which is misleading or contravening the provisions of Food Safety and Standards Act, 2006 (34 of 2006) or the rules/regulations made thereunder.

(g) Exemptions from labelling requirements-

- (i) Where the surface area of the package is not more than 100 square centimeters, the label of such package shall be exempted from the requirements of list of ingredients, Lot Number or Batch Number or Code Number, nutritional information and instructions for use, but these information shall be given on the wholesale packages or multi piece packages, as the case may be.
- (ii) the 'date of manufacture' or 'best before date' or 'expiry date' may not be required to be mentioned on the package having surface area of less than 30 square centimeters but these information shall be given on the wholesale packages or multipiece packages, as the case may be;
- (iii) in case of liquid products marketed in bottles, if such bottle is intended to be reused for refilling, the requirement of list of ingredients shall be exempted, but the nutritional information specified in regulation 2.2.2 (4) these regulations shall be given on the label.
 - Provided that in case of such glass bottles manufactured after March 19, 2009, the list of ingredients and nutritional information shall be given on the bottle.
- (iv) in case of food with shelf-life of not more than seven days, the 'date of manufacture' may not be required to be mentioned on the label of packaged food articles, but the 'use by date' shall be mentioned on the label by the manufacturer or packer.
- (v) In case of whole sale packages the particulars regarding list of ingredients, nutritional information, Date of manufacture/ packing, best before, expiry date labelling of irradiated food and, vegetarian logo/non vegetarian logo, may not be specified.

(h) Restrictions of Advertisement and Prohibition as to Unfair Trade Practices (Section 24 of FSS Act)

- (i) The advertisement of any food made should not be misleading or deceiving or contravening the provisions of this Act, the rules and regulations made there under.
- (ii) No person shall engage himself in any unfair trade practice for purpose of promoting the sale, supply, use and consumption of articles of food or adopt any unfair or deceptive practice including the practice of making any statement, whether orally or in writing or by visible representation which -
 - (aa) falsely represents that the foods are of a particular standard, quality, quantity or gradecomposition;
 - (ab) makes a false or misleading representation concerning the need for, or the usefulness;
 - (ac) gives to the public any guarantee of the efficacy that is not based on an adequate or scientific justification thereof:
 - Provided that where a defence is raised to the effect that such guarantee is based on adequate or scientific justification, the burden of proof of such defence shall lie on the person raising such defence.