Food Safety and Standards Authority of India

[FOOD SAFETY AND STANDARDS (FOOD PRODUCT STANDARDS AND FOOD ADDITIVES) REGULATION, 2011 AND FAQ]

INTRODUCTION:

The Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011 came into force on 5th August, 2011 and deals with the implementation of various Standards of Food contained therein. The salient features of the regulation are that these standards are vertical standards and they provide the detailed standards of various food products, and prescribes the limits of various food additives used across different food groups; and lays down microbiological requirement for different foods.

The regulation is divided into three chapters. Chapter 1 deals with the implementation period and definitions of various food product and their processing techniques. Chapter 2 lays down vertical standards and provides information on detailed standards of various food products including proprietary food and irradiation of food. Chapter 3 defines various substances (additives) that can be added to food and prescribes standard limits across different food groups.

Features of the Regulation:

Chapter 1.

The first part of the chapter prescribes the date on which these regulations shall come into force. The first proviso for the Regulation 1.1.2 gives the exemption to some standards and their limits which were followed in the earlier Acts/ Orders as mentioned in the second schedule of the Food safety and Standards Act 2006. While integrating previous Acts/ Orders, a stand was taken that standards outlined under PFA shall remain applicable. However, there were certain standards for caramel, natural colour etc which are at variance with the existing Regulation. In

order to consider these standards and additives an exemption was given to them, till such time standards are finalized and notified by FSSAI. The second part of the chapter prescribes the definitions for various food products and different processing techniques which can be referred in the regulation.

Chapter 2:

Defines various categories of food products and standards of individual food items. These are vertical standards and here the food products are arranged/ grouped under the major categories as per the Codex system and the standards of individual items of food products are listed out. The major categories of food products under this chapter are as follows:

Regulation 2.1 Dairy Products and Analogues

Regulation 2.2 Fats, oils and fat Emulsion

Regulation 2.3 Fruit and Vegetable Products

Regulation 2.4 Cereal and Cereal Products

Regulation 2.5 Meat and Meat products

Regulation 2.6 Fish and Fish Products

Regulation 2.7 Sweets and Confectionary

Regulation 2.8 Sweetening Agents including Honey

Regulation 2.9 Salt, Spices, Condiments and related products

Regulation 2.10 Beverages, (other than dairy and fruits and Vegetables based)

Regulation 2.11 Other Food Product and Ingredients

Regulation 2.12 Proprietary Food

Regulation 2.13 Irradiation of Food.

As per the standards specified therein, the Food Business Operator should comply with the standards for their food products for which they have been granted the license/ registration. These food products should comply with the specifications mentioned in Appendix A (which contains the limits of various additives to be used in individual food products) and Appendix B (which prescribes the limits for various microbiological standards) where in table 2 of Appendix B is newly introduced microbiological standard for milk products.

Regulation 2.1 Dairy Products And Analogues:

Under this regulation, the detailed compositional and chemical standards of Milk, Cream, Malai, Dahir/ curd, Chehha / Paneer, Cheese, dairy based desserts/ Confections, Evaporated/ condensed Milk and Milk Products,

Foods for infant nutrition, Butter, ghee and milk fats, chakka, shrikhand, fermented milk products, whey products and edible casein products are covered.

Regulation 2.1.1 Milk; deals with the standards for different classes and designations of milk from different regions of the country along with their milk fat contents and minimum percent of milk solid not fat is covered. The regulation also prescribes the various designated milk and their heat treatment for eg. In case of Pasteurized Milk pasteurization is the heat treatment similarly for flavoured milk Pasteurization or sterilization is the heat treatment.

Regulation 2.1.2 Cream: Classifies cream into three categories i.e. Low fat cream, medium fat cream and high fat cream along with the compositional and chemical standard for cream powder.

Regulation 2.1.3 Malai; Regulation 2.1.4: Dahi or Curd; and Regulation 2.1.5: Chhena or Paneer cover the compositional and chemical standards of the said products.

Regulation 2.1.6 Cheese: Describes the brief composition of various types of cheese and their chemical standards.

The regulation also prescribes that cheese products must comply to the food additives permitted as per Appendix A and microbiological requirement prescribed in Appendix B also it should be in compliance to label declaration as provided in regulation of Food Safety and Standards (Packaging and Labelling) Regulation, 2011.

Following types of cheese are covered under this regulation: Processed cheese, Processed cheese spread, Cheddar Cheese, Danbo Cheese, Edam Cheese, Gouda Cheese, Havarti Cheese, Tilsiter, Cottage cheese and Creamed cottage cheese, Cream cheese, Coulommiers Cheese,

Camembert cheese, Brie cheese, Saint Patulin, Samsoe, Emmentaler, provolone, Extra hard grating cheese etc.

Regulation 2.1.7 Dairy based desserts/ confections: prescribes the compositional and chemical standards for ice cream, kulfi, Chocolate ice cream or softy, dried ice cream mix/ dried frozen dessert/ confection, frozen dessert/ frozen dessert/ frozen confection.

Regulation 2.1.8 Evaporated/ Condensed milk and Milk Products: which covers standards for Evaporated milk, Milk powder and Sweetened condensed milk.

Regulation 2.1.9: Foods for infant's nutrition: lays down the description of infant formula and also gives the compositional, chemical and microbiological standards for various products for infants which includes standards for products like Infant milk food, Infant Formula, Whey, Processed cereal based complementary food, Follow up Formula-Complementary Food. The regulation also prescribes the nutritional standards across different infant food products also covers standards for premature/ low birth weight infant milk substitutes, Lactose free milk substitutes and hypo allergic infant milk substitute.

Similarly standards have also been laid in **Regulation 2.1.10 Butter, ghee and milk fats; Regulation 2.1.11 Chakka and Shrikhand; Regulation 2.1.12: Fermented Milk products like yoghurt; Regulation 2.1.13: whey products; and Regulation 2.1.14: Edible casein Products.**

Regulation 2.2: Fats, oils and fat emulsions:

Under this Regulation Fats and Oils for human consumption have been divided into six major groups as follows

Regulation 2.2.1 oils: Under this regulation, the composition of different types of oil and essentially their chemical standards have been defined.

The various oils covered in these regulations are Coconut oil, Cotton seed oil, Groundnut oil, linseed oil, Mahua oil, Rape seed oil, olive oil, poppy seed oil, Safflower seed oil, Taramira oil, Til oil, Niger seed oil, soybean oil, Blended edible vegetable oil etc.

Regulation 2.2.2 Interesterified vegetable fat: prescribes the definition of interesterified vegetable fat along with the chemical standards.

Regulation 2.2.3 Partially hydrogenated soybean oil: gives the description of Partially hydrogenated and winterised soyabean oil and partially hydrogenated soyabean oil along with their chemical standards.

Regulation 2.2.4 Edible fats: defines different types of fats, their chemical standard and composition like beef fat, mutton fat, goat fat, lard, Cocoa butter, Refined Salseed fat and Kokum fat etc. In addition to these they shall also comply to food additives requirements only permitted in Appendix A annexed in this regulation.

Regulation 2.2.5 Margarine and fat spread, Regulation 2.2.6 Hydrogenated Vegetable Oils: covers the product description as well as chemical standards therein.

Regulation 2.3 Fruits and Vegetable products

These regulations contains regulations for thermally processed fruits and vegetables like canned/ bottled/ flexible packaged/ aseptically packed fruits and vegetables it also includes thermally processed vegetables, thermally processed curried vegetables/ready to eat vegetables, thermally processed vegetable soups, fruit juices, vegetable juices, tomato sauce, synthetic syrups, murabba, culinary pastes, fruit jelly, dehydrated fruits and vegetables, fruit based beverages, vinegar, nuts and raisins etc.

The regulation talks about the product description, their compositional characteristics (fruit contents), type of packaging, chemical standards like

minimum Total Soluble Solids, Acidity percentage moisture etc. It also permits use of food additives as laid down in Appendix A of the regulation and prescribes microbiological standards as mentioned in Appendix B of this regulation.

Regulation 2.4 Cereal and Cereal Products: This Regulation deals with two major categories of cereals: first, raw cereals: (food grains); and second, products derived after processing of cereals. Under raw cereals following are the type of cereals covered atta, maida, semolina, besan, pearl barley, food grains (which includes all the pulses). Processed cereals covers the following type of products like cornflour, corn flakes, custard powder, macaroni products, malted and malt based foods, rolled oats, solvent extracted flours, starchy foods, bakery products etc.

The regulations describes the Physical standards like moisture content, foreign matter, damaged grains, weevilled grains and chemical standards like uric acid across raw cereals and Chemical standards like moisture, total ash, ash insoluble, crude fibre etc in processed cereal products. The microbiological limits of the processed cereal products have also been laid in the said standards.

Regulation 2.5 Meat and Meat products: This regulation gives definition for animal, carcass, meat, meat food products, and slaughter house. It also includes the product description, packaging standard, types of additives used and microbiological standards across different meat products like Canned corned beef, Canned Luncheon Meat, Canned Cooked Ham, Canned Chopped Meat, Canned Chicken, Canned Mutton and Goat Meat, frozen Mutton, Chicken and Goat and Buffalo Meat.

Regulation 2.6 Fish and Fish Products: This regulation gives the description of the fish which includes the species, genera etc for (1) frozen shrimps or prawns, (2) frozen Lobsters, (3)Frozen Squids, (4)Frozen finfish,

(5) Frozen fish fillets or minced fish flesh or mixtures thereof where in product under article 1,2,3,4 and 5 shall be frozen in an appropriate equipment quickly to minus (-) 18 deg C or cooler at the thermal centre after thermal stabilization (6) Dried shark fins, (7) salted fish/ dried salted fish describe the product in dried and salted condition (8) Canned finfish, (9) canned shrimp, (10) canned sardines or sardine type products, (11) canned salmon, (12) canned crab, (13) canned tuna and bonito prescribed the standards for canned fish products.

Regulation 2.7 Sweets and Confectionery: Various confectionaries like Sugar boiled confectionery, Lozenges, Chewing gum and Bubblegum, Chocolate, Ice lollies or edible ices are described and also the standards for individual items are prescribed. In case of chocolate, the different types of chocolates like milk chocolates, milk covering chocolates plain chocolate, blended chocolate, white chocolate, filled chocolate and composite chocolates have been defined and the standards for each one has been given in the table.

Regulation 2.8 Sweetening agents including honey: The standards and composition both quantitative and qualitative characters have been prescribed. Composition of various type of sugar like plantation white sugar, khandsari sugar, bura sugar, cube sugar, icing sugar, and misri. It also describes the standard for honey and jiggery including their composition. This regulation further describes the standards for artificial sweeteners like saccharin sodium, aspartyl phenyl alanine methyl ester, acesulfame potassium, and sucralose.

Regulation 2.9 Salt, Spices, Condiments and related products: This regulation gives the standards for all spices and condiments. The qualitative standards (Physical standards) are prescribed like extraneous matter, malformed, immature, moisture, total ash, insect damaged matter

etc. These products also conform to standards prescribed in Appendix A and B of this Regulation, Regulation 2.9.30 prescribes the standards for edible common salt, iodized salt and the standards for fortification of salt.

Regulation 2.10 Beverages, (other than dairy and fruit and vegetables based). This regulation provides the scope, description and composition of various type of tea, coffee including chicory beverag. Regulation 2.10.5 prescribes the standards for toddy classified as alcoholic beverage. However, the regulation does not prescribe any standards for alcoholic beverages. Regulation 2.10.6 of this category provides standards for non alcoholic carbonated beverages which include standards for packaged drinking water including carbonated water impregnated with carbon- di-oxide under pressure. This regulation also describes and classifies the different types of mineral water and its standards. However BIS also prescribes mandatory standards for this product.

Regulation 2.11 Other Products and Ingredients: It lays down standards for food products and ingredients which have not been covered so far in the Regulation. These are baking powder, catechu, silver leaf, gelatine, pan masala, low and high fat carob powder and carob powder. In case of pan masala, it should also comply with Food Safety and Standards (Packaging and Labeling) Regulation, 2011.

Regulation 2.12 Proprietary Foods: Proprietary food includes all those food products which have no standards. However, they shall comply with the provisions specified in the regulation and Appendix A and B.

Regulation 2.13 Irradiation of Food: The regulation prescribes the minimum, maximum and average dose of irradiation in different foods along with the requirements for the process of irradiation. As per Regulation 2.13.2, the facility for irradiation of food must be approved and licensed under Atomic Energy (Control of Irradiation of Food) Rules, 1991.

Regulation 2.13.3 prescribes that irradiation shall conform to the dose limits and the radiation source strictly as mentioned in Atomic Energy (Control of Irradiation of Food) Rules, 1991.

Regulation 2.13.4 Record of irradiation of food defines that any treatment of food by irradiation shall be recorded by an officer authorized by the competent authority as specified under the Atomic Energy (Control of Irradiation of Food) Rules, 1991. Further this regulation also covers Standards of Irradiated food which should comply with Food Safety and Standards Regulation, Storage sale of irradiated food and Restriction on sale of irradiated Food.

Chapter 3:

Prescribes the standards of food additives and the quantity of additives added to food at their maximum levels. It also mentions the usage of various food additives across different food products. The various types of Food Additives covered under this chapter are as follows;

Regulation 3.1.2 Coloring matter describes the unauthorized prohibited coloring matter and authorized colouring matters like natural colours, synthetic food colours, lake colours, permitted synthetic food colours and their maximum limits in food .

Regulation 3.1.3 Artificial Sweeteners prescribes the use and sale of artificial sweeteners in food; it gives the maximum limits of artificial sweeteners across different articles of foods, their combinations and labeling requirements. The various type of sweeteners are Sacchrin Sodium, Aspartame, Acesulfame potassium, Sucralose and Neotame. The regulation also prescribes standards for use of polysols and polydextrose

in foods. The regulation also refers to follow the labeling requirement while use in food as per Food Safety and Standards (Packaging and Labeling) Regulation, 2011.

Regulation 3.1.4 Preservatives: This regulation classifies the preservatives into Class I and II and describes the use of preservatives in various foods and also it gives the use of Class II preservatives restricted in food. The use of Class I preservative should also comply with Appendix A annexed with this regulation.

Regulation 3.1.5 Anti-oxidants: the regulation describes the functions of antioxidants and their restriction on use as antioxidants in various foods including oils and fats.

Regulation 3.1.6 Emulsifying and Stabilizing agents: it lists out the permitted emulsifying and stabilizing agents in food products and also provides their restriction in food.

Regulation 3.1.7 Anti caking Agents: Provides the limit of ant caking agent in food products specifically mentioned.

Regulation 3.1.8 Antifoaming agents in edible oils and fats, Regulation 3.1.9 use of release agents in confectionary: prescribe the limit of antifoaming agent in oils and use of release agents in confectionaries.

Regulation 3.1.10 Flavoring agents and related substances: It classifies and defines the flavouring agents into three categories and also prescribes the use of other food additives in the flavoring agents. It also gives the information regarding flavors which are prohibited in food.

Regulation 3.1.11 Flavor Enhancers: It describes the use of mono sodium glutamate as per provisions contained in Appendix A of this regulation along with proper labeling declaration as per Food Safety and Standards

(Packaging and Labeling) Regulation, 2011.

Regulation 3.1.12 Sequestering and Buffering Agents: the regulation prescribes the use of sequestering and buffering agents in food products as per the table mentioned therein.

Regulation 3.1.13 use of Glycerol Esters of wood resins, Regulation 3.1.14 use of sucrose acetate isobutyrate, Regulation 3.1.15 use of lactulose syrup in foods, Regulation 3.1.16 use of dimethyl di carbonate: The regulation prescribes their maximum level usage in food products.

Regulation 3.1.17other substances to be used in specified limits, gives their permissible limit in food.

Regulation 3.2 Standards of Additives deals with the standards of permitted food colors with their characteristics and quality.

Appendix

Appendix A. Contains fifteen tables of various Food Additives used in different food products. The food products shall comply with the listed additives as specified in Chapter 3 and in Appendix A.

Following are the tables enlisted in Appendix A:

Table 1. List of Food Additives for use in bread and biscuits.

Table 2. List of Food Additives for use in Foods.

Table 3. Food Additives in Foods not specified.

Table 4. List of Food Additives for use in edible oils and fats.

Table 5. List of Food Additives for use in Fish and Fish Products.

Table 6. List of Food Additives for use in Thermally Processed Fruits.

Table 7. List of Food Additives in thermally processed vegetables.

Table 8. List of Food Additives for use in food products.

Table 9. List of Food Additives for use in food products.

Table 10. List of Food Additives for use in Food products.

Table 11. List of Food Additives for use in food products.

Table 12 List of Food Additives for use in Sugars and Salt.

Table 13 List of Food Additives for use in Cocoa powder, Chocolate, Sugar boiled confectionery, Chewing gum/ Bubble gum.

Table 14 List of Food Additives for use in Milk products.

Table 15 (Use of Food Additives in individual variety cheeses).

Appendix B Prescribes the microbiological requirement/ parameter for various food products as mentioned below;

Table 1: Microbiological requirements for sea foods

Table 2: Microbiological parameter for milk products

Table 3: Microbiological parameters for spices

Table 4: Microbiological requirements of food products given below.

International Numbering System (INS):

These lists are meant only for identification of Food additives and their synonyms as published in Codex on 23/11/05. The listed additives in these tables cannot be taken as approved additives as per this Regulation. However, this list also enlists Food Additives which are permitted in the Regulations.

Under International Numbering Systems there are two tables i.e. A. List sorted by INS number where the additives are arranged/ listed/ sorted based on the INS numbering and B. List sorted in alphabetical order.

Other Requirements:

In addition to the standards prescribed in this regulation the Food Business Operator shall also refer the following regulation wherever applicable.

Food Safety and Standards (Packaging and Labeling) Regulation, 2011.

Food Safety and Standards (Contaminants, toxins and Residues) Regulation, 2011.

Food Safety and Standards (Prohibition and Restriction on Sales) Regulation, 2011.

Frequently Asked Questions (FAQ)

Q1. What type of food standards are covered in this Regulation?

Ans. This regulation provides detailed standards of various food products, It prescribes the limits of various food additives used across different food groups; and lays down microbiological requirement for different foods. It essentially consists of physical, chemical and microbiological standards of different foods.

Q2. Are these food standards Mandatory or Voluntary?

Ans. These standards are mandatory in nature

Q3. What is the procedure for Fixing Standards for food in FSSAI?

Ans. At present the standards in Food Safety and Standards Regulation were adopted from Prevention of Food Adulteration act, 1954 which were notified in the Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011 on August 1, 2011.

The procedure for fixing standards are as follows

(i) The new standards under Food Safety and Standards Act, 2006 are made from time to time and is ongoing process.

(i) The standards are placed before the Scientific Panels and Scientific Committee for their opinions / recommendation.

(ii) The standards approved by the Food Authority, are sent to the Ministry for previous approval of Central Government. Subsequently, draft standards in the form of regulations are notified for seeking comments of all stakeholders.

(iii) The draft regulation is also notified to WTO Member Countries for their comments.

(iv) A time period of normally 60 days is given for information of the persons likely to be affected thereby and sending the comments to the FSSAI.

(v) The comments received on the draft notification are examined by the FSSAI.

With approval of the Central Government, the final regulation is notified and published in the Gazette of India giving date of effects of its implementation and simultaneously it is notified to the WTO Member Countries for information & reference.

Q4. What are proprietary foods?

Ans. The food whose standards are not prescribed in this regulation falls under the category of Proprietary foods.

Q5. Which Food product Standards are introduced in this regulation for the first time?

Ans. Following were the food products which were introduced in this regulation

2.1.6 (1)(2)(3)- Cheese, Processed cheese, Processed cheese spread.

2.1.7 (1)Dairy based desserts/ confections- Ice cream, kulfi, chocolate ice cream or softy ice cream.

2.1.7(2) Dried Ice Cream Mix/ Dried Frozen Dessert/ Confection.

2.1.7(3) Frozen Dessert / Frozen Confection.

2.1.7(4) Milk Ice or Milk Lolly.

2.1.12(1) Yoghurt and entries relating in table 14 of appendix A and table 2 of Appendix B and in regulation 2.1.8(1) Evaporated Milk, (3) Milk Powder and 2.1.11(1) Chakka, (2) Shrikhand only relating entries in table which shall come into force after six months.

Q6. What is INS system? Are all the food additives mentioned in the INS system approved by FSSAI?

Ans. International numbering System is a numbering system of Food additives meant only for identification of Food additives and their synonyms as published in Codex on 23/11/05. The listed additives cannot be taken as approved additives as per the FSSAI regulation. However, it does enlist Food Additives which are permitted in the FSSAI Regulations.

Q7. Is the INS numbering for identification of food additives mentioned in this regulation same as codex numbering?

Ans. Yes, the INS numbering as mentioned in FSS regulation is same as codex numbering for identification of food additives.

Q8. Are there any guidelines specified for microbiological contamination in food in India?

Ans: There are no microbiological guidelines for microbiological contamination of food in India, however the microbiological standards are prescribed in FSSAI regulations for foods.

Q9. Which food products need to have BIS certification?

Ans. Food products like Infant foods and packed drinking water have to comply with BIS standards mandatory.

Q10.Is there a provision to address differences/variances in standards prescribed in previous acts and orders which were repealed and the FSSAI standards?

Ans. While integrating all the previous Acts/ Orders to the Food Safety and Standards Regulation, a stand was taken that standards outlined under PFA shall remain applicable. However, there were certain standards for caramel, natural color etc which are at variance in the existing FSS Regulation. In order to consider these standards and additives an exemption was given to them, till such time standards are finalized and notified by FSSAI.

Eg. Caramel was G.M.P in FPO whereas in PFA its limit prescribed is 100 ppm, similarly in case of natural colors and synthetic colors which were allowed in FPO, 1955 are not permitted by PFA in all such cases initially a six months was given to comply with the FSS regulation from their date of notification and the time have been extended further till the standards for the same has been finalized.

Q11. Whether Appendix A and B mentioned in this Regulation are also applicable to food product standards?

Ans. Yes these are all horizontal standards and applicable for all food products.

Q12. Which food products require product approval?

Ans. Those products which are not having standards as per extant Food product Standards and Food Additives Regulation, 2011.