

Module 10

Regulations - FSSAI

Module coverage



Topic	Sub-topics covered	Learning objectives
10) Regulations – FSSAI	• Overview of FSSAI. • Food Safety and Standards Act, 2006. • Food Safety and Standards Regulations, 2011. • Labelling regulations. • Food fortification regulations. • Understanding nutrition and health claims.	✓ Understand the role of FSSAI in ensuring food safety and quality. Learn about the key regulations governing food production, processing, and labelling. Develop an understanding of the legal framework for food businesses. Identify the implications of FSSAI regulations on food businesses and consumers.

Food safety and standards regulations



The act provides the overarching legal framework, while the regulations provides the specific rules and procedures.

FSSAI

The Food Safety and Standards Authority of India (FSSAI) has been established under the Food Safety and Standards, 2006, which consolidates various acts & orders that have hitherto handled food-related issues in various Ministries and Departments. FSSAI has been created for laying down science-based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure the availability of safe and wholesome food for human consumption. ^[113]

Food Safety and Standard Act, 2006

The act aims to establish a single reference point for all matters relating to food safety and standards, by moving from multi-level, multi-departmental control to a single line of command. ^[113]

Food Safety and Standards Regulations, 2011

The regulations provide the detailed rules and guidelines for implementing the Food Safety and Standards Act, 2006. It covers various aspects of food safety, including licensing and registration of food businesses, food product standards and food additives, packaging and labelling, contaminants, toxins, and residues, and laboratory and sample analysis.

Key FSSAI regulations for nutrition



- Regulations on food fortification (vitamins and minerals).
- Standards for special dietary foods (infant food, medical foods).
- Labelling requirements for nutritional information.
- Regulations on health supplements and nutraceuticals.



Packaging and Labelling Regulations Overview



Packaging and Labelling Regulations: Mandatory nutritional labelling on food products

- Key Requirements: Energy, protein, fat, carbohydrates, vitamins, and minerals.
- Consumer-friendly labelling for informed choices.
- Advertising and Claims Regulations.
- Monitoring health and nutrition claims: Ensures claims are truthful and evidence-based.
- Prevents misleading advertisements.

FSSAI Initiatives:

- **Trans Fat Reduction:** 3% target by 2021, 2% by 2022.
- **Front-of-Pack Labelling:** Clear nutrition symbols for easier consumer understanding.

Challenges and Opportunities

- Challenges: Compliance among small businesses and awareness among consumers and stakeholders.
- Opportunities: Better health outcomes.
- Enhanced consumer trust in food products.

Other Food Safety and Standards Regulations



1. Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011.
2. Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011.
3. Food Safety and Standards (Prohibition and Restriction of Sales) Regulation, 2011.
4. Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011.
5. Food Safety and Standards (Laboratory and Sampling Analysis) Regulation, 2011.
6. Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016.
7. Food Safety and Standards (Food Recall Procedure) Regulation, 2017.
8. Food Safety and Standards (Import) Regulation, 2017.
9. Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017.
10. Food Safety and Standards (Organic Food) Regulation, 2017.
11. Food Safety and Standards (Alcoholic Beverages) Regulation, 2018.
12. Food Safety and Standards (Fortification of Food) Regulation, 2018.
13. Food Safety and Standards (Food Safety Auditing) Regulation, 2018.

Food Safety and Standards Regulations



13. Food Safety and Standards (Food Safety Auditing) Regulation, 2018.
14. Food Safety and Standards (Recognition and Notification of Laboratories) Regulation, 2018.
15. Food Safety and Standards (Advertising and Claims) Regulation, 2018.
16. Food Safety and Standards (Packaging) Regulation, 2018.
17. Food Safety and Standards (Recovery and Distribution of Surplus food) Regulation, 2019.
18. Food Safety and Standards (Safe food and balanced diets for children in school) Regulations, 2020.
19. Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020.
20. Food Safety and Standards (Labelling and Display) Regulations, 2020.
21. Food Safety and Standards (Ayurveda Asahara) Regulations, 2022.
22. Food Safety and Standards (Vegan Foods) Regulations, 2022.

Suggested read: Refer to the fssai.gov.in website for the complete list of regulations

Food Safety and Standards (Safe food and balanced diets for children in school) Regulations, 2020



1. Responsibilities of the School Authority to ensure safe food and balanced diets on school premises.
2. Promotion of safe food and a balanced diet in and around the school campus.
3. Food marketing, advertising, and selling to children in school.
4. Monitoring and surveillance.

Key takeaways FSSAI Regulations for School Meals:

- Safety First: All food handlers must be registered/licensed.
- Strict hygiene practices are mandatory.
- Safe and balanced meals are a must.
- Healthy Choices: Foods high in fat, sugar, and salt are restricted.
- Focus on local, seasonal, and nutritious foods.
- Promote balanced diets through education.
- School Responsibility: Ensure compliance with FSSAI regulations.
- Monitor food quality and safety. Create a "Health & Wellness" program.
- No Junk Food: Ban on junk food sales and advertising in schools.
- Restrictions on unhealthy food marketing near schools.
- Collaborations: Involve nutritionists and parents in menu planning. Work with FSSAI and local authorities for implementation.

Food for special medical purposes means food intended for:

- Dietary use of specially processed or formulated products: The dietary management of persons is used only under medical advice.
- The exclusive or partial feeding of persons with a limited, impaired or disturbed capacity to take, digest, absorb, metabolize or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites.
- Other medically determined nutrient requirements, whose dietary management cannot be achieved solely.
- By modification of the normal diet, by food for specific nutritional use, or a combination of them.
- Food with added prebiotic ingredients means food that contains added prebiotic ingredients, which are nonviable food components that confer health benefits to the consumer by modulation of gut microbiota.
- Food with added probiotic ingredients means food with live micro-organisms beneficial to human health.
- Nutrient ingredients mean vitamins, minerals, and amino acids as specified in Schedule I and Schedule II.
- Pre-mixes means a combination of two or more ingredients specified in the Schedules in a specific proportion.
- with or without additives, packed and meant for use in formulating a product falling under any category of these regulations or the categories specified in the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.

Title: Food Safety and Standards (Fortification of Foods) Regulations, 2018

General principles

(1) Micronutrients may be appropriately added to foods to contribute to any of the following, as mentioned in Schedule I:

- Preventing or reducing the risk of, or correcting, a demonstrated deficiency of one or more micronutrients in the population or specific population group.
- Reducing the risk of, or correcting, inadequate nutritional status of one or more micronutrients in the population or a specific population group
- Meeting requirements or recommended intake of one or more micronutrients.
- Maintaining or improving health and the nutritional quality of foods.

Title: Food Safety and Standards (Fortification of Foods) Regulations, 2018

General principles

- (2) When fortification of a food is made mandatory, it shall be based on the severity and extent of public health need as demonstrated by generally accepted scientific evidence.
- (3) The Food Authority may specify mandatory fortification of any staple food at the direction of the Government of India.
- (4) Wherever “Iron (As Fe)” is used as a source of nutrient, heme iron shall not be used in any form in any article of food.
- (5) Fortified processed foods may be prepared from fortified food articles that may be cereals and/or milk.
- (6) The fortified processed food shall provide 15-30% of the Indian adult RDA of micronutrients based on an average calorie intake of 600 kcal from processed foods (approximately 1/3rd of the daily energy requirement for an adult).
- (7) High-fat, sugar, salt (HFSS) Foods shall be excluded from the fortified processed foods category.

Some food products and its fortification standards



Title: Food Safety and Standards (Fortification of Foods) Regulations, 2018.

Fortified Milk

- Species identified milk like (buffalo milk, cow milk, goat milk, sheep milk and camel milk), full cream milk, toned milk, double toned milk, skimmed milk and standardized milk, when fortified, shall be fortified with the following micronutrients at the level given in the table below:

Sr. no	Nutrients/Source	Level of nutrient per l of specified identified milk
1.	Vitamin A - Retinyl acetate or Retinyl palmitate	270 – 450
2.	Vitamin D - *Cholecalciferol or*Ergocalciferol (*Only from plant source)	5-7.5

Some food products and its fortification standards



Fortified Oil

Sr. no	Nutrients	Level of nutrient	Source of nutrient
1.	Vitamin A	6ug RE – 9.9 µg RE per gm of oil	Retinyl acetate or Retinyl palmitate
2.	Vitamin D	0.11 ug - 0.16 µg per gm of oil	Vitamin D - *Cholecalciferol or*Ergocalciferol (*Only from plant source).

Fortified Salt

Sr. no	Nutrients	Dosage (mg/kg)
1.	Iodine – Potassium iodate	15.30 ppm

Fortified Fruit Juices

Sr. no	Nutrients	Level of nutrients per 100ml
1.	Vitamin C (mg) Ascorbic acid	6-12

Food Safety and Standards (Advertising and Claims) Regulations, 2018

- Health claim means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health.

General Principles:

- Claims must be honest and easy to understand: It should not be misleading and must help consumers clearly understand the information.
- Claims must not encourage overeating: It should not suggest or promote excessive consumption of any food.
- Claims must not imply that a normal, balanced diet is inadequate: It must not suggest that only the claimed food can meet the body's nutritional needs.
- Preparation method must be mentioned if it affects the benefit: If the health or nutrition claim depends on how the food is prepared, that method must be included on the label.

To be continued...

Understanding claims



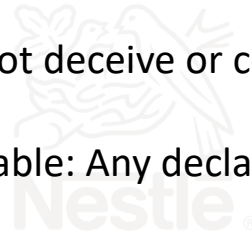
- Serving size must be mentioned: The number of servings per day needed to get the claimed benefit must be clearly stated.
- Claims must be scientifically proven: Any nutrition or health-related claim must be supported by valid scientific evidence and testing methods.
- Brand names with words like "natural" or "pure" must carry a disclaimer if misleading: If a brand name uses terms like “natural,” “authentic,” or similar words that might mislead consumers about the product’s nature, a disclaimer in at least 3mm font size must state: *"This is only a brand name or trade mark and does not represent its true nature."*
- Disclaimers must be clear and readable: All disclaimers related to claims should be easy to see and read.
- FSSAI logo and license number cannot be used for promotion: Even though it is mandatory to show the FSSAI logo and license number, these should not be used to advertise or promote the food product.
- Advertisements must support healthy living: It should not undermine or ignore the importance of a healthy lifestyle.

To be continued...

Understanding claims



- Ads must not promote food or beverages as meal replacements: Unless specifically allowed by other FSSAI regulations, ads must not suggest that these products can replace regular meals.
- Ads must match the product label: The information in advertisements must be consistent with what is written on the food or drink's label.
- No misleading advertisements: Advertisements must not deceive or confuse consumers.
- All required declarations in ads must be clear and readable: Any declaration that must appear in advertisements should be easy to notice and read.



Health claims - Food Safety and Standards (Advertising and Claims) Regulations, 2018



SCHEDULE – I [See regulation 5 (3) and (4) and regulation 7 (1)(b)] Nutrition Claims

S.L No.	Nutrient/Component	Claim Type	Condition to Claim	Solid/Liquid
1	Calories (Energy)	Low	≤ 40 kcal/100g (solids), ≤ 20 kcal/100ml (liquids)	Both
		Free	≤ 4 kcal/100ml	Liquid
2	Fat	Low	≤ 3 g/100g (solids), ≤ 1.5 g/100ml (liquids)	Both
		Free	≤ 0.5 g/100g or 100ml	Both
3	Cholesterol	Low	≤ 20 mg/100g + ≤ 1.5 g saturated fat	Solid
		Free	≤ 5 mg/100g + ≤ 1.5 g saturated fat	Solid
4	Saturated Fat	Low	≤ 1.5 g/100g or ≤ 0.75 g/100ml	Both
		Free	≤ 0.1 g/100g or 100ml	Both
5	Unsaturated Fat	High	$\geq 70\%$ of total fat from unsaturated fats	~
6	Trans Fat	Free	< 0.2 g/100g or 100ml	Both
7	MUFA	High	$\geq 45\%$ of total fat from MUFA	~
8	PUFA	High	$\geq 45\%$ of total fat from PUFA	~
9	Omega-3	Source	≥ 0.3 g ALA or ≥ 40 mg EPA+DHA per 100g & 100kcal	Solid
		High	≥ 0.6 g ALA or ≥ 80 mg EPA+DHA per 100g & 100kcal	Solid
10	Sugar	Low	≤ 5 g/100g or ≤ 2.5 g/100ml	Both
		Free	≤ 0.5 g/100g or 100ml	Both
11	Protein	Source	$\geq 10\%$ RDA/100g or $\geq 5\%$ RDA/100ml or 100kcal	Both
		High	$\geq 20\%$ RDA/100g or $\geq 10\%$ RDA/100ml or 100kcal	Both
12	Vitamins/Minerals	Source	$\geq 15\%$ RDA/100g or $\geq 7.5\%$ RDA/100ml	Both
		High	$\geq 30\%$ RDA/100g or $\geq 15\%$ RDA/100ml	Both
13	Sodium	Low	≤ 0.12 g/100g or 100ml	Both
		Very Low	≤ 0.04 g/100g or 100ml	Both
		Free	≤ 0.005 g/100g or 100ml	Both
14	Dietary fiber	Source	≥ 3 g/100g or ≥ 1.5 g/100kcal	Solid
		High	≥ 6 g/100g or ≥ 3 g/100kcal	Solid
15	Probiotics	Source	$\geq 10^8$ CFU per serving	Both
16	Glycemic Index	Low GI	GI value < 55	~

FSSAI notification on misleading information



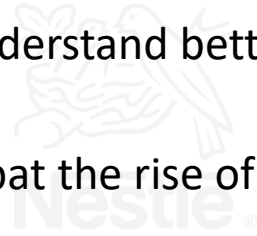
Clarification regarding categorization of 'Health Drinks / Energy Drinks' on ECommerce website -reg.

- The Food Safety and Standards Authority of India (FSSAI) has asked all e-commerce Food Business Operators (FBOs) to ensure appropriate categorization of food products being sold on their websites. FSSAI has noted instances of food products licensed under 'Proprietary Food' with the nearest category – Dairy Based Beverage Mix or Cereal Based Beverage Mix or Malt Based Beverage – being sold on e-commerce websites under the category 'Health Drink', 'Energy Drink' etc.
- FSSAI has clarified that the term 'Health Drink' is not defined or standardized anywhere under the FSS Act 2006 or rules/regulations made thereunder. Therefore, FSSAI has advised all e-commerce FBOs to promptly rectify this misclassification by removing or de-linking such drinks or beverages from the category of 'Health Drinks / Energy Drinks' on their websites and place such products in the appropriate category as provided under the extant law.
- This corrective action aims to enhance clarity and transparency regarding the nature and functional properties of the products, ensuring that consumers can make well-informed choices without encountering misleading information.

Conclusion



- FSSAI's regulations are pivotal for food safety and nutrition.
- Initiatives like fortification and labelling improve public health.
- Collaboration among food businesses, policymakers, and consumers is essential for long-term success.
- FSSAI approves proposal to display nutritional information labelling of total sugar, salt and saturated fat in bold letters and bigger font size in 44th meeting of Food Authority.
- Amendment aims to empower consumers to understand better the nutritional value of the products they are consuming and make healthier decisions.
- It would also contribute towards efforts to combat the rise of Non-Communicable Diseases and promote public health and well-being.



In the future.....



- Personalized nutrition based on established methodologies of nutrigenomics and emerging applications of AI will revolutionize the way food is understood and consumed.
- AI tools can collect large and continuous datasets, which can also be highly personal, analyze and interpret the physiological as well as clinical outcomes, and provide relevant nutritional/dietary suggestions.
- A lot of false and fake information about nutrition that is floating around in social media, with enormous consequences to individual and public health, needs to be removed/ignored, and the onus lies on the qualified experts, such as yourselves, in the future to do this.

