

Unit 3: India

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3.1 The Food Safety and Standards Act 2006

The **Food Safety and Standards Act, 2006** is the foundation statute of Indian food law and the first topic of this unit. Before it, Indian food regulation was a patchwork of separate laws and orders administered by different ministries, of which the Prevention of Food Adulteration Act 1954 was the best known. The 2006 Act consolidated that patchwork into a **single statute and a single authority**, shifted the system's centre of gravity from punishing adulteration after the event to science based standard setting and prevention, and brought manufacture, storage, distribution, sale and import of food under one framework administered through the Ministry of Health and Family Welfare. Its architecture is the standard Indian regulatory pattern. The Act establishes the Food Safety and Standards Authority of India and the state food safety machinery, empowers the making of regulations that carry the detailed standards, creates the licensing and registration system for food businesses, sets the offences and penalties, and provides for food recall and for the adjudication and tribunal machinery. For this subject its decisive feature is its **breadth of the word food**: the Act's framework reaches articles intended for human consumption including health supplements, nutraceuticals and foods for special dietary and medical purposes, which the detailed regulations then take up category by category in section 3.4. A product that is a food under this Act is regulated by FSSAI, and the same article presented as a medicine would fall to the drug authorities: classification at the border, once again, decides the regulator.

3.2 FSSAI: organization and functions

The **Food Safety and Standards Authority of India (FSSAI)** is the statutory authority the 2006 Act created, headquartered in New Delhi, working through its central office, regional and technical structures, and the state food safety commissioners and their licensing and enforcement officers. Its organisation follows the Act: a chairperson and members drawn from government, industry, science, consumer and farming interests, advised by a scientific committee and scientific panels of experts, because the Act intends standards to be set on scientific advice and not by administrative habit. Its **functions** are the syllabus list in substance: to frame regulations and lay down standards and guidelines for articles of food; to lay down the accreditation and certification machinery for food safety management systems and laboratories; to specify the licensing and registration system for food businesses; to collect and analyse data on food consumption, hazards and risks, and to run surveillance and risk communication; to promote food safety awareness and training; and to act as the national reference point for international food safety work, including Codex. The operational division of labour mirrors MRA104T's drug architecture: **standards are central**, set by FSSAI for the whole country, while **licensing and enforcement run in two tiers**, central licensing for the larger and specified categories of business and state licensing and registration below it, executed by state authorities. The regulatory professional deals with FSSAI as standard setter, licensor, and, through its food safety officers and adjudication machinery, enforcer.

India: the three FSSAI licensing tiers



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Figure: The three tier licensing structure of section 3.2: basic registration for the smallest food businesses, the state licence for mid scale businesses, and the central licence for the largest and for specified categories including importers and nutraceutical manufacturers, all under standards set centrally by FSSAI (Unit 3, section 3.2).

3.3 Licensing: registration, state licence and central licence

No food business in India may operate without the licence or registration the Act requires, and nutraceutical manufacture sits at the supervised end of the system. The structure is three tiered by scale and category.

Registration covers the smallest, petty food businesses, issued locally on simple conditions. A **state licence** covers mid scale manufacture, storage and sale within the state system. A **central licence**, issued by FSSAI itself, is required for the largest businesses and for categories the regulations reserve to the centre, which include importers and the manufacture of the specialised product categories of this subject, health supplements and nutraceuticals among them. The licence is not a mere tax receipt: its conditions carry the hygiene and manufacturing requirements of the regulations, its grant follows scrutiny of the premises and the business, it must be renewed, and operating without it, or in breach of its conditions, is an offence under the Act. Beside the business licence stands **product discipline**: a nutraceutical may only be formulated from ingredients the regulations permit, in the forms and within the limits they set, which is the subject of the next section, so that the Indian system controls both the maker (by licence and GMP conditions) and the recipe (by positive lists), the two handed control the comparison with America in Unit 4 will throw into relief.

3.4 Regulations for import, manufacture and sale of nutraceutical products in India

The detailed Indian law of this subject lives in the regulations FSSAI has made under the Act, whose centrepiece for this unit is the dedicated regulations for **health supplements, nutraceuticals, food for special dietary use, food for special medical purpose, prebiotic and probiotic food** (first made in 2016 and revised since, the 2022 regulations being the current consolidated form students should name with its revision history in mind). Their method is the **positive list**: schedules list the permitted nutrients (vitamins, minerals, amino acids and other nutrients), the permitted plants and botanicals, and the permitted molecules, isolates and extracts, with prebiotics and probiotics dealt with in their own schedule. A product may be built only from what the schedules permit, in the dosage forms the regulations allow, and its nutrient levels are disciplined by reference to the RDA framework of section 3.5. **Manufacture** requires the central licence of section 3.3 and compliance with the good manufacturing and hygienic practices the regulations prescribe. **Import** runs through the food import clearance system: the importer must hold the central licence and import authorisation, consignments are cleared through FSSAI's import machinery with sampling and testing, and a product built on an ingredient India does not permit is not made lawful by being lawful abroad. **Sale** is governed by the labelling and claims discipline: the product must be labelled as its category requires, with the declarations the labelling regulations prescribe, and its claims are confined by the

advertising and claims regulations to permitted nutrient and health language, with disease cure claims prohibited and the standing instruction that such products are not intended to diagnose, treat, cure or prevent any disease and are not a substitute for a varied diet, in the form the regulations require. Products that fall outside the permitted lists altogether require the **prior approval route for non specified food and food ingredients**, under which FSSAI examines the safety of the novel article before it may be marketed, India's functional equivalent of the European novel food gate of Unit 5.

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Placing a nutraceutical on the Indian market
Are every ingredient and its level inside the schedules
of the nutraceutical regulations?
|
No, and no prior approval -> do not launch; seek the
non specified food approval route first
|
Yes
|
Central licence held? Premises and GMP conditions met?
|
Label and claims checked against the labelling and
claims regulations: category name, declarations,
no disease claims
|
Manufacture or import under licence; import consignments
cleared with sampling and testing
|
Sale with recall readiness and complaint handling
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3.5 Recommended Dietary Allowances in India

Recommended Dietary Allowances are the reference values for the daily intake of energy and nutrients considered adequate for the maintenance of health in the population for which they are set. In India the values are set on the scientific work of the **Indian Council of Medical Research through its National Institute of Nutrition (ICMR NIN)**, whose expert committees review the evidence, Indian dietary patterns, body weights and activity patterns, and publish the RDA tables by age, sex and physiological group, revising them as the evidence and the population change; the same scientific stable produces the complementary estimated average requirement concept, the average need figure from which the RDA, set safely above it, is derived. The syllabus asks for RDA in India as a regulatory topic, and its regulatory uses are three. **Formulation discipline**: the nutraceutical regulations of section 3.4 tie permitted nutrient levels in supplements to the RDA framework, so that a supplement is designed to fill the gap between dietary intake and the RDA rather than to deliver unbounded multiples of it. **Labelling**: nutrient declarations are read against the RDA, so the consumer and the examiner can both see what fraction of the day's requirement a serving supplies. And **claims discipline**: nutrient content claims are judged against thresholds expressed in relation to reference values. The values themselves are deliberately not recited in these notes: they are revised by expert committee, differ by nutrient and by life stage group, and the professional skill the syllabus tests is knowing whose values they are, what they are for, and where they bind the product, not memorising a table that a revision can supersede.

3.6 India in one view

The Indian settlement can now be stated in a paragraph, as the examinations will ask for it. One statute (2006), one authority (FSSAI), one licensing ladder with the specialised categories at its central tier, positive ingredient schedules that decide what may be sold, GMP and hygiene conditions on the maker, prescribed labels and a claims fence, an import gate with testing, and a prior approval route for anything the schedules do not cover. It is the most **premarket** of the three systems in this course: where America largely trusts the market and polices afterwards, India decides the recipe in advance. Hold that contrast for the synthesis at

the end of Unit 5.

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