

Unit 5: European Union

Free notes at pharmacolearn.fyi

5.1 The European Food Safety Authority (EFSA): organization and functions

The European Union separates the assessment of food risk from the management of it, and **EFSA** is the assessment side of that separation. Founded under the General Food Law of 2002, in the reform that followed the European food safety crises of the 1990s, EFSA is an independent European agency, based in Parma, Italy, funded by the Union and governed by a management board, an executive director, an advisory forum that links it to the member states' own food safety bodies, and a scientific committee and scientific panels of independent experts, of which the panel on nutrition, novel foods and food allergens is the one this subject deals with. Its **functions** are scientific: to provide independent scientific advice and opinions on food and feed safety, nutrition and related questions, at the request of the European Commission, the European Parliament, member states or on its own initiative; to collect and analyse data and monitor risks; and to communicate risks to the public. Its opinions are the mandatory scientific foundation for the decisions this unit studies: the authorisation of health claims, the safety assessment of novel foods, and the setting of dietary reference values. What EFSA does **not** do is equally definitional: it grants no authorisations, issues no licences and enforces nothing. Authorisation decisions are taken by the **European Commission together with the member states** (the risk managers), and enforcement belongs to the member states' own authorities. The division mirrors the WHO lesson of Unit 2 at regional scale: assessment advises, management decides, enforcement polices, and confusing the three is the standard examination trap in this unit.

5.2 EU directives and regulations for manufacture and sale of nutraceuticals and dietary supplements

Europe has no single nutraceutical statute; the category is governed by a family of instruments, and the syllabus topic is the family itself. The foundation is the **General Food Law (Regulation (EC) No 178/2002)**, which lays down food safety principles, the rule that food business operators are responsible for the safety of what they place on the market, traceability, and the EFSA structure of section 5.1. The category instrument is the **Food Supplements Directive (2002/46/EC)**, which defines food supplements as foodstuffs whose purpose is to supplement the normal diet, being concentrated sources of nutrients or other substances with a nutritional or physiological effect, marketed in dose form; it harmonises the field through **positive lists of the vitamins and minerals, and their chemical forms, that may be used**, leaving member states a continuing role on other ingredients such as botanicals, which is why the European supplement market is harmonised at its centre and national at its edges. Around these stand the **addition of nutrients Regulation (Regulation (EC) No 1925/2006)** for vitamins and minerals added to ordinary foods, the **food hygiene and official controls** framework under which manufacture and sale are policed by member states, the requirement that food businesses operate under hygiene rules and hazard analysis discipline, and the **claims Regulation (Regulation (EC) No 1924/2006)** of section 5.4's neighbour topic: no nutrition or health claim may be made in the Union unless it is authorised and entered in the Union list, on an EFSA opinion. Manufacture and sale therefore run on operator responsibility plus positive lists plus authorised claims, supervised nationally: a mid position between the Indian premarket recipe control of Unit 3 and the American market access model of Unit 4, and the comparison is the natural close of the course.

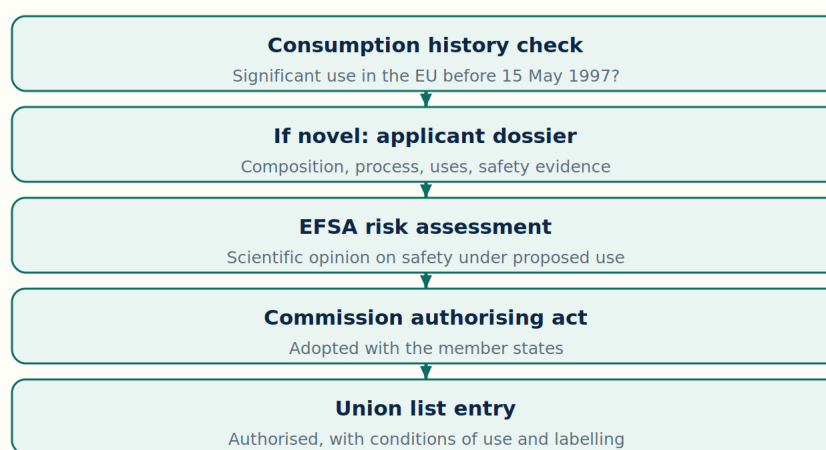
5.3 Nutrition labelling in the European Union

European nutrition labelling is governed by the **Food Information to Consumers Regulation (Regulation (EU) No 1169/2011)**, which made a standard nutrition declaration mandatory on most prepacked foods and prescribes its content, order and expression. The declaration states energy value and the amounts of fat, saturates, carbohydrate, sugars, protein and salt, expressed per 100 grams or 100 millilitres and, additionally, per portion, with a defined set of voluntary additions; for food supplements the directive framework requires the amounts of the nutrients or substances with a nutritional or physiological effect to be declared per the recommended daily dose, expressed also as a percentage of the **nutrient reference value**, the Union's labelling reference (the European RDA instrument of section 5.6). The labelling rules also carry the supplement specific warnings discipline: the product is not a substitute for a varied diet, the stated recommended daily dose must not be exceeded, and products are to be kept out of the reach of children, in the form the directive prescribes. As in America, the label is a legal document: a claim printed on it must be an authorised claim, a value declared on it must follow the prescribed reference system, and the member state authorities enforce it as such.

5.4 The European regulation on novel foods and novel food ingredients

A **novel food** in Union law is a food that was not used for human consumption to a significant degree within the Union before the reference date the legislation fixes (15 May 1997, the date of the first novel food regulation), and which falls within the categories the current regulation lists, including foods with a new or modified molecular structure, foods made from microorganisms, fungi or algae, foods from cell or tissue culture, foods produced by new processes that significantly change them, and engineered nanomaterials, among others. The governing instrument is **Regulation (EU) 2015/2283 on novel foods**, which replaced the original 1997 regulation and centralised the system. Its logic is a **premarket gate**, the strictest in this course beside India's non specified food approval: a novel food may not be placed on the Union market unless it is authorised and entered in the **Union list of authorised novel foods**, with its conditions of use and labelling requirements. The route runs in stages: the applicant prepares a dossier demonstrating safety under the proposed conditions of use; the application goes to the European Commission, which requests a scientific opinion from **EFSA**, whose risk assessment examines composition, production process, proposed uses and use levels, nutritional character and toxicological evidence; on a favourable assessment the Commission brings forward the authorising act through the committee procedure with the member states, and the food is added to the Union list, sometimes with data protection for the applicant's proprietary evidence for a period. The regulation also provides a lighter **notification route for traditional foods from third countries**, with a history of safe use outside the Union, under which objections on safety grounds determine whether a full application is required. For this subject the novel food gate is where new nutraceutical territory is won or lost in Europe: a botanical extract, algal oil or fermented ingredient without a Union consumption history before the reference date is a novel food first and a supplement ingredient second, and no supplement directive argument can cure the defect.

The EU novel food authorisation route

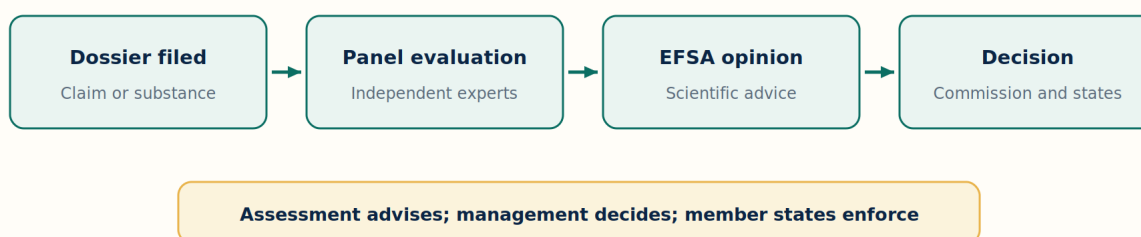


Traditional foods from third countries: a lighter notification route

© 2026 PharmacoLearn, pharmacolearn.fyi

Figure: The novel food route of section 5.4 under Regulation (EU) 2015/2283: consumption history before the 1997 reference date decides novelty, the applicant dossier goes to the Commission, EFSA delivers the safety opinion, and authorisation enters the food in the Union list with its conditions of use (Unit 5, section 5.4).

EFSA: assessment to authorisation decision



© 2026 PharmacoLearn, pharmacolearn.fyi

Figure: The EFSA assessment flow behind sections 5.1 and 5.2: a claim or substance dossier is validated, the competent scientific panel evaluates the evidence and adopts an opinion, and the Commission with the member states takes the authorisation decision that enters, or refuses, the Union list (Unit 5, section 5.1).

5.5 Regulation of functional foods in the European Union

Unit 1 established that the functional food is a scientific and marketing category in search of a legal one, and Europe is the proof. The Union has **no functional food directive and no functional food authorisation**: a yoghurt, spread or drink positioned on a health benefit is regulated by the ordinary instruments, each doing its own work. The product must be a lawful food under the General Food Law, made by a responsible operator under the hygiene framework. Anything **added** to give it its function must be permitted: added vitamins and minerals under the addition Regulation of section 5.2, and any ingredient without a Union consumption history must first clear the **novel food gate** of section 5.4. Its **benefit may only be spoken in authorised language**: the claims Regulation permits a health claim, including the reduction of disease risk claims it treats most strictly, only where EFSA has assessed the evidence and the claim stands in the Union list, in its authorised wording and conditions. And its label must carry the standard nutrition declaration of section 5.3. The European position is therefore best stated as a sentence: functional foods are fully regulated, but as foods with ingredients and claims, never as a class. The contrast the examiner wants is with a system that names the category, India, whose regulations expressly list functional territory inside their health supplement and nutraceutical framework, and with the United States, where the same product is a conventional food whose benefit language is judged under the health claim and structure

and function rules of Unit 4.

5.6 Recommended Dietary Allowances in Europe

Europe's reference value system is set scientifically by **EFSA**, which publishes **Dietary Reference Values (DRVs)** for nutrients and energy for the Union: a family of values, including the average requirement, the population reference intake (the European counterpart in function to the RDA, the intake adequate for practically all healthy people in a group), adequate intakes where the evidence supports no population reference intake, and tolerable upper intake levels, set by age, sex and life stage group and revised on the evidence. The values are scientific opinions, not law in themselves: they serve the Commission and member states in setting policy, dietary guidance and labelling references, and the labelling expression of them is the **nutrient reference value** of section 5.3, the single set of reference figures the Food Information Regulation prescribes for percentage declarations on labels. The three RDA sections of this course now assemble into one comparison, which is the synthesis this subject has been building toward.

Point	India	United States	European Union
Scientific body	ICMR through its National Institute of Nutrition	Food and Nutrition Board of the National Academies	EFSA, through its nutrition panel
Reference family name	Recommended Dietary Allowances (with estimated average requirements)	Dietary Reference Intakes, including the RDA	Dietary Reference Values, including the population reference intake
RDA counterpart	RDA itself	RDA itself	Population reference intake
Ceiling concept	Carried in the ICMR framework	Tolerable upper intake level in the DRI family	Tolerable upper intake level in the DRV family
Labelling expression	Declaration read against the RDA	Daily Value percentage on Supplement Facts	Nutrient reference value percentage
Regulatory use in this subject	Disciplines permitted nutrient levels in the nutraceutical regulations	Frames formulation and label percentages, no product limit in itself	Frames labelling percentages and policy; authorisation is separate

Reference values: India, US and Europe

INDIA	UNITED STATES	EUROPEAN UNION
Scientific body: ICMR NIN	Body: Food and Nutrition Board	Scientific body: EFSA
Family: RDA values	Family: Dietary Reference Intakes	Family: Dietary Reference Values
Set by expert committees	RDA is one DRI member	Counterpart: population intake
Labels read against RDA	Labels use FDA Daily Value	Labels: nutrient reference value

Scientific values advise; the label reference is set by the regulator in each system

© 2026 PharmacoLearn, pharmacolearn.fyi

Figure: The three reference value systems of Units 3 to 5 side by side: ICMR NIN and the Indian RDA, the Food and Nutrition Board with the Dietary Reference Intakes and the FDA Daily Value for labels, and EFSA with the Dietary Reference Values and the nutrient reference value for labels (Unit 5, section 5.6).

5.7 The three systems compared: the close of the course

The course ends where a regulatory professional's judgment begins, in the comparison. India controls the **recipe in advance**: positive schedules decide what may be sold, the maker is centrally licensed for these

categories, and anything outside the schedules needs prior approval. America controls the **market in motion**: no premarket approval, ingredient notification at one gate, GMP on the factory, a disciplined claims ladder on the label, and enforcement, adverse event reporting and recall against what fails. Europe controls by **list and opinion**: positive lists for vitamins and minerals, EFSA assessed authorisation for claims and for novel foods, operator responsibility under a general food law, and national enforcement. The same capsule can therefore be lawful in one system, reformulation work in a second, and an unauthorised novel food in the third, and none of the three is a failed version of the others: each is a coherent answer, weighted differently, to the border question of Unit 1. The habits this subject rewards follow directly. Classify the product first. Check the ingredient against the destination's list or gate. Build it under GMP and be able to prove it. Write the label from the destination's rulebook, not from the home market's. And never let the claim say in marketing language what the evidence and the authorisation do not say in regulatory language.

Frequently Asked Questions

Q: What is a nutraceutical, and how does it differ from a dietary supplement and a functional food?

A nutraceutical is a food or food component, in measured form, that provides a physiological benefit beyond basic nutrition and helps maintain health. A dietary supplement is the statutory category of products intended to supplement the diet with dietary ingredients such as vitamins, minerals and botanicals. A functional food is a conventional food in ordinary food form with a benefit beyond basic nutrition. The nutraceutical is the broad trade and Indian regulatory term, the supplement the defined American category, and the functional food a category most systems regulate through ingredient, fortification and claims law rather than by a separate licence.

Q: Why are nutraceuticals regulated as foods and not as drugs? Because their intended purpose is health maintenance and dietary supplementation, not the diagnosis, treatment, cure or prevention of disease. All three systems in this course keep them inside food law, with drug style elements added where the risk sits: positive ingredient lists or notification gates, GMP manufacture, prescribed labels and fenced claims. A product presented with a disease purpose leaves the food framework and is judged as a drug.

Q: What does NSF certification attest, and is it a legal approval? NSF certification attests, after formulation and label review, laboratory testing for contents and contaminants, and a GMP audit of the facility, that a supplement meets a published NSF standard, with continuing surveillance and retesting to maintain it. It is a voluntary third party attestation, not a government approval or licence, and a certified product must still comply with the law of every market where it is sold.

Q: What did the Food Safety and Standards Act 2006 change in India? It consolidated a patchwork of older food laws and orders into a single statute, created the Food Safety and Standards Authority of India as the single national authority, moved the system toward science based standards and prevention, and brought manufacture, storage, distribution, sale and import of food, including nutraceuticals and health supplements, under one licensing and standards framework.

Q: How are nutraceuticals controlled in India before they reach the market? By positive list and licence. The FSSAI regulations for health supplements, nutraceuticals and related categories permit only scheduled nutrients, botanicals, molecules, isolates, extracts, prebiotics and probiotics, within the prescribed discipline; manufacture of these categories requires a central licence and GMP and hygiene compliance; imports pass through licensing and clearance with sampling and testing; and an article outside the schedules needs the prior approval route for non specified foods.

Q: What is the RDA, and who sets it in India, the US and Europe? The Recommended Dietary Allowance is the daily nutrient intake level considered adequate for nearly all healthy people in a defined

group. In India the values come from the ICMR through its National Institute of Nutrition; in the United States the RDA sits inside the Dietary Reference Intakes of the Food and Nutrition Board of the National Academies, with the FDA Daily Value as the labelling expression; in Europe EFSA sets Dietary Reference Values, whose RDA counterpart is the population reference intake, with nutrient reference values used on labels.

Q: What is the difference between FSMA and DSHEA? DSHEA, 1994, is the category statute: it defines dietary supplements, fixes ingredient responsibility and the new dietary ingredient notification, and builds the labelling and claims regime, with no premarket approval. FSMA, 2011, is a food safety statute for the whole food supply: preventive controls, facility registration and risk based inspection, foreign supplier verification, traceability and mandatory recall authority. A supplement business in the US lives under both.

Q: What claims may a dietary supplement make in the United States? Authorised health claims where the FDA has authorised them on significant scientific agreement; qualified health claims with qualifying language about the evidence; nutrient content claims under their defined terms; and structure and function claims, which need manufacturer substantiation, notification to the FDA, and the disclaimer that the statement has not been evaluated by the FDA and the product is not intended to diagnose, treat, cure or prevent any disease. Disease treatment claims are forbidden and make the product an unapproved drug.

Q: What does EFSA do, and what does it not do? EFSA provides independent scientific risk assessment and communication for the European Union: opinions on claims, novel foods, substances and dietary reference values, through its scientific committee and panels. It does not authorise products, issue licences or enforce the law. Authorisation decisions are taken by the European Commission with the member states, and enforcement belongs to member state authorities.

Q: What is a novel food in the European Union, and how is it authorised? A novel food is a food without a history of human consumption to a significant degree in the Union before the 1997 reference date, within the categories listed in Regulation (EU) 2015/2283. It may be marketed only after authorisation and entry in the Union list: the applicant files a safety dossier, EFSA delivers the scientific risk assessment, and the Commission with the member states adopts the authorising act with conditions of use. A lighter notification route exists for traditional foods from third countries with a history of safe use.

*More free M.Pharm notes and unit wise PDFs at pharmacolearn.fyi
Free video lectures on the PharmacoLearn YouTube channel*