

Unit 1: Nutraceuticals, Introduction

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Regulatory Aspects of Food and Nutraceuticals, subject code MRA204T, is the fourth and final core theory subject of M.Pharm Regulatory Affairs, Semester 2. It carries 4 credits and 60 hours of theory, taught at 4 hours per week, for 100 marks. The three subjects before it regulated medicines, biologics and devices. This subject regulates the products that sit on the border between food and medicine: the vitamin capsule, the fortified drink, the probiotic, the botanical extract and the formula feed. That border position is the whole difficulty of the field, and the whole interest of it. A nutraceutical is sold as a food, so it escapes the premarket proof of efficacy that a drug must supply; but it is bought for a health purpose, often in a capsule that looks exactly like a medicine, so it cannot be left to ordinary food law alone. Every system in this course is a different answer to the same question: how much drug style control should be applied to a product that is legally a food? This course is designed to impart fundamental knowledge on the regulatory requirements, registration and labelling regulations of nutraceuticals in India, USA and Europe, and to prepare students to learn in detail the regulatory aspects for nutraceuticals and food supplements. The units move from the product family outward to the world and then through the three great jurisdictions. Unit 1 defines the family: the history of food and nutraceutical regulation, the meanings of nutraceuticals, dietary supplements, functional foods and medical foods, and the scope and opportunities of the market. Unit 2 takes the international layer: the WHO guidelines on nutrition, NSF International with its certification and its standards for food and dietary supplements, and good manufacturing practice for nutraceuticals. Unit 3 studies India: the Food Safety and Standards Act 2006, the Food Safety and Standards Authority of India (FSSAI), the regulations for import, manufacture and sale of nutraceutical products, and Recommended Dietary Allowances in India. Unit 4 studies the United States: the Food Safety Modernization Act and the Dietary Supplement Health and Education Act, the rules for manufacture and sale, labelling and label claims, and RDA in the US. Unit 5 studies the European Union: the European Food Safety Authority (EFSA), the directives and regulations for manufacture and sale, nutrition labelling, the novel foods regulation, RDA in Europe, and the regulation of functional foods. One discipline runs through the notes and should be stated at the start: these products are regulated as foods in all three systems, so no system in this course grants a marketing authorisation of the drug kind, and no claim in this course may promise to treat, cure or prevent a disease unless the product has crossed the border and become a drug. The regulatory professional's craft here is classification, ingredient permissibility, manufacturing quality, honest labelling and disciplined claims.

1.1 Introduction: products between food and medicine

Ordinary food law was built to answer two questions: is this food safe, and is it what its label says it is? Drug law was built to answer a harder question as well: does this product do what it claims to do, proved before sale? Nutraceuticals strain both frameworks because consumers buy them precisely for the third question. A fish oil capsule, a glucosamine tablet, a protein powder and a probiotic drink are foods in law, taken in food like forms or as measured supplements to the diet, but they are marketed on health territory that food law historically left alone and drug law would have demanded trials for. The regulatory settlement every jurisdiction reaches has the same broad shape, and the units of this course are its working out system by system. The product stays a food. Its ingredients are controlled by positive lists, safety assessments or notification duties. Its factory is held to good manufacturing practice closer to the pharmaceutical pattern than to the bakery pattern. Its label is tightly prescribed, because the label is where the health promise is

made. And its claims are fenced: nutrition and health support language is permitted under conditions, disease treatment language is not. Learn that settlement once, and the Indian, American and European chapters of this course read as three dialects of one language.

1.2 History of food and nutraceutical regulations

Food regulation is old because food fraud is old: ancient market rules punished watered milk and weighted bread, and nineteenth century adulteration scandals produced the first modern food statutes, which defined adulteration and misbranding and created inspectorates to police them. The twentieth century added the safety disasters and the nutritional science that together built the modern framework. Toxic colourants, contaminated products and drug tragedies pushed legislatures toward premarket safety control of additives and, for drugs, of the products themselves, while the discovery of vitamins and deficiency diseases created a new, positive idea: that specific nutrients, identified and dosed, could prevent specific diseases. Fortification followed, with nutrients added to staple foods as public health policy, and with it the first regulatory question of the nutraceutical age, how a nutrient added on purpose differs in law from a drug. The supplement industry grew through the middle of the century in a legal grey zone, sold under food law, claimed in drug language, and periodically provoking attempts to regulate it as a drug. The modern settlement dates from the 1990s and 2000s, and its landmarks are the statutes of Units 3 to 5: in the United States the Dietary Supplement Health and Education Act of 1994 defined the dietary supplement category and its claim rules; in the European Union the Food Supplements Directive of 2002 harmonised the category across member states; and in India the Food Safety and Standards Act of 2006 consolidated a patchwork of older food laws into one statute and one authority, inside which the nutraceutical category was then expressly regulated. The word itself is younger than most of the law: the term nutraceutical, joining nutrition and pharmaceutical, was coined by Dr Stephen DeFelice in 1989 for foods and food components that provide medical or health benefits. The history lesson for the examination is the direction of travel: from punishing fraud, to assuring safety, to governing health benefit claims, with each step leaving the product legally a food.

1.3 Nutraceuticals: meaning and character

A **nutraceutical** is, in the widely used working sense, a food or a component of food that provides a physiological or health benefit beyond basic nutrition and helps in maintaining health. The category is defined by concentration and purpose. Its members include isolated nutrients (vitamins, minerals, amino acids), dietary ingredients of botanical origin (extracts, isolates and purified compounds from plants), probiotics and prebiotics, and substances such as fatty acids and enzymes, presented in measured forms: tablets, capsules, powders, granules and liquids that resemble medicines in presentation while remaining foods in law. Three limits define the category against its neighbours. A nutraceutical is **not a drug**: it is not intended to diagnose, treat, cure or prevent a disease, and the moment a product is presented with that intention it leaves this subject and enters the drug framework of MRA201T. A nutraceutical is **not an ordinary food** either: it is taken in a measured dose for a health purpose, which is why positive ingredient lists, dose discipline and claim control attach to it. And its benefit claim is a **health maintenance claim**, support of normal structure, function or general wellbeing, which must be truthful and substantiated but is not proved by the clinical trial programme of a medicine. In the Indian regulations the category is drawn in exactly this spirit, as foods consisting of extracts, isolates and purified chemical compounds having a physiological benefit and helping to maintain health, a definition Unit 3 returns to.

1.4 Dietary supplements

A **dietary supplement**, in the statutory sense the United States gave the term and the world has broadly followed, is a product intended to supplement the diet, containing one or more dietary ingredients: a

vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance used to supplement the diet by increasing total dietary intake, or a concentrate, metabolite, constituent, extract or combination of any of these. It is taken by mouth, in a measured form such as a tablet, capsule, powder or liquid, and it is not represented for use as a conventional food or as the sole item of a meal or diet. The definition does three regulatory jobs. It fixes the **ingredient universe**: a supplement may only be built from dietary ingredients, and an ingredient that is neither a food component nor a permitted dietary ingredient takes the product out of the category. It fixes the **form**: measured, medicine like dosage forms are inside the category, while an ordinary food bar or drink making the same promise may fall under conventional food rules instead, a boundary companies test constantly. And it fixes the **legal character**: a supplement is a subcategory of food, not of drug, with all the consequences Unit 4 develops, no premarket approval, manufacturer responsibility for safety, and a claims regime of its own.

1.5 Functional foods

A **functional food** is a conventional food, eaten as part of the normal diet in normal food form, which has been shown or designed to provide a health benefit beyond the basic nutrition its nutrients would ordinarily supply. The contrast with the supplement is form and context: the functional food stays on the plate. Yoghurt carrying live probiotic cultures, oats whose beta glucan fibre is the point of the product, spreads fortified with plant sterols, and drinks fortified with vitamins are the standard examples. The category is scientifically natural and legally awkward, which is itself an examination point. Most systems have **no separate statutory category** called functional food: the product is regulated as an ordinary food, its added ingredients must be permitted, any fortification must follow the fortification rules, and any health benefit it advertises must pass through the general health claims regime of its jurisdiction. Europe, which the syllabus asks about expressly in Unit 5, handles the category in exactly that way, through ingredient, fortification and claims law rather than through a functional food licence. The professional habit follows: when a client says functional food, translate the phrase into the operative legal questions, what has been added, is it permitted, and what exactly will the label claim?

1.6 Medical foods

A **medical food** is the most drug adjacent member of the family, and the most tightly fenced. In the United States definition, which is the standard teaching form, it is a food formulated to be consumed or administered enterally under the supervision of a physician, and intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognised scientific principles, are established by medical evaluation. Enteral nutrition formulas for patients who cannot eat normally, and formulas designed for the dietary management of specific metabolic disorders, are the characteristic members. Every element of the definition is a gate. **Under medical supervision** separates it from self selected supplements. **Distinctive nutritional requirements** separates it from ordinary foods for special dietary use: the patient's disease must create nutritional needs that an ordinary diet cannot meet, not merely needs the product happens to suit. And **dietary management**, not treatment, keeps it a food: the product feeds the patient's condition specific nutritional requirement; it does not claim to cure the condition. Medical foods are therefore few, specialised and institutionally channelled, in contrast to the mass retail market of supplements, and systems that lack the category handle the same products under foods for special medical purposes, the European and Indian label for the same territory, which Unit 3 and Unit 5 meet.

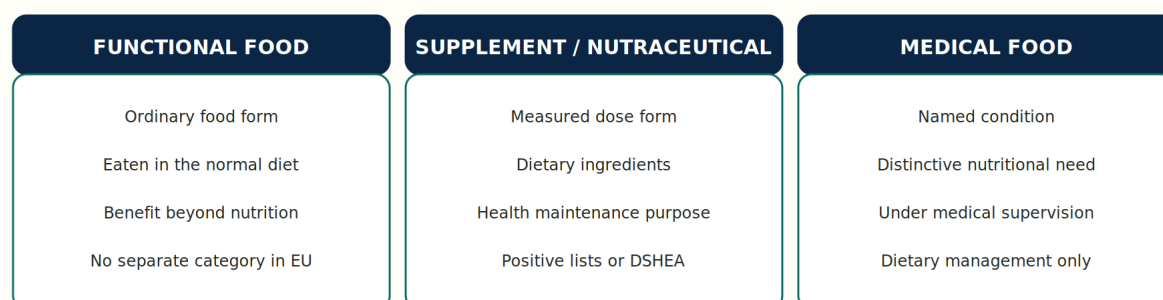
1.7 The family compared

The four terms of this unit are used loosely in trade language and must be used precisely in regulatory language. The table states the working distinctions on the points an examiner will test: form, intention, user

and legal treatment.

Point	Nutraceutical	Dietary supplement	Functional food	Medical food
Basic idea	Food component with a physiological benefit, in measured form	Product that supplements the diet with dietary ingredients	Conventional food with a benefit beyond basic nutrition	Food for the dietary management of a specific disease or condition
Typical form	Capsule, tablet, powder, extract	Tablet, capsule, powder, liquid	Ordinary food form: yoghurt, cereal, spread, drink	Enteral formula, condition specific formula
Intended user	General consumer seeking health maintenance	General consumer filling a dietary gap	General consumer, as part of the normal diet	Patient, under medical supervision
Disease relationship	None permitted: no treatment claims	None permitted: structure and function support only	None permitted: authorised health claims only	Tied to a named condition, but manages its diet, does not treat it
Legal character	A regulated food category, expressly named in India	A defined subcategory of food, defined by statute in the US	Usually no separate category: food, fortification and claims law	A narrow defined category (US); foods for special medical purposes in the EU and India

The product family: food to medicine border



Disease treatment claims cross the border: the product becomes a drug

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Figure: The four member family of sections 1.3 to 1.6 arranged by form and by closeness to medicine: the functional food in ordinary food form at the food end, the supplement and the nutraceutical in measured forms in the middle, and the medical food, tied to a named condition and used under supervision, nearest the drug border it must not cross (Unit 1, section 1.7).

1.8 Scope and opportunities in the nutraceutical market

The syllabus names scope and opportunities as a topic, and it is taught here qualitatively, because the drivers of the market are structural and durable while any figure quoted for its size would date and would differ by source. The demand side rests on four pillars. **Preventive health behaviour:** consumers increasingly spend on maintaining health rather than only on treating illness, and supplements and functional foods are the retail form of that intention. **Lifestyle disease burden:** the rise of conditions associated with diet and sedentary life creates a large population managing weight, blood lipids, blood sugar and joint and gut health through diet adjacent products, within the claim limits of section 1.3. **Ageing populations:** older consumers are the heaviest users of supplements for bone, eye, cognitive and general health support. And **the sports, beauty and convenience segments:** protein and performance products, beauty from within products, and fortified convenience foods extend the family well beyond the pharmacy shelf. The supply side offers its own opportunities: India's botanical heritage and its traditional medicine ingredient base give its industry a distinctive raw material position, contract manufacturing and private label work are substantial businesses, and exports are governed by exactly the three jurisdiction literacy this

course teaches, since a product lawful in one system may need reformulation, relabelling or a notification in another. The regulatory opportunity inside the commercial one deserves emphasis: as claim control and ingredient positive lists tighten in all three systems, the firm whose regulatory work is sound, ingredients verified against the lists, claims inside the authorised language, GMP documented, holds a market advantage over the firm whose products are one inspection or one complaint away from withdrawal. That is the professional promise of this subject.

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The border discipline of this subject
Is the article eaten as food, or presented in a measured
dose form for a health purpose?
|
Ordinary form, no added health ingredient or claim
-> conventional food law
|
Measured form, dietary ingredients, health maintenance
-> nutraceutical and supplement law (this subject)
|
Named condition, distinctive nutritional requirement,
medical supervision
-> medical food / food for special medical purposes
|
Presented to diagnose, treat, cure or prevent disease
-> a drug: leave this subject, drug law applies
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