Name of university, Name of faculty: Trnava University
Faculty of Law

INFORMATION SHEET OF THE SUBJECT

Code: XNDVb001	**Name:** Legal Regulation of Food Supplements	
Cover: Intellectual Property, Technologies and Product Law Department		
Type of educational activity: Lecture, Practise **Scope of educational activity (in hours):** **Weekly:** 2/0 **For term of study:** LS 60/,24 **Method of educational activity:** Combined	**Number of credits:** 3	**Recommended semester:** ST **Study grade:** Bachelor

Recommended semester	Study programme
1.year ST	Law (XDŠBc-PR)
2.year ST	Law (XDŠBc-PR)

Underlie subjects:

Conditions for passing the course:
Method of evaluation: Completion by a continuing assessment

Continuous evaluation: The continuous assessment consists of a written test to be completed by the student at the end of the teaching part of the semester. The test consists of ten questions, for each question the student may obtain a maximum of 10 points.
Grade: A: 100-91 points; B: 90-81 points; C: 80-71 points; D: 70-61 points; E: 60-51 points; FX: less than 51 points.
Final evaluation: Completion by a continuing assessment
Finished: By continuous evaluation.

Learning outcomes:
After completing the course Legal regulation of food supplements, the student can define food supplements and characterize their components. The student is familiar with the basic and related legislation that regulates the production, storage, distribution and sale of food supplements. The student knows the legal regulation of the biological and chemical safety of food supplements. Knows how to define performance enhancers in food supplements. The student can also correctly label food supplements, including the use of nutrition and health claims on food supplements. The student knows the legal regulation of the packaging of food supplements and the legal regulation of materials and articles intended to come into contact with food supplements. The student is able to describe the state health supervision and official control of food supplements, and is able to explain and also to propose procedural procedures for the exercise of state health supervision and official control of food supplements.

Schedule of subject:
1. Introduction to the study of the subject, basic legislation on food supplements, Codex Alimentarius and food supplements, the concept of food supplement, relationship to food and medicines.
2. Composition of food supplements, legal regulation of sources of nutrients (vitamins and minerals used for the production of food supplements - purity criteria, maximum amounts for daily consumption), other substances with nutritional or physiological effect and other ingredients used in food.
3. Food enhancers and food supplements (fortifiers, food additives, food enzymes, flavourings and food ingredients with flavouring properties).
4. Legal regulation of the biological and chemical safety of food supplements (hygiene of food supplements, contaminants and residues in food supplements).
5. Labelling and advertising of food supplements - mandatory information on food supplements (mandatory information according to Article 9(1) of the FIC Regulation and mandatory information according to specific regulations), presentation of mandatory information on food supplements.
6. Voluntary information on food supplements, labelling of environmental and social aspects on food supplements.
7. Nutritional and health claims on food supplements.
8. Packaging of food supplements, legal regulation of materials and articles intended to come into contact with food supplements.
9. Placing on the market of food supplements, notification of first placing on the market.
10. State health surveillance and official control of food supplements.
11. Novel foods and food supplements.
12. Tasks of the European Food Safety Authority in the field of food supplements.

Recommended reading:
Basic recommended literature:
- VENHARTOVÁ, J. – RYBNIKÁR, S. – GÁBRIŠ, T. et al. Potravinové právo. 1st ed. Šamorín: Heuréka, 2017.
- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.
- Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.
- Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods.
- Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.
- Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food.

- Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006.
- Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.
- Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97.
- Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC.
- Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.
- Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.
- Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.
- Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive').
- Act No. 152/1995 Coll. on Foodstuffs.
- Act No 355/2007 Coll. on the Protection, Promotion and Development of Public Health and on Amending and Supplementing Certain Acts.
- Act No 147/2001 Coll. on Advertising and on Amendments and Additions to Certain Acts.
- Act No 108/2024 Coll. on Consumer Protection and on Amendments to Certain Acts.
- Decree No 16826/2007-OL of the Ministry of Agriculture of the Slovak Republic and the Ministry of Health of the Slovak Republic of 25 July 2007, issuing the title of the Food Code of the Slovak Republic regulating the requirements for foods for special nutritional purposes and for nutritional supplements.

Further materials will be provided to students in the MOODLE e-learning system.

Language requirements: Slovak

Notes:
Student's workload: 75 hours
Combined study (lectures, seminars, consultations): 24 hours
Study for seminars, final evaluation and study of submitted materials and documents in Moodle (individual study): 51 hours

Course evaluation:
Assessed students in total: 27

A	B	C	D	E	FX
96%	0%	0%	0%	0%	4%

Lecturers:
Mgr. Samuel Rybnikár, PhD., lecturer, examiner

Date of last change: 01.09.2026

Approved by: prof. PhDr. JUDr. Tomáš Gábriš, PhD., LLM., MA