Regulations whose amendment is included in the updated form

Law	205	01.07.2024	07.07.2024	
Amendment	88	20.10.2023	20.03.2024	
Emergency Government Ordinance	88	20.10.2023	24.10.2023	Approved through Law 205/2024

Parliament of Romania

LAW No. 56*)
of 31 March 2021 on food supplements

***) Note:**

It includes all the amendments brought to the official regulation published in the Official Gazette, including those provided for in:

Law no. 205/01.07.2024 published in the Official Gazette of Romania no. 632/04.07.2024

Promulgated by Decree No. 256 of 31 March 2021.

The Parliament of Romania hereby adopts this Law.

SECTION I

General provisions

Art. 1 - (1) This Law establishes the legal framework regarding food supplements, marketed as food products and presented as such.

(2) The Ministry of Health is the competent authority in the field of food supplements based on:

a)vitamins, minerals;

b) vitamin and/or mineral mixtures;

c) substances with a nutritional or physiological effect, other than vitamins and minerals;

d) vitamin and/or mineral mixtures with substances with nutritional or physiological effects, other than vitamins and minerals;

e) mixtures of substances with nutritional or physiological effect, with plants and/or plant/animal extracts and/or beehive products;

f) mixtures of substances with nutritional or physiological effect, other than vitamins and minerals, with plants and/or plant/animal extracts and/or beehive products;

g) mixtures of any of the ingredients provided for in points a) - f).

(3) For the mixtures specified in paragraph (2) points e)-g), the plants included in the list provided for in Article 8 paragraph (1) point b) may be used as ingredients.

(4) The provisions of this Law protect consumers' health, ensure the conditions for provision of correct and complete information to consumers, in accordance with the legal regulations in force, and for prevention of unfair commercial practices.

(5) The provisions of this Law are not applicable to medicinal products defined in Title XVIII "The medicinal product" of Law no. 95/2006 on the healthcare reform, republished, as further amended and supplemented, nor to food supplements based on medicinal and aromatic plants and beehive products, regulated by Law no. 491/2003, republished, as further amended and supplemented.

Art. 2 - For the purposes of this Law, the terms and expressions below have the following meaning:

a) **Food supplements** - food products whose purpose is to supplement the diet and which represent concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in 'dose' form,

namely in presentation forms such as capsules, tablets, pills or other similar forms, powder sachets, liquid ampoules, dropper bottles and other similar forms of liquids and powders intended to be taken in small, unitary, measured quantities;

b) **nutrients** - vitamins, minerals and other substances with nutritional or physiological effect;

c) **substances with a nutritional or physiological effect, other than vitamins and minerals** - macronutrients, amino acids, enzymes, live microorganisms, dietary fibres, essential fatty acids, plants, algae, lichens, fungi, as well as their essential oils, plant extracts and/or animal extracts, authorised novel foods, included in Commission Implementing Regulation (EU) 2017/2.470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods;

d) **extract** - substance or mixture of substances prepared by concentrating products extracted from various plant or animal materials, fresh or dried, to a certain degree;

e) **counterfeit food supplement** - food supplement for which the identity, including packaging and labelling, name and composition with regard to any of its components, including the quantity of those components, is falsely presented;

f) **beehive products which can be ingredients in food supplements** - pollen, propolis, honey and royal jelly, according to Art. 1 (2) point h) of Law no. 491/2003, republished, as further amended and supplemented;

g) **notification** - notification to the competent authority regarding the intention to place a food supplement on the market;

h) **notification certificate** - administrative act issued by the National Institute of Public Health, through its structures, within 15 working days from the date of notification of the product, according to the technical rules for the manufacturing, marketing and use of food supplements, which are approved through Government decision;

i) **daily consumption dose** - the quantity recommended by the manufacturer for daily consumption, depending on the packaging form of the respective food supplement;

j) **commercial communication** - any form of communication intended to promote, directly or indirectly, the products, services, image, name or denomination, company or emblem of a trader or member of a liberal profession.

SECTION II

General conditions regarding food supplements

Art. 3 - (1) The placing on the market by the manufacturer, importer or person responsible for placing the product on the Romanian market of food supplements is carried out on the basis of the notification certificate.

(2) Changes to the quality and/or composition of food supplements require a new notification of the product, with the issuance of a new notification certificate.

(3) The notification certificate is cancelled if the food supplement endangers human health or if its composition contains substances prohibited or withdrawn by intra-community regulatory documents subsequent to issuance of the Notification certificate.

Art. 4 - Food supplements are sold to the final consumer only in pre-packaged form.

Art. 5 - (1) Food supplements containing the ingredients provided for in Art. 1 (2) points a) and b) shall be notified to the National Institute of Public Health, by submitting a standard notification request, accompanied by the model of the label for the product in question, including the original label and the technical specification of the product, submitted in paper or electronic format. After analysing the notification file, for products compliant with the provisions of this Law, the National Institute of Public Health shall issue the notification certificate.

(2) *** Repealed by Emergency Ordinance no. 88/2023 of 24 October 2023

(3) Only vitamins and minerals included in community legislation may be used in the manufacturing of food supplements.

(4) The maximum amounts of vitamins and minerals present in food supplements, in the daily consumption portion recommended by the manufacturer, are established considering the upper safe levels of vitamins and minerals established by scientific risk assessment, based on generally accepted scientific data.

(5) To ensure the presence of certain amounts of vitamins and minerals in food supplements, minimum amounts must represent 15% of the reference values of the nutrient, as provided for in Community legislation.

(6) Food supplements containing the ingredients provided for in Art. 1 (2) points c) - g) shall be notified to the National Institute of Public Health, based on the notification file submitted in paper or electronic format. After analysing the notification file, for products which comply with the provisions of this Law, the National Institute of Public Health shall issue the notification certificate.

(7) The food supplements provided for in paragraphs (1) and (6) may not be placed on the market before the date of issuance of the notification certificate by the specialised structure designated at competent authority level.

Art. 6 - (1) Food supplements referred to in Art. 1 (2) notified in another Member State of the European Union and/or the European Economic Area may be placed on the market in Romania for the first time by notification to the National Institute of Public Health, by submitting a standard notification application, accompanied by a model of the product label in Romanian, including the original label and the mutual recognition declaration, in line with the provisions of Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008. Following the analysis of the documents, the National Institute of Public Health issues the notification certificate.

(2) For food supplements originating from third countries, manufacturers, importers or the person responsible for placing them on the market shall request a notification certificate from the competent authority, in accordance with the provisions of the rules set out in Art. 15.

Art. 7 - (1) The name under which the products provided for in this Law are marketed is that of **food supplement.**

(2) In the labelling, presentation and commercial communications regarding food supplements, addressed to consumers and healthcare professionals, attributing properties for the prevention, treatment or cure of a human disease or referring to such properties is prohibited.

(3) In the labelling, presentation and commercial communications regarding food supplements, using direct statements or statements suggesting that a varied and balanced diet cannot provide adequate amounts of nutrients is prohibited.

(4) Without prejudice to the provisions of 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, the label of food supplements must contain the following information:

a) the names of the categories of nutrients or substances which characterise the product or an indication of the nature of these nutrients or substances;

b) the recommended daily portion;

c) a warning against exceeding the recommended daily portion;

d) a warning against using food supplements as a substitute for a varied diet;

e) a warning that the products in question should be kept out of reach of small children.

(5) Commercial communications for the promotion of food supplements shall comply with the provisions of this law and of the regulatory acts on advertising; commercial communications for the promotion of food supplements shall use exclusively the information present on the food supplement label, analysed in the context of the notification certification procedure by the National Institute of Public Health, in accordance with the provisions of the national/European legislation in force.

Art. 8 - (1) The Ministry of Health shall post on its official website the following:

a) the documents required for the notification of food supplements;

b) the list of plants admitted in food supplements, taken from the Ministry of Agriculture and Rural Development;

c) the list of substances with nutritional or physiological effect admitted in food supplements;

d) the list of food supplements already notified to the Ministry of Health, through the specialised structures, namely the regional public health centres, since 2007, until the date of entry into force of this Law.

(2) The Ministry of Health shall display and update on its website, on a monthly basis, the list of food supplements provided for in Art. 1 paragraph (2), notified by the National Institute of Public Health.

SECTION III

Control and sanctions

Art. 9 - (1) The following deeds are considered contraventions:

a) labelling of food supplements non-compliant with the legislation in force, also taking into account the provisions of Art. 14 paragraph (2);

b) classifying food supplements in another category of food products or medical devices, with the aim of circumventing the provisions of this Law;

c) the marketing of food supplements which have exceeded their minimum durability date;

d) marketing of food supplements without a notification certificate;

e) failure to comply with the legal provisions relating to the ingredients in the lists provided for in Art. 8 b) and c);

d) advertising of food supplements, non-compliant with the legislation in force.

(1) The deeds provided for in paragraph (1) points a) and f) are sanctioned with a legal fine of 3,000 to 10,000 lei and a temporary suspension from marketing, until the deed becomes legal.

(2) The act provided for in paragraph (1) point b) is sanctioned with a legal fine of 10,000 to 12,000 lei and a suspension from marketing, until the offense is remedied.

(3) The deed provided for in paragraph (1) point c) is sanctioned with a legal fine of 7,000 to 9,000 lei and a permanent ban on marketing.

(4) The deeds provided for in paragraph (1) points d) and e) are sanctioned with a legal fine of 13,000 to 15,000 lei and a permanent ban on marketing.

(5) In the case of the contravention referred to in paragraph (1) point e), the non-compliance shall be notified on the rapid alert system for food and feed, and the notification certificate shall be cancelled by the competent authority.

Art. 10 - (1) The competent authority ensures the control of compliance with the provisions of this Law, establishes contraventions and applies sanctions for non-compliance with its provisions.

(2) The finding of contraventions and the application of sanctions for the acts provided for in Art. 9 (1) points a) and f) are made by the National Authority for Consumer Protection, upon notification of the competent authority.

Art. 11 - The contraventions of this Law and the sanctions are supplemented by the provisions of Government Decision no. 857/2011 on the establishment and sanctioning of contraventions of public health regulations, as further amended and supplemented, issued on the basis of Law no. 254/2010 repealing Law no. 98/1984 on the establishment and sanctioning of contraventions of public health and hygiene regulations.

Art. 12 - The provisions of Art. 9 are supplemented by the provisions of Government Ordinance no. 2/2001 on the legal regime of contraventions, approved as amended and supplemented by Law no. 180/2002, as further amended and supplemented.

Art. 13 - The deed of a person preparing or manufacturing counterfeit food supplements, as well as placing on the market, offering, selling or distributing such food supplements, knowing that they are counterfeit, is a crime punishable according to the provisions of Law No. 286/2009 on the Criminal Code, as further amended and supplemented.

SECTION IV

Final provisions

Art. 14 - (1) Food supplements placed on the market prior to the date of entry into force of this Law, which comply with its provisions, may continue to be marketed without requiring a new notification, in compliance with the conditions that were the basis for issuing the notification certificate.

(2) On this Law's entry into force, food supplements which do not comply with its provisions may be marketed until the expiry of the 'best before' date, but no later than 12 months, provided that they do not contain ingredients other than those mentioned in the lists provided for in Art. 8 paragraph (1) points b) and c) or do not represent a risk for consumers and are labelled in accordance with the legal provisions in force when placed on the market.

(2[1]) Advertising materials are subject to approval by the competent authority according to the procedure and requirements regulated by the technical rules for the application of this law, developed by the Ministry of Health and approved by Government Decision.

(3)*** Repealed by Emergency Ordinance no. 88/2023 of 24 October 2023

(4) In the event of information indicating that a food supplement endangers human health although it complies with the provisions of this Law, the competent authority may temporarily suspend or restrict the marketing of the food supplement in question on the Romanian territory; prompt notification of the European Commission shall be carried out in accordance with the legislation in force.

Art. 15 - (1) *The Ministry of Health develops the technical rules for the manufacture, marketing, advertising and use of food supplements, which are approved by Government Decision.*

(2) On the date of entry into force of the technical rules provided for in paragraph (1), Order of the Minister of Public Health no. 1069 of 19 June 2007 for the approval of the Rules on food supplements, published in the Official Gazette of Romania, Part I, no. 455 of 5 July 2007, as further amended, is repealed.

(3) Within 30 days from the entry into force of this Law, central public authorities with responsibilities regarding food supplements shall amend and/or supplement the subsequent legislation in the field, in accordance with the provisions of this Law.

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This law transposes Art. 1, Art. 2, Art. 6, Art. 7, Art. 10, Art. 12 paragraph (1), Art. 15 of 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, as amended by Commission Directive 2006/37/EC of 30 March 2006 amending Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards the inclusion of certain substances, by Regulation (EC) No 1137/2008 of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of the Treaty to Council Decision 1999/468/EC, as further amended and supplemented, and creates the legal framework necessary for the direct implementation of 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, as amended, as regards the lists of vitamins and

minerals and the forms in which they may be added to foods, including food supplements, and 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, as amended, as well as Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008.

This Law was adopted by the Romanian Parliament, in compliance with the provisions of Art. 75 and Art. 76 paragraph (1) of the Constitution of Romania, republished.

On behalf of the PRESIDENT OF THE CHAMBER OF DEPUTIES,

FLORIN IORDACHE

On behalf of the PRESIDENT OF THE SENATE,

ROBERT-MARIUS CAZANCIUC