

LONG AWAITED ROMANIAN LAW ON FOOD SUPPLEMENTS FINALLY ENACTED

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Abstract

The aim of this study is to raise awareness and to improve knowledge of food supplements legislation in Romania.

Special attention should be given to the new piece of legislation applicable in Romania – Law no. 56/2021 on food supplements, which is intended to bring light and transparency in this field, after transposing the 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 other European Union legislative acts.

After several years of legislative struggle, the Law no. 56/2021 has been promulgated on March 31, 2021 through the Presidential Decree no. 256/2021. Since the fines are consistent, attention should be given by the private players on the Romanian food supplements' market in order to comply with the new rules.

Therefore, this study intends to provide guidance for both legal professionals, and non-specialist legal professionals working in the field of food supplements.

Keywords: food supplements, dietary supplements, Law no. 56/2021, Health Ministry, Romania.

1. Introductory Remarks – What About Food Supplements in Romania?

Food (dietary) supplements are products that are becoming, each day, worldwide more attractive for the consumers. Their increasing interest in everyday consumption of food supplements push the international and national legislators to rule effectively in order to protect the health of the consumers, who should be correctly and completely informed by the producers or importers of such products.

In Romania the legal framework for food supplements is very complex, being applicable both European and national specific legislation.

Very recently the Romanian legislation applicable to food supplements has been amended through the promulgation of the Law no. 56/2021 on food supplements (hereinafter “*the Law no. 56/2021*”). Special attention should be given to this new law which is intended to align the Romanian applicable legislation to the European legislation, and to prevent unfair commercial practices in this field.

Since the fines provided by the Law no. 56/2021 are consistent, attention should be given by the private players on the Romanian food supplements' market in order to comply with the new rules.

In Romania, the regulation of food supplements is an attribute of the Health Ministry, and of the National Institute of Research and Development for Food Bioresources (in Romanian “*Institutul National de Cercetare-Dezvoltare pentru Bioresurse*”).

“*Alimentare*” – hereinafter abbreviated “*IBA*”), as we will emphasize in the second part of the study.

Please note that the National Agency for Medicines and Medical Devices of Romania (hereinafter abbreviated “*NAMMDR*”), the public institution operating as a legal entity subordinated to the Health Ministry, and which develops national strategies and policies in the field of medicines and medical devices, is not competent to regulate food supplements (as well as cosmetic products, controlled substances, and veterinary medicines). Therefore, we emphasize that the food supplements legislative framework is clearly different that the one regulating medicines.

According to the applicable legislation, food supplements may not legally claim a medicinal effect or combat diseases. In order to establish the medicinal product status of a product marketed as a food supplement, the NAMMDR has to investigate first its ingredients and to study its public presentation.

2. Certain Aspects Regarding the Applicable Legal Framework in Romania

Please note that the food supplements market in Europe “presents a less permissive specific comparative to the US”¹, whereas a specific legislative framework was created starting with the European 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 supplements² (hereinafter “*the Directive*”).

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¹ Emilia Stancu, Adriana-Elena Taerel, Valentina Soroceanu, Cristina Rais, Manuela Ghica, *Ethical Aspects of Food Supplements in EU and Romania*, in *Farmacia*, vol. 67, no. 4/2019, p. 736.

² Available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02002L0046-20170726> (consolidated version).

2002/46/EC”). The aim of this Directive is to create a legal framework for the food supplements’ producers/importers in order to ensure consumer protection in the European Community.

Among the most important aspects regulated by this Directive, we mention the creation of the list of vitamin and mineral supplements, the definition and the establishment of the purity criteria for substances and of the maximum amount of vitamins and minerals per daily portion of consumption, the setting up of the classification of micronutrients in a risk category.

Through art. 10 of the Directive 2002/46/EC, it was imposed to notify the food supplements in each Member State to the competent authority: “[t]o facilitate efficient monitoring of food supplements, Member States may require the manufacturer or the person placing the product on the market in their territory to notify the competent authority of that placing on the market by forwarding it a model of the label used for the product”.

As for the Romanian legislation, please bear in mind that the most relevant food supplements normative acts are:

- Emergency Government Ordinance no. 97/2001 regarding the production, circulation and commercialization of food (hereinafter abbreviated “*EGO 97/2001*”) approved by Law no. 57/2002;

- Joint Order no. 243/402/2005 of the Minister of Agriculture, Forests and Rural Development and Health Minister on the approval of technical rules for the production, processing, processing and marketing of medicinal and aromatic plants;

- Joint Order no. 1228/244/63/2005 of the Minister of Agriculture, Forests and Rural Development, Health Minister and President of the National Sanitary Veterinary and Food Safety Authority approving the Technical Norms on the commercialization of pre-dosed food supplements of animal and vegetal origin and/or of their mixtures with vitamins, minerals and other nutrients (hereinafter “*the Order no. 1228/2005*”);

- Health Minister Order no. 1069/2007 on approving the Norms on food supplements (hereinafter “*the Order no. 1069/2007*”);

- Law no. 56/2021 on food supplements.

Please note that, according to art. 15 para. (1) of the Law no. 56/2021, in 90 days from the entry into force of this law, the Health Ministry shall elaborate the technical norms for manufacturing, marketing, and use of food supplements (hereinafter “*the Norms on food supplements*”) which shall be approved through a government decision and shall abrogate the Order no. 1069/2007.

Moreover, please bear in mind that according to the art. 15 para. (2) of the Law no. 56/2021, on the date of entry into force of the technical norms above-mentioned, the Health Minister Order no. 1069/2007 on

approving the Norms on food supplements shall be abrogated.

But what are more precisely the food supplements? Pursuant to art. 2 letter a) of the Directive 2002/46/CE, food supplements means „*foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities*”³.

According to art. 10 of the Directive 2002/46/EC, „[t]o facilitate efficient monitoring of food supplements”, a manufacturer or the person placing on the market a food supplement shall notify the competent authority of that placing on the market, by forwarding it a model of the label used for the respective product.

Depending on the composition of foodstuffs, food supplements in Romania, have to be notified either before the Health Ministry or before the IBA.

As regards the notification before the Health Ministry, attention should be given to the Norms on food supplements, because once these Norms shall be adopted, the actual procedure set-up in the Order no. 1069/2007 shall be changed, although in the present the Health Ministry already represents the competent authority for the notification of food supplements consisting of nutrients (i.e. vitamins and minerals).

The notification procedure set-up by the Order no. 1069/2007 is quite simple, having an informative purpose, rather than an analytical one. According to art. 10 para. (1) of the norms contained in the Order no. 1069/2007, this procedure consists of submitting a notification form together with a template of the food supplement’s label (in hard and soft copy). According to art. 11 of the norms contained in the Order no. 1069/2007, the Health Ministry representatives shall evaluate the information on the label and shall issue the form attesting the registration of the notification within 48 hours from the moment of the notification submission, while in 15 days shall deliver the notification.

As regards the notification before the IBA, the provisions of the Order no. 1228/2005 are relevant, taking into consideration that certain products may be commercialized on the Romanian market only further to a prior notification to this institute.

Having in view the novelty character of the Law no. 56/2021, which has been published in the Romanian Official Gazette no. 332 dated April 1st, 2021, we shall further analyse it, considering the high interest in this piece of legislation.

³ Please note that this is also the exact definition used by the Romanian legislator in art. 2 letter a) of the Law no. 56/2021.

3. The Legislative Process of the Law no. 56/2021

We consider that the legislative process⁴ of the Law no. 56/2021 is very interesting to follow, reason for which we shall further analyse it. Even from the beginning we must emphasize that the Law no. 56/2021 has been promulgated after 8 years from the moment it was put on the table of the parliamentarians (i.e. no. L333/10.09.2012 / PL-x 468/12.11.2012⁵).

The first Chamber of the Parliament was the Senate, and the initiator of the law was the Government.

On October 30, 2012, the Senate has rejected the bill of law, and on November 12, 2012 it was presented in the Permanent Office of the Chamber of Deputies.

After receiving the notices from the Juridical, Discipline and Immunities Commission (on January 15th, 2013) and from the Commission for education (on February 19th, 2013), as well as the favorable report from the Commission for agriculture, silviculture, food industry and specific services and the Commission for health and family (on September 30, 2020), it has been submitted to debates on October 14th, 2020 and October 20th, 2020.

On October 20th, 2020, the Chamber of Deputies has adopted the bill of law establishing the legal framework regarding food supplements, commercialized as foodstuffs, bill that has been sent for promulgation, on October 26th, 2020, to the Romanian President.

On November 25th, 2020, the Romanian President, Mr Klaus Werner Iohannis, has attacked the bill of law to the Constitutional Court, arguing that, by means of its adoption, the law violates art. 61 para. (2) and art. 75 para (1) of the Romanian Constitution, being breached the competence of the Senate as the first chamber seized of the Parliament.

Arguing that the form of the initiator of the law provided a shared competence of several authorities⁶ depending on the composition of the food supplements, the Romanian President underlined that the final form of the piece of law overruled the constitutional principle of bicameralism.

On March 24, 2021, the Constitutional Court has rejected the objections of unconstitutionality through the Decision no. 902 dated December 16, 2021.

On March 31st, 2021, through the Presidential Decree no. 256/2021, the bill of law was enacted, becoming the Law no. 56/2021. The following day, on April 1st, 2021, the law has been published in the Romanian Official Gazette no. 332, and it came into force in 3 days after its publication date according to the first thesis of the art. 78 of the Romanian Constitution⁷.

4. The Provisions of the Law no. 56/2021 Under the Magnifying Lens

Establishing the legal framework of the food supplements⁸, please note that the provisions of this law are not applicable for (i) the drugs defined in title XVIII „Drug” of the Law no. 95/2006 regarding the reform in the health domain, republished, with the subsequent amendments and completions and for (ii) the food supplements based on medicinal and aromatic plants, as well as beehive products, ruled by the Law no. 491/2003, republished, with subsequent amendments and completions.

Even from the beginning of the law, the Romanian legislator clarifies on the establishment of the “*Health Minister as the competent authority in the field of the food supplements based on* [emphasis added]:

- a) vitamins, minerals;
- b) mixtures of vitamins and/or minerals;
- c) substances having a nutritional or physiological effect other than vitamins and minerals⁹;
- d) mixtures of vitamins and/or minerals with substances having a nutritional or physiological effect other than vitamins and minerals;
- e) mixtures of vitamins and/or minerals with vegetable and/or animal extracts;
- f) mixtures of vitamins and/or minerals with plant and/or animal extracts, with substances having a nutritional or physiological effect, with plants and/or beehive products¹⁰.”¹¹

Please note that according to art. 1 para. (3) of the Law no. 56/2021, in the use of mixtures containing vitamins, minerals, or substances having a nutritional or physiological effect other than vitamins and minerals; “*consumed as ingredients foreseen in para. 2 letters d)-f), the notification¹² shall be made to the*

⁴ Please see the information available on the website of the Chamber of Deputies (http://www.cdep.ro/pls/proiecte/upl_pck.proiect?idp=12983) or of the Senate (https://senat.ro/legis/lista.aspx?nr_cls=L333&an_cls=2012).

⁵ The number of the bill of law, given by the Senate and by the Chamber of Deputies.

⁶ E.g. the Health Minister, the Agriculture Minister and the Anti-Dopping National Agency instead of the Health Minister as unique competent authority in this field.

⁷ For the English version of the Romanian Constitution, please see the website of the Romanian Constitutional Court - <https://www.ccr.ro/en/constitution-of-roumania/>.

⁸ According to art. 1 para. (1) of the Law no. 56/2021.

⁹ By the expression “substances having a nutritional or physiological effect other than vitamins and minerals” the Romanian legislator understands “*amino acids, enzymes, prebiotics and probiotics, essential fatty acids, plant extracts, including plants, algae, lichens, fungi, as well as their essential extracts and oils and/or animal extracts, bioactive substances authorised and included in the Novel-Food Catalogue - new foods, of the European Union*” – please see art. 2 letter c) of the Law no. 56/2021.

¹⁰ I.e. pollen, propolis, honey and royal jelly according to art. 1 para. (2) letter h) of the Law no. 491/2003 regarding medicinal and aromatic plants, as well as beehive products.

¹¹ According to art. 1 para. (2) of the Law no. 56/2021.

¹² By “notification” it should be understood notifying the competent authority of the placing on the market of a food supplement.

*Health Ministry, after receipt of the technical advisory opinion issued by the Technical Committee referred to in art. 5 of Law no. 491/2003 regarding medicinal and aromatic plants, as well as beehive products, republished, with the subsequent amendments and completions, and for vegetal extracts, medicinal and aromatic plants, as well as for beehive products, the technical advisory opinion shall be requested by the Health Ministry.*¹³

The notification procedure in order to place a food supplement¹⁴ on the Romanian market has to be performed either by the manufacturer, the importer or the responsible person for placing the product on the market. The placing on the Romanian market is subject to the obtention of the notification certificate for the respective food supplement, and we underline that it shall not be possible to place a product on the market before the obtention of such certificate¹⁵.

The notification procedure is provided by art. 5 of the Law no. 56/2021, depending on the type of the ingredients of the food supplement to be placed on the Romanian market:

a) for the food supplements containing *only vitamins and minerals and/or mixtures of vitamins and minerals*¹⁶: the notification file consisting in a printed notification request, the notification form, accompanied by the model of the label for the product concerned, in electronic and *folio* form; the file shall be transmitted to the Health Ministry;

b) for the food supplements based on *substances with nutritional or physiological effect, other than vitamins and minerals, mixtures of vitamins and/or minerals with substances having a nutritional or physiological effect, other than vitamins and minerals, mixtures of vitamins and/or minerals with plant and/or animal extracts, mixtures of vitamins and/or minerals with plant and/or animal extracts, medicinal and/or aromatic plants and/or beehive products*: the notification file (in two copies, with the exact content) shall be notified to the institutions under the authority of the Health Ministry. A copy of the notification file submitted on which it shall be applied the visa for conformity with the original (in Romanian “*viza de conformitate cu originalul*”) shall be returned to the applicant with the notification certificate issued by the specialised structure of the Health Ministry.

Please note that the notification certificate to be issued by the competent authority is an administrative act¹⁷, which can be attacked according to the provisions of the Law no. 554/2004 on contentious administrative, with the subsequent amendments and completions.

The notification certificate shall be canceled in case of amendment of the quality and composition of

the respective food supplement¹⁸, no information being provided regarding the annulment procedure.

Article 6 of the Law no. 56/2021 brings new solutions to the problems existing on the food supplements Romanian market regarding the placing on the market of certain products:

“(1) The food supplements referred to in art. 5 paras. (1) and (6) notified in another Member State of the European Union and/or in the European Economic Area [emphasis added], can be placed for the first time on the Romanian market by notification to the competent authority, accompanied by a model of the product label and documents attesting that it is legally placed on the market in a Member State of the European Union and/or in the European Economic Area, in accordance with the provisions of the Regulation (EU) no. 515/2019 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully traded in another Member State and repealing the Regulation (EC) no. 764/2008. In this case, the competent authority shall issue a notification certificate.

2. For food supplements originating in third countries [emphasis added], manufacturers, importers or the person responsible for placing them on the market shall apply for a notification certificate from the competent authority in accordance with the provisions of the rules referred to in art. 15.”

These new provisions of Law no. 56/2021 do not answer, unfortunately, to essential questions, in our opinion.

Firstly, according to the Law no. 56/2021, it might be possible to notify food supplements containing plant and/or animal extracts not listed neither in the list of permitted ingredients, nor in the list of forbidden ingredients? A partial answer to this question can be found in art. 2 letter c) of the Law no. 56/2021 which provides that the ingredients of the food supplements must be authorised and included in the Novel Food Catalogue of the European Union. Taking into consideration the procedure to authorise and include new ingredients in the Novel Food Catalogue, it results that a new ingredient can be used for food supplements after it has been proven with safety and efficacy trials that the respective ingredient is safe for human use consumption.

Secondly, will it be sufficient for the notification of a new food supplement to file the certificate of notification issued by the country of origin? We cannot imagine, at this stage, this situation, having in view that before the Law no. 56/2021, these type of food supplements could not be notified upon IBA except the situation the food supplement contained ingredients

¹³ According to art. 1 para. (2) of the Law no. 56/2021.

¹⁴ Each food supplement shall be marketed to the final consumer only in prepackaged form.

¹⁵ According to art. 5 para. (7) of the Law no. 56/2021.

¹⁶ Please see art. 5 para. (1) of the Law no. 56/2021. We underline that for the manufacture of food supplements only vitamins and minerals provided in the European Union’s legislation can be used.

¹⁷ Please see Marta-Claudia Cliza, Constantin-Claudiu Ulariu, *Drept administrativ, revised edition according to the amendments of the Administrative Code*, Pro Universitaria Publishing House, Bucharest, 2020, p. 12.

¹⁸ According to art. 3 para. (2) of the Law no. 56/2021.

authorised by IBA. It is obvious that the Norms will be essential in order to answer this question.

Thirdly, during the notification procedure, in order to accept the health claims of a new food supplement, will the Health Ministry accept as proof the clinical trials conducted in third countries where domestic legislation accepts these trials on food supplements¹⁹ which do not treat any disease, just helps maintaining the health of the consumer?

We cannot imagine this situation because in Romania, the central authorities involved in the approval of any clinical trial are NAMDMR and the National Bioethics Committee for Medicines and Medical Devices (for ethical reasons) for drugs and medical devices only, and not competent (yet) for food supplements. If the Health Ministry decides to authorise NAMDMR for food supplements notification and research, NAMDMR will become as like a “Food and Drugs Administration” authority.

Fourthly, under the Law no. 56/2021, will IBA continue to notify food supplements containing medicinal and aromatic plants, as well as beehive products? Having in view that (i) at the moment of the entry into force of the Law no. 56/2021, IBA has suspended the activity of notification for new products according to Order no. 1228/2005, and that (ii) art. 15 para. (1) of the Law no. 56/2021 provides that in 90 days from the entry into force of this law, the Health Ministry shall elaborate the Norms which shall be approved through a government decision and shall abrogate the Order no. 1069/2007, we consider that the decision of IBA is either premature, or it betrays the direction in which the Norms shall be construed. In any case, the Norms will clarify which authority will be competent to notify the categories of food supplements in Romania.

As a result of the fact that the Health Ministry is the competent authority according to Law no. 56/2021, please bear in mind that it must display on its official website²⁰ several lists of:

- a) documents necessary for the notification of food supplements;
- b) plants accepted in food supplements, taken from the Ministry of Agriculture and Rural Development;
- c) substances having a nutritional or physiological effect permitted in food supplements;
- d) food supplements already notified to the Health Ministry, through the specialized structures, i.e. the regional public health centres, from 2007 until the date of entry into force of Law no. 56/2021;
- e) food supplements to be marketed in Romania,

as well as their label and their leaflets. This list shall be updated monthly.

According to the art. 14 para. (1) of the Law no. 56/2021, it is underlined that food supplements already notified *before* the entry into force of this law, will not require any other notification if are respected the conditions that have stood at the issuance of the notification certificate. However, please note that the food supplements that do not comply with the provisions of the Law no. 56/2021 may be marketed on the Romanian market “*until the expiration of the date of minimum durability, but not later than 12 months*”, provided that:

i. they do not contain ingredients other than those listed in the list of plants accepted in food supplements, taken from the Ministry of Agriculture and Rural Development or in the list of substances having a nutritional or physiological effect permitted in food supplements [art. 8 para. (1) letters b) and c) of the Law no. 56/2021]; *or*

ii. they do not constitute a risk for consumers and to be labeled in accordance with the legal provisions in force at the time of placing on the Romanian market²¹.

It is also important to underline that “[i]n the case of information (our note – not suspicion!) according to which a food supplement endangers human health even if it is in accordance with the provisions of this law, the competent authority (our note – the Health Ministry) may temporarily suspend or restrict the marketing of the food supplement in question in Romania; the European Commission shall be notified promptly in accordance with the legislation in force.”²².

As for the transitional provisions mentioned in the Law no. 56/2021, a few aspects deserve to be pointed out in order to discover how the correlation with other rules was thought by the legislator, so that the implementation of the Law no. 56/2021 proceeds naturally and avoids retroactivity or the conflict between successive norms.

As mentioned before, please note that, according to art. 15 para. (1) of the Law no. 56/2021, in 90 days from the entry into force of this law, the Health Ministry shall elaborate the Norms which shall be approved through a government decision and shall abrogate²³ the Order no. 1069/2007.

It is also expressly provided that, within 30 days from the entry into force of the Law no. 56/2021, “*the central public authorities that have attributions regarding the food supplements modify and/or complete the subsequent legislation in the field according to the provisions of the present law*”²⁴.

As regards the purpose of preventing unfair

¹⁹ Please see the case of a clinical trial conducted upon *Antrodia camphorata* used in a food supplement. *Antrodia camphorata* it is a rare and endemic fungus species originated in Taiwan island forestries. This trial is available at <https://www.clinicaltrials.gov/ct2/show/NCT01007656>.

²⁰ According to art. 8 of the Law no. 57/2021. At the moment of writing this study, we made a research on the website of the Health Ministry, but these lists were not yet available on www.ms.ro.

²¹ According to art. 14 para. (2) of the Law no. 57/2021.

²² According to art. 14 para. (4) of the Law no. 57/2021.

²³ According to art. 15 para. (2) of the Law no. 56/2021.

²⁴ According to art. 15 para. (3) of the Law no. 56/2021.

commercial practices, please have in mind that “[i]n the labelling, presentation and commercial communications relating to food supplements addressed to the consumers and health professionals, it is prohibited to assign the properties of prevention, treatment or cure of a human disease or to refer to such properties.”²⁵ It is also prohibited “the use of direct or suggesting statements that varied and balanced nutrition cannot provide adequate amounts of nutrients.”²⁶

Emphasis should be made that “[w]ithout prejudice to the rules in force on food labelling, the labelling of food supplements shall contain the following additional mentions:

a) the names of categories of nutrients and/or other substances having a nutritional or physiological effect characterising the product;

b) the daily dose recommended by the manufacturer;

c) the warning not to exceed the daily dose recommended by the manufacturer;

d) the warning that food supplements should not replace a varied and adequate diet;

e) the warning that products must be kept out of the reach of children.”²⁷

Additionally, please note that “[c]ommercial communications for the promotion of food supplements shall comply with the provisions of this law and of the special regulatory acts on advertising; in commercial communications to promote the properties of food supplements, shall be used only the information on the label and in the food supplement leaflet, information

approved by the competent authority, in accordance with the provisions of the national/European legislation in force.”²⁸ By “commercial communication” the legislator understands “any form of communication intended to promote, directly or indirectly, the products, services, image, name or corporate name, firm or emblem of a trader or of a member of a liberal profession”²⁹ without being made any reference to the clinical trials, scientific communication and fairs, usually considered as professional communication. Should we include here the reference to clinical trials made for the respective product? We consider that, in order to protect the innovation and the scientific progress, the citations should be permitted having in mind that the Law no. 56/2021 does not expressly prohibit it.

5. Control and Sanctions Imposed by the Law no. 57/2021. Final Provisions of the Law

The Health Ministry, in its capacity of competent authority according to the Law no. 56/2021, “shall ensure compliance with the provisions of this law, being able to establish infringements and apply penalties for the non-compliance with the provisions thereof.”³⁰

The following deeds, foreseen in art. 9 para. (1) of the Law no. 56/2021, constitute offences according to the table below (made by us in order to simplify the legal information):

Letter	Offence	Sanction
a)	labelling noncompliant with the legislation in force for food supplements	civil fine from 3,000 to 10,000 RON and temporary stop from marketing until the entry into legality
b)	classifying food supplements in other category of foodstuffs or medical devices for the purpose of circumventing the provisions of this Law	civil fine from 10,000 to 12,000 RON and temporary stop from marketing until the misconduct is remedied
c)	marketing of food supplements exceeding the date of minimum durability	civil fine from 7,000 to 9,000 RON and definitive stop from marketing
d)	marketing of food supplements without a certificate of notification	civil fine from 13,000 to 15,000 RON and definitive stop from marketing
e)	failure to comply with the legal provisions relating to the plants and substances having a nutritional or physiological effect, permitted in food supplements ³¹	civil fine from 13,000 to 15,000 RON and definitive stop from marketing
f)	advertising non-compliant with the legislation in force for food supplements	civil fine from 3,000 to 10,000 RON and temporary stop from marketing until the entry into legality

²⁵ According to art. 7 para. (2) of the Law no. 56/2021.

²⁶ According to art. 7 para. (3) of the Law no. 56/2021.

²⁷ According to art. 7 para. (4) of the Law no. 56/2021.

²⁸ According to art. 7 para. (5) of the Law no. 56/2021.

²⁹ Please see art. 2 letter j) of the Law no. 56/2021.

³⁰ According to art. 10 par. (1) to the Law no. 56/2021.

³¹ Please note that the non-compliance shall be notified on the rapid alert system for food and feedingstuffs and the notification certificate shall be cancelled by the Health Ministry.

Please note that the rules regarding the offences and sanctions provided in the Law no. 56/2021 shall be completed with the legal provisions of the (i) Government Decision no. 857/2011 on the establishment and sanctioning of offences of public health rules, with subsequent amendments and completions, issued on the basis of Law no. 254/2010 for the repeal of Law no. 98/1984 on the establishment and sanctioning of the offences to the legal rules of hygiene and public health, as well as with the provisions of the (ii) Government Decision no. 2/2021 on the regime of offences, approved with amendments and completions through Law no. 180/2002, with subsequent amendments and completions.

Additionally, please bear in mind that “the deed of the person to prepare or manufacture counterfeit food supplements, as well as to introduce, offer, sell or distribute such food supplements on the market, knowing that they are counterfeit, constitutes a crime and it is punished according to the provisions of Law no. 286/2009 on the Criminal Code, with subsequent amendments and completions.”³².

6. Concluding Remarks – What the Future Holds for the Romanian Food Supplements Market?

Having in view that it is undisputed that the global consumption of food supplements is fastly growing, even in Romania, we consider that the topic of our study will be of high interest for both legal professionals and non-specialist legal professionals working in the field of food supplements.

Containing vegetal and animal substances, together with minerals, vitamins, and other micro- or macronutrients, the food supplements have the role to complete a normal diet in order to maintain health or to improve it, and not to treat it.

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- www.senat.ro.

Although the Law no. 56/2021 has been waited among the years to change certain things in the food supplements market, things are quite unclear until the Norms on food supplements will be adopted further on.

The Norms on food supplements are being awaited by the food supplements market. Many questions arise to all the players in the market, out of which we mention the following:

i. What institution of the Health Ministry shall be competent to analyse the notification file – the NAMMDR?

ii. What will contain the notification file?

iii. Besides the documentation required, would it also be required a statement of commitment of the applicant?

iv. What will contain the notification certificate?

Hoping that the new legislation’s requirements, contrary to the Order no. 1228/2005, shall not go beyond the notification requirements imposed under the Directive 2002/46/EC and shall not affect the goal of this Directive, namely affecting the free movement of such food supplements and the creation equal conditions of competition for the players acting in the internal market. We strongly believe that the placing on the Romanian market must be in line with the European law.

In order not to be victims of the food supplements market, the consumers found on the Romanian territory must benefit of a clear and coherent legal frame.

Of course that special attention should be given to the online marketing of food supplements because in the recent years many alert signals had been given regarding the charlatanism with certain food supplements³³.

Even though many questions arise and, in the present, the Romanian legislation seems unclear and incomplete, we shall see very soon what the future reserves to us, when the Norms shall be adopted.

Until then, stay connected and informed about all the changes in the food supplement market.

³² According to art. 13 of the Law no. 56/2021.

³³ Please see, for example, the recent investigation made by the Recorder.ro specialists, revealing a a business worth tens of millions of euros, investigation published online on 25 February, 2021, on <https://recorder.ro/uriasa-escrocherie-a-suplimentelor-alimentare-milioane-de-euro-din-minciuni-care-impanzesc-internetul/>.