

The supplement, at the border between food and medicine Suplimentul, la granița dintre aliment și medicament

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Cuvinte cheie: *supliment, hrană complementară, medicament, animale de companie*
Keywords: *supplements, complementary feed, medicine, companion animals*

Rezumat

Acest articol își propune să exploreze statutul juridic incert al suplimentelor pentru animale, situate la granița dintre aliment și medicament, din perspectiva legislației europene și naționale. Conform legislației europene, în cazul suplimentelor de uz veterinar nu este utilizat termenul de „supliment alimentar pentru animale”, acestea fiind încadrate în categoria furajelor complementare sau a aditivilor furajeri. În timp ce hrana pentru animalele de fermă este reglementată strict prin Regulamentele (CE) nr. 183/2005, hrana pentru animalele de companie este exclusă din această normă, creând o lacună legislativă semnificativă. Această excludere face ca suplimentele pentru animalele de companie să nu fie supuse aceluiași cerințe stricte privind siguranța, trasabilitatea și controlul calității. Mai mult, suplimentele nu sunt încadrate clar nici în categoria hranei, nici în cea a medicamentelor, ceea ce complică procesul de autorizare și comercializare. Lucrarea analizează aceste neconcordanțe și evidențiază necesitatea elaborării unei legislații clare care să reglementeze suplimentele pentru animale, asigurând standarde unitare de siguranță și eficiență.

Abstract

This article aims to explore the uncertain legal status of animal supplements, positioned at the intersection between feed and medicine, from the perspective of both European and national legislation. According to European law, the term "animal dietary supplement" is not used in the context of veterinary products; instead, such products are classified as either complementary feed or feed additives. While feed intended for farm animals is strictly regulated under Regulations (EC) No. 183/2005, pet food is excluded from this provision, resulting in a significant legislative gap. This exclusion means that supplements for companion animals are not subject to the same stringent requirements regarding safety, traceability, and quality control. Furthermore, these supplements are not clearly categorized as either feed or medicine, which complicates the processes of authorization and commercialization. This paper analyzes these inconsistencies and highlights the need for clear legislation to govern animal supplements, ensuring uniform standards of safety and efficacy.

Introduction

Food supplements are products that contain nutrients or other substances with a nutritional or physiological effect, intended to supplement the diet.

At the European level, food supplements for human use are regulated by Directive 2002/46/EC, which defines them as "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" [3].

In Romania, food supplements for human use are regulated by Law No. 56/2021, which transposes the requirements of the European directive and sets conditions regarding their composition, labeling, and marketing.

According to this law, food supplements must contain safe ingredients, and manufacturers are required to ensure their traceability.

Moreover, food supplements for human use must not be presented as having properties for preventing, treating, or curing diseases [7].

In the case of supplements for veterinary use, European legislation does not use the term "food supplement for animals," but rather classifies them as complementary feed or feed additives.

According to Regulation (EC) No. 1831/2003 on additives for use in animal nutrition, animal supplements are considered feed additives if they are intended to improve the nutritional value of feed or support certain physiological functions [4].

Although Regulation (EC) No. 767/2009 regulates how feed may be placed on the market and used within the European Union, it does not provide a clear framework for food supplements intended for companion animals.

In fact, although the regulation also applies to feed for animals not kept for food production (such as dogs and cats), its provisions focus mainly on basic nutrition and do not specifically cover products that have a physiological or behavioral effect, as is the case with many modern supplements [6].

To highlight the essential differences between the regulations applicable to food supplements for human use and those for companion animals, a comparative table is presented below (Table 1).

Table 1.

Differences between regulations applicable to dietary supplements for human use and those for pets

Regulated aspect	Supplements for human use	Supplements for pets
European legal framework	Directive 2002/46/EC	Reg. (EC) 1831/2003, Reg. (EC) 767/2009 (unclear)
National legal framework (Romania)	Law No. 56/2021	No specific regulation
Term recognized in legislation	Yes – "food supplement"	No – terms such as "complementary feed" are used
Traceability and safety	Mandatory by law	Lack of explicit requirements for companion animals
Clarity on product classification	Clear (food vs. medicine)	Unclear (between feed, additive, medicine)
Labeling and promotion	Strictly regulated	Unevenly regulated, different interpretations
Authorization of manufacturing units	Clearly established	Unclear, unevenly applied by local authorities

In addition, the definitions provided by current legislation — such as those of complementary feed, feed intended for particular nutritional purposes, or feed additive — are not sufficient to cover products containing ingredients with an active physiological role.

For example, a product containing tryptophan, valerian extract, and B-complex vitamins has effects on the animal's emotional and cognitive state but cannot be strictly classified as either feed or medicine, which

creates authorization and labeling issues for manufacturers [4,6].

This difficulty is also mentioned in Commission Recommendation 2011/25/EU, which highlights the fact that national authorities often face challenges in correctly classifying such products, which may hinder their free movement within the internal market.

Although the Commission provides a set of guidelines for distinguishing between feed materials, additives, and medicinal products, there is no clear set of priority criteria, but

rather an individual case-by-case approach, which generates legal uncertainty [2].

For a synthetic representation of the regulatory framework applicable to food supplements depending on their intended use,

Figure 1 illustrates the main differences and gaps between the regulations applicable to human use and those applicable to veterinary use, with a focus on the specific situation of companion animals.

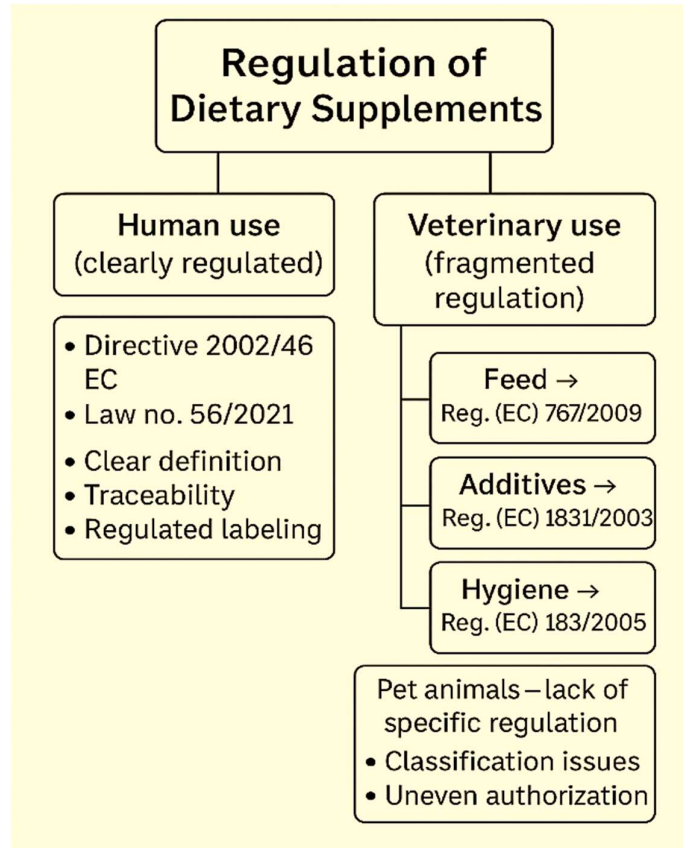


Figure 1. Structure of regulation of food supplements for human and veterinary use

Another important aspect is related to product safety and traceability.

Regulation (EC) No. 183/2005 on feed hygiene sets strict rules for all stages of the production and distribution of animal feed but excludes, through Article 2, feed intended for animals not kept for food production, namely companion animals.

As a result, an entire segment of products escapes the requirements related to traceability, hygiene, and authorization, which may lead to less controlled products in terms of quality [5].

This exclusion is concerning in the context where companion animals can be just

as vulnerable to chemical or microbiological contaminants as farm animals.

At the same time, the beneficiaries (in this case, pet owners) are increasingly attentive to the quality and safety of the products administered to their animals.

However, the absence of a specific legal framework leads to a fragmented market, where manufacturers formulate ineffective products merely to avoid the risk of reclassification as veterinary medicinal products [6].

A major problem faced by economic operators in Romania who intend to produce feed or supplements for companion animals is

the lack of a clear legislative framework for the authorization of manufacturing units.

Order No. 44/2017 issued by the National Sanitary Veterinary and Food Safety Authority (ANSVSA), which approves the veterinary-sanitary norm on the authorization procedure of units in the field of animal feed, refers strictly to feed for farm animals, without explicitly mentioning its applicability in the case of companion animals.

In the absence of a clear provision in the text of the order, county authorities interpret the requirements inconsistently, with some categorically refusing to grant authorization to units that do not produce feed intended for the human food chain, but exclusively for dogs, cats, or other companion animals [1].

In the absence of specific regulation, there is no clear mechanism for authorizing factories that wish to produce complementary feed — the category under which most supplements for companion animals fall.

These products, which include combinations of vitamins, minerals, amino acids, plant extracts, or essential fatty acids, cannot be authorized either as additives (which require a lengthy European procedure), nor as classical feed, because they are not intended for farm animals and do not meet the basic criteria of complete feed [8,9].

Therefore, the need for dedicated legislation for food supplements intended for companion animals — a category at the intersection of feed and medicine — is becoming increasingly clear.

The absence of a specific authorization framework for pet food and supplements in Romania stands in stark contrast to the legislation of other EU member states, which have adopted complementary regulations or have explicitly extended the applicability of existing norms.

Creating such a category, similar to food supplements for human use, would enable the safe and effective use of active ingredients, ensure uniform labeling and marketing

conditions, and encourage innovation in this emerging field.

Conclusions

The regulation of food supplements highlights a significant difference between products intended for human consumption and those for companion animals.

While supplements for humans benefit from a clear and unified legal framework at both the European and national levels, those for companion animals suffer from a lack of specific regulation, which creates legal uncertainties, authorization difficulties, and safety risks.

This legislative gap undermines both animal protection and consumer trust.

Therefore, the development of a dedicated regulatory framework is necessary, one that distinctly governs food supplements for companion animals, in order to ensure traceability, quality, and the responsible use of these products on the Romanian and European markets.

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