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Regulatory Aspects of Omega Polyunsaturated Fatty Acids in Dietary Supplements

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Authors' contributions

This work was carried out in collaboration between all authors. Author BH designed the study and wrote the first draft of the manuscript. Authors VP and DO managed the processing of the data of the study and performed the final draft of the study. Author SI managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Background: Food additives are subject to certain regulatory requirements, as in some countries, the control is very strict, while in others there is almost no control. Some food supplements can affect existing diseases or interact with some medications, food and beverage, a fact that is not mentioned on the packaging or in product instructions.
Methods: The aim of the study is to analyze the legislative framework for authorization and use of omega polyunsaturated fatty acids in the US and the European Union. The documents of 10 pieces of legislation were analyzed.
Results: Since 1994 the dietary supplements in the United States has been governed by the Dietary Supplement Health and Education Act (DSHEA). The European Union (EU) directive on

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food additives 2002/46/EC specifies harmonized rules for labeling of supplements and introduces specific rules on vitamins and minerals used in food supplements. The aim is to harmonize legislation and ensure that these products are safe and appropriately labeled so that consumers can make informed choices.

Conclusions: Due to heightened expectations and requirements for food additives worldwide regulation and legislation will continue to increase and ensure their quality, as well as their effects and safe use in all possible mechanisms.

Keywords: Food additives; omega polyunsaturated fatty acids; legislation.

1. INTRODUCTION

Certain food additives are usually marketed to relieve symptoms or to address systemic conditions, and the only real requirement of the Dietary Supplement Health and Education Act was in "labeling" of food additives related to specific disease and possible side-effects. Manufacturers are not required to indicate their qualitative and quantitative composition [1]. In the medical literature, reports have been published on unexpected toxicity of unauthorized food additives. They include reported toxic effects of cardiac glycosides, elevated estrogen with clinical effects from using herbal products marketed for "improving the immune system" for patients with prostate cancer [2], and undeclared potentially toxic substances or heavy metals as one-third of Asian food supplements patented in California [3].

Some of the most popular and best-selling nutritional supplements (food additives) worldwide fall into the following groups: hondroprotectors - glucosamine, chondroitin, hyaluronic acid; Cardioprotectants - Lycopene, omega-3 polyunsaturated fatty acids, co-Q10; Probiotics - based on B. Essensis, L. Bulgaricus, Str. thermophilus; Prebiotics and synbiotics; Soy isoflavones; Eye protectors - lutein and zeaxanthin; Minerals - calcium and magnesium; Herbs - green tea, ginkgo biloba, ginseng, and garlic [4].

A growing interest has been observed in dietary supplements containing omega-3 polyunsaturated fatty acids (PUFAs) because of the established relationship between fish consumption (source of omega-3 PUFA) or omega-3 in the form of supplements and a reduced risk of cognitive decline or Alzheimer's disease (AD) as Omega-3 polyunsaturated fatty acids have multiple mechanisms of action in the brain and vascular systems that are protective against cognitive decline and dementia. Primarily they reduce cardiovascular risk factors such as triglyceridemia and improve cerebral circulation found in rat models [5,6].

1.1 Purpose

To analyse the legislative framework for authorization and use of omega polyunsaturated fatty acids in the US and countries of the European Union.

2. MATERIALS

The documents of 10 pieces of legislation were analysed, including:

The Food and Drug Administration Amendments Act (FDAAA) of 2007;

Dietary supplement health and education act (DSHEA);

Regulation (EC) № 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives;

Directive 2000/13/ EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to labeling, presentation and advertising of foodstuffs;

Directive 2002/46 / EC;

Regulation (EU) № 1333/2008;

Regulation (EU) № 116/2010;

Regulations 2013 (WSI 2013 No. 1591 (W255));

Regulation (Northern Ireland) 2013 (SR 2013 No.220);

Rules of Procedure (Scotland) Act 2013 (SSI 2013 No. 266);

Through systematic review of keywords "food supplements", "polyunsaturated fatty acids",

"omega polyunsaturated fatty acids" in scientific databases: Scopus, Medline, Google Scholar, Springer and others were identified in 10 documents connected with regular aspects at the national level. The data were processed statistically.

3. RESULTS AND DISCUSSION

3.1 Food Additives in the US

In 1958, ammendments to laws on food additives corrected the Law on Food, Drug and Cosmetics created in 1938 in the US. These changes aimed to improve on the safety of new food additives. The amendments provided a precise definition of a food additive and required proof of safety for these substances by scientific experts, based on a long history of use extending back before 1958 or based on scientific research. Under this law, new food additives are required to undergo testing, including guidelines stipulated by the so-called Delaney clause. The Delaney clause is a regulation in the amendment that requires that if a substance has demonstrated a potential possibility to cause cancer in humans or animals, then it should not be used as a food additive (dietary supplement) [7].

Since 1994 the sale of dietary supplements in the United States has been governed by the Dietary Supplement Health and Education Act (DSHEA). Under DSHEA, a manufacturer is obliged to ensure that supplements are safe for consumption and not harmful to human health before they are marketed. A dietary supplement (food additive) is a product taken orally, contains a "dietary ingredient intended to supplement the diet," as "food ingredients" in these products may include vitamins, minerals, herbs or other botanicals, amino acids and substances such as enzymes, organ tissues, and metabolites. Food additives may be extracts or concentrates, and may be in various forms: tablet, capsule, gelcap, liquid, or powder [8].

The manufacturer is not required to register products under the regulatory authority - the administration of food and medicines by the Food and Drug Administration (FDA), or obtain approval before producing or marketing products. The manufacturer is responsible for the information on the label - whether it is true and not misleading. The FDA intervenes in cases where unsafe products appear on the market [8].

Food additives and nutrients are subject to a different standard of efficacy and safety unlike pharmaceutical products and functional foods, even though they may share the goal of improving health. The Dietary Supplement Health and Education Act (DSHEA), approved by the US Congress in 1994, was designed to facilitate public access to so-called "natural" drugs. The law assumes that all dietary supplements marketed before October 1994 are safe and that new additives may be marketed only to ensure safety of the manufacturer, bypassing the normal procedures of the FDA, which requires proof of safety for the public consumption of pharmaceutical products [7-9].

3.2 Food Additives in the European Union

The specific characteristics of food additives and their historically prolonged use have warranted special attention by the European Community legislation on food.

According to the World Health Organization, the Department of Food Safety and the European Food Safety Authority / EFSA /a significant number of supplements, even those known for a long time and produced by large companies (so-called "recognized leaders") around the world do not meet certain criteria of European legislation.

The European Union (EU) directive on food additives 2002/46 / EC specifies harmonized rules for labeling of supplements and introduces specific rules on vitamins and minerals used in food supplements. From August 2005 Annex II to the Directive became law, which contained a list of vitamins and minerals that can be used in supplements. In the so-called positive list 28 vitamins and minerals considered safe for health were included.

According to Directive 2002/46/ EC of the European Parliament, food additives are concentrated sources of nutrients or other substances with a nutritional or physiological effect, whose purpose is to supplement the normal diet. They are marketed in ‘dose’ forms, i.e. as tablets, capsules, liquids in measured doses, etc. The aim is to harmonize legislation and ensure that these products are safe and appropriately labeled so that consumers can make informed choices.

Table 1 shows similarities and differences in European and American legislation on food additives. The most common definition can be

found in US law and a detailed definition found in the Bulgarian legislation, noting that essential fatty acids, fish and vegetable oils belong to classification substances with a nutritional or physiological effect. In all four legal documents there is a clear classification of food additives.

Table 2 shows that all four regulatory documents are similar in terms of expectations for dosage and standardization of food additives and in testing and proving the quality, effectiveness and safety of food additives. Some important differences can be found in regulation and registration, such as how US producers are not obliged to register products with the regulatory authority (FDA), or obtain approval before producing or marketing products. The US manufacturer is responsible for the information on the label - whether it is true and not misleading. The FDA intervenes in cases in which unsafe products appear on the market. Unlike the US, in Bulgaria, manufacturers marketing supplements in Bulgaria for the first time must inform the premarket Regional Health Inspectorate (RHI) and register their product with them. This likely ensures stricter control of food in Bulgaria. Also, in contrast to the United States and the FDA, European legislation is very strict in terms of criteria for defining the minimal amount of certain substances, such as omega PUFA, needed to be in a given product for it to be labeled as containing this substance, as shown in Table 3.

Table 1. Analysis of legislation on the definition and classification of food additives

Country	Legal document	Definition of food additives	Classification
USA	Dietary Supplement Health and Education Act (DSHEA) [8].	A product taken orally that contains a "dietary ingredient intended to supplement the diet."	Yes
European Union	Directive on food additives 2002/46 / EC Regulation (EU) № 1333/2008 [9]	Food additives are concentrated sources of nutrients or other substances with a nutritional or physiological effect, whose purpose is to supplement a normal diet.	Yes
England, Scotland, Ireland	Regulation (EU) № 1333/2008 is implemented in England by food regulations 2013 (SI Regulation (Northern Ireland) 2013 (Sr 2013 no. 220) Rules of Procedure (Scotland) Act 2013 (ssi 2013 no. 266) [10]	The term "food additive" is defined in each of the three normative Acts considered.	Yes
Bulgaria	Decree № 47 of December 28, 2004 [11]	Nutrients "are: a) vitamins; b) minerals. "The substances with a nutritional or physiological effect" are provitamins, protein, amino acids, peptides, essential fatty acids, fish and vegetable oils, carbohydrates, fiber, metabolites, probiotics and prebiotics, bee products, food concentrates, enzymes, parts and extracts of plants, organic and inorganic bioactive substances, alone or in combination.	Yes

Table 2. Analysis of legislation on regulation, standardization and dosage of food supplements

Country	Regulation	Dosage	Standardization in terms of quality, efficiency, and safety
USA	Manufacturer not required to register products with regulatory authority (FDA), or obtain approval before producing or marketing products. Manufacturer is responsible for information on label - whether it is true and not misleading. FDA intervenes in cases where unsafe products appear on the market.	Yes	Yes
European Union	Food additives should be approved and used only if they fulfill criteria laid down in the Regulations. Food additives must be safe when used; there must be a scientific justification for their use; their use must not mislead the consumer and must bring a benefit to consumers.	Yes	Yes
England Scotland Ireland	Responsibility for the application and interpretation of the law lies with the British law enforcement authorities, Courthouse UK, and in extreme cases with the European Court of Justice (ECJ). Relevant directives, however, provide for disputes on specific issues regarding the interpretation to be resolved, if necessary, by reference to the Standing Committee of the European Committee on the Food Chain and Animal Health (hereinafter referred to soon: Standing Committee on Food)	Yes	Yes
Bulgaria	Dietary supplements are marketed only if they meet requirements of this Ordinance. Manufacturers or retailers in Bulgaria marketing supplements for first time inform the premarket Regional Health Inspectorate (RHI) in its headquarters, and if there is no such local office in the Republic of Bulgaria - in their chosen Regional Health Inspectorate (RHI)	Yes	Yes

Table 3. Differences in categories of fat, according to European legislation

Health claims	Content
“Source of omega-3 fatty acids “	A claim that a food is a source of omega-3 fatty acids, and any claim likely to have the same meaning for the consumer, may only be made when the product contains at least 0.3 g alpha-linolenic acid per 100 g and per 100 kcal, or at least 40 mg of the sum of Eicosapentaenoic acid and Docosahexaenoic acid per 100 g and per 100kcal.
“High omega-3 fatty acids”‘	A claim that a food is high in omega-3 fatty acids, and any claim likely to have the same meaning for the consumer may only be made when the product contains at least 0.6 g alpha-linolenic acid per 100 g and per 100 kcal, or at least 80mg of the sum of Eicosapentaenoic acid and Docosahexaenoic acid per 100g and per 100kcal.

Health claims	Content
"High monounsaturated fat"	A claim that a food is high in monounsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made when at least 45% of the fatty acids present in the product are derived from monounsaturated fat under the condition that monounsaturated fat provides more than 20% of energy of the product.
"High polyunsaturated fat"	A claim that a food is high in polyunsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made when at least 45% of the fatty acids present in the product are derived from polyunsaturated fat under the condition that polyunsaturated fat provides more than 20% of energy of the product.
'High unsaturated fat'	A claim that a food is high in unsaturated fat, and any claim likely to have the same meaning for the consumer may only be made when at least 70% of fatty acids present in the product are derived from unsaturated fat under the condition that unsaturated fat provides more than 20% of energy of the product.

4. CONCLUSIONS

Due to heightened expectations and requirements for food additives worldwide regulation and legislation will continue to increase and ensure their quality, as well as their effects and safe use in all possible mechanisms. Control over their resources, raw materials, technologies of extraction, transportation, processing, production cycle, formulation, packaging, labeling, advertising and marketing practices will continue to increase and will become more precisely regulated. This additional regulation will involve increasingly more market monitoring by independent bodies such as government and non-governmental organizations and individuals, as well as the associations of producers and importers of food additives, consumer associations, medical experts, and users.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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