

THE MEMBERS OF FLAVON-FAMILY ARE HEALTH-CONSCIOUS DIETARY SUPPLEMENTS

What should we know about dietary supplements?

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Functional food and dietary supplements are in the middle of the interest of trading, marketing, and media. In order to obey the regulations of law and not to deceive the consumer about the product, it is necessary to clearly understand what we can claim, say about a product. The aim of current compilation is to sum up the information to be observed about the main USA and EU regulations and guidelines related to dietary supplements.

1.) Historical background

The supplement of food with physiologically important ingredients is not the modern age's invention. Until 10,000–8,000 B.C. mankind got food from nature. We can say that until that time, the human race was on "real bionutrition" /e.g. the intake of fat was about the half and the consumption of salt was about the 1/6 of today's; they consumed twice or three times as much protein; did not consume refined sugar; the amount of alcohol consumption was zero or very minimal; compared to these days, people ate 4 or 5 times as much of Vitamin-C as today, they ate more fibers, calcium, kalium, etc./.

Using plant materials and/or animal organs as supplement, the supplement of food in order to be stronger and faster is more thousands of years old, which are proven by the stone tables of the Sumerian and the ancient artifacts found at the rivers Tigris and Euphrates and in China, too, around 400 B.C. Persian doctor Melanpaus suggested his king to put steel wool in the wine of the soldiers in order to enhance their strength. In 1831, French doctor Boussingault suggested salt to be iodized for the prevention of struma (goitre). In 1920 USA FDA permitted cod-liver oil with high Vitamin-D and -A content for "special nutrition aims". In 1929 R. Lee published the basic idea of dietary supplement: "During food processing nutrients are lost, so we need to supplement them." Not long after this statement, in 1934 the company 'Hoffmann-La Roche' launched their 'Redoxon Vitamin C' pills on the market.

Nowadays, the yearly turnover of dietary supplements of the world is over hundreds of billions of dollars.

2.) The USA (EU) regulations of dietary supplements

The dietary supplement law entered on the 15th of October, 1994 in the USA, subscribed by Bill Clinton and still valid today is the:

"Dietary Supplement Health and Education Act /DSHEA/"

According to this law's definition:

"...Dietary supplements supplement nutrition with vitamins, minerals, plant (other than tobacco) ingredients, extracts, metabolites or the combination of the mentioned, and with materials that are historically used for supplement diets."

Dietary supplements are not traditional food, they are in the form of tablets, pills, powders, liquids, extracts, and they contain the mark 'dietary supplement' on their packages.

USA DSHEA /1994/ regulates dietary supplements as "food" and not as "medicines", and if the product turns out to be "harmful for the body", they forward the issue to the FDA's competence and claim that the same good manufacturing practices /GMPs/ are valid for dietary supplements as for food.

The definitions of basic concepts according to laws and scientific research so far:

- "food": is a material (of natural origin) which helps maintain life and growing;

- “diet”: the (personal/social/religious) form of consuming food, nutrition and drinks;
- “supplement”: what helps supply and complete deficiencies and maintain the need;
- “The aim of dietary supplement is to improve the person’s nutrition state.”

When it comes to agents, USA DSHEA distinguishes “old” and “new” ingredients:

- “old” agents are those which had already been on the market before the law was entered /October 15, 1994/ and they had been consumed constantly. These are considered as “safe” (“Generally Recognised as Safe” = GRAS). The producer does not need to certify the safety of these agents to the FDA, they only have obligation to notify.
- in case of “new” ingredients the producer need to prove the agent being “really safe” by submitting documents to the FDA, at least 75 days before introducing a new dietary ingredient into interstate commerce.

USA DSHEA allows us to give and mediate scientific articles, scientific information which help consumers make informed choices related to the particular dietary supplement product.

USA DSHEA is clear about dietary supplements: “This product is not intended to diagnose, treat, cure, or prevent any disease.”

Current laws /in the EU, too/ say that claims about dietary supplements must be based on a scientific agreement and must be in accordance with the latest and current scientific results. It is obvious that the nutrition role and the pharmacological role of a dietary supplement need to be distinguished (as much as possible).

Dietary supplement should be judged from the “disorder” in the balance of the existing nutrition state, and should not be considered as “absolutely necessary”.

The following types of claims can be stated about dietary supplements:

- health claim: it draws attention to the coherence between an ingredient or the product and the lowering of the risk of a disease or diseases or the health state.
- statement concerning an ingredient or the composition: it draws attention to the relative amount of a particular ingredient or more ingredients in the product.
- Nutritional Support statement: it draws attention to the possible effects of the product on the working of the body’s organs/systems, but must not refer to any specific disease.

So, we cannot cure with dietary supplement products and we cannot assign curing effect to them, but we can make claims that refer to the product having effects on the construction, function, or “good feeling” state of the body, for example:

- “Calcium builds strong bones and teeth.”
- “The proper amount of Calcium in the food of teenagers and young women can lower the risk of osteoporosis later on in their lives.”

Examples for what we “cannot say” and what we “can say”:

- 1.) we cannot say: “The product treats breast cancer.”
but we can say: “The product supports the health of the breast.”

- 2.) we cannot say: “The high antioxidant content of the product cures vascular disorders and heart-attacks.”
but we can say: “The high antioxidant content of the product provides a strong antioxidant defense for the heart and the cardiovascular system.”

The most important keywords of claims related to dietary supplements: “HELP”, “PROVIDE”, “MAINTAIN”, “SUPPORT”.

To sum up, it can be established that there is no coherently accepted international legal definition. There are slightly different /sometimes more different/ interpretations between different countries, like the USA and the EU. On the July 1, 2011, American senator Dick Durbin introduced S.1310, the “Dietary Supplement Labeling Act of 2011”. Senator Durbin’s bill was directed the FDA to define “conventional foods”, require manufacturers to register dietary supplements with the FDA, require labels to disclose the known risks of ingredients.

In the 5th program point (“Encourage food product reformulation and safe production of dietary supplements”) of the “FDA Foods and Veterinary Medicine Program Strategic Plan 2012-2016” /2012 April/ they made statements about the development of healthier food and the enhancement of the safety of dietary supplements.

The following definition is the one being in the greatest accordance with current regulations and scientific results:

“Dietary supplements are products occurring in a non-usual lifestyle, complementing our daily food and nutrition with nutrient or non-nutrient materials which are indispensable for the normal functioning of our body, for maintaining our quality of life, and which are not absorbed or utilized in an appropriate form and/or quantity during our personal daily nutrition.”

Dietary supplements are not panaceas, but they can be useful depending on health-state, age, and lifestyle.

From the aspect of the physiological effects and values of dietary supplements, there are many factors (of which many are still not known exactly) to be referred to and to be considered. Two of the important factors are the bioavailability and synergism of the ingredients. We should take into account that the bioavailability of certain physiologically important ingredients is better in dietary supplement form than in natural food form (e.g. Vitamin-B9), while of others – e.g. of calcium – is better from natural sources.

It is very important to say that dietary supplements are not substitutes for a harmonious and complex diet, their aim is to supply the diet in order to maintain the normal working of the body and to keep and improve the quality of life with physiologically important ingredients.

Of course, as the biological effect of every material/element/compound is dose-dependent, dietary supplements can also have dose-dependent side-effects.

We should use dietary supplements health-consciously, in complex nutrition environment.

The members of Flavon-family are scientifically confirmed, safe, fruit- and vegetable based dietary supplements in accord with legal regulations! They are natural quality of life improvers, and they help us age with health.

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