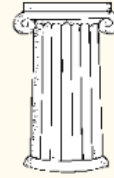


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'Fortified' Functional Food Definition

The concept of **Functional Foods** is a market concept, not an FDA regulatory category, not subject to FDA control. It was created as a response to perceived consumer desires that were not addressed by the laws and regulations governing dietary supplements, including the Dietary Supplement Health and Education Act of 1994, passed unanimously by Congress, which secured Americans' right to speak more freely about the benefits of nutrients. While a major step forward, DSHEA continued some restrictions on speaking the truth about food and health.

We did move beyond the prior era when FDA raiders would tear the "Health Food" sign off health food stores as we were not permitted to associate 'health' and 'food' together. Now we could speak truthfully about the relationship between nutrients and the normal structure and function of the body. That was a partial victory which engendered the vibrant natural products industry in America and globally that is heading toward a trillion dollars a year! [1]

The concept of Functional Foods developed from the need to describe the functional benefits of food to a growing marketplace. One definition proposed for the concept was,

"Functional foods cover a variety of foods. Minimally processed, whole foods along with fortified, enriched or enhanced foods, can all be functional foods. Generally, these foods have a potentially beneficial effect on health when consumed on a regular basis and at certain levels." [2]

Certain Functional Foods, such as, say Orange Juice as a source of Vitamin C, provide their benefits as they are, naturally. Other foods, when fortified with nutrients, can provide even greater benefits.

"Another area that is often questioned is food fortification — when products include added vitamins and other nutrients. Fortified foods can have a place in a healthy eating plan. Some may help to provide nutrients that might be low or missing.

For example, there are only a few foods that naturally contain vitamin D, so products that are fortified with it, such as milk, are a main source of vitamin D for many people." [3]

Thus **Fortified Functional Food** is a category of nutrition which has potential benefit when fortified with more of the key nutrient, or with other nutrients that complement the key nutrient in the food. Such foods are not used merely to 'supplement' the diet, as allowed by DSHEA, but to provide health benefits that go beyond mere supplementation.

Such Fortified Functional Foods, in their most sophisticated formulations, may very well qualify as **Medical Foods**, permitted under the Orphan Drug Act Medical Food provision, to be recommended by a physician for the dietary management of a health condition. Thus, Fortified Functional Foods may claim more than just 'supporting' normal form and function. The act states that such foods are

"...intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation...." [4]

In 2004 WHO, the World Health Organization, defined NCDs, the "preventable non-communicable diseases of under nutrition..." (such as cancer, diabetes, heart disease, obesity) as a major health concern that can be addressed through a "strategy [that] includes the promotion of a healthy diet." [5]

Fortified Functional Foods are intended to promote wellness through providing targeted nutrition based on the on-going development of nutritional science.

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[1] <https://www.businesswire.com/news/home/20210121005382/en/Global-1.1-Trillion-Health-and-Wellness-Foods-Market-to-2027-U.S.-Accounts-for-Over-28.9-of-Global-Market-Size-in-2020-While-China-is-Forecast-to-Grow-at-a-7.5-CAGR-by-2027---ResearchAndMarkets.com>

[2] <https://www.eatright.org/health/wellness/healthful-habits/functional-foods>

[3] Ibid.

[4] Section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3))

[5] <https://www.unnutrition.org/sites/default/files/2024-02/NCDs-Diets-Nutrition%20brief-EN-WEB.pdf>

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